MENTOR

Product Insert Data Sheet

MENTOR MEMORYGEL® SILTEX™ BECKER EXPANDER/BREAST IMPLANTS

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INTRODUCTION - *DIRECTIONS TO THE PHYSICIAN*

The information supplied in this physician labelling document is intended to provide an overview of essential information about Mentor's MemoryGel® Siltex™ Becker Expander/Breast Implants, including a device description, instructions for use, indications, contraindications, warnings, precautions, important factors to discuss with a patient, adverse events, other reported conditions, clinical study results, device identification card, device retrieval efforts, how to report problems with an implant, and returned goods authorization.

Patient Counselling Information

You should review this document and patient labelling prior to counselling the patient about Mentor's MemoryGel® Siltex™ Becker Expander/Breast Implants and breast implant surgery. Please familiarize yourself with the content of this document and resolve any questions or concerns prior to proceeding with use of the device. As with any surgical procedure, breast reconstruction using breast implants is NOT without risks.

Breast reconstruction is an elective procedure, and the patient must be well counselled and understand the risk/ benefit relationship.

Before making the decision to proceed with surgery, the surgeon or a designated patient counsellor should instruct the patient to read ***Important Information for Reconstruction Patients About Mentor MemoryGel® Siltex™ Becker Expander/Breast Implants*** (patient labelling) and discuss with the patient the warnings, contraindications, precautions, important factors to consider, complications, Round Gel Study, CPG Core Study, and Product Availability (Adjunct) Study results, and all other aspects of the patient labelling. The physician should advise the patient of the potential complications and that medical management of serious complications may include additional surgery and explantation.

Informed Decision

Each patient should receive Mentor's ***Important Information for Reconstruction Patients About Mentor MemoryGel® Siltex™ Becker Expander/Breast Implants*** during her initial visit/consultation, to allow her sufficient time to read and adequately understand the important information on the risks, follow-up recommendations, and benefits associated with silicone gel-filled breast implant surgery.

Allow the patient an adequate amount of time (generally between 1 to 2 weeks) before deciding whether to have breast reconstruction surgery, unless an earlier surgery is deemed medically necessary

In order to document a successful informed decision process, the patient labelling includes an **Acknowledgment of Informed Decision** form at the end of the document, which is to be signed by both the patient and the surgeon and then retained in the patient's file.

DEVICE DESCRIPTION: SILTEX™ BECKER EXPANDER/BREAST IMPLANT

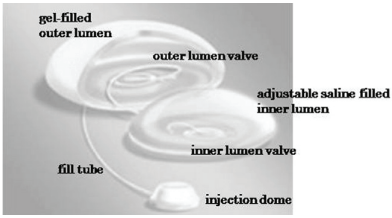

Figure 1: Becker Expander/Breast Implant

Postoperative volume adjustment with saline is made available through a remote injection dome/filling port connected to the implant by a removable fill tube passing through the dual valve system. The silicone elastomer fill tube is pre-inserted into the dual self-sealing valve system at the time of manufacture and is joined to the injection dome by the connector system at the time of surgery.

Round Becker 25
Gel volume 25 percent nominal implant size

Cohesive I® (standard) gel filling materia

Round Becker 50
Gel volume 50 percent nominal implant size

Cohesive I® (standard) gel filling material

Contour Profile Becker 35
Gel volume 35 percent nominal implant size

Cohesive II® (moderate) gel filling material

The SILTEX™ Becker Expander/Breast Implant has a low-bleed, gel-filled outer lumen and an adjustable saline-fillable inner lumen. In order to provide a prosthesis with elasticity and integrity, the outer and inner shells are made with successive cross-linked layers of silicone elastomer.

The textured SILTEX™ shell provides a disruptive surface for collagen interface.

In addition, the SILTEX™ Becker Expander/Breast Implants possess the following unique design features not present in other permanent expander/implants:

- a low-bleed, gel-filled outer lumen and an adjustable saline-fillable inner lumen combine the advantages of tissue expanders with the feel of a gel breast implant,
- silicone gel fills the superior aspect of the implant giving a natural curve to the upper and lower poles,
- the choice of two remote filling ports (also referred to as injection domes) and connectors can better address surgeon preference and patient size,
- the filling port/injection dome and fill tube are removed entirely (recommended up to 6 months post-implantation), whereas other gel expander/implants have built-in permanent injection domes,
- designed for up to 25% overexpansion capability,
- the Contour Profile Becker 35 design has orientation marks to assist surgeons with implant positioning,
- controlled low pole expansion of the Contour Profile Becker 35 design yields a natural anatomical breast shape,
- the incidence of wrinkling and rippling is considerably reduced compared to saline expander implants,[1] and
- controlled overexpansion may address the early phases of capsular contracture because periprosthetic tissue could be stretched and released by overexpansions and deflations.[2]

Postoperative volume adjustment with saline is made available through a remote injection dome/filling port connected to the implant by a removable fill tube passing through the dual valve system (Figure 1; also refer to Product Insert Data Sheet for the Injection Domes with Connection Systems). The silicone elastomer fill tube is pre-inserted into the dual self-sealing valve system at the time of manufacture and is joined to the injection dome by the connector system at the time of surgery. The fill tube should be handled carefully to avoid accidental dislodgment from its prepositioned location. Do not hold the device by its fill tube.

Two types of connector systems and injection domes are provided with each Becker product and either may be used. The inner lumen can be gradually filled with saline over an extended period of time via the fill tube and injection dome. The saline-filled inner lumen of the Becker Breast Implant provides the physician with the ability to control, within specified limits, the amount of expansion desired.

Once expanded to the desired volume, the fill tube and injection dome are removed through a small incision under local anaesthetic, and the prosthesis remains in position as a breast implant. It is recommended that the duration of expansion not exceed six months as tissue adhesions may make it difficult to easily remove the fill tube or compromise valve integrity. The valve system is designed to self-seal upon removal of the tubing.

Connecter and Injection Dome/Filling Port Options:

Each prosthesis is supplied with a choice of two connector systems and a choice of two injection domes.

- Connector Systems (for additional information refer to **WARNINGS** and **PRECAUTIONS**)
  1. The Mentor True-Lock™ connector does not require a suture tie (Figure 2; for additional information refer to the "True-Lock Connector" section provided in the connector and dome package).

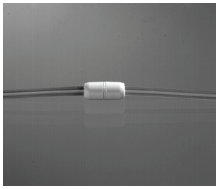

Figure 2: True-Lock Connector

  2. The stainless steel connector does require suture material tied around tube and connector to secure the connection (Figure 3).

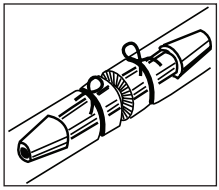

Figure 3: Stainless Steel Connector

- Injection Domes/Filling Ports (Figure 4; used for temporary subcutaneous implantation)
  1. The micro injection dome may be used when diminished palpability is desirable. This dome is designed to withstand up to 10 total injections. It is suggested that the dome be placed in a relatively superficial location to allow ease of identification and access during subsequent filling procedures. Inflation is accomplished by using sterile isotonic saline. Use a 23 gauge (or finer) standard or butterfly 12° bevel needle. Extreme care should be taken to puncture only the center of the top surface of the micro injection dome.
  2. The standard injection dome is larger in diameter and height than the micro injection dome and can withstand up to 20 total injections.

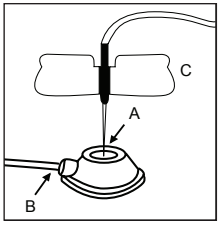

Figure 4: Injection Dome

A - Injection Area; B - Tubing that is connected to the implant; C - butterfly needle [not provided]

Implant Options Available:

1. SILTEX™ Round Becker 25 Expander/Breast Implant
   Gel volume 25 percent nominal implant size
   Cohesive I® (standard) gel filling material

INSTRUCTIONS FOR USE

(For additional information on the Becker Breast Implants refer to **WARNINGS** and **PRECAUTIONS**.)

Testing Procedure for Becker Breast Implants

The device should be tested for patency and shell integrity immediately prior to use. Partially inflate the device with air or saline through the fill tube, taking care not to damage the tube. Visually inspect the device for leakage and for any compromise of the outer shell using firm hand manipulation. Remove any air from the device prior to filling.

Filling and Connection Procedure

1. Prior to inserting the prosthesis into the surgically prepared pocket, deflate the device completely.
2. Fold the prosthesis and insert it into the surgically prepared pocket. (Some surgeons prefer to partially fill the prosthesis prior to placement.) Whatever method is used, evacuation of air from the implant and the fill tube as indicated in Step 1 will minimize the air to be removed in Step 4.
3. Use a syringe filled with **STERILE, PYROGEN-FREE, SODIUM CHLORIDE U.S.P. SOLUTION FOR INJECTION** to inflate the prosthesis to the recommended volume. A luer adapter and check valve have been included to facilitate intraoperative filling of the device, and **must not be implanted** (Figure 5). The enclosed two-way check valve opens when a syringe is attached, and closes when the syringe is removed. Prior to adding fluid to the implant, the two-way check valve should be attached to the luer adapter of the fill tube. **ONLY STERILE, PYROGEN-FREE, SODIUM CHLORIDE U.S.P. SOLUTION FOR INJECTION**, drawn from its original container, should be used.

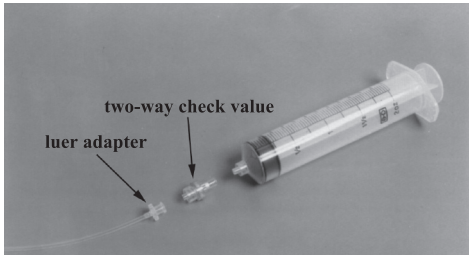

Figure 5: Luer Adapter and Two-Way Check Valve

CAUTION: The prosthesis must not be filled to a volume less than or greater than specified. The prosthesis must be filled to the "Final Volume Range" before removing the fill tube.

4. Entrapped air may be removed by using the attached filling syringe. Any remaining air will eventually diffuse out and be absorbed by tissue.

NOTE: Should adjustment of volume be necessary during surgery, fluid may be added or removed by following Steps 3 and 4.

5. If the device will not be postoperatively adjusted, the fill tube must be removed. The self-sealing valve will close to create the long-term implant.
6. Should postoperative adjustability be desired, connect the fill tube to the injection dome after trimming the fill tube and discarding the luer adapter and check valve. Connect the fill tube to the desired injection dome using one of the connectors supplied with the injection dome (refer to **Connecter and Injection Dome/Filling Port Options**). Care should be taken to tailor the length of the tube so that it will not kink or shorten as the implant expands.

NOTE: If the standard or micro dome with **stainless steel connector** is selected, non-absorbable suture material should be tied around the tube and connector (Figure 3) to secure the connection. It is important to **securely tie the fill tube both distally and proximally to the connector** so the entire filling port assembly (fill tube and filling port/injection dome) will be removed from the patient. Care must be taken to secure the tube to the connector with ligatures in such a manner as to avoid cutting or occluding the tube or connector. (Further detail is provided in the 'Injection Domes with Connection Systems' instructions located in the connector and dome package.)

Once the injection dome is connected to the fill tube, the assembly is referred to as the filling port assembly.

CAUTION: Forceps or hemostats to aid in the connection and suture tying process should NOT be used as tube or connector damage may lead to deflation of the device.

NOTE: Instructions for use of the **True-Lock connector** are included in the 'Injection Domes with Connection Systems' instructions located in the connector and dome package. Read the instructions carefully before using this connection system. It is important to securely assemble both sides of the fill tube to the connector so that the entire fill tube will be removed when the injection dome is removed from the patient (for additional information, refer to **WARNINGS** and **PRECAUTIONS**).

It is suggested that the filling port assembly (injection dome and fill tube) be placed high in the subcutaneous tissue adjacent to the device to allow easy identification and access during subsequent filling. A common placement location for the filling port is against the chest wall under the arm; however, other placement locations can be used depending on the surgeon and patient preference.

The dome should be placed no less than three inches from the prosthesis to avoid damage to the device during postoperative filling. Inflation is accomplished by using STERILE, PYROGEN-FREE, SODIUM CHLORIDE U.S.P. SOLUTION FOR INJECTION. Use a 23 gauge (or finer) standard or butterfly needle. Extreme care should be taken to puncture only the center of the top surface of the injection dome at an angle perpendicular ± 30° to the top surface (Figure 6).

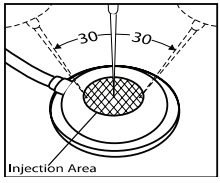

Figure 6: Top of Injection Dome

7. Before closing the surgical incisions, confirm that the device is patent. This can be done by inserting the 23 gauge butterfly needle, with syringe attached, into the injection dome, infusing or withdrawing fluid and observing for proper inflation/deflation of the prosthesis. CAUTION: At the time of wound closure, extreme care should be taken not to damage the prosthesis with surgical instruments. Preplacement of deep sutures may help to avoid inadvertent product contact with suture needles and subsequent product damage.

Postoperative Expansion Procedure

1. Use a syringe filled with STERILE, PYROGEN-FREE, SODIUM CHLORIDE U.S.P. SOLUTION FOR INJECTION, drawn from its original container, to inflate the prosthesis to the recommended volume.
2. The patient must be monitored during the volume adjustment period to guard against sloughing, necrosis, wound dehiscence, and other complications associated with tissue expansion. If at any time the overlying tissue exhibits any of these symptoms, the device should be reduced in volume by reversing the filling procedures and withdrawing fluid from the prosthesis. **If signs persist, the device must be removed**.

(Refer to the additional information under **WARNINGS** and **PRECAUTIONS**)

CAUTION: The Final Expansion Volume should not be less than the minimum recommended volume or greater than the maximum recommended volume. Underfilled prostheses may buckle, fold, or wrinkle causing crease/fold failure of the device and subsequent deflation and/or rupture. Inflation beyond the maximum recommended volume may also cause crease/fold failure or shell rupture.

NOTE: It is recommended that the duration of expansion not exceed six months as tissue adhesions may make it difficult to easily remove the fill tube or compromise valve integrity. Damage to the implant may result. Mentor recommends that periodic volume adjustments are made up through six months based on the specific needs of each patient and the physician's medical judgment. Upon achievement of the desired expansion result, the fill tube and injection dome must be removed.

Removal of Filling Port Assembly (Injection Dome/Filling Port Connected to Fill Tube)

Once expansion is complete, the filling port assembly (injection dome/filling port and fill tube) must be carefully removed from the Becker dual valve system.

NOTE: The implant must be filled to the "Final Volume Range" before removing the filling port assembly. **The tubing must be removed from the implant before separating the injection dome from the tubing**.

a. Make a small incision at the location of the injection dome/filling port.
b. **It is important to grasp the tubing beyond the injection dome and the connector and as close to the implant as possible**. Avoid instrument damage to the fill tube that may result in tube breakage, retraction of the tube into the pocket, and subsequent deflation and/or rupture of the device. The injection dome must remain attached to the fill tube during removal of the fill tube from the implant dual valve system.
c. Place the opposite hand on the adjustable implant to secure it in place while pulling the fill tube.
d. Exert a slow, steady, even force when withdrawing the fill tube. **If the fill tube turns white, relax the tube and re-grasp the fill tube closer to the implant**. Again, exert a slow, steady, even force to withdraw the tube.
e. Gentle massage of the adjustable implant and valve while withdrawing the tube may help facilitate removal. You, or the patient, may feel the implant move in its pocket when the fill tube is withdrawn. This is a normal sensation.

f. The implant dual valve system is designed to self-seal after removal of the tubing.

g. There should be a 'notch' at the end of the tubing that is removed, indicating that it separated at the desired point and is completely removed.

