

CLAIMANT INFORMATION GUIDE

DOW CORNING SILICONE MATERIAL CLAIMANTS/
PARTICIPATING FOREIGN GEL CLAIMANTS
(CLASS 7)

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PARTICIPATING FOREIGN GEL CLAIMANTS**

(CLASS 7)

A note about the use of capitalized terms in this Claimant Information Guide:

When you see capitalized terms that are not otherwise defined, they have the meaning assigned to them in the following documents in the following order:

1. Amended Joint Plan
 2. Amended Disclosure Statement
 3. Dow Corning Settlement Program and Claims Resolution Procedures
 4. Funding Payment Agreement
 5. Litigation Facility, Inc. Agreement (this document and the preceding ones in this list are collectively referred to as the "Plan Documents")
 6. Bankruptcy Code
-

Contact us at:

Settlement Facility-Dow Corning Trust
P.O. Box 52429
Houston, Texas 77052
U.S.A.
(Toll Free) 1-866-874-6099

www.dcssettlement.com

December 2002

This "Claimant Information Guide" was produced by the office of the Settlement Facility-Dow Corning Trust. The information contained in this Claimant Information Guide is intended to summarize the information contained in the Plan Documents. Any conflicts between the information in this Claimant Information Guide shall be controlled by the provisions in the Plan Documents in the order reflected on the cover sheet.

This Claimant Information Guide may be copied freely without amendment or deletion.

The Settlement Facility reserves the right to make changes to the Claimant Information Guide without notice.

Date of publication: December 2002

CLAIMANT INFORMATION GUIDE

SILICONE MATERIAL CLAIMANTS PARTICIPATING FOREIGN GEL CLAIMANTS (CLASS 7)

This “Claimant Information Guide” provides the most current information about the Settlement Options and criteria for receiving payment for Silicone Material Claimants/Participating Foreign Gel Claimants (Class 7). Please use only these materials when you complete your Claim Forms.

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SECTION 1 – GENERAL INFORMATION ABOUT THIS CLAIMS PACKAGE/CLASSIFICATION OF CLAIMS

Q1-1. What documents are in the Claims Package?

The Claims Package for Class 7 Claimants includes the following four (4) documents. If you are missing any of these, call the Settlement Facility Toll Free at 1-866-874-6099.

1. Settlement Facility Newsletter, Vol. 2
2. "Participation Form" and instructions (white edge)
3. "Silicone Material Claimants/Participating Foreign Gel Claimants Claim Form" (brown edge)
4. This Claimant Information Guide

The Claim Forms in this package (items 2.-3. above) are the forms you use to apply for settlement payments.

Q1-2. I completed claim forms in the original global settlement and/or the Revised Settlement Program ("RSP"). Do I need to fill out another Claim Form now?

Yes. You must fill out the Claim Forms in this Claims Package. However, if you have already sent medical records to the MDL Claims Office, then you do not have to re-send the same medical records. The Settlement Facility will have access to all records you submitted to the MDL Claims Office.

Q1-3. My friend didn't receive a Claims Package. Can I copy mine and give it to her?

No. **Do not copy your Claim Forms for someone else to use.** Tell her to call the Settlement Facility Toll Free at 1-866-874-6099.

Q1-4. My friend received a Claims Package, but it has different Claim Forms and documents than are in my Claims Package. Are there different Claims Packages?

Yes, there are seven (7) different Claims Packages for seven (7) different types of claimants. The different types of claimants are defined in Q1-5.

Q1-5. What are the seven (7) different types of claimants?

Claims are classified based on your 1) citizenship or country of residence, 2) the location where you received your implant, and 3) the type of implant listed on your Proof of Claim form (i.e., breast, hip, TMJ, etc.).

The different types or Classes of claimants are:

Class 5 (Domestic Dow Corning Breast Implant Claimants) - if you were implanted with a Dow Corning breast implant and either you are a U.S. citizen or resident alien, or your Dow Corning implant was implanted in the U.S., then you are a member of Class 5.

Class 6 (Foreign Dow Corning Breast Implant Claimants) - if you were implanted with a Dow Corning breast implant, it was implanted outside of the U.S., and you are not a citizen of the U.S., or a resident alien within the U.S., Puerto Rico, or the territories and possessions of the U.S., then you are a member of Class 6. There are six (6) subclasses in Class 6:

Class 6.1 - you reside in one (1) of the countries listed in Category 1 or 2 on the chart located at Tab 2.

Class 6.2 - you reside in one (1) of the countries listed in Category 3 or 4 on the chart located at Tab 2.

Class 6A - you are a member of the Class of plaintiffs in a class action filed in the province of Quebec.

Class 6B - you are a member of the Class of plaintiffs in a class action filed in the province of Ontario.

Class 6C - you are a member of the Class of plaintiffs in a class action filed in the province of British Columbia. The Class includes resident claimants in British Columbia who did not opt out of the class action as well as those claimants who are residents of any province of Canada other than British Columbia, Quebec and Ontario who timely elected to be bound by the British Columbia class action.

Class 6D - you are a resident of Australia or received your implants in Australia, and you timely elected to participate in the Australia Breast Implant Settlement Option on your ballot on the Amended Joint Plan in 1999.

Classes 6A-6D are governed by specific definitions contained in the class action settlements and judgments relating to these Classes. Membership in these Classes is based on residence at specific periods of time. If you are a member of one (1) of these Classes, you will receive a separate notice.

Class 7 (Silicone Material Claimants/Participating Foreign Gel Claimants) - if you were implanted with a silicone gel breast implant after January 1, 1976 and before January 1, 1992 from either Baxter, Bioplasty, Bristol, Cox-Uphoff, Mentor, Koken, Silimed, Societe Prometel, or Medasil Surgical, and you have never had a Dow Corning implant, then you are a member of Class 7 regardless of your country of residence or citizenship.

Class 9 (Domestic Dow Corning Other Products Claimants) - if you were implanted with an eligible Dow Corning implant (other than a breast implant) listed in Tab 1, Part II, and are a U.S. citizen or resident alien, or if your eligible Dow Corning implant was implanted in the U.S., then you are a member of Class 9.

Class 10 (Foreign Dow Corning Other Products Claimants) - if you were implanted with an eligible Dow Corning implant (other than a breast implant) listed in Tab 1, Part II, and it was implanted outside of the U.S., and you are not a citizen of the U.S. or a resident alien within the U.S., Puerto Rico, or the territories and possessions of the U.S., then you are a member of Class 10. There are two (2) subclasses in Class 10:

Class 10.1 - you reside in one (1) of the countries listed in Category 1 or 2 on the chart located at Tab 2.

Class 10.2 - you reside in one (1) of the countries listed in Category 3 or 4 on the chart located at Tab 2.

Q1-6. What is my initial classification?

Based on the information you provided on your Proof of Claim form, you have initially been placed in Class 7 for Silicone Material Claimants/Participating Foreign Gel Claimants.

Q1-7. Where can I find a list of the eligible implants for each of these Classes?

Tab 1, Part I to this Claimant Information Guide lists the eligible Dow Corning breast implants for Classes 5, 6.1 and 6.2.

Tab 1, Part II lists the eligible Dow Corning implants for Classes 9, 10.1 and 10.2.

Tab 1, Part III lists the eligible silicone gel breast implants for Class 7.

Q1-8. Where can I find a list of the categories of countries for Classes 6.1, 6.2, 10.1 and 10.2?

Tab 2 to this Claimant Information Guide lists the categories of countries for each of these Classes.

Q1-9. I have a Dow Corning breast implant (Class 5) and a Bristol silicone gel breast implant implanted in 1985 (Class 7). Can I recover benefits from both Classes 5 and 7?

No. You are eligible for benefits only from Class 5. You are not eligible for payment from Class 7. If you are in Class 5, you cannot also be in Class 7.

Q1-10. If I don't belong in Class 7, should I fill out the Claim Form anyway?

No. If you do not have a breast implant made by any of the companies listed in Q1-5 (Class 7) above and at Question 2 in the Silicone Material Claimants/Participating Foreign Gel Claimants Claim Form Instructions, then you are not eligible for settlement benefits in Class 7. Complete and return the Participation Form, but do not fill out the Claim Form. Call the Settlement Facility Toll Free at 1-866-874-6099. There may be deadlines running to opt-out and litigate or to apply for benefits in your appropriate Class, so call the Settlement Facility as soon as possible.

SECTION 2 – WHAT ARE MY SETTLEMENT OPTIONS?

Q2-1. What is the Silicone Material Claimants' Fund?

Read Question 1 in the Silicone Material Claimants and Participating Foreign Gel Claimants Claim Form Instructions.

Q2-2. What silicone gel breast implants qualify for settlement benefits?

Read Question 2 in the Silicone Material Claimants and Participating Foreign Gel Claimants Claim Form Instructions.

Q2-3. What are the settlement options for Silicone Material Claimants?

Silicone Material Claimants can receive payment for:

(A) Expedited Release Payment -You can receive payment simply by showing that you were implanted with a silicone gel breast implant at any time after January 1, 1976 and before January 1, 1992 from one (1) of the following manufacturers: Bioplasty, Baxter, Bristol, Cox-Uphoff (CUI), or Mentor.

OR

(B) Disease Payment -You can receive payment for one (1) of the nine (9) eligible diseases and conditions if you submit medical records and documents that show that you have one (1) of the diseases or conditions listed below and you have a related disability or meet the severity criteria for that disease or condition:

- Atypical Connective Tissue Disease (ACTD)
- Atypical Neurological Disease Syndrome (ANDS)
- Primary Sjogren's Syndrome (PSS)
- Mixed Connective Tissue Disease (MCTD)/Overlap Syndrome
- Systemic Sclerosis/Scleroderma (SS)
- Systemic Lupus Erythematosus (SLE)
- Polymyositis (PM)
- Dermatomyositis (DM)
- General Connective Tissue Symptoms (GCTS).

Q2-4. What are the payment amounts?

The payment grid is listed below:

Class 7 Settlement Options	Total (U.S.)
Expedited Release Payment Option	To be determined by Claims Administrator
Disease Payment Option 1: Disability C or D	Up to \$4,000
Disease Payment Option 1: Disability B	Up to \$8,000
Disease Payment Option 1: Disability A	Up to \$20,000
Disease Payment Option 2: GCTS Severity B	Up to \$30,000
Disease Payment Option 2: GCTS Severity A or PM/DM	Up to \$44,000
Disease Payment Option 2: Systemic Sclerosis or Lupus Severity C	Up to \$60,000
Disease Payment Option 2: Systemic Sclerosis or Lupus Severity B	Up to \$80,000
Disease Payment Option 2: Systemic Sclerosis or Lupus Severity A	Up to \$100,000

Q2-5. Can I use the medical records that I have already sent to the MDL Claims Office to support my claim?

Yes. You do not have to re-submit the same medical records or documents. You must, however, complete and return the Claim Form.

Q2-6. What do I need to do to receive a payment?

Read Question 8 in the Silicone Material Claimants/Participating Foreign Gel Claimants Claim Form Instructions.

Q2-7. The last time I submitted medical records for my claim was in 1994. Since that time, I have been examined and treated by additional doctors. Can I submit these additional medical records and have them considered as part of my claim?

Yes.

For assistance or questions call Toll Free at 1-866-874-6099 or go to www.dcsettlement.com.

Q2-8. I read somewhere that the payments will be made over sixteen (16) years? Is this true? Will my claim be paid out over sixteen (16) years?

No, payments for approved claims will not be paid over sixteen (16) years. Approved claims in the Settlement Facility will be paid as soon as reasonably practicable after the Effective Date.

Q2-9. What are the settlement options for Participating Foreign Gel Claimants?

You are eligible to receive a payment if there is excess money in the Silicone Material Claimants' Fund after all approved Silicone Material Claimants have been paid. You are not eligible for the Expedited Release or Disease Payment.

Q2-10. Do I have to complete the Claim Form(s) in English? Do I have to have my medical records and documents translated into English?

If your medical records are in Dutch, French, German, Korean, Portuguese, Spanish, Swedish, or Vietnamese, you may submit your Claim Form, medical records and documentation in your own language or translated into English. You do not have to translate medical and hospital records offered as proof of manufacturer if, without any translation, the Settlement Facility will be able to determine if the proof is acceptable.

If you have your medical records and documents translated into English, you 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 you or your attorney.

Q2-11. Will my payment be paid in U.S. dollars or in the currency in my own country?

When the Settlement Facility notifies you that your claim is approved, you will be given the option to receive your payment in either U.S. dollars or your local currency.

SECTION 3 – REJECTING THE SETTLEMENT OPTION TO FILE A LAWSUIT AGAINST DCC LITIGATION FACILITY, INC.

Q3-1. What is DCC Litigation Facility, Inc.?

DCC Litigation Facility, Inc. is a corporation that was created to defend lawsuits filed by claimants who reject the settlement benefits. (These claims are referred to as opt-out claims.) DCC Litigation Facility, Inc. is the entity that has assumed all liabilities of Dow Corning, its shareholders, and other "Released Parties" for personal injury claims arising from certain Dow Corning products including breast implants.

Q3-2. What does it mean to file a lawsuit and try my case against DCC Litigation Facility, Inc.?

