

# EXHIBIT

5

**DOW CORNING SETTLEMENT PROGRAM AND  
CLAIMS RESOLUTION PROCEDURES**

**ANNEX A  
TO SETTLEMENT FACILITY  
AND FUND DISTRIBUTION AGREEMENT**

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**DOW CORNING SETTLEMENT PROGRAM AND  
CLAIMS RESOLUTION PROCEDURES**

The “Dow Corning Settlement Program and Claims Resolution Procedures” (“Claims Resolution Procedures”) outlines the guidelines for electing to settle or litigate and for processing, submitting, reviewing, evaluating and resolving and paying Settling Personal Injury Claims as required by the Plan and the Settlement Facility Agreement. The Claims Administrator will administer these Claims Resolution Procedures consistent with the terms of the Settlement Facility and Fund Distribution Agreement (“Settlement Facility Agreement”).

**ARTICLE I  
DEFINITIONS**

**1.01 *Incorporation of Definitions.*** The capitalized terms used herein and not otherwise defined herein shall have the meanings defined in the Plan, the Disclosure Statement, the Settlement Facility Agreement, the Depository Trust Agreement, the Funding Payment Agreement, the Litigation Facility Agreement and the Bankruptcy Code — in that order. All definitions in the Plan Documents and the Code are incorporated herein by reference.

**1.02 *Additional Definitions.*** When used in this Annex A or in the Settlement Facility Agreement, if capitalized, the following terms shall be defined as set forth below.

**1.03 *Base Payment*** -- shall mean that portion of a Disease or Rupture Payment for Breast Implant Claimants or Medical Condition Payment for Other Products Claimants that is designated as a Base Payment on the Settlement Grid. A Base Payment shall be a First Priority Payment.

**1.04 *Covered Condition*** -- shall mean any symptom grouping, medical condition or disease defined as compensable under Disease Payment Option I or Disease Payment Option II in Schedule II to these Claims Resolution Procedures.

**1.05 *Premium Payment*** -- shall mean that portion of a Disease or Rupture Payment for Breast Implant Claimants or Medical Condition Payment for Covered Other Products Claimants designated as a Premium Payment on the Settlement Grid. A Premium Payment shall be a Second Priority Payment.

**ARTICLE II  
ELIGIBLE CLAIMANTS**

**2.01 *Scope of Claims Covered.*** The Claims of all Settling Personal Injury Claimants shall be resolved under the terms of these Claims Resolution Procedures.

**2.02 *Determination of Eligible Claims Based on Proof of Claims.***

**(a) *Proof of Claim/Registration.*** Claimants who timely filed a Proof of Claim in the Case will be deemed to have their Claims registered with the Claims Office. All such forms,

documentation, and the Bankruptcy Court (Daticon) database containing information about these Claims will be delivered to the Claims Office as soon as practicable following the Effective Date, if not previously delivered. The Proof of Claim Form and information contained in the Claimant's submission in the Case shall be deemed as and shall become Claims Office files.

**(b) Rule 3005 Claims.**

**(i) Filing of Notice of Intent.** Claimants who did not timely file a Proof of Claim in the Case but on whose behalf a Proof of Claim has been timely filed pursuant to Bankruptcy Rule 3005 ("Rule 3005 Claim or Claimant") may file a notice of intent with the Court as provided in Bankruptcy Rule 3005 to act on her or his own behalf with respect to such Claim ("Notice of Intent"). Notwithstanding Bankruptcy Rule 3005, a Rule 3005 Claimant will be entitled to file the Notice of Intent on or before the date that is 90 days after the Effective Date. Such Claimant will thereby have all rights as specified in the 3005 filing and be subject to all deadlines applicable to Claimants who are deemed registered under (a) above. The Claims of Rule 3005 Claimants who do not timely file a Notice of Intent shall be disallowed.

**(ii) Submission of Participation Forms.** If a Rule 3005 Claimant timely files a Notice of Intent under paragraph 2.02(b)(i) above and returns a signed Participation Form to the Claims Office on or before the six-month anniversary of the Effective Date, as specified in Section 3.02(c) below, such Claimant will have the right to elect settlement or litigation unless the time deadline to elect litigation has expired. Rule 3005 Claimants who do not timely elect litigation or who do not return a signed Participation Form to the Claims Office on or before the six-month anniversary of the Effective Date shall be deemed Settling Personal Injury Claimants for all purposes of this Annex A to the Settlement Facility Agreement and the Plan as set forth in Section 3.02 below.

**(iii) Late Submission of Notice of Intent.** Claimants who do not timely submit to the Settlement Facility a Notice of Intent on or before the date that is 90 days after the Effective Date shall be notified that their claim is not timely, and they may appeal this decision to the Bankruptcy Court.

**ARTICLE III  
DEVELOPMENT AND DISTRIBUTION OF CLAIM FORMS**

**3.01 Development and Mailing of Participation Form and Other Forms.**

**(a) Responsibility of Claims Administrator.** The Claims Administrator in cooperation with the Claimants' Advisory Committee and the Debtor's Representatives shall develop appropriate informational materials advising Claimants of settlement options and procedures for submission of claim forms.

**(b) Content of Initial Mailing to Claimants.** The Claims Office shall mail to each Personal Injury Claimant (including those Rule 3005 Claimants who have timely filed a Notice of Intent under Section 2.02(b)(i) above) a package of materials. The package shall contain:

- C The Participation Form, by which eligible Personal Injury Claimants shall elect to settle or to opt out of this Dow Corning Settlement Program (“Dow Corning Settlement Program” or “Settlement Program”) and litigate. The Participation Form shall be mailed at or near the Effective Date only to those Personal Injury Claimants who have not previously waived their right to elect to opt out of the Settlement Facility and litigate.
- C Informational materials explaining the effect of the election.
- C Instructions outlining the procedures for filing Claims.
- C A Proof of Manufacturer Form and instructions for completing it. The Proof of Manufacturer Form shall allow Claimants to check the appropriate boxes to inform the Claims Office of Claims previously submitted to the MDL 926 Claims Office and/or documentation for Proof of Manufacturer, Explantation, Rupture or Disease Payment Option benefits.
- C Explantation Payment Option Form for Breast Implant Claimants.
- C Rupture Payment Option Form for Breast Implant Claimants.
- C Medical Condition Payment Option Form(s) for Other Product Claimants.
- C Silicone Material Claim Form.
- C Disease or Expedited Release Payment Option Form for Breast Implant Claimants.

**(c) *Mailing of Claim Forms.*** To the extent feasible and consistent with efficient processing, all Claim Forms and instructions shall be provided to Claimants together in a single package to minimize the need for multiple submissions.

**(d) *Mailing of Applicable Claim Forms.*** The Claims Administrator shall mail to Claimants only those forms applicable to the Claimant’s covered Dow Corning product or Claim.

**(e) *Acceptance of Submissions.*** The Claims Administrator may accept as timely Claims submissions and Participation Forms that are submitted in error (but which are otherwise timely, as defined herein) to the District Court, the MDL Court, the Revised Settlement Program, Dow Corning, Daticon, or the Dow Corning Claims Administration Facility.

**(f) *Mailing of Election Forms to Class 12 Claimants and Class 13 Claimants.*** The Claims Administrator shall mail to Class 12 Claimants and Class 13 Claimants appropriate election forms in accordance with these Claims Resolution Procedures and with Section 6.02 of the Settlement Facility Agreement.

### **3.02 *Litigation Right and Procedure.***

**(a) *Right to Elect Litigation.*** Except as otherwise specified in the Plan, Claimants have a right to elect to pursue or institute litigation against the Litigation Facility instead of

participating in the Settlement Program. To obtain resolution under the terms of the Litigation Facility Agreement the Claimant must affirmatively elect to litigate within the deadline specified herein.

**(b) *Content of Participation Form.*** The Participation Form shall inform Claimants of the consequences of an election to settle or litigate and of the procedures applicable for resolving Claims through the Settlement Program and the Litigation Facility. The Parties will provide a form of Participation Form.

**(c) *Election Deadline/Acknowledgment/Revocation of Election for Personal Injury Claimants.***

**(i)** Personal Injury Claimants (including any person for whom a Proof of Claim Form has been timely filed) must make their election by completing, signing and returning the Participation Form to the Claims Office on or before the six (6)-month anniversary of the Effective Date (“Election Deadline”). In the event that an appeal is filed from the Confirmation Order that raises a Release/Funding Issue, the Election Deadline shall be one hundred eighty (180) calendar days after the date the Participation Form is mailed to the Personal Injury Claimants. To be timely a Participation Form must be: (1) received on the applicable Election Deadline, (2) postmarked by certified or registered mail on the applicable Election Deadline, or (3) sent by a delivery service where the documentation provided by the delivery service contains a date showing that the material was sent on or before the Election Deadline. If the Election Deadline or any deadline in the Claims Resolution Procedures falls on a Saturday, Sunday or federal holiday, the next business day shall be the applicable Deadline.

**(ii)** The Claims Office shall acknowledge receipt of Participation Forms only when the Claimant has elected litigation. Settling Personal Injury Claimants will not receive an acknowledgment of their election. The Claims Office will notify those Claimants who elected litigation of their right to revoke that election and allow such Claimants thirty (30) calendar days from the date of the acknowledgment to revoke that election to litigate. To revoke the election to litigate, the Claimant (or the Claimant’s counsel) must submit a written statement confirming the Claimant’s decision to revoke the election. The revocation must be postmarked no later than 30 calendar days after the date of the acknowledgment letter. The Claims Administrator shall have discretion to accept those revocations postmarked after such 30 calendar days as long as they were received within a reasonable amount of time thereafter, as determined by the Claims Administrator, and as long as the Claims Administrator reasonably determines that accepting the revocation would not be detrimental to other Settling Personal Injury Claimants.

**(iii)** Except as otherwise specified in the Plan or Plan Documents, Personal Injury Claimants who elect settlement on the Participation Form or who do not timely submit a completed Participation Form to the Claims Office on or before the Election Deadline shall be deemed “Settling Personal Injury Claimants” for all purposes of the Settlement Facility Agreement and the Plan. Those Claimants eligible to become Participating Foreign Gel Claimants who elect litigation will remain in Class 8, and will have their Claims treated pursuant to the Litigation Facility Agreement.

(iv) As soon as practicable after the Election Deadline, the Claims Administrator shall identify the Non-Settling Personal Injury Claimants and Class 8 Claimants and provide this information to the Litigation Facility Manager, the Claimant's Advisory Committee, the Debtor's Representatives, and the Finance Committee.

(v) Claimants who elect litigation must sign the Participation Form. If the Claimant is represented by counsel, then the Claimant's counsel must also sign the form confirming that the Claimant has consulted with that counsel. The failure of the Claimant's counsel to sign the form will not invalidate the litigation election.

(d) ***Appeals Related to Election.*** A Claimant whose Participation Form is rejected because it was not submitted by the Election Deadline may appeal to the Appeals Judge.

(e) ***Election by Claimants in Classes 12 and 13.*** The procedures for electing to settle or litigate applicable to Claimants in Classes 12 and 13 are provided in Sections 6.02(b) and (c), respectively, of the Settlement Facility Agreement.

(f) ***Administration of Settling Claims.*** Claimants who elect settlement or are deemed Settling Claimants will have their Claims administered by the Claims Office in accordance with the Settlement Facility Agreement and these Claims Resolution Procedures.

(g) ***Waiver of Litigation Right.*** Prior to the distribution of the Participation Form, Personal Injury Claimants may waive their right to elect litigation as specified at Section 7.04.

#### ARTICLE IV GENERAL PROCEDURE FOR APPLYING FOR BENEFITS

**4.01 General.** To apply for compensation, Settling Personal Injury Claimants must submit appropriate forms and documentation required to support a Claim as defined at Section 6.02 for Breast Implant Claimants, Section 6.03 for Other Products Claimants and Section 6.04 for Silicone Material Claimants subject to the terms of subparagraph 4.02 below.

#### **4.02 Submissions for Settling Breast Implant Claimants with Prior Filings.**

(a) ***Prior Disease Compensation Form.*** Settling Breast Implant Claimants who submitted a Disease Compensation Form, along with the required medical documentation, to the MDL 926 Claims Office in connection with the Original Global Settlement or the Revised Settlement Program or the Foreign Revised Settlement Program are not required to submit these same forms and supporting documents to apply for compensation under the Disease Payment Option; however, such disease claims will not be processed unless and until (1) the Claimant first submits a "Disease or Expedited Payment Option Claim Form" or (2) all other Disease Claims have been processed. Breast Implant Claimants may submit new or supplemental medical documentation in addition to any disease claim previously filed in the Original Global Settlement, Revised Settlement Program, or the Foreign Revised Settlement Program.

(b) ***Prior Proof of Manufacturer Documents.*** Settling Breast Implant Claimants who submitted a Proof of Manufacturer Form and/or proof of one or more Breast Implants to the MDL 926 Claims Office must complete and submit a Proof of Manufacturer Form and proof



specific to the Dow Corning Settlement Program before Proof of Manufacturer will be processed. The Claims Administrator has an obligation, as specified at Section 5.01, to determine that there is acceptable proof of a Dow Corning implant according to Schedule I to this Annex A.

**(c) Access to Prior Submissions.** At the Claimant's request (or that of her counsel) and expense the Claims Office shall provide the Claimant or his/her counsel a copy of all material previously submitted by or for the Claimant to the MDL 926 Claims Office or to Daticon as part of the Proof of Claim in the Case.

**(d) Procedure for Claimants With Prior Submissions.** Breast Implant Claimants who previously submitted Proof of Manufacturer or a Disease Claim shall advise the Claims Office in accordance with Section 7.02(c) of these Claims Resolutions Procedures. The Claims Administrator shall have the authority to rely on the disease and disability determination made by the MDL 926 Claims Office for individual claimants provided that there is no disqualifying information submitted to the Settlement Facility and subject to the general obligation of the Claims Administrator to conduct fraud and quality control reviews.

## ARTICLE V THRESHOLD ELIGIBILITY CRITERIA FOR ALL SETTLING CLAIMANTS/INCLUSION OF FAMILY MEMBERS

**5.01 Eligible Breast Implant, Other-Product, Silicone Material and Participating Foreign Gel Claimants.** To be eligible to participate in the Dow Corning Settlement Program the Claimant must satisfy the following criteria in addition to the specific criteria applicable for each settlement option:

**(a)** The Claimant (or the Claimant's predecessor) has not released the Claim against Dow Corning or its Shareholders (or had such Claim resolved by final judgment, dismissal or order); and

**(b)** The Claim has not been disallowed by the Court except that (1) a Claim disallowed as untimely by the Court will not be barred if such Claim can be categorized as a Rule 3005 Claim pursuant to Section 2.02(b) above and the Claimant fulfills all provisions set forth therein, and (2) any adverse determination(s) in the Litigation Protocol, as provided at Section 5.4.1 of the Plan, shall not apply to or affect any rights of Settling Personal Injury Claims; and

**(c)** The Claimant has not timely elected litigation; and

**(d)** The Claimant has filed a timely Proof of Claim in the Case or a timely Proof of Claim has been filed on his or her behalf pursuant to Rule 3005; and

**(e)** The Claimant has not transferred his or her right to recover with respect to the Claim such that the Claim can be asserted by another person. (The fact that a Claimant has executed a "subrogation agreement" with a health insurer or that a statutory provision grants to any governmental entity rights of subrogation shall not of itself be construed as a transfer of the Claimant's right to recover.); and

(f) The Claimant submits acceptable Proof of Manufacturer, as set forth in Schedule I, Part I and/or II or III, or section 6.04 (e), as applicable, of these Claims Resolution Procedures.

**5.02 Family Members.** Participation by a Claimant also constitutes participation by that person's estate and the Consortium Claims of family members shall be deemed released by the treatment afforded the primary Claimant, as specified at Section 5.4.1.4 of the Plan. Children Direct Claims are unaffected by a primary Claimant's election to settle and shall be treated pursuant to the terms of the Litigation Facility Agreement. Notwithstanding the foregoing, all Family Member Claims, including Children Direct Claims, related to Claims in Classes 6A, 6B, 6C and 6D shall be deemed released by the treatment afforded the primary Claimant under the terms of their respective settlement agreement or option.

## **ARTICLE VI SETTLEMENT OPTIONS**

**6.01 General.** This section describes the criteria for Settling Personal Injury Claimants to obtain compensation. A Claimant who is eligible for both the Settlement Program for Breast Implant Claimants and the Settlement Program for Other Products Claimants is eligible to apply for compensation from both programs for each of his/her covered products. Claimants who are eligible for or receive compensation as a Breast Implant Claimant or an Other-Product Claimant are not eligible to apply for compensation under the Settlement Program for Silicone Material Claimants.

**6.02 Settlement Program For Eligible Domestic Dow Corning Breast Implant Claimants -- Classes 5, 6.1, and 6.2.**

(a) **Summary of Payment Options.** Settling Breast Implant Claimants who have been implanted with one or more Breast Implants and satisfy the eligibility criteria of Section 5.01 ("Eligible Breast Implant Claimants") may participate in and receive compensation from any and all of the following options:

(i) **Explantation Payment Option.** A one-time payment of \$5,000 will be paid to all Eligible Breast Implant Claimants whose Breast Implant(s) has/have been or is/are explanted after December 31, 1990 and on or before the tenth anniversary of the Effective Date.

(ii) **Disease or Expedited Release Payment Option.**

- a. Eligible Breast Implant Claimants may elect compensation for Disease Payment Option benefits based either on the disease definitions listed in the Original Global Settlement (Disease Payment Option I) or on the criteria set forth in the Long Term Benefit Schedule of the Revised Settlement Program (Disease Payment Option II) any time on or before the fifteenth anniversary of the Effective Date.
- b. Eligible Breast Implant Claimants may instead release all present and future Claims to receive Disease Payment Option benefits (but not

Rupture or Explantation Payment Option benefits) and receive an Expedited Release Payment of \$2,000 upon providing acceptable proof of implantation of a Dow Corning Breast Implant.

**(iii) Rupture Payment Option.** An Eligible Breast Implant Claimant whose Breast Implant(s) has/have been or is/are explanted on or before the second anniversary of the Effective Date and who submits acceptable proof that her Dow Corning silicone gel Breast Implant is ruptured will be compensated a Base Payment of \$20,000 and an additional Premium Payment of \$5,000, subject to the terms of the Settlement Facility Agreement.

**(b) Eligibility Criteria Applicable to All Options: Proof of Manufacturer.**

**(i) Form.** Except as provided at Section 4.02(b), Eligible Breast Implant Claimants who want to participate in the Dow Corning Settlement Program must submit to the Claims Office a Proof of Manufacturer Form and supporting documentation, as defined in Schedule I, Part I.

**(ii) Proof.** All Breast Implant Claimants must submit acceptable proof of a Dow Corning Breast Implant to receive benefits. The standards of acceptable proof of a Dow Corning Breast Implant are set forth at Schedule I, Part I to these Claims Resolution Procedures.

**(iii) Multiple Manufacturer Claims.** Breast Implant Claimants who participated in the Revised Settlement Program or the Foreign Revised Settlement Program and received a fifty (50)-percent reduction in compensation because they asserted they had or have a Dow Corning Breast Implant must satisfy the Proof of Manufacturer requirements for a Dow Corning Breast Implant set forth at Schedule I, Part I of this Annex A to be eligible under this Dow Corning Settlement Program. Such Claimants who have a deficiency in their Proof of Manufacturer submission will be directed to the Claims Assistance Program (defined at Section 7.01(e)). The Claims Assistance Program may submit the Proof of Manufacturer documentation to Reorganized Dow Corning for review and/or to the appropriate manufacturer in the Revised Settlement Program for consideration of payment.

**(c) Explantation Payment Option: Specific Eligibility Criteria and Terms.** A one-time payment of \$5,000 will be paid to Eligible Breast Implant Claimants on proof of removal of a Dow Corning Breast Implant after December 31, 1990 and on or before the tenth anniversary of the Effective Date. A Claimant may receive payment under the Explantation Payment Option in addition to payments under the other compensation options available in the Dow Corning Settlement Program.

**(i)** The amount of compensation available under the Explantation Payment Option will not vary based on the amount of actual expense involved or the number of Dow Corning implants removed.

**(ii)** Breast Implant Claimants whose Dow Corning Breast Implant(s) was/were explanted during 1991 shall not be entitled to an Explantation Payment if they received a replacement silicone gel breast implant during that explantation procedure. Claimants

whose Dow Corning Breast Implant(s) were removed after January 1, 1992 shall not be entitled to an Explantation Payment if they received a replacement silicone gel breast implant either during that explantation surgical procedure or in any subsequent procedure.

(iii) Breast Implant Claimants who had their implants removed and replaced with saline implants are eligible to claim Explantation Payment Option benefits.

(iv) Explant Assistance Program: Breast Implant Claimants who want to have their Dow Corning Breast Implant removed but do not have the funds to pay for the surgery may request the Claims Office to make arrangements to compensate the appropriate persons or entities (up to a maximum of \$5,000) directly. The Claims Office shall be authorized to develop appropriate guidelines for direct payment to the appropriate person or entity who provided the explantation service upon receipt from the Claimant and surgeon of all required documentation, including a signed release. The Claims Office shall obtain from the Claimant a signed release releasing the Claims Office, the Debtor, Reorganized Dow Corning, the Claimants Advisory Committee, Debtor's Representatives, and the Released Parties from any claims or actions arising out of the explant procedure. (Such release will not affect the Claimant's ability to recover benefits under this Settlement Program.) If the cost of explantation is less than the \$5,000 Explantation Payment Option benefit, the Claims Office shall pay the difference between the actual cost and \$5,000 to the Breast Implant Claimant. Prior to disbursing payment for the surgery to the appropriate persons or entities, the Claims Office shall obtain from the explanting surgeon and, if applicable, the pathologist, any information necessary for the Explantation Payment Option Form and, if applicable, the Rupture Payment Option Form on behalf of the Breast Implant Claimant and an agreement to cooperate with her and the Claims Office to provide information relevant to these benefits. Claimants will not be denied an Explantation Payment if they participated in this direct payment procedure but were not explanted by the deadline for the Explantation Payment Option solely because the surgeon failed timely to return documents and/or releases. Claimants will not be denied a Rupture Payment if they participated in this direct payment procedure but were not explanted by the deadline for the Rupture Option solely because the surgeon failed to timely return documents and/or releases.

(v) Reorganized Dow Corning may, at its discretion, provide a list of surgeons who have advised Reorganized Dow Corning of a willingness to perform explantation surgeries for up to \$5,000. If such surgeon agrees, the Claims Office shall be authorized to release the names of such surgeons to Claimants. Should any Claimant elect to use any such surgeon and/or to arrange for payment of such surgeon through the Claims Office as provided at subparagraph (iv) above, then the Claimant must execute a release releasing the Claims Office, the Debtor, Reorganized Dow Corning, the Claimants Advisory Committee, Debtor's Representatives, and the Released Parties from any liability or claim arising out of such surgery (except that such release will not affect the Claimant's ability to recover benefits under this Settlement Program). Prior to releasing payment for the surgery to the appropriate persons or entities, the Claims Office shall obtain from the explanting surgeon and, if applicable, from the pathologist information necessary for the Explantation Payment Option Form and, if applicable, the Rupture Payment Option Form on behalf of the Breast Implant Claimant and an agreement to

cooperate with her and the Claims Office to provide information relevant to these benefits.

(vi) To obtain benefits under the Explantation Payment Option the Claimant must submit proof of explantation. Proof of explantation must contain or indicate the date of the explantation surgery and may be made by any of the following means:

- a. an itemized hospital bill;
- b. the bill from the explanting surgeon;
- c. the surgical report;
- d. an insurance company's statement of benefits;
- e. contemporaneous hospital records (including the hospital pathology report);
- f. the explanting surgeon's contemporaneous office notes;
- g. a pre-operative medical document, together with confirmation from a medical provider or insurance company that surgery actually took place as scheduled; or
- h. the presence of the implant recipient's name on the list provided by Dow Corning to the Settlement Facility of confirmed participants in the Removal Assistance Program.

(vii) The Claims Office will not inquire about the Breast Implant Claimant's reason for choosing to have her Breast Implant(s) removed and will not deny benefits to Breast Implant Claimants based on the reason for explantation.

(viii) Each Eligible Breast Implant Claimant may receive only one payment under the Explantation Payment Option, regardless of the number of qualifying surgeries or implants.

**(d) Disease Payment Option.** Eligible Breast Implant Claimants will receive benefits under the Disease Payment Option upon proof, on or before the fifteenth anniversary of the Effective Date, of having developed a Covered Condition defined in Disease Payment Option I, Schedule II, Part A (the Disease Schedule of the Original Global Settlement which is called the Fixed Amount Benefit Schedule of the Revised Settlement Program), or a Covered Condition defined in Disease Payment Option II, Schedule II, Part B (the Long-Term Benefit Disease Schedule of the Revised Settlement Program).

**(i) Disease Payment Options Defined.** Disease Payment Option I consists of the compensable diseases and conditions defined in the Original Global Settlement and the Fixed Amount Benefit Schedule of the Revised Settlement Program. Disease Payment Option II consists of the compensable diseases and conditions defined in the Long-Term Benefit Schedule of the Revised Settlement Program.

The criteria for qualifying for benefits under Disease Payment Option II are much stricter than those under Disease Payment Option I. No claims based solely on atypical or "like" presentations of disease are compensable for Systemic Lupus, Systemic Sclerosis, or Polymyositis/Dermatomyositis under Disease Payment Option II. A Breast Implant Claimant must clearly suffer from those diseases exactly as defined in Schedule II, Part B. Breast Implant Claimants who meet the criteria under Disease Payment Option II and who also have additional signs, symptoms or conditions which are not

required for that disease category will still be eligible for compensation under Disease Payment Option II. Only four of the Covered Conditions in Disease Payment Option I — Lupus, Scleroderma, Polymyositis, and Dermatomyositis — are included in Disease Payment Option II. One additional Covered Condition — General Connective Tissue Symptoms (GCTS) — is contained in Disease Payment Option II. Although many of these GCTS symptoms are somewhat similar to symptoms and findings contained in the ANDS and ACTD categories of Disease Payment Option I, the symptoms listed in the GCTS category have stringent qualifications and requirements.

**(ii) *Election of Disease Payment Option/Designation of Application of Covered Condition.*** The Disease or Expedited Release Payment Option Claim Form distributed to Claimants will instruct Claimants to identify the particular Covered Condition for which they seek benefits.

**(iii) *Processing Protocol for Disease Payment Option Claims.***

**a.** Claims asserting Systemic Sclerosis, Systemic Lupus, Polymyositis or Dermatomyositis and GCTS shall be reviewed, categorized and paid based on the following protocol:

**1.** The Claims Office shall evaluate the Claim under both Disease Payment Option I and Disease Payment Option II.

**2.** The Claims Office will send to each such Breast Implant Claimant or, if represented, to her attorney of record a Notification of Status letter (as described at Section 7.06). The Notification of Status letter shall advise the Claimant of the following:

**(1)** All Covered Condition(s) evaluated and approved.

**(2)** The Disease Payment Option in which each approved Covered Condition falls.

**(3)** The compensation level approved.

**(4)** Any deficiencies in any Covered Condition the Claimant identified on the Claim Form based on both Disease Payment Options regardless of whether the Claim is approved for any Covered Condition, as well as any deficiencies in any Covered Condition evaluated by the Claims Office.

**3.** If the Claims Office determines that such Claim has any deficiency under Disease Payment Option II, then the Claimant shall have one year from the date of the Notification of Status letter to cure that Disease Payment Option II deficiency. If the deficiency is not cured within the one year period, then the Claim will automatically be designated a Disease Payment Option I Claim, and the Allowed amount of compensation provided under Disease Payment Option I for that Claim will be reduced by 25 percent from the amount



specified on the Disease Payment Option I Compensation Schedule and otherwise allowable.

4. At any time during the one year period for cure of the deficiency the Claimant may elect to proceed under Disease Payment Option I instead of Disease Payment Option II. If such election is made prior to the expiration of the one year period then payments issued under Disease Payment Option I will not be reduced.
  5. If the Claim is not approved under either Disease Payment Option, then the Claimant shall have an opportunity to cure the deficiency as specified at Section 7.09.
- b. All other Disease Payment Option Claims shall be reviewed, categorized and paid based on the following protocol:
1. All other Disease Payment Option Claims shall initially be evaluated under Disease Payment Option I.
  2. The Claims Office will send to such Breast Implant Claimant or, if represented, to her attorney of record a Notification of Status letter (as described at Section 7.06). The Notification of Status letter shall advise the Claimant of the following:
    - (1) any Covered Condition approved under Disease Payment Option I;
    - (2) the compensation level approved; and
    - (3) any deficiencies in any Covered Condition the Claimant identified on the Claim Form but which is not approved.
  3. If the Claimant has any deficiency in the Disease Payment Option I Claim and elects to proceed under Disease Payment Option I, then the Claimant shall have one year from the date of the Notification of Status letter to cure any deficiencies in the Claim as provided in Section 7.09.