CAUTION: Tissue ingrowth can occur when using the True-Lock connector. Surgeons should anticipate the need to dissect the capsule prior to removing the fill tube and injection dome. Grasp beyond the connector and remove the tube before taking out the injection dome.

(Refer to the additional information under **WARNINGS** and **PRECAUTIONS**)

Recording Procedure for Becker Expander/Breast Implant

Each breast implant is supplied with two Patient Record Labels showing the catalogue number, lot number, and serial number for that device. Patient Record Labels are located on the internal product packaging attached to the label. To complete the Patient ID Card, adhere one Patient Record Label for each implant on the back of the Patient ID Card. The other labels should be attached to the patient's chart. The implanted position (left or right side), date of surgery, and the fill volume (expansion record) of each breast implant should be indicated on the label. If a Patient Record Label is unavailable, the lot number, catalogue number, description of the device may be copied by hand from the device label. In addition, the fill volume (expansion record) should be recorded by hand if the Patient Record Label is unavailable.

INDICATIONS

Mentor MemoryGel® Siltex™ Becker Expander/Breast Implants are indicated for females for the following use (procedure):

- **Breast Reconstruction**. Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the results of a primary breast reconstruction surgery.

CONTRAINDICATIONS

Patient Groups in which the product is contraindicated:

- Women with active infection anywhere in their body.
- Women with existing cancer or pre-cancer who have not received adequate treatment for those conditions.
- Women who are currently pregnant or nursing.

WARNINGS

Breast Implant Associated – Anaplastic Large Cell Lymphoma (BIA-ALCL) – BIA-ALCL is not breast cancer. It is a type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases, it can spread throughout the body. The potential to develop BIA-ALCL must be discussed with your patient pre-operatively as part of your informed decision discussion. Please review detailed information on BIA-ALCL found in the **ADVERSE EVENTS** section of this document.

1. ***Avoiding Implant Damage During Surgery and Medical Treatment or Procedures***

Iatrogenic events inadvertently induced by a physician or surgeon, or by medical treatment or procedures, may contribute to premature implant failure.

- Do not allow sharp instruments, such as scalpels or needles, to contact the device during the implantation or other surgical procedures. Patients should be instructed to inform other treating physicians to observe this warning.
- The technique for inserting a gel device is significantly different than for a saline implant. Ensure that excessive force is not applied to a very small area of the shell during insertion of the device through the incision. Instead, apply force over as large an area of the implant as possible when inserting it. Avoid pushing the device into place with one or two fingers in a localized area, as this may create an area of weakness on the shell.
- An incision should be of appropriate length to accommodate the style, size, and profile of the implant. The incision will be longer than the one typically made for a saline breast augmentation. This will reduce the potential for creating excessive stress to the implant during insertion.
- The anatomical limitations of periareolar and axillary incision sites may make insertion of the implant more difficult, increasing the risk of damage to the implant.
- Avoid creating wrinkles or folds in the device during the implantation or other procedures (e.g., revision surgery). A typical practice is to run your finger around the implant before closing to ensure the implant is lying flat and has no folds or wrinkles. Submuscular placement of the device makes the inspection for wrinkles or folds more difficult.
- Do not treat capsular contracture by closed capsulotomy or forceful external compression, which will likely result in implant damage, rupture, folds, and/or hematoma.
- Use care in subsequent procedures such as open capsulotomy, breast pocket revision, hematoma/seroma aspiration, biopsy, and lumpectomy to avoid damage to the implant shell. Re-positioning of the implant during subsequent procedures should be carefully evaluated by the medical team and care taken to avoid contamination of the implant. Use of excessive force during any subsequent procedure can contribute to localised weakening of the breast implant shell potentially leading to decreased device performance.

- Do not contact the implant with cautery devices.
- Do not immerse the implant in Betadine® solution. If Betadine is used in the pocket, ensure that it is rinsed thoroughly so no residual solution remains in the pocket.
- Do not alter the implants or attempt to repair or insert a damaged implant.
- Do not re-use or resterilize any product that has been previously implanted. Breast implants are intended for single use only.
- Do not place more than one implant per breast pocket.
- Do not use the periumbilical approach to place the implant.
- Do not introduce or make injections of drugs or other substances into the implant. Injections through the implant shell will compromise the product's integrity, causing it to leak while in use and eventually deflate and/or rupture.
- Excessive inflation of the device may result in tissue necrosis/thrombosis.
- Final Expansion Volume should not be less than the minimum recommended volume or more than the maximum recommended volume. Underfilled prostheses may buckle, fold, or wrinkle causing crease/fold failure of the device and subsequent deflation and/or rupture. Inflation beyond the maximum recommended volume may also cause crease/ fold failure or shell rupture.

2. *Microwave Diathermy*

Do not use microwave diathermy in patients with breast implants, as it has been reported to cause tissue necrosis, skin erosion, and implant extrusion.

PRECAUTIONS

1. *Specific Populations*

Safety and effectiveness has not been established in patients with:

- Autoimmune diseases (e.g., lupus and scleroderma).
- A compromised immune system (e.g., currently receiving immunosuppressive therapy).
- Patients with conditions or medications which interfere with wound healing ability (e.g., poorly controlled diabetes or corticosteroid therapy) or blood clotting (such as concurrent coumadin therapy).
- Reduced blood supply to breast or overlying tissue.
- Patients undergoing radiation therapy.
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please advise the patient to discuss any history of mental health disorders with you prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

There may be other patients with complicated medical histories, who in the surgeon's judgment present risk factors such that breast implant safety and effectiveness have not been established. As with all surgery, you should review your patient's medical history to ensure that she is an appropriate candidate for breast implant surgery.

2. *Surgical Precautions*

- **Device integrity** – The device should be tested for patency and shell integrity immediately prior to use. This can be accomplished by gently manipulating the prosthesis with hand and fingers, while carefully examining for rupture or leakage sites.
- **Surgical technique** – The implantation of silicone gel-filled breast implants involves a variety of surgical techniques. Therefore, the surgeon is advised to use the method which her/his own practice and discretion dictate to be best for the patient, consistent with this product insert data sheet. It is advisable to have more than one size breast implant in the operating room at the time of surgery to allow for flexibility in determining the appropriate size implant to be used. A backup implant should also be available.
- **Implant Selection**
  Some of the important surgical and implant sizing variables that have been identified include the following:
  - The implant should be consistent in size with the patient's chest wall dimensions, including base width measurements, bearing in mind the laxity of the tissue and the projection of the implant.
  - A thorough discussion should be conducted with the patient, employing appropriate visual aids such as imaging, sizing implants, or other options to clarify their objectives and reduce the incidence of reoperation for size change.
  - The following may cause implants to be more palpable: textured implants, larger implants, subglandular placement, and an insufficient amount of skin/tissue available to cover the implant.
  - Available tissue must provide adequate coverage of the implant.
  - One report indicates that larger sized implants (>350 cc) may increase the risk of developing complications such as implant extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling requiring surgical intervention to correct these complications[3].
- **Implant Placement Selection**
  - A well-defined, dry pocket of adequate size and symmetry must be created to allow the implant to be placed flat on a smooth surface.

- Submuscular placement may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to perform some reoperation procedures than subglandular placement. The possible benefits of this placement are that it may result in less palpable implants, less likelihood of capsular contracture,[4] and easier imaging of the breast for mammography. Also, submuscular placement may be preferable if the patient has thin or weakened breast tissue.
- Subglandular placement may make surgery and recovery shorter, may be less painful, and may be easier to access for reoperation than the submuscular placement. However, this placement may result in more palpable implants, greater likelihood of capsular contracture, [3, 5] and increased difficulty in imaging the breast with mammography.

- **Maintaining Hemostasis/Avoiding Fluid Accumulation**
  - Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, implantation of the device should be delayed until bleeding is controlled. Postoperative evacuation of hematoma or seroma must be conducted with care to avoid breast implant contamination, or damage from sharp instruments, retraction, or needles.
- **Recording Procedure**
  - Each breast implant is supplied with two Patient Record Labels showing the catalogue number, lot number, and serial number for that device. Patient Record Labels are located on the internal product packaging attached to the label. To complete the Patient ID Card, adhere one Patient Record Label for each implant on the back of the Patient ID Card. The other label should be attached to the patient's chart. The implanted position (left or right side), date of surgery, and the fill volume (expansion record) of each breast implant should be indicated on the label. If a Patient Record Label is unavailable, the lot number, catalogue number, description of the device may be copied by hand from the device label. In addition, the fill volume (expansion record) of each breast implant should be recorded by hand if the Patient Record Label is unavailable.
- **Postoperative Care**
  - You should advise your patient that she will likely feel tired and sore for several days following the operation, and that her breasts may remain swollen and sensitive to physical contact for a month or longer. You should also advise her that she may experience a feeling of tightness in the breast area as her skin adjusts to her new breast size. For at least a couple of weeks, the patient should avoid any strenuous activities that could raise her pulse and blood pressure. She should be able to return to work within a few days. Breast massage exercises may also be recommended as appropriate.
- **Additional Precautions for the SILTEX™ Becker Expander/Breast Implants**
  - The dual self-sealing valve of the Becker Breast Implant family of prostheses is unique and may be unfamiliar to the surgeon. The fill tube is inserted into the prosthesis at the time of manufacture and should be handled carefully to avoid accidental dislodgment from its prepositioned location. Do not hold the device by its fill tube.
  - The silicone elastomer shell, fill tube, and injection dome may be easily cut by a scalpel or ruptured by excessive stress, manipulation with blunt instruments, or penetration by a needle. Subsequent deflation and/or rupture will result. All prostheses should be carefully inspected for structural integrity prior to and during implantation.
  - **When removing the fill tube and injection dome (filling port assembly), the fill tube should be removed first**. Grasp the fill tube beyond the connector to prevent separation of the injection dome from the fill tube. Do not exert sudden or undue tension on the fill tube during removal. Avoid instrument damage to the fill tube which may result in tube breakage, retraction of tube into the pocket, and subsequent deflation and/or rupture of the device.
  - Tissue ingrowth can occur when using the True-Lock connector. Surgeons should anticipate the need to dissect the capsule prior to removing the fill tube and injection dome. Grasp beyond the connector and remove the tube before taking out the injection dome.
  - The tube which connects the implant to the injection dome should be carefully sized to avoid kinks. Careful attachment of the fill tube to the connector is important to prevent separation. Failure of the device to inflate may be due to kinking of the tube, leakage, separation of the components, or injections which do not penetrate the injection dome.
  - Extreme care should be taken when connecting the fill tube to the connector. The tube is easily damaged with surgical instrumentation (e.g., contact with forceps), and their use should be avoided.
  - Surgeons should ensure themselves of the position of the injection dome prior to adding or withdrawing fluid.
  - Potential for contamination exists when fluid is added to or removed from the device. Use aseptic technique in the introduction of saline into the implant; a single-use, sterile saline container is recommended.

IMPORTANT FACTORS TO BE DISCUSSED WITH PATIENTS AS PART OF PHYSICIAN CONSULTATION

Breast implantation is an elective procedure and the patient must be thoroughly counselled on the risks, as well as the benefits, of these products and procedures. You should advise your patient that she must read the patient labelling for reconstruction. You must read the patient labelling in its entirety. The labelling is intended as the primary means to relate uniform risk and benefit information to assist your patient in making an informed decision about primary reconstruction and revision-reconstruction surgery (as applicable), but are not intended to replace consultation with you. The patient should be advised to wait an adequate amount of time (generally between one to two weeks) after reviewing and considering this information, before deciding whether to have this surgery, unless an earlier surgery is deemed medically necessary.

Both you and your patient will be required to sign the "Acknowledgement of Informed Decision" form prior to surgery. The form can be found on the last page of the patient labelling. The form, once signed, acknowledges the patient's full understanding of the information provided in the patient labelling. The form should be retained in the patient's permanent clinical record.

Below are some of the important factors your patients need to be aware of when using silicone gel-filled breast implants. Section 1.4 of the patient labelling provides a more detailed listing of important factors for patients.

Breast Implant Associated – Anaplastic Large Cell Lymphoma (BIA-ALCL) – The potential to develop BIA-ALCL must be discussed with your patient during your informed decision discussion prior to breast surgery. Please review detailed information on BIA-ALCL found in the **ADVERSE EVENTS** section of this document.

- **Rupture** – Rupture of a silicone gel-filled breast implant is most often silent (i.e., there are no symptoms experienced by the patient and no physical sign of changes with the implant) rather than symptomatic. The following six-step process is recommended for screening for silent rupture:
  1. Patient self-examination;
  2. New symptom or sign suspected;
  3. Physician physical examination, related to a periodic review or new symptoms and signs, suggests findings that warrant further investigation;
  4. Ultrasound, mammogram, or both, of the implant and the breast involved should be acquired;
  5. MRI if ultrasound is inconclusive. The MRI should be performed at a centre with a breast coil with a magnet of at least 1.5 Tesla. The MRI should be read by a radiologist who is familiar with looking for implant rupture; and
  6. If signs of rupture are seen on ultrasound, mammogram, and/or MRI, then you should advise your patient to have her implant removed.
- **Explantation** – Implants are not considered lifetime devices, and patients likely will undergo implant removal(s), with or without replacement, over the course of their life. When implants are explanted without replacement, changes to the patient's breasts may be irreversible. Complication rates are higher following revision surgery (removal with replacement).
- **Reoperation** – Additional surgeries to the patients' breasts and/or implants will likely be required, either because of rupture, other complications, or unacceptable cosmetic outcomes. Patients should be advised that their risk of future complications increases with revision surgery as compared to primary reconstruction surgery. There is a risk that implant shell integrity could be compromised inadvertently during reoperation surgery, potentially leading to product failure.
- **Infection** – Signs of acute infection reported in association with breast implants include erythema, tenderness, fluid accumulation, pain, and fever. In rare instances, as with other invasive surgeries, Toxic Shock Syndrome (TSS) has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms of TSS occur suddenly: a high fever (102°F, 38.8°C or higher), vomiting, diarrhoea, a sunburn-like rash, red eyes, dizziness, light-headedness, muscle aches, and drops in blood pressure which may cause fainting. Patients should contact a physician immediately for diagnosis and treatment for any of these symptoms.
- **Breast Examination Techniques** – Patients should perform breast self-examinations monthly and be shown how to distinguish the implant from their breast tissue. The patient should not manipulate or squeeze the implant excessively. The patient should be told that the presence of lumps, persistent pain, swelling, hardening, or change in the implant shape may be signs of symptomatic rupture of the implant. If the patient has any of these signs, they should be told to report them, and possibly have an MRI evaluation to screen for rupture.
- **Mammography** – Patients should be instructed to undergo routine mammography exams as per their primary care physician's recommendations. The importance of having these exams should be emphasized. Patients should be instructed to inform their mammographers about the presence, type, and placement of their implants. Patients should request a diagnostic mammography, rather than a screening mammography, because more pictures are taken with diagnostic mammography. Breast implants may complicate the interpretation of mammographic images by obscuring underlying breast tissue and/or by compressing overlying tissue. Accredited mammography centres, technicians with experience in imaging patients with breast implants, and use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast. The current recommendations for preoperative/screening mammograms are no different for women with breast implants than for those women without implants. Presurgical mammography with a mammogram following the procedure may be performed to establish a baseline for routine future mammography.
- **Lactation** – Breast implant surgery may interfere with the ability to successfully breast feed, either by reducing or eliminating milk production.
- Avoiding Damage During Treatment - Patients should inform other treating physicians of the presence of implants to minimize the risk of damage to the implants.
- **Smoking** – Smoking may interfere with the healing process.
- **Radiation to the Breast** – Mentor has not tested the *in vivo* effects of radiation therapy in patients who have breast implants. The literature suggests that radiation therapy may increase the likelihood of capsular contracture, necrosis, and implant extrusion and, therefore, should be carefully considered when deciding on the course of treatment. The challenge of increased incidence of these complications may be addressed with the right reconstruction techniques.[6,7]

- **Mental Health and Elective Surgery** – It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Request that your patient openly discuss with you, prior to surgery, any history that she may have of depression or other mental health disorders.
- **Long-Term Effects** – Mentor will continue its MemoryGel® Round Gel and Contour Profile Gel (CPG) Core Studies through 10 years and the ongoing Product Availability (Adjunct) Study (refer to specific clinical study sections in brochure for more details). In addition, Mentor has undertaken a separate 10-year postapproval study in the U.S. and Canada to address specific issues for which the Round Gel Core Study was not designed to fully answer, as well as to provide a real-world assessment of some endpoints. The endpoints in the large postapproval study include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and results. Mentor will update its labelling as appropriate with the results of its clinical studies. It is also important for you to relay any new safety information to your patients as it becomes available.