If you reject the Settlement Option, you must file a lawsuit in the U.S. District Court in Michigan and try your case against DCC Litigation Facility, Inc. You are strongly encouraged to consult with an attorney prior to making this decision. If you file a lawsuit, you must follow the Case Management Order. If you reject the settlement benefits, then:

- ◆ You will not be eligible for any settlement benefits from the Settlement Facility.
- ◆ Your choice to reject the settlement benefits is permanent. You cannot return to the Settlement Option in the future or receive any settlement benefits from the Settlement Facility. If you lose your case, you cannot return to the Settlement Option, and you cannot receive any payment.
- ◆ You will have the burden of proving that your breast implant caused your disease or other problems. DCC Litigation Facility, Inc. will contest your claim that your implant caused your disease or other problems.
- ◆ Your case will not be set for trial until the District Court certifies that you have met the requirements in the Case Management Order and are ready to proceed to trial. The trial will be either in the Eastern District of Michigan, the federal district court in the district where your claim arose, or in an appropriate state court as defined in the Case Management Order.
- ◆ If you live outside the U.S., DCC Litigation Facility, Inc. may try to have your case referred to a court in your country under the doctrine of “forum non conveniens.”
- ◆ Other than filing your lawsuit within the deadline in the Case Management Order, no litigation will be permitted until after the Plan of Reorganization becomes effective. The “Effective Date” occurs after all appeals are concluded, there is a confirmed Plan of Reorganization, and other conditions described in the Plan Documents have been met. The litigation option will take more time and effort on your part than the Settlement Option, since it often takes years before cases are set for trial.
- ◆ You will not be permitted to recover punitive damages.
- ◆ You must file a lawsuit in court against DCC Litigation Facility, Inc. (unless you have a previous action pending). The lawsuit must follow the procedures and deadlines established in the Case Management Order Sections 5(a) and 5(f). Read the Case Management Order Outline and MDL Orders 40, 44 and 44a and other applicable MDL Orders (the MDL orders are located at www.fjc.gov/BREIMLIT/mdl926.htm).
- ◆ If you do not file your lawsuit by the deadline in the Case Management Order or any applicable statute of limitation, your case will be dismissed and barred forever, and you will not be able to recover any payment.
- ◆ You must comply with case specific discovery requirements set out in Section 9(b) and Section 11 in the Case Management Order. These include — as in any litigation — responding to interrogatories, producing your relevant medical records, and appearing for depositions.
- ◆ Pursuant to Section 10 in the Case Management Order, the MDL documents and depositions located in the National Depository, and the report of the 706 Panel (including any depositions) may be used in your individual trials in accordance with the Federal Rules of Evidence and various orders of the MDL court. Additional non-case specific discovery will be allowed only if recommended by the Special Master and approved by the federal court for the Eastern District of Michigan.

- ◆ Your identity and Proof of Claim form will be publicly available and will not be confidential as it will be if you choose the Settlement Option. Claims in the Settlement Option will be confidential.

Q3-3. Where are the rules for filing a case against DCC Litigation Facility, Inc.?

Read the Case Management Order Outline at Tab 3, or the entire CMO at www.dcsettlement.com.

Q3-4. What court has jurisdiction over cases against DCC Litigation Facility, Inc.?

Judge Denise Page Hood of the United States District Court, Eastern District of Michigan, has jurisdiction over all claimants who reject the Settlement Option.

Q3-5. How much money is allocated to DCC Litigation Facility, Inc.?

There is a cap of \$400 million Net Present Value available to pay all defense costs, administrative costs, and costs of judgments and/or settlements for opt out personal injury claimants.

Q3-6. Is there a cap or limit on how much I can recover on my individual claim?

The Plan Documents do not place a limit on any individual litigation recovery. However, if the total value of resolved claims against DCC Litigation Facility, Inc. exceeds \$400 million (Net Present Value), the Finance Committee will have authority to recommend reductions in payments to claimants who rejected the Settlement Option. In no event will more than \$400 million (Net Present Value) be allotted to pay claims against DCC Litigation Facility, Inc.

Q3-7. What should I do before I make my decision to settle or file a lawsuit against DCC Litigation Facility, Inc.?

Read this entire Claimant Information Guide and the Case Management Order carefully to understand what will be required of you. If you are represented by an attorney, consult with your attorney before you make a decision. If you do not have an attorney, you are strongly encouraged to obtain one if you decide to reject the Settlement Option.

The Settlement Facility and the Claims Assistance Program cannot advise you on what decision you should make and cannot give you any legal advice. If you choose the Settlement Option, you are not required to have an attorney to submit a claim for benefits. However, if you are represented by an attorney, contact your attorney regarding your claim.

Q3-8. My husband wants me to file a lawsuit, but I want to settle my claim in the Settlement Facility. Can he file a lawsuit if I choose to settle?

No. If you choose to settle your claim, your spouse cannot file a lawsuit.

Q3-9. If I decide to file a lawsuit but later change my mind, can I apply for settlement benefits?

When we receive your Participation Form stating that you are rejecting settlement benefits and are filing a lawsuit, we will send you a letter confirming your decision.

You will have thirty (30) days from the date on that letter to inform us if you made a mistake or change your mind and want to settle your claim. After that thirty (30) day time period has expired, you will not be able to change your mind and apply for settlement payments.

Q3-10. I have a breast implant made by Dow Corning (Class 5) and a silicone gel breast implant from Bristol (Class 7). Can I file a lawsuit for my Dow Corning breast implant and receive settlement benefits from Class 7 for my Bristol silicone gel breast implant?

No.

Q3-11. The Participation Form asks for information about my implant and case. Do I have to fill this out?

Yes. This information will assist the District Court and DCC Litigation Facility, Inc. in identifying your case and file. It may also be used to determine if you have a presently manifested injury, which triggers the time period to file your lawsuit.

Q3-12. What is a “manifested injury?”

A manifested injury means that you have an illness or symptoms of sufficient severity to support a disease payment under either Disease Option 1 or Disease Option 2.

Q3-13. The Participation Form has a place for my attorney to sign. Does my attorney have to sign this form for me to file a lawsuit? What if (s)he won't sign?

If you are represented by an attorney, consult with your attorney about your decision. Your attorney is supposed to sign the Participation Form stating that (s)he has consulted with you. If your attorney refuses to sign, you can still submit it and it will be valid.

Q3-14. Who will be given access to my decision to file a lawsuit? Will it be kept confidential?

The Participation Forms for all claimants who reject the settlement benefits will be filed in the United States District Court for the Eastern District of Michigan. They will become public documents. They will also be provided to the Physicians and Health Care Providers in Classes 12 and 13, as well as to the U.S. Government, as provided for in the Settlement Facility Agreement.

Q3-15. I read or received a copy of MDL Order Number 44 and 44A, signed by U.S. District Judge Sam C. Pointer. He dismissed my Dow Corning lawsuit in 1998. Does this mean that I am not eligible to participate in the Settlement Facility?

Judge Pointer entered MDL Order 44 on April 6, 1998 and Order 44A on September 21, 1998. These Orders dismissed pending lawsuits filed by breast implant claimants against Dow Corning and/or its Shareholders. The cases listed in Orders 44, 44A and other orders, which are listed at the MDL 926 website (www.fjc.gov/BREIMLIT/mdl926.htm), were dismissed without prejudice. If you were a plaintiff in one (1) of the cases listed in either Order 44 or 44A, you are still eligible to participate in the Settlement Facility. However, if you reject the settlement benefits, you may have to re-file a new lawsuit. Read Section 3 of this Claimant Information Guide and the Case Management Order Outline carefully.

SECTION 4 – RESERVED FOR FUTURE USE

SECTION 5 – SUBMITTING A CLAIM TO THE SILICONE MATERIAL CLAIMANTS FUND

Q5-1. Why do I need to submit medical records or documents that show I was implanted with an eligible silicone gel breast implant?

To settle your claim you will need to submit medical records or documents that show that you were implanted at any time after January 1, 1976 and before January 1, 1992 with a silicone gel breast implant made by Baxter, Bristol, Bioplasty, Cox-Uphoff (CUI), Mentor, Koken, Silimed, Societe Prometel, or Medasil Surgical.

Q5-2. How can I get a copy of my medical records and documents to show who made my breast implant?

Read through this Section and Tab 1, Part III (1.3) carefully to understand the medical records or documents you need to obtain. Contact the doctor or hospital where your implants were implanted and request a copy of your medical records. Those records often list a brand name, catalog number, implant label, or other identifying information about the breast implant you received. You may need a “certified copy” of these medical records. Your doctor’s office or hospital will know what this means. *(Read Q5-11 for a definition of certified copy.)*

Compare the information in your medical records with the information in this Section to see if it matches any of the criteria for a silicone gel breast implant made by Baxter, Bioplasty, Bristol, Cox-Uphoff (CUI), Mentor, Koken, Silimed, Societe Prometel, or Medasil Surgical.

Q5-3. What medical records or documents can I submit to show that my silicone gel breast implant was made by Baxter, Bioplasty, Bristol, Cox-Uphoff (CUI), Mentor, Koken, Silimed, Societe Prometel, or Medasil Surgical?

There are many ways that you can show that your silicone gel breast implant was made by Baxter, Bioplasty, Bristol, Cox-Uphoff (CUI), Mentor, Koken, Silimed, Societe Prometel, or Medasil Surgical. Any one (1) of the following are acceptable ways to do this provided that your records establish that you are implanted with the eligible implant after January 1, 1976 and before January 1, 1992:

- A.** Hospital records of the surgeon’s report of the surgery — written at or near the time of the implantation surgery — that specify one (1) of the eligible brand names or list an eligible implant manufacturer.
- B.** A certified copy of your medical records that contains the date of implantation and the implant package label demonstrating one (1) of the eligible breast implants as listed at Tab 1, Part III. Note: a certified copy is required *only if*:

1. The label is on a page that does not affirmatively reveal it to be a part of your hospital or medical records and does not have a lot number, serial number, or catalog number on it; or
 2. The hospital records are organized so that the implant label/sticker was put on a page by itself. 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 Settlement Facility to tell that it came from your records, it falls into the acceptable proof category of contemporaneous hospital records, and does not have to be certified.
- C. Implant labels clearly marked with a lot, serial or catalog number and which shows the date of implantation after January 1, 1976 and before January 1, 1992. The Settlement Facility will maintain a list of these lot, serial and catalog numbers, to ensure that no duplicates are used. These labels do not have to be certified.
- D. Records of the implanting surgeon — written at the time of the implantation surgery after January 1, 1976 and before January 1, 1992 – that specify one (1) of the eligible brand names or list an eligible implant manufacturer.
- E. An affirmative statement from the implanting physician (or a responsible person at the treating facility where the implantation took place) attesting that you were implanted with an eligible silicone gel breast implant along with proof that you were implanted with that breast implant after January 1, 1976 and before January 1, 1992. 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 paragraphs A and B above are not available, and must include a description of what steps were taken to secure the types of proof outlined in paragraphs A and B above and explain why those records were not available. The statement of steps taken can be provided by your attorney. This statement cannot rest upon unacceptable proof as listed in Q5-9.
- F. A health insurance claim form, signed by your implanting physician reasonably close to the date of the surgery, naming the type of implant used as listed above. The health insurance form should show that your eligible silicone gel breast implant was implanted after January 1, 1976 and before January 1, 1992.
- G. Medical records of the explanting physician (or other physician or appropriate professional who examined your 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 Baxter, Bioplasty, Bristol, Cox-Uphoff (CUI), Mentor, Koken, Silimed, Societe Prometel or Medasil Surgical implants as listed in Q5-7. You must still provide a statement or other records to establish that your eligible silicone gel breast implant was implanted after January 1, 1976 and before January 1, 1992.

- H. A photograph of an explanted breast implant that shows one (1) of the characteristics unique to an eligible silicone gel breast implant, as listed in Q5-7, 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 you. You must still provide a statement or other records to establish that your eligible silicone gel breast implant was implanted after January 1, 1976 and before January 1, 1992.
- I. Brand-specific implant control sheets, with cross-references to you, that reasonably appear to be contemporaneously kept records in the hospital or implanting physician’s office. You must still provide a statement or other records to establish that your eligible silicone gel breast implant was implanted after January 1, 1976 and before January 1, 1992.
- J. An invoice or packing list from either Baxter, Bioplasty, Bristol, Cox-Uphoff (CUI), Mentor, Koken, Silimed, Societe Prometel or Medasil Surgical contained in your medical or hospital records relating to the implant surgery. If the Settlement Facility 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. You must still provide a statement or other records to establish that your eligible silicone gel breast implant was implanted after January 1, 1976 and before January 1, 1992.
- K. A catalog from Baxter, Bioplasty, Bristol, Cox-Uphoff, Mentor, Koken, Silimed, Societe Prometel or Medasil Surgical with a particular type or style of implant circled or otherwise marked, if contained in a certified copy of your medical or hospital records relating to the implant surgery after January 1, 1976 and before January 1, 1992 which were compiled and/or produced before or about the time of that surgery.
- L. Patient Informed Consent forms signed by you and dated close to the date of the implantation surgery after January 1, 1976 and before January 1, 1992, accompanied by other contemporaneous medical or hospital records verifying that the implantation surgery actually occurred and identifying an eligible silicone gel breast implant as the manufacturer.
- M. Admissions in pleadings or letters written by Baxter, Bioplasty, Bristol, Cox-Uphoff, Mentor, Koken, Silimed, Societe Prometel or Medasil Surgical to you, your representative or your physician acknowledging that your breast implants were manufactured by them. You must still provide a statement or other records to establish that your eligible silicone gel breast implant was implanted after January 1, 1976 and before January 1, 1992.
- N. Warranties mentioning a breast implant brand listed at Tab 1, Part III as being a covered implant, if the warranty is contained in a certified copy of your medical or hospital records.
- O. Written acceptance of your implant manufacturer from either Baxter, Bioplasty, Bristol, Cox-Uphoff (CUI), Mentor, Koken, Silimed, Societe Prometel, or Medasil Surgical (as appropriate to your type of implant).

Q5-4. What brand names are acceptable?

A complete list of acceptable brand names is in Tab 1, Part III.

Q5-5. Are there other words or references I may look for in my medical records to show that my silicone gel breast implant was made by one (1) of the eligible manufacturers?

Yes. You can look for "Unique Identifiers" described in Q5-6 and Q5-7 or for lot or catalog numbers as described in Q5-8.

Q5-6. What are the "Unique Identifiers?"

Unique Identifiers are a list of features or characteristics that are unique to breast implants made by each company. If your breast implants are removed and examined by the physician who removed them or other physician or appropriate professional and (s)he points out specific characteristics of the breast implant that are on the list below in Q5-7, then this is acceptable proof.

Q5-7. What "Unique Identifiers" are acceptable?