**(iv) *Effect of Election Among Disease Payment Options.*** Eligible Breast Implant Claimants who elect compensation under Disease Payment Option I or whose claims are automatically designated Disease Payment Option I Claims may not, in the future, receive benefits under Disease Payment Option II.

**(v) *Multiple Manufacturer Reduction.*** Eligible Breast Implant Claimants who opted out of the original global settlement or the Revised Settlement Program and received compensation from either Bristol, Baxter or 3M outside of the Revised Settlement Program shall be deemed to have acceptable proof of a Bristol, Baxter or 3M breast implant for purposes of the Plan and the Multiple Manufacturer Reduction. Eligible Breast Implant Claimants whose Disease Payment Option Claims are approved



shall have the Allowed amount of their Claim reduced by fifty (50) percent if they also have acceptable proof of implantation of a silicone gel breast implant manufactured by or attributed to Bristol, Baxter or 3M (as such manufacturers are described and defined in Exhibit G to the Revised Settlement Program, which Exhibit G is set forth in relevant part at Schedule I, Part III, Section C). The fifty (50)-percent reduction shall apply to all Breast Implant Claimants regardless of whether they recovered benefits in the Revised Settlement Program or whether they recovered any payments in settlement or judgment, including but not limited to payments recovered as an opt-out to the Revised Settlement Program.

**(vi) Compensation Schedule for Disease Payment Option I.** Compensation for approved Disease Payment Option I benefits will be paid under the schedule below, subject to the provisions of the Funding Payment Agreement and the Settlement Facility Agreement. Each Eligible Breast Implant Claimant may receive payment for only one compensable condition under Disease Payment Option I, except as provided at subparagraph (viii) below.

#### **DISEASE PAYMENT OPTION I COMPENSATION SCHEDULE**

Original Global Settlement Criteria (Fixed Amount Benefit Schedule of the Revised Settlement Program) Disability/Severity Level for Covered Conditions	Dow Corning Breast Implant and no Bristol, Baxter or 3M silicone gel breast implant		
	Base Payment	+ Premium Payment	= Total Payment
A	\$50,000	+ \$10,000	= \$60,000
B	\$20,000	+ \$4,000	= \$24,000
C or D	\$10,000	+ \$2,000	= \$12,000

**(vii) Pre-existing Conditions for Disease Payment Option I Claims.**

- a. Claimants shall not be eligible to receive compensation for a Covered Condition that became manifest prior to the implantation of a Breast Implant except as provided in this subsection.
- b. Under the ACTD category in Disease Payment Option I, no symptom is considered for purposes of establishing ACTD if it existed before the date of first implantation with a Breast Implant.
- c. A Breast Implant Claimant who, before her first breast implantation, had a Covered Condition listed on the Disease Payment Option I schedule is eligible for benefits if that condition increased in severity after implantation with a Breast Implant. The amount of the benefit will be the difference between the amount Allowed for the new disease and disability/severity level and the amount that would have been allowed for the pre-existing condition.

- d. It is the intention of the provision to adopt and follow the protocols employed by the MDL 926 Claims Office to determine Claims with pre-existing conditions.

**(viii) Increased Severity for Disease Payment Option I Claims.** If before the fifteenth anniversary of the Effective Date an approved Disease Payment Option I Claimant documents an increase in the severity of her condition that meets the criteria for Severity Level A under Disease Payment Option I, that Claimant shall be entitled at that time to apply for an additional payment from the Settlement Facility based on that Severity Level A Condition. The maximum amount for which that Claimant may qualify is the difference between the maximum Allowable payment amount for Level A (which amount would be \$60,000 if the full Premium Payment of twenty (20) percent of the Base Payment were Allowed) and the amount previously Allowed for the Claim. This additional payment shall be classified and paid as a Second Priority Payment and will be paid from the Increased Severity Fund, subject to the limitations of that Fund as set forth in Section 3.02(b)(i) of the Settlement Facility Agreement, and subject to the requirements for the distribution of Premium Payments as specified in the Settlement Facility Agreement.

**(ix) Compensation Schedule for Disease Payment Option II.** Compensation for approved Disease Payment Option II Claimants will be paid according to the Disease Payment Option II Schedule below, subject to the terms of the Funding Payment Agreement and the Settlement Facility Agreement. Each Eligible Breast Implant Claimant may receive payment for only one Covered Condition under Disease Payment Option II, except as provided at subparagraph (xi) below.

#### **DISEASE PAYMENT OPTION II COMPENSATION SCHEDULE**

Long-Term Benefit Schedule of the Revised Settlement Program: Covered Condition: Disease or Symptomology/ Compensation Level	Dow Corning Breast Implant and no Bristol, Baxter or 3M silicone gel breast implant		
	Base Payment	+ Premium Payment	= Total Payment
Scleroderma (SS) or Lupus (SLE); Compensation Level A	\$250,000	+ \$50,000	= \$300,000
Scleroderma (SS) or Lupus (SLE); Compensation Level B	\$200,000	+ \$40,000	= \$240,000
Scleroderma (SS) or Lupus (SLE); Compensation Level C	\$150,000	+\$30,000	= \$180,000
General Connective Tissue Symptoms (GCTS), Polymyositis (PM) or Dermatomyositis (DM); Compensation Level A	\$110,000	+ \$22,000	= \$132,000
General Connective Tissue Symptoms (GCTS); Compensation Level B	\$75,000	+ \$15,000	= \$90,000

**(x) Pre-existing Conditions for Disease Payment Option II Claims.** Benefits may not be obtained for a Covered Condition if the qualifying symptoms existed before the date of the first implantation with a Breast Implant.

**(xi) Increased Severity for Disease Payment Option II Claims.** If, before the fifteenth anniversary of the Effective Date, an approved Disease Payment Option II Claimant documents a Covered Condition under Disease Payment Option II that would entitle her to a larger payment than previously Allowed, the Claimant is eligible to apply for an additional payment in an amount equal to the difference between the new amount Allowable and any amount previously Allowed under this Schedule. This additional payment shall be classified and paid as a Second Priority Payment.

**(e) Rupture Payment Option.** To qualify for the Rupture Payment Option a Breast Implant Claimant must meet the requirements listed below:

**(i) Definition.** “Rupture” means the failure of the elastomer envelope(s) surrounding a silicone-gel Breast Implant to contain the gel (resulting in contact of the gel with the body), not solely as a result of “gel bleed”, but due to a tear or other opening in the envelope after implantation and prior to the explantation procedure.

**(ii) Eligibility.** To be eligible under the Rupture Payment Option, Eligible Breast Implant Claimants must submit:

- a. acceptable proof of implantation with one or more Dow Corning silicone gel Breast Implants in accordance with Schedule I, Part I and;
- b. documentation that a Dow Corning silicone gel Breast Implant has been removed; and
- c. documentation, as specified at subparagraph (v) below, showing that the removed Dow Corning silicone gel Breast Implant was ruptured as defined above.

**(iii) Rupture Proof.**

- a. Breast Implant Claimants explanted prior to January 1, 1992 must submit a contemporaneous operative or pathology report documenting the Rupture.
- b. Breast Implant Claimants explanted on or after January 1, 1992 and on or before the Effective Date must submit a contemporaneous operative report and, if available, a pathology report together with a statement as to whether the ruptured implants have been preserved and, if so, the name and address of the custodian.
- c. **1.** Breast Implant Claimants explanted after the Effective Date must submit a contemporaneous operative report and, if available, a contemporaneous pathology report. In addition, the Claimant must provide a statement from the explanting surgeon (or other appropriate professional approved by the Claims Office) affirming that, in his or her opinion, the Rupture did not occur during or after the explantation procedure. This statement must describe the

results of the inspection and provide a factual basis for the opinion (e.g., in light of silicone granuloma formation on the exterior of the biologic capsule, or findings concerning the nature of the destruction of the elastomer envelope). The Claimant shall use her best efforts to cause the removed implant to be preserved.

2. If the explanting surgeon refuses to write the supplemental report giving his or her opinion of when the Rupture occurred, the Claimant may submit the supplemental statement from another doctor who examined the removed implant. Claimants must also submit the contemporaneous operative report that documents the Rupture and, if available, a contemporaneous hospital report.

**(iv) *Criteria for Rupture Claims Where Explantation is Medically Contraindicated.***

**a. *Eligibility for Consideration.***

**1. *Eligible Claimants.*** Breast Implant Claimants who demonstrate acceptable Proof of Manufacture based on the criteria set forth at Schedule I, Part I, Section B (and not on unique identifiers as set forth at Schedule I, Part I, Section D) of implantation with a Dow Corning silicone gel or double lumen Breast Implant and that such Breast Implant has not been removed, and who meet the requirements of subparagraphs 2 and 3 below, shall be eligible to receive benefits under the Rupture Payment Option, notwithstanding the fact that the Breast Implant has not been removed.

**2. *Proof of Rupture.*** To qualify under this subsection, Breast Implant Claimants with acceptable Proof of Manufacturer as defined in subparagraph 1., above, must submit documentation of Rupture as defined in the Settlement Facility Agreement and these Claims Resolution Procedures. The proof will be deemed acceptable if:

- (1) The Rupture is documented by MRI conducted by a qualified facility and read by a qualified radiologist; and
- (2) The MRI is an appropriately high resolution MRI conducted using dedicated breast coil and applying silicone selective sequences and water suppression sequences as appropriate using fast spin echo technique or its equivalent for these purposes; and
- (3) The MRI shows a definite Rupture (tear or failure of the silicone envelope surrounding the silicone gel portion of the Breast Implant) confirmed by a finding of definite “linguini” sign, or a double linguini sign (i.e., linguini of both envelopes of a double lumen type implant) or “C” signs (where “double linguini” and “C” signs are as defined in “Magnetic Resonance Evaluation of Breast Implants and Soft-tissue Silicone,” Topics in Magnetic Resonance Imaging, 9(2): 92-137 (1998)),

accompanied by the presence of silicone observable outside of the envelope surrounding the silicone gel.

**3. Proof of Medical Condition.** The Breast Implant Claimant must submit a written statement and diagnosis by a physician along with supporting documentation describing a serious chronic medical condition that precludes the surgical removal of the Breast Implant. The medical documentation must contain objective findings that will permit the Claims Administrator to make a determination as to the severity of the condition and the diagnosis. For a Claim to qualify for a Rupture payment under this subsection, the Claims Administrator must make a specific finding that the Breast Implant Claimant's medical condition is such that the surgery required to remove the Breast Implant is medically contraindicated (i.e., likely, in the exercise of reasonable medical judgment, to result in significant complications or have a significant adverse effect on the Claimant's medical condition). The medical condition (as described above) must be present at the time of the MRI discovery of the Rupture and during the period allowed under the Settlement Program for submission of Rupture Claims. The following medical conditions, if supported with objective medical documentation, may support a finding that Breast Implant removal surgery is medically contraindicated. The Claims Administrator shall have discretion to accept other similarly serious medical conditions provided they meet the criteria outlined above.

**a. Claimant With Severe Cardiac Condition.** A Claimant who experienced a myocardial infarction within six (6) months prior to the time removal surgery would have to occur to make a timely Rupture claim.

**b. Claimant With Pulmonary Condition.** A Claimant who has severe pulmonary impairment such as pulmonary involvement with Systemic Sclerosis, Systemic Lupus, Polymyositis or Dermatomyositis, where such impairment results in a substantially abnormal diffusion capacity (e.g., diffusion capacity of less than 30 percent of predicted value).

**c. Claimant With Renal Condition.** A Claimant with a history of Scleroderma renal crisis, or who is on dialysis or who has severely reduced renal function with creatine clearance of less than 20 cc/min. measured by an adequate urine collection.

**b. Review of Submission.** The Claims Administrator may at his or her discretion require a reading of the MRI by an independent radiologist and/or an independent review of the medical records to confirm that the removal surgery is medically contraindicated as defined herein.

**(v) General Processing.** The Claims Office shall process Rupture Claims with the understanding that physicians have and will use different terminology to describe an implant that is ruptured. Simply because the relevant record does not use the word "rupture" is not a basis to deny the Rupture Claim.

(vi) **Individual Review Process for Certain Rupture Claims.** Eligible Breast Implant Claimants whose documentation of Rupture is classified as unacceptable but whose documentation meets the criteria at subparagraph b.1. or b.2. below may participate in the Individual Review Process outlined in this section. Breast Implant Claimants whose documentation does not meet the criteria at subparagraph b.1. or b.2. below are not eligible to participate in the Individual Review Process but such Claimants may appeal their Rupture Payment Option determination to the Claims Administrator pursuant to Article VIII of these Claims Resolution Procedures.

**a. Notification of Claims Administrator/Process.** Within sixty (60) days of receipt of his/her Notification of Status letter regarding the Rupture Claim, a Breast Implant Claimant who is eligible to participate in this Individual Review Process must notify the Claims Administrator in writing of her intention to participate in this Individual Review Process. The Claims Administrator shall establish a process to obtain and forward to Reorganized Dow Corning the Rupture documentation relied on by the Claimant to support the Rupture Claim. In forwarding the Claimant's information to Reorganized Dow Corning, the Claims Office shall maintain the confidentiality of the Claimant's identity and information. Reorganized Dow Corning may, at its expense, request that explant materials and/or pathology slides, if preserved, be provided for the purpose of conducting testing. The Claimant must promptly comply with the request and, if preserved, provide all requested materials in the Claimant's possession or control. Reorganized Dow Corning will have sixty (60) days to accept or reject the Rupture Claim after the documentation is submitted to Reorganized Dow Corning. Reorganized Dow Corning shall submit a written response to the Claims Administrator for each Rupture Claim submitted to it under this Individual Review Process. The Claims Administrator shall notify the Claimant of Reorganized Dow Corning's response and, if the Rupture Claim has been rejected, advise the Claimant of the procedure for appealing the determination to the Appeals Judge. If the Rupture Claim is rejected, Reorganized Dow Corning shall return all explant materials and pathology slides to the Claimant (as directed by the Claims Office) and provide the Claimant with a copy of any test results or reports conducted on such materials.

**b. Criteria for Participation in Individual Review Process/Standard for Review.** Claimants who meet the criteria listed below are eligible to participate in this Individual Review Process. Reorganized Dow Corning shall not unreasonably deny a Rupture Claim submitted through this Individual Review Process that includes:

1. medical documentation, created before explantation surgery or within a reasonable time after explantation of the Dow Corning single or double-lumen silicone gel Breast Implant, demonstrating visual confirmation of a breach in the elastomer envelope found upon or prior to removal of the Dow Corning silicone gel Breast Implant, or



2. medical documentation demonstrating migration along tissue planes distant from the site of breast implantation of a substantial mass of material confirmed by biopsy to be silicone from a ruptured Dow Corning single or double-lumen silicone gel Breast Implant.

**c. *Appeal.*** If Reorganized Dow Corning rejects any Claim eligible for and submitted through the above-described Individual Review Process, the Claimant may appeal to the Appeals Judge. The decision of the Appeals Judge is final and binding on both Reorganized Dow Corning and the Claimant.

**d. *Simultaneous Submission to Cure Deficiencies.*** Breast Implant Claimants who elect to participate in the Individual Review Process outlined in this subsection may simultaneously proceed with an appeal to the Claims Administrator pursuant to Article VIII and this Individual Review Process.

**(vii) *Unacceptable Proof.*** The following types of proof are examples of unacceptable proof of rupture:

- a. Non-contemporaneous statements from medical personnel recalling that a Claimant's Breast Implant was ruptured upon explantation, or a similar statement from the Claimant (or a Claimant's relative or friend).
- b. Proof that fails to show that the ruptured Breast Implant has been surgically removed.
- c. Proof that affirmatively reveals that the Breast Implant was intact before the explant surgery, but was ruptured during the explant surgery.
- d. Proof that reveals no Rupture as defined (including proof that shows only gel bleed).
- e. Proof that shows that only the saline portion of a double-lumen Breast Implant ruptured, leaving the gel portion intact.
- f. For explantations after 1/1/92, a pathology report alone, with no contemporaneous operative report.

**(viii) *Compensation.*** Subject to the Funding Payment Agreement and the Settlement Facility Agreement, Eligible Breast Implant Claimants who qualify for the Rupture Payment Option under any of the provisions of this Section 6.02(e) will be compensated a Base Payment of \$20,000 and an additional Premium Payment of \$5,000 regardless of whether they also have a Disease Payment Option Claim or an Explantation Payment Option Claim. Each Eligible Breast Implant Claimant may receive only one payment (including both the Base Payment and the Premium Payment) under the Rupture Payment Option regardless of the number of qualifying Ruptures.



**(ix) *Multiple Manufacturer Reduction.*** There will not be a multiple manufacturer reduction for the Rupture Payment Option except as follows: If the Claimant qualifies for both the Disease Payment Option and the Rupture Payment Option and has received a rupture enhancement payment under the Revised Settlement Program, then the Allowed amount of the compensation for both the Disease Payment Option Claim and the Rupture Payment Option Claim will be reduced by 50 percent.

**(f) *Expedited Release Payment Option.*** Eligible Breast Implant Claimants may elect to receive compensation of \$2,000 for a complete release of their right to participate in the Disease Payment Option. Breast Implant Claimants who elect this Expedited Release Payment Option will (if eligible) be allowed to recover under the Explantation Payment Option and the Rupture Payment Option.

**(i) *Duration.*** The Expedited Release Payment Option will be available until the third anniversary of the Effective Date, except as provided at paragraph (iii) below and at Section 7.09 below. The Claims Administrator shall have the discretion to extend the Expedited Release Payment Option for an additional time period.

**(ii) *Eligibility.*** To qualify for the Expedited Release Payment Option, the Claimant must submit acceptable proof of implantation with a Dow Corning Breast Implant in accordance with the standards specified at Schedule I, Part I.

**(iii) *Extension of Expedited Release Payment Option Program.*** Eligible Breast Implant Claimants who have a deficiency in their Disease Payment Option submission and who fail to cure the deficiency within one year of the date of their Notification of Status letter shall be eligible for an Expedited Release Payment Option notwithstanding subparagraph (i) above.

**6.03 *Settlement Program for Covered Other Products Claimants.*** Claimants who have been implanted and explanted with one or more of the “Other Products” listed below will be eligible for compensation from the Dow Corning Settlement Program for Other Products if they satisfy the eligibility criteria and documentation requirements specified herein.

**(a) *Eligible Other Products Types.*** The Other Products types covered by the Settlement Program for Other Products Claimants are listed in this subparagraph (a) (“Covered Other Product” or “Covered Implant”). The specific Covered Other Products are listed at Schedule I, Part II.

**(i)** Temporomandibular Joint (TMJ) defined as: A spacer constructed of SILASTIC® sheeting or a TMJ implant made of SILASTIC® Block manufactured by Dow Corning;

**(ii)** Wilkes Temporomandibular Joint Implant;

**(iii)** SILASTIC® Temporomandibular Joint Implant H.P. of:

- a. size 1;
- b. size 2; or
- c. size 3;

- (iv) Chin, facial, nasal gel or silicone implant;
- (v) Small Joint (Small Joint Orthopedic Implant) (Finger, toe, wrist, hand, foot);
- (vi) Large Joint Orthopedic device — Knee;
- (vii) Large Joint Orthopedic device — Hip;
- (viii) Testicular implant;
- (ix) Penile implant.

**(b) *Eligible Claimants.*** An Eligible Other Products Claimant is a Claimant who meets the conditions for a Claim as described in this Section 6.03 and who meets the threshold eligibility criteria specified at Section 5.01 of these Claims Resolution Procedures and subsection (c) below regarding the deadline for submission of Claims under the Settlement Program. Covered Other Products Claims for implants implanted prior to 1980 are not compensable except that the Claims Administrator may determine, in accordance with the provisions of Section 6.03(i), to permit compensation of such Claims if there are any excess funds in the Other Products Fund (as defined in the Settlement Facility Agreement) after payment of all Eligible Settling Other Products Claims. Other Products Claims that are not Covered Other Products Claims do not have an option under the Settlement Program. Such claims can be Allowed only by pursuing litigation against the Litigation Facility.

**(c) *Deadline for Submission.*** To be eligible to receive compensation a Covered Other Products Claimant must submit the appropriate Claim Form, Proof of Manufacturer and supporting documentation on or before the second anniversary of the Effective Date.

**(d) *Summary of Settlement Options For Covered Other Products Claimants.*** Covered Other Products Claimants may receive compensation under any one of the following options. Each option is mutually exclusive.

**(i) *Expedited Release Payment.*** The Expedited Release Payment consists of payment of the sum of \$1,000 for any Covered Other Products Claimant who meets the initial eligibility requirement specified at Section 5.01, and who submits acceptable Proof of Manufacturer of a Covered Other Product as specified at Schedule I, Part II. Claimants who elect to receive this compensation will not be able to receive the Medical Condition Payment. A Claimant is entitled to one Expedited Release Payment, regardless of the number of implants or implant types.

**(ii) *Medical Condition Payment.*** Covered Other Products Claimants may elect to obtain compensation for one of the specific medical conditions described at paragraphs (ii) a., b., c. or d. below (“Medical Condition”). Claimants who meet the eligibility criteria for any one of these Medical Conditions described will be compensated in accordance with the schedule at Section 6.03(h). Each Medical Condition is mutually exclusive and Claimants shall be entitled to payment for only one eligible Medical Condition for each Covered Other Product implant type.

**a. *Implant Failure Payment.*** Eligible Covered Other Products Claimants who submit acceptable Proof of Manufacturer of a Covered Other Product and

who demonstrate that a Covered Other Product has failed in accordance with the criteria at Section 6.03(f)(i) will be compensated as described in Section 6.03(h).

**b. *Inflammatory Foreign Body Response.*** Eligible Covered Other Products Claimants who submit acceptable Proof of Manufacturer of a Covered Other Product and provide acceptable documentation of an Inflammatory Foreign Body Response as defined at Section 6.03(f)(ii), will be compensated as described in Section 6.03(h).

**c. *Rupture.*** Eligible Covered Other Products Claimants who submit acceptable proof of implantation of a Covered silicone gel Other Product and who provide acceptable documentation of a Rupture as described in Section 6.03(f)(iii) will be compensated as described in Section 6.03(h).

**d. *TMJ Enhanced Payment.*** Eligible Covered Other Products Claimants who meet the requirements of Section 6.03(f)(iv) will be compensated as described at Section 6.03(h).

**(e) *Expedited Release Payment -- Criteria for Compensation.***

**(i) *Proof and Compensation.*** Claimants who provide acceptable Proof of Manufacturer as described at Schedule I, Part II of any Covered Other Products and who satisfy the initial eligibility requirements at Section 5.01 herein may elect to receive compensation of \$1,000. Payment of this sum will release all present and future Claims the Claimant may have.

**(f) *Medical Condition Payment -- Criteria for Compensation.***

**(i) *Implant Failure Payment.*** Other Products Claimants will be compensated for the failure of any Covered Other Products if they meet the requirements listed below.

**a. *Implants Eligible.*** Implant types eligible for an Implant Failure Payment consist of:

1. TMJ;
2. SMALL JOINT ORTHOPEDIC IMPLANT;
3. LARGE JOINT ORTHOPEDIC IMPLANT — knee, hip;
4. Testicular implant;
5. Penile implant;

Specific Covered brands are listed at Schedule I, Part II.

**b. *Eligibility Requirements.*** To obtain compensation for Implant Failure, Claimants must submit:

1. Acceptable Proof of Manufacturer of an Other Product (in accordance with the requirements for acceptable Proof of Manufacturer specified at Schedule I, Part II);

2. Documentation that the Claimant meets the initial eligibility requirements as described at Section 5.01 of these Claims Resolution Procedures;
3. Documentation of Implant Failure as specified at subparagraph c. below.

**c. Requirements for Compensation for Implant Failure.**

**1. Definition.** “Implant Failure” of a solid silicone or metal implant means a Dow Corning Other Product that has a tear, fracture, or break which is the result of fatigue failure, or a separation of implant component parts, which is seen or observed without microscopic examination at explantation. To be compensable, the broken implant must cause clinical failure resulting in explantation.

**2. Exclusions.** If a Claimant’s medical records affirmatively document any of the following, the implant failure is not compensable and such Claims will be rejected by the Claims Office: (i) an identifiable traumatic event including damage of the implant during implant or explant surgery, (ii) disassembly of modular parts that were assembled at or during surgery, but not in accordance with the manufacturer’s specifications, (iii) identifiable abuse or misuse of the implant documented in the medical records.

**3. Documentation.** To demonstrate a compensable claim for Implant Failure the Claimant must submit:

- (1) x-ray, MRI, roentgenogram or a report from a roentgenogram x-ray report or MRI report of examination, performed post-implantation of the Other Product but prior to explant, finding that the Covered Implant has failed as defined above; and
- (2) contemporaneous operative report from the explantation surgery describing the condition of the Covered Implant upon gross inspection of the implant by the explanting surgeon, a contemporaneous pathology report describing the condition of the Covered Implant upon gross inspection, a statement as to whether the Covered Implant was fractured, torn or had its structural integrity otherwise compromised during or after the Covered Implant and explant surgery and the factual basis for the opinion as to the status of the Covered Implant before the explant surgery commenced; and
- (3) any medical and hospital records documenting the presence of any of the exclusions listed at Section 6.03(f)(i)c.2. during the period of time such Covered Implant(s) was/were in place. If no such records exist, then the Claimant shall provide an affidavit describing any traumatic injury to the affected joint or Covered Implant; and

(4) if preserved, the identity and the location of the custodian of the removed Covered Implant(s). The Claims Administrator may require the presentation of the removed Covered Implant(s) for examination by an individual or entity designated by the Claims Administrator to confirm the Implant Failure.

**4. Compensation.** Claimants who satisfy the eligibility criteria shall be compensated according to the Base Compensation Level specified at Section 6.03(h).

**5. Deficiencies.** In the event that the Claim Form or supporting documentation is deficient, the Claimant shall have six (6) months from the date of the Notification of Status (deficiency) to submit additional documentation to cure the deficiency. If the Claimant does not cure the deficiency, the Claimant is eligible for an Expedited Release Payment if he or she has a Covered Other Product.

**(ii) Inflammatory Foreign Body Response Payment.** To obtain compensation for Inflammatory Foreign Body Response, the Claimant must meet the following requirements:

**a. Implants Eligible.** Implants eligible for an Inflammatory Foreign Body Response Payment consist of:

1. TMJ;
2. SMALL JOINT ORTHOPEDIC IMPLANT;
3. LARGE JOINT ORTHOPEDIC IMPLANT.

Specific Covered brands are listed at Schedule I, Part II.

**b. Eligibility Requirements.**

1. Acceptable Proof of Manufacturer of the Other Product (in accordance with the requirements for acceptable Proof of Manufacturer specified at Schedule I, Part II); and
2. Documentation that the Claimant meets the initial eligibility requirements as described at Section 5.01 of these Claims Resolution Procedures; and
3. Documentation of Inflammatory Foreign Body Response as specified at subparagraph c. below.

**c. Requirements for Compensation for Inflammatory Foreign Body Response.**

**1. Definition.** “Inflammatory Foreign Body Response” means a cellular response characterized by the presence of macrophages and giant cells containing particles of silicone, polyethylene, or metallic alloy found at the site of the Covered Implant. To be compensable,

the Inflammatory Foreign Body Response must be chronic (as defined herein), occur outside the encapsulated joint and result in explantation. For purposes of this definition, chronic Inflammatory Foreign Body Response shall mean that such Inflammatory Foreign Body Response continued and was documented as described below more than three months after implantation of the Covered Implant.

**2. Exclusions.** If a Claimant's medical records affirmatively document any of the following, the Inflammatory Foreign Body Response is not compensable and such Claims will be rejected by the Claims Office: (i) damage to the Covered Implant during implant surgery; (ii) identifiable abuse or misuse of the Covered Implant documented in the medical records; (iii) the patient's extreme sensitivity to the implanted materials; (iv) Inflammatory Foreign Body Response attributable to a prior bone resorption condition.

**3. Documentation.** To demonstrate a compensable claim for "Inflammatory Foreign Body Response," the Claimant must submit:

- (1) if they exist, pathology slides or a pathology report taken more than three months after implantation of tissue resected at explantation from the site of the Covered Implant (outside of the encapsulated joint), which show findings of macrophages and giant cells containing particles of polyethylene, silicone or metallic alloy; and
- (2) explantation surgical notes or treating surgeon's pre-explantation office notes stating that the revision or explantation surgery was required because of Inflammatory Foreign Body Response as defined at subparagraph c.1. above; and
- (3) All medical records documenting the presence of any of the exclusions noted in Section 6.03(f)(ii)c.2. above during the period of time such Covered Implant(s) was/were in place.

**d. Compensation.** Claimants who satisfy the eligibility criteria shall be compensated according to the Base Compensation Level specified at Section 6.03(h).

**e. Deficiencies.** In the event that the Medical Condition Payment Option Form or supporting documentation is deficient, the Claimant shall have six (6) months from the date of the Notification of Status (deficiency) to submit additional documentation to cure the deficiency. If the Claimant does not cure the deficiency, the Claimant is eligible for an Expedited Release Payment if he or she has a Covered Other Product.