MENTOR CLINICAL STUDIES

The safety and effectiveness of Mentor's MemoryGel® silicone gel-filled implants have been evaluated in open- label multicentre clinical studies, referred to as the Round Gel Core Study and the Contour Profile Gel Core Study. In addition, the safety of MemoryGel® Round Breast Implants and Becker Round Expander/Breast Implants has been studied in the large Mentor Product Availability (Adjunct) Study.

The rates of adverse events reported in the Mentor clinical studies are presented in the following section. Overall, the results of the Round Gel Core Study, CPG Core Study, and the Product Availability (Adjunct) Study demonstrate that these devices are safe and effective for breast reconstruction patients. The rates for complications reported in the Core Studies are generally comparable to or lower than those reported in the Product Availability (Adjunct) Study.

Due to the differences in study design and data analysis, it is difficult to draw conclusions from comparisons of complication rates in the Core and Product Availability (Adjunct) studies. The Product Availability (Adjunct) Study is being accomplished under a limited clinical protocol in which specific parameters are required but with controls somewhat less stringent than those normally required in Investigational Device Exemption Trials (i.e., "Core" studies). The following may contribute to complication rate differences:

- The patient study visit schedules and case report forms are different among studies.
- Mild occurrences of asymmetry, breast pain, nipple sensation changes, and wrinkling were excluded from the Core study complication rates presented in this brochure.
- Becker patients are one-stage reconstruction patients and experience additional complications associated with an expansion phase as well as the presence of a breast implant.

Because the entire MemoryGel® breast implant family, including the Becker, shares identical raw materials and the reconstruction indication, the clinical data presented in this brochure provide an overall safety and efficacy profile for all MemoryGel® breast implants.

ADVERSE EVENTS

The Becker implants have a long history of use worldwide and the Becker Round devices have been studied for safety for over 16 years in the ongoing U.S. FDA-approved Product Availability (Adjunct) Clinical Study. No serious, unanticipated adverse device effects have been reported. The complications reported are consistent with the type of complications reported in other gel-filled breast implants studies.

Clinical evidence demonstrating the Becker is safe and effective for breast reconstruction is also reported in the published literature.[7,8,9,10,11,12] These published studies showed lower or comparable complication rates for the Becker as compared to alternative breast implants as well as a high rate of patient satisfaction. In addition, Guay and Haykal[13] have reported on the benefits of using the Becker for delayed single-stage breast reconstruction.

Complications associated with the Becker expander/implant are consistent with the type of complications associated with other single-stage expander/implants, 2-stage tissue expanders with implants, and autologous tissue reconstructions. Based on the literature, the capsular contracture rate for Becker permanent expander/ implants (3-29%) is comparable to rates observed with 2-stage reconstructions (10-29%).[14,15] When compared to autologous breast reconstructions (i.e. TRAM Flap), procedural complications such as abdominal hernia, flap necrosis, and donor site cosmesis are avoided in single-stage Becker reconstructions. Good aesthetic results with low complication rates have been observed using single-stage expander/implants, although patient selection and a well-dissected submuscular pocket play an important role.[16] Becker combined with autologous flap reconstructions can obtain good aesthetic results in patients receiving adjuvant therapy, by using a large flap without redundant skin and close follow-up during and after chemotherapy and radiation therapy.[15]

Below is a description of potential adverse events that may occur with silicone gel-filled breast implant. For specific adverse event rates/ outcomes for Mentor implants, refer to the clinical trial study sections in this brochure. The rates of adverse events reported in these sections are from clinical studies on the use of MemoryGel® Round, CPG, and Becker Round devices. Because the entire Memory Gel breast implant family, including the Becker, shares identical raw materials and the reconstruction indication, these clinical data provide an overall safety and efficacy profile for all MemoryGel® breast implants.

Potential adverse events that may occur with silicone gel-filled breast implant surgery include the following: implant rupture, capsular contracture, reoperation, implant removal, pain, changes in nipple and breast sensation, infection, scarring, asymmetry, wrinkling, implant displacement/ migration, implant palpability/visibility, breast feeding complications, hematoma/seroma, implant extrusion, necrosis, delayed wound healing, breast tissue atrophy/chest wall deformity, calcium deposits, and lymphadenopathy.

The rates of adverse events reported in these sections are from published literature and Mentor's clinical studies on the use of MemoryGel® Round, CPG, and Becker Expander/Breast Implant devices.

- **Rupture**

Breast implants are not lifetime devices. Breast implants rupture when the shell develops a tear or hole. Rupture can occur at any time after implantation, but rupture is more likely to occur the longer the implant is implanted.

Silicone gel-filled implant ruptures are most often silent. This means that most of the time neither you nor your patient will know if the implant has a tear or hole in the shell. However, sometimes there are symptoms associated with gel implant rupture. These symptoms include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.

The following things may cause implants to rupture: damage by surgical instruments, stressing the implant during implantation and weakening it, folding or wrinkling of the implant shell, excessive force to the chest (e.g., during closed capsulotomy; refer to WARNINGS), trauma, compression during mammographic imaging, and severe capsular contracture. Breast implants may also simply wear out over time. Laboratory studies have identified some of the types of rupture for Mentor's product; however, it is not conclusively known whether these tests have identified all causes of rupture. These laboratory studies are continuing postapproval.

As a note, supplemental safety information was also obtained from the U.K. Sharpe/Collis Study and the literature to help assess long-term rupture rate and the consequences of rupture. The literature, which had the most available information on the consequences of rupture, was also used to assess other potential complications associated with silicone gel-filled breast implants. The key literature information is referenced in this document.

Rupture - Round Gel Core Study

Mentor's Round Gel Core Study had 251 women undergoing primary breast reconstruction and 60 women undergoing revision-reconstruction. Of the 251 primary reconstruction patients, 134 were enrolled in the MRI sub- study, of which 97 underwent MRI screening for silent rupture at 4 years. The rupture rate was 3.1% in primary reconstruction patients through 4 years. There was 1 patient with a suspected rupture by MRI who died. There were 2 patients with suspected ruptures by MRI that were confirmed to be intact on explant in the reconstruction group. Of the 60 revision-reconstruction patients, 28 were patients enrolled in the MRI sub-study, of which 18 underwent MRI screening. The rupture rate was 0% in revision-reconstruction patients through 4 years. There were no confirmed ruptures in patients outside the MRI sub-study. The Round Gel Core Study is currently ongoing, with a total of 10 years of follow-up planned to help determine the long-term rupture rate for Mentor implants. Further information on the estimated incidence rate of rupture for MemoryGel® implants is provided by a limited set of long-term follow-up data from an MRI study in the U.K. (Sharpe and Collis). In this study, textured MemoryGel® implants placed subglandularly in 101 patients by a single physician, with follow-up of 4-12 years, were evaluated for rupture status by MRI with confirmation by explantation. Based on their results, at 12 years, the estimated cumulative rate of silent ruptures is 15% for the patients and 9% for implants. By implant, at 12 years, the cumulative rate of 9% is the best statistical estimate, and 19% is a worst case statistical estimate. By patient, at 12 years, the cumulative rate of 15.1% is the best statistical estimate, and 24.5% is the worst case statistical estimate. These data are consistent with a published MRI-based rupture study of current silicone gel-filled breast implants from a variety of manufacturers.[17]

Rupture - CPG Core Study

Mentor's CPG Core Study had 191 women undergoing primary breast reconstruction and 68 women undergoing revision-reconstruction. There were no ruptures reported in the MRI or non-MRI cohorts for either the primary reconstruction or revision-reconstruction patients through 3 years. Of the 191 primary reconstruction patients, 74 were enrolled in the MRI sub-study, of which 56 underwent MRI screening for silent rupture at 2 years. For primary reconstruction patients in the MRI cohort, the rupture rate was 0% through 3 years. Of the 68 revision-reconstruction patients, 37 were enrolled in the MRI sub-study, of which 31 underwent MRI screening at 2 years. For the 37 revision-reconstruction patients, the rupture rate was 0% through 3 years. The CPG Core Study is currently ongoing, with a total of 10 years of follow-up planned to help determine the long-term rupture rate for Mentor implants.

Rupture- Product Availability (Adjunct) Study

The MemoryGel® Round and Becker Round implants have been studied for safety for over 16 years in the ongoing U.S. FDA-approved Product Availability (Adjunct) Clinical Study. The study includes 9,227 primary reconstruction and 3,008 revision-reconstruction patients implanted with Becker devices, and 57,828 primary reconstruction and 18,491 revision-reconstruction patients implanted with the MemoryGel® Round devices. Each patient is followed for 5 years.

Becker Round

Through 5 years, 8% of primary reconstruction patients and 10% of revision-reconstruction patients experienced a rupture.

MemoryGel® Round

Through 5 years, 3% of primary reconstruction patients and 5% of revision-reconstruction patients experienced a rupture.

Health Consequences of Rupture

If rupture occurs, silicone gel may either remain within the scar tissue capsule surrounding the implant (intracapsular rupture), move outside the capsule (extracapsular rupture), or gel may move beyond the breast (migrated gel). No confirmed cases of extracapsular rupture of Mentor's Round or CPG MemoryGel® breast implants were observed in Mentor's Round Gel and CPG Core Studies, or in a limited, long-term follow-up study from the U.K. (Sharpe & Collis) of Mentor's MemoryGel® devices.

Studies of Danish women evaluated with MRI involving a variety of manufacturers and implant models showed that about three-fourths of implant ruptures are intracapsular and the remaining one-fourth is extracapsular.18 Extracapsular ruptures appear largely to be the result of closed capsulotomy (refer to WARNINGS) and/or trauma to the chest area. For example, there was a significantly higher prevalence of extracapsular ruptures (14.7%) in these Danish women who had undergone closed capsulotomy as compared to those who had not.[18] In a study of British women, one patient observed to have severe bilateral silicone granulomas and bilateral extracapsular ruptures suffered a fractured sternum in a traffic accident.[19]

There is a possibility that rupture may progress from intracapsular to extracapsular and beyond. Studies of Danish women indicate that over a 2-year period, about 10% of the implants with intracapsular rupture progressed to extracapsular rupture as detected by MRI.[20] Approximately half of the women whose ruptures had progressed from intra- to extracapsular reported that they experienced trauma to the affected breast during this time period or had undergone mammography. In the other half, no cause was given. In the women with extracapsular rupture, after 2 years, the amount of silicone seepage outside the scar tissue capsule increased for about 14% of these women. This type of information pertains to a variety of silicone implants, from a variety of manufacturers and implant models, and is not specific to Mentor's implants.

The health consequences of implant rupture have not been fully established. There have been rare reports of gel movement to nearby tissues such as the chest wall, armpit, or upper abdominal wall, and to more distant locations down the arm or into the groin. This has led to nerve damage, granuloma formation and/or breakdown of tissues in direct contact with the gel in a few cases. There have been reports of silicone presence in the liver of patients with silicone breast implants. Movement of silicone gel material to lymph nodes in the axilla also has been reported, even in women without evidence of rupture, leading to lymphadenopathy, as discussed below.[21] These reports were in women who had implants from a variety of manufacturers and implant models.

Local breast complications reported in the published literature that were associated with rupture include breast hardness, a change in breast shape or size, and breast pain.[20] These symptoms are not specific to rupture, as they also are experienced by women who have capsular contracture. Most of the Danish women evaluated in these studies, whose ruptured implants were left in place for two years, reported no symptoms.

Concerns have been raised over whether ruptured implants are associated with the development of connective tissue or rheumatic diseases and/or symptoms such as fatigue and fibromyalgia.[22,23,24,25] A number of epidemiology studies have evaluated large populations of women with breast implants from a variety of manufacturers and implant models. These studies do not, taken together, support an association of breast implants and a diagnosed rheumatic disease.[26] Other than one small study,[24] these studies do not distinguish whether the women had ruptured or intact implants.

The autoantibody status of 64 Danish women who had at least 1 ruptured implant according to MRI evaluation was compared to 98 Danish women who had intact implants.[20] Blood samples were obtained to measure antinuclear antibodies, rheumatoid factor, and cardiolipin immunoglobulin G and M antibodies, which are all used to assess the presence of autoimmune disease. There was no increase in any of these autoantibodies in the women with ruptured implants as compared to those with intact implants, and women whose ruptures progressed from intracapsular to extracapsular over a period of 2 years did not have progression of autoantibody production. In fact, a number of women who had measurable levels of 1 or more antibodies 2 years prior to this evaluation no longer had measurable levels at the subsequent examination.

When MRI findings of rupture are found (such as subcapsular lines, characteristic folded wavy lines, teardrop sign, keyhole sign, or noose sign), or if there are signs or symptoms of rupture, you should remove the implant and any gel you determine your patient has, with or without replacement of the implant. It also may be necessary to remove the tissue capsule, as well as the implant, which will involve additional surgery, with associated costs. If your patient has symptoms, such as breast hardness, a change in breast shape or size, and/or breast pain, you should recommend that she has an MRI to determine whether rupture is present.[4,20]

- **Capsular Contracture**

The scar tissue (capsule) that normally forms around the implant may tighten over time and compress the implant, making it feel firm and leading to what is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in patients undergoing revision surgery than in patients undergoing primary implantation surgery. Capsular contracture is a risk factor for implant rupture, and it is one of the most common reasons for reoperation in reconstruction patients.

Symptoms of capsular contracture range from mild firmness and mild discomfort to severe pain, distorted shape of the implant, and palpability (ability to feel the implant). Capsular contracture is graded into 4 levels depending on its severity. Baker Grades III or IV are considered severe and often additional surgery is needed to correct these grades:

Baker Grade I:	the breast is normally soft and looks natural
Baker Grade II:	the breast is a little firm but looks normal
Baker Grade III:	the breast is firm and looks abnormal
Baker Grade IV:	the breast is hard, painful, and looks abnormal

Capsular Contracture - Round Gel Core Study

In Mentor's Round Gel Core Study, the risk of capsular contracture Baker Grades III/IV through 4 years was 10.1% for primary reconstruction and 19.7% for revision-reconstruction.

