

## **PRODUCT IDENTIFICATION DOCUMENTATION GUIDELINES**

### **DOW CORNING/BRITISH COLUMBIA AND OTHER PROVINCES BREAST IMPLANT LITIGATION SETTLEMENT**

**PRODUCT IDENTIFICATION DOCUMENTATION MUST BE SUBMITTED WITH YOUR CLAIM FORM, ON OR BEFORE DECEMBER 1, 2004. ALL CLAIMANTS (Expedited, Raw Material, Current, Ongoing and Rupture) MUST SUBMIT PRODUCT IDENTIFICATION DOCUMENTATION**

The Dow Corning/British Columbia and Other Provinces Breast Implant Litigation Settlement Agreement (the "Agreement") requires Claimants to submit Product Identification Documentation ("PID") with the Claim Form prior to the Initial Deadline (December 1, 2004).

The PID must be sufficient to establish that the Class Member's Breast Implant(s) are or were Dow Corning Breast Implants or contained Dow Corning Breast Implant Raw Materials.

Below you will find an extract from the Dow Corning/British Columbia and Other Provinces Breast Implant Litigation Settlement Agreement, detailing what PID information is required. A complete copy of this agreement is available at

[www.canadianbreastimplantsettlement.com/documents.html](http://www.canadianbreastimplantsettlement.com/documents.html)

#### **Paragraph 2.4 - Product Identification Documentation (Exhibit D of the Agreement)**

- i) To be deemed sufficient to establish that the Class Member's Breast Implant(s) are or were Dow Corning Breast Implants PID shall consist of any one of the following:
  - (a) contemporaneous hospital records or the implanting surgeon's report of the surgery specifying that the Class Member was implanted with Dow Corning Breast Implants; or
  - (b) contemporaneous copies of medical records that contain the package label for the Dow Corning Breast Implant(s) with which the Class Member was implanted; or
  - (c) a product identification report pursuant to Subparagraphs I.B.7 and I.B.8 of Schedule I to Annex A to Settlement Facility and Fund Distribution Agreement of the Confirmed Plan of Reorganization identifying the Dow Corning Breast Implant pursuant to the unique product identifiers defined in Section I.D of Schedule I to Annex A to Settlement Facility and Fund Distribution Agreement of the Confirmed Plan of Reorganization. *(For ease of reference, we include a copy of the sections and subparagraphs mentioned above on page three (3) of this document); or*
  - (d) if the PID specified in above Subparagraphs (a), (b), or (c) is not available, a written statement signed by the implanting surgeon or by an authorized representative of the hospital or clinic where the implantation of the Class Member's Dow Corning Breast Implant(s) was performed, attesting that the Class Member was implanted with Dow Corning Breast Implant(s).

These guidelines summarize sections of the Agreement and Schedule 1 of Annex A of the Settlement Facility and Fund Distribution Agreement of the Confirmed Plan of Reorganization. In the event of contradiction between these guidelines and the Agreements, the Agreements shall govern.

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Such statement cannot rest upon unacceptable and insufficient proof of product identification as outlined in Subparagraph 2.4(iii), below, and it must be accompanied by an affidavit from the Class Member stating:

- the steps taken by the Class Member to obtain PID as outlined in Subparagraphs 2.4(i)(a) and (b) above; and
  - the responses, if any, to those steps.
- ii) If a Class Member is unable to provide PID as outlined in Subparagraphs 2.4(i)(a), (b), (c), or (d), above, the Class Member may submit to the Claims Administrator such other objective verification of the identification of the Dow Corning Breast Implant(s) as may be acceptable to the Claims Administrator, subject to the approval of Class Counsel and Dow Corning, neither of whose approval shall be unreasonably withheld. Such objective verification cannot rely upon unacceptable and insufficient proof of product identification as described in Subparagraph 2.4(iii) below.

Such other objective verification must be accompanied by an affidavit from the Class Member stating:

- the steps taken by the Class Member to obtain the PID outlined in paragraph 2.4 above; and
  - the responses, if any, to those steps.
- iii) Statements from medical personnel describing their typical or general practices concerning implant usage during a given time period, or a statement from the Class Member or any other person that seeks to identify the manufacturer or brand based upon recollection, shall be unacceptable and insufficient proof of product identification.
- iv) PID of Dow Corning Breast Implant Raw Materials is equivalent to the proof otherwise require in this Paragraph 2.4 except the proof shall demonstrate the claimant's Breast Implant(s) was a Breast Implant of the types that are listed in Part III, Paragraphs B and D of Schedule I to Annex A to the Settlement Facility and Fund Distribution Agreement of the Confirmed Plan of Reorganization. *(Due to the length of Paragraphs B and D of Schedule I to Annex A we have not reproduced a copy of these paragraphs in this document, however a copy of the Schedule I to Annex of the Settlement Facility and Fund Distribution Agreement of the Confirmed Plan of Reorganization is available at [www.canadianbreastimplantsettlement.com/documents.html](http://www.canadianbreastimplantsettlement.com/documents.html))*