**(iii) Rupture Payment.** Other Products Claimants who document implantation with one of the following silicone gel Covered Implants are eligible to receive compensation for a Rupture of the Covered Implant if the criteria listed at subparagraphs b. and c. below are met:

**a. *Implant Eligibility.***

1. silicone gel chin;
2. silicone gel facial;
3. silicone gel testicular.

Specific Covered brands are listed at Schedule I, Part II.

**b. *Eligibility Criteria.***

1. Acceptable Proof of Manufacturer that the Other Product (in accordance with the requirements for acceptable Proof of Manufacturer specified at Schedule I, Part II); and
2. Documentation that the Claimant meets the initial eligibility requirements as described at Section 5.01 of these Claims Resolution Procedures; and
3. Documentation of Rupture as defined at paragraph c.2. below.

**c. *Requirements for Compensation.***

**1. *Definition of Rupture.*** “Rupture” means the failure of the elastomer envelope(s) surrounding a silicone gel Covered Implant to contain the gel (resulting in contact of the gel with the body) not solely as a result of “gel bleed” but due to a tear or other opening in the envelope after implantation and prior to the explantation procedure.

**2. *Documentation.*** To be eligible for compensation, the Claimant must have experienced a Rupture of a Covered Implant and the Rupture must be confirmed by explantation of the Covered Implant for which a Rupture is claimed. The Claimant must submit:

- (1) A verified contemporaneous operative report and, if available, a pathology report documenting the Rupture; and
- (2) Other Products Claimants explanted on or after the Effective Date must submit a contemporaneous operative report and, if available, a contemporaneous pathology report. In addition, the Claimant must provide a statement from the explanting surgeon (or other appropriate professional approved by the Claims Office) affirming that, in his or her opinion, the Rupture did not occur during or after the explantation procedure. This statement must describe the results of the inspection and provide a factual basis for the opinion. The Claimant shall use his or her best efforts to cause the removed Covered Implant to be preserved.



- (3) If the Ruptured Covered Implant(s) has/have been preserved, a statement of the identity and the location of the custodian of the Covered Implant(s). The Claims Administrator may require the presentation of the removed Covered Implant(s) for examination by an individual or entity designated by the Claims Administrator to confirm the Rupture and/or that the Covered Implant was manufactured by Dow Corning.

**3. *Deadline.*** Other Products Claimants must submit the Rupture Payment Option Form, Proof of Manufacturer and supporting documentation demonstrating proof of Rupture on or before the second anniversary of the Effective Date, except that notwithstanding the provisions of Section 6.03(c), Claimants explanted within the 90-day period preceding the second anniversary of the Effective Date shall have until thirty (30) days after that deadline to submit the Form and supporting documentation.

**d. *Compensation.*** Claimants who satisfy the eligibility criteria specified herein shall be compensated according to the Base Compensation Levels described at Section 6.03(h) below.

**e. *Deficiencies.*** In the event that the Rupture Payment Option Form or supporting documentation is deficient, the Claimant shall have six (6) months from the date of the Notification of Status identifying the deficiency to submit additional documentation to cure the deficiency. If the Claimant does not cure the deficiency, the Claimant is eligible for an Expedited Release Payment if he or she has a Covered Other Product.

**(iv) *TMJ Implant Enhanced Payment.***

**a. *Eligibility Requirements for Enhanced TMJ Implant Payment Option.*** To qualify for the Enhanced TMJ Implant Payment Option, the Claimant must document the following:

- (i) Acceptable Proof of Manufacturer of a Dow Corning TMJ product as specified at Schedule I, Part II; and
- (ii) Documentation that the Claimant meets the initial eligibility requirements as specified at Section 5.01 of these Claims Resolution Procedures; and
- (iii) Documentation of an Inflammatory Foreign Body Response With Active, Localized Bone Resorption as defined at subparagraph b. below.

**b. *Definition.*** “Inflammatory Foreign Body Response With Active, Localized Bone Resorption” means a cellular response characterized by the presence of macrophages and giant cells containing particles of silicone found at the site of a localized, active bone resorption with a scalloped, balloon, or erosive pattern in the bone adjacent to the implanted

joint. To be compensable, the inflammatory response must be chronic as defined at Section 6.03(f)(ii) and the Inflammatory Foreign Body Response With Active, Localized Bone Resorption must be the result of dysfunction of the Covered Implant causing clinical failure and resulting in explantation.

**c. Exclusions.** If a Claimant's medical records affirmatively document any of the following, the Inflammatory Foreign Body Response With Active, Localized Bone Resorption is not compensable and such Claims will be rejected by the Claims Office: (i) damage to the Covered Implant during implant surgery; (ii) identifiable abuse or misuse of the Covered Implant documented in the medical records; (iii) the patient's extreme sensitivity to the implanted materials; or (iv) Inflammatory Foreign Body Response attributable to a prior bone resorption condition.

**d. Documentation.** To demonstrate an Inflammatory Foreign Body Response With Active, Localized Bone Resorption the Claimant must submit:

(i) if they exist, pathology slides or a pathology report, of tissue or bone resected at explantation from the site of the active, localized bone lysis adjacent to the Covered Implant documented by the studies described in subparagraph (ii) below, which show findings of macrophages and giant cells containing particles of silicone; and

(ii) x-ray, MRI, roentgenogram or a report from a roentgenogram, x-ray report or MRI report of examination, taken within two months prior to explantation, which shows findings of active, localized bone lysis with a scalloped, balloon or erosive pattern in the bone adjacent to the implanted joint (the Claims Administrator shall have the discretion in appropriate cases to grant an exception to the two-month time limitation for such reports); and

(iii) explantation surgical notes or treating surgeon's pre-explantation office notes stating that the revision or explantation surgery was required because of bone resorption due to Inflammatory Foreign Body Response With Active, Localized Bone Resorption as defined at subparagraph b. above; and

(iv) All medical records documenting the presence of any of the exclusions noted in subparagraph c. above during the period of time such Covered Implant(s) was/were in place.

**e. Compensation.** Eligible TMJ Other Products Claimants who satisfy the criteria under this section shall be compensated according to the TMJ Enhanced Compensation Level specified at Section 6.03(h).

**f. Deficiencies.** In the event that the TMJ Enhanced Payment Form or supporting documentation is deficient, the Claimant shall have six (6) months from the date of the Notification of Status (deficiency) to submit

additional documentation to cure the deficiency. If the Claimant does not cure the deficiency, the Claimant is eligible for an Expedited Release Payment if he or she has a Covered Other Product.

***(g) Supporting Material — Guidelines for Submission of Required Documentation for Medical Condition Claims.***

***(i) Minimum Documentation.*** To substantiate a claim for a Medical Condition Payment the Claimant must submit the documentation described herein, and to be considered by the Claims Office all medical records/proof submitted must consist of records of the physician(s) who has/have examined the Claimant and/or the Covered Implant, as appropriate, made the specific finding, observed the specific symptom and contemporaneously documented the same. The physician must be a Board-certified physician specializing, as appropriate to the Claim, in oral and maxillofacial, orthopedic, podiatric, urologic or plastic surgery.

***(ii) Acceptability.*** In determining the acceptability of supporting documents, the Claims Administrator shall accept only personal examination findings, laboratory results and diagnoses that are in writing and submitted under the authority of the examining physician or laboratory. The physician whose records are relied upon must have been licensed to practice medicine in the applicable jurisdiction at the time the diagnosis or examination is made.

***(iii) Obligations of the Claims Administrator/Verification of Evidence.***

- a.** The Claims Administrator shall determine the presence of a compensable condition and the absence of exclusionary factors and shall approve Claims if the information in the records satisfies the requirements for compensation specified herein. The Claims Administrator shall require such further submissions as necessary to confirm the compensable condition and absence of exclusionary factors.
- b.** Consistent with Section 5.04 of the Settlement Facility Agreement, the Claims Administrator may (a) obtain independent reports or evaluations from medical physicians to assist in the review of any Claimant's submission, (b) audit the reliability of medical evidence, and (c) exclude medical evidence of questionable validity.

***(h) Compensation Schedule for Medical Condition Payment.***

***(i)*** If the Claim meets the proof set forth in Section 6.03(f) for one of the qualifying conditions, the Allowed amount shall be as specified below, subject to adjustment as specified in Section 7.03 of the Settlement Facility Agreement, subparagraph (ii) below and Section 6.03(i) below.

<b>Implant Type</b>	<b>Expedited</b>	<b>Base Payment</b>	<b>Enhanced Payment</b>
Chins, facial and nasal implants	\$1,000	\$5,000	N/A
Small Joint Orthopedic (fingers, wrists, hands, toes)	\$1,000	\$5,000	N/A
Large Joint Orthopedic:			N/A
hip	\$1,000	\$10,000	
knee	\$1,000	\$7,500	
TMJ	\$1,000	\$5,000	\$10,000
Testicular and penile	\$1,000	\$5,000	N/A

**(ii) Multiple Manufacturer Adjustment.** The Allowed Amount shall be reduced by fifty (50) percent for any Claimant seeking compensation for a TMJ Covered Other Product who has been implanted with both a Dow Corning TMJ Covered Implant and a TMJ implant product manufactured by any other manufacturer (including Vitek).

**(iii)** Notwithstanding the above schedule, the Claims Administrator shall have the authority to reduce payments to Covered Other Products Claimants who: (1) qualify under the Medical Condition Payment Option and (2) whose Other Product has been implanted for more than five years. Such authority to reduce payments shall occur only if the Claims Administrator determines, after evaluating all timely filed Other Products Claims and placing such Claims on the Compensation Schedule, that without such a reduction, the amount of the Other Products Fund may be insufficient to pay all Settling Other Products Claims the full amount specified by the Compensation Schedule (Section 6.03(h)). In computing any reduction in the payment amount, the Claims Administrator shall give consideration to a mechanism for reducing payments that increases the amount of the reduction for each year the implant has been implanted beyond the fifth year of implantation. Nothing in this subparagraph shall affect the obligations of the Claims Administrator and Settlement Facility regarding the limitations imposed by the Other Products Fund on payments to Other Products Claimants or the provisions of Section 7.03(c) of the Settlement Facility Agreement.

**(iv)** The Allowed amount is determined per Claimant by Implant type and will not vary depending on the number of Implants within an Implant type.

**(i) Capped Aggregate Payment for Other Products Claims/Premium Payments/Administrative Costs/Additional Distributions.**

**(i)** Notwithstanding the specification of compensation amounts at Section 6.03(h), as specified in the Settlement Facility Agreement the aggregate amount that may be paid for resolution of Claims of Settling Personal Injury Claimants (including both payments to Claimants and administrative expenses) based on Other Products shall equal the sum of \$30 million Net Present Value, (which amount shall be deemed a “Base Payment Amount”) plus the sum of \$6 million Net Present Value which sum shall be deemed and treated as a Premium Payment (collectively, the “Other Products Fund”).

(ii) The Claims Administrator shall review and evaluate all timely Other Products Claims before distributing Medical Condition Payments to Other Products Claimants. The Claims Administrator may determine to issue Expedited Release Payments to approved Claims prior to the expiration of the deadline provided such distribution will not materially affect payments to other eligible Claimants to the Other Products Fund. In the event that the Allowed payments to Other Products Claimants based on the criteria and compensation schedule outlined herein equals a sum less than the Other Products Fund, then the Claimants' Advisory Committee and the Claims Administrator shall determine guidelines under which the Claims Administrator will distribute the excess amount (i.e., the sum equal to the amount by which the Allowed aggregate amount paid to the Other Products Claimants including administrative expenses is less than \$36 million Net Present Value, less administrative costs associated with any excess distribution) to the TMJ Claimants and Other Products Claimants with other implant types who have qualified for a Base or Enhanced Payment and who have documented the most serious injuries or conditions.

(iii) The Claims Office shall analyze the projected administrative costs in connection with the resolution of Other Products Claims. In the event that a projection that takes into account actual claims-processing experience indicates that administrative costs will exceed ten (10) percent of the Other Products Fund, then the Claims Administrator shall, in consultation with the Debtor's Representatives and the Claimants' Advisory Committee, develop an administrative process that will allow resolution of the Other Products Claims within the limits of the \$36 million Net Present Value Other Products Fund with administrative costs not to exceed ten (10) percent of that amount. Such projection of administrative costs may be based on a sufficient random sample of initial Other Products Claims and the calculation of administrative costs for purposes of this section shall include direct costs of processing such Claims on a per-claim basis and an appropriate pro rata share reflecting the sample or reviewed group of Claims as a percentage of all Other Products Claims submitted and projected to be submitted of general costs that have been or will be incurred in connection with staff training, quality control reviews and reporting related to Other Products Claims.

#### **6.04 *Silicone Material Claimants and Participating Foreign Gel Claimants.***

(a) ***Eligible Silicone Material Claimants.*** Eligible Silicone Material Claimants are Claimants who meet the following requirements:

(i) The Claimant has acceptable Proof of Manufacturer as set forth at subparagraph (b) below; and

(ii) The Claimant meets the eligibility criteria in Section 5.01 of these Claims Resolution Procedures; and

(iii) The Claimant does not have a Dow Corning Breast Implant or Covered Other Products implant.

(b) ***Acceptable Proof of Manufacturer for Silicone Material Claimants.*** To be eligible, the Claimant must:

(i) submit acceptable Proof of Manufacturer, as defined at Schedule I, Part III, of implantation of a silicone gel breast implant identified as a Bristol, Baxter, Bioplasty, Cox-Uphoff, or Mentor breast implant on Exhibit G to the Revised Settlement Program (a “Qualified Breast Implant”); and

(ii) the Claimant must submit Proof of Manufacturer of a Qualified Breast Implant implanted after January 1, 1976 and before January 1, 1992.

(c) **Documentation of Manufacturer/Eligibility as a Silicone Material Claimant.** To be eligible, the Silicone Material Claimant must submit (1) a Silicone Material Claim Form listing all breast implantations along with documentation necessary to demonstrate acceptable proof of implantation of at least one breast implant meeting the requirements of (b) above, (2) an affirmative statement identifying all other breast implantations and manufacturers of such breast implants, (3) an affirmative statement that the Claimant has never been implanted with a Breast Implant or Covered Other Product, and (4) for Silicone Material Claimants seeking compensation under the Disease Payment Option as provided at subparagraph (e) below, all documentation required to document a Covered Condition as specified in Section 6.02 and Schedule II of these Claims Resolution Procedures.

(d) **Eligible Participating Foreign Gel Claimants.** Eligible Participating Foreign Gel Claimants are Claimants who meet the following requirements:

(i) The Claimant is a Settling Personal Injury Claimant; and

(ii) The Claimant has acceptable Proof of Manufacturer as set forth at subparagraph (e) below; and

(iii) The Claimant meets the eligibility criteria in Section 5.01 of these Claims Resolution Procedures; and

(iv) The Claimant does not have a Dow Corning Breast Implant or Covered Other Products implant.

(e) **Acceptable Proof of Manufacturer for Participating Foreign Gel Claimants.** To be eligible, the Claimant must:

(i) submit acceptable Proof of Manufacturer, pursuant to procedures to be developed by the Debtor’s Representatives and the Claimants’ Advisory Committee, of implantation of a silicone gel breast implant manufactured by a foreign manufacturer using medical grade gel systems purchased from Dow Corning. The Plan Proponents have identified the following four manufacturers’ implants as eligible: Medasil, Silimed, Societe Promotel, and Koken; and

(ii) the Claimant must submit Proof of Manufacturer of a qualified breast implant implanted after January 1, 1976 and before January 1, 1992.

(f) **Documentation of Manufacturer/Eligibility as a Participating Foreign Gel Claimant.** To be eligible, the Participating Foreign Gel Claimant must submit (1) a Silicone Material Claim Form listing all implantations along with documentation necessary to demonstrate acceptable proof of implantation of at least one implant meeting the requirements of



(e) above, (2) an affirmative statement identifying all other implantations and manufacturers of such implants; and (3) an affirmative statement that the Claimant has never been implanted with a Breast Implant or Other Product.

**(g) *Aggregate Silicone Material Claimants' Fund/Settlement Options.*** As provided in the Settlement Facility Agreement, the sum of \$57.5 million Net Present Value shall be allocated for resolution of Claims of all Silicone Material Claimants and Participating Foreign Gel Claimants, including all administrative expenses associated with the processing, resolution and payment of all Silicone Material Claims and Participating Foreign Gel Claims.

**(h) *Distribution of Fund/Settlement Options/Determination of Settlement Payment.***

**(i)** Silicone Material Claimants will be entitled to apply for either the Expedited Release Payment Option or the Disease Payment Option. The criteria for compensation under each Option shall be the same criteria established under Section 6.02 of these Claims Resolution Procedures.

**(ii)** All Silicone Material Claimants and Participating Foreign Gel Claimants must submit their Silicone Material Claim Forms and supporting documentation on or before the second anniversary of the Effective Date.

**(iii)** No distributions for Disease Claims will be made from the Silicone Material Claimants' Fund until each timely Silicone Material Claim is reviewed and evaluated under the Settlement Option selected and the one-year deadline to cure deficiencies, if any, has expired. Silicone Material Claimants who do not timely cure deficiencies in their disease claims shall be placed in the Expedited Release Option for Silicone Material Claimants. The Claims Administrator may determine to issue Expedited Release Payments to approved Claims prior to the expiration of the deadline provided such distribution will not materially affect payments to other eligible Claimants to the Silicone Material Claimants' Fund.

**(iv)** After evaluating all Silicone Material Claims, the Claims Administrator shall determine the amount that can be Allowed for each Silicone Material Claim based on the settlement option approved and the number of eligible Silicone Material Claimants. The Silicone Material Claimants' Fund shall be allocated on a proportional basis such that all Silicone Material Claimants who elect the Expedited Release Payment Option receive the same amount, subject to the terms of subparagraph (v) below and such that Silicone Material Claims under the Disease Payment Option are Allowed in an amount no greater than 40 percent of the Allowed amount for Base Payments for Breast Implant Claimants under the equivalent level of the Disease Payment Option Compensation Schedule.

**(v)** To be eligible to receive a payment from the Silicone Material Claimants' Fund, Silicone Material Claimants shall be required to marshal recoveries from the manufacturers of their breast implants. Silicone Material Claimants who do not marshal all recoveries from all manufacturers by the deadline for submission of Silicone Material Claims are not eligible to receive a payment. All such recoveries received by or for the benefit of the Silicone Material Claimant shall reduce, on a dollar-for-dollar basis, the amount otherwise Allowable under the terms of this Section 6.04. For purposes of this subparagraph, those Silicone Material Claimants whose sole manufacturers are not released under or are not participating in the Revised Settlement Program and consist



specifically of any combination of Bioplasty, Cox-Uphoff, or Mentor shall be deemed to have marshaled all recoveries and there shall be no reduction of the Allowed amount for such Claimants based on any other recovery. Claimants who have both a breast implant made by any combination of Bioplasty, Cox-Uphoff, or Mentor and any breast implant made by any other manufacturer (except a Claimant who is classified as an “Other Registrant” as defined in the Revised Settlement Program with only a post-August 1984 McGhan breast implant, along with any combination of a Bioplasty, Cox-Uphoff, or Mentor breast implant) will be required to marshal all recoveries by such other manufacturers as stated above. The Claims Administrator shall determine whether all recoveries have been marshaled and shall require the Claimant to document the amount of recovery so that the Allowed amount can be calculated.

(vi) Participating Foreign Gel Claimants will only participate in distributions pursuant to subparagraph (i) below.

**(i) *Supplemental Distribution of Excess Funds in Silicone Material Claimants Fund.***

The Claims Administrator shall have discretion to distribute any excess amount in the Silicone Material Claimants’ Fund after allocation to Silicone Material Claimants in accordance with paragraph (h) above to eligible Silicone Material Claimants and Participating Foreign Gel Claimants on a pro rata basis.

**6.05 *Foreign Claimants.***

**(a) *Settlement Options.*** Except for those Claimants in Classes 6A, 6B, 6C, and 6D, the Limited Proof of Manufacturer Expedited Payment Settlement Option for Class 6.2 in the following subparagraph, the Limited Disease Payment Option for Class 6.2 in subparagraph (c) below, the Increased Explantation Benefit for class 6.2 in subparagraph (d) below, and the Alternative Expedited Release Payment Option in subparagraph (e) below, Settling Foreign Breast Implant Claimants shall be subject to the terms of and entitled to select and receive compensation under the options outlined in Sections 6.02 of these Claims Resolution Procedures, Settling Foreign Other Products Claimants shall be subject to the terms of and entitled to select and receive compensation under the options outlined in Section 6.03 of these Claims Resolution Procedures, and Settling Foreign Silicone Material Claimants shall be subject to the terms of and entitled to select and receive compensation under the options outlined in Section 6.04 of these Claims Resolution Procedures.

**(b) *Option 3: Limited Proof of Manufacturer Expedited Payment Settlement Option (Class 6.2).*** In addition to the other available settlement options, Claimants in Class 6.2 shall have the additional option to elect the Limited Proof of Manufacturer Expedited Payment Option, which option shall provide for the following:

(i) The option is available to all Class 6.2 Claimants who filed a Proof of Claim in the Case on or before the February 14, 1997 bar date indicating that they used a Dow Corning manufactured Breast Implant and who file an Option 3 Claim Form on or before the fifteenth anniversary of the Effective Date;

(ii) The settlement amount of \$600 will be payable to each electing Class 6.2 Claimant in cash sixty (60) days after the Effective Date or sixty (60) days after the election of this option to settle, whichever is later; provided the Claimant has complied with items (iii) and (iv) below;

(iii) Settling Claimants will be required to submit a statement signed under the penalty of perjury attesting to their use of a Dow Corning Breast Implant;

(iv) Settling Claimants will be required to deliver a signed release on behalf of themselves and their Family Members releasing all Claims against the Released Parties before the settlement payment is made; and

(v) Attorneys' fees payable out of the settlement amount would be limited to ten percent (10%) or \$60.00.

(c) **Option 4: Limited Disease Payment Option (Class 6.2).** As an alternative to all other available settlement options, Claimants in Class 6.2 may elect the Limited Disease Payment Option as follows:

(i) **Eligibility.** This option is available to all Class 6.2 Claimants who filed a timely Proof of Claim or Notice of Intent provided the qualification criteria set forth herein are established.

(ii) **Qualification Criteria.**

- a. To qualify for this option a Claimant must provide documentary evidence (as defined at b. below) that she is unable to provide Proof of Manufacturer as specified at Annex A, Schedule I because (1) all documents constituting acceptable Proof of Manufacturer were destroyed as a result of a verifiable war or natural disaster (e.g., fire, earthquake) that occurred before the Effective Date and (2) her implanting physician or other qualified individual is either deceased or cannot be located.
- b. Documentary evidence shall consist of the following:

The sworn statement of the Claimant attesting to the following:

- C The approximate date and place (i.e., hospital, clinic, doctor's office, city, country, etc.) of all implantation and removal surgeries involving breast implants, including the manufacturer of each such implant or, if such manufacturer is unknown, that this information is unknown.
- C The name of the physician, hospital or clinic who performed the implantation of the Claimant's Dow Corning Silicone Gel Breast Implant or the hospital in which the implantation of the Claimant's Dow Corning Silicone Gel Breast Implant was inserted.
- C The Claimant's efforts to locate the implanting physician, clinic or hospital and his or her records and results of such efforts.
- C A statement indicating the reason for the Claimant's belief that she is, at the time of the submission of the Claim, implanted with a Dow Corning Silicone Gel Breast Implant.

C A description of the verifiable war or natural disaster (as defined) that resulted in the destruction of all relevant records regarding the Claimant's implantation surgeries. The description must include sufficient details of the location of the Claimant's records relating to implantation and the manner in which the records were destroyed so as to connect the war or natural disaster to the loss of records.

c. *Proof of Implantation.*

1. For purposes of this Limited Disease Option, Dow Corning will provide to the Claims Office, in accordance with Schedule I, Part I.F. of these Claims Resolution Procedures, a list of all physicians and hospitals (including distributors or sales persons who may have provided the implants to such physicians or hospitals) in each of the countries classified in Class 6.2 that purchased Dow Corning Silicone Gel Breast Implants and all sales persons or entities that sold Dow Corning Silicone Gel Breast Implants and the time period of such purchase. Such list shall be compiled from Dow Corning's existing sales records, including the records of its distributors and Subsidiaries, and Dow Corning shall not be required to perform any investigation to create such list. If Dow Corning cannot locate any information regarding sales to physicians or hospitals in the relevant countries, Dow Corning shall so notify the Claims Office.

2. The Claims Office shall determine whether the information provided by the Claimant regarding the identity of the implanting physician or hospital matches the information provided by Dow Corning regarding sales to physicians, hospitals or clinics in the Claimant's country of residence. The Claims Office shall further determine whether, based on the information provided by Dow Corning, the date of the sale of Dow Corning Silicone Gel Breast Implants occurred on or within a reasonable amount of time before the Claimant received her breast implant. If the Claims Office makes such findings, then the Claimant shall be eligible to participate in the Limited Disease Payment Option for Class 6.2 Claimants. If Dow Corning has no records or limited records, then the Claims Office will make its determination based upon the documentary evidence produced by the Claimant.

3. *Settlement Benefits Available.*

(a) Claimants who are eligible to participate in the Limited Disease Payment Option shall be eligible to receive either a Limited Expedited Release Payment or a Limited Disease Payment.

i. ***Limited Expedited Release Payment.*** The Limited Expedited Release Payment shall consist of a one-time

payment in the amount of \$750. To qualify for this payment the Claimant must satisfy the eligibility requirements specified in this Section 6.05 (c) and must execute a release and waiver of all Claims against the Released Parties and any and all Claims against the Settlement Facility or Litigation Facility.

- ii. **Limited Disease Payment.** Claimants who establish product identification in accordance with this Section 6.05 (c) may elect the Limited Disease Payment. Under this Option the Claimant shall receive payment in an amount equal to 30 percent of the amount payable to domestic Breast Implant Claimants for any of the eligible conditions under Disease Option I. To qualify for this payment the Claimant must submit the documentation required by these Claims Resolution Procedures to establish the criteria for payment under Disease Option I.
- iii. **Waiver of Explant and Rupture Claims.** Claimants who elect the Limited Disease Payment Option shall not be entitled to make any Claims or receive any payment under the Explantation Payment Option or the Rupture Payment Option.

**(d) Option 1: Class 6.2.** Class 6.2 Claimants who elect Option 1 shall be subject to the terms of and entitled to select and receive compensation under the options outlined in Section 6.03 of these Claims Resolution Procedures, and Settling Foreign Silicone Material Claimants shall be subject to the terms of and entitled to select and receive compensation under the options outlined in Section 6.04 of these Claims Resolution Procedures. As an alternative to the Explantation Payment Option which is available to Class 6.2 Claimants, a Class 6.2 Claimant may instead elect to participate in the Increased Explantation Benefit Option.

**(i) Qualification.** To qualify for this Option the Claimant must (1) be a Class 6.2 Claimant, (2) satisfy the threshold eligibility criteria outlined at Section 5.01 herein, and (3) waive all rights to receive any Premium Payment under the Rupture Payment Option.

**(ii) Compensation.** The payment amount for the Increased Explantation Benefit for Class 6.2 Claimants shall be \$3,000.

**(e) Option 2: Alternative Expedited Release Payment Option (Class 6.2).** Claimants in Class 6.2 may elect, as an alternative to all of the other Settlement Options outlined above, the Alternative Expedited Release Payment Option.

**(i)** To qualify for the Alternative Expedited Release Payment Option a Class 6.2 Claimant must satisfy all of the threshold eligibility criteria set forth at Section 5.01 of these Claims Resolution Procedures.

**(ii)** The payment amount under the Alternative Expedited Release Payment Option shall be \$1,200.

(iii) A Claimant who elects the Alternative Expedited Release Payment Option shall not be eligible to participate in any other Settlement Option or receive any other compensation from the Settlement Facility and shall expressly waive any rights to receive payment for Disease Payment Options I and II, the Rupture Payment Option, and the Explantation Payment Option.

(iv) The Alternative Expedited Release Payment Option shall expire on the third anniversary of the Effective Date.

(f) ***Submissions to Claims Office.*** The Claims Office shall provide all forms and instructions translated into the languages of the Class 6.2 countries, including Notification of Status letters if it is reasonably cost effective to do so. The Claims Administrator shall have discretion to determine whether the forms and instructions should be translated if the number of affected Claimants in a particular country in Class 6.2 would render such translation not cost effective. Class 6.2 Claimants shall be permitted to submit all Claim Forms and supporting documentation in their own language or translated into English. If the documents are translated into English, the Claimant must submit a translator's statement (under penalties of perjury) attesting that the translator is proficient in English, that the document has been correctly translated and that the translator has no personal or business relationship with the Claimant or the Claimant's attorney.

Notwithstanding the above, no such translation shall be required for medical and hospital records offered as Proof of Manufacturer if, without any translation, the Claims Office will be able to determine that the proof is acceptable under any of the criteria in subparts 1-4, 6, 9-12 and 15 of Schedule I, Part I, Section B.