Capsular Contracture - CPG Core Study

In Mentor's CPG Core Study, the risk of capsular contracture Baker Grades III/IV through 3 years was 6.0% for primary reconstruction and 15.9% for revision-reconstruction.

Capsular Contracture - Product Availability (Adjunct) Study

Becker Round

Through 5 years, 12% of primary reconstruction patients and 13% of revision-reconstruction patients experienced capsular contracture Baker Grades III/IV.

Percentage of capsular contracture in the literature for single-stage permanent expander/implants varies from 0 to 29%.[2,7,8,10,11,12,16,27,28,29] This is comparable to the 10-29% rate observed for classical 2-stage tissue expander reconstruction.[30,31]

MemoryGel® Round

Through 5 years, 8% of primary reconstruction patients and 11% of revision-reconstruction patients experienced capsular contracture Baker Grades III/IV.

Patients should also be advised that additional surgery may be needed in cases where pain and/or firmness are severe. This surgery ranges from removal of the implant capsule tissue to removal and possible replacement of the implant itself. This surgery may result in loss of breast tissue. Capsular contracture may happen again after these additional surgeries. Capsular contracture may increase the risk of rupture.[4]

- **Reoperation**

The patient should assume that she will need to have additional surgeries (reoperations). Patients may decide to change the size or type of their implants, requiring a reoperation, or they may have a reoperation to improve or correct their outcome.

Reoperation - Round Gel Core Study

The risk rate of reoperation at least 1 time through 4 years was 31.2% for primary reconstruction and 32.8% for revision-reconstruction. Problems, such as, but not limited to, rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional surgery. Summary tables are provided in the Mentor Round Gel Core Study section that describes the reasons for reoperation during the first 4 years after receiving the implants.

Reoperation - CPG Core Study

The risk of reoperation at least 1 time through 3 years was 34.6% for primary reconstruction and 24.3% for revision-reconstruction. Problems, such as, but not limited to, rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional surgery. Summary tables are provided in the Mentor CPG Core Study section that describes the reasons for reoperation during the first 3 years after receiving the implants.

Reoperation - Product Availability (Adjunct) Study

Becker Round

Through 5 years, 18% of primary reconstruction patients and 11% of revision-reconstruction patients experienced reoperation. Due to the Product Availability (Adjunct) Study design, reoperation rates were calculated using only additional surgery data.

MemoryGel® Round

Through 5 years, 7% of primary reconstruction patients and 9% of revision-reconstruction patients experienced reoperation. Due to the Product Availability (Adjunct) Study design, reoperation rates were calculated using only additional surgery data.

- **Implant Removal**

Implant Removal - Round Gel Core Study

Among the 37 (14.7%) women in the primary reconstruction cohort who had an explanation, the most frequently reported reasons for explantation through 3 years were patient request for style/size change, asymmetry, and capsular contracture. Among the 10 (16.7%) women in the revision-reconstruction cohort who had an explanation, the most frequently reported reasons for explantation through 3 years were capsular contracture, asymmetry, patient request for style/size change, and symmastia.

Implant Removal - CPG Core Study

Among the 26 (13.6%) women in the primary reconstruction cohort who had an explanation, the most frequently reported reasons for explantation through 3 years were asymmetry and patient requested size change. Among the 14 (20.6%) women in the revision-reconstruction cohort who had an explanation, the most frequently reported reasons through 3 years for explantation were asymmetry, wrinkling, and position dissatisfaction.

Implant Removal - Product Availability (Adjunct) Study

Becker Round

Through 5 years, 18% of primary reconstruction patients and 11% of revision-reconstruction patients experienced implant removal.

MemoryGel® Round

Through 5 years, 11% of primary reconstruction patients and 13% of revision-reconstruction patients experienced implant removal.

Most women who have their implants removed, have them replaced with new implants, but some women do not. If patients choose not to replace their implants, they should be advised that they may have cosmetically unacceptable dimpling, puckering, wrinkling, and/or other potentially permanent cosmetic changes of the breast following removal of the implant. Even if a patient has her implants replaced, implant removal may result in loss of breast tissue. Also, implant replacement increases a patient's risk of future complications. For example, the risks of severe capsular contracture double for primary reconstruction patients with implant replacement compared to first time placement. Patients should consider the possibility of having her implants replaced and its consequences when making their decision to have implants.

- **Filling Port Assembly**

A low number of complications related to the filling port assembly have been reported in the Mentor Product Availability (Adjunct) Study of Becker implants, including tubing and connector breakage during removal, migration of injection port, leakage, discomfort, pain, and infection at the injection site.

- **Pain**

Pain of varying intensity and length of time may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain. The surgeon should instruct his or her patient to inform them if there is significant pain or if pain persists.

- **Changes in Nipple and Breast Sensation**

Feeling in the nipple and breast can increase or decrease after implant surgery, and are typically lost after complete mastectomy where the nipple itself is removed, and can be severely lessened by partial mastectomy. Radiation therapy also can significantly reduce sensation in the remaining portions of the breast or chest wall. The placement of breast implants for reconstruction may further lessen the sensation in the remaining skin or breast tissue. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. While some of these changes can be temporary, they can also be permanent, and may affect the patient's sexual response or ability to nurse.

- **Infection**

Infection can occur with any surgery or implant. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. In addition, breast and nipple piercing procedures may increase the possibility of infection. Infections in tissue with an implant present are harder to treat than infections in tissue without an implant. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved. As with many other surgical procedures, in rare instances, Toxic Shock Syndrome has been noted in women after breast implant surgery, and it is a life- threatening condition. Symptoms include sudden fever, vomiting, diarrhoea, fainting, dizziness, and/or sunburn-like rash. Patients should be instructed to contact a doctor immediately for diagnosis and treatment if they have these symptoms.

- **Hematoma/Seroma**

A hematoma is a collection of blood within the space around the implant and a seroma is a build-up of fluid around the implant. Having a hematoma and/or seroma following surgery may result in infection and/or capsular contracture later on. Symptoms from a hematoma or seroma may include swelling, pain, and bruising. If a hematoma or seroma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, some will require surgery, typically involving draining and potentially placing a surgical drain in the wound temporarily for proper healing. A small scar can result from surgical draining. Implant rupture also can occur from surgical draining if there is damage to the implant during the draining procedure.

- **Unsatisfactory Results**

Unsatisfactory results such as wrinkling, asymmetry, implant displacement/migration, incorrect size, implant palpability/visibility, scar deformity, and/or hypertrophic scarring, may occur. Some of these results may cause discomfort. Pre-existing asymmetry may not be entirely correctable by implant surgery. Revision surgery may be recommended to maintain patient satisfaction, but carries additional considerations and risks.

Careful preoperative planning and surgical technique can minimize but not always prevent unsatisfactory results.

- **Breast Feeding Complications**

Breast feeding difficulties have been reported following breast surgery. If you use a periareolar surgical approach, it may further increase the chance of breast feeding difficulties.

- **Calcium Deposits in the Tissue Around the Implant**

Calcium deposits can form in the tissue capsule surrounding the implant. Symptoms may include pain and firmness. Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer. If additional surgery is necessary to examine and/or remove calcifications, this may cause damage to the implants. Calcium deposits also occur in women who undergo breast reduction procedures, in patients who have had hematoma formation, and even in the breasts of women who have not undergone any breast surgery. The occurrence of calcium deposits increases significantly with age.

- **Extrusion**

Extrusion may occur when the wound has not closed or when breast tissue covering the implants weakens. Radiation therapy has been reported to increase the likelihood of extrusion. Extrusion requires additional surgery and possible removal of the implant, which may result in additional scarring and/or loss of breast tissue.

- **Necrosis**

Necrosis may prevent or delay wound healing and require surgical correction, which may result in additional scarring and/or loss of breast tissue. Implant removal may also be necessary. Factors associated with increased necrosis include infection, use of steroids, smoking, chemotherapy, radiation, and excessive heat or cold therapy.

- **Delayed Wound Healing**

Some patients may experience a prolonged wound healing time. Smoking may interfere with the healing process. Delayed wound healing may increase the risk of infection, extrusion, and necrosis. Depending on the type of surgery or the incision, wound healing times may vary.

- **Breast Tissue Atrophy/Chest Wall Deformity**

The pressure of the breast implant may cause breast tissue thinning (with increased implant visibility and palpability) and chest wall deformity. This can occur while implants are still in place or following implant removal without replacement. Either of these conditions may result in additional surgeries and/or unacceptable dimpling/ puckering of the breast.

- **Lymphadenopathy**

Literature reports associate lymphadenopathy with both intact and ruptured silicone breast implants. One study reported that armpit lymph nodes from women with both intact and ruptured silicone gel implants had abnormal tissue reactions, granulomas, and the presence of silicone.[21] These reports were in women who had implants from a variety of manufacturers and implant models.

Other Reported Conditions

There have been reports in the literature of other conditions in women with silicone gel-filled breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. Although no cause and effect relationship has been established between breast implants and the conditions listed below, you should be aware of these reports. Furthermore, there is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants. It should also be noted that the cited references include data from augmentation and/or reconstruction patients, as well as from a variety of manufacturers and implant models.

- **Connective Tissue Disease (CTD)**

Connective tissue diseases include diseases such as lupus, scleroderma, and rheumatoid arthritis. Fibromyalgia is a disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue. There have been a number of published epidemiological studies which have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease. The study size needed to conclusively rule out a smaller risk of connective tissue disease (°‹2) among women with silicone gel-filled breast implants would need to be very large.[4,23,24,25,32,33,34,35,36,37] The published studies taken together show that breast implants are not significantly associated with a risk of developing a typical or defined connective tissue disease.[4,33,34,35] These studies do not distinguish between women with intact and ruptured implants. Only one study evaluated specific connective tissue disease diagnoses and symptoms in women with silent ruptured versus intact implants, but it was too small to rule out a small risk.[24]

- **CTD Signs and Symptoms**

Literature reports have also been made associating silicone breast implants with various rheumatological signs and symptoms such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. Scientific expert panels and

literature reports have found no evidence of a consistent pattern of signs and symptoms in women with silicone breast implants.[4,22,38,39,40] Having these rheumatological signs and symptoms does not necessarily mean that a patient has a connective tissue disease; however, you should advise your patient that she may experience these signs and symptoms after undergoing breast implantation. If a patient has an increase in these signs or symptoms, you should refer your patient to a rheumatologist to determine whether these signs or symptoms are due to a connective tissue disorder or autoimmune disease.

- **Immunotoxicity**

While there is no scientific evidence that silicone can cause hypersensitivity reactions in humans, some animal testing reports in the literature suggest that silicone gel may cause an adjuvant effect. The biological mechanism and clinical significance for these findings in animal models remain unknown.

- **Cancer**

Breast Cancer - Reports in the medical literature indicate that patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer.[41,42,43,44,45] Some reports have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy; however, other reports in the published medical literature indicate that breast implants neither significantly delay breast cancer detection nor adversely affect cancer survival of women with breast implants.[41,45,46,47,48]

Brain cancer - One study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population.[49] The incidence of brain cancer, however, was not significantly increased in women with breast implants when compared to women who had other plastic surgeries. Another recently published review of four large studies in women with cosmetic implants concluded that the evidence does not support an association between brain cancer and breast implants.[50]

Respiratory/lung cancer - One study has reported an increased incidence of respiratory/lung cancer in women with breast implants.[49] Other studies of women in Sweden and Denmark have found that women who get breast implants are more likely to be current smokers than women who get breast reduction surgery or other types of cosmetic surgery.[51,52,53]

Cervical/vulvar cancer - One study has reported an increased incidence of cervical/vulvar cancer in women with breast implants.[49] The cause of this increase is unknown.

Lymphomas, including Breast Implant Associated - Anaplastic large Cell Lymphoma (BIA-ALCL) - Based on information reported to global regulatory agencies and found in medical literature, an association has been identified between breast implants and the development of anaplastic large cell lymphoma (ALCL), a type of non-Hodgkin's lymphoma. Women with breast implants have a very small but increased risk of developing Breast Implant Associated ALCL (BIA-ALCL) in the fluid or scar capsule adjacent to the implant, with documented potential for local, regional, and distant spread of the cancer with mortality reported in rare cases.

BIA-ALCL has been reported globally in patients with an implant history that includes Mentor's and other manufacturers' breast implants with various surface properties, styles, and shapes. Most of the cases in the literature reports describe a history of the use of textured implants. The risk of BIA-ALCL is higher for textured surface breast implants versus smooth surface breast implants. Reports in the medical literature show that high-surface-area textured breast implants are associated with an increased risk of developing BIA-ALCL as compared to low-surface-area textured implants.[54,55,56]

You should consider the possibility of BIA-ALCL when a patient presents with late onset, persistent peri-implant seroma. In some cases, patients presented with capsular contracture or masses adjacent to the breast implant. When testing for BIA-ALCL, collect fresh seroma fluid and representative portions of the capsule, and send to a laboratory with appropriate expertise for pathology tests to rule out ALCL, including immunohistochemistry testing for CD30 and ALK (anaplastic lymphoma kinase). If your patient is diagnosed with peri-implant BIA-ALCL, develop an individualized treatment plan in coordination with a multidisciplinary care team. Because of the small number of cases worldwide, there is no worldwide consensus on the treatment regimen for peri-implant BIA-ALCL. However, the National Comprehensive Cancer Network (NCCN) recommends surgical treatment that includes implant removal and complete capsulectomy ipsilaterally as well as contralaterally, where applicable.

Other cancers - One study has reported an increased incidence of stomach cancer and leukemia in women with breast implants compared to the general population.[49] This increase was not significant when compared to women who had other types of plastic surgeries.

- **Neurological Disease, Signs, and Symptoms**

Some women with breast implants have complained of neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking, or remembering things) or diseases (such as multiple sclerosis), which they believe are related to their implants. A scientific expert panel report found that the evidence for a neurological disease or syndrome caused by or associated with breast implants is insufficient or flawed.[4]

- **Suicide**

In several studies, a higher incidence of suicide was observed in women with breast implants.[57,58,59,60] The reason for the observed increase is unknown, but it was found that women with breast implants had higher rates of hospital admission due to psychiatric causes prior to surgery, as compared with women who had breast reduction or in the general population of Danish women.[58]

- **Effects on Children**

At this time, it is not known if a small amount of silicone may pass through from the breast implant silicone shell into breast milk during breastfeeding. Although there are no current established methods for accurately detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone gel-filled implants when compared to women without implants.[61]

In addition, concerns have been raised regarding potential damaging effects on children born to mothers with implants. Two studies in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery.[62,63] Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding.[64] This author recommended further research on infant health.

- **Potential Health Consequences of Gel Bleed**

Small quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse ("bleed") through an intact implant shell.[4,65] Studies on implants implanted for a long duration have suggested that such bleed may be a contributing factor in the development of capsular contracture4 and lymphadenopathy.[66] Evidence against gel bleed being a significant contributing factor to capsular contracture and other local complications, is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast implants than for saline-filled breast implants. Saline-filled breast implants do not contain silicone gel and, therefore, gel bleed is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in the Mentor implants does not cause toxic reactions when large amounts are administered to test animals. It should also be noted that studies reported in the literature have demonstrated that the low concentration of platinum contained in breast implants is in the zero oxidation (most biocompatible) state.[67,68,69,70] In addition, two separate studies sponsored by Mentor have demonstrated that the low concentration of platinum contained in its breast implants is in the zero oxidation (most biocompatible) state.