For Bristol the unique identifiers are:

- A. Polyurethane for implantations before September 1, 1971 and after December 8, 1978.
- B. Bilumen implants described as having a standard gel implant within, but not attached to, an outer inflatable elastomer shell.
- C. An implant having an SSI valve. An SSI valve can be mentioned by name, or by description; a circular valve that looks like a button, having a slightly rounded dome. It is dacron-mesh reinforced.
- D. An implant having a Quin-Seal valve. This valve is flat and its entry site is marked with a white dot.
- E. An adjustable reconstructive implant with two puncture seal sites (shell and column).
- F. An implant with "SCL" molded on the shell.
- G. An implant with radiopaque size markers.
- H. For implantations before September 1, 1971 or after December 8, 1978, an implant shell exhibiting roughness due to adhesive can be treated as a "polyurethane" implant even if the foam cover is gone.
- I. An implant with a "Y-shaped septum."

For Baxter the unique identifiers are:

- A. Polyurethane for implantations from September 1, 1971 to December 8, 1978.
- B. For implantations September 1, 1971 to December 8, 1978, an implant shell exhibiting roughness due to adhesive can be treated as a “polyurethane” implant even if the foam cover is gone.
- C. An implant with horizontal thin silicone tubing approximately 1 mm in diameter. The tubing lies from edge to edge of patch for orientation purposes. Ends of tubing are “RTV” closed.
- D. An implant with a butterfly silicone fixation patch which is perforated to allow tissue ingrowth. The edges of the patch, but not the face, are adhered to the main patch.
- E. An implant with a molded or cast number composed of a single letter A, B, or C and followed by a single-digit number.
- F. An implant with a “spiral” or “target” imprinted design composed of concentric rings located on the main patch.
- G. An implant with a retention valve positioned at an acute angle to flange.
- H. An implant with a diagraph (Jenny) valve placed on the anterior face of the implant. (On round styles, valve will be at the apex of the anterior face.)

Baxter identifiers C-H above related only to implantations before March 31, 1984.

Q5-8. What are the lot and catalog numbers?

Breast implant manufacturers used catalog numbers in sales brochures and breast implant package materials. These numbers were sometimes written down in a patient’s medical records and can be used to identify the breast implants. The lot numbers are different numbers that identify when the implants were made. Call the Claims Assistance Program Toll Free at 1-866-874-6099 to ask about the lot or catalog numbers listed in your medical records.

Q5-9. What medical records and documents are unacceptable as proof of manufacturer?

Examples of unacceptable proof include:

1. Your own recollection (or that of a friend or a relative) regarding the brand name or manufacturer of your breast implants.
2. Records from the International Implant Registry.
3. Identifying reports from a physician who examined your breast implants during or after removal surgery, 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 breast implant was made by a certain manufacturer.

For assistance or questions call Toll Free at 1-866-874-6099 or go to www.dcsettlement.com.

4. A non-contemporaneous statement by the implanting physician, attempting to supply the acceptable proof listed in the Proof of Manufacturer Form Instructions 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.
5. A non-contemporaneous statement by your implanting physician, attempting to provide the acceptable proof that does not name you 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.

Q5-10. What types of problems or deficiencies are there for proof of manufacturer?

Several minor deficiencies may be found in proof that would otherwise be acceptable. These minor deficiencies include:

1. You submit acceptable proof but do not submit a Claim Form. It is necessary to submit the completed and signed Claim Form.
2. You fail to provide a certified copy of medical records for acceptable proof.
3. An affirmative statement from the implanting physician has been submitted, but the physician failed to provide the basis for his/her conclusion that you received a certain brand of implants. (S)he must write a statement explaining why (s)he believes you received a certain brand of implants.
4. Medical records have been submitted, but there is no identification on the records themselves indicating that these records relate to you. You will need to obtain a certified copy of the medical records from your implanting physician's office or hospital verifying that the medical records are yours.
5. The Settlement Facility needs confirmation that the statement or proof you submit came from the physician or someone on the treating facility or physician's staff.
6. The proof you submit has contradictory evidence of the brand of implant you received. For example, the operative report lists one brand, but you submitted a label of another brand, and both types of proof refer to the same surgery.
7. You submit a photograph of a breast implant showing one (1) of the Unique Identifiers but you do not provide a statement from the explanting physician identifying the implant in the photograph as the one he/she removed from you. You need to obtain this statement from the physician.

Q5-11. What is a “certified copy” of my medical records?

A certified copy 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 accurate copies of records in a particular patient’s file.

Q5-12. What is an implant package label? How can I recognize it?

An implant package label is a label made by the manufacturer with pre-printed information about the breast implant. The label will almost always have the name of the manufacturer, the type of breast implant (saline for example), the catalog number, and the lot number. Doctors frequently placed these implant labels in a patient’s medical files following the implant surgery.

Q5-13. What if I can’t get my medical records (for example, the doctor has since died, the records were destroyed or lost, or the doctor won’t give them to me)? What can I do?

If you cannot find your implanting physician or his/her office no longer has a copy of your records, you can ask for the name of an appropriate responsible person at that office (such as a nurse, a person in charge of the files or records, or another doctor) who can write a letter stating under oath identifying the manufacturer of your implant and stating the basis for this conclusion.

If you cannot locate anyone qualified to write this letter, there may be other ways to show who made your breast implants. For assistance, call the Claims Assistance Program Toll Free at 1-866-874-6099 or e-mail your question to the Settlement Facility at info@sfdct.com.

Q5-14. My proof of manufacturer documents are not covered by the rules above. Can I still submit them?

You may send in proof — even though it is of a type that is not addressed by the existing rules — if it reliably establishes what kind of implant you received. The Settlement Facility will then advise you if new rules have been adopted to cover your situation.

Q5-15. Can my attorney write the statement describing the efforts he/she made to get my medical records?

Yes.

Q5-16. Do I have to provide information on my entire breast implant history, or can I just submit proof for my breast implant?

You must complete the entire Claim Form and submit medical records regarding those implants.

SECTION 6 – EXPEDITED RELEASE PAYMENT— SILICONE MATERIAL CLAIMANTS

Q6-1. What is the Expedited Release Payment?

You will receive the Expedited Release Payment simply by showing (1) that you were implanted with a Baxter, Bioplasty, Bristol, Cox-Uphoff (CUI) or Mentor silicone gel breast implant and (2) that the implant was implanted after January 1, 1976 and before January 1, 1992. You must submit the Claim Form and supporting documents on or before two (2) years after the Effective Date.

Q6-2. What do I have to submit to qualify for the Expedited Release Payment?

Check Box 7A (page 3) on the Claim Form.

Q6-3. If I receive the Expedited Release Payment, can I apply for a Disease Payment later if I become sick?

No.

Q6-4. If I decide to apply for a Disease Payment and don't qualify, can I then decide to take the Expedited Release Payment?

Yes. If your Disease Payment claim is not approved, you will be offered the Expedited Release Payment.

SECTION 7 – DISEASE PAYMENT – SILICONE MATERIAL CLAIMANTS

PART A – ELIGIBLE DISEASES AND GUIDELINES FOR PAYMENT

Q7-1. What is the Disease Payment Option?

The Disease Payment Option provides a payment if you submit medical records and documents that show that you have one (1) of the diseases or conditions in Disease Option 1 or Disease Option 2 as listed in Q7-2.

Q7-2. What are the eligible diseases and conditions?

Eligible diseases and conditions in Disease Option 1 are:

- Atypical Connective Tissue Disease (ACTD)
- Atypical Neurological Disease Syndrome (ANDS)
- Primary Sjogren's Syndrome (PSS)
- Mixed Connective Tissue Disease (MCTD)/Overlap Syndrome
- Systemic Sclerosis/Scleroderma (SS)
- Systemic Lupus Erythematosus (SLE)
- Polymyositis (PM)
- Dermatomyositis (DM)

For assistance or questions call [Toll Free at 1-866-874-6099](tel:1-866-874-6099) or go to www.dcsettlement.com.

Eligible diseases and conditions in Disease Option 2 are:

- Systemic Sclerosis/Scleroderma (SS)
- Systemic Lupus Erythematosus (SLE)
- Polymyositis (PM)
- Dermatomyositis (DM)
- General Connective Tissue Symptoms (GCTS)

Q7-3. What is the difference between Disease Option 1 and Disease Option 2?

Disease Option 1 uses the same medical criteria and definitions that were used in the original global settlement. If you are familiar with the Revised Settlement Program (RSP), these same criteria were also used in the Fixed Amount Benefit Schedule. Eligible diseases include both classic and atypical presentations of the rheumatic diseases listed in Q7-2. Disease Option 1 also includes two (2) conditions – Atypical Neurological Disease Syndrome (ANDS) and Atypical Connective Tissue Disease (ACTD). You must document a disability or severity that is related to your compensable disease or condition.

The diseases and condition in **Disease Option 2** were not part of the original global settlement. They were defined in the RSP and were contained in the “Long Term Benefit Schedule.” In general, the medical criteria to qualify for a Disease Option 2 claim are more restrictive and require more medical documentation and laboratory testing than those in Disease Option 1. You must document a disability or severity level that is related to your compensable disease or condition. Also, the payments for Disease Option 2 are higher than payments for Disease Option 1. *(Read Q2-4 for more information on the payment amounts.)*

Q7-4. What are the payment amounts for approved disease claims in Disease Option 1 and Disease Option 2

Read Q2-4.

Q7-5. When should I submit my claim for the Disease Payment?

Complete and submit your Claim Form and medical records only after you obtain all of the medical records and statements necessary to support your claim for an eligible disease or condition and a related disability or severity level. *(Read this Guide and Tab 5 for the medical criteria and documents you will need.)* Do not send your medical records to the Settlement Facility in a piecemeal fashion because this may trigger a review of your disease claim. If you do not have all of the necessary records, a letter notifying you of a problem with your claim will be sent. Remember that the deadline to submit your Claim Form and supporting medical records is on or before two (2) years after the Effective Date.

Q7-6. What are the definitions for the disability or severity criteria?

The criteria needed to support a disability or severity claim are listed at Tab 5. Read these carefully. Each disease or condition has its own disability or severity criteria.

Q7-7. Some diseases, such as Scleroderma (SS) and Lupus (SLE) are listed under both Disease Option 1 and Disease Option 2. Do they have the same criteria? Why are they listed under both Options?

Four (4) diseases are listed in both Disease Option 1 and Disease Option 2. They are Scleroderma (SS), Systemic Lupus Erythematosus (SLE), Polymyositis (PM) and Dermatomyositis (DM). The disease criteria are similar, but the criteria for the disability or severity level are different under each Disease Option. If you apply for one (1) of these four (4) diseases, the Settlement Facility will evaluate your claim under both Disease Options 1 and 2 to determine if you qualify for payment. You may, but are not required to, submit documents that support a disability or severity level determination for one (1) of these diseases under both Disease Options 1 and 2.

Q7-8. What are the criteria for a disability statement for ANDS or ACTD in Disease Option 1?

The payment amounts for ANDS and ACTD are based on the degree to which you are “disabled” by the condition in question, as determined by your treating physician or “Qualified Medical Doctor” in accordance with the following guidelines (*Read Q8-4 for a definition of a QMD; read Q8-3 for a definition of treating physician*):

1. The determination of disability will be based on the cumulative effect of the symptoms on the claimant’s ability to perform her vocational, avocational, or usual self-care activities.
2. Vocational means activities associated with work, school and homemaking.
3. Avocational means activities associated with recreation and leisure.
4. Usual self-care means activities associated with dressing, feeding, bathing, grooming, and toileting.
5. In evaluating the effect of your symptoms, the treating physician or QMD must take into account the level of pain and fatigue resulting from the symptoms.
6. The disability percentages for Levels “A,” “B,” and “C” (described at Q7-9 through Q7-11) are not intended to be applied with numerical precision, but are, instead, intended to serve as a guideline for the treating physician or QMD in the exercise of his or her professional judgment.

Q7-9. What is the definition of Level “A” disability for ANDS and ACTD in Disease Option 1?

Read the criteria for ANDS and ACTD disability level “A” at Tab 5.

You are eligible for Level “A” disability for death or total disability resulting from your compensable disease or condition. You will be considered totally disabled if you demonstrate a functional capacity adequate to consistently perform none or only a few of your usual duties or activities of vocation or self-care.

In preparing a claim for a Level “A” disability, be aware that the definition of this assigned disability level is a difficult one to meet. You must be unable to do any of your normal activities or only able to do very few of them. Disability Level “A” claims will be reviewed to determine if there is enough description of your daily life and limitations to determine

that you meet this strict definition of total disability. It must also be clear in your submission that your total disability is due to the symptoms of your disease or condition and not to other medical conditions or injuries.

If your QMD determines that the death or total disability is clearly and specifically caused by a disease or occurrence other than the compensable disease or condition, the Level “A” disability determination will not be approved.

Q7-10. What is the definition of Level “B” disability for ANDS and ACTD in Disease Option 1?

Read the criteria for ANDS and ACTD disability level “B” at Tab 5.

You will be eligible for Level “B” disability if you are 35% disabled due to the compensable disease or condition. You shall be considered 35% disabled if you demonstrate a loss of functional capacity that renders you unable to perform some of your usual activities of vocation, avocation, and self-care, or if you can perform them only with regular or recurring severe pain.

Level “B” disability claims must be based on severe pain or an inability to do certain activities. If Level “B” is based on pain, 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. We must be able to verify that the credited ANDS or ACTD symptoms themselves are the cause of the severe pain. If the Level “B” disability is based on limitations on your activities, your submission must provide information concerning the activities that are limited. A conclusory statement, with no information about you or your limitations, will result in a deficiency being assigned. The disability assessment must demonstrate a connection between the symptoms and the specific activities that you can no longer perform. The disability must be due to the compensable disease or condition. The Settlement Facility must have enough information about what the limitations are and the cause of those limitations to be able to verify that your condition meets the requirements for a Level “B” disability.

Q7-11. What is the definition of Level “C” disability for ANDS and ACTD in Disease Option 1?

Read the criteria for ANDS and ACTD disability level “C” at Tab 5.

You are eligible for Level “C” disability if you are 20% disabled due to the compensable disease or condition. You shall be considered 20% disabled if you can perform some of your usual activities of vocation, avocation, and self-care with only regular or recurring moderate pain.

If your submission describes your pain as being only “mild” or “slight,” your disability determination will not be approved.