(g) ***Alternative Claims Facility.***

(i) The Claims Administrator shall establish a single Claims facility in Europe and may establish other Claims facilities for the purpose of processing Claims of Settling Foreign Claimants. Such facilities, if established, shall be designed, in the best efforts of their administrators, to receive and process Claims in the local languages of the Claimants whose Claims are being reviewed. The Claims Administrator shall establish the European facility in a location that will further the cost-effective processing of Claims. Such facilities shall be permitted, under the direct supervision of the Claims Administrator, to review and evaluate Settling Foreign Claims in accordance with the guidelines and criteria specified herein and in the Settlement Facility Agreement. The Claims Administrator shall institute mechanisms to assure that Claims processed by any such facility are processed in the same manner and consistent with Claims processed by the Claims Office. After consulting with the Claimants' Advisory Committee and the Debtor's Representatives, the Claims Administrator shall close such facility if it is not cost effective to maintain such facility in light of claims volume.

(ii) Payment for any Claims processed and approved pursuant to this Section 6.05(g) shall be issued by the Trust upon the direction of the Finance Committee. The Claims Administrator and paying agent shall institute procedures to assure accuracy of payment and application of the appropriate adjustment to the Allowed payment as specified at Section 6.05(h) below and consistent with the Settlement Facility Agreement.

(iii) Any particular alternative Claims facility as authorized by subsection (i) above may be established and maintained only if the Claims Administrator determines that the administrative cost — on a per-claim basis — of resolving Claims with such facility is equivalent to or more cost efficient than the per-claim cost of resolution of the same categories of Claims by the Claims Office. For purposes of determining the equivalent administrative costs, the Claims Administrator shall not include in the calculation of per-claim resolution costs any fees or expenses associated with investment of funds, the distribution of payments, issuance of reports, or costs of the Finance Committee.

(iv) The Plan Proponents may establish a procedure for alternative processing of certain Australian claims consistent with the terms of the Motion by Plan Proponents to Approve Claim Processing in Australia for Certain Breast Implant Claimants in Classes 6.1 and 7, to Cap Liability Therefor, to Resolve Pending Confirmation Appeal by Australian Claimants, and for Expedited Consideration, filed on June 16, 2003 and granted by Order dated July 17, 2003.

(h) **Compensation.** The amount payable to Foreign Claimants who qualify for payment shall be a percentage of the Allowed amount specified in the applicable Compensation Schedule. Such percentage shall be computed based on Schedule III to these Claims Resolution Procedures. The percentage of payment is based on the Claimant's country of residence.

(i) **Categorization of Countries.** For purposes of determining the applicable compensation, Foreign Claimants shall be classified based on their country of residence. The categorization of countries shall be based on the following formula: Category 1 — countries with a common law legal system (Australia, New Zealand, Canada, United Kingdom); Category 2 — countries with a per-capita GDP greater than 60 percent of the GDP of the United States, along with countries in the European Union that are not in Category 1; Category 3 — countries with a per-capita GDP of between 30 percent and 60 percent of that of the United States; Category 4 — countries with a per-capita GDP of less than 30 percent of that of the United States. The per-capita GDP is to be determined by the most current version of The World Factbook (United States Central Intelligence Agency).

(ii) **Adjustment to Categories.** The Claims Administrator, with the agreement of the Claimants' Advisory Committee and the Debtor's Representatives, may adjust the categorization of countries in Schedule III if, due to changed economic conditions, the application of the formula specified at subparagraph (h)(i) above would result in the placement of any country in a category different than that specified on the then current version of Schedule III. Such adjustments shall occur no more than once per calendar year and any re-categorization shall apply to all Claimants residing in such country whose Claims are paid in the year of re-categorization or thereafter. Foreign Claimants who believe that due to changed economic conditions their country of residence is not correctly categorized in accordance with the terms of subparagraph (h)(i) above may submit to the Finance Committee a request for re-categorization. If the Debtor's Representatives and/or the Claimants' Advisory Committee and/or the Finance Committee do not agree to re-categorization, the Foreign Claimant may file a motion in the District Court seeking re-categorization.



## ARTICLE VII PROCESSING PROTOCOLS

### 7.01 *General Guidelines.*

(a) ***Adoption of MDL 926 Claims Office Protocols.*** Unless otherwise provided herein or in the Settlement Facility Agreement or subsequently modified as provided in the Settlement Facility Agreement, the Claims Office shall process all Claims in accordance with the guidelines and protocols established by the MDL 926 Claims Office as set forth in Section 4.03 of the Settlement Facility Agreement. The Claims Administrator shall consult with the Claimants' Advisory Committee and Debtor's Representatives regarding the applicability of any particular guidelines.

(b) ***Confidentiality.*** The Claims Office shall adopt procedures to maintain the confidentiality of all Claim files and Claimants' identities and shall not disclose such information to any person except to the extent provided herein or in the Settlement Facility Agreement.

(c) ***Consistency and Fairness.*** As specified in the Settlement Facility Agreement, the Claims Administrator shall institute procedures to assure consistency of processing and of application of criteria in determining eligibility and to ensure fairness in processing of Claims and appeals and to ensure an acceptable level of reliability and quality control of Claims.

(d) ***Access to Files.*** The Claims Office shall provide each Claimant (and/or her counsel) at the Claimant's cost with access to his/her file and shall maintain a system by which Claimants (and/or their counsel) can determine the current status of his/her Claim by contacting the Claims Office.

(e) ***Claims Assistance.*** The Claims Administrator, with advice and input from the Claimants' Advisory Committee, shall develop, staff and maintain a program for providing claims assistance ("Claims Assistance Program"). This program shall be a part of the Claims Office, staffed by employees of the Claims Office, and is intended to provide assistance to all Claimants about Claims Office procedures, eligibility guidelines, submission requirements (including documentation required), deficiencies, appeal procedures, the status of a Claimant's Claim, processing requests to Reorganized Dow Corning for individual acceptance of Proof of Manufacturer that have been classified as unacceptable by the Claims Office, and processing submissions to Dow Corning under the Individual Review Process for Rupture Claims outlined at Section 6.02(e)(vi) of these Claims Resolution Procedures. The Claims Assistance Program shall not represent Claimants, provide legal advice or serve as an advocate for Claimants.

### 7.02 *Order of Processing.*

(a) ***Proof of Manufacturer.*** The Claims Office shall process a Breast Implant Claimant's Proof of Manufacturer submission before processing Disease Payment Option Forms. The Claims Office shall to the extent possible identify those Claimants who have previously alleged implantation of a Dow Corning Breast Implant.

(b) ***Explant and Rupture Payment Options.*** The Claims Office shall record and process information, if applicable or if available from the Claimant's submission, about the proof for



Explantation and Rupture Payment Options based on a review of the Proof of Manufacturer submission.

**(c) Other Payment Options.** The Claims Office will not process Claims for Disease Payment Option benefits unless the Claimant has submitted acceptable (or has only a minor deficiency in) Proof of Manufacturer of an eligible implant.

**(i)** For Breast Implant Claimants, the Proof of Manufacturer and other Claim Form(s) shall request information regarding whether the Breast Implant Claimant:

- a. is making a new Claim for one of the benefit options (i.e., has never filed documentation with the MDL 926 Claims Office);
- b. has previously filed documentation (Proof of Manufacturer and/or disease documentation) with the MDL 926 Claims Office and received a Notification of Status letter from the MDL 926 Claims Office concerning her eligibility for disease benefits under the Revised Settlement Program;
- c. has previously filed documentation (Proof of Manufacturer and/or disease documentation) with the MDL 926 Claims Office and has no additional documentation to submit for the Dow Corning Settlement Program;
- d. has previously filed documentation (Proof of Manufacturer and/or disease documentation) with the MDL 926 Claims Office and has supplemental documentation to be considered under the Dow Corning Settlement Program; or
- e. if the Claimant is making a Disease Payment Option Claim, the particular Covered Condition for which the Claimant seeks to apply.

**(d) Processing Order.** As a general rule, and to the extent consistent with efficient administration and the Plan, the Claims Office shall process Claims within each category of payment option in the order in which the Claims form(s) and supporting materials for that option are received. The Claims Office shall deem the date of such receipt as the “submission date.” The Claims of Class 6.2 Claimants shall be processed separately in the order in which the Class 6.2 Claim submissions are received by the Claims Office.

**(e) Simultaneous Processing of Payment Options.** The Claims Office may process Claims for payment options selected by a Claimant either simultaneously or seriatim so as to expedite processing and payment and is encouraged to process Proof of Manufacturer, Explantation Payment Option, and Rupture Payment Option Forms simultaneously.

**(f) Processing of Disease Payment Option Claims.** The Claims Office will review a Disease Payment Option Claim upon receipt of: (1) a request by the Claimant to review a previously submitted disease claim as specified in paragraph (c) above or (2) receipt of new or additional documentation regarding the Disease Payment Option Claim. In accordance with Section 7.02(c), the Claims Office will provide Claimants with appropriate forms by which they can request a review of their prior submission. If the Claimant does not so notify the Claims

Office in accordance with Section 7.02(c) and does not submit any additional documentation by the time all other pending Disease claims have been reviewed, then the Claims Office will evaluate the Claim based on the prior submission.

**(g) *Payment of Claims.*** The Claims Administrator will distribute payment in accordance with the Settlement Facility Agreement. Payments for each benefit option selected by a Claimant can be made separately so that distribution of payments need not await final review of all benefit options sought by the Claimant. For example, assuming eligibility, payment for Explantation Payment Option benefits can be made immediately and need not await final review of other types of benefits the Breast Implant Claimant has sought (e.g., the Breast Implant Claimant can receive an Explantation Payment Option benefit even though review of her Rupture submission or Disease Payment Option submission has not yet been completed).

**(h) *Supplementation.*** A Breast Implant Claimant whose Disease Payment Option Claim is approved at a compensation level lower than that applied for may either accept the lower compensation level or Covered Condition or seek to cure the deficiency in the higher compensation level, subject to the time limitations specified at Section 7.08 of these Claims Resolution Procedures.

**(i) *Pre-Effective Date Evaluation.*** Once claims packages are mailed, the Claims Office shall process all mail received and communicate with Personal Injury Claimants about unclear or incorrect or conflicting information, such as the instance in which the Claimant has received the wrong package. The Claims Office shall review Claimants' Proof of Manufacturer submissions ("Product ID" or "Proof of Manufacturer") as part of its initial procedures to classify claims and shall determine whether the claim satisfies the requirements of Section 5.01.

### **7.03 *Notification of Status for Proof of Manufacturer Submissions.***

**(a) *Purpose.*** After evaluating the Claimant's Proof of Manufacturer submission, the Claims Office shall provide to the Claimant or, if represented, to her attorney of record a Notification of Status letter as provided below.

**(b) *Content.*** The Notification of Status letter shall advise the Claimant of:

1. Whether the Claimant has submitted acceptable Proof of Manufacturer of a Dow Corning product and the settlement options and deadlines, if any, available to her/him;
2. Whether the Claimant's Proof of Manufacturer has a deficiency and, if it does, the Notification of Status letter shall specifically identify the deficiency, state whether it is a minor or major deficiency, and inform the Claimant of procedures for correcting the deficiency including the availability of the Claims Assistance Program and/or appealing the ruling to the Claims Administrator.
3. For Breast Implant Claimants, the Notification of Status letter shall state whether the Claimant has submitted acceptable proof of one or more silicone gel breast implant(s) manufactured by Bristol, Baxter or 3M (as these implants are identified on Exhibit G to the Revised Settlement Program).

**(c) *Definition of Minor Deficiencies in Proof of Manufacturer Submission.*** Minor deficiencies in the Proof of Manufacturer submission include:

1. The Claimant submitted acceptable Proof of Manufacturer of a Dow Corning product but did not submit a Proof of Manufacturer Form.
2. The Claimant failed to provide a certified copy of medical records for acceptable proof where required (items 2, 10, 11 and 14 listed at Schedule I, Part I, Section B.).
3. An affirmative statement from the implanting physician has been submitted (item 5 in the list of acceptable proof, Schedule I, Part I, Section B., but no explanation was included as to why medical records are not available to supply manufacturer proof.
4. An affirmative statement from the implanting physician has been submitted (item 5 in the list of acceptable proof, Schedule I at Part I. B., but the physician has failed to provide the basis for his/her conclusion that the Claimant received a certain brand of implants.
5. Medical records have been submitted, but there is no identification on the records themselves indicating that these records relate to the Claimant.
6. The Claims Office needs confirmation that the statement or proof the Claimant submitted came from the physician or someone on the treating facility or physician's staff.
7. The proof the Claimant submitted has contradictory evidence of the brand of implant the Claimant received. For example, the operative report lists one brand, but the Claimant submitted a label of another brand, and both types of proof reference the same surgery.
8. The Claimant submitted a photograph of a Breast Implant showing one of the unique identifiers but has not provided a statement from the explanting physician identifying the implant in the photograph as one removed from the Claimant.

**(d) *Deficiency.*** Claimants who have a deficiency in their Proof of Manufacturer submission shall be directed to the Claims Assistance Program.

**7.04 *Timing of Distribution of Notification of Status Letters/Pre-Effective Date/Waiver of Opt-Out Right/Scope of Pre-Effective Date Evaluation.***

**(a)** Proof of Manufacturer Notification of Status letters may be distributed pre-Effective Date to Claimants or, if represented, to their attorneys of record with acceptable proof or proof with a minor deficiency under the following procedures:

1. If the Claimant has submitted acceptable Proof of Manufacturer, the Notification of Status will advise the Claimant that he or she is eligible to participate in the Dow Corning Settlement Program, having met the requirements of Section 5.01. The Notification of Status will further advise that, if the Claimant signs a waiver

of the Claimant's right to opt into the Litigation Facility, the Claims Office will proceed to evaluate the Claimant's submission of documentation for the various Settlement Options. Upon completion of those reviews, the Claims Office will be authorized to provide preliminary status letters to Claimants advising the Claimants of any additional documentation or information required. The Settlement Facility will send Notification of Status letters, as that term is used throughout the Plan Documents, as soon as possible after the Effective Date. Those post-Effective Date Notification of Status letters will trigger the deficiency curing deadlines.

2. If the Claimant has submitted Proof of Manufacturer that has a minor deficiency as defined by Section 7.03(c) of Annex A, the Notification of Status will advise that, upon curing that deficiency, the Claimant is eligible to participate in the Dow Corning Settlement Program, having met the requirements of Section 5.01. The Notification of Status will further advise that, if the Claimant cures the minor deficiency and waives the right to opt out, the Claims Office will proceed to evaluate the Claimant's submission of documentation for the various Settlement Options. Upon completion of those reviews, the Claims Office will be authorized to provide preliminary status letters to Claimants advising the Claimants of any additional documentation or information required. The Settlement Facility will send Notification of Status letters, as that term is used throughout the Plan Documents, as soon as possible after the Effective Date. Those post-Effective Date Notification of Status letters will trigger the deficiency curing deadlines.

**(b)** For claimants with unacceptable proof of a Dow Corning Breast Implant or Other Product, if the Claimant has submitted Proof of Manufacturer that the Claims Office determines constitutes Unacceptable Proof under Schedule I, the Claimant will receive a Preliminary Status letter informing the Claimant that (1) there is a problem with the proof submitted; (2) if the Claimant conditionally waives the right to opt into the Litigation Facility, the Claims Office will submit the Proof of Manufacturer to Dow Corning for review; and (3) the waiver is conditional upon Dow Corning's acceptance of the Proof of Manufacturer.

1. If the Claimant signs the conditional waiver form, the Claims Office shall submit the Proof of Manufacturer information to Dow Corning as authorized by Schedule I, Part F of Annex A to the Settlement Facility Agreement. Dow Corning shall act expeditiously and in good faith to review the submitted files. The Parties recognize that Dow Corning's ability to provide its evaluation is dependent on the volume of claims that fall into this category compared to the qualified technical staff at Dow Corning available. Dow Corning will inform the Claims Office of the anticipated review period required as files are submitted. A Claimant can withdraw her conditional waiver during the period starting with the 120<sup>th</sup> day of the opt-out period and ending on the 180<sup>th</sup> day of the opt-out period only if Dow Corning has not finished its evaluation of the Proof of Manufacturer at the time the claimant seeks to withdraw the claim. In the event that Dow Corning determines the Proof of Manufacturer to be acceptable, it shall notify the Claims Office. The Claims Office will then be authorized to begin review of other submissions by that Claimant for the various Settlement Options as specified at Section 7.04(a).

2. In the event that Dow Corning rejects the Proof of Manufacturer, the Claims Office shall send the Claimant or, if represented, to her attorney of record a Notification of Status (1) stating that he or she has submitted Unacceptable Proof; (2) encouraging the submission of additional documentation; and (3) informing the Claimant of the right to appeal the Claims Administrator's decision (not Dow Corning's). When and if the Claims Office or Appeals Judge deems the Proof of Manufacturer acceptable, the claimant is eligible for further review if he or she waives the opt-out right as specified at Section 7.04(a). There will be no review of any other submissions any such Claimants may make so long as Proof of Manufacturer is deemed unacceptable or Proof of Manufacturer with a minor deficiency.

#### ***7.05 Notification of Status for Explantation and Rupture Payment Options.***

**(a) Content.** For Breast Implant Claimants and certain Covered Other Products Claimants, the Notification of Status letter shall state whether the submission is acceptable pursuant to Sections 6.02(c), 6.02(e), or 6.03(f)(iii) as applicable. If the submission is not acceptable, the letter shall specifically identify the deficiency and inform the Claimant of procedures for curing the deficiency, the availability of the Claims Assistance Program and/or the process for appealing the determination to the Claims Administrator.

**(b) Definition of Minor Deficiencies in Rupture Proof.** There are four minor deficiencies in Rupture proof.

1. If a Breast Implant Claimant's Dow Corning Breast Implant was removed on or before the Effective Date, the Claim has a minor deficiency if the Breast Implant Claimant failed to state whether the ruptured implant has been preserved and, if so, the name and address of the custodian.

2. If the ruptured implant was removed after the Effective Date, the Claim has a minor deficiency if the Breast Implant Claimant failed to provide the Claims Office with the required statement concerning preservation of implants or failed to provide a statement from the explanting surgeon (or the hospital pathologist, a physician who assisted in the explantation surgery or from another doctor who examined the removed implant, as provided herein) affirming that, in his or her opinion, the Rupture did not occur during or after the explantation procedure and providing a factual basis for that opinion.

3. If the Claimant was explanted after January 1, 1992 but did not submit a pathology report or indicate that the pathology report was unavailable, the Claim has a minor deficiency that can be cured by submission of the report or the required statement.

4. If the Claimant timely submitted the supporting documentation demonstrating Rupture but did not submit a Rupture Payment Option Form, the Claim has a minor deficiency which can be cured by submitting the Rupture Payment Option Form.

Breast Implant Claimants may cure deficiencies in Rupture proof by sending to the Claims Office the appropriate written statement, clearly marked at the top as Rupture Proof.

**(c) Timing of Distribution of Notification of Status letters.** Explant or Rupture Notification of Status letters can only be distributed after the Effective Date. Prior to the

Effective Date, the Claims Office may distribute preliminary status letters as specified at Section 7.04. The preliminary status letter will include language designating it as a confidential communication from the Settlement Facility and the District Court. It will request that the claimant maintain confidentiality by conferring only with her attorney, physician(s), Claims Assistance Program, and/or Tort Claimants' Committee regarding the content of the preliminary status letter and/or the submission of her Settlement Options.

**7.06 Notification of Status for Disease Payment Option Claims.**

**(a) Content.** The Notification of Status letter shall inform the Breast Implant Claimant and her counsel of the results of the evaluation of the Claim, as specified at Section 6.02(d) herein, and shall inform the Claimant of the election options.

**(b) Deficiency.** If the Claim has a deficiency, the Notification of Status letter shall specifically identify the deficiency, state whether it is a minor or major deficiency, and inform the Claimant of procedures for correcting the deficiency and/or appealing the ruling to the Claims Administrator. For Claims with deficiencies, the Notification of Status letter shall also inform the Claimant that she may release all present and future rights to the Disease Payment Option and instead, receive \$2,000 as an Expedited Release Payment. If the Claim is approved at a lower compensation level or Covered Condition than that applied for, the Notification of Status letter shall state the deficiency or the reason(s) why the higher level or Covered Condition was not approved.

**(c) Timing of Distribution of Notification of Status letters.** Disease Notification of Status letters may be distributed only after the Effective Date. Prior to the Effective Date, the Claims Office may distribute preliminary status letters as specified at Section 7.04. The preliminary status letter will include language designating it as a confidential communication from the Settlement Facility and the District Court. It will request that the claimant maintain confidentiality by conferring only with her attorney, physician(s), Claims Assistance Program, and/or Tort Claimants' Committee regarding the content of the preliminary status letter and/or the submission of her Settlement Options.

**(d) Types of Deficiencies.** The Claims Office shall inform the Breast Implant Claimant of any of the following deficiencies:

**1. Failure to document specific ACTD symptoms.**

The word "documented" precedes several ACTD symptoms. It is not possible to give one precise definition of the word "documented" because its meaning is often dependent on the particular symptom involved. Generally, it means that it is based on some reliable information other than simply the Claimant's complaint or oral history. For some symptoms, "documented" means that the physician has verified the symptom on physical examination. For others, particularly those that are entirely subjective, it can mean that the physician has questioned the Claimant sufficiently to be able to form a professional opinion, utilizing all that doctor's knowledge and training, that the complaint is a valid one. "Documented" can also mean that written notations of that symptom are found several times in the Claimant's past medical records. This deficiency can be cured, then, by providing (1) proof of verification of the symptom through physical examination; (2) a supplemental statement from the Claimant's Qualified Medical Doctor ("QMD")



as defined at Schedule II, Part A revealing that (s)he questioned the Claimant sufficiently about this symptom and concluded that the complaint is valid; or (3) additional medical records reflecting that the Claimant complained about this symptom on other occasions.

2. All the records on which the QMD based his/her determination of the Claimant's disability were not submitted with the Claim.

If the Claimant's QMD indicated that (s)he relied on some documents in making a disability determination, but those other documents have not been submitted the Claim will be deemed deficient. Before the Claims Office can confirm the Claimant's disability, the Claims Office must have all of the records that the QMD used to make the disability determination. The Claimant can cure this deficiency by filing those documents.

3. The Claimant needs one more symptom to qualify for a compensable condition.

This deficiency can be cured by providing medical records or a supplemental statement from the Claimant's QMD reflecting any additional symptoms that the Claimant has that satisfy the criteria of Schedule II, Part A.

4. Information contained in the Claimant's documents indicate that the Claimant is not disabled by a compensable condition.

The Claimant's documentation affirmatively reveals that the Claimant is not disabled. If this is correct, this deficiency can possibly be cured by providing a statement from the Claimant's QMD or treating physician describing the Claimant's current disability and providing a satisfactory explanation for the contradictory information submitted earlier.

5. Information contained in the Claimant's documents indicates that the disability determination is inconsistent with the disease criteria of Schedule II, Part A.

The Claimant's QMD or treating physician made a determination of the Claimant's disability, but information about the Claimant's pain or limitations on his/her activities (either in the QMD's statement or elsewhere in the Claimant's records) conflicts with the requirements for that disability level. This deficiency can possibly be cured by a statement from the Claimant's QMD or treating physician assigning a disability level that is appropriate for the Claimant's condition or providing information about the Claimant's disability that is consistent with criteria for that level. If the Claimant's supplemental documentation provides new information in support of the disability level the Claimant originally claimed, the Claimant should provide an explanation for the contradictory information submitted earlier.

6. The Claimant's documents contain insufficient information about the Claimant's condition to evaluate whether the disability determination is consistent with disease criteria of Schedule II, Part A.



Although the Claimant's QMD or treating physician made a determination of the Claimant's disability, there is not enough information in the Claimant's file to allow the Claims Office to determine if that disability level was appropriately assigned by the physician. This deficiency can be cured by providing a supplemental statement from the Claimant's treating physician or QMD describing the Claimant's level of pain or limitations on his/her activities. If the Claimant's disability is caused in part by a disease or condition that is not compensable under Disease Payment Option I, the Claimant can only be approved for the level of his/her disability that is caused by the Covered Condition. In that situation, the Claimant should make sure that in describing the Claimant's Covered Condition, the physician clearly indicates the extent of the Claimant's disability caused by the Covered Condition covered by Schedule II, Part A.

7. Information contained in the Claimant's documents indicates that the Claimant is no longer disabled by a Covered Condition.

The Claimant's documentation clearly indicates that the Claimant is no longer suffering from any earlier disability the Claimant may have had. This deficiency can only be cured if the Claimant is once again disabled. The Claimant should provide a statement from her QMD or treating physician describing the Claimant's current disability and explaining the change from her earlier-reported condition.

8. The Claimant's documents did not contain a determination by a treating physician or QMD of the Claimant's disability.

The Claimant's file contained no determination of the Claimant's disability by either the Claimant's treating physician or a QMD. If the Claimant's file did contain a disability determination from a physician, this deficiency can be assigned if the Claims Office is unable to confirm that the physician who made that disability determination was either a treating physician or an appropriate Board-certified specialist. This deficiency can be cured by obtaining a determination of disability from the Claimant's treating physician or a physician Board-certified in one of the specialties qualifying as QMD specialties.

9. The Claimant needs more than one additional symptom to qualify for a compensable condition.

The Claimant needs two or more additional symptoms to qualify for the applicable disease or condition. This deficiency can be cured by providing medical records or a supplemental statement from the Claimant's QMD reflecting any additional symptoms the Claimant has that meet the criteria for that Covered Condition.

10. Specific ACTD symptoms existed before the Claimant received her first breast implant.

The Claimant's records reflect that she suffered from the specified ACTD symptoms before she had her first breast implant. The Claims Office is not permitted to credit those pre-existing symptoms. The only time this deficiency

can be cured is if there are typographical errors in the dates in the Claimant's records. If there are indeed typographical errors in those dates, the Claimant must provide an affirmative statement from the physician whose records contain those errors explaining in detail the nature of those errors and the true dates that should have been reflected in those records.

- 11.** The Claimant's QMD statement or diagnosis was not signed.

This deficiency can be cured by submitting the signed QMD statement or diagnosis.

- 12.** The Claimant's QMD determination of disability or severity level was not signed.

A statement or diagnosis from a QMD must have that physician's signature. A Claimant can cure this deficiency by having the QMD sign a copy of the original statement or diagnosis, and filing that signed copy with the Claims Office. If the deficiency noted is lack of signature on the disability statement, the Claimant should ensure that the statement which the physician signs is the one that contains his or her determination of the Claimant's disability.

- 13.** Information contained in the Claimant's documents indicates that the compensable condition from which she suffered before her first breast implant has not increased in severity or disability since that breast implant was implanted.

The Claimant's records show that she suffered from the disease noted on her Notification of Status letter before she received her first breast implant. That condition is compensable only if it increased in severity or in its impact on the Claimant's disability after implantation. The Claimant can cure this deficiency by providing either a supplemental report from her treating physician or QMD that affirmatively reveals that her condition has worsened to the point that she is now in a higher compensation category or medical records that demonstrate that increase.

- 14.** The Claimant's medical records did not reveal whether the specified lab tests were performed by the method required by the criteria in Schedule II or if the results of those tests meet the criteria in Schedule II.

The Settlement Program requires that the lab tests noted be performed by a certain stated method or that the results of those tests meet certain minimum values. If the Claimant's tests did meet that stated criteria but her original documentation failed to reveal that fact, the Claimant can cure this deficiency by providing a statement from either the lab or the physician who ordered the test reflecting the method by which it was run and the results reported in the value required by the settlement. If the Claimant's tests did not, in fact, meet the stated criteria, the Claimant can cure the deficiency by having them re-taken in the manner required by Schedule II.

- 15.** Specified signs and symptoms do not meet the criteria of Schedule II.

The symptoms noted were not shown in the Claimant's file to meet the criteria that Disease Payment Option I specifies. The complaints may not rise to the level required for the Claims Office to credit the Claimant with that particular symptom, or the records revealed that the complaint fell within a category affirmatively excluded by the Disease Payment Option. This deficiency can be cured by providing either a supplemental statement from the Claimant's QMD or the medical records demonstrating that her symptom does indeed meet the criteria stated in Disease Payment Option I.

16. The Claimant's documents contain insufficient information about the Claimant's condition to evaluate whether the disability determination is consistent with the criteria in Schedule II.

This deficiency means that there is not enough information about the Claimant's symptoms for the Claims Office to know that the criteria for the claimed disability level have been satisfied.