Mentor performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact implants into the body. The test method was developed to represent, as closely as possible, conditions in the body surrounding an intact implant. The results indicate that only the LMW silicones D4, D5, and D6, and platinum, bled into the serum in measurable quantities. In total, 4.7 micrograms of these 3 LMW silicones was detected. Platinum levels measured at 4.1 micrograms by 60 days, by which time an equilibrium level was reached and no more platinum was extracted from the device. Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence.

- **Additional Factors to be Considered with SILTEX™ Becker Expander/Breast Implants**

Complications Correlated with Predisposing Factors

An analysis of complication rates and their correlation with potential predisposing factors while using the Becker Expander/Breast Implant in 111 patients (120 implants) was conducted by Camilleri et al.[12] Patients with mastectomy (90), congenital asymmetry (16), acquired asymmetry (3) and implant rupture (2) comprised the study group. Thirty-seven patients were heavy smokers (>20 cigarettes daily) and 28 patients had previously received adjuvant radiotherapy. Becker devices were placed subpectorally (74), using a latissimus dorsi (LD) flap (36), or subglandularly (10). Statistical analysis showed that heavy smoking and previous adjuvant radiotherapy were significant predisposing factors to skin necrosis ($p <= 0.05$).

Significant Baker III or Baker IV capsular contracture was detected in 10 (9%) patients on follow-up. The authors attributed this low rate to the overexpansion process, which inhibits myofibroblast function[12] Furthermore, speed of expansion and degree of overexpansion did not influence capsular contracture rates, similar to that seen with 2-stage reconstruction.[14] The authors concluded that breast reconstruction using the Becker device is a reliable alternative to other reconstructive methods, but good patient selection is essential for satisfactory results.

Eskenazi's review of 322 consecutive breast reconstructions with Mentor's Becker and Spectrum expander/ implants over 14 years showed that it is possible to preserve soft results even with the advent of postoperative radiation therapy.[15] The keys to a soft irradiated breast are to create a large flap without redundant skin and to maintain close follow-up during and after chemotherapy and radiation therapy.

Eskenazi also noted that the forces of motion and gravity greatly influence the short- and long-term results.[15] To achieve symmetry in a single- stage reconstruction, anticipation of these forces must be taken into account. This is the most difficult and subtle factor that influences the surgical learning curve with this technique. Hence, the importance of extra-surgical factors may play a role in the aesthetic complication of asymmetry for single-stage reconstructions. Furthermore, Eskenazi noted that with careful biopsy incision placement and aggressive early debridement of flaps, there was enough skin available for all the reconstructions (i.e. no LD flaps required). This indicates that pre-surgical planning by both the general and plastic surgeons for single-stage reconstructions can greatly influence the depth of the procedure selected and its outcome.

Immediate vs. Delayed Reconstructions - Complications

In a study by Mandrekas et al, results of 19 immediate breast reconstructions versus 25 delayed breast reconstructions with an expander/ implant (Cox-Uphoff, USA) were compared.[71] All patients had a biopsy-proven diagnosis of breast cancer treated by modified or radical mastectomy. Complications occurred in both groups of patients: a total of 15 patients experienced 16 complications. Capsular contracture at 12 months follow-up

(Baker II-IV) was 16% (3 patients) and 28% (7 patients) in the immediate and delayed groups, respectively. A Mantel-Haenszel test showed a non-significant result (p=0.46) demonstrating there was no difference in the severity of capsular contracture according to the Baker classification between the 2 groups. This observation was limited to this small sample size; the authors postulate that if the sample size was much larger, there would be a detectable difference in capsular contracture being greater for the delayed reconstruction cohort. Overall, 7 (37%) of 19 immediate reconstruction patients experienced complications, and 9 (36%) of 25 in the delayed group had complications. The maximum follow-up in this series was 7 years; the authors considered the aesthetic results to be excellent.

MENTOR ROUND GEL CORE STUDY

The safety and effectiveness of Mentor's Round silicone gel-filled implants were evaluated in an open-label multicentre clinical study, referred to as the Round Gel Core Study.

As a note, supplemental safety information was also obtained from the U.K. Sharpe/Collis Study and the literature to help assess long-term rupture rate and the consequences of rupture for this product. The literature, which had the most available information on the consequences of rupture, was also used to assess other potential complications associated with silicone gel-filled breast implants. The key literature information is referenced in this document.

Mentor's Round Gel Core Study results indicate that the risk of any complication (including reoperation) at some point through 4 years after implant surgery is 52% for primary reconstruction patients and 55% for revision- reconstruction patients. The information below provides more details about the complications and benefits your patients may experience.

Study Design:

The Round Gel Core Study is a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision (augmentation and reconstruction) patients. The Round Gel Core Study consists of 1,008 patients, including 552 primary augmentation patients, 145 revision- augmentation patients, 251 primary reconstruction patients and 60 revision-reconstruction patients. The following presents the data for the reconstruction subset of patients (primary reconstruction and revision-reconstruction).

Patients' medical histories were collected at baseline. Patient follow-up is at 6 months and annually through 10 years. MRI scans to detect silent rupture of the implant for a subset of patients are scheduled at 1, 2, 4, 6, 8, and 10 years. Safety assessments include complication rates and rates of reoperation. Effectiveness assessments include measures of patients' satisfaction and assessments of quality of life (QoL). The results through 4 years for reconstruction patients are currently being reported, and the study is currently ongoing. Mentor will periodically update this labelling as more information becomes available.

Patient Accounting and Baseline Demographic Profile:

The Round Gel Core Study had 251 primary reconstruction patients and 60 revision-reconstruction patients. The follow-up rates through 4 years for the primary reconstruction and revision-reconstruction patients are 87% and 77%, respectively.

One hundred and thirty-four primary reconstruction patients and 28 revision-reconstruction patients are in the MRI cohort, which means that they are assessed for silent rupture by MRI at years 1, 2, 4, 6, 8, and 10. At this time, MRIs have been performed at years 1, 2 and 4, and the follow- up rates at the 4-year timepoint for the MRI primary reconstruction and revision-reconstruction cohorts were 76% and 64%, respectively.

Demographic information for the Round Gel Core Study:

Reconstruction Cohort

With regard to race, 92% were Caucasian, 3% were African American, and 5% were other. The mean age at surgery was 45 years and 69% were married. Seventy-nine percent had at least some college education.

Revision-Reconstruction Cohort

With regard to race, 93% were Caucasian, 3% were African American, and 4% were other. The mean age at surgery was 51 years and 67% were married. Seventy-five percent had at least some college education.

With respect to surgical baseline factors in the Round Gel Core Study, for primary reconstruction patients, the most frequently used devices were textured surface implants, the most common incision site was the mastectomy scar, and the most frequent site of placement was submuscular. For revision-reconstruction patients, the most frequently used devices were smooth implants, the most common incision site was mastectomy scar, and the most frequent site of placement was submuscular.

Round Gel Core Effectiveness Outcomes:

Effectiveness was assessed by patient satisfaction and quality of life (QoL). Mentor's patient satisfaction was based on a single question of "Would the patient have this breast surgery again?" The QoL measures were the Rosenberg Self Esteem Scale, the Body Esteem Scale, the Tennessee Self Concept Scale (TSCS), the SF-36, and the Functional Living Index of Cancer.

Primary Reconstruction Patients:

For primary reconstruction patients, 155 (62%) out of the original 251 patients were included in the analysis of circumferential chest size at 4 years. Of these 155 patients, the average increase in circumferential chest size was 3.6 centimetres.

At 4 years, 189 (75%) of the 251 patients enrolled answered the patient satisfaction question. Of these 189 patients, 185 (98%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 4 years for primary reconstruction patients, no change was observed in the Functional Living Index of Cancer or the Rosenberg Self Esteem Scale. The Tennessee Self Concept Scale (TSCS) is a survey completed by the patient that evaluates how the patient sees herself and what she does, likes, and feels. There was no change in the overall score for the TSCS. There was no change on the overall score of the Body Esteem Scale. The Chest Score of the Body Esteem Scale significantly improved. The SF-36 is a collection of scales assessing mental and physical health. Seven of the 10 scores were similar postoperatively as compared to preoperatively. After adjusting for the aging effect, none of the 10 scores showed a statistically significant overall mean change from baseline.

Revision-Reconstruction Patients:

For revision-reconstruction patients, 36 (60%) out of the original 60 patients were included in the analysis of circumferential chest size at 4 years. Of these patients, the average increase in circumferential chest size was 3.8 centimetres.

At 4 years, 40 (67%) of the 60 revision-reconstruction patients enrolled answered the patient satisfaction question. Of these 40 patients, 37 (93%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 4 years for revision-reconstruction patients, no change was observed on the Rosenberg Self Esteem Scale or on the Tennessee Self Concept Scale. For the Body Esteem Scale, after adjusting for the aging effect, no significant changes were observed. The Sexual Attractiveness Subscale of the Body Esteem Scale significantly improved over time. The SF-36 is a collection of scales assessing mental and physical health. Although most of the 10 scales showed decreases over time, only 2 scores showed statistically significant overall mean change from baseline after adjusting for the aging effect.

Safety Outcomes - Complications:

Mentor's 10-year Round Gel Core Study is continuing. All patients available for follow-up have been evaluated at the 4-year timepoint. Complications from the primary reconstruction and revision-reconstruction cohorts are provided in Tables 1a and 1b below. Note: Complications are defined as adverse events occurring in connection with the breast implant surgery, breast implants and/or the breast mound, and systemic diseases.

TABLE 1a. Round Gel Core Study: 4-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Primary Reconstruction Cohort

N=251 Patients

Key Complications		CI
Reoperation	31.2	25.7, 37.6
Capsular Contracture Baker Grade III/IV	10.1	6.8, 14.9
Implant Removal with Replacement with Study Device	7.9	5.1, 12.1
Implant Removal with Replacement with Unknown Device	1.1	0.3, 4.2
Implant Removal without Replacement	7.8	4.9, 12.4
Infection	6.2	3.8, 10.0
Rupture[1]	3.1	1.0, 9.5
Complications >1%[2]	**%**	**CI**
Other (Non-cosmetic)[3]	8.3	5.3, 13.0
Asymmetry[4]	7.6	4.8, 12.0
Ptosis	6.3	3.7, 10.7
Hypertrophic Scarring	6.3	3.9, 10.3
Seroma	4.8	2.8, 8.4
Breast mass	4.1	2.2, 7.9

TABLE 1a. Round Gel Core Study: 4-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Primary Reconstruction Cohort (continued)

N=251 Patients

Complications >1%[2]	%	CI
Wrinkling[4]	3.1	1.5, 6.6
Breast Pain[4]	2.2	0.9, 5.1
Recurrent Breast Cancer[5]	2.2	0.9, 5.3
Nipple Sensation Changes[4]	2.1	0.9, 5.1
Implant Malposition/Displacement	2.1	0.9, 5.0
Metastatic disease	1.8	0.7, 4.7
Capsular Contracture Baker Grade II with Surgical Intervention	1.8	0.7, 4.7
Extrusion (intact)	1.6	0.6, 4.3
New Diagnosis of Breast Cancer	1.4	0.5, 4.4
Hematoma	1.3	0.4, 3.9
New Diagnosis of Rheumatic Disease	1.1	0.3, 4.6

[1] There was 1 patient with a suspected ruptures by MRI who died, there were 2 patients with suspected ruptures by MRI that were confirmed to be intact on explant in the reconstruction group at 4 years.

[2] The following complications occurred at a rate less than 1%: breast sensation changes, burning sensation in nipple, capsular contracture secondary to radiation therapy, deep vein thrombosis, delayed wound healing, distant metastasis (sternum, back, and liver), distortion of breast shape not related to capsular contracture, dog ear scars from mastectomy, external injury not related to breast implant, loss of fullness, loss of inframammary fold, lymphadenopathy, muscle spasms, necrosis, nipple complications, occasional burning discomfort of skin, rash, redness, skin lesion, stitch abscess, surgical complications related to technique, tight benelli suture, and wide scars.

[3] Any complication other than ptosis, hypertrophic scarring, asymmetry, or wrinkling.

[4] Mild occurrences were excluded.

[5] The general recurrence rate for breast cancer reported in the medical literature ranges from 5 to 25%.[72,73,74]

TABLE 1b. Round Gel Core Study: 4-Year Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Revision-Reconstruction Cohort

N=60 Patients

Key Complications	%	CI
Reoperation	32.8	22.2, 46.7
Capsular contracture III/IV	19.7	11.4, 32.9
Implant Removal with Replacement with Study Device	8.6	3.7, 19.4
Implant Removal with Replacement with Unknown Device	2.3	0.3, 15.4
Implant Removal without Replacement	7.9	2.9, 20.2
Infection	0	-
Rupture	0	-
Complications >1%	**%**	**CI**
Asymmetry[2]	13.2	6.4, 26.1
Ptosis	7.3	2.8, 18.5
Wrinkling[2]	6.9	2.6, 17.3
Breast mass	5.2	1.7, 15.3

TABLE 1b. Round Gel Core Study: 4-Year Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Revision-Reconstruction Cohort (continued)

N=60 Patients

Complications >1%	%	CI
Implant Malposition/Displacement	5.1	1.7, 15.0
Granuloma	5.0	1.6, 14.7
Surgical Complications Related to Technique	5.1	1.7, 15.1
Nipple Sensation Changes[2]	3.9	1.0, 14.9
Breast Pain[2]	3.4	0.9, 12.9
Hematoma	3.4	0.9, 13.0
New Diagnosis of Rheumatic Disease	3.4	0.9, 12.9
Symmastia	3.4	0.9, 12.8
Indented Scar	2.4	0.4, 16.1
Pain	2.0	0.3, 13.6
Secondary Injury While Moving	1.9	0.3, 12.7
Breast Sensation Changes	1.9	0.3, 12.4
Lack of Projection	1.9	0.3, 12.9
Lack of Definition of Fold	1.9	0.3, 12.4
Nipple Related Unplanned	1.8	0.3, 11.8
Hypertrophic Scarring	1.8	0.3, 11.8
Numbness in Both Hands at Night	1.8	0.3, 11.8
Capsular Contracture II with Surgical Intervention	1.8	0.3, 11.8
Irritated Breast Scars	1.7	0.2, 11.3
Seroma	1.7	0.2, 11.3
Inflammation	1.7	0.2, 11.4
Recurrent Breast Cancer	1.7	0.2, 11.4
New Diagnosis of Breast Cancer	1.7	0.2, 11.4
Delayed Wound Healing	1.7	0.2, 11.3
External Injury Not Related to Breast Implant	1.7	0.2, 11.3
Capsule Tear	1.7	0.2, 11.3
Extrusion (intact)	1.7	0.2, 11.3
Follicular Cyst	1.7	0.2, 11.4

[1] No complications occurred at a rate of <1%.

[2] Mild occurrences were excluded.

Safety Outcomes - Main Reasons for Reoperation:

This section includes the main reasons for reoperation. The rates exclude planned secondary surgeries and reoperations. If more than one reason for the reoperation was reported, the hierarchy used was: rupture/deflation, infection, capsular contracture, necrosis/extrusion, hematoma/seroma, delayed wound healing, breast pain, implant malposition, wrinkling, palpability/visibility, asymmetry, ptosis, scarring, nipple complications, device injury/ iatrogenic, breast cancer mass, biopsy, and patient request for style/size change.