PART B – ELIGIBILITY GUIDELINES FOR DISEASE PAYMENT CLAIMS

Q7-12. Is there a distinction between “current claimants” and “other registrants” like there was in the Revised Settlement Program (RSP) and Foreign Settlement Program (FSP)?

No.

For assistance or questions call [Toll Free at 1-866-874-6099](tel:1-866-874-6099) or go to www.dcsettlement.com.

Q7-13. What types of breast implants are eligible for a Disease Payment? Are saline and silicone gel breast implants both eligible?

No, only silicone gel breast implants are eligible, and only those which were made by one (1) of the companies listed in Q2-3 and which were implanted after January 1, 1976 and before January 1, 1992.

Q7-14. Can I apply for both a Disease Payment and the Expedited Release Payment?

No.

Q7-15. Do I have to have my breast implants removed to be eligible for a Disease Payment?

No.

PART C – HOW TO APPLY FOR A DISEASE PAYMENT

Q7-16. Do I have to choose between Disease Option 1 and Disease Option 2 when I apply for a Disease Payment?

No. Simply check the box on the Claim Form indicating the disease or condition that you want to be evaluated for.

Q7-17. If I receive a Disease Option 1 Payment, can I later receive payment for one (1) of the diseases or conditions in Disease Option 2?

No.

Q7-18. My disease is not on the list of eligible diseases or conditions in either Disease Option 1 or Disease Option 2. Can I still apply for a Disease Payment?

No. Not every disease or medical condition is covered by the Disease Option. If you do not have one (1) of the eligible diseases or conditions, then you cannot receive payment for your disease or condition.

Q7-19. I was diagnosed with Fibromyalgia. I don't see this on the list of eligible diseases or conditions in either Disease Option 1 or Disease Option 2. Can I still apply for a Disease Payment?

Fibromyalgia is not an eligible disease, so you cannot receive payment based solely on this diagnosis. Many – if not most – of the symptoms of Fibromyalgia though are listed in the criteria for Atypical Connective Tissue Disease (ACTD).

Q7-20. Can I rely on the medical records that I sent to the MDL Claims Office in Houston years ago, or do I have to resend these documents to the Settlement Facility?

You can rely on the records that you submitted to the MDL Claims Office in Houston, Texas. You do not have to re-submit any records.

Q7-21. I submitted medical records to the MDL Claims Office in 1994. Since that time, my condition has changed and I have new and additional records. Can I send those in and have them considered by the Settlement Facility?

Yes.

Q7-22. Can I get a copy of the medical records and documents that I submit to the Settlement Facility?

Keep a copy of the Claim Form and documents that you submit. If you did not keep a copy, write or call the Settlement Facility to get a copy. Depending on the number of pages in your file, there may be a minimal copying charge.

Q7-23. I don't know how to and can't afford to get a copy of my medical records. Can the Settlement Facility or Claims Assistance Program obtain copies of my medical records for me?

No. You need to obtain these yourself by calling or writing your doctors and requesting a copy of your medical file.

Q7-24. Is there a particular way that I should organize my medical records? Should I put them in a binder or folder? How should I submit them?

The Settlement Facility does not have any guideline on how your medical records should be organized and submitted. The Settlement Facility will review the substance of each claim, and no extra consideration will be based on packaging. Please do not send any extra copies of the Claim Form.

SECTION 8 – DISEASE OPTION 1 GUIDELINES

Q8-1. I've read the medical criteria for disease and disability at Tab 5. I think I qualify for ACTD. What do I need to submit to support my disease claim under Disease Option 1?

Submit all records that contain information relevant to the criteria for the disease for which you are applying. This includes:

1. Medical records relating to the relevant signs, symptoms, findings and test results for the disease or condition you are applying for; and
2. Medical records showing the severity of your disease or, if applicable, a determination of a disability level by either a Qualified Medical Doctor (QMD) or your treating physician.

Q8-2. Do I need to submit all of my medical records from every doctor I have ever seen?

Submit those medical records or documents that your physician relied upon in arriving at the diagnosis and findings in your QMD statement or diagnosis. It is not possible to define in advance precisely what medical records will be needed by the Settlement Facility in addition to the statement or diagnosis in order to process any particular claim. This will largely depend upon the nature of the examination or review conducted by the doctor and the form and content of the statement or diagnosis.

Your submission 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 your doctor needed to review earlier medical records obtained from other physicians to make a definitive statement about your condition or disability, then those records must also be submitted, if available. If your physician has first-hand knowledge of

everything that is the basis of his or her opinion based on his/her examination of you, and the statement or diagnosis sets out that knowledge in sufficient detail, it is possible that no additional records will be required.

Q8-3. What is a “treating physician?”

A “treating physician” is one who has seen, examined, and treated you on several occasions, and not a doctor you have seen only for purposes of getting an evaluation to make a claim under Disease Option 1.

Q8-4. What is a Qualified Medical Doctor or “QMD”?

“Qualified Medical Doctor” is a term used to describe 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 you filed in support of your disease claim.

Q8-5. Is a Qualified Medical Doctor a “treating physician”?

“Treating physician” includes a Qualified Medical Doctor if that QMD states that (s)he has the information necessary to form a professional opinion about your disability and sets forth in the statement or diagnosis (or a supplemental statement) the information upon which that opinion is based and the source of that information.

Q8-6. What does “Board-certified” mean?

“Board-certified” means certification in a particular medical specialty by the American Board of Medical Specialists. For Foreign Claimants the Settlement Facility will define standards for equivalent certification in each country. The Settlement Facility has adopted the existing standards of the MDL claims office.

The certification standards defined to date are as follows:

England: Fellows in good standing of the Royal College of Surgeons of England who have been awarded that organization’s Certificate of Completion of Specialist Training in Neurosurgery. Also, Fellows in good standing of the Royal College of Physicians of England who have been awarded that organization’s Certificate of Completion of Specialist Training in Neurology, General (Internal) Medicine, Immunology, or Rheumatology.

Finland: A postgraduate specialty degree in allergology, immunology, neurosurgery, neurology, internal medicine, or rheumatology from the Universities of Helsinki, Turku, Tampere, Oulu, or Kuopio in Finland.

Germany: Designation of medical specialist in internal medicine, rheumatology, neurosurgery, or neurology, granted by the German Federal Medical Board.

Israel: Physicians licensed by the Department of Medical Professions of the State of Israel to practice as a specialist in internal medicine, immunology, rheumatology, neurology, or neurosurgery.

Norway: Specialist approval by the Norwegian Medical Association in internal medicine, neurology, neurosurgery, or rheumatology.

South Africa: Medical specialists in neurology, neurosurgery, internal medicine, or rheumatology registered with the South African Medical and Dental Council.

Sweden: Specialist approval by the Swedish National Board of Health and Welfare in neurosurgery, internal medicine, allergology, neurology, or rheumatology.

Switzerland: Title of medical specialist granted by FMH Swiss Medical Association in allergology and clinical immunology, internal medicine, neurology, neurosurgery, and rheumatology.

Q8-7. Can a doctor who is “Board-eligible” but not yet Board-certified write my disease diagnosis or statement?

No. Only “Board-certified” physicians can submit the statement or diagnosis. His/her records can, however, be part of the records submitted to allow the Settlement Facility to classify your claim.

Q8-8. Can a doctor of osteopathy (D.O.) be a Qualified Medical Doctor and write my statement or diagnosis?

Yes. D.O.s may also write diagnoses for disease claims as long as they are Board-certified by the same Board that certifies Medical Doctors and that certification is within an appropriate specialty to the disease option for which you are requesting an evaluation.

Q8-9. What are “appropriate” Board-certified specialists for disease claims in Disease Option 1?

Doctors who write a statement or diagnosis of your disease must be Board-certified in an appropriate specialty to your disease claim. What specialty is appropriate depends on the complaints and symptoms you have.

Q8-10. What would be an appropriate specialty for Scleroderma, Lupus, Polymyositis, Dermatomyositis, MCTD, Primary Sjogren’s, or ACTD?

These diseases are all rheumatic diseases or conditions. A Board-certified internist or rheumatologist would be an appropriate specialist for any of these diseases. If you want to pursue a disease claim for Scleroderma, Lupus, Polymyositis or Dermatomyositis under Disease Option 2, then you must be personally examined by a Board-certified rheumatologist. A Board-certified internist will not be acceptable for Disease Option 2 claims.

Q8-11. What would be an appropriate specialty for Atypical Neurological Disease Syndrome (ANDS)?

Atypical Neurological Disease Syndrome (ANDS) involves neurological complaints; therefore, a Board-certified neurologist would be an appropriate specialist for ANDS.

Q8-12. Several of the eligible diseases and conditions are clustered together, and the same criteria seem to apply to each (i.e., ACTD/ARS/NAC). When a Qualified Medical Doctor (QMD) is writing my statement or diagnosis of these conditions, what name should (s)he give it? All three (3) or any particular one (1)?

Atypical Connective Tissue Disease (ACTD), Atypical Rheumatic Syndrome (ARS), and Nonspecific Autoimmune Disease (NAC) are listed together because they are sometimes used interchangeably by physicians. Depending on the physician, any one of them may be used to describe the particular mix of symptoms and/or findings that are present in a particular case.

Q8-13. Does my treating physician have to be Board-certified to write the statement or diagnosis for my Disease Option 1 claim?

Yes, (s)he must be Board-certified to write the QMD statement or diagnosis of your disease.

Q8-14. Does my treating physician have to be Board-certified to write my disability statement for my Disease Option 1 claim?

No, (s)he does not have to be Board-certified to write the disability statement.

Q8-15. If my disability criteria is based on the severity of my disease in Disease Option 1 (such as claims for Scleroderma, Lupus, Polymyositis, Dermatomyositis, MCTD/Overlap Syndrome, or Primary Sjogren's Syndrome), what do I have to submit to the Settlement Facility to document my disability?

You must submit all of the medical records that the physician relied upon in making his or her disability determination. This includes, for example, any disability questionnaire that you completed to assist in the physician's determination.

Q8-16. I was in a car accident and was disabled as a result. Can I use that disability rating from my Disease Option 1 claim?

No. Your disability must be related to your compensable condition. The pain must be due to your ACTD or ANDS symptom(s). For example, ACTD symptoms such as alopecia (hair loss), chronic fatigue and loss of breast function normally do not have a pain component. For your ACTD disability to be approved, you must be experiencing pain from at least one (1) of your qualifying symptoms. Also, pre-existing diseases and conditions are not eligible for consideration.

Q8-17. Can my treating physician or QMD write my disease and/or disability statement tracking the language in the disability definition? Will that be sufficient for my claim to be approved?

No. Generalized statements by your QMD that track the disease or disability language cannot replace the responsibility of the Settlement Facility to review, on a detailed level, all of the claim documentation provided.

Q8-18. In several places in the Disease Option 1 criteria, especially in the ACTD criteria, the word “documented” precedes a listed symptom. What does “documented” mean?

It is not possible to give one precise definition of this word, 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 patient's complaint or oral history.

For some symptoms, this means that the physician has verified the condition on physical examination or through a lab test.

For others, primarily those symptoms that are entirely subjective, it can mean that the physician has performed a physical examination and questioned the patient about the complaint sufficiently to be able to form a professional opinion, utilizing all the 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 comfortable in concluding that the problems do indeed exist.)

“Documented” can also mean that written notations of the symptom are found in the patient's medical records that predate her coming to a physician for purposes of obtaining a statement or diagnosis to submit with her disease claim.

Q8-19. Can I use an official document stating that the Social Security Administration has declared me to be totally disabled to support my claimed disability level?

No. You may only use determinations of disability made by a treating physician or a Qualified Medical Doctor (QMD).

Q8-20. I am not sure if I have lupus or ACTD. The Disease Payment Option Claim Form says I may pick only one (1) disease. How do I decide which to select?

If you ask the claims office to evaluate any disease, the claims office will review your claim for ACTD or ANDS if, in the judgment of the claims office, it appears that you may qualify for one of these conditions.

SECTION 9 – DISEASE OPTION 2 GUIDELINES

Q9-1. How can I determine if I qualify for a Disease Option 2 Payment?

Review the criteria at Tab 5 and discuss your condition with your physician.

Q9-2. In addition to the medical criteria and severity level documentation required in Disease Option 2, what else am I required to submit or have to qualify for a Disease Option 2 payment?

In addition to the medical criteria and severity level documentation (where applicable), you must also submit or meet the following criteria:

1. You must submit all medical records establishing the required findings or laboratory abnormalities; and
2. Qualifying findings must have occurred within a single 24-month period within the five (5) years immediately preceding the submission of the claim except that this period is tolled from May 15, 1995 to the Effective Date. Findings supplemented in response to a deficiency letter sent by the Settlement Facility do not have to fall within the 24-month period outlined above; and
3. 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; and
4. 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; and
5. All medical records establishing the required findings or laboratory abnormalities must be submitted to the Settlement Facility. In addition, you must supply all underlying office charts, radiology/pathology reports, and tests results in the possession of the physician who makes the required findings or statements, or who ordered the required tests; and
6. QMD statements may be acceptable proof under Disease Option 2 if:
 - A. The physician is a Board-certified rheumatologist – for Lupus, Scleroderma, Polymyositis or Dermatomyositis – or is Board-certified in the appropriate specialty to make the required GCTS findings; and
 - B. The statement covered all of the detailed findings that are required in Disease Option 2; and

- C. The QMD personally examined you; and
- D. 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 Disease Option 2 claims.

Q9-3. What are the “affirmative statements” and “exclusions” referenced in Q9-2 above?

An affirmative statement is a written statement by the physician stating that the listed exclusion for your diagnosed disease is not present in your case. Exclusions are contained in the “General Guidelines” preface to Disease Option 2 and in bracketed language in each of the Disease Option 2 diseases, and begin with the word “Exclusion.” For example, criterion #5 (arthritis) for SLE contains a bracketed Exclusion of erosive arthritis. If your SLE diagnosis is based on arthritis, the diagnosing rheumatologist must affirmatively state in your medical records or letter that you do not have erosive arthritis.