For Disease Payment Option I Disability Level C: Under Disease Payment Option I, the definition of Level C provides that the Claimant must be experiencing moderate pain on a regular or recurring basis. The pain must be due to the Claimant's ACTD or ANDS. To cure the deficiency, the Claimant should look at her claim documentation to see what ACTD or ANDS symptoms she has to check if all of the ACTD or ANDS symptoms are ones that normally have no pain component, like alopecia, chronic fatigue, or loss of function of the breast. If that is the case, then the Claims Office cannot approve a "C" disability rating unless there is evidence that the Claimant is experiencing pain from one of these symptoms or unless the Claimant supplies evidence that she has an additional symptom from the Disease Payment Option I that does cause pain. If the claim documentation does mention a pain-related symptom, the Claimant should look at her Notification of Status letter to see if another deficiency is listed that specifically mentions that symptom. For example, if the Claimant has had myalgias but her Notification of Status letter says that the myalgias have not been "documented" and myalgia was her only pain-related symptom, then the Claims Office cannot verify a "C" disability level until the Claimant has provided a supplemental documentation to satisfy the "documented" requirement. This deficiency might also be assigned because there is nothing upon which the Claims Office could base a conclusion that the pain is "regular or recurring" if the Claimant's physician described the pain as being only "mild" or "slight."

For Disease Payment Option I Disability Level B: If the Claimant's physician assigned disability level "B" and her Notification of Status letter states the deficiency listed above, the Claimant should read the definition of that level and look to see whether the "B" level is based on severe pain or an inability to do certain activities. If the "B" determination was pain-related, the Claimant should look to see what ACTD or ANDS symptoms are found in the Claimant's documentation. If there are no symptoms that cause pain, that fact may explain this deficiency. If there are pain-producing symptoms, the Claimant should look to see if there is any evidence that these symptoms result in severe pain on a regular or recurring basis. Generalized statements about "severe pain" may not be enough. The Claims Office needs to be able to verify that the ACTD/ANDS

symptoms themselves are the cause of that severe pain. If the “B” level is based on limitations of the Claimant’s activities, the Claimant should look to see if there is any information provided concerning what activities are limited. A conclusory statement alone, with no information about the Claimant and her limitations, will result in this deficiency being assigned. Is there a connection between the specific activities that the Claimant can no longer do and the ACTD/ANDS symptoms that she has? The Claimant’s disability must be due to the Claimant’s compensable condition. The Claims Office must have enough information about what the Claimant’s limitations are and the cause of those limitations to be able to verify that her condition meets the settlement’s requirements for a “B” disability level.

For Disease Payment Option I Disability Level A: If the Claimant’s physician assigned disability level “A,” the Claimant should keep in mind that the settlement’s definition of this assigned disability level is a difficult one to meet. The Claimant must be unable to do any of her normal activities or only be able to do a very few of them. The Claimant should review the Claim documents carefully to ensure that there is enough description of her daily life and limitations to allow a reader to know that she does indeed meet this strict definition of total disability. It must be clear that the Claimant’s total disability is due to the symptoms of her applicable disease or condition.

#### ***7.07 Notification of Status for Other Products/Medical Condition.***

**(a) Content.** The Notification of Status letter shall inform the Covered Other Products Claimant and her counsel of the results of the evaluation of the Claim as specified at Section 6.03.

**(b) Deficiency.** If the Claim has a deficiency, the Notification of Status letter shall specifically identify the deficiency, state whether it is a minor or major deficiency, and inform the Claimant of procedures for correcting the deficiency and/or appealing the ruling to the Claims Administrator.

**(c) Pre-Effective Date Notification of Status/Waiver of Opt Out and Evaluation.** Pre-Effective Date review and evaluation of Other Products Claims (including communications to Claimants) shall be conducted in accordance with the provisions of Section 7.04.

#### ***7.08 Notification of Status for Silicone Material Claims and Participating Foreign Gel Claims.***

**(a) Content.** The Notification of Status letter shall inform the Silicone Material Claimant and her counsel of the results of the evaluation of the Claim as specified at Section 6.04.

**(b) Deficiency.** If the Claim has a deficiency, the Notification of Status letter shall specifically identify the deficiency, state whether it is a minor or major deficiency, and inform the Claimant of procedures for correcting the deficiency and/or appealing the ruling to the Claims Administrator.

(c) ***Pre-Effective Date Notification of Status/Waiver of Opt Out and Evaluation.*** Pre-Effective Date review and evaluation of Silicone Material Claims and Participating Foreign Gel Claims (including communications to Claimants) shall be conducted in accordance with the provisions of Section 7.04.

***7.09 Guidelines for the Timing of Submissions/Time Period to Cure Deficiencies for Breast Implant Claims.***

(a) ***Explantation Payment Option for Breast Implant Claims.***

(i) ***Deadline for Submission of Explantation Claims.*** Explantation Payment Option Claims must be submitted on or before the 10th anniversary of the Effective Date.

(ii) ***Deficiencies.*** If the Explantation Payment Option submission is not acceptable, the Notification of Status letter shall so inform the Breast Implant Claimant and her counsel and shall identify with specificity the deficiencies, state what documentation is needed to correct the deficiencies, inform the Claimant of the availability of the Claims Assistance Program and/or the process for appealing the determination of the Claims Administrator. If the deficiencies are corrected timely, the Claims Office shall issue a new Notification of Status letter stating that the Claim has been approved.

(iii) ***Cure of Deficiency.*** The Claimant shall have six (6) months from the date of the Notification of Status letter to cure a deficiency in her Explantation Payment Option Claim.

(b) ***Disease Payment Option for Breast Implant Claims.***

(i) ***Deadline for Submission of Disease Payment Option Claims.*** Eligible Settling Breast Implant Claimants who do not otherwise release their Disease Payment Option may apply for Disease Payment Option benefits at any time on or before the fifteenth anniversary of the Effective Date.

(ii) ***Deadline to Cure Deficiencies in Disease Payment Option Claims.*** Except as provided at Section 6.02(d)(iii), the following defines the deadlines for curing deficiencies in Disease Payment Option Claims:

1. Claimants shall have one year from the date of the Notification of Status letter to cure any deficiency in the Claim.
2. Claimants who fail to cure the deficiency within the one-year period are still eligible to receive the Expedited Release Payment Option (even if the Expedited Release Payment Option has concluded).
3. Claimants who fail to cure the deficiency within the one-year period shall not be barred from submitting a Claim and receiving payment for a new compensable condition that manifests after the conclusion of the one-year period (provided that the Claimant has not otherwise released all Disease Payment Option Claims).

(iii) ***Re-review.*** The Claims Office may establish regulations relating to the submission of medical documentation and set reasonable periods during which to conduct

the evaluation or re-evaluation of a Claimant's eligibility and benefits based on supplemental submissions and for submission of supplemental documentation after notice of deficiencies. Generally, the Claims Office will not review a Claimant's submission(s) in response to a deficiency notice more than twice; however, the Claims Administrator may conduct a third review after the completion of the review of all other Claims for Disease Payment Option Benefits.

**(c) *Rupture Payment Option for Breast Implant Claims.***

**(i) *Deadline.*** Breast Implant Claimants must submit the Rupture Payment Option Form and supporting documentation set forth at Section 6.02 on or before the second anniversary of the Effective Date, except that Claimants explanted within the ninety (90)-day period preceding the second anniversary of the Effective Date shall have until thirty (30) days after that deadline to submit the appropriate Form and supporting documentation.

**(ii) *Deficiency.*** In the event that the Rupture Payment Option Form or supporting documentation is deficient, the Claimant shall have six (6) months from the date of the Notification of Status letter identifying the deficiency to submit additional documentation to cure the deficiency.

**ARTICLE VIII  
PROCEDURE FOR ERROR CORRECTION AND APPEALS**

**8.01 *Error Correction.*** Claimants who believe the Claims Office made a mistake may write to the Claims Office detailing the information the Claimant feels should be corrected. If the Claims Office determines that it did make a mistake, it will correct the error and notify the Claimant in writing.

**8.02 *Error Correction Procedure.*** The error correction procedure is an administrative procedure which ensures that the records of the Claims Office relating to the status of a Claimant's Claim and the Claim itself are as accurate as possible. It is not the same as the appeal process set forth at Sections 8.04 and 8.05. The appeal process at Section 8.04 is only available after all possible corrections have been made, and the Claimant has submitted all documentation (s)he wishes to be included in the determination of the Claimant's eligibility or in the processing of any Claims.

**8.03 *Record for Appeal.*** Before a Claimant can appeal, (s)he must first submit any additional documentation (s)he wishes to have considered. If, after the Claims Office reviews the supplemental documentation, the Claimant is still dissatisfied with the determination, (s)he can appeal to the Claims Administrator by filing a written document, clearly marked as "Appeal to Claims Administrator." In that document, the Claimant should identify the determination with which the Claimant disagrees and state the reasons for the disagreement.

**8.04 *Appeals to the Claims Administrator.*** If the Claimant is unsuccessful in his/her efforts to cure any deficiencies or if the Claimant is dissatisfied with the allowed benefits, (s)he may appeal the decision to the Claims Administrator. The appeal is limited to the benefit status contained in the Notification of Status letter. Because there may be multiple Notification of Status letters for each of the settlement options, Claimants may appeal each of the rulings. The Claims Administrator shall conduct a *de novo* review and promptly issue a ruling in writing to



the Claimant and/or his/her counsel. The Claims Administrator may request further submissions from the Claimant, or may seek further information from the Claimant's physicians in deciding the appeal. In the event that the Claims Office determines that the Qualified Medical Doctor or records submitted in support of the Claim are unreliable, the Notification of Status letter shall advise the Claimant of such determination and shall identify the particular records or statements that are deemed unreliable. The Claimant shall have the right to appeal any such determination to the Claims Administrator and the Appeals Judge in the same manner and under the same procedures applicable to appeals regarding any other deficiency.

**8.05 Appeals to Appeals Judge.** Claimants who disagree with the ruling of the Claims Administrator may appeal to the Appeals Judge by submitting a written statement outlining the Claimant's position and statement as to why the Claimant believes the Claims Office and Claims Administrator have erred. The Appeals Judge shall review the appeal record and Claim file in deciding the appeal. The Appeals Judge shall apply the guidelines and protocols established in this Annex A to the Settlement Facility Agreement, including the provisions of the Revised Settlement Program as adopted by this Annex A, and the appeals process shall not result in any modification of substantive eligibility criteria. Any appeal that involves a new interpretation of the substantive eligibility criteria must be submitted to the Debtor's Representatives and the Claimants' Advisory Committee consistent with Section 5.05 of the Settlement Facility Agreement. The Appeals Judge shall issue a determination on the appeal in writing. The decision of the Appeals Judge will be final and binding on the Claimant. The decisions of the Appeals Judge will be served on the Claimant (and his/her counsel), the Debtor's Representatives, and the Claimants' Advisory Committee.

**8.06 Reorganized Dow Corning's Role in Appeals.** Reorganized Dow Corning will have the same right to participate in individual appeals as the manufacturers participating in the Revised Settlement Program. Reorganized Dow Corning shall have no right of appeal from a specific decision of the Appeals Judge or right of appeal or review from determinations made by the Claims Office.

## **ARTICLE IX ATTORNEYS' FEES**

**9.01 Privately-Retained Counsel.** Fees and expenses of attorneys individually retained by Claimants who do not timely elect litigation will be borne by such persons based on applicable state law and the individual arrangements made between them and their attorneys, but subject to the limitations indicated below.

(a) The fees charged by individually-retained attorneys to a Claimant who elects to participate in the Dow Corning Settlement Program shall not exceed the sum of:

- (i) 10 percent of the first \$10,000 paid to such Claimant;
- (ii) 22.5 percent of the next \$40,000 paid to such Claimant; and
- (iii) 30 percent of the amount in excess of \$50,000 paid to such Claimant.



(b) Amounts paid to or on behalf of Claimants as Explantation Payment Option or Expedited Release Payment Option benefits shall not be counted as amounts paid to a Claimant for purposes of calculating the above limitations.

(c) Claimants in Class 6.1 or 6.2 or attorneys representing Claimants in Class 6.1 or 6.2 may request that the District Court adjust the attorney fee schedule set forth in subparagraph (a) above to reflect the fact that payments to Class 6.1 Claimants are 60% and payments to Class 6.2 Claimants are 35% of the amounts payable to Domestic Claimants and that the schedule therefor will not provide proportional treatment of attorney fees without an adjustment. The Plan Proponents shall not object to any such request.

(d) Claimants may retain an attorney of their choice for advice concerning their rights or to provide services either in presenting a Claim under the Dow Corning Settlement Program or in instituting litigation, but they will be responsible for the fees and expenses of such attorney as explained above. Claimants are not required to have private counsel to submit Claims under the Settlement Program.

**9.02 Common Benefit/Substantial Contribution Claims.** In the event that the Proof of Claim(s) filed on behalf of and seeking contribution to the Common Benefit Fund established in Order No. 13 issued by the MDL 926 Court (In re Silicone Gel Breast Implants Products Liability Litigation, Order No. 13 (Establishing Plaintiffs' Litigation Expense Fund to Compensate and Reimburse Attorneys for Services Performed and Expenses Incurred for the Common Benefit)) is/are withdrawn, then claims for substantial contribution consistent with the standard under Section 503(b) of the Bankruptcy Code may be asserted, and neither Reorganized Debtor nor the Shareholders will oppose any such claims if asserted by a member of the Tort Claimants' Committee on the ground that the claimant is or was a member of the Tort Claimants' Committee. In the event that after tabulation and any weighting of votes Class 9 Claimants are determined to have voted to accept the Amended Joint Plan, then claims for substantial contribution consistent with the standard under Section 503(b) of the Bankruptcy Code may be submitted to the District Court by any bankruptcy counsel for Other Products Claimants (including bankruptcy counsel for the TMJ MDL Steering Committee). Reorganized Debtor, the Shareholders, and the Claimants' Advisory Committee, and the Finance Committee retain the right to evaluate any such claim on the merits and to take any position with respect to the claim. Nothing in this Section 9.02 will limit Reorganized Debtor's or Shareholders' rights to oppose such claim on the merits. The compensation and/or reimbursement for any "substantial contribution claim" shall be determined by the District Court and any amounts Allowed by the District Court shall be paid by the Trust (subject to the direction of the Finance Committee) from the Settlement Fund, except that any substantial contribution claim Allowed by the District Court for counsel representing Other Products Claimants shall be paid by the Trust (subject to the direction of the Finance Committee) from the Other Products Fund. The Tort Claimants' Committee agrees to use its best efforts to attain the withdrawal of the Claim(s) filed on behalf of or for the benefit of the Common Benefit Fund (defined above), and if such Claim(s) is/are not withdrawn, to oppose the Allowance of any such Claim(s). Pursuant to Paragraph 11 of the Confirmation Order, the District Court will establish procedures for the submission of Claims under this Section.

**SCHEDULE I  
ACCEPTABLE PROOF OF MANUFACTURER**

**PART I. Breast Implant Claimants**

Part I of this Schedule lists the company name, implant brands and manufacturer names that may be used in medical records to describe a Dow Corning Breast Implant. The brand/manufacturer names listed in Part A below identify a Dow Corning product if the Claimant submits acceptable Proof of Manufacturer, as defined at Part B of this Schedule I, Part I.

In determining the acceptability of manufacturer proof, the Claims Administrator shall apply the protocols and procedures developed in connection with the Revised Settlement Program for evaluating documentation of manufacturer proof, including procedures for evaluating Claims submitted with inconsistent, incomplete or contradictory manufacturer proof.

***A. Brand and Implant Names for Dow Corning Breast Implants.***

<b>Brand/Manufacturer Name</b>	<b>Status</b>
Cronin	Covered: 1963-1971
Dow Corning, Dow Corning Wright, DC, or DCW	Covered
Mueller, V. or V. Mueller	Covered for implants implanted after 1/1/68 and before 8/31/74
SILASTIC or Silastic	Covered
SILASTIC II or Silastic II	Covered
SILASTIC MSI or Silastic MSI	Covered
Varifil	Covered
If the medical or hospital records says only “silastic-type” (lower case) without any additional identifying information (e.g., lot or catalog number)	Not Covered

<p>“silastic” — in all lower case letters — contained in the contemporaneous operative report for breast implantations occurring prior to 1969 provided there is no other information in the Claimant’s records inconsistent with a Dow Corning product. This shall be used as a brand name only if the Claimant does not have explant records demonstrating a unique identifier.</p>	<p>Covered.</p>
<p>“silastic” — in all lower case letters — for implantations during or after 1969.</p>	<p>Not Covered.</p>

**B. Proof of Manufacturer.** The following Section specifies the types of proof that shall be acceptable proof:

1. Hospital records of the surgeon’s report of the surgery — written at or near the time of the implantation surgery — that specify a Dow Corning brand name or Dow Corning as the manufacturer, as specified in Part A above.
2. A certified copy of the Claimant’s medical records that contain the implant package label demonstrating a Dow Corning Breast Implant. Note: a certified copy is only required if the label —
  - a. is on a page that does not affirmatively reveal it to be a part of the Claimant’s hospital or medical records and
  - b. does not have a lot number, serial number, or catalog number on it.
  - c. If the page containing the implant label/sticker clearly comes from the hospital’s contemporaneous record of the implant surgery, has other information relating to the Claimant’s hospitalization on that page, and has sufficient patient identification for the Claims Office to tell that it came from the Claimant’s records, it falls into the acceptable proof category of contemporaneous hospital records, and does not have to be certified. If the hospital records are organized so that the implant label/sticker was put on a page by itself, it must be certified.
3. Implant labels clearly marked with a lot, serial or catalog number. The Claims Office will maintain a list of these numbers, to ensure that no duplicates are used. These labels do not have to be certified.
4. Records of the implanting surgeon — written at the time of the implantation surgery — that specify a Dow Corning brand name or Dow Corning as the manufacturer as set forth in this Schedule I, Part I, Section A.

5. An affirmative statement from the implanting physician (or a responsible person at the treating facility where the implantation took place) attesting that the Claimant was implanted with a Dow Corning Breast Implant. The person making this affirmative statement must also provide the basis for that conclusion. This type of proof is acceptable only if the records outlined in subparagraphs 1 and 2 above are not available, and must include a description of what steps were taken to secure the types of proof outlined in subparagraphs 1 and 2 above and explain why those records were not available. The statement of steps taken can be provided by the Claimant's counsel. This statement cannot rest upon unacceptable proof as noted in Section E below. The Settlement Facility is authorized to accept an affirmative affidavit or statement from a surgeon even if that affidavit was not written for the specific Claimant if the affidavit or statement states unequivocally that the surgeon only used Dow Corning products during a defined period and if the Claimant seeking to use the affidavit submits credible medical records demonstrating that she had implantation surgery performed by the same surgeon during the specified time frame.
6. A health insurance claim form, signed by the implanting physician reasonably close to the date of the surgery, naming the type of implant used as set forth in this Schedule I, Part I, Section A.
7. Medical records of the explanting physician (or other physician or appropriate professional who examined the Claimant's implant during or after removal surgery) — written at the time of the examination of the Breast Implant — if that physician or other appropriate professional points out a specific characteristic of the Breast Implant that is on the list of characteristics unique to Dow Corning implants as specified at Section D, below.
8. A photograph of an explanted Breast Implant that shows one of the characteristics unique to a Dow Corning Breast Implant, as specified at Section D, below, if the photograph is accompanied by a statement from the explanting physician identifying the Breast Implant in the photograph as one (s)he removed from the Claimant.
9. Dow Corning or brand-specific implant control sheets, with cross-references to the Claimant, that reasonably appear to be contemporaneously kept records in the hospital or implanting physician's office.
10. Dow Corning's invoice or packing list contained in the Claimant's medical or hospital records relating to the implant surgery. If the Claims Office cannot determine that the invoice or packing list actually was included in those records, they may require a certified copy of the records or a supplemental statement from the records custodian.
11. Dow Corning's catalog with a particular type or style of implant circled or otherwise marked, if contained in a certified copy of the Claimant's medical or

hospital records relating to the implant surgery which were compiled and/or produced before or about the time of that surgery.

12. Patient Informed Consent forms signed by the Claimant and dated close to the date of the implantation surgery, accompanied by other contemporaneous medical or hospital records verifying that the implantation surgery actually occurred and identifying Dow Corning as the manufacturer of the Breast Implant.
13. a) Admissions in pleadings or letters written by Dow Corning to the Claimant, her representative or her physician acknowledging that the Claimant's breast implants were manufactured by Dow Corning.  
  
b) Internal memoranda prepared by Dow Corning or a Dow Corning employee affirming that the implant is a Dow Corning product but only if it is clear that Dow Corning made an independent determination that the product was a Dow Corning product and was not simply describing or restating a determination made by a third party.
14. For breast implants occurring after July 1986, participation in Dow Corning's PREP program as documented by a signed PREP brochure, statement, or similar document if contained in a certified copy of the Claimant's contemporaneous medical or hospital records.
15. Participation in Dow Corning's Removal Assistance Program (after March 1992) documented by correspondence enclosing payment for uninsured medical expenses issued under the program based on receipt of proper documentation. If the Claimant is identified by Dow Corning as having participated in the Removal Assistance Program, the Claimant need not submit additional proof.
16. This paragraph only applies to Claimants in Class 6.2. Dow Corning invoice, sales receipt, packing statement, or import receipt that would ordinarily have accompanied a Breast Implant sold for implantation, where such invoice, receipt, or statement references a Breast Implant product for a Dow Corning Breast Implant and further contains either the Claimant's name or other information identifying the Claimant. Such Proof of Manufacturer shall be acceptable only if accompanied by medical records documenting that the Claimant was later implanted with a Breast Implant within a reasonable amount of time after the date of such invoice, sales receipt, statement, or import receipt.
17. Claimants whose names appear on Dow Corning's Device Custodian list (provided by Dow Corning to the Settlement Facility) as having a confirmed Dow Corning implant shall be deemed to have satisfied product identification requirements for that particular implant.

18. Claimants whose names appear on Dow Corning's list of participants in the "Ben Gregory" clinical study shall be deemed to have satisfied product identification requirements for that particular implant.
19. Contemporaneous medical records stating that the Claimant was implanted with a "Rubin," "Rubin Design," or "Q7-2573 " implant shall be deemed to have "acceptable" proof of manufacturer for implants implanted between 1984 and 1986.

**C. Definition of Certified Copy of Medical Record/Requirements for Certified Records.**

1. A "certified copy" of medical records is a copy of records with a certificate attached, usually signed by the custodian of records for that office or facility, affirming that the attached pages are true and correct copies of records in a particular patient's file.
2. If a Claimant's proof consists only of the implant package label, the Claimant must provide a certified copy of the medical records that contain that label.
3. Photocopies of the certificate for certified medical records are acceptable. The original certificate and original records do not have to be submitted as long as a photocopy is submitted.

**D. Unique Product Identifiers.** The following unique product identifiers of a Dow Corning Breast Implant(s) shall be considered as acceptable proof where the removed implants are examined by a physician who identifies the manufacturer or brand. See paragraph 7 of Section B above:

1. For implantations or implants manufactured between 1969 and 1973 a high profile contour "ski slope" design implant with Dacron® fixation patches on the posterior with the upper portion of the implant being concave and the bottom portion convex. If the fixation patch has detached from the implant, then the Claims Office shall accept and shall deem as acceptable proof a photograph of the implant showing an imprint consisting of 3-4 linear impressions of the Dacron® mesh embedded in the elastomer shell.
2. An implant with fixation patches where white Dacron® knit mesh loops were either sewn or bonded to the elastomer patch surface with the fixation patches in turn bonded to the envelope posterior. Products with the following configurations of fixation patches are acceptable:
  - (i) For implants implanted or manufactured between 1963 and 1965, a single large Dacron® mesh-reinforced fixation patch covering all or almost all of the posterior implant surface of a silicone gel-filled implant with a prominent non-everted peripheral seam where the fixation patch is constructed of Dacron® mesh-reinforced silicone elastomer sheeting to



which non-embedded Dacron® mesh had been sewn with Dacron® sutures. (1963-1965)

- (ii) For implants implanted or manufactured between 1963 and 1969, four (4) Dacron® mesh-reinforced fixation patches, one in each quadrant on the posterior implant shell, asymmetric or symmetric, with a distinct peripheral seam everted or non-everted, where the fixation patches are constructed of Dacron® mesh-reinforced silicone elastomer sheeting to which non-embedded Dacron® mesh has been sewn with Dacron® sutures.
  - (iii) For implants implanted or manufactured between 1968 and 1982, two (2) to five (5) circular Dacron® mesh fixation patches on the posterior implant shell of the embedded/pleated design, consisting of a clear elastomer disc about 22-25 mm diameter, with a pattern of embedded Dacron® mesh in a pleated pattern, with the actual Dacron® mesh present or absent.
  - (iv) For implants implanted or manufactured between 1968 and 1976, a dumbbell-shaped Dacron® mesh-reinforced fixation patch on the posterior implant shell, together with one, three, or four additional round fixation patches on the implant shell. Internal to the dumbbell-shaped fixation patch are either two round shell holes (one larger than the other) separated by a slit in the shell, or a single round shell hole.
3. For implants implanted or manufactured between 1971 and 1975, an eccentrically placed racetrack (oval) shaped posterior shell patch, Dacron® mesh-reinforced, outside the implant shell. Internal to the patch are either two round shell holes (one larger than the other) separated by a slit in the shell, or a single round shell hole.
4. A leaflet valve consisting of a proximal round part, attached to which is a distally rounded leaflet valve. The junction of the proximal and distal parts of the valve is also rounded (flared). (This identifier applies to Saline implants implanted or manufactured between 1979-1984; and to gel/saline implanted between 1981-1992.)
5. An implant having one of the following as an imprinted logo on the posterior (for double-lumen implants such markings are only present on the inner lumen patch):
- (i) DOW CORNING (1978 to 1992)
  - (ii) SILASTIC II (1981 to 1992)
  - (iii) DOW CORNING WRIGHT (1989 to 1992).
6. An implant with both (a) Mandrel Code and (b) Designation Number imprinted together on the posterior centered or near the patch of the implant envelope. These shell markings consist of a single letter or one or two numerals

approximately 4 mm height with a close-by series of three or four approximately 2 mm height numerals. For double-lumen implants such markings will be on both shells. The following Mandrel Codes and Designation Numbers are acceptable:

- (i) Mandrel Codes (numbers 1-16, 20, 30, 40, 50, 60 or single uppercase letters A-R) (1969 to 1992) and
  - (ii) Mandrel Designation Numbers (three, or rarely four, digit numbers where the characters are between 1/16 inch and 5/64 inch (1.5 mm to 2.0 mm) in height (1974 to 1992).
7. An implant with a 1.7 inch-long orientation bar (a linear raised strip of elastomer permanently bonded to the posterior of the shell of contour shaped implants) aligned with the long axis of the implant (1975 to 1986).
  8. An implant (SILASTIC® MSI) with a surface covered by tiny micro pillars (1989 to 1992).

**E. Unacceptable Proof.** Only Claimants who submit acceptable proof will be eligible for the Settlement Program. The following examples will be considered unacceptable proof of a Dow Corning Breast Implant.

1. A Claimant's own recollection (or that of a friend or relative) regarding the brand name or manufacturer of her implants.
2. Records from the International Implant Registry.
3. Identifying reports from a physician who examined the implants during or after removal surgery, if identifiers not on the list of unique identifiers found herein at section D above are the basis of the identification, or the physician fails to specify the characteristics assumed to be unique, or the physician merely opines, based on his or her experience, that the prosthesis was made by a certain manufacturer.
4. A non-contemporaneous statement by the implanting physician, attempting to supply the acceptable proof found in section B above but qualifying the affirmative statement concerning the type of implant used in a particular patient by phrases like "if I remember correctly" or "to the best of my memory." Statements from medical personnel describing their typical or general practices concerning implant usage during a given time period will be unacceptable proof (For example, a statement from the doctor's nurse that "we usually used Dow Corning implants").
5. A non-contemporaneous statement by the implanting physician, attempting to provide the acceptable proof set forth in section B above, that does not name the Claimant as a person receiving a particular type or brand of implant will be treated as unacceptable proof.

6. Records indicating the brand or manufacturer of implants the surgeon planned to use, without confirmation from the implanting physician (or in records relating to the implant surgery) that type of implant was actually used.

**F. Cooperation.** Reorganized Dow Corning will cooperate fully with the Claims Office, including the staff members working in the Claims Assistance Program and individual Claimants in providing assistance for and acceptance of manufacturer identification of Dow Corning Breast Implants, including using its best efforts to provide a list of physicians and hospitals to whom Dow Corning sold Breast Implants, listing the time frame of sales to these physicians or hospitals, and providing a list of lot numbers, serial numbers, any other identifying information about Dow Corning Breast Implants, and information to assist in the translation of product labels in foreign languages. Dow Corning shall also provide lists of any sales persons or entities that sold Dow Corning Breast Implants. Any such lists described herein shall be provided to the Claims Office. Reorganized Dow Corning will also review, at the request of the Claims Office and/or the Claims Assistance Program, Proof of Manufacturer submissions that do not meet the standard for acceptable proof. Reorganized Dow Corning's agreement to accept individual submissions shall have no precedential effect with respect to any other Claims unless expressly agreed to in writing by Reorganized Dow Corning and the Claimants' Advisory Committee. Reorganized Dow Corning and the Claimants' Advisory Committee will provide a joint training session for the Claims Office on Proof of Manufacturer for Dow Corning products.

