

**Updated Rules for Proof of Manufacturer**  
June 2, 1997

Acceptable Proof

1. Hospital records of the surgeon's report of the surgery – written at the time of the implantation surgery – that specify the brand name or manufacturer of the implants that were implanted.
2. A certified copy of medical records that contain the implant package label. Note: a certified copy is only required if the label –
  - (1) is on a page that does not affirmatively reveal it to be a part of your hospital or medical records and
  - (2) does not have a lot number or serial number on it.
3. Implant labels clearly marked with lot or serial number. The Claims Office will maintain a list of these numbers, to ensure that no duplicates are used. These labels do not have to be certified.
4. Records of the implanting surgeon – written at the time of the implantation surgery – that specify the brand name or manufacturer of the implants that were implanted.
5. 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 a particular manufacturer's implants. 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 #1 and #2 are not available, and must include a description of what steps were taken to secure the types of proof outlined in #1 and #2 above and explain why those records were not available.
6. A health insurance claim form, signed by the implanting physician reasonably close to the date of the surgery, naming the type of implant used.
7. Medical records of the explanting physician (or other physician or appropriate professional who examined the implant during or after removal surgery) – written at the time of the examination of the implant – if that physician or other appropriate professional points out a specific characteristic of the implant that is on the list of characteristics unique to specific manufacturers or brands of implants. (See list of unique identifiers below.)
8. A photograph of an explanted breast implant that shows one of the characteristics unique to a certain manufacturer 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 participant. (See list of unique identifiers below.)
9. McGhan's form Biocell "Patient Acknowledgment" signed by the implant recipient.
10. Manufacturer or brand-specific implant control sheets, with cross-references to a specific patient, that reasonably appear to be contemporaneously kept records in the hospital or implanting physician's office.
11. Manufacturer's invoice of packing list contained in claimant's medical or hospital records relating to the implant surgery. If the Claims Office cannot determine that the invoice or packing list actually was included in those records, we may require a certified copy of the records or a supplemental statement from the records custodian.
12. Manufacturer's catalog with a particular type of implant circled or otherwise marked, if contained in a certified copy of the participant's medical or hospital records relating to the implant surgery.
13. Warranties mentioning a breast implant noted on Exhibit C as being a covered implant, if contained in a certified copy of the participant's medical or hospital records.
14. Surgitek's form "Patient Informed Consent - Gel Filled Mammary Implants" signed by the implant recipient and dated close to the date of the implantation surgery; accompanied by other contemporaneous medical or hospital records verifying that the implantation surgery actually occurred.
15. For explantations before January 1, 1996, contemporaneous medical records of the explanting physician specifically stating that an explanted breast implant is a "McGhan" or a "3M." (In this limited instance, the physician does not have to state the basis for that conclusion. The statement identifying McGhan or 3M must, however, be a statement of fact and not merely an expression of opinion.)

### Unique Identifiers

For Bristol, the unique identifiers are:

1. Polyurethane for implantations before 9/1/71 or after 12/8/78)
2. Bilumen Implants described as having a standard gel implant within, but not attached to, an outer inflatable elastomer shell
3. 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
4. An implant having a Quin-Seal valve. This valve is flat and its entry site is marked with a white dot.
5. An adjustable reconstructive implant with two puncture seal sites (shell and column)
6. An implant with "SCL" molded on the shell
7. An implant with radiopaque size markers
8. For implantations before 9/1/71 or after 12/8/78, an implant shell exhibiting roughness due to adhesive can be treated as a "polyurethane" implant even if the foam cover is gone.
9. For implantations before 9/1/71 or after 12/8/78, an implant having a Y-shaped septum.

For Baxter, the unique identifiers are:

1. Polyurethane (for implantations 9/1/71 to 12/8/78)
2. For implantations 9/1/71 to 12/8/78, an implant shell exhibiting roughness due to adhesive can be treated as a "polyurethane" implant even if the foam cover is gone.
3. An implant with horizontal thin silicone tubing approximately 1mm in diameter. The tubing lies from edge to edge of patch for orientation purposes. Ends of tubing are "RTV'd" closed.
4. 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.
5. An implant with a molded or cast number composed of a single letter A, B, or C and followed by a single-digit number
6. An implant with a "spiral" or "target" imprinted design composed of concentric rings located on the main patch
7. An implant with a retention valve positioned at acute angle to flange
8. An implant with a diaphragh (Jenny) valve placed on the anterior face of the implant (On round styles, valve will be at apex of the anterior face.)

[Baxter Identifiers 3 - 8 above related only to implantations before 3/31/84.]

For 3M, the unique identifiers are:

1. An implant with "3M" or "3M McGhan" stamped on the outside of the envelope
2. For implants after March 1, 1975, and before August 3, 1984, an implant containing a patch with two concentric circles and a white dot in the center

For McGhan, the unique identifier is:

1. An implant with "McGhan" stamped on the outside of the envelope

### Unacceptable Proof

1. Your own recollection (or that of a friend or relative) regarding the brand name or manufacturer of your implants

2. Records from the International Implant Registry
3. Identifying reports from a physician who examined the implants during or after removal surgery. If identifiers not on the list of unique characteristics are the basis of identification, or the physician fails to specify the characteristics assumed to be unique, or the physician merely opines, based on his or her experience, that the prosthesis was made by a certain manufacturer
4. A non-contemporaneous statement by the implanting physician, attempting to supply the acceptable proof found in #5 of the list of acceptable proof, 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"
5. A non-contemporaneous statement by the implanting physician, attempting to provide the acceptable proof found in #5 on the list of acceptable proof, that does not name the participant as the person receiving a particular type or brand of implant
6. Pre-operative records indicating the brand or manufacturer of implants the surgeon planned to use in a surgery that took place later

**How to determine if a McGhan implant, implanted after 8/2/84, will be considered a 3M implant for purposes of the revised settlement program:**

You must provide proof that the implant had the name "3M" on it or that it has a 3M serial number or that it has a catalog number that was only used by 3M (and never used by McGhan). The list of 3M serial numbers, as well as the list of McGhan and 3M catalog numbers, is available upon request from the Claims Office.

**How to determine if a Heyer-Schulte implant, implanted after 3/30/84, will be considered a Baxter implant for purposes of the revised settlement program:**

You must provide proof that your implants have a Baxter lot number or the implant package label showing that it is an American Heyer-Schulte implant. This list of Heyer-Schulte lot numbers qualifying as Baxter implants is available upon request from the Claims Office. A catalog or style number is not the same as a lot number. Heyer-Schulte catalog and style numbers do establish that implants are Heyer-Schulte, but do not allow us to classify them as Baxter if implantation was after 3/30/84.

**Claims Office  
Revised Breast Implant Settlement Program  
P.O. Box 56666  
Houston, Texas 77256  
800/600-0311  
713/951-9106**