Q9-4. What Board-certified specialist is required to provide a diagnosis of Scleroderma, Lupus, Polymyositis or Dermatomyositis in Disease Option 2?

To qualify for Scleroderma, Lupus, Polymyositis or Dermatomyositis in Disease Option 2, you must be personally examined and have a diagnosis by a Board-certified rheumatologist.

Q9-5. I was diagnosed with one (1) of the Disease Option 2 diseases (Scleroderma, , SLE, Polymyositis or Dermatomyositis) and my medical records contain all of the required findings. Can I rely on this diagnosis even though it was not made by a Board-certified rheumatologist?

No.

Q9-6. My treating rheumatologist (who isn’t Board-certified) diagnosed me with one (1) of the Disease Option 2 diseases. Can I submit my medical records along with a letter from a Board-certified rheumatologist stating that (s)he has reviewed all of these records and agrees with and confirms my disease diagnosis?

No. A diagnosis by a Board-certified rheumatologist must be based upon his or her personal examination of you. (S)he cannot rely solely on reviewing your medical records to provide the diagnosis required in Disease Option 2.

Q9-7. Does a claim for “General Connective Tissue Symptoms” have to be supported by a diagnosis made by a Board-certified rheumatologist?

No. No diagnosis is required for this category under Disease Option 2.

Q9-8. What do I have to submit to support a claim for GCTS?

Your medical documentation must establish that one (1) of the required combinations of findings from the three (3) groups of findings are present. Some findings can only be made by a particular type of medical specialist. Read the GCTS criteria at Tab 5 carefully.

Q9-9. The general guidelines for Disease Option 2 claims require that qualifying findings must have occurred within a single 24-month period within the five (5) years immediately preceding the submission of the claim. What date is used to determine the date the claim was submitted?

The date can be either the date the Settlement Facility receives the Claim Form or the date your original disease Claim Form was received by the MDL Claims Office in 1994. We will apply the date that, in your particular situation, allows you to meet this requirement.

Q9-10. I was a current claimant in the RSP, and under that program I could not apply for GCTS initially. Am I allowed to make a claim for GCTS under the Dow Corning settlement plan or do I have to first file a claim for ACTD?

You are permitted to make a claim directly for GCTS.

SECTION 10 – PROCESSING OF DISEASE CLAIMS AND NOTIFICATION OF STATUS LETTERS

Q10-1. What types of problems or “deficiencies” are there for disease claims? What do they mean, and how can I cure them if my claim is found to be deficient in some way?

A non-exhaustive list of the deficiencies that may appear in your Notification of Status letter is included here, with explanations as well as information concerning how the deficiency might be cured. While it is impossible to anticipate every situation, the Settlement Facility has established certain deficiency standards that will guide the review of disease claims.

A. Documentation Criteria

Deficiency: “The following ACTD symptoms were not documented: (specific symptoms listed here).”

Guidelines to cure this Deficiency: Read Q8-18 for a description of the term “documented.” This deficiency can be cured then by providing (1) proof of verification of your symptom through physical examination, (2) a supplemental statement from your QMD revealing that (s)he questioned you sufficiently about this symptom and concluded that the complaint is valid, or (3) additional medical records reflecting that you complained about this symptom on other occasions.

B. Disability Deficiencies

Deficiency: “All the records on which the QMD based his/her determination of your disability were not submitted with your claim.”

Guidelines to cure this Deficiency: Your QMD indicated that (s)he relied on some documents in making your disability determination, but those other documents have not been submitted. Before we can confirm your disability, we must have all the records that the QMD used to make that determination. You can cure this deficiency by filing those documents.

Deficiency: “Information contained in your claim documents indicates that you are not disabled by a compensable condition.”

Guidelines to cure this Deficiency: Your medical documentation affirmatively reveals you are not disabled. If this is incorrect, this deficiency can possibly be cured by providing a statement from your QMD or treating physician describing your current disability and providing a satisfactory explanation for the contradictory information submitted earlier.

Deficiency: “Information contained in your claim documents indicates that the disability determination is inconsistent with settlement criteria.”

Guidelines to cure this Deficiency: Your QMD or treating physician made a determination of your disability, but information about your pain or limitations on your activities (either in the QMD’s statement or elsewhere in your records) conflicts with the requirements for that disability level. The deficiency can possibly be cured by a statement from your QMD or treating physician assigning a disability level that is appropriate for your condition or providing information about your disability that is consistent with settlement criteria for that level. (If your supplemental documentation provides new information in support of the disability level you originally claimed, please also provide an explanation for the contradictory information submitted earlier.)

Deficiency: “Your claim documents contain insufficient information about your condition to evaluate whether the disability determination is consistent with settlement criteria.”

Guidelines to cure this Deficiency: Although your QMD or treating physician made a determination of your disability, there is not enough information in your claim file to allow the Settlement Facility to determine if that disability level was appropriately assigned by the physician. This deficiency can be cured by providing a supplemental statement from your treating physician or QMD describing your level of pain or limitations on your activities. If your disability is caused in part by a disease or condition that is not compensable under the original disease schedule, you can only be approved for the level of your disability that is caused by the covered disease or condition. In that situation, make sure that in describing your disability, your physician clearly indicates the extent of your disability caused by the disease or condition covered by the settlement terms.

Deficiency: “Information contained in your claim documents indicates that you are no longer disabled by a compensable condition.”

Guidelines to cure this Deficiency: Your claim documentation clearly indicates that you are no longer suffering from any earlier disability you may have had. This deficiency can only be cured if you are once again disabled. Provide a statement from your QMD or treating physician describing your current disability and explaining the change from your earlier-reported condition.

Deficiency: “Your claim documents did not contain a determination by a treating physician or QMD of your disability.”

Guidelines to cure this Deficiency: Your file contained no determination of your disability by either your treating physician or a QMD. If your file did contain a disability determination from a physician, this deficiency was assigned because we were unable to confirm that the physician who made that disability determination was either a treating physician or an appropriate Board-certified specialist. This disability can be cured by obtaining a determination of disability from your treating physician or a physician Board-certified in one (1) of the specialties qualifying as “QMD” specialties.

C. Number of Symptoms

Deficiency: “In addition to the other deficiencies noted in this letter, you need one more symptom to qualify for a compensable condition.”

Guidelines to cure this Deficiency: After curing any other symptom-related deficiencies noted in your Notification of Status, you will still need one (1) more symptom to qualify. This deficiency can be cured by providing medical records or a supplemental statement from your QMD reflecting any additional symptoms you have that satisfy settlement criteria.

Deficiency: “In addition to the other deficiencies noted in this letter, you need more than one (1) additional symptom to qualify for a compensable condition.”

Guidelines to cure this Deficiency: After curing any other symptom-related deficiencies noted in your Notification of Status, you will still need two (2) or more additional symptoms to qualify for the applicable disease or condition. This deficiency means that your claim documentation contained few (or perhaps none) of the signs, symptoms, and findings required to support a claim for the particular disease or condition mentioned in your Notification of Status. You need to review in detail the exact requirement for establishing your disease or condition. These requirements are found at Tab 5. Look carefully through the claim documentation you submitted to see which, if any, of the signs, symptoms, and findings required by the Disease Schedule at Tab 5 can be found in your documentation. A thorough comparison of these documents should give you the answers you need. The deficiency can be cured by providing medical records or a supplemental statement from your QMD reflecting any additional symptoms you have that meet the criteria for that disease or condition.

D. Pre-Existing Conditions

Deficiency: “The following ACTD symptoms existed before you received your first breast implant: (specific symptoms listed here).”

Guidelines to cure this Deficiency: Your claim records reflect that you suffered from these ACTD symptoms before you had your first breast implant. The Settlement Facility 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 your records. If there are indeed typographical errors in those dates, you 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.

Deficiency: “Information contained in your claim documents indicates that the compensable condition from which you suffered before your first implant has not increased in severity or disability since that implant.”

Guidelines to cure this Deficiency: Your records show that you suffered from the disease noted on your Notification of Status before you received your first breast implant. That condition is now compensable only if it increased in severity or in its impact on your disability after implantation. You can cure this deficiency by providing either a supplemental report from your treating physician or QMD that affirmatively reveals that your condition has worsened to the point that you are now in a higher payment category or medical records that demonstrate that increase.

E. Physician Signature

Deficiency: “Your QMD’s statement or diagnosis was not signed.” “Your QMD’s determination of disability or severity level was not signed.”

Guidelines to cure this Deficiency: A statement or diagnosis from a QMD must have that physician’s signature. You can cure this deficiency by having the QMD sign a copy of the original statement or diagnosis, and filing that signed copy with the Settlement Facility. If the deficiency noted is lack of signature on the disability statement, be sure that the statement which you have the physician sign is the one that contains his or her determination of your disability.

F. Failure to Meet Settlement Criteria

Deficiency: “Your medical records did not reveal whether the following lab tests were performed by the method required by the settlement or if the results of those tests meet settlement criteria: (specific test listed here).”

Guidelines to cure this Deficiency: The settlement 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 your tests did meet that stated criteria, but your original documentation failed to reveal that fact, you 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 your tests did not, in fact, meet the stated criteria, you can cure this deficiency by having them retaken in the manner required by the original disease schedule.

Deficiency: “The following signs and symptoms did not meet settlement criteria: (specific symptoms listed here).”

Guidelines to cure this Deficiency: The symptoms noted were not shown in your claim file to meet the criteria that the original disease schedule specifies. Perhaps your complaints were not shown to rise to the level required for us to credit you with that particular symptom. Perhaps the records revealed your complaint fell within a category affirmatively excluded by settlement criteria. This deficiency can be cured by providing either a supplemental statement from your QMD or the medical records demonstrating that your symptom does indeed meet the criteria stated in the original disease schedule.

Q10-2. My Notification of Status says I have a few deficiencies in my ACTD claim. I have recently been diagnosed with Lupus. Can I submit a new claim for Lupus instead of only correcting my ACTD deficiencies?

Yes.

Q10-3. My Notification of Status letter says that “upon cure of appropriate deficiencies” my claim will be approved. What does “appropriate deficiencies” mean?

Certain deficiencies, such as pre-existing ACTD symptoms, are probably not curable, but we provided this information to let you know how these factors were evaluated.

Q10-4. The Plan says that if I fail to cure any deficiency in my disease claim within one (1) year, I am barred from re-filing that claim, but I can bring a new disease claim if I have a new compensable condition that shows up after that one-year period. What is a new compensable condition?

The Settlement Facility cannot provide a precise definition. The determination of whether you have a new compensable condition depends on the unique circumstances of each case and medical records.

SECTION 11 – SUBMITTING A CLAIM — PARTICIPATING FOREIGN GEL CLAIMANTS

Q11-1. What is a “Participating Foreign Gel Claimant?”

You are a Participating Foreign Gel Claimant if your silicone gel breast implants were made by Koken, Silimed, Societe Prometel and/or Medasil Surgical and were implanted after January 1, 1976 and before January 1, 1992.

Q11-2. I am a Participating Foreign Gel Claimant. Can I submit a Claim for an Expedited Release or Disease Payment?

No.

Q11-3. I am a Participating Foreign Gel Claimant. How do I submit a Claim?

Read Question 10 on the Silicone Material Claimants/Participating Foreign Gel Claimants Claim Form Instructions.

SECTION 12 – MARSHALING RECOVERIES FROM OTHER IMPLANT MANUFACTURERS

Q12-1. What is “Marshaling?”

“Marshaling” means that you must try to collect payments from your implant manufacturer before you can receive a payment from the Silicone Material Claimants’ Fund. Marshaling applies only if your implant manufacturer is Baxter, Bristol, Koken, Medasil, Silimed, or Societe Prometel. If you have a breast implant from one (1) of these companies but have not received payment, then you must describe the efforts you have taken to obtain a payment.

If your implant manufacturer is Bioplasty, Cox-Uphoff (CUI), or Mentor, then you do not have to try to collect any payment or report any payment you received from that manufacturer.

Q12-2. If I received payment from one (1) of the companies listed in Q12-1 above, what do I do?

Check Box 6B on the Claim Form to indicate that you have received payment.

Q12-3. I received \$10,000 in the RSP for my Baxter silicone gel breast implant. How will this affect my claim in the Silicone Material Claimants’ Fund?

Your payment will be reduced by the sum of \$10,000.

Q12-4. I opted out of the RSP and settled my case with Bristol. The settlement was confidential. Do I still have to report it?

Yes.

Q12-5. I opted out of the RSP and have been trying — but have not been able — to recover payment directly from one (1) of the companies listed in Q12-1 above. Have I marshaled?

Check Box 6C on the Claim Form and describe your efforts to obtain payment. The Claims Administrator will determine whether your efforts are sufficient.

Q12-6. I received a payment from the MDL fund for my Bioplasty and Mentor silicone gel breast implants. Do I have to report this amount in Question 6, part B8?

No. You do not have to report any payment you received from Bioplasty, Cox-Uphoff or Mentor.

Q12-7. If I don’t provide the information about whether I have received payment from my implant manufacturer, can I still recover payment from the Silicone Material Claimants’ Fund?

No. You will receive a letter stating that your claim is deficient. You must provide the information within one (1) year from the date of the letter informing you of the deficiency or your claim will be permanently denied.

Q12-8. I am an other registrant in the RSP and received \$1,000 for acceptable proof of my Bristol (or Baxter or 3M) breast implant. I have not received any other money. Have I marshaled?

No, because you can still apply for a disease claim during the remainder of the 15-year disease program in the RSP.

Q12-9. I am an other registrant in the RSP and received \$1,000 for acceptable proof of my Bristol (or Baxter or 3M) breast implant, plus an explant payment of \$3,000. Have I marshaled?

No, because you can still apply for a disease claim during the remainder of the 15-year disease program in the RSP.

Q12-10 I am an other registrant in the RSP and accepted the \$2,500 settlement offer for a complete release of all claims against my manufacturer (either Bristol, Baxter and/or 3M). (This offer expired June 1999.) I also received \$1,000 advance payment for acceptable proof of my manufacturer. Have I marshaled?

Yes. Check Box 6B on the Claim Form.

Q12-11. I was a late registrant in the RSP. I am eligible only for a disease claim to the extent that funds are available to pay those claims. Have I marshaled?