There were 166 additional surgical procedures performed in 92 reoperations involving 75 primary reconstruction patients. The most common reason for reoperation through 4 years was because of asymmetry (20% of 92 reoperations). Table 2a below provides the main reasons for the reoperations following initial implantation that were performed through 4 years for primary reconstruction patients.

TABLE 2a. Main Reasons for Reoperation through 4 Years for Primary Reconstruction Cohort

Reason for Reoperation	n	% (of 92 Reoperations)
Asymmetry	18	19.6
Biopsy	13	14.1
Capsular Contracture Baker Grade II, III, IV	14	15.2
Implant Malposition	8	8.7
Patient Request for Style/Size Change	11	12.0
Infection	4	4.3
Scarring/Hypertrophic Scarring	5	5.4
Ptosis (sagging)	3	3.3
Hematoma/Seroma	3	3.3
Breast Cancer	4	4.3
Extrusion of Intact Implant	2	2.2
Delayed Wound Healing	1	1.1
Breast Pain	3	3.3
Implant Palpability/Visibility	1	1.1
Muscle Spasm	1	1.1
Loss of Fullness	1	1.1
Total	92	100

There were 59 additional surgical procedures performed in 28 reoperations involving 19 revision-reconstruction patients. The most common reason for reoperation through 4 years was because of biopsy (29% of 28 reoperations). Table 2b below provides the main reason for each reoperation following initial implantation that was performed through 4 years for revision-reconstruction patients.

TABLE 2b. Main Reasons for Reoperation through 4 Years for Revision-Reconstruction Cohort

Reason for Reoperation	n	% (of 28 Reoperations)
Biopsy	8	28.6
Capsular Contracture Baker Grade III/IV	4	14.3
Implant Malposition	2	7.1
Ptosis (sagging)	2	[1]7.1
Hypertrophic Scarring	2	7.1
Suspected Rupture[1]	1	3.6
Asymmetry	1	3.6
Breast Cancer	1	3.6
Extrusion of Intact Implant	1	3.6
Hematoma/Seroma	1	3.6
Patient Request for Style/Size Change	1	3.6

TABLE 2b. Main Reasons for Reoperation through 4 Years for Revision-Reconstruction Cohort (continued)

Reason for Reoperation	n	% (of 28 Reoperations)
Breast Pain	1	3.6
Wrinkling	1	3.6
Capsular Tear	1	3.6
Palpable Nodule	1	3.6
Total	28	100

[1] The device was removed and found to be intact (not ruptured).

Safety Outcomes - Reasons for Implant Removal:

The main reasons for implant removal among primary reconstruction patients in the Round Gel Core Study over the 4 years are shown in Table 3a below. Of the 251 primary reconstruction patients, there were 37 patients (15%) who had 50 implants removed over the 4 years of follow-up in the Round Gel Core Study. Of the 50 primary reconstruction implants removed, 25 (50%) were replaced. The most common reason for implant removal was patient request (36% of the 50 implants removed) for primary reconstruction patients.

TABLE 3a. Main Reasons for Implant Removal through 4 Years for Primary Reconstruction Cohort

Reasons for Removal	n	% (of 50 Explants)
Patient Request for Style/Size Change	18	36.0
Asymmetry	11	22.0
Capsular Contracture Baker Grade II, III, IV	7	14.0
Implant Malposition	3	6.0
Breast Pain	2	4.0
Extrusion of Intact Implant	2	4.0
Infection	2	4.0
Hematoma	1	2.0
Lack of Projection	1	2.0
Muscle Spasm	1	2.0
Recurrent Breast Cancer	1	2.0
Ptosis	1	2.0
Total	50	100

The main reasons for implant removal among revision-reconstruction patients in the Round Gel Core Study over the 4 years are shown in Table 3b below. Of the 60 revision-reconstruction patients, there were 10 patients (17%) who had 13 implants removed over the 4 years of follow-up in the Round Gel Core Study. Of the 13 implants removed, 7 (54%) were replaced. The most common reason for implant removal was capsular contracture Baker Grade III/IV (31% of the 13 implants removed) for revision-reconstruction patients.

TABLE 3b. Main Reasons for Implant Removal through 4 Years for Revision-Reconstruction Cohort

Reasons for Removal	n	% (of 13 of Explants)
Capsular Contracture Baker Grade III/IV	4	30.8
Asymmetry	2	15.4
Patient Request for Style/Size Change	2	15.4
Symmastia	2	15.4
Breast Pain	1	7.7

TABLE 3b. Main Reasons for Implant Removal through 4 Years for Revision-Reconstruction Cohort (continued)

Reasons for Removal	n	% (of 13 of Explants)
Extrusion of Intact Implants	1	7.7
Pocket Tear	1	7.7
Total	13	100

Other Clinical Data Findings

Below is a summary of clinical findings from Mentor's Round Gel Core Study with regard to connective tissue disease (CTD), CTD signs and symptoms, cancer, lactation complications, reproduction complications, and suicide. These issues, along with other endpoints, are being further evaluated as part of a Mentor postapproval study of patients followed through 10 years.

CTD Diagnoses

Two primary reconstruction patient and two revision-reconstruction patients in the Mentor Round Gel Core Study were reported to have a new diagnosis of CTD according to a rheumatologist. These diagnoses were two cases of fibromyalgia, both at one year, pyoderma gangrenosum at one year, and Morton's Neuroma at three years.

These data should be interpreted with caution because there was no comparison group of similar women without implants.

CTD Signs and Symptoms

Data on over 100 self-reported signs and symptoms, including about 50 self-reported rheumatological symptoms, were collected. Compared to before having the implants, a significant increase was found for joint pain and frequent muscle cramps in the primary reconstruction patients, and an increase in combined pain was found in the revision-reconstruction patients. These increases were not found to be related to simply getting older over time.

The Mentor Round Gel Core Study was not designed to evaluate cause and effect associations because there is no comparison group of women without implants, and because other contributing factors, such as medications and lifestyle/exercise, were not studied. Therefore, it cannot be determined whether these increases were due to the implants or not. However, your patient should be aware that she may experience an increase in these symptoms after receiving breast implants.

Cancer

For primary reconstruction patients, 3 (1.2%) patients had a new diagnosis of breast cancer and 5 (2.0%) patients had a reoccurrence of breast cancer. For revision-reconstruction, 1 (1.7%) patient had a new diagnosis of breast cancer and 1 (1.7%) patient had a recurrence of breast cancer. There were no reports of other cancers, such as brain, respiratory, or cervical/vulvar in any indication.

Lactation Complications

For primary reconstruction patients, the 1 (0.4%) woman who attempted to breastfeed experienced no lactation difficulties. None of the revision- reconstruction patients attempted to breastfeed.

Reproduction Complications

For primary reconstruction patients, 4 (1.6%) patients reported a miscarriage. There were no reports of miscarriage in revision-reconstruction patients.

Suicide

There were no reports of suicide in Mentor's Round Gel Core Study through 4 years.

MENTOR CPG CORE STUDY

The safety and effectiveness of Mentor's MemoryGel® CPG Breast Implant were evaluated in an open-label multicentre clinical study, referred to as the CPG Core Study.

As a note, supplemental safety information was also obtained from the literature to help assess long-term rupture rate and the consequences of rupture for this product. The literature, which had the most available information on the consequences of rupture, was also used to assess other potential complications associated with silicone gel- filled and CPG implants. The key literature is referenced in this document.

Mentor's CPG Core Study results indicate that the risk of any complication or reoperations at some point through 3 years after implant surgery is 48% for primary reconstruction patients and 51% for revision-reconstruction patients. The information below provides more details about the complications and benefits your patients may experience.

Study Design:

The CPG Core Study is a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision (augmentation and

reconstruction) patients. The CPG Core Study consisted of 955 patients, including 572 augmentation patients, 124 revision-augmentation patients, 191 reconstruction patients, and 68 revision- reconstruction patients. The following presents the data for the reconstruction subset of patients (primary reconstruction and revision-reconstruction).

Patients' medical histories were collected at baseline. Patient follow-up is at 10 weeks and annually through 10 years. MRI scans to detect silent rupture of the implant for a subset of patients are scheduled at 1, 2, 4, 6, 8, and 10 years. Safety assessments include complication rates and rates of reoperation. Effectiveness assessments include measures of patients' satisfaction and quality of life. The results through 3 years are currently being reported, and the study is currently ongoing. Mentor will periodically update this labelling as more information becomes available.

Patient Accounting and Baseline Demographic Profile:

The CPG Core Study had 191 reconstruction patients and 68 revision-reconstruction patients. The follow-up rates through 3 years for the primary reconstruction and revision-reconstruction patients are 90% and 89%, respectively Seventy-four primary reconstruction patients and 37 revision-reconstruction patients are in the MRI cohort, which means that they are assessed for silent rupture by MRI at years 1, 2, 4, 6, 8, and 10. At this time, MRIs have been performed at years 1 and 2, and the follow-up rates at the 2- year timepoint for the MRI primary reconstruction and revision-reconstruction cohorts were 81% and 86%, respectively.

Demographic information for the CPG Study:

Reconstruction Cohort

With regard to race, 94% were Caucasian, 5% were African American, and 1% were other. The mean age at surgery was 48 years and 76% were married. Eighty-three percent had some college education.

Revision-Reconstruction Cohort

With regard to race, 97% were Caucasian, 2% were African American, and 1% were other. The mean age at surgery was 53 years and 69% were married. Eighty-one percent had some college education.

With respect to surgical baseline factors in the CPG Core Study, for both the primary reconstruction patients and the revision-reconstruction patients, the most common incision site was the mastectomy scar and submuscular placement was the most frequent site of placement.

CPG Core Study Effectiveness Outcomes:

Effectiveness was assessed by patient satisfaction and body image/self-esteem. Mentor's patient satisfaction was based on a single question of "Would the patient have this breast surgery again?" The body image/self-esteem measurements were the Rosenberg Self Esteem Scale, the Body Esteem Scale, the Tennessee Self Concept Scale (TSCS), the SF-36, and the Breast Evaluation Questionnaire (BEQ).

Primary Reconstruction Patients: For primary reconstruction patients, 150 (79%) out of the original 191 patients were included in the analysis of circumferential chest size at 3 years. Of these 150 patients, the average increase in circumferential chest size was 0.8 centimetres, indicating that the chest mound has been restored.

Mentor's satisfaction assessment was based on a single question of "Would the patient have this breast surgery again?" At 3 years, 158 (83%) out of 191 primary reconstruction patients enrolled answered that question. Of these 158 patients, 148 (94%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years for primary reconstruction patients, no change was observed on Rosenberg Self Esteem Scale or the overall score of the Body Esteem Scale. The Chest Subscale of the Body Esteem Scale significantly improved. The SF-36 is a collection of scales assessing mental and physical health, and there was significant improvement in the Physical Functioning, Mental Health, and Vitality Scales. The Breast Evaluation Questionnaire (BEQ) is a questionnaire developed to access breast satisfaction and quality of life outcomes among breast surgery patients. When asked how satisfied she was with the general appearance of her breasts, the large majority of primary reconstruction patients (75.3%) said they were "very satisfied or somewhat satisfied." For the 3 factors of 1) Comfort when not fully dressed, 2) Comfort when fully dressed, and 3) Satisfaction with breast attributes, there was a significant improvement in the primary reconstruction cohort for all 3 factors.

Revision-Reconstruction Patients: For revision-reconstruction patients, 51 (75%) out of the original 68 patients were included in the analysis of circumferential chest size at 3 years. Of these patients, the average increase in circumferential chest size was 0.8 centimetres.

Mentor's patient satisfaction was based on a single question of "Would the patient have this breast surgery again?" At 3 years, 51 (75%) out of 68 revision-reconstruction patients enrolled answered that question. Of these 51 patients, 48 (94%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years for revision-reconstruction patients, no change was observed on the Rosenberg Self Esteem Scale, the SF-36, or the overall Body Esteem Scale. However, the Chest Subscale of the Body Esteem Scale significantly improved over time. When asked how satisfied she was with the general appearance of her breasts, the majority of revision-reconstruction patients (60.3%) said they were "very satisfied or somewhat satisfied." For the 3 factors of 1) Comfort when not fully dressed, 2) Comfort when fully dressed, and 3) Satisfaction with breast attributes, there was a significant improvement in the revision-reconstruction cohort for all 3 factors.

Safety Outcomes – Complications:

Mentor's 10-year CPG Core Study is continuing. Complications from the primary reconstruction and revision-reconstruction cohorts are provided in Tables 4a and 4b below. Note: Complications are defined as adverse events occurring in connection with the breast implant surgery, breast implants and/or the breast mound, and systemic diseases.

TABLE 4a. CPG Core Study: 3-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Primary Reconstruction Cohort

N=191 Patients

Key Complications	%	CI
Any Reoperation	34.6	28.2, 42.0
Explant without Replacement	7.9	4.8, 13.1
Explant with Replacement with Study Device	6.6	3.8, 11.4
Baker III, IV Capsular Contracture	6.0	3.3, 11.0
Infection	2.2	0.8, 5.8
Implant Rotation	3.5	1.6, 7.6
Rupture	0	-
Non-Cosmetic Complications = 1%[1]		
Baker III Capsular Contracture	5.0	2.5, 9.9
Lack of Projection	4.6	2.3, 9.1
Excess Tissue	3.3	1.5, 7.2
Seroma	2.7	1.1, 6.4
Irritation/Inflammation	2.7	1.1, 6.3
Nipple Sensation Changes[2]	2.3	0.9, 6.1
Scarring	2.3	0.9, 5.9
Patient Dissatisfied with Aesthetic Appearance of Breast	2.2	0.8, 5.7
Baker II Capsular Contracture w/Surgical Intervention	1.7	0.6, 5.3
Recurrent Breast Cancer	1.7	0.5, 5.1
Breast Pain[2]	1.7	0.5, 5.0
Baker IV Capsular Contracture	1.6	0.5, 4.9
Mass/Cyst	1.5	0.4, 6.0
New Diagnosis of Rheumatic Disease	1.1	0.3, 4.4
Loss of Definition of Inframammary Fold	1.1	0.3, 4.3
Delayed Wound Healing[2]	1.0	0.3, 4.1

[1] The following complications occurred at a rate less than 1%: breast mass/cyst not associated with breast implant, breast sensation changes, external injury not related to breast implants, metastatic disease, necrosis, nipple complication, position dissatisfaction, skin blistering, skin lesion, suture complication, swelling (excessive), tightness of skin over implant, wound dehiscence, and wound itching.

[2] Mild occurrences were excluded.

TABLE 4b. CPG Core Study: 3-Year Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Revision-Reconstruction Cohort

N=68 Patients

Key Complications	%	CI
Any Reoperation	24.3	15.7, 36.7
Explant without Replacement	17.6	10.1, 29.5
Baker III, IV Capsular Contracture	15.9	8.5, 28.9
Explant with Replacement with Study Device	4.4	1.4, 13.1
Infection	3.0	0.8, 11.4
Implant Rotation	1.5	0.2, 10.4
Rupture	0	-
Non-Cosmetic Complications = 1%[1]		
Baker III Capsular Contracture	15.9	8.5, 28.9
Lack of Projection	12.7	6.2, 25.1
Patient Dissatisfied with Aesthetic Appearance of Breast	6.3	2.4, 15.9
Position Dissatisfaction[2]	5.0	1.6, 14.8
Seroma	4.6	1.5, 13.5
Palpability-Implant[2]	4.2	1.0, 16.1
Irritation/Inflammation	3.0	0.8, 11.3
Breast Pain[2]	1.9	0.3, 12.9
Excess Tissue	1.6	0.2, 11.1
Metastatic Disease	1.6	0.2, 10.9
Baker II Capsular Contracture w/Surgical Intervention	1.5	0.2, 10.4
Skin Paresthesia	1.5	0.2, 10.4
Tightness of Skin Over Implant	1.5	0.2, 10.4
Recurrent Breast Cancer	1.5	0.2, 10.3
Scarring	1.5	0.2, 10.3
Atrophy of Pectoralis Muscle	1.5	0.2, 10.1
Hematoma	1.5	0.2, 10.0
Swelling (Excessive)	1.5	0.2, 10.0
Erythema	1.5	0.2, 10.0
Loss of Definition of Inframammary Fold	1.5	0.2, 10.0

[1] No complications occurred at a rate of <1%.