## **PART II. Other Products Claims**

Parts A and B of this Schedule I, Part II lists the implant brands and manufacturer names that may be used in medical records to describe a Dow Corning Other Product. The following brand/manufacturer names identify Dow Corning products if (i) the form of acceptable proof is as specified at Sections D and F below; (ii) it is clear from the Claimant's records as a whole (including product descriptions and any lot or catalog references) that the brand/manufacturer name was used in those records to signify a Dow Corning product and not simply as a generic statement signifying the use of an other product implant (examples of generic references include the terms "silastic-type" and "silastic" (all lower case)); (iii) there is nothing in the records that is inconsistent with the conclusion that the brand/manufacturer name is a Dow Corning product; and (iv) the dimensions, design, shape, chemical make-up and unique identifiers are consistent with a Dow Corning product. Examples of inconsistent information include lot, size, catalog number, brand or style descriptions that do not describe any known Dow Corning product or that are consistent with another manufacturer's product.

**A. Acceptable Brand/Manufacturer Names.** These are covered if they appear in the medical records together with an acceptable product name.

1. Dow Corning, Dow Corning Wright, DC or DCW
2. SILASTIC®

**B. Acceptable Product Names.**

<u>Product Names</u>	<u>Years</u>	<u>Dimensions</u>
<b>Hip or Knee Joint</b>		<b>Dimensions provided as necessary to the Claims Office.</b>
Aufranc Turner Total Hip Prosthesis		
Centralized Runner™ EMB Tibial Prosthesis		
Centralized Runner™ Metal Base Tibial Component		
CFS™ Total Patello-Pemoral Replacement		
Elliptical Neck/Eccentric Cup Total Hip Prosthesis		
EVOLUTION™ Hip		
EXSRP™ Hip		
Gustilo Total Knee		
INFINITY™ Hip		
Lacey Condylar Knee		
Lacey P.F.C.®		
Lacey PFC™		
Lacey Posterior Stabilized Knee		
Lacey Primary Condylar Knee		
Lacey Primary Knee		
Lacey Primary Total Knee		
Lacey Rotating Hinge Knee		
Lacey Total Knee System		
McCutchen Hip		
NEXUS™ Hip		
Ortholoc® Advantim™ Total Knee System		
R.A.M. Total Knee		

<u>Product Names</u>	<u>Years</u>	<u>Dimensions</u>		
SILASTIC® Bone Plug [hip or knee]				
SLR™ Bipolar Hip Endoprosthesis				
SLT McCutchen Hip				
S.O.S.™ Segmented Oncology System				
SSA™ Hip				
TF-II™ Total Hip System				
TITAN™ Hip Prosthesis				
U.C.I. Knee				
Whiteside Calcar Hip				
Whiteside EPS® Hip				
Whiteside Hip				
Whiteside Knee				
Whiteside Long Stem Revision Hip				
Whiteside Modular Revision Knee				
Whiteside Ortholoc® I Modular Knee				
Whiteside Ortholoc® II Modular Knee				
Whiteside Ortholoc® II-C Modular Knee				
Whiteside Ortholoc® Modular Knee				
Whiteside Ortholoc® Modular Revision Knee				
Wright Choice Hip				
<b>Chin</b>				
SILASTIC® brand Chin Implant	1968 - 1992	<u>Size</u>	<u>Length (mm)</u>	<u>Width (mm)</u>
SILASTIC® brand Chin Implant, Safian Technique	1968 - 1992	Small	30	5
		Med. Small	34	7
		Medium	38	8
		Large	48	8
Dow Corning SILASTIC® brand Chin Implant, Safian Technique	1968 - 1992			

<u>Product Names</u>	<u>Years</u>	<u>Dimensions</u>			
Dow Corning SILASTIC® brand Gel Chin Implant	1978 - 1992	<u>Size</u>	<u>Length (mm)</u>	<u>Width (mm)</u>	
Dow Corning SILASTIC® brand Chin Implant (Snyder Design)	1978 - 1992	3 mm	21	3	
		5 mm	27	5	
		7 mm	33	7	
		9 mm	42	9	
Dow Corning SILASTIC® brand Chin Implant (Snyder Design) Q7-2307	1978 - 1992				
<b>Nose -- (Solid Elastomer) Implant</b>					
SILASTIC® brand Rhinoplasty Implant, Safian Technique	1965 - 1992	<u>Size</u>	<u>Length (mm)</u>	<u>Depth (mm)</u>	
Dow Corning SILASTIC® brand Rhinoplasty Implant, Safian Technique	1965 - 1992	Small	29	4.8	
		Medium	29	6.0	
		Large	29	8.0	
Dow Corning Wright SILASTIC® Brand Nasal Implant, S-Type (Shirakabe Design)	1982-1992	<u>Size</u>	<u>Length (mm)</u>	<u>Length (mm)</u>	<u>Width (mm)</u>
		I, II, III & Soft	35	60	9.5
<b>Testicular</b>					
<u>(Solid Elastomer) Type</u>		<u>Size</u>	<u>Diameter</u> x	<u>Height</u>	
SILASTIC® brand Testicular Prosthesis	1963-1972	Youth	2 cm	2 ½ cm	
		Adult	2 ½ cm	3 ½ cm	
Dow Corning SILASTIC® brand Testicular Prosthesis	1963-1972				



<u>Product Names</u>	<u>Years</u>	<u>Dimensions</u>			
<u>(Gel Filled) Type Initial Product Model</u>					
SILASTIC® brand Gel-filled Testicular Implant (Lattimer Design)	1972-1979	<u>Size</u>	<u>Width (cm)</u>	<u>Height (cm)</u>	
Dow Corning SILASTIC® brand Gel-Filled Testicular Implant, (Lattimer Design)	1972-1979	Child	2.0	2.5	
		Youth	2.4	3.4	
		Adult (avg)	2.8	4.2	
		Adult (lge)	3.0	4.7	
<u>Second Product Model</u>					
Dow Corning SILASTIC® brand Gel-Filled Testicular Implant II, (Lattimer Design)	1979-1992				
Dow Corning SILASTIC® brand Q7-2461 Testicular Implant II, (Lattimer Design)	1979-1992				
<b>Penile</b> No inflatable silicone penile prostheses are Dow Corning products					
<u>(Lash Design)</u>					
Dow Corning SILASTIC® brand Penile Implant, (Lash Design)	1967 - 1973	<u>Length</u> 12 cm	<u>Width</u> 10 mm	<u>Height</u> 12 mm	
Dow Corning Penile Implant (Lash-Loeffler Design)	1967 - 1973				
<u>(Pearman Design)</u>					
Dow Corning SILASTIC® brand Penile Implant (Pearman Design)	1967 - 1973	<u>Length</u> 13.5 cm	<u>Width</u> 13 mm		
SILASTIC® Inter-Corpus Cavernosum, (Pearman Design)	1967 - 1973				
<u>(Gerow Design)</u>					
SILASTIC® Penile Implant (Gerow Design)	1978 - 1984	<u>Size</u>	<u>Length (cm)</u>	<u>Width Distal (cm)</u>	<u>Width Proximal (cm)</u>
SILASTIC® brand Penile Implant (Gerow Design)	1978 - 1984	Small	10.5	2.22	1.71
		Medium	11.7	2.22	1.69
		Large	13.1	2.22	1.68
Dow Corning SILASTIC® brand Penile Implant (Gerow Design)	1978 - 1984				
Dow Corning SILASTIC® brand Penile Implant (Gerow Design, Patent Number 3,991,752)	1978 - 1984				

<u>Product Names</u>	<u>Years</u>	<u>Dimensions</u>			
<u>Penile Implant/Paired Set Design (Subrini Design) (U.S.A. labeling)</u> Dow Corning SILASTIC® brand Penile Implant (Subrini Design)	1978 - 1991	Length			
		Distal	Proximal	Diameter	
		Size	(mm)	(mm)	(mm)
		10 mm	80	120	10
		11 mm	90	110	11
<u>Penile Implant/Paired Set Design (Subrini Design (European labeling))</u> SILASTIC® Penile Penis Penieene Penien Peneal Implant H.P. (Subrini Design)	1979 - 1991				
<b>Temporomandibular Joint</b>					
Wilkes Temporomandibular Joint Implant (A spacer constructed of paddle-shaped SILASTIC® silicone sheeting manufactured by Dow Corning)	1987 - 1992	(in mm)			
			L	W	Th
		Size 1	50	20	0.8
		Size 2	55	22	0.8
	Size 3	61	24	0.8	
SILASTIC® Temporomandibular Joint Implant H.P. (A spacer constructed of paddle-shaped SILASTIC® silicone sheeting manufactured by Dow Corning) of:	1987 - 1992				

<u>Product Names</u>	<u>Years</u>	<u>Dimensions</u>
<u>Sheeting Used in TMJ:</u>		
SILASTIC® Medical Grade Sheeting	1964 - 1992	8" x 6" x .005" Non-Reinforced .010" .020" .040" .062" .060" (1979)
SILASTIC® Brand Sheeting	1964-1992	8" x 6" x .007" Reinforced .020" .030" .040" 8" x 6" x .040" Non-Reinforced, .080" Extra Firm .120"
SILASTIC® Brand H.P. Sheeting	1984-1992	8" x 6" x .020" .030" .040" .080"
<u>Block Used in TMJ:</u>		
SILASTIC® Block also known as SILASTIC® Medical Grade Block (soft, medium, and firm) {Qualifies only if used in TMJ}	1964-1992	2¾" x 4½" x ½" (66 mm x 109 mm x 130 mm)
<b>Angled Great Toe</b>		
SILASTIC® ANGLED GREAT TOE IMPLANT, H.P. (SWANSON DESIGN) WEIL MODIFICATION	1978 - 1993	<u>Oval Shape</u> (3 sizes) Short Diameter: 13 - 16 mm Long Diameter: 15 - 18 mm Stem Length: 12 - 17 mm
<b>Great Toe</b>		
SILASTIC® GREAT TOE IMPLANT (SWANSON DESIGN)	1970 - 1975	<u>Oval Shape</u> (5 sizes) Short Diameter: 12 - 18 mm Long Diameter: 14 - 21 mm Overall Length: 18 - 28 mm
SILASTIC® GREAT TOE IMPLANT H.P., (SWANSON DESIGN)	1975 - 1993	<u>Oval Shape</u> (5 sizes) Short Diameter: 11 - 17 mm Long Diameter: 13 - 20 mm Overall Length: 18 - 32 mm
SILASTIC® GREAT TOE IMPLANT H.P. (SWANSON DESIGN) Small Stem	1984 - 1993	<u>Oval Shape</u> (5 sizes) Short Diameter: 11 - 17 mm Long Diameter: 13 - 20 mm Overall Length: 18 - 32 mm

<u>Product Names</u>	<u>Years</u>	<u>Dimensions</u>
Dow Corning Wright Swanson Titanium Great Toe Implant	1987 - 1993	<u>Oval Shape Head</u> (5 sizes) Overall Height: 12 - 17 mm Head Length: 13 - 20 mm Head Width: 11 - 17 mm
<b>Hammertoe</b>		
SILASTIC® H.P. HAMMERTOES IMPLANT (SWANSON TYPE) WEIL DESIGN	1982 - 1986	(7 sizes) Diameter: 6 - 8 mm Stem length: 8.4 - 9.1 mm Width: 2.0 - 5.3 mm
SILASTIC® H.P. 100 HAMMERTOES IMPLANT (SWANSON TYPE) WEIL DESIGN	1987 - 1992	(7 sizes) Diameter: 6 - 8 mm Stem length: 8.4 - 9.1 mm Width: 2.0 - 5.3 mm
<b>Flexible Hinge Toe</b>		
SILASTIC® FLEXIBLE HINGE TOE IMPLANT H.P. (SWANSON DESIGN)	1978 - 1985	(14 sizes) Length: 28 - 73 mm Width: 8 - 21 mm Thickness: 5 - 12 mm
SILASTIC® H.P. 100 SWANSON FLEXIBLE HINGE TOE IMPLANT (Regular stems)	1986 - 1993	(14 sizes) Length: 28 - 73 mm Width: 8 - 21 mm Thickness: 5 - 12 mm
SILASTIC® H.P. 100 SWANSON FLEXIBLE HINGE TOE IMPLANT (Small Stem)	1986 - 1993	(6 sizes) Length: 37 - 51 mm Width: 16 - 20 mm Thickness: 8 - 11 mm

<u>Product Names</u>	<u>Years</u>	<u>Dimensions</u>
<b>Wrist</b>		
SILASTIC® WRIST JOINT PROSTHESIS, SWANSON DESIGN	1971 - 1974	(5 sizes) Length: 75 - 137 mm Width: 16 - 28 mm Thickness: 7 - 10 mm
SILASTIC® WRIST JOINT HP (RADIOCARPAL), SWANSON DESIGN	1975 - 1985	(5 sizes) Length: 75 - 137 mm Width: 16 - 28 mm Thickness: 7 - 10 mm
SILASTIC® WRIST JOINT HP (RADIOCARPAL), SWANSON DESIGN, WIDE	1982 - 1985	(5 sizes) Length: 75 - 137 mm Width: 19 - 35 mm Thickness: 7 - 10 mm
SILASTIC® WRIST JOINT IMPLANT HP 100 SWANSON DESIGN (WIDE MID-SECTION WITH SHORT DISTAL STEM)	1986 - 1993	(5 sizes) Length: 63 - 109 mm Width: 19 - 35 mm Thickness: 7 - 10 mm
SILASTIC® WRIST JOINT IMPLANT HP 100 SWANSON DESIGN (WIDE MID-SECTION WITH SHORT DISTAL STEM WITH GROMMETS)	1991 - 1993	(5 sizes) Length: 63 - 109 mm Width: 19 - 35 mm Thickness: 7 - 10 mm
<b>STA-PEG</b>		
Dow Corning Wright Smith Subtalar Peg	1981-1987	(2 sizes) <u>Oval Shape</u> Head Diameter: 11 - 12 mm Head Height: 5 -7 mm Stem Length: 8 - 10 mm
Dow Corning Wright STA-Peg Subtalar Arthrorisis Implant (Smith Design)	1985-1993	(2 sizes) <u>Oval Shape</u> Head Diameter: 11 - 12 mm Head Height: 5 -7 mm Stem Length: 8 - 10 mm
Dow Corning Wright STA-Peg (Angled) Subtalar Arthrorisis Implant (Smith Design)	1985-1993	(3 sizes) <u>Angled Shape</u> Head Diameter: 10 - 12 mm Head Height: 4 - 8 mm Stem Length: 8 mm

<u>Product Names</u>	<u>Years</u>	<u>Dimensions</u>
<b>Carpal Lunate</b>		
SILASTIC® CARPAL LUNATE IMPLANT (SWANSON DESIGN)	1970 - 1976	(3 sizes) Length (Head): 15 - 18 mm Width (Head): 12 - 16 mm Length (Stem): 8 - 10 mm
SILASTIC® H.P. CARPAL LUNATE IMPLANT (SWANSON DESIGN)	1977 -1990	(5 sizes) Length (Head): 15 - 20 mm Width (Head): 15 - 19 mm Length (Stem): 6 - 8 mm
SILASTIC® CARPAL LUNATE IMPLANT C.S.E., (SWANSON DESIGN)	1987 - 1993	(5 sizes) Length (Head): 15 - 20 mm Width (Head): 15 - 19 mm Length (Stem): 6 - 8 mm
Dow Corning Wright Swanson Titanium Carpal Lunate Implant	1990-1993	(5 sizes) Length (Head): 13 - 19 mm Width (Head): 15 - 20 mm Height (Head): 10 - 15 mm
<b>Carpal Scaphoid</b>		
SILASTIC® CARPAL SCAPHOID PROSTHESIS (SWANSON DESIGN)	1970 - 1977	(3 sizes, right; 3 sizes, left) Width: 13 - 16 mm Thickness: 10-12 mm
SILASTIC® SWANSON CARPAL SCAPHOID IMPLANT, CSE (ORIGINAL DESIGN)	1987 - 1993	(5 sizes, right; 5 sizes, left) Width: 11-18 mm Thickness: 9-15 mm (no stem)
SILASTIC® SWANSON CARPAL SCAPHOID IMPLANT, H.P.	1977 - 1989	(7 sizes, right; 7 sizes, left) Width: 16-24 mm Thickness: 11-18 mm Stem Length: 6-9 mm
Dow Corning Wright Swanson Titanium Carpal Scaphoid Implant	1988 - 1993	(5 sizes, right; 5 sizes, left) Length: 25 - 32 mm Width: 12 - 16 mm Thickness: 10 - 13 mm
<b>Radial Head</b>		
SILASTIC® Radial Head Prosthesis (Swanson Design)	1970 - 1975	(3 sizes) Overall Length: 35-43 mm Diameter (Head): 19-24 mm Height (Head): 10-15 mm



<b><u>Product Names</u></b>	<b><u>Years</u></b>	<b><u>Dimensions</u></b>
SILASTIC® Radial Head Implant H.P., (Swanson Design)	1975 - 1986	(8 sizes, includes x-long) Overall Length: 32-55 mm Diameter (Head): 19-23 mm Height (Head): 10-22 mm
SILASTIC® H.P. 100 SWANSON RADIAL HEAD IMPLANT	1987 - 1993	(8 sizes, includes x-long) Overall Length: 32-55 mm Diameter (Head): 19-23 mm Height (Head): 10-22 mm
<b>Scapholunate</b>		
SILASTIC® SCAPHOLUNATE H.P. (Swanson Design)		(4 sizes, left; 4 sizes, right) Length: 34 - 42 mm Width: 16 - 19 mm Thickness: 15 - 19 mm
<b>Trapezial</b>		
SILASTIC® TRAPEZIAL IMPLANT H. P. (ASHWORTH-BLATT DESIGN)	1979 - 1993	(2 sizes) Head Diameter: 16-19 mm Stem Diameter: 5-9 mm Stem Length: 5.3 mm
<b>Trapezium</b>		
SILASTIC® TRAPEZIUM PROSTHESIS, SWANSON DESIGN	1970 - 1975	(5 sizes) Length: 29-46 mm Diameter (Head): 13-17 mm Thickness (Head): 9-14 mm
SILASTIC® TRAPEZIUM IMPLANT H.P., SWANSON DESIGN	1975 - 1986	(5 sizes) Length: 27-43 mm Diameter (Head): 12-16 mm Thickness (Head): 9-13 mm
SILASTIC® H.P. 100 SWANSON TRAPEZIUM IMPLANT	1988 - 1990	(5 sizes) Length: 27-43 mm Diameter (Head): 12-16 mm Thickness (Head): 9-13 mm
SILASTIC® SWANSON TRAPEZIUM IMPLANT CSE	1987 - 1993	(5 sizes) Length: 27-43 mm Diameter (Head): 12-16 mm Thickness (Head): 9-13 mm
<b>Ulnar Head</b>		
SILASTIC® ULNAR HEAD PROSTHESIS (SWANSON DESIGN)	1970 - 1975	(4 sizes) Overall Length: 27-41 mm Height (Head): 13-19 mm

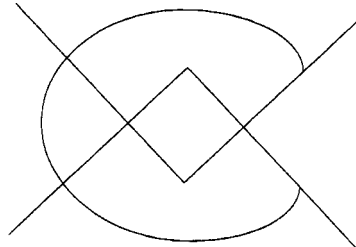
<u>Product Names</u>	<u>Years</u>	<u>Dimensions</u>
SILASTIC® H.P. ULNAR HEAD IMPLANT (SWANSON DESIGN)	1975 - 1986	(8 sizes) Overall Length: 32-50 mm Diameter (Head): 8-16 mm Height (Head): 14-25 mm
SILASTIC® H. P. 100 SWANSON ULNAR HEAD IMPLANT	1988 - 1992	(7 sizes) Overall Length: 30-43 mm Diameter (Head): 9-15 mm Height (Head): 12-18 mm
<b>Condylar</b>		
SILASTIC® CONDYLAR IMPLANT HP, (CONVEX) SWANSON DESIGN	1979 - 1993	(13 sizes) <u>Oval Shape</u> Overall Height: 8-26 mm Head Length: 6-18 mm Head Width: 4-16 mm
<b>Tendon Passer</b>		
SILASTIC® TENDON PASSER H.P. (CAPLIN-YOUNG DESIGN)	1982 - 1993	(1 size) <u>Oval Shape Head</u> Overall Length: 181 mm Head Length: 6.7 mm Head Width: 5.3 mm
<b>Tendon Spacer</b>		
SILASTIC® TENDON SPACER H.P. (SWANSON-HUNTER DESIGN)	1978 - 1993	(4 sizes) <u>Oval Cross Section</u> Length: 240 mm Short Width: 1.5-3 mm Long Width: 3-6 mm
<b>Finger Joints</b>		
SILASTIC® FINGER JOINT PROSTHESIS (Swanson Design)	1968 - 1974	(8 sizes) Length: 30-74 mm Width: 11-17 mm Thickness: 5-9 mm
SILASTIC® FINGER JOINT IMPLANT H.P. (Swanson Design)	1975 - 1985	(11 sizes) Length: 25-81 mm Width: 8-18 mm Thickness: 3-10 mm
SILASTIC® H.P. 100 SWANSON FINGER JOINT IMPLANT	1986 - 1993	(11 sizes) Length: 25-81 mm Width: 8-18 mm Thickness: 3-10 mm

<u>Product Names</u>	<u>Years</u>	<u>Dimensions</u>
SILASTIC® H.P. 100 SWANSON FINGER JOINT IMPLANT (with Grommets)	1986 - 1993	(11 sizes) Length: 25-81 mm Width: 8-18 mm Thickness: 3-10 mm
Swanson Titanium Basal Thumb Implant	1988 - 1993	(5 sizes) Head Diameter: 9-14 mm Overall Length: 19-26 mm Stem Length: 13-17 mm

**C. Unique Identifiers for Other Products.** The following product-specific unique identifiers together with dimensions, design, shape and chemical make-up shall be considered acceptable proof where the removed implants are examined consistent with the standard of acceptable proof as specified at Section D, below.

**1. Large Joint Orthopedic Implant — Hip, Knee.** The following logos etched or engraved on the implant during manufacture as visible on the explanted device:

- a. WRIGHT (1977)
- b. DCW (1978 - June 1993)
- c. WRIGHT/DOW CORNING (1978)
- d. DOW CORNING WRIGHT (1978 - June 1993)
- e. ALL PRODUCTS MUST CONTAIN THE FOLLOWING LOGO:



**2. Chin.**

- a. There are no unique identifiers for solid silicone chins.
- b. For Dow Corning SILASTIC® gel chin implants, a one centimeter (1 cm) triangular patch of DACRON® velour fabric placed in the center of the posterior side of the implant with the base of the triangle sitting at the midline of the implant.

**3. Nose, Face.**

- a. There are no unique identifiers for nose or face implants.

**4. Testicular.**

- a. There are no unique identifiers for elastomer testicular implants.
- b. For Dow Corning SILASTIC® gel-filled testicular implants (1972-1979), a DACRON® woven fabric reinforced fixation tab located on one exterior end of the ovoid-shaped device. The initial design had the fixation tab with square corners (years) later modified with round corners (years).
- c. For SILASTIC® gel-filled testicular implants (Lattimer Design, 1979-1991), if the medical record references a removable Teflon® insert strip in the suture loop.

**5. Penile.**

- a. There are no unique identifiers for penile implants.
- b. No inflatable silicone penile prostheses were made by Dow Corning.

**6. Finger, Toe, Wrist, Hand.**

- a. Design, shape and dimensions consistent with a Dow Corning product.

**7. TMJ.**

- a. For the Wilkes TMJ implant, a paddle-shaped silicone sheeting with catalog and lot numbers (together) specific to Dow Corning.

**D. Acceptable Forms of Proof.** The following are types of acceptable proof, based on implantation records, that the Other Product was manufactured by Dow Corning:

(a) Hospital records of the surgeon's report of the surgery — written at or near the time of the implantation surgery — that specify a Dow Corning brand name or Dow Corning as the manufacturer, as specified at this Schedule I, Part II, Sections A and B.

(b) A certified copy of the Claimant's medical records that contains the implant package label demonstrating a Covered Implant. Note: a certified copy is only required if the label:

(i) is on a page that does not affirmatively reveal it to be a part of the Claimant's hospital or medical records, and

(ii) does not have a lot number, or catalog number and lot number together on it.

(iii) if the page containing the implant label/sticker clearly comes from the hospital's contemporaneous record of the implant surgery, has other information relating to the claimant's hospitalization on that page, and has sufficient patient identification for the Claims Office to tell that it came from the Claimant's records, it falls into the acceptable proof category of contemporaneous hospital records, and does not have to be certified. If the hospital records are organized so that the implant label/sticker was put on a page by itself, it must be certified.

(c) Original implant labels clearly marked with a lot or catalog number accompanied by sufficient hospital records to determine that the Dow Corning product was actually implanted into the Claimant. The Claims Office will maintain a list of these numbers, to ensure that no duplicates are used.

(d) Records of the implanting surgeon — written at the time of the implantation surgery — that specify a Dow Corning brand name or Dow Corning as the manufacturer as set forth in this Schedule I, Part II.

(e) An affirmative statement from the implanting physician attesting that the Claimant was implanted with an Other Product. The physician making this affirmative statement must also provide the basis for that conclusion. This type of proof is acceptable only if the records outlined in (a), (b), (c), or (d) above are not available, and must include a description of what steps were taken to secure the types of proof outlined in (a), (b), (c), or (d) above and explain why those records were not available. This statement cannot rest upon unacceptable proof as noted in Section F, below.

(f) A health insurance claim form, signed by the implanting physician reasonably close to the date of the surgery, naming the type of implant used as set forth in Schedule I, Part II.

(g) Dow Corning or brand-specific implant control sheets, with cross-references to the Claimant that reasonably appear to be contemporaneously kept records in the hospital or physician's office.

(h) Patient Informed Consent forms signed by the Claimant and dated close to the date of the implantation surgery, accompanied by other contemporaneous medical or hospital records verifying that the implantation surgery actually occurred and identifying Dow Corning as the manufacturer of the implant.

(i) Dow Corning's invoice or packing list contained in the Claimant's medical or hospital records relating to the implant surgery. If the Claims Office cannot determine that the invoice or packing list actually was included in those records it may require a certified copy of the records or a supplemental statement from the records custodian.

(j) Statements filed in court pleadings by an authorized Dow Corning representative specifically acknowledging that the Claimant's implants were manufactured by Dow Corning.

***E. Definition of Certified Copy of Medical Records/Requirements for Certified Records.***

1. A “certified copy” of medical records is a copy of records with a certificate attached, usually signed by the custodian of records for that office or facility, affirming that the attached pages are true and correct copies of records in a particular patient's file.
2. If a Claimant's proof consists only of the implant package label, the Claimant must provide a certified copy of the medical records that contain that label.

3. Photocopies of the certificate for certified medical records are acceptable. The original certificate and original records do not have to be submitted as long as a photocopy is submitted.

**F. *Acceptable Forms of Proof Based on Explantation.*** Specified unique identifiers of Dow Corning Small Joint Orthopedic Implants and Large Joint Orthopedic Implants shall be considered acceptable proof when demonstrated as specified at paragraphs (a), (b), and (c) below.

(a) Medical records of the explanting physician, created at or within 30 days of the time of explantation, that describe a Unique Identifier from Section C of this Schedule I, Part II of a Dow Corning Large Joint Orthopedic Implant or Small Joint Orthopedic Implant product.

(b) A photograph of an explanted implant depicting one of the Unique Identifiers of a Dow Corning Large Joint Orthopedic Implant or Small Joint Orthopedic Implant as set forth at Schedule I, Part II, Section C. The photograph must be accompanied by a statement from the explanting physician identifying the implant in the photograph as one (s)he removed from the claimant. The photograph must also be accompanied by statement advising of whether this implant has been preserved. The Claims Administrator may require the presentation of a removed implant if preserved.

(c) The implant, if preserved, along with the identity and location of the custodian of the implant. The Claims Administrator may require the presentation of the removed implant(s) for examination by an individual or entity designated by the Claims Administrator.

**G. *Unacceptable Proof.*** Only proof specifically described herein as acceptable proof or proof expressly agreed to by Dow Corning in a writing provided to the Claims Office will be sufficient to establish Proof of Manufacturer of a Dow Corning Other Product. Any other proof will be deemed unacceptable proof of a Dow Corning implant. The following are examples of unacceptable proof:

(a) A Claimant's own recollection (or that of a friend or relative) regarding the brand name or manufacturer of his/her implants.

(b) Records from the International Implant Registry.

(c) Records from the explanting surgeon attempting to supply the acceptable proof at Section C above if identifiers not on the list of unique identifiers are the basis of the identification, or the physician fails to specify the characteristics assumed to be unique, or the physician merely opines, based on his or her experience, that the prosthesis was made by a certain manufacturer.

(d) A non-contemporaneous statement by the implanting physician qualifying the statement concerning the type of implant used in a particular patient by phrases like "if I remember correctly" or "to the best of my memory." Statements from physicians describing their typical or general practices concerning implant usage during a given time period will be unacceptable proof (for example, a statement that "we usually used Dow Corning implants").