No, because you can still apply for a disease claim during the remainder of the 15-year disease program in the RSP.

SECTION 13 – GENERAL DEADLINES/DELIVERY METHODS/ EFFECTIVE DATE/DEADLINES TO APPLY FOR SETTLEMENT BENEFITS

PART A – DEADLINES TO RETURN THE PARTICIPATION FORM/DELIVERY METHODS

Q13-1. If I choose to settle my claim (Box 2A on the Participation Form), what is the deadline and what do I have to do?

If you check Box 2A on the Participation Form, then sign and return the Participation Form (the white edge) on or before two (2) years after the Effective Date. (*Read Q13-5 for more information about the Effective Date.*) If you do not return the Participation Form, you will still be able to settle your claim in the Settlement Option by completing and submitting the Claim Form.

Q13-2. If I choose to reject settlement and file a lawsuit (Box 2B on the Participation Form), what is the deadline and what do I have to do?

If you check Box 2B on the Participation Form (the white edge), then you must complete and return the Participation Form on or before [T.B.D.].

Q13-3. If I choose to withdraw my claim from the bankruptcy case, what do I have to do?

You must send a letter indicating that you wish to withdraw to the Claims Administrator. Remember to include your signature on all correspondence with the Settlement Facility. There is no deadline to withdraw your claim.

By withdrawing you will no longer be eligible to receive settlement benefits or file a lawsuit against any of the released parties.

Q13-4. What are the acceptable methods to mail or deliver my Participation Form to the Settlement Facility

Mail or deliver the Participation Form to the Settlement Facility using one (1) of the following three (3) delivery methods:

1. Use a delivery service (e.g., Federal Express, Airborne Express, U.P.S., etc.) and make sure that the airbill or invoice clearly lists the date of mailing as on or before [T.B.D.] if you are withdrawing your claim or on or before [T.B.D.] if you are rejecting settlement and intend to file a lawsuit against DCC Litigation Facility, Inc.; OR
2. Mail the Participation Form by United States certified or registered mail as long as the certified or registered mail is postmarked on or before [T.B.D.] if you are withdrawing your claim or on or before [T.B.D.] if you are rejecting settlement and intend to file a lawsuit against DCC Litigation Facility, Inc. Please check with the U.S. Post Office on how to send a certified or registered letter so that it has the correct postmark (for claimants who reside outside of the U.S., the Settlement Facility will rely on the postmark date used by your country's version of "certified" or "registered" mail); OR
3. If you mail the Participation Form by regular U.S. mail or by using a national mail service in the country in which you reside, then the Participation Form must be *received* by the Settlement Facility by 5:00 p.m. Central Time on or before [T.B.D.] if you are withdrawing your claim and on or before [T.B.D.] if you are rejecting settlement and intend to file a lawsuit against DCC Litigation Facility, Inc. It is important to mail your Participation Form early enough so that the Settlement Facility *receives* it on or before the applicable deadline. The postmark date on the envelope will **NOT** be used by the Settlement Facility if you use regular U.S. mail or a national mail service in a country other than the U.S.

PART B – EFFECTIVE DATE

Q13-5. What is the Effective Date?

The Effective Date — which has not yet occurred — is the date when all preconditions listed in the settlement documents (Sections 7.1 and 7.2 of the Amended Joint Plan of Reorganization) have been met. Some of these preconditions include:

1. There is a final order confirming (approving) the Amended Joint Plan of Reorganization of Dow Corning; and
2. All appeals of such confirmation must be completed; and
3. The order confirming the Amended Joint Plan approves and provides for the implementation of various settlement documents such as the Domestic Health Insurer Settlement Agreement.

Once all of the preconditions are met, the Plan Documents will be signed and there will be an “Effective Date.” You will receive a notice in the mail when the Effective Date occurs. Settlement payments can then be made on all approved claims.

PART C – DEADLINES TO APPLY FOR SETTLEMENT PAYMENTS

Q13-6. What is the deadline to submit my Silicone Material Claimants’ Fund Claim Form and medical records or documents?

You must return your Claim Form and medical records or documents on or before two (2) years after the Effective Date. (*Read Q13-5 for more information about the Effective Date.*)

Q13-7. What are the acceptable methods to mail or deliver my Claim Form to the Settlement Facility?

Mail or deliver the Claim Forms to the Settlement Facility using one (1) of the following three (3) delivery methods:

1. Use a delivery service (e.g., Federal Express, Airborne Express, U.P.S., etc.) and make sure that the airbill or invoice clearly lists the date of mailing as on or before the deadline; OR
2. Mail the Claim Forms by U.S. certified or registered mail as long as the certified or registered mail is postmarked on or before the deadline. Please check with the U.S. Post Office on how to send a certified or registered letter so that it has the correct postmark (for claimants who reside outside of the U.S., the Settlement Facility will rely on the postmark date used by your country’s version of “certified” or “registered” mail); OR
3. If you mail the Claim Forms by regular U.S. mail or by using a national mail service in the country in which you reside, then the Claim Forms must be received by the Settlement Facility by 5:00 p.m. Central Time on or before the deadline. It is important to mail your Claim Forms early enough so that the Settlement Facility receives them on or before the deadline for that

settlement benefit. The postmark date on the envelope will **NOT** be used by the Settlement Facility if you use regular U.S. mail or a national mail service in a country other than the U.S.

Q13-8. What if a deadline falls on a Saturday, Sunday or federal holiday?

If a deadline falls on a Saturday, Sunday or federal holiday, the deadline is the next business day.

Q13-9. What are the deadlines to correct problems on my claim submission?

If there is a problem with your claim, the Settlement Facility will inform you of the problem in writing. You must correct deficiencies one year from the date of the letter notifying you of the problem. If you do not correct the problem within the time frame allowed, then your claim will be denied, and you will not be able to recover payment for that settlement option.

Q13-10. If I move and forget to notify the Settlement Facility in writing, my Notification of Status letter might take days or weeks to be forwarded to my new address. Will any of the time periods and deadlines be extended because of this?

No, unless your move occurred close in time to the date of the Notification of Status letter in which case the Claims Administrator will review and make individual case determinations. It is your responsibility to notify the Settlement Facility of any address change.

Q13-11. I moved and did not notify the Bankruptcy Court or Settlement Facility of my new address, and I missed the deadline to file the Participation Form to elect to withdraw or litigate. Can I file it now?

No. You have an affirmative obligation to update your address with the Settlement Facility and the Bankruptcy Court.

SECTION 14 – CONTACT INFORMATION

Q14-1. How can I contact the Settlement Facility with a question?

Call 1-866-874-6099 Toll Free or send a question by e-mail to the Settlement Facility at info@sfdct.com.

Q14-2. What is the mailing address of the Settlement Facility?

All Claim Forms and correspondence to the Settlement Facility should be sent to the following address:

Settlement Facility-Dow Corning Trust
P.O. Box 52429
Houston, TX 77052-2429
U.S.A.

-OR-

Settlement Facility-Dow Corning Trust
P.O. Box 94355
1090 GJ Amsterdam
The Netherlands

For overnight delivery address, use:
Settlement Facility-Dow Corning Trust
3100 Main Street, Suite 700
Houston, TX 77002
U.S.A.

Q14-3. Can I check the status of my claim on the Settlement Facility website?

No. As of the date of the publication of this Claimant Information Guide, the Settlement Facility's website did not permit the checking of individual claims. However, the Settlement Facility hopes to make that service available. Please check our website at www.dcsettlement.com.

Q14-4. Can I e-mail my completed Claim Forms to the Settlement Facility?

No.

Q14-5. Can I fax my Claim Forms and documents to the Settlement Facility?

No, unless you have received written permission from the Settlement Facility beforehand.

Q14-6. How can I contact the Tort Claimants' Committee?

The Tort Claimants' Committee ("TCC") has a website that you can visit at www.tortcomm.org. You can also send them an e-mail at info@tortcomm.org. If you do not have access to a computer or the Internet, you can write to the TCC at:

Tort Claimants' Committee
P.O. Box 61406
Houston, TX 77208-1406.
U.S.A.

Q14-7. Can I contact the Tort Claimants' Committee for legal assistance on my claim?

No. The Tort Claimants' Committee cannot act as your attorney or advise you on your case or claim.

Q14-8. I moved since I sent my proof of claim to the Bankruptcy Court. Can I e-mail my new address to you or give it to you over the telephone?

No. Changes in address must be made in writing, signed by you or your attorney or representative. There is a place on your Claim Forms to indicate that your name, address or other personal information has changed since your last contact with the Bankruptcy Court or MDL Claims Office.

Q14-9. I sent my Proof of Claim form to the Bankruptcy Court in 1997. I have since married and changed my name. How can I update my file with my new married name?

Changes in name must be made in writing, signed by you or your attorney or representative. There is a place on your Claim Forms to indicate that your name, address or other personal information has changed since your last contact with the Bankruptcy Court or MDL Claims Office. If you have more than one (1) name change, please list all former names that are associated with your Social Security Number or Claim Number on a separate piece of paper and return this with your Participation Form or Claim Form.

SECTION 15 – ATTORNEY FEES AND EXPENSES

Q15-1. What attorney fees are allowed on my settlement benefits?

Fees charged by an attorney cannot exceed the sum of —

1. 10% of the first \$10,000;
2. 22.5% of the next \$40,000; and
3. 30% of the amount in excess of \$50,000 paid.

Q15-2. Are attorneys fees allowed on the Expedited Release Payment?

No, but certain expenses may be deducted as described in Q15-3.

Q15-3. What expenses can my attorney deduct from any payments I receive from the Settlement Facility?

Certain expenses — if allowable under applicable law and the individual arrangement between you and your attorney — can be charged against your payment if they are solely attributable to your claim or case. Chargeable expenses are limited to the following types of cost incurred on your behalf: medical evaluation expenses, expenses incurred in obtaining copies of your medical records, medical bills paid on your behalf, court costs, court reporter expenses, expert witness fees, expenses of medical witnesses, and travel costs incurred for depositions or court appearances in your case.

Q15-4. I had an attorney but now want to handle the claim myself. What do I need to do?

Write a letter to the Settlement Facility asking that your attorney be removed as the attorney of record. The Settlement Facility will notify the lawyer and (s)he may then assert a lien on any recovery you may receive. Be sure to put your full name and Social Security Number or Claim Number on the letter. If your attorney continues to assert a claim for a fee for the earlier representation, any benefit check will be made jointly payable to you and your attorney.

Q15-5. If I choose to litigate against DCC Litigation Facility, Inc., how much can my attorney keep for fees?

Generally, the payment of your attorney's fees will be governed by the individual agreement between you and your attorney and any applicable state law.

Q15-6. I opted-out of the RSP but I want to settle my claim for my Dow Corning breast implant in the Settlement Facility. What attorney fees will I be responsible for from my payment from the Settlement Facility?

Fees charged by an attorney cannot exceed the sum of:

1. 10% of the first \$10,000;
2. 22.5% of the next \$40,000; and
3. 30% of the amount in excess of \$50,000 paid.

SECTION 16 – CLAIMS FILED ON BEHALF OF AN ESTATE OF A DECEASED CLAIMANT

Q16-1. My wife/mother died several years ago. What do I need to do to file a claim on behalf of her estate?

Only the properly appointed executor or administrator of an estate can file a claim, so you will need to provide the Settlement Facility with evidence that you have been appointed to serve in one of those capacities.

Q16-2. How can I be appointed as executor or administrator of the estate?

This is a matter of state law in each individual state or country. The Settlement Facility cannot tell you what it will take to be appointed in your state or country. Contact the Probate Court for the area in which you live and ask for the information or speak with an attorney for additional information. If you reside outside of the U.S., consult with a local attorney on how to file a claim in the appropriate court in your country.

Q16-3. It may take some time to get the right papers appointing me as the executor or administrator. Can my wife's (or mother's) claim be processed now without this appointment?

The Settlement Facility can accept and process the claim but we cannot pay the claim until we receive the proper papers showing that you have been appointed the executor or administrator of her estate.

Q16-4. Can the Claims Assistance Program help me with probate issues?

No. The Claims Assistance Program cannot advise you concerning probate or guardianship matters. This is a matter of state law.

SECTION 17 – REIMBURSEMENT AND LIENS

Q17-1. What is the agreement that was reached with the health care providers, and how does it affect me?

An agreement was reached between the Plan Proponents (Dow Corning and the Tort Claimants' Committee) and certain U.S. health insurers which provides a separate fund for insurers to recover. Settling health insurers are required to release any claims for reimbursement or subrogation against any personal injury claimant. To determine if your insurer is one of the settling health insurers, call the Settlement Facility Toll Free at 1-866-874-6099. If your health insurer is a settling insurer, you will not be required to reimburse or repay that insurer with any settlement benefits you recover in the Settlement Facility.

Q17-2. My insurance company paid for 80% of the cost of my implant removal surgery. Can I still receive the Settlement Payment?

Yes. If your insurance company settled its claims against Dow Corning, the insurance company cannot file a claim for reimbursement against any of your settlement benefits and/or require you to reimburse or repay the insurance company for any medical expenses paid on your behalf.

Q17-3. My insurance company is not on the list of settling insurers. What effect does that have on my claim?

If your insurance company did not settle its claims against Dow Corning, it may request that the Settlement Facility notify the insurance company when payment of your claim has been approved. Although this notice will not delay the payment of your claim, it will place your insurance company on notice of your settlement and they may attempt to recover any amount of your settlement payment directly from you in accordance with the insurance contract. For further information concerning this, consult your own attorney.

Q17-4. My former attorney indicated that he might file a lien claim for out-of-pocket expenses and fees. If he does file a claim, how will that be handled?

If your attorney files a lien claim, the Settlement Facility will notify you and advise you of the procedures to handle resolution of the issue and the processing of any settlement check.

Q17-5. If my former attorney filed a lien against me in the RSP, is it still valid in the Dow Corning Settlement Facility?

No.

GLOSSARY OF TERMS

This Glossary of Terms defines some of the terms used in the Claimant Information Guide.