[2] Mild occurrences were excluded.

Safety Outcomes - Main Reasons for Reoperation:

This section includes the main reasons for reoperation. The rates exclude planned secondary surgeries and reoperations. If more than one reason for the reoperation was reported, the hierarchy used was: rupture/deflation, suspected rupture, infection, granuloma, irritation/ inflammation, Baker Grade II capsular contracture w/surgical intervention, Baker Grade III capsular contracture, Baker Grade IV capsular contracture, capsular contracture, extrusion, extrusion/necrosis, hematoma, hematoma/seroma, seroma, delayed wound healing, wound dehiscence, breast pain, breast pain not associated with any other complication, implant malposition, implant movement, implant rotation, wrinkling, palpability/visibility of implant, asymmetry, ptosis, hypertrophic scarring, scarring, nipple complication, nipple complications, device injury/iatrogenic, breast cancer, new diagnosis

of breast cancer, new diagnosis of rheumatic disease, specify where indicated, breast mass / cyst not associated with breast implant, mass / cyst, calcification, biopsy, pat dissatisfied with aesthetic appearance of breast, patient request for style/size change, position dissatisfaction, size change-patient request, size change-physician assessment only, lack of projection, excess tissue, loss of definition of inframammary fold, and other.

There were 126 additional surgical procedures performed in 73 reoperations involving 64 primary reconstruction patients. The most common reason for reoperation through 3 years was because of asymmetry (12% of 73 reoperations). Table 5a below provides the main reasons for the reoperations following initial implantation that were performed through 3 years for primary reconstruction patients.

TABLE 5a. Main Reasons for Reoperation through 3 Years for Primary Reconstruction Cohort

Reason for Reoperation	n	% (of 73 Re-operations)
Asymmetry	9	12.3
Excess Tissue	7	9.6
Position Dissatisfaction	6	8.2
Scarring	4	5.5
Patient Requested Size Change	4	5.5
Size Change (Physician Assessment Only)	4	5.5
Wrinkling	4	5.5
Lack of Projection	3	4.1
Implant Rotation	3	4.1
Breast Mass/Cyst Not Associated with Breast Implant	2	2.7
Capsular Contracture III	2	2.7
Capsular Contracture IV	2	2.7
Implant Extrusion	2	2.7
Mass/Cyst	2	2.7
Patient Dissatisfied with Aesthetic Appearance of Breast	2	2.7
Recurrent Breast Cancer	2	2.7
Seroma	2	2.7
Capsular Contracture II with Surgical Intervention	1	1.4
Delayed Wound Healing	1	1.4
Infection	1	1.4
Nipple Complication	1	1.4
Skin Lesion	1	1.4
Reason Unknown	8	11.0
Total	73	100

There were 48 additional surgical procedures performed in 18 reoperations involving 16 revision-reconstruction patients. The most common reason for reoperation through 3 years was wrinkling (17% of 18 reoperations). Table 5b below provides the main reason for each reoperation following initial implantation that was performed through 3 years for revision-reconstruction patients.

TABLE 5b. Main Reasons for Reoperation through 3 Years for Revision-Reconstruction Cohort

Reason for Reoperation	n	% (of 18 Reoperations)
Wrinkling	3	16.7
Asymmetry	2	11.1
Capsular Contracture III	2	11.1
Patient Requested Size Change	2	11.1
Position Dissatisfaction	2	11.1
Capsular Contracture II with Surgical Intervention	1	5.6
Breast Pain	1	5.6
Lack of Projection	1	5.6
Infection	1	5.6
New Diagnosis of Breast Cancer	1	5.6
Patient Dissatisfied with Aesthetic Appearance of Breast	1	5.6
Seroma	1	5.6
Total	18	100

Safety Outcomes - Reasons for Implant Removal:

The main reasons for implant removal among primary reconstruction patients in the Mentor CPG Core Study over the 3 years are shown in Table 6a below. Of the 191 primary reconstruction patients, there were 26 patients (13.6%) who had 34 implants removed over the 3 years of follow-up in the Mentor CPG Core Study. Of the 34 primary reconstruction implants removed, 12 (35%) were replaced. The most common reason for implant removal was asymmetry and patient requested size change (17.6% of the 34 implants removed) for primary reconstruction patients.

TABLE 6a. Main Reasons for Implant Removal through 3 Years for Primary Reconstruction Cohort

Reason for Reoperation	n	% (of 34 Explants)
Asymmetry	6	17.6
Patient Dissatisfied with Aesthetic Appearance of Breast	4	11.8
Patient Requested Size Change	6	17.6
Capsular Contracture III/IV	3	8.8
Size Change (Physician Assessment Only)	4	11.8
Lack of Projection	4	11.8
Wrinkling	3	8.8
Implant Extrusion	1	2.9
Infection	1	2.9
Implant Rotation	1	2.9
Reason Unknown	1	2.9
Total	34	100

The main reasons for implant removal among revision-reconstruction patients in the Mentor CPG Core Study over the 3 years are shown in Table 6b below. Of the 68 revision-reconstruction patients, there were 14 patients (20%) who had 22 implants removed over the 3 years of follow-up in the Mentor CPG Core Study. Of the 22 implants removed, 4 (18%) were replaced. The most common reason for implant removal was asymmetry, position dissatisfaction, and wrinkling (18% of the 22 implants removed) for revision-reconstruction patients.

TABLE 6b. Main Reasons for Implant Removal through 3 Years for Revision-Reconstruction Cohort

Reason for Removal	n	% (of 22 Explants)
Asymmetry	4	18.2
Wrinkling	4	18.2
Position Dissatisfaction	4	18.2
Patient Request for Size Change	2	9.1
Lack of Projection	2	9.1
Infection	1	4.5
New Diagnosis of Breast Cancer	1	4.5
Seroma	1	4.5
Capsular Contracture II with Surgical Intervention	1	4.5
Breast Pain	1	4.5
Patient Dissatisfied with Aesthetic Appearance of Breast	1	4.5
Total	22	100

Other Clinical Data Findings

Below is a summary of clinical findings from Mentor's CPG Core Study with regard to connective tissue disease (CTD), CTD signs and symptoms, cancer, neurological disease, neurological signs and symptoms, lactation complications, reproduction complications, and suicide. These issues, along with other endpoints, are being further evaluated as part of a Mentor Round Gel postapproval study of patients followed through 10 years.

CTD

Two primary reconstruction patients in the Mentor CPG Core Study were reported to have a new diagnosis of CTD according to a rheumatologist. These diagnoses were 1 case of rheumatoid arthritis at 10 months and 1 case of reactive arthritis at 11 months. These data should be interpreted with caution because there was no comparison group of similar women without implants.

CTD Signs and Symptoms

Data on over 100 self-reported signs and symptoms, including about 50 self-reported rheumatological symptoms, were collected. Compared to before having the implants, there were no statistically significant increases or decreases found for primary reconstruction patients and revision-reconstruction patients. The Mentor CPG Core Study was not designed to evaluate cause and effect associations because there is no comparison group of women without implants, and because other contributing factors, such as medications and lifestyle/exercise, were not studied. Therefore, patients should be aware that they may experience an increase in these symptoms after receiving breast implants.

Cancer

For primary reconstruction patients, 3 (1.6%) patients had a diagnosis of recurrent breast cancer and for revision-reconstruction, 1 (1.5%) patient had a diagnosis of recurrent breast cancer. There were no reports of new diagnoses in revision-reconstruction patients and no reports of other new cancers, such as brain, respiratory, or cervical/vulvar in either indication.

Neurological Disease, Signs, and Symptoms

In the Mentor CPG Core Study, data on patient-reported neurological disease and signs and symptoms were collected at each postoperative visit. Examples of neurological symptoms included weakness, numbness of feet, ringing in ears, and fatigue. Investigators also performed a physical exam at each postoperative visit.

Through 3 years, there were no reports of patients with neurological diseases in either indication. Compared to before implantation, no significant increases for neurological signs and symptoms were found in primary reconstruction or revision-reconstruction patients.

Lactation Complications

None of the primary reconstruction or revision-reconstruction patients attempted to breast feed.

Reproduction Complications

There were no reports of miscarriage in Mentor's CPG Core Study through 3 years.

Suicide

There were no reports of suicide in Mentor's CPG Core Study through 3 years.

MENTOR PRODUCT AVAILABILITY (ADJUNCT) STUDY

The Becker Round implants have been studied for safety for over 16 years in the ongoing U.S. FDA-approved Product Availability (Adjunct) Study, designed to collect safety data through 5 years for reconstruction patients. The Product Availability (Adjunct) Study is also collecting safety data on the use of MemoryGel® Round implants. No serious, unanticipated adverse device effects have been reported. The complications that have been reported are consistent with the type of complications associated with other implant studies (refer to the Mentor Clinical Studies section).

Study Design:

The Mentor Product Availability (Adjunct) Study was designed to collect safety data through 5 years on MemoryGel® Round and Becker Round devices. This study is being accomplished under a limited clinical protocol in which specific parameters are required but with controls somewhat less stringent than those normally required in Investigational Device Exemption Trials (i.e., "Core" studies). Objectives of the study are to gather study data regarding short term, post-implant events to supplement the data that is being collected in the more extensive "Core" studies for the MemoryGel® Round and CPG implants. The study includes an enrollment period of 15 years, which began in 1992, and a patient follow-up period of 5 years. Follow-up visits are scheduled at 1, 3 and 5 years post-implantation. Mentor will periodically update this brochure as more information becomes available.

The Mentor Product Availability (Adjunct) Study consists of 9,227 primary reconstruction, 3,008 revision-reconstruction, and 681 revision-augmentation patients implanted with Becker devices, and 57,828 primary reconstruction, 18,491 revision-reconstruction, and 60,290 revision-augmentation patients implanted with MemoryGel® Round devices. The following presents the data for the reconstruction subset of patients (primary reconstruction and revision-reconstruction).

Patient Accounting and Baseline Demographic Profile:

The Mentor Product Availability (Adjunct) Study includes 9,227 primary reconstruction and 3,008 revision-reconstruction implanted with Becker devices, and 57,828 primary reconstruction and 18,491 revision- reconstruction patients implanted with MemoryGel® devices.

Becker Round- Primary Reconstruction Cohort

The follow-up rates through 1, 3, and 5 years for primary reconstruction patients were 54%, 33%, and 21%, respectively.

Becker Round- Revision-Reconstruction Cohort

The follow-up rates through 1, 3, and 5 years for revision-reconstruction patients were 53%, 32%, and 19%, respectively.

MemoryGel® Round- Primary Reconstruction Cohort

The follow-up rates through 1, 3, and 5 years for primary reconstruction patients were 35%, 25%, and 18%, respectively.

MemoryGel® Round- Revision-Reconstruction Cohort

The follow-up rates through 1, 3, and 5 years for revision-reconstruction patients were 39%, 29%, and 19%, respectively.

Demographic information for the Product Availability (Adjunct) Study:

Becker Round - Primary Reconstruction Cohort

With regard to race, 88% were Caucasian, 5% were African American, and 7% were other. The mean age at surgery was 50 years and 68% were married. Seventy-two percent had at least some college education.

Becker Round - Revision-Reconstruction Cohort

With regard to race, 91% were Caucasian, 3% were African American, and 6% were other. The mean age at surgery was 52 years and 67% were married. Seventy-four percent had at least some college education.

MemoryGel® Round - Primary Reconstruction Cohort

With regard to race, 88% were Caucasian, 3% were African American, and 9% were other. The mean age at surgery was 43 years and 64% were married. Eighty percent had at least some college education.

MemoryGel® Round - Revision-Reconstruction Cohort

With regard to race, 91% were Caucasian, 2% were African American, and 6% were other. The mean age at surgery was 50 years and 66% were married. Seventy-seven percent had at least some college education.

Safety Outcomes – Complications:

Mentor's Product Availability (Adjunct) Study is continuing with patient follow-up at 1, 3, and 5 years.

Complications from the Primary reconstruction and revision-reconstruction cohorts are provided in the tables below.

Becker Round

TABLE 7a. Product Availability (Adjunct) Study – Becker Round: Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Primary Reconstruction Cohort

Key Complications[1]	1 Year N=5,465		3 Year N=2,786		5 Year N=1,127	
	%	CI	%	CI	%	CI
Reoperation[2]	8.0	7.3, 8.8	12.6	11.3, 13.9	17.7	15.3, 20.1
Capsular Contracture Baker Grade III/IV	3.8	3.2, 4.4	8.0	6.9, 9.1	12.1	10.0, 14.2
Implant Removal with Replacement	5.0	4.4, 5.6	7.7	6.7,8.8	9.1	7.3, 10.9
Implant Removal without Replacement	2.5	2.1, 3.0	4.7	3.9, 5.6	8.9	7.0, 10.7
Infection	1.3	1.0, 1.7	1.8	1.3, 2.3	2.3	1.4, 3.2
Rupture	1.9	1.5, 2.3	3.8	3.1, 4.6	7.5	5.8, 9.2
Complications >1%[3]					**%**	**CI**
Asymmetry	11.3	10.4, 12.2	24.2	22.5, 26.0	34.6	31.6, 37.6
Breast Pain	3.4	2.9, 4.0	7.8	6.7, 8.9	11.7	9.7, 13.8
Calcification	<1	-	1.0	0.6, 1.4	2.3	1.4, 3.3
Delayed Healing	1.1	0.8, 1.4	1.5	1.0, 1.9	1.4	0.7, 2.1
Extrusion	<1	-	<1	-	1.0	0.4, 1.6
Hypertrophic Scarring	1.4	1.0, 1.7	3.8	3.0, 4.6	5.4	3.9, 6.8
Irritation/Inflammation	1.2	0.8, 1.5	2.2	1.6, 2.7	2.8	1.8, 3.9
Lymphadenopathy	<1	-	<1	-	1.4	0.6, 2.1
Seroma	<1	-	1.3	0.9, 1.8	<1	-
Wrinkling	4.1	3.5, 4.7	11.3	10.0, 12.5	18.3	15.8, 20.8
Other	2.0	1.6, 2.4	3.8	3.0, 4.6	6.1	4.5, 7.6

[1] N=patients who returned for at least 1 postoperative visit

[2] Additional surgeries, excluding procedures performed for planned staged reconstruction (nipple revision, staged reconstruction and flap procedures)

[3] The following complications occurred at a rate less than 1%: hematoma, necrosis

TABLE 7b. Product Availability (Adjunct) Study – Becker Round: Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Revision-Reconstruction Cohort