(e) A non-contemporaneous statement by the implanting physician, attempting to provide the acceptable proof set forth in Section D (e), above, that does not name the Claimant as a person receiving a particular type or brand of implant will be treated as unacceptable proof.

(f) Records indicating the brand or manufacturer of implants the surgeon planned to use, without confirmation from the implanting physician (or in records relating to the implant surgery) that type of implant was actually used.

(g) The mere use of the word “Silastic” without capitalization of the first letter and other indications of a Dow Corning product shall be unacceptable proof that a Dow Corning product was used in the Claimant.

(h) Records containing the catalog number, lot number, brand name, dimensions, chemical make-up and unique identifiers consistent with a non-Dow Corning implant.

**H. Cooperation.** Dow Corning will assist the Claims Office including the staff of the Claims Office by providing a list of lot numbers, catalog numbers and any other identifying information about Dow Corning Other Products.

### **PART III. Silicone Material Claimants**

**A. Brand/Manufacturer Names.** For purposes solely of the Settlement Program for Silicone Material Claimants, the brand/manufacturer names listed at Exhibit G to the Revised Settlement Program (as reproduced at Section C. below) and Exhibit G2 to the Foreign Revised Settlement Program (as reproduced at Section D. below) as attributable to Baxter, Bristol, Cox-Uphoff, Mentor or Bioplasty shall identify a breast implant product covered under the Silicone Material Claimant Settlement Program if the Claimant submits acceptable Proof of Manufacturer as defined at Section B below.

**B. Acceptable Proof.** The types of proof defined as acceptable under the Revised Settlement Program along with the unique identifiers specified in the Revised Settlement Program for breast implants manufactured by the entities listed at Section A above shall be acceptable Proof of Manufacturer for purposes of the Silicone Material Claimant Settlement Program. The types of proof identified as unacceptable proof under the Revised Settlement Program for such manufacturers shall be deemed as unacceptable proof for purposes of the Silicone Material Claimant Settlement Option.

### **C. EXHIBIT G -- Implant Brands and Manufacturers.**

(Adjusted to include only those identified as Baxter, Bristol, Cox-Uphoff (CUI), Mentor, or Bioplasty. (3M is identified solely for purposes of Section 6.02(d)(v).))

*The left-hand column is a list of companies, implant brands, "designer" implant names, and other names or phrases that might be used in medical records to describe a particular type of breast implant. The column to the right identifies the company with which that brand is associated for purposes of the Revised Settlement Program. If implantation date ranges are supplied for an implant, an appropriate notation is to the right of each date range.*

*Implants noted as Mentor that have a star (\*) before Mentor will be treated as Baxter implants if a Baxter lot number can be supplied for that implant.*

<b>Brand/Manufacturer Name</b>	<b>Status in Revised Program</b>
3M	3M
AHS	Baxter
Aesthetech	Bristol
American Heyer-Schulte	Baxter
American Hospital Supply	Baxter
Ashley Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Baxter	Baxter
Becker	Mentor
Biomanufacturing	Bioplasty
Bio-oncotic	Bioplasty
Bioplasty	Bioplasty
Birnbaum	Baxter
Capozzi Implanted before 9/1/71 Implanted after 8/31/71	Bristol Baxter
Cavon	Bristol
CBI Medical	Bristol
Cooper Surgical	Bristol
Corbet	Bristol
Cox Uphoff	CUI
CZV/CRS (Croissant Versafil Low Profile)	CUI
Dahl	Bristol
Directa Span	Mentor
DRI	CUI
DRIE	CUI
Edward Laboratories	Baxter
EHP (Enhanced High Profile)	CUI
Edward Weck & Co. Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Flat Span	Mentor
FZV/SFV (Round Versafil LP Tissue Expander)	CUI
Georgiade	Bristol
Gibney	CUI

Guthrie Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Hartley	Baxter
Heyer-Schulte Implanted before 3/31/84 Implanted after 3/30/84	Baxter *Mentor
Heyer-Schulte Mentor	Mentor
Intrashiel Implanted before 8/3/84	3M
Intravent	CUI
IOC (Cylindrical Intraoperative Tissue Expander)	CUI
IOM (Intravent Intraoperative Expander)	CUI
IOS (Spherical Intraoperative Tissue Expander)	CUI
Isle	Mentor
Jenny	Baxter
Jobe	Baxter
Klein	Bioplasty
Mammatech	Bioplasty
Mark/M Surgical Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Markham Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Markham Medical Int'l Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
McGhan Implanted before 8/3/84	3M
MEC	Bristol
Medical Engineering Corporation	Bristol
Meme	Bristol
Meme ME	Bristol
Meme MP	Bristol
Mentor	Mentor
MFE (Man Facelift Expander)	CUI
Microcell	CUI
Misty	Bioplasty
Misty Gold	Bioplasty
Mueller, V. Implanted 11/1/78 to 3/30/84	Baxter

Munna	Bristol
Natrashiel	3M
Natural Y Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Norman	Bristol
OHP (Oval High Profile)	CUI
OLP (Oval Low Profile)	CUI
Optimam	Bristol
Pangman	Baxter
Papillon	Bristol
Perras	Bristol
Perras-Papillon	Bristol
Polyurethane Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Poly Plastic Implanted before 9/1/71 Implanted after 8/31/71	Bristol Baxter
Poly Plastic Adjustable	Baxter
Quin-Seal	Bristol
Radovan	Mentor
RCP (Round Conical Profile)	CUI
RCR (Ruiz-Cohen Expanders)	CUI
RDD (Reverse Double Lumen DRIE)	CUI
RDL (Reverse Double Lumen)	CUI
RDL-XPAND	CUI
RDX (Round Double Lumen)	CUI
Replicon	Bristol
Reverse Double Lumen	CUI
RHD (Round High Profile)	CUI
RHP (Round High Profile)	CUI
RLD (Round Low Profile DRIE)	CUI
RLP (Round Low Profile)	CUI
Roger Klein	Bioplasty
RTV/RTT (Smooth/Textured)	CUI
Ruiz-Cohen	CUI
RZV/SRV (Rectangular Versafil Tissue Expander)	CUI
SCC (Cylindrical Tissue Expander)	CUI
SCL	Bristol

SCS (Crescent Tissue Expander)	CUI
SEE (Mini-crescent Tissue Expander)	CUI
Seropian	Baxter
SFS (Saline Fill Skin and Tissue Expander)	CUI
SGO (Saline Gel Oval)	CUI
SGR (Saline Gel Round)	CUI
Siltex	Mentor
Siltex Becker	Mentor
Siltex Spectrum	Mentor
SLP (Single Lumen Adjustable)	CUI
SLS (Longitudinally Curved Tissue Expander)	CUI
Snyder	Bristol
SOE (Small Oval Tissue Expander)	CUI
SOS (Ear Shaped Tissue Expander)	CUI
Spectrum	Mentor
SPS (Pear Shaped Tissue Expander)	CUI
SRS (Rectangular Tissue Expander)	CUI
SSS (Spherical Tissue Expander)	CUI
Sterling	Baxter
Summit Medical	Bristol
Surgical Specialties	Bristol
Surgitek	Bristol
SWS (Wedge Shaped Tissue Expander)	CUI
SZR (Round Low Profile Sizer)	CUI
Tabari	Baxter
Tecknar	Mentor
TLL (Triple Lumen Round)	CUI
Travenol	Baxter
Tri-Lumen	CUI
TRL (Tri-Lumen Implants)	CUI
TSO (Triple Lumen Low Profile Oval)	CUI
TSR (Triple Lumen Round Low Profile)	CUI
Uroplasty	Bioplasty
Versafil	CUI
V. Mueller Implanted 11/1/78 to 3/30/84	Baxter
Vogue	Bristol
Wagner	Baxter
Webster	Bristol

Weck Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Williams	Baxter
Wood	Bristol

**D. EXHIBIT G2--Implant Brands and Manufacturers.**

(Adjusted to include only those identified as Baxter, Bristol, Cox-Uphoff (CUI), Mentor, or Bioplasty. (3M is identified solely for purposes of Section 6.02(d)(v).))

*The left-hand column is a list of companies, implant brands, "designer" implant names, and other names or phrases that might be used in medical records to describe a particular type of breast implant. The column to the right identifies the company with which that brand is associated for purposes of the Foreign Settlement Program ("FSP"). If implantation date ranges are supplied for an implant, an appropriate notation is to the right of each date range.*

BRAND/MANUFACTURER NAME	STATUS IN FOREIGN SETTLEMENT PROGRAM
3M	3M
AHS	Baxter
Aesthetech	Bristol
American Heyer-Schulte	Baxter
American Hospital Supply	Baxter
Ashley Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Baxter	Baxter
Birnbaum	Baxter
Capozzi Implanted before 9/1/71 Implanted after 8/31/71	Bristol Baxter
Cavon	Bristol
CBI Medical	Bristol
Cooper Surgical	Bristol
Corbet	Bristol
Dahl	Bristol
Edward Laboratories	Baxter
Edward Weck & Co. Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Georgiade	Bristol
Guthrie Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol

Hartley	Baxter
Heyer-Schulte Implanted before 3/31/84 Implanted after 3/30/84	Baxter Generally not covered; may be Baxter on special proof--see explanation following table
Intrashiel Implanted before 8/3/84 Implanted after 8/2/84	3M Generally not covered; may be 3M on special proof--see explanation following table
Jenny	Baxter
Jobe	Baxter
Mark/M Surgical Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Markham Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Markham Medical Int'l Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
McGhan Implanted before 8/3/84 Implanted after 8/2/84	3M Generally not covered; may be 3M on special proof--see explanation following table
MEC	Bristol
Medical Engineering Corporation	Bristol
Meme	Bristol
Meme ME	Bristol
Meme MP	Bristol
Mueller Implanted 9/1/74 to 10/31/78	Baxter
Munna	Bristol
Natrashiel	3M
Natural Y Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Norman	Bristol
Optimam	Bristol
Pangman	Baxter
Papillon	Bristol
Perras	Bristol
Perras-Papillon	Bristol
Polyurethane Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol



Poly Plastic Implanted before 9/1/71 Implanted after 8/31/71	Bristol Baxter
Poly Plastic Adjustable	Baxter
Quin-Seal	Bristol
Replicon	Bristol
SCL	Bristol
Seropian	Baxter
Snyder	Bristol
Sterling	Baxter
Summit Medical	Bristol
Surgical Specialities	Bristol
Surgitek	Bristol
Tabari	Baxter
Travenol	Baxter
V. Mueller Implanted 9/1/74 to 10/31/78	Baxter
Vogue	Bristol
Wagner	Baxter
Webster	Bristol
Weck Implanted before 9/1/71 Implanted 9/1/71 to 12/8/78 Implanted after 12/8/78	Bristol Baxter Bristol
Williams	Baxter
Wood	Bristol

**SCHEDULE II  
MEDICAL CONDITIONS AND CHARACTERISTICS  
OUTLINE OF DEFINITIONS AND CLASSIFICATION CRITERIA**

**PART A. DISEASE AND DISABILITY/SEVERITY DEFINITIONS:  
DISEASE PAYMENT OPTION 1**

**GENERAL GUIDELINES**

The following are general guidelines, which are adopted from and are intended to be applied consistently with the Revised Settlement Program and interpretations thereof, to be used in the submission and evaluation of a Claim for compensation under Disease Payment Option I:

There are two ways to document a claim for Disease Payment Option I compensation: (a) a Claimant can provide a statement or diagnosis from a physician Board-certified in an appropriate specialty, together with the medical records upon which that statement or diagnosis is based or (b) a Claimant can provide the medical records that, themselves, will enable the Claims Office to place the Claimant on the Disease Payment Option I Schedule.

A Claimant should submit all records that contain information relevant to the criteria for Disease Payment Option I, including (1) records relating to the relevant signs, symptoms, findings and test results set forth in Disease Payment Option 1 and (2) records showing the severity of a Claimant's disease or, if applicable, a determination of disability level by either a Qualified Medical Doctor or the Claimant's treating physician. In general, whatever the physician relied upon in arriving at the diagnosis and findings in the statement or diagnosis should be provided. Typically, this might include a patient questionnaire, physical findings obtained from an assistant's notes in the office chart, and certain lab or other test reports. If the doctor needed to review earlier medical records obtained from other physicians to make a definitive statement about the Claimant's condition or disability, then those records must also, if available, be submitted. If, however, based on an examination of the Claimant, the physician has first-hand knowledge of everything that is the basis for his or her opinion, and the statement or diagnosis sets out that knowledge in sufficient detail, it is possible that no additional records will be required.

As used herein, the term "Qualified Medical Doctor" or "QMD" means a physician who is Board-certified (not Board-eligible) in internal medicine, rheumatology (a sub-specialty of internal medicine), neurology, neurological surgery, or immunology who prepares the statement or diagnosis that the Claimant must file in support of a Disease Payment Option I Claim. Only a Board-certified physician can submit the statement or diagnosis of one of the compensable diseases included in Disease Payment Option I. The physician writing a statement or diagnosis of one of the compensable diseases in Disease Payment Option I must be Board-certified in an appropriate specialty. The type of specialty depends on the complaints and symptoms with which a Claimant presents. "Board-certified" means certification in a particular medical specialty by the American Board of Medical Specialists. A Doctor of Osteopathy can be a Qualified Medical Doctor if he or she is Board-certified by the same Board that certifies Medical Doctors. A Doctor of Osteopathy may also submit diagnoses or disease compensation claims so long as his or her certification is within an appropriate specialty.

The Claims Office is authorized to determine whether physicians in other countries have degrees or certifications that are the equivalent of those accorded in the United States and should therefore be treated as Qualified Medical Doctors. The Claims Office shall determine which certification systems of foreign countries are the equivalent of U.S. Board certification using the procedures applied by the MDL 926 Claims Administrator in the Foreign Settlement Program. The Plan Proponents or the Claimants' Advisory Committee and Debtor's Representatives shall specify the categories, degrees or certification of doctors that will qualify as Qualified Medical Doctors in Class 6.2 countries.

As used herein, the term "treating physician" is one who has seen, examined, and treated the Claimant on several occasions, and not a doctor whom the Claimant has seen only for purposes of getting an evaluation to make a claim under this Disease Payment Option. Treating physician includes a Qualified Medical Doctor if such Qualified Medical Doctor states that he or she has the information necessary to form a professional opinion about the Claimant's disability and sets forth in the statement or diagnosis (or in a supplemental statement) the information upon which that opinion is based and the source of that information.

As used herein, the term "documented" means that it is based on some reliable information other than simply the Claimant's complaint or oral history. For some symptoms, "documented" means that the physician has verified the symptom on physical examination or through a lab test. For others, primarily those that are entirely subjective, it can mean that the physician has performed a physical examination and questioned the Claimant sufficiently to be able to form a professional opinion, utilizing all that doctor's knowledge and training, that the complaint is a valid one. (In this situation, it is important that the physician relying on these complaints does not qualify the diagnosis by stating that these "findings" are based solely on the patient's history given at the time of the single visit to the Board-certified specialist. The physician needs to feel confident in concluding that the problems do indeed exist.) "Documented" can also mean that written notations of that symptom are found several places in the Claimant's medical records. Thus, to show that a symptom is "documented," a Claimant can submit (1) proof of verification of the symptom through physical examination; (2) a statement from the Claimant's QMD revealing that (s)he questioned the Claimant sufficiently about the symptom and concluded that the complaint is valid; or (3) medical records reflecting that the Claimant had complained about this symptom on other occasions.

To the extent the severity of a Claimant's disease is based on a disability rating, as defined herein, the Claimant must submit all of the records that the physician relied upon in making his or her disability determination. This would include, as an example, any disability questionnaire that the Claimant completed in order to assist in the physician's determination. A non-Board-certified treating physician can provide a disability determination.

In preparing submissions for Disease and Disability Option 1 and in curing any deficiencies that may be noted when the submission is processed, Claimants and their physicians (and their counsel if applicable) should be aware that the disability must be related to the compensable condition. That is, the pain must be due to the Claimant's Atypical Connective Tissue Disease or Atypical Neurological Disease. Thus, a threshold requirement in evaluating a disability submission is whether the Claimant's qualifying symptoms are ones such as alopecia, chronic fatigue, or loss of breast function that normally have no pain component. A disability determination cannot be approved unless there is evidence that the Claimant is experiencing pain from at least one of her qualifying symptoms or unless the Claimant, in response to a deficiency

determination, supplies evidence that she has an additional qualifying symptom that does cause pain. In addition, Claimants and their physicians (and their counsel if applicable) should be aware that a “C” level disability requires that the pain be “regular or recurring.” Thus, if a Claimant’s pain is described in her records as being only “mild” or “slight,” the disability determination will not be approved.

With respect to a claim for a “B” level disability, the claim must be based on severe pain or an inability to do certain activities. In order to qualify, there must be pain-producing symptoms that result in severe pain on a regular or recurring basis. Generalized statements about “severe pain” may not be enough. The Claims Office must be able to verify that the Atypical Connective Tissue Disease or Atypical Neurological Disease symptoms themselves are the cause of the severe pain. If the “B” level disability claim is based on limitations on a Claimant’s activities, the claim submission must provide information concerning the activities that are limited. A conclusory statement, with no information about the Claimant and her limitations, will result in a deficiency being assigned. The disability assessment must demonstrate a connection between the specific activities that the Claimant can no longer perform. The disability must be due to the compensable condition. The Claims Office must have enough information about what the limitations are and the cause of those limitations to be able to verify that the Claimant’s condition indeed meets the requirements for a “B” disability level.

In preparing a claim for an “A” level disability, Claimant’s and their physicians (and their counsel, if applicable) should be aware that the definition of this assigned disability level is a difficult one to meet. A Claimant must be unable to do any of her normal activities or only be able to do a very few of them. In preparing a submission, it should be reviewed to determine whether there is enough description of the Claimant’s daily life and limitations to allow a reader to know that she does indeed meet this strict definition of total disability. In addition, it must be clear that the Claimant’s total disability is due to the symptoms of the applicable disease or condition.

Generalized statements by the QMD that track the disease and disability language cannot replace the responsibility of the Claims Office to review, on a detailed level, all of the claim documentation provided.

If the Breast Implant Claimant's Qualified Medical Doctor determines that her death or total disability is clearly and specifically caused by a disease or occurrence other than the compensable disease, she will not be eligible for compensation in Severity/Disability Category A.

## **DISEASE PAYMENT OPTION I: DEFINITION OF COVERED CONDITIONS**

### **SYSTEMIC SCLEROSIS/SCLERODERMA (SS)**

1. A diagnosis of systemic sclerosis shall be made in accordance with the criteria established in Kelley, et al., Textbook of Rheumatology (4th ed.) at 1113, et seq.
2. Application of these diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of classical systemic sclerosis but who nonetheless have a systemic sclerosis-like (scleroderma-like) disease, except that an individual will not be compensated in this

category if her symptomology more closely resembles MCTD, ACTD, or any other disease or condition defined below. A "systemic sclerosis-like" or "scleroderma-like" disease is defined as an autoimmune/rheumatic disease that fulfills most of the accepted standards for the diagnosis of systemic sclerosis but is in some manner atypical of systemic sclerosis or scleroderma.

3. Severity/Disability Compensation Categories

- A. Death or total disability resulting from SS or an SS-like condition. An individual will be considered totally disabled if the individual satisfies the functional capacity test set forth in Severity/Disability Category A for ACTD/ARS/NAC or if the individual suffers from systemic sclerosis with associated severe renal involvement manifested by a decrease in glomerular filtration rates.
- B. Cardio-pulmonary involvement or diffuse (Type III) scleroderma as defined by Barnett, A Survival Study of Patients with Scleroderma Diagnosed Over 30 Years (1953 - 1983): The Value of a Simple Cutaneous Classification in the Early Stages of the Disease, 15 *The Journal of Rheumatology* 276 (1988) and Masi, Classification of Systemic Sclerosis (Scleroderma): Relationship of Cutaneous Subgroups in Early Disease to Outcome and Serologic Reactivity, 15 *The Journal of Rheumatology*, 894 (1988).
- C. Other including CREST, limited, or intermediate scleroderma, except that any Breast Implant Claimant who manifests either severe renal involvement, as defined above, or cardio-pulmonary involvement, will be compensated at either category A or B as appropriate.
- D. Other not covered above, including localized scleroderma.

**SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)**

- 1. A diagnosis of systemic lupus erythematosus (SLE) shall be made in accordance with 1982 Revised Criteria for the Classification of Systemic Lupus Erythematosus, 25 Arthritis and Rheumatism No. 11 (November 1982) adopted by the American College of Rheumatology. See Kelley, 4th ed. at 1037, Table 61-11: A diagnosis of lupus is made if four of the eleven manifestations listed in the table were present, either serially or simultaneously, during any interval of observations.

CRITERION	DEFINITION
Malar rash	Fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds
Discoid rash	Erythematous raised patches with adherent keratotic scaling and follicular plugging; atrophic scarring may occur in older lesions
Photosensitivity	Skin rash as a result of unusual reaction to sunlight, by patient history or physician observation

Oral ulcers	Oral or nasopharyngeal ulceration, usually painless, observed by a physician
Arthritis	Nonerosive arthritis involving two or more peripheral joints, characterized by tenderness, swelling or effusion
Serositis	(a) Pleuritis — convincing history of pleuritic pain or rub heard by a physician or evidence of pleural effusion or (b) Pericarditis — documented by ECG or rub or evidence of pericardial effusion
Renal disorder	(a) Persistent proteinuria greater than 0.5 g/day or greater than 3 + if quantitation not performed or (b) Cellular casts - may be red cell, hemoglobin, granular, tubular, or mixed
Neurologic disorder	(a) Seizures - in the absence of offending drugs or known metabolic derangements; e.g., uremia, ketoacidosis, or electrolyte imbalance or (b) Psychosis - in the absence of offending drugs or known metabolic derangements; e.g. uremia, ketoacidosis, or electrolyte imbalance
Hematologic disorder	(a) Hemolytic anemia - with reticulocytosis or (b) Leukopenia - less than 4000/mm total on 2 or more occasions or (c) Lymphopenia - less than 1500/mm on 2 or more occasions or (d) Thrombocytopenia - less than 100,000/mm in the absence of offending drugs
Immunologic disorder	(a) Positive LE cell preparation or (b) Anti-DNA - antibody to native DNA in abnormal titer or (c) Anti-Sm - presence of antibody to Sm nuclear antigen or (d) False positive serologic test for syphilis known to be positive for at least 6 months and confirmed by Treponema pallidum immobilization or fluorescent treponemal antibody absorption test
Antinuclear antibody	An abnormal titer of antinuclear antibody by immunofluorescence or an equivalent assay at any point in time and in the absence of drugs known to be associated with drug-induced lupus syndrome

2. The application of the ACR diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of SLE but who nonetheless have a systemic lupus erythematosus-like disease, except that an individual will not be compensated in this category if her symptomology more closely resembles mixed connective tissue disease (MCTD), ACTD, or any other disease or condition defined below.

3. Severity/Disability Compensation Categories:

- A. Death or total disability resulting from SLE or an SLE-like condition. An individual will be considered totally disabled based on either the functional capacity test set forth in Severity/Disability Category A for ACTD/ARS/NAC or severe renal involvement.
- B. SLE with major organ involvement defined as SLE with one or more of the following: glomerulonephritis, central nervous system involvement (i.e. seizures or Lupus Psychosis), myocarditis, pneumonitis, thrombocytopenic purpura, hemolytic anemia

(marked), severe granulocytopenia, mesenteric vasculitis. See Immunological Diseases, Max Samter, Ed. Table 56-6, at 1352.

C. Non-major organ SLE requiring regular medical attention, including doctor visits and regular prescription medications. An individual is not excluded from this category for whom prescription medications are recommended but who, because of the side effects of those medications, chooses not to take them.

D. Non-major organ SLE requiring little or no treatment. An individual will fall into this category if she is able to control her symptoms through the following kinds of conservative measures: over-the-counter medications, avoiding sun exposure, use of lotions for skin rashes, and increased rest periods.

### **ATYPICAL NEUROLOGICAL DISEASE SYNDROME (ANDS)**

1. A diagnosis of Atypical Neurological Disease Syndrome (ANDS) shall be based upon the clinical findings and laboratory tests set forth below. The clinical and laboratory presentation of these neurological syndromes will have an atypical presentation from the natural disease and will also have additional neuromuscular, rheumatological or nonspecific autoimmune signs and symptoms.
2. Eligibility for Atypical Neurological Disease Syndrome requires both:
  - C satisfying the requirements for one of the four neurological diseases set forth in paragraph 5 below, and
  - C any three additional (nonduplicative) neuromuscular, rheumatic, or nonspecific symptoms or findings set forth in the definition for Atypical Connective Tissue Disease (ACTD).
3. An individual will fit into this category if her primary symptoms are characteristic of a neurological disease as diagnosed by a Board-certified neurologist or by a physician Board-certified in internal medicine.
4. If the individual's Qualified Medical Doctor determines that a symptom is clearly and specifically caused by a source other than breast implants, that symptom will not be utilized in the diagnosis of Atypical Neurological Disease Syndrome unless the Claims Office determines that other submissions indicate that the symptom should be utilized. A symptom that may be caused only in part by a source other than breast implants is not excluded from such utilization.
5. Neurological disease types:

Polyneuropathies. This disease category requires either (1) a diagnosis of a polyneuropathy that is confirmed by one or more of the following or (2) submission of sufficient evidence of, and the required findings confirming, such condition:

- C Objectively-demonstrated loss of sensation to pinprick, vibration, touch, or position



- C Proximal or distal muscle weakness
- C Tingling and/or burning pain in the extremities
- C Signs of dysesthesia
- C Loss of tendon reflex

Plus one or more of the following laboratory findings:

- C Abnormal levels of anti-mag or anti-sulfatide or anti-GM1 antibodies
- C Abnormal sural nerve biopsy
- C Abnormal electrodiagnostic testing (EMG or nerve conduction studies, etc.)

Multiple Sclerosis-like Syndrome. This disease category requires definite evidence of central nervous system disease, with history and physical findings compatible with Multiple Sclerosis or Multiple Sclerosis-like syndrome, involving one or more of the following signs and symptoms:

- C Weakness in the pyramidal distribution
- C Evidence of optic neuritis documented by ophthalmologist
- C Increased Deep Tendon reflexes
- C Absent superficial abdominal reflexes
- C Ataxia or dysdiadochokinesia as the sign of cerebellar involvement
- C Neurologically induced tremors
- C Internuclear ophthalmoplegia and/or bladder or speech involvement secondary to central nervous system disease

Plus one or more of the following:

- C Abnormal Brain MRI with foci of increased signal abnormality suggestive of demyelinating lesions
- C Delayed visual evoked responses or abnormal evoked potentials
- C Abnormal CSF with oligoclonal bands

ALS-like Syndrome. This disease category requires documented evidence of progressive upper and widespread lower motor neuron disease and/or bulbar involvement, plus one or more of the following:

- C Neurological autoantibodies such as anti-mag, anti-sulfatide, anti-GM1
- C Abnormal sural nerve biopsy
- C Chronic inflammation on muscle or nerve biopsies
- C Abnormal EMG
- C Documentation on neurological exam of both upper and lower motor neuron disease and/or bulbar involvement

Disease of Neuromuscular Junction. This disease category requires either (1) a diagnosis of Myasthenia Gravis or Myasthenia Gravis-like syndrome or disorders of the NMJ, made by a Board-certified neurologist and confirmed by abnormal EMG showing typical findings of decrement on repetitive stimulation testing and/or elevated acetylcholine receptor antibodies or (2) submission of sufficient evidence of, and the required findings confirming, such condition.

6. Severity/Disability Compensation Categories. The compensation level for ANDS will be based on the degree to which the individual is "disabled" by the condition, as the individual's treating physician determines in accordance with the following guidelines. The determination of disability under these guidelines will be based on the cumulative effect of the symptoms on the individual's ability to perform her vocational,<sup>1</sup> avocational,<sup>2</sup> or usual self-care,<sup>3</sup> activities. In evaluating the effect of the individual's symptoms, the treating physicians will take into account the level of pain and fatigue resulting from the symptoms. The disability percentages appearing below are not intended to be applied with numerical precision, but are, instead, intended to serve as a guideline for the physician in the exercise of his or her professional judgment.

A. Death or total disability due to the compensable condition. An individual shall be considered totally disabled if she demonstrates a functional capacity adequate to consistently perform none or only few of the usual duties or activities of vocation or self-care.

B. A Breast Implant Claimant will be eligible for category B compensation if she is 35 percent disabled due to the compensable condition. An individual shall be considered 35 percent disabled if she demonstrates a loss of functional capacity which renders her unable to perform some of her usual activities of vocation, avocation, and self-care, or if she can only perform them only with regular or recurring severe pain.

C. A Breast Implant Claimant will be eligible for category C compensation if she is 20 percent disabled due to the compensable condition. An individual shall be considered

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<sup>1</sup> Vocational means activities associated with work, school, and homemaking.