“Case Management Order:”

A written order that was issued by Judge Denise Page Hood of the United States District Court for the Eastern District of Michigan on November 13, 2000. The Case Management Order, also called the “CMO,” describes some of the rights and duties of claimants against DCC Litigation Facility, Inc. who wish to litigate – rather than settle – their claims.

“Class of claimants:”

A grouping of claimants created for purposes of the Amended Joint Plan. The groupings are specified in the Plan. The claimants are divided into Classes based on the types of implants received by claimants and the different countries in which the claimants live, are citizens, or received their implants.

“Deficiency:”

In the Settlement Facility-Dow Corning Trust, a “deficiency” means that the proof submitted does not meet the requirements for the Settlement Facility to approve the claim.

“Effective Date:”

Read Q13-5 of this Claimant Information Guide.

“Explant:”

To remove an implant by surgical procedure.

“Litigation” or “litigate:”

To resolve a dispute through the court system. Litigation involves the filing of a lawsuit in a court before a judge.

“Manifested injury:”

Under the Plan a “manifested injury” means that the claimant has an illness or symptoms of sufficient severity to support a disease payment under either Disease Option 1 or Disease Option 2.

“MDL Claims Office:”

The claims office that is administering the settlement of the claims against implant manufacturers other than Dow Corning. The MDL Claims Office is administering the Revised Settlement Program, also known as the “RSP.”

“Operative report:”

A report issued by a doctor about a surgical operation on a person. An operative report may be kept in the records of a doctor or of the hospital or other medical facility at which the surgical operation was performed.

“Original global settlement:”

A class action settlement in 1994 of claims against a group of breast implant manufacturers and suppliers.

“Settlement Facility:”

The entity that administers the settlement of personal injury claims involving Dow Corning products.

“TMJ:”

An abbreviation for “temporo-mandibular joint.” The TMJ is the hinge at which a person’s lower and upper jaws connect with each other.

TAB I

ACCEPTABLE PROOF OF MANUFACTURE

PART I BREAST IMPLANT CLAIMANTS

TAB I, 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.

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.

<u>BRAND/MANUFACTURER NAME</u>	<u>STATUS</u>
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
"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.	Covered.
"silastic" — in all lower case letters — for implantations during or after 1969.	Not Covered.

TAB I

ACCEPTABLE PROOF OF MANUFACTURE

PART II OTHER PRODUCTS CLAIMANTS

TAB I, PART II

OTHER PRODUCTS CLAIMANTS

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 in the instructions to the Proof of Manufacturer Form; (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>
HIP OR KNEE JOINT		Dimensions provided as necessary to the Claims Office.
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		

PRODUCT NAMES	YEARS	DIMENSIONS
HIP OR KNEE JOINT		Dimensions provided as necessary to the Claims Office.
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		
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		

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<u>PRODUCT NAMES</u>	<u>YEARS</u>	<u>DIMENSIONS</u>
HIP OR KNEE JOINT		Dimensions provided as necessary to the Claims Office.
Whiteside Ortholoc® II Modular Knee		
Whiteside Ortholoc® II-C Modular Knee		
Whiteside Ortholoc® Modular Knee		
Whiteside Ortholoc® Modular Revision Knee		
Wright Choice Hip		

<u>PRODUCT NAMES</u>	<u>YEARS</u>	<u>DIMENSIONS</u>		
CHIN				
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
		Medium		
		Small	34	7
		Medium	38	8
		Large	48	8
Dow Corning SILASTIC® brand Chin Implant, Safian Technique	1968-1992			
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			

PRODUCT NAMES	YEARS	DIMENSIONS		
NOSE – (SOLID ELASTOMER) IMPLANT				
SILASTIC® brand Rhinoplasty Implant, Safian Technique	1965-1992	<u>Size</u>	<u>Length</u> <u>mm</u>	<u>Depth</u> <u>mm</u>
Dow Corning SILASTIC® brand Rhinoplasty Implant, Safian Technique	1965-1992	Small Medium Large	29 29 29	4.8 6.0 8.0
Dow Corning Wright SILASTIC® Brand Nasal Implant, S-Type (Shirakabe Design)	1982-1992	<u>Length</u> <u>Size</u> I, II, III & Soft	<u>Length</u> <u>(mm)</u> 35	<u>Width</u> <u>(mm)</u> 60 9.5

PRODUCT NAMES	YEARS	DIMENSIONS		
TESTICULAR				
(Solid Elastomer) Type				
SILASTIC® brand Testicular Prosthesis	1963-1972	<u>Size</u>	<u>Diameter</u>	x <u>Height</u>
Dow Corning SILASTIC® brand Testicular Prosthesis	1963-1972	Youth Adult	2 cm 2 1/2 cm	2 1/2 cm 3 1/2 cm
(Gel Filled) Type <u>Initial Product Model</u>		<u>Size</u>	<u>Width</u> <u>(cm)</u>	x <u>Height</u> <u>(cm)</u>
SILASTIC® brand Gel-filled Testicular Implant (Lattimer Design)	1972-1979	Child Youth Adult (avg) Adult (lge)	2.0 2.4 2.8 3.0	2.5 3.4 4.2 4.7
Dow Corning SILASTIC® brand Gel-Filled Testicular Implant, (Lattimer Design)	1972-1979			
<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			

<u>PRODUCT NAMES</u>	<u>YEARS</u>	<u>DIMENSIONS</u>			
PENILE <i>No inflatable silicone penile prostheses are Dow Corning products</i>					
<u>(Lash Design)</u>					
Dow Corning SILASTIC® brand Penile Implant, (Lash Design)	1967-1973	<u>Length</u> 12cm	<u>Width</u> 10mm	<u>Height</u> 12mm	
Dow Corning Penile Implant (Lash-Loeffler Design)	1967-1973				
<u>(Pearman Design)</u>					
Dow Corning SILASTIC® brand Penile Implant (Pearman Design)	1968-1973	<u>Length</u> 13.5cm		<u>Width</u> 13mm	
SILASTIC® Inter-Corpus Cavernosum, (Pearman Design)	1968-1973				
<u>(Gerow Design)</u>					
SILASTIC® Penile Implant (Gerow Design)	1978-1984		<u>Width Length (cm)</u>	<u>Width Distal (cm)</u>	<u>Proximal (cm)</u>
SILASTIC® brand Penile Implant (Gerow Design)	1978-1984	<u>Size</u>			
Dow Corning SILASTIC® brand Penile Implant (Gerow Design)	1978-1984	Small Medium Large	10.5 11.7 13.1	2.22 2.22 2.22	1.71 1.69 1.68
Dow Corning SILASTIC® brand Penile Implant (Gerow Design, Patent Number 3,991,752)	1978-1984				
<u>Penile Implant/Paired Set Design (Subrini Design) (U.S.A. labeling)</u>			<u>Length Distal (mm)</u>	<u>Proximal (mm)</u>	<u>Diameter (mm)</u>
Dow Corning SILASTIC® brand Penile Implant (Subrini Design)	1978-1991	<u>Size</u>			
<u>Penile Implant/Paired Set Design (Subrini Design) (European labeling)</u>		10 mm 11 mm	80 90	120 110	10 11
SILASTIC® Penile Penis Penieene Penien Peneal Implant H.P. (Subrini Design)	1979-1991				

PRODUCT NAMES	YEARS	DIMENSIONS																
TEMPOROMANDIBULAR JOINT																		
Wilkes Temporomandibular Joint Implant (A spacer constructed of paddle-shaped SILASTIC® silicone sheeting manufactured by Dow Corning)	1987-1992	(in mm) <table> <tr> <td></td> <td>L</td> <td>W</td> <td>Th</td> </tr> <tr> <td>Size 1</td> <td>50</td> <td>20</td> <td>0.8</td> </tr> <tr> <td>Size 2</td> <td>55</td> <td>22</td> <td>0.8</td> </tr> <tr> <td>Size 3</td> <td>61</td> <td>24</td> <td>0.8</td> </tr> </table>		L	W	Th	Size 1	50	20	0.8	Size 2	55	22	0.8	Size 3	61	24	0.8
	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>Sheeting Used in TMJ:</u>																		
SILASTIC® Medical Grade Sheeting	1964-1992	8" x 6" x .005" .010" .020" .040" .062" .060" (1979) Non-Reinforced																
SILASTIC® Brand Sheeting	1964-1992	8" x 6" x .007" .020" .030" .040" 8" x 6" x .040" .080" .120" Reinforced Non-Reinforced, Extra Firm																
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	2 3/4" x 4 1/2" x 1/2" (66 mm x 109 mm x 130 mm)																

PRODUCT NAMES	YEARS	DIMENSIONS
ANGLED GREAT TOE		
SILASTIC® ANGLED GREAT TOE IMPLANT, H.P. (SWANSON DESIGN) WEIL MODIFICATION	1978-1993	<u>Oval Shape (3 sizes)</u> Short Diameter: 13 - 16 mm Long Diameter: 15 - 18 mm Stem Length: 12 - 17 mm

PRODUCT NAMES	YEARS	DIMENSIONS
GREAT TOE		
SILASTIC® GREAT TOE IMPLANT (SWANSON DESIGN)	1970-1975	<u>Oval Shape (5 sizes)</u> 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 (5 sizes)</u> 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 (5 sizes)</u> Short Diameter: 11 - 17 mm Long Diameter: 13 - 20 mm Overall Length: 18 - 32 mm
Dow Corning Wright Swanson Titanium Great Toe Implant	1987-1993	<u>Oval Shape Head (5 sizes)</u> Overall Height: 12 - 17 mm Head Length: 13 - 20 mm Head Width: 11 - 17 mm

PRODUCT NAMES	YEARS	DIMENSIONS
HAMMER TOE		
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

PRODUCT NAMES	YEARS	DIMENSIONS
FLEXIBLE HINGE TOE		
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

PRODUCT NAMES	YEARS	DIMENSIONS
WRIST		
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

PRODUCT NAMES	YEARS	DIMENSIONS
STA-PEG		
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

PRODUCT NAMES	YEARS	DIMENSIONS
CARPAL LUNATE		
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

PRODUCT NAMES	YEARS	DIMENSIONS
CARPAL SCAPHOID		
SILASTIC® CARPAL SCAPHOID PROSTHESIS (SWANSON DESIGN)	1970-1977	(3 sizes, right; 3 sizes, left) Width (Head): 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 (no Stem): 9 - 15 mm
SILASTIC® SWANSON CARPAL SCAPHOID IMPLANT, H.P.	1977-1989	(7 sizes, right; 7 sizes, left) Width (Head): 16 - 24 mm Thickness: 11 - 18 mm Length (Stem): 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

PRODUCT NAMES	YEARS	DIMENSIONS
RADIAL HEAD		
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
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

PRODUCT NAMES	YEARS	DIMENSIONS
SCAPHOLUNATE		
SILASTIC® SCAPHOLUNATE H.P. (Swanson Design)		(4 sizes, left; 4 sizes, right) Length: 34 - 42 mm Width: 16 - 19 mm Thickness: 15 - 19 mm

<u>PRODUCT NAMES</u>	<u>YEARS</u>	<u>DIMENSIONS</u>
TRAPEZIAL		
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

<u>PRODUCT NAMES</u>	<u>YEARS</u>	<u>DIMENSIONS</u>
TRAPEZIUM		
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

<u>PRODUCT NAMES</u>	<u>YEARS</u>	<u>DIMENSIONS</u>
ULNAR HEAD		
SILASTIC® ULNAR HEAD PROSTHESIS (SWANSON DESIGN)	1970-1975	(4 sizes) Overall Length: 27-41 mm Height (Head): 13-19 mm
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

<u>PRODUCT NAMES</u>	<u>YEARS</u>	<u>DIMENSIONS</u>
CONDYLAR		
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

<u>PRODUCT NAMES</u>	<u>YEARS</u>	<u>DIMENSIONS</u>
TENDON PASSER		
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

<u>PRODUCT NAMES</u>	<u>YEARS</u>	<u>DIMENSIONS</u>
TENDON SPACER		
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

<u>PRODUCT NAMES</u>	<u>YEARS</u>	<u>DIMENSIONS</u>
FINGER JOINTS		
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
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

For assistance or questions call Toll Free at 1-866-874-6099 or go to www.dcsettlement.com.

TAB I

ACCEPTABLE PROOF OF MANUFACTURE

PART III SILICONE MATERIAL CLAIMANTS

TAB I, 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 Baxter and Bristol 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.*

BRAND/MANUFACTURER NAME	STATUS IN REVISED 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
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

BRAND/MANUFACTURER NAME	STATUS IN REVISED PROGRAM
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

BRAND/MANUFACTURER NAME	STATUS IN REVISED PROGRAM
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

BRAND/MANUFACTURER NAME	STATUS IN REVISED PROGRAM
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

BRAND/MANUFACTURER NAME	STATUS IN REVISED PROGRAM
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.

<u>BRAND/MANUFACTURER NAME</u>	<u>STATUS IN FOREIGN SETTLEMENT PROGRAM</u>
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

<u>BRAND/MANUFACTURER NAME</u>	<u>STATUS IN FOREIGN SETTLEMENT PROGRAM</u>
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

For assistance or questions call Toll Free at 1-866-874-6099 or go to www.dcsettlement.com.

<u>BRAND/MANUFACTURER NAME</u>	<u>STATUS IN FOREIGN SETTLEMENT PROGRAM</u>
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

TAB II

**CATEGORIZATION OF COUNTRIES FOR
CALCULATION OF ALLOWED AMOUNT
FOR ELIGIBLE FOREIGN CLAIMS**

TAB II

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 (1) of four (4) 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. This calculation is reflected in the Forms, Instructions, and Claimant Information Guide for the applicable class.