These guidelines summarize sections of the Agreement and Schedule 1 of Annex A of the Settlement Facility and Fund Distribution Agreement of the Confirmed Plan of Reorganization. In the event of contradiction between these guidelines and the Agreements, the Agreements shall govern.

**EXTRACTS FROM THE SETTLEMENT FACILITY AND FUND DISTRIBUTION  
AGREEMENT OF THE CONFIRMED PLAN OF REORGANIZATION**

A complete copy of Schedule I to Annex A of the Settlement Facility and Fund Distribution Agreement of the Confirmed Plan of Reorganization can be obtained from our website at [www.canadianbreastimplantsettlement.com/documents.html](http://www.canadianbreastimplantsettlement.com/documents.html)

**Subparagraphs I.B.7 and I.B.8 of Schedule I to Annex A**

I.B.7 Medical records of the explanting physician (or other physician or appropriate professional who examined the Claimant’s implant during or after removal surgery) – written at the time of the examination of the Breast Implant – if that physician or other appropriate professional points out a specific characteristic of the Breast Implant that is on the list of characteristics unique to Dow Corning implants as specified at Section D, below.

I.B.8 A photograph of an explanted Breast Implant that shows one of the characteristics unique to a Dow Corning Breast Implant, as specified at Section D, below, if the photograph is accompanied by a statement from the explanting physician identifying the Breast Implant in the photograph as one (s)he removed from the Claimant.

**Section I-D of Schedule I to Annex A**

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

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

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- ii. For implants implanted or manufactured between 1963 and 1969, four (4) Dacron ® mesh –reinforced fixation patches, one in each quadrant on the posterior implant shell, asymmetric or symmetric, with a distinct peripheral seam everted or non-everted, where the fixation patches are constructed of Dacron ® mesh-reinforced silicone elastomer sheeting to which non-embedded Dacron ® mesh has been sewn with Dacron ® sutures.
    - iii. For implants implanted or manufactured between 1968 and 1982, two (2) to five (5) circular Dacron ® mesh fixation patches on the posterior implant shell of the embedded/pleated design, consisting of a clear elastomer disc about 22-25mm diameter, with a pattern of embedded Dacron ® mesh in a pleated pattern, with the actual Dacron ® mesh present or absent.
    - iv. For implants implanted or manufactured between 1968 and 1976, a dumbbell-shaped Dacron ® mesh-reinforced fixation patch on the posterior implant shell, together with one, three or four additional round fixation patches on the implant shell. Internal to the dumbbell-shaped fixation patch are either two round shell holes (one larger than the other) separated by a slit in the shell, or a single round shell hole.
3. For implants implanted or manufactured between 1971 and 1975, an eccentrically placed racetrack (oval) shaped posterior shell patch, Dacron ® mesh-reinforced, outside the implant shell. Internal to the patch are either two round shell holes (one larger than the other) separated by a slit in the shell, or a single round shell hole.
4. A leaflet valve consisting of a proximal round part, attached to which is a distally rounded leaflet valve. The junction of the proximal and distal parts of the valve is also rounded (flared). (This identifier applies to Saline implants implanted or manufactured between 1979-1984; and to gel/saline implanted between 1981-1992.)
5. An implant having one of the following as an imprinted logo on the posterior (for double-lumen implants such markings are only present on the inner lumen patch):
  - i. DOW CORNING (1978 to 1992)
  - ii. SILASTIC II (1981 to 1992)
  - iii. DOW CORNING WRIGHT (1989 to 1992)
6. An implant with both (a) Mandrel Code and (b) Designation Number imprinted together on the posterior centered or near the patch of the implant envelope. These shell markings consist of a single letter or one or two numerals approximately 4mm height with a close-by series of three or four approximately 2mm height numerals. For double –lumen implants such markings will be on both shells. The following Mandrel Codes and Designation Numbers are acceptable:
  - i. Mandrel Codes (numbers 1-16, 20, 30, 40, 50, 60 or single uppercase letters A-R) (1969 to 1992); and

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

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