<sup>2</sup> Avocational means activities associated with recreation and leisure.

<sup>3</sup> Usual self-care means activities associated with dressing, feeding, bathing, grooming, and toileting.

20 percent disabled if she can perform some of her usual activities of vocation, avocation, and self-care only with regular or recurring moderate pain.

### **MIXED CONNECTIVE TISSUE DISEASE (MCTD)/OVERLAP SYNDROME**

1. A diagnosis of mixed connective tissue disease (MCTD) shall be based on the presence of clinical symptoms characteristic of two or more rheumatic diseases (systemic sclerosis, SLE, myositis, and Rheumatoid Arthritis), accompanied by positive RNP Antibodies. See, e.g., Kelley, et al., Table 63-1, at 1061.
2. Overlap Syndrome is defined as any one of the following three: (a) Diffuse cutaneous scleroderma, (b) limited cutaneous scleroderma, or (c) Sine scleroderma, occurring concomitantly with diagnosis of systemic lupus erythematosus, inflammatory muscle disease, or rheumatoid arthritis. See Kelley, et al., Table 66-2, at 1114.
3. The application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of MCTD but who nonetheless have an Overlap Syndrome, except that an individual will not be compensated in this category if her symptomology more closely resembles an atypical connective tissue disease condition/atypical rheumatic syndrome/non-specific autoimmune condition.
4. Severity/Disability Compensation Categories
  - A. Death or total disability resulting from MCTD or Overlap Syndrome. An individual will be considered totally disabled based on the functional capacity test set forth in Severity/Disability Category A of Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome.
  - B. MCTD or Overlap Syndrome, plus major organ involvement or major disease activity including central nervous system, cardio-pulmonary, vasculitic, or renal involvement or hemolytic anemia (marked) or thrombocytopenic purpura or severe granulocytopenia.
  - C. Other.

### **POLYMYOSITIS/DERMATOMYOSITIS**

1. A diagnosis of polymyositis or dermatomyositis shall be made in accordance with diagnostic criteria proposed by Bohan and Peter, i.e., (a) symmetrical proximal muscle weakness; (b) EMG changes characteristic of myositis including (1) short duration, small, low amplitude polyphasic potential, (2) fibrillation potentials, (3) bizarre high-frequency repetitive discharges; (c) elevated serum muscle enzymes (CPK, aldolase, SGOT, SGPT, and LDH); (d) muscle biopsy showing evidence of necrosis of type I and II muscle fibers, areas of degeneration and regeneration of fibers, phagocytosis, and an interstitial or perivascular inflammatory response; (e) dermatologic features including a lilac (heliotrope), erythematous, scaly involvement of the face, neck, shawl area and extensor surfaces of the knees, elbows and medial malleoli, and Gottron's papules. A diagnosis of dermatomyositis requires presence of three of the criteria plus the rash (fifth criterion). A

diagnosis of polymyositis requires the presence of four criteria without the rash. See, Kelley, et al., at 1163.

2. The application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of polymyositis or dermatomyositis but who nonetheless have a polymyositis or dermatomyositis-like disease, except that an individual will not be compensated in this category if her symptomology more closely resembles an Atypical Connective Tissue Disease.
3. Severity/Disability Compensation Categories:
  - A. Death or total disability resulting from polymyositis or dermatomyositis. An individual will be considered totally disabled based on the functional capacity test set forth for Severity/Disability Category A for Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome.
  - B. Polymyositis or dermatomyositis with associated malignancy and/or respiratory muscle involvement.
  - C. Other, including polymyositis or dermatomyositis with muscle strength of Grade III or less.

#### **PRIMARY SJOGREN'S SYNDROME**

1. A clinical diagnosis of Primary Sjogren's Syndrome shall be made in accordance with diagnostic criteria proposed by Fox et al. See Kelley, et al., Table 55-1, at 932, or Fox, RI, et al., "Primary Sjogren's Syndrome: Clinical and Immunopathologic Features," *Seminars Arthritis Rheum.*, 1984; 4:77-105.
2. Application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of Primary Sjogren's Syndrome but who nonetheless have a Primary Sjogren's-like disease.
3. Severity/Disability Compensation Categories
  - A. Death or total disability due to the compensable condition. An individual will be considered totally disabled based on the functional capacity test set forth in Severity/Disability Category A for Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome.
  - B. Primary Sjogren's with associated central nervous system or severe cardio-pulmonary involvement or primary Sjogren's with pseudolymphoma or associated lymphoma.
  - C. Other.

**ATYPICAL CONNECTIVE TISSUE DISEASE (ACTD)  
ATYPICAL RHEUMATIC SYNDROME (ARS)  
NON-SPECIFIC AUTOIMMUNE CONDITION (NAC)**

1. This category will provide compensation for Breast Implant Claimants experiencing symptoms that are commonly found in autoimmune or rheumatic diseases but which are not otherwise classified in any of the other compensable disease categories. This category does not include individuals who have been diagnosed with classical rheumatoid arthritis in accordance with ACR criteria, but will include individuals diagnosed with undifferentiated connective tissue disease (UCTD). However, such inclusion is not intended to exclude from this category persons who do not meet the definition of UCTD, it being intended that individuals not meeting the classic definitions of UCTD will be compensated pursuant to the provisions contained herein relative to ACTD, ARS, and NAC.
2. As with other individuals who fit within this disease compensation program, the fact that a breast implant recipient has been in the past mis-diagnosed with classic rheumatoid arthritis or the fact that the symptoms of classic rheumatoid arthritis may coexist with other symptoms will not exclude the individual from compensation herein. Persons who meet the criteria below and may have a diagnosis of atypical rheumatoid arthritis will not be excluded from compensation under this category.
3. Eligibility criteria and compensation levels for eligible Breast Implant Claimants are set forth below in the Compensation Categories, which classify individuals in accordance with the following groups of symptoms. If the Breast Implant Claimant's Qualified Medical Doctor determines that a symptom is clearly and specifically caused by a source other than breast implants, that symptom will not be utilized in the diagnosis of Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome unless the Claims Office determines that other submissions indicate that the symptom should be utilized. A symptom that may be caused only in part by a source other than breast implants is not excluded from such utilization.
4. A diagnosis of ACTD, ARS, or NAC must satisfy one of the following sets of criteria:
  - C any two of the three signs and symptoms listed in 5(a) (Group I)
  - C any one of the three signs and symptoms listed in 5(a) (Group I), plus any one of the ten signs and symptoms listed in 5(b) (Group II)
  - C any three of the ten signs and symptoms listed in 5(b) (Group II)
  - C any two of the ten signs and symptoms listed in 5(b) (Group II), plus any one additional (nonduplicative) sign or symptom from the eighteen listed in 5(c) (Group III)
  - C five nonduplicative signs or symptoms listed in 5(a) (Group I), 5(b) (Group II), or 5(c) (Group III)

5. Symptom Groupings:

(a) Group I Signs and Symptoms:

- C Raynaud's phenomenon evidenced by the patient giving a history of two color changes, or visual evidence of vasospasm, or evidence of digital ulceration
- C Polyarthritis defined as synovial swelling and tenderness in three or more joints lasting greater than six weeks and observed by a physician
- C Keratoconjunctivitis Sicca: subjective complaints of dry eyes and/or dry mouth, accompanied by any one of the following:
  - C lacrimal or salivary enlargement
  - C parotid enlargement
  - C abnormal Schirmer's test
  - C abnormal Rose-Bengal staining
  - C filamentous keratitis
  - C abnormal parotid scan or ultrasound
  - C abnormal CT or MRI of parotid
  - C abnormal labial salivary biopsy

(b) Group II Signs and Symptoms:

- C Myalgias determined by tenderness on examination
- C Immune mediated skin changes or rash as follows:
  - C changes in texture or rashes that may or may not be characteristic of SLE, Systemic Sclerosis (scleroderma), or dermatomyositis
  - C diffuse petechiae, telangiectasias, or livedo reticularis
- C Pulmonary symptoms or abnormalities, which may or may not be characteristic of SLE, Systemic Sclerosis (scleroderma), or Sjogren's Syndrome, as follows:
  - C pleural and/or interstitial lung disease
  - C restrictive lung disease
  - C obstructive lung disease as evidenced by characteristic clinical findings and either:

characteristic chest X-ray changes or characteristic pulmonary function test abnormalities in a non-smoker (e.g. decreased DLCO or abnormal arterial blood gases)

- C Pericarditis defined by consistent clinical findings and either EKG or echocardiogram
- C Neuropsychiatric symptoms: cognitive dysfunction (memory loss and/or difficulty concentrating) which may be characteristic of SLE or MCTD as determined by a SPECT scan or PET scan or MRI or EEG or neuropsychological testing
- C Peripheral neuropathy diagnosed by physical examination showing one or more of the following:
  - C loss of sensation to pinprick, vibration, touch, or position
  - C tingling, paresthesia or burning pain in the extremities
  - C loss of tendon reflex
  - C proximal or distal muscle weakness (loss of muscle strength in extremities or weakness of ankles, hands, or foot drop)
  - C Signs of dysesthesia
  - C entrapment neuropathies
- C Myositis or myopathy:
  - C diagnosed by weakness on physical examination or by muscle strength testing
  - C abnormal CPK or aldolase
  - C abnormal cybex testing
  - C abnormal EMG
  - C abnormal muscle biopsy
- C Serologic abnormalities -- any one of the following:
  - C ANA > or equal to 1:40
  - C positive ANA profile such as Anti-DNA, SSA, SSB, RNP, SM, Scl-70, centromere, Jo-1, PM-Scl or dsDNA (preferable to use ELISA with standard cutoffs)



- C other autoantibodies, including thyroid antibodies, anti-microsomal, or anti-cardiolipin, or RF (by nephelometry with 40 IU cutoff)
- C elevation of immunoglobulin (IgG, IgA, IgM)
- C serologic evidence of inflammation such as elevated ESR, CRP
- C Lymphadenopathy (as defined by at least 1 lymph node greater than or equal to 1x1 cm) documented by a physician
- C Dysphagia with positive cine-esophagram, manometry or equivalent imaging

(c)Group III Signs and Symptoms:

- C Documented arthralgia
- C Documented Myalgias
- C Chronic fatigue
- C Lymphadenopathy
- C Documented Neurological symptoms including cognitive dysfunction or paresthesia
- C Photosensitivity
- C Sicca symptoms
- C Dysphagia
- C Alopecia
- C Sustained balance disturbances
- C Documented sleep disturbances
- C Easy bruisability or bleeding disorder
- C Chronic cystitis or bladder irritability
- C Colitis or bowel irritability
- C Persistent low grade fever or night sweats
- C Mucosal ulcers confirmed by physician
- C Burning pain in the chest, breast, arms or axilla, or substantial loss of function in breast due to disfigurement or other complications from implants or explantation

- C Pathological findings: granulomas or siliconomas or chronic inflammatory response, or breast infections

6. Severity/Disability Compensation Categories

The compensation level for ACTD/ARS/NAC will be based on the degree to which the individual is “disabled” by the condition, as the individual’s treating physician determines in accordance with the following guidelines. The determination of disability under these guidelines will be based on the cumulative effect of the symptoms on the individual’s ability to perform her vocational,<sup>4</sup> avocational,<sup>5</sup> or usual self-care<sup>6</sup> activities. In evaluating the effect of the Breast Implant Claimant’s symptoms, the treating physicians will take into account the level of pain and fatigue resulting from the symptoms. The disability percentages appearing below are not intended to be applied with numerical precision, but are, instead, intended to serve as a guideline for the physician in the exercise of his or her professional judgment.

- A. Death or total disability resulting from the compensable condition. An individual will be considered totally disabled if she demonstrates a functional capacity adequate to consistently perform none or only few of the usual duties or activities of vocation or self-care.
- B. A Breast Implant Claimant will be eligible for category B compensation if she is 35 percent disabled due to the compensable condition. An individual shall be considered 35 percent disabled if she demonstrates a loss of functional capacity which renders her unable to perform some of her usual activities of vocation, avocation, and self-care, or she can perform them only with regular or recurring severe pain.
- C. A Breast Implant Claimant will be eligible for category C compensation if she is 20 percent disabled due to the compensable condition. An individual shall be considered 20 percent disabled if she can perform some of her usual activities of vocation, avocation, and self-care only with regular or recurring moderate pain.

**PART B. DISEASE AND DISABILITY/SEVERITY DEFINITIONS:  
DISEASE PAYMENT OPTION II**

**GENERAL**

- A. A claimant must file with the Claims Office all medical records establishing the required findings or laboratory abnormalities. Qualifying findings must have occurred within a single 24-month period within the five years immediately preceding the submission of the claim except that this period is tolled during the pendency of the bankruptcy (May 15,

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<sup>4</sup>Vocational means activities associated with work, school, and homemaking.

<sup>5</sup>Avocational means activities associated with recreation and leisure.

<sup>6</sup>Usual self-care means activities associated with dressing, feeding, bathing, grooming, and toileting.

1995 until the Effective Date). (Findings supplemented in response to a deficiency letter sent by the Claims Office do not have to fall within the 24-month period outlined above.)

- B. If exclusions are noted for a required finding, the physician making the finding or ordering the test must affirmatively state that those listed exclusions are not present. The physician recording a GCTS finding or making a disease diagnosis must also affirmatively state that the qualifying symptoms did not exist before the date of first implantation. (This statement can be based upon patient history so long as consistent with medical records in the physician's possession.) Failure to make these affirmative statements will result in a deficiency letter. All underlying office charts, radiology/pathology reports, and test results must be supplied to the Claims Office.
- C. QMD statements may be acceptable proof under Disease Payment Option II if the physician is a Board-certified rheumatologist — for Lupus, Scleroderma, or Polymyositis/Dermatomyositis Claims — or is Board-certified in the appropriate specialty to make the required GCTS findings, if the statement covered all of the detailed findings that are required in Disease Payment Option II, if the QMD personally examined the Claimant, and if the doctor included all of the additional statements required concerning listed exclusions and pre-existing symptoms. In most cases, additional physician statements will have to be submitted for claims under Disease Payment Option II.
- D. Claimants who seek benefits under Disease Payment Option II must file all medical records establishing the required findings or laboratory abnormalities. Claimants must also supply all office charts, radiology/pathology reports, and test results in the possession of the physician(s) who make the required findings or statements, or who order the required tests.

## **DISEASE PAYMENT OPTION II: DEFINITION OF COVERED CONDITIONS**

### **SCLERODERMA (SS)**

A claim for scleroderma must include a diagnosis of systemic sclerosis/scleroderma made by a Board-certified rheumatologist based upon personal examination of the patient. [Exclusion: localized scleroderma.] Supporting medical documentation must affirmatively reveal that the major or at least two of the minor criteria listed below are present:

- A. Major Criterion: Proximal scleroderma — symmetric thickening, tightening, and induration of the skin of the fingers and the skin proximal to the metacarpophalangeal or metatarsophalangeal joints. The changes may affect the entire extremity, face, neck, and trunk (thorax and abdomen). Description of this criterion is adequate if the Board-certified rheumatologist records that physical examination of the patient revealed scleroderma skin thickening, and adequately describes the parts of the body where that thickened skin was found.
- B. Minor Criteria:
  - 1. Sclerodactyly: Above-indicated skin changes limited to the fingers.

2. Digital pitting scars or loss of substance from the finger pad: Depressed areas at tips of fingers or loss of digital pad tissue as a result of ischemia.
3. Bibasilar pulmonary fibrosis: Bilateral reticular pattern of linear or lineonodular densities most pronounced in basilar portions of the lungs on standard chest roentgenogram; may assume appearance of diffuse mottling or "honeycomb lung." These changes should not be attributable to primary lung disease.

Compensation Levels:

- A. Death resulting from SS, or severe chronic renal involvement manifested by a glomerular filtration rate of less than 50 percent of the age- and gender-adjusted norm, as measured by an adequate 24-hour urine specimen collection.
- B. Clinically significant cardio-pulmonary manifestations of scleroderma<sup>7</sup> or proximal scleroderma on the trunk (thorax and abdomen).
- C. A diagnosis of scleroderma in accordance with the above criteria that does not involve the findings in A or B above.

**LUPUS (SLE)**

A claim for SLE must include a diagnosis of SLE (lupus) made by a Board-certified rheumatologist based upon personal examination of the patient. [Exclusion: mild lupus (SLE not requiring regular medical attention including doctor visits and regular prescription medications).] Supporting medical documentation must affirmatively reveal that at least four of the following 11 criteria are present:

Criterion	Definition
1. Malar rash	Fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds
2. Discoid rash	Erythematous raised patches with adherent keratotic scaling and follicular plugging; atrophic scarring may occur in older lesions
3. Photosensitivity	Skin rash as a result of unusual reaction to sunlight, by patient history or physician observation
4. Oral ulcers	Oral or nasopharyngeal ulceration, usually painless, observed by a physician
5. Arthritis	Nonerosive arthritis involving two or more peripheral joints, characterized by tenderness, swelling, or effusion [Exclusion: erosive arthritis]

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<sup>7</sup>As manifested by interstitial fibrosis (based upon physical examination findings and abnormalities seen on chest x-rays or chest CT) or pulmonary hypertension (based upon physical examination findings and 2-D Echo doppler or angiography with hemodynamic measurements showing pulmonary artery pressures of greater than 25 TORR).

6. Serositis
  - (a) Pleuritis -- convincing history of pleuritic pain or rub heard by a physician or evidence of pleural effusion, or
  - (b) Pericarditis — documented by ECG or rub or evidence of pericardial effusion
  
7. Renal disorder
  - (a) Persistent proteinuria greater than 0.5 grams per day or greater than 3+ if quantitation not performed, or
  - (b) Cellular casts -- may be red cell, hemoglobin, granular, tubular, or mixed
  
8. Neurologic disorder Seizures -- in the absence of offending drugs or known metabolic derangements, *e.g.* uremia, ketoacidosis, or electrolyte imbalance
  
9. Hematologic disorder
  - a) Hemolytic anemia -- with reticulocytosis, or
  - b) Leukopenia — less than 4,000/mm total on two or more occasions, or
  - c) Lymphopenia — less than 1,500/mm on two or more occasions, or
  - d) Thrombocytopenia — less than 100,000/mm in the absence of offending drugs
  
10. Immunologic disorder
  - a) Positive LE cell preparation, or
  - b) Anti- DNA: antibody to native DNA in abnormal titer, or
  - c) Anti-Sm: presence of antibody to Sm nuclear antigen, or
  - d) False positive serologic test for syphilis known to be positive for at least 6 months and confirmed by *Treponema pallidum* immobilization or fluorescent *treponema* antibody absorption test
  
11. Antinuclear antibody An abnormal titer or antinuclear antibody by immunofluorescence or an equivalent assay at any point in time and in the absence of drugs known to be associated with “drug-induced lupus” syndrome.

Compensation Levels:

- A. Death resulting from SLE, or severe chronic renal involvement manifested by a glomerular filtration rate of less than 50 percent of the age- and gender-adjusted norm, as measured by an adequate 24-hour urine specimen collection.
  
- B. SLE with involvement of one or more of the following: glomerulonephritis, seizures in the absence of offending drugs or known metabolic derangements, Lupus Psychosis, myocarditis, pneumonitis, thrombocytopenic purpura, hemolytic anemia (with hemoglobin of 10 grams or less), severe granulocytopenia (with a total white cell count less than 2000), or mesenteric vasculitis.
  
- C. A diagnosis of lupus in accordance with the above criteria that does not involve the findings in A or B above. (Default compensation level.)

## **POLYMYOSITIS (PM)/DERMATOMYOSITIS (DM)**

A claim for polymyositis or dermatomyositis must include a diagnosis of the disease made by a Board-certified rheumatologist based upon personal examination of the patient. Supporting medical documentation must affirmatively reveal that the following criteria are present:

- for polymyositis, the first four criteria without the rash;
- for dermatomyositis, three of the first four criteria, plus the rash (#5).

Criteria:

1. symmetrical proximal muscle weakness;
2. EMG changes characteristic of myositis including (a) short duration, small, low-amplitude polyphasic potential, (b) fibrillation potentials, (c) bizarre high-frequency repetitive discharges;
3. elevated serum muscle enzymes (CPK, aldolase, SGOT, SGPT, and LDH);
4. muscle biopsy showing evidence of necrosis of type I and II muscle fibers areas of degeneration and regeneration of fibers, phagocytosis, and an interstitial or perivascular inflammatory response;
5. dermatologic features including a lilac (heliotrope), erythematous, scaly involvement of the face, neck, shawl area and extensor surfaces of the knees, elbows and medial malleoli, and Gottron's papules.

Compensation Level:

All confirmed PM/DM diagnoses will be compensated at the GCTS/PM/DM--A level.

## **GENERAL CONNECTIVE TISSUE SYMPTOMS (GCTS)**

A claim for GCTS does not have to include a diagnosis for "General Connective Tissue Symptoms," but the medical documentation must establish that the combination of findings listed below are present. [Exclusion: classical rheumatoid arthritis diagnosed in accordance with the revised 1958 ACR classification criteria.]

For compensation at Level A:

- (1) any two findings from Group I; or
- (2) any three non-duplicative findings from Group I or Group II.

For compensation at Level B:

- (1) one finding from Group I plus any four non-duplicative findings from Group II or Group III; or
- (2) two findings from Group II plus one non-duplicative finding from Group III.

The following duplications exist on the list of findings:

- rashes (#3 and #8)
- sicca (#2 and #12)
- serological abnormalities (#4 and #9)

In addition to the medical verification of the required findings, a claim for GCTS must include the affirmative physician statements outlined in General Guidelines above.

## GROUP I FINDINGS

1. Polyarthritis, defined as synovial swelling and tenderness in three or more joints in at least two different joint groups observed on more than one physical examination by a Board-certified physician and persisting for more than six weeks. [Exclusion: osteoarthritis.]
2. Keratoconjunctivitis Sicca, defined as subjective complaints of dry eyes and/or dry mouth, accompanied (a) in the case of dry eyes, by either (i) a Schirmer's test less than 8 mm wetting per five minutes or (ii) a positive Rose-Bengal or fluorescein staining of cornea and conjunctiva; or (b) in the case of dry mouth, by an abnormal biopsy of the minor salivary gland (focus score of greater than or equal to two based upon average of four evaluable lobules). [Exclusions: drugs known to cause dry eyes and/or dry mouth, and dry eyes caused by contact lenses.]
3. Any of the following immune-mediated skin changes or rashes, observed by a Board-certified rheumatologist or Board-certified dermatologist: (a) biopsy-proven discoid lupus; (b) biopsy-proven subacute cutaneous lupus; (c) malar rash -- fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds [Exclusion: rosacea or redness caused by sunburn]; or (d) biopsy-proven vasculitic skin rash.

## GROUP II FINDINGS

4. Positive ANA greater than or equal to 1:40 (using Hep2), on two separate occasions separated by at least two months and accompanied by at least one test showing decreased complement levels of C3 and C4; or a positive ANA greater than or equal to 1:80 (using Hep2) on two separate occasions separated by at least two months. All such findings must be outside of the performing laboratory's reference ranges.
5. Abnormal cardiopulmonary symptoms, defined as (a) pericarditis documented by pericardial friction rub and characteristic echocardiogram findings (as reported by a Board-certified radiologist or cardiologist); (b) pleuritic chest pain documented by pleural friction rub on exam and chest x-ray diagnostic of pleural effusion (as reported by a Board-certified radiologist); or (c) interstitial lung disease in a non-smoker diagnosed by a Board-certified internist or pulmonologist, confirmed by (i) chest x-ray or CT evidence (as reported by a Board-certified radiologist) and (ii) pulmonary function testing abnormalities defined as decreased DLCO less than 80 percent of predicted.
6. Myositis or myopathy, defined as any two of the following: (a) EMG changes characteristic of myositis: short duration, small, low amplitude polyphasic potential; fibrillation potentials; and bizarre high-frequency repetitive discharges; (b) abnormally elevated CPK or aldolase from the muscle (outside of the performing laboratory's reference ranges) on two separate occasions at least six weeks apart. (If the level of the initial test is three times normal or greater, one test would be sufficient.) [Exclusions: injections, trauma, hypothyroidism, prolonged exercise, or drugs known to cause abnormal CPK or aldolase]; or (c) muscle biopsy (at a site that has not undergone EMG testing) showing evidence of necrosis of type 1 and 2 muscle fibers, phagocytosis, and an interstitial or perivascular inflammatory response interpreted as characteristic of myositis or myopathy by a pathologist.



7. Peripheral neuropathy or polyneuropathy, diagnosed by a Board-certified neurologist, confirmed by (a) objective loss of sensation to pinprick, vibration, touch, or position; (b) symmetrical distal muscle weakness; (c) tingling and/or burning pain in the extremities; or (d) loss of tendon reflex, plus nerve conduction testing abnormality diagnostic of peripheral neuropathy or polyneuropathy recorded from a site that has not undergone neural or muscular biopsy. [Exclusions: thyroid disease, antineoplastic treatment, alcoholism or other drug dependencies, diabetes, or infectious disease within the last three months preceding the diagnosis.]

### **GROUP III FINDINGS**

8. Other immune-mediated skin changes or rashes, observed by a Board-certified rheumatologist or Board-certified dermatologist: (a) livedo reticularis; (b) lilac (heliotrope), erythematous scaly involvement of the face, neck, shawl area and extensor surfaces of the knees, elbows and medial malleoli; (c) Gottron's sign, pink to violaceous scaling areas typically found over the knuckles, elbows, and knees; or (d) diffuse petechiae.
9. Any of the following serologic abnormalities: (a) ANA greater than or equal to 1:40 (using Hep2) on two separate occasions separated by at least two months; (b) one or more positive ANA profile: Anti-DNA, SSA SSB, RNP, SM, Scl-70, centromere, Jo-1 PM-Scl, or double-stranded DNA (using ELISA with standard cutoffs); (c) anti-microsomal, anti-cardiolipin, or RF greater than or equal to 1:80.
10. Raynaud's phenomenon, evidenced by a physician-observed two (cold-related) color change as a progression, or by physician observation of evidence of cold-related vasospasm, or by physician observation of digital ulceration resulting from Raynaud's phenomenon.
11. Myalgias, defined as tenderness to palpation, performed by a physician, in at least three muscles, each persisting for at least six months.
12. Dry mouth, subjective complaints of dry mouth accompanied by decreased parotid flow rate using Lashley cups with less than 0.5 ml per five minutes. [Exclusion: drugs known to cause dry mouth.]

## SCHEDULE III

## Categorization of Countries for Calculation of Allowed Amount for Eligible Foreign Claims

For purposes of determining the appropriate amount payable, Foreign Claimants with Allowed Personal Injury Claims will be categorized in one of four groups (as specified below in this Schedule III) based on their place of residence. Each "country group" is assigned a specific percentage (as specified below) -- which percentage shall be multiplied against the Allowed amount applicable to the Allowed Claim in terms of U.S. dollars. The resulting dollar amount is the amount payable to the Foreign Claimant with an Allowed Claim.

Country	Percentage of Domestic Amount for Applicable Compensation Level	Country	Percentage of Domestic Amount for Applicable Compensation Level
<b>Category 1 Countries</b>		<b>Category 4 Countries</b>	
	{60%}		{35%}
Australia		Algeria	
Canada		Belize	
New Zealand		Bolivia	
<u>United Kingdom</u>		Botswana	
		Brazil	
<b>Category 2 Countries</b>		Bulgaria	
	{60%}	Cambodia	
Austria		Central African Republic	
Bahamas		China	
Belgium		Colombia	
Bermuda		Cook Islands	
Cayman Islands		Costa Rica	
Denmark		Cote d'Ivoire (Ivory Coast)	
Finland		Croatia	
France including:		Cuba	
French Polynesia		Dominican Republic	
New Caledonia		Ecuador	
Germany		Egypt	
Greece		Estonia	
Hong Kong		Fiji	
Iceland		Ghana	
Ireland		Grenada	
Italy		Guatemala	
Japan		Guyana	
Kuwait		Haiti	
Liechtenstein		Honduras	
Luxembourg		Hungary	
Monaco		India	
Netherlands		Indonesia	
Norway		Jamaica	
Portugal		Jordan	
Singapore		Kenya	
Spain		Lebanon	
Sweden		Lithuania	
Switzerland		Mali	
<u>United Arab Emirates</u>		Mexico	
		Morocco	
<b>Category 3 Countries</b>		Namibia	
	{35%}	New Guinea	
Argentina		Nicaragua	
Barbados		Nigeria	
British Virgin Islands		Oman	
Chile		Pakistan	
Cyprus		Panama	
Czech Republic		Paraguay	
Israel including:		Peru	
Gaza Strip		Philippines	
West Bank		Poland	
Korea		Saint Kitts and Nevis	
Malaysia		Senegal	
Malta		South Africa	
Mauritius		Thailand	
Qatar		Tonga	
Saudi Arabia		Turkey	
<u>Taiwan</u>		Uruguay	
		Venezuela	
		Vietnam	
		Zambia	
		<u>Zimbabwe</u>	

Schedule III to Annex A - Categorization of Countries