CATEGORY 1 COUNTRIES

60% of Domestic Amount for Applicable Compensation Level

Australia	Canada	New Zealand	United Kingdom
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CATEGORY 2 COUNTRIES

60% of Domestic Amount for Applicable Compensation Level

Austria	France including: French Polynesia New Caledonia	Ireland	Netherlands
Bahamas	Germany	Italy	Norway
Belgium	Greece	Japan	Portugal
Bermuda	Hong Kong	Kuwait	Singapore
Cayman Islands	Iceland	Liechtenstein	Spain
Denmark		Luxembourg	Sweden
Finland		Monaco	Switzerland
			United Arab Emirates

CATEGORY 3 COUNTRIES

35% of Domestic Amount for Applicable Compensation Level

Argentina	Cyprus	Korea	Qatar
Barbados	Czech Republic	Malaysia	Saudi Arabia
British Virgin Islands	Israel including: Gaza Strip West Bank	Malta	Taiwan
Chile		Mauritius	

CATEGORY 4 COUNTRIES

35% of Domestic Amount for Applicable Compensation Level

Algeria	Cuba	Jamaica	Paraguay
Belize	Dominican Republic	Jordan	Peru
Bolivia	Ecuador	Kenya	Philippines
Botswana	Egypt	Lebanon	Poland
Brazil	Estonia	Lithuania	Saint Kitts and Nevis
Bulgaria	Fiji	Mali	Senegal
Cambodia	Ghana	Mexico	South Africa
Central African Republic	Grenada	Morocco	Thailand
China	Guatemala	Namibia	Tonga
Colombia	Guyana	New Guinea	Turkey
Cook Islands	Haiti	Nicaragua	Uruguay
Costa Rica	Honduras	Nigeria	Venezuela
Cote d'Ivoire (Ivory Coast)	Hungary	Oman	Vietnam
Croatia	India	Pakistan	Zambia
	Indonesia	Panama	Zimbabwe

TAB III

CASE MANAGEMENT ORDER OUTLINE

TAB 3

OUTLINE OF CASE MANAGEMENT ORDER NO. 1

The Court has previously entered Case Management Order No. 1. If you are considering opting out — that is, rejecting the Settlement Facility benefits — to pursue litigation, it is important that you read the entire Order before making your decision. You may obtain a copy of the complete Order either through the Court via Docket No. 00-CV-00001 or from the Court's website: www.mied.uscourts.gov. The Order contains information about the following topics:

- The court in which your case may be tried
- Deadlines that you must meet, including:
 - ✦ Deadlines for filing your lawsuit, and
 - ✦ Deadlines for responding to certain court-ordered discovery
- Discovery that may be available to you from other litigation
- Case-specific discovery that you may be required to complete
- Common issue motions that may be filed
- Common issue hearings that may be conducted
- The process for and timing of setting cases for trial
- The types of damages you may seek to recover (no punitive damages allowed)
- The mechanics of filing papers with this court

TAB IV

EXCERPT FROM THE CONFIRMATION ORDER OF THE AMENDED JOINT PLAN OF REORGANIZATION

TAB 4

**Excerpt from the Confirmation Order of the
Amended Joint Plan of Reorganization
November 30, 1999**

B. By December 24, 1999 [Dates have been superceded], the Debtor shall mail to each Personal Injury Claimant a notice: (i) summarizing the provisions of this paragraph 5; (ii) informing them that beneficiaries of the United States Government who received medical care or reimbursement for medical care expenses from certain agencies or programs of the United States Government, such as the Veterans Administration, the Bureau of Indian Affairs, the Department of Defense, and Medicare, may have a duty to notify the Government upon settlement of any claim against the Debtor or the Reorganized Debtor and to share such settlement amount with the Government, and (iii) advising them that Claimants may wish to seek legal counsel or the assistance of the Claimants' Advisory Committee with respect to this issue.

C. Personal Injury Claimants obligated by law to inform the United States Government of a settlement with the Debtor shall notify the Government by letter addressed to: Glenn Gillett, Department of Justice, P.O. Box 875, Ben Franklin Station, Washington, D.C., 20044, within 24 hours of the time that the Claimant and the Settlement Facility agree to a settlement amount.

D. Personal Injury Claimants shall have until February 25, 2000 [Dates have been superceded] to withdraw their proofs of claim and to thereby preserve confidentiality as to them. By doing so, however, they forfeit their right to participate in any recovery from the estate or the Reorganized Debtor.

E. Commencing March 1, 2000 [Dates have been superceded], the United States of America may examine and copy at its own expense proofs of claim of all Personal Injury Claimants which have not been withdrawn, but subject to the following restrictions with respect to the claims of Personal Injury Claimants who elect to settle within the Settlement Facility: (i) the information contained on proofs of claim shall be available only to those persons within the Government having a need to know; and (ii) the Government may not release such information to any person outside of the Government (whether or not requested under the Freedom of Information Act or other provision of law) except other parties in this case who already have access to the same information. This order shall be deemed to be merely a modification of the existing confidentiality orders of this Court.

TAB 4

TAB V

MEDICAL CONDITIONS AND CHARACTERISTICS OUTLINE OF DEFINITIONS AND CLASSIFICATION CRITERIA

TAB 5

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 1:

There are two (2) ways to document a claim for Disease Payment Option 1 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 1 Schedule.

A Claimant should submit all records that contain information relevant to the criteria for Disease Payment Option 1, 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 1 Claim. Only a Board-certified physician can submit the statement or diagnosis of one of the compensable diseases included in Disease Payment Option 1. The physician writing a statement or diagnosis of one of the compensable diseases in Disease Payment Option 1 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 (1) 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, Claimants 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.

TAB 5

DISEASE PAYMENT OPTION 1: 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 (4) of the eleven (11) 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 (1) 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:

- ◆ satisfying the requirements for one (1) of the four (4) neurological diseases set forth in paragraph 5 below, *and*
- ◆ any three (3) 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:

- ◆ Objectively-demonstrated loss of sensation to pinprick, vibration, touch, or position
- ◆ Proximal or distal muscle weakness
- ◆ Tingling and/or burning pain in the extremities
- ◆ Signs of dysesthesia
- ◆ Loss of tendon reflex

Plus one (1) or more of the following laboratory findings:

- ◆ Abnormal levels of anti-mag or anti-sulfatide or anti-GM1 antibodies
- ◆ Abnormal sural nerve biopsy
- ◆ 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 (1) or more of the following signs and symptoms:

- ◆ Weakness in the pyramidal distribution
- ◆ Evidence of optic neuritis documented by ophthalmologist
- ◆ Increased Deep Tendon reflexes
- ◆ Absent superficial abdominal reflexes
- ◆ Ataxia or dysdiadochokinesia as the sign of cerebellar involvement

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- ◆ Neurologically induced tremors
- ◆ Internuclear ophthalmoplegia and/or bladder or speech involvement secondary to central nervous system disease

Plus one (1) or more of the following:

- ◆ Abnormal Brain MRI with foci of increased signal abnormality suggestive of demyelinating lesions
- ◆ Delayed visual evoked responses or abnormal evoked potentials
- ◆ 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 (1) or more of the following:

- ◆ Neurological autoantibodies such as anti-mag, anti-sulfatide, anti-GM1
- ◆ Abnormal sural nerve biopsy
- ◆ Chronic inflammation on muscle or nerve biopsies
- ◆ Abnormal EMG
- ◆ 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, avocational, or usual self-care, 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% disabled due to the compensable condition. An individual shall be considered 35% 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 with regular or recurring severe pain.

C. A Breast Implant Claimant will be eligible for category C compensation if she is 20% disabled due to the compensable condition. An individual shall be considered 20% disabled if she can perform some of her usual activities of vocation, avocation, and self-care 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 (2) 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 (1) of the following three (3): (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 (3) of the criteria plus the rash (fifth criterion). A diagnosis of polymyositis requires the presence of four (4) 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:

- ◆ any two (2) of the three (3) signs and symptoms listed in 5(a) (Group I)
- ◆ any one (1) of the three (3) signs and symptoms listed in 5(a) (Group I), plus any one (1) of the ten (10) signs and symptoms listed in 5(b) (Group II)

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- ◆ any three (3) of the ten (10) signs and symptoms listed in 5(b) (Group II)
- ◆ any two (2) of the ten (10) signs and symptoms listed in 5(b) (Group II), plus any one (1) additional (nonduplicative) sign or symptom from the eighteen (18) listed in 5(c) (Group III)
- ◆ five (5) 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:

- ◆ Raynaud's phenomenon evidenced by the patient giving a history of two (2) color changes, or visual evidence of vasospasm, or evidence of digital ulceration
- ◆ Polyarthritis defined as synovial swelling and tenderness in three (3) or more joints lasting greater than six (6) weeks and observed by a physician
- ◆ Keratoconjunctivitis Sicca: subjective complaints of dry eyes and/or dry mouth, accompanied by any one (1) of the following:
 - lacrimal or salivary enlargement
 - parotid enlargement
 - abnormal Schirmer's test
 - abnormal Rose-Bengal staining
 - filamentous keratitis
 - abnormal parotid scan or ultrasound
 - abnormal CT or MRI of parotid
 - abnormal labial salivary biopsy

(b) Group II Signs and Symptoms:

- ◆ Myalgias determined by tenderness on examination
- ◆ Immune mediated skin changes or rash as follows:
 - changes in texture or rashes that may or may not be characteristic of SLE, Systemic Sclerosis (scleroderma), or dermatomyositis
 - diffuse petechiae, telangiectasias, or livedo reticularis

- ◆ Pulmonary symptoms or abnormalities, which may or may not be characteristic of SLE, Systemic Sclerosis (scleroderma), or Sjogren's Syndrome, as follows:
 - pleural and/or interstitial lung disease
 - restrictive lung disease
 - 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)
- ◆ Pericarditis defined by consistent clinical findings and either EKG or echocardiogram
- ◆ 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
- ◆ Peripheral neuropathy diagnosed by physical examination showing one (1) or more of the following:
 - loss of sensation to pinprick, vibration, touch, or position
 - tingling, paresthesia or burning pain in the extremities
 - loss of tendon reflex
 - proximal or distal muscle weakness (loss of muscle strength in extremities or weakness of ankles, hands, or foot drop)
 - Signs of dysesthesia
 - entrapment neuropathies
- ◆ Myositis or myopathy:
 - diagnosed by weakness on physical examination or by muscle strength testing
 - abnormal CPK or aldolase
 - abnormal cybex testing

- abnormal EMG
 - abnormal muscle biopsy
 - ◆ Serologic abnormalities – any one (1) of the following:
 - ANA > or equal to 1:40
 - 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)
 - other autoantibodies, including thyroid antibodies, anti-microsomal, or anti-cardiolipin, or RF (by nephelometry with 40 IU cutoff)
 - elevation of immunoglobulin (IgG, IgA, IgM)
 - serologic evidence of inflammation such as elevated ESR, CRP
 - ◆ Lymphadenopathy (as defined by at least one (1) lymph node greater than or equal to 1x1 cm) documented by a physician
 - ◆ Dysphagia with positive cine-esophagram, manometry or equivalent imaging
- (c) Group III Signs and Symptoms:
- ◆ Documented arthralgia
 - ◆ Documented Myalgias
 - ◆ Chronic fatigue
 - ◆ Lymphadenopathy
 - ◆ Documented Neurological symptoms including cognitive dysfunction or paresthesia
 - ◆ Photosensitivity
 - ◆ Sicca symptoms
 - ◆ Dysphagia
 - ◆ Alopecia
 - ◆ Sustained balance disturbances
 - ◆ Documented sleep disturbances

- ◆ Easy bruisability or bleeding disorder
- ◆ Chronic cystitis or bladder irritability
- ◆ Colitis or bowel irritability
- ◆ Persistent low grade fever or night sweats
- ◆ Mucosal ulcers confirmed by physician
- ◆ 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
- ◆ 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 vocational³, avocational⁴, or usual self-care⁵ 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% disabled due to the compensable condition. An individual shall be considered 35% 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% disabled due to the compensable condition. An individual shall be considered 20% disabled if she can perform some of her usual activities of vocation, avocation, and self-care only with regular or recurring moderate pain.

³ Vocational means activities associated with work, school, and homemaking.

⁴ Avocational means activities associated with recreation and leisure.

⁵ Usual self-care means activities associated with dressing, feeding, bathing, grooming, and toileting.

**PART B. DISEASE AND DISABILITY/SEVERITY DEFINITIONS:
DISEASE PAYMENT OPTION 2**

GENERAL GUIDELINES

- 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 (5) years immediately preceding the submission of the claim except that this period is tolled during the pendency of the bankruptcy (May 15, 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 2 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 2, 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 2.
- D. Claimants who seek benefits under Disease Payment Option 2 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 2: 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 (2) 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% 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 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 (4) of the following eleven (11) criteria are present:

<u>Criterion</u>	<u>Definition</u>
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]
6. Serositis	(a) Pleuritis – convincing history of pleuritic pain or rub heard by a physician or evidence of pleural effusion, <u>or</u> (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 three (3)+ if quantitation not performed, <u>or</u> (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, <u>or</u> b) Leukopenia — less than 4,000/mm total on two (2) or more occasions, <u>or</u> c) Lymphopenia — less than 1,500/mm on two (2) or more occasions, <u>or</u> d) Thrombocytopenia — less than 100,000/mm in the absence of offending drugs

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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 treponemal 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% of the age- and gender-adjusted norm, as measured by an adequate 24-hour urine specimen collection.

B. SLE with involvement of one (1) 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 (4) criteria without the rash;
- for dermatomyositis, three (3) of the first four (4) 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 (2) findings from Group I; or
- (2) any three (3) non-duplicative findings from Group I or Group II.

For compensation at Level B:

- (1) one (1) finding from Group I plus any four (4) non-duplicative findings from Group II or Group III; or
- (2) two (2) findings from Group II plus one (1) 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 (3) or more joints in at least two (2) different joint groups observed on more than one (1) physical examination by a Board-certified physician and persisting for more than six (6) 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 (2) based upon average of four (4) 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 (2) separate occasions separated by at least two (2) months and accompanied by at least one (1) test showing decreased complement levels of C3 and C4; or a positive ANA greater than or equal to 1:80 (using Hep2) on two (2) separate occasions separated by at least two (2) 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% of predicted.

6. Myositis or myopathy, defined as any two (2) 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 (2) separate occasions at least six (6) weeks apart. (If the level of the initial test is three (3) times normal or greater, one (1) 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 (3) 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 (2) separate occasions separated by at least two (2) months; (b) one (1) 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 (2) (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 (3) muscles, each persisting for at least six (6) 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.]