Key Complications[1]	1 Year N=1,819		3 Year N=980		5 Year N=409	
	%	CI	%	CI	%	CI
Reoperation[2]	5.6	4.5, 6.6	9.4	7.5, 11.3	11.1	7.9, 14.3
Capsular Contracture Baker Grade III/IV	2.3	1.6, 3.1	5.9	4.3, 7.5	12.7	9.1, 16.3
Implant Removal with Replacement	2.8	2.0, 3.6	3.4	2.2, 4.5	6.6	4.0, 9.1
Implant Removal without Replacement	1.6	1.0, 2.2	3.2	2.0, 4.4	4.7	2.4, 7.0
Infection	1.0	0.6, 1.5	1.5	0.7, 2.3	1.6	0.3, 2.8
Rupture	2.1	1.4, 2.7	4.9	3.5, 6.3	10.4	7.1, 13.6

TABLE 7b. Product Availability (Adjunct) Study – Becker Round: Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Revision-Reconstruction Cohort (continued)

Complications >1%[3]	%	CI	%	CI	%	CI
Asymmetry	11.7	10.2, 13.3	27.6	24.6, 30.5	34.2	29.2, 39.2
Breast Pain	3.7	2.8, 4.6	9.4	7.4, 11.3	14.0	10.4, 17.7
Calcification	0.1	0.0, 0.3	1.2	0.4, 1.9	2.0	0.5, 3.6
Delayed Healing	<1	-	1.3	0.6, 2.0	1.3	0.2, 2.5
Hematoma	<1	-	<1	-	1.4	0.2, 2.5
Hypertrophic Scarring	1.0	0.5, 1.5	2.1	1.1, 3.1	2.5	0.9, 4.1
Irritation/Inflammation	1.3	0.8, 1.9	1.7	0.9, 2.6	2.4	0.9, 4.0
Lymphadenopathy	<1	-	<1	-	1.9	0.4, 3.3
Seroma	<1	-	1.4	0.7, 2.2	1.4	0.2, 2.7
Wrinkling	5.0	3.9, 6.1	13.2	10.9, 15.4	17.1	13.2, 21.1
Other	1.6	1.0, 2.2	4.1	2.8, 5.4	4.8	2.5, 7.0

[1] N=patients who returned for at least 1 postoperative visit

[2] Additional surgeries, excluding procedures performed for planned staged reconstruction (nipple revision, staged reconstruction and flap procedures)

[3] The following complications occurred at a rate less than 1%: extrusion, necrosis

MemoryGel® Round

TABLE 7c. Product Availability (Adjunct) Study – MemoryGel® Round: Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Primary Reconstruction Cohort

Key Complications[1]	1 Year N=24,019		3 Year N=10,024		5 Year N=3,635	
	%	CI	%	CI	%	CI
Reoperation[2]	3.1	2.9, 3.3	4.8	4.4, 5.2	6.7	5.9, 7.6
Capsular Contracture Baker Grade III/IV	2.0	1.8, 2.2	5.1	4.6, 5.6	7.5	6.6, 8.5
Implant Removal with Replacement	2.5	2.3, 2.7	4.9	4.4, 5.3	6.7	5.8, 7.5
Implant Removal without Replacement	1.2	1.1, 1.4	2.6	2.2, 2.9	4.2	3.4, 4.9
Infection	0.4	0.3, 0.5	0.7	0.5, 0.9	0.7	0.5, 1.0
Rupture	0.4	0.3, 0.4	1.4	1.2, 1.6	2.9	2.3, 3.5
Complications >1%[3]	**%**	**CI**	**%**	**CI**	**%**	**CI**
Asymmetry	6.8	6.5, 7.2	15.4	14.7, 16.2	23.1	21.7, 24.6
Breast Pain	2.4	2.2, 2.6	6.1	5.6, 6.6	8.9	7.9, 10.0
Delayed Healing	<1	-	<1	-	1.2	0.8, 1.5
Hypertrophic Scarring	1.4	1.3, 1.6	2.9	2.5, 3.2	3.7	3.0, 4.3
Irritation/Inflammation	<1	-	<1	-	1.2	0.8, 1.6
Wrinkling	2.6	2.4, 2.8	7.7	7.2, 8.3	13.4	12.2, 14.6
Other	1.5	1.4, 1.7	2.7	2.4, 3.0	3.6	2.9, 4.3

[1] N=patients who returned for at least 1 postoperative visit

[2] Additional surgeries, excluding procedures performed for planned staged reconstruction (nipple revision, staged reconstruction and flap procedures)

[3] The following complications occurred at a rate less than 1%: calcification, extrusion, hematoma, lymphadenopathy, necrosis, seroma

TABLE 7d. Product Availability (Adjunct) Study – MemoryGel® Round: Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Revision-Reconstruction Cohort

Key Complications[1]	1 Year N=8,980		3 Year N=4,885		5 Year N=2,203	
	%	CI	%	CI	%	CI
Reoperation[2]	3.5	3.1, 3.8	5.8	5.1, 6.4	8.5	7.3, 9.7
Capsular Contracture Baker Grade III/IV	2.9	2.5, 3.2	7.5	6.7, 8.3	11.4	10.0, 12.8
Implant Removal with Replacement	2.8	2.4, 3.1	5.1	4.5, 5.7	7.7	6.5, 8.9
Implant Removal without Replacement	1.6	1.3, 1.8	3.0	2.5, 3.5	5.3	4.3, 6.4
Infection	0.6	0.5, 0.8	0.9	0.7, 1.2	1.3	0.8, 1.8
Rupture	0.7	0.5. 0.9	2.2	1.8, 2.7	5.3	4.2, 6.3
Complications >1%3	**%**	**CI**	**%**	**CI**	**%**	**CI**
Asymmetry	8.9	8.3, 9.5	18.8	17.7, 20.0	25.8	23.8, 27.7
Breast Pain	3.7	3.3, 4.1	8.8	8.0, 9.7	12.6	11.1, 14.1
Calcification	<1	-	<1	-	1.2	0.7, 1.7
Hematoma	<1	-	<1	-	1.3	0.8, 1.8
Hypertrophic Scarring	1.0	0.7, 1.2	2.4	2.0, 2.9	3.0	2.3, 3.8
Irritation/Inflammation	<1	-	1.6	1.2, 1.9	2.4	1.7, 3.1
Seroma	<1	-	<1	-	1.1	0.6, 1.6
Wrinkling	4.6	4.1, 5.0	11.4	10.4, 12.3	17.4	15.7, 19.1
Other	1.8	1.5, 2.0	3.3	2.8, 3.9	4.8	3.8, 5.7

[1] N=patients who returned for at least 1 postoperative visit

[2] Additional surgeries, excluding procedures performed for planned staged reconstruction (nipple revision, staged reconstruction and flap procedures)

[3] The following complications occurred at a rate less than 1%: delayed healing, extrusion, lymphadenopathy, necrosis

Safety Outcomes - Reasons for Implant Removal:

Becker Round

The main reasons for implant removal among primary reconstruction patients were infection (22.8% of explants) and capsular contracture (22.0% of explants).

TABLE 8a. Becker Round: Main Reasons for Implant Removal for Primary Reconstruction Cohort (Years 1 through 16)

Reason	N = 1,591 Explants
Asymmetry	61 (3.8%)
Biopsy	0 (0.0%)
Breast Pain	33 (2.1%)
Cancer/Cancer Treatment	5 (0.3%)
Capsular Contracture	350 (22.0%)
Delayed Wound Healing/Inflammation	36 (2.3%)
Hematoma/Seroma	18 (1.1%)
Infection	363 (22.8%)
Leakage/Rupture/Deflation	230 (14.5%)

TABLE 8a. Becker Round: Main Reasons for Implant Removal for Primary Reconstruction Cohort (Years 1 through 16) (continued)

Reason	N = 1,591 Explants
Migration	2 (0.1%)
Necrosis/Extrusion	58 (3.6%)
Palpability/Visibility	38 (2.4%)
Patient Request/Size and Implant Change	100 (6.3%)
Planned 2nd Stage	0 (0.0%)
Ptosis	0 (0.0%)
Revision/Reconstruction	48 (3.0%)
Scarring	2 (0.1%)
Trauma	0 (0.0%)
Wrinkling/Rippling	26 (1.6%)
Other	49 (3.1%)
Not Available[1]	172 (10.8%)

[1] No information was provided by the physician

The main reasons for implant removal among revision-reconstruction patients were capsular contracture (21.4% of explants) and infection (21.2% of explants), and leakage/rupture/deflation (20.2%).

TABLE 8b. Becker Round: Main Reasons for Implant Removal for Revision-Reconstruction Cohort (Years 1 through 16)

Reason	N = 397 Explants
Asymmetry	4 (1.0%)
Biopsy	0 (0.0%)
Breast Pain	8 (2.0%)
Cancer/Cancer Treatment	1 (0.3%)
Capsular Contracture	85 (21.4%)
Delayed Wound Healing/Inflammation	10 (2.5%)
Hematoma/Seroma	8 (2.0%)
Infection	84 (21.2%)
Leakage/Rupture/Deflation	80 (20.2%)
Migration	0 (0.0%)
Necrosis/Extrusion	3 (0.8%)
Palpability/Visibility	11 (2.8%)
Patient Request/Size and Implant Change	20 (5.0%)
Planned 2nd Stage	1 (0.3%)
Ptosis	1 (0.3%)
Revision/Reconstruction	7 (1.8%)
Scarring	1 (0.3%)
Trauma	0 (0.0%)

TABLE 8b. Becker Round: Main Reasons for Implant Removal for Revision-Reconstruction Cohort (Years 1 through 16) (continued)

Reason	N = 397 Explants
Wrinkling/Rippling	18 (4.5%)
Other	10 (2.5%)
Not Available[1]	45 (11.3%)

[1] No information was provided by the physician

MemoryGel® Round

The main reasons for implant removal among primary reconstruction patients were capsular contracture (37.8% of explants) and infection (13.7% of explants).

TABLE 8c. MemoryGel® Round: Main Reasons for Implant Removal for Primary Reconstruction Cohort (Years 1 through 16)

Reason	N=3,618 Explants
Asymmetry	214 (5.9%)
Biopsy	0 (0.0%)
Breast Pain	55 (1.5%)
Cancer/Cancer Treatment	43 (1.2%)
Capsular Contracture	1369 (37.8%)
Delayed Wound Healing/ Inflammation	54 (1.5%)
Hematoma/Seroma	30 (0.8%)
Infection	497 (13.7%)
Leakage/Rupture/Deflation	289 (8.0%)
Migration	7 (0.2%)
Necrosis/Extrusion	96 (2.7%)
Palpability/Visibility	64 (1.8%)
Patient Request/Size and Implant Change	320 (8.8%)
Planned 2nd Stage	1 (0.0%)
Ptosis	4 (0.1%)
Revision/Reconstruction	44 (1.2%)
Scarring	7 (0.2%)
Trauma	1 (0.0%)
Wrinkling/Rippling	61 (1.7%)
Other	95 (2.6%)
Not Available[1]	367 (10.1%)

[1] No information was provided by the physician

The main reasons for implant removal among revision-reconstruction patients were capsular contracture (37.5% of explants), leakage/rupture/deflation (12.2%), and infection (11.7% of explants).

TABLE 8d. MemoryGel® Round: Main Reasons for Implant Removal for Revision-Reconstruction Cohort (Years 1 through 16)

Reason	N=1,696 Explants
Asymmetry	85 (5.0%)
Biopsy	0 (0.0%)
Breast Pain	42 (2.5%)
Cancer/Cancer Treatment	6 (0.4%)
Capsular Contracture	636 (37.5%)
Delayed Wound Healing/Inflammation	30 (1.8%)
Hematoma/Seroma	21 (1.2%)
Infection	198 (11.7%)
Leakage/Rupture/Deflation	207 (12.2%)
Migration	3 (0.2%)
Necrosis/Extrusion	20 (1.2%)
Palpability/ Visibility	15 (0.9%)
Patient Request/Size and Implant Change	110 (6.5%)
Planned 2nd Stage	0 (0.0%)
Ptosis	2 (0.1%)
Revision/Reconstruction	23 (1.4%)
Scarring	2 (0.1%)
Trauma	0 (0.0%)
Wrinkling/Rippling	36 (2.1%)
Other	52 (3.1%)
Not Available[1]	208 (12.3%)

[1] No information was provided by the physician

Other Clinical Data Findings

The Mentor Product Availability (Adjunct) Study is designed to assess short-term safety complications. Although connective tissue/ rheumatological diseases and symptoms are not a focus of this study, these data were collected at baseline and the 3-year and 5-year postoperative visits. There is no provision on either the baseline form or the postoperative form to indicate whether a rheumatologist was consulted and confirmed a rheumatological syndrome or symptom. Therefore, all connective tissue disease syndromes and symptoms are patient reported.

Becker Round

Rheumatoid arthritis was the most common patient reported rheumatic disease at 1.0%, and fibromyalgia at 0.9% was the most commonly reported rheumatic syndrome for Becker patients in the Mentor Product Availability (Adjunct) Study.

MemoryGel® Round

Rheumatoid arthritis was the most common patient reported rheumatic disease at 0.8%, and fibromyalgia and Raynaud's phenomenon at 0.9% and 0.7%, respectively, were the most commonly reported rheumatic syndrome for MemoryGel® patients in the Mentor Product Availability (Adjunct) Study.

These issues, along with other endpoints, are being further evaluated as part of a Mentor Round Gel post approval study of patients followed through 10 years.

DEVICE IDENTIFICATION CARD

Enclosed with each silicone gel-filled breast implant is a Patient ID Card. To complete the Patient ID Card, place one device identification sticker for each implant on the back of the card. Stickers are located on the internal product packaging attached to the label. If a sticker is unavailable, the lot

number, catalogue number, and description of the device may be copied by hand from the device label. In addition, the fill volume (expansion record) should be recorded by hand if the Patient Record Label is unavailable. Patients should be provided with these cards for personal reference.

RETURNED GOODS AUTHORIZATION

- **Canadian Customers**

Authorization for return of merchandise should be obtained from Mentor, a unit of Johnson & Johnson Medical Products, a division of Johnson & Johnson Inc. Please call +1 (800) 668-6069 or contact your local Mentor sales representative.

Devices may be sent to:
Mentor, a unit of Johnson & Johnson Medical Products, a division of Johnson & Johnson Inc.
200 Whitehall Drive
Markham, Ontario
Canada L3R 0T5

HOW TO REPORT PROBLEMS WITH AN IMPLANT

Mentor requires that any complications or explantation resulting from the use of this device be brought to our immediate attention. Please refer to the Returned Goods Authorization process for instructions and shipping information for return of affected product.

Product Replacement Policy and Limited Warranties

The following is a description of the assistance available from the Mentor Lifetime Product Replacement Policy, and the Mentor Advantage Limited Warranty.

Mentor's Free Lifetime Product Replacement Policy

- Automatically applies to all recipients of Mentor breast implant products.
- Provides that regardless of the age of the implant, when confirmed deflation or rupture occurs, you are eligible for 1 to 2 no charge replacement breast implant products of any size in a similar style.

The **Mentor Advantage** is free of charge to all patients who are implanted with Mentor saline-filled breast or silicone gel-filled implant products. When the limited warranty applies, Mentor provides the following:

- Lifetime product replacement policy*
- 10 years and up to $1200(CAD) financial assistance for operating room, anesthesia, and surgical charges not covered by insurance**
- Free contralateral (opposite side) implant replacement upon surgeon request
- Non-cancellable terms.

With the Mentor Advantage Limited Warranty, it is important for the patient to also maintain her own records to ensure validation of her enrollment.

Products Covered

The Mentor Advantage coverage applies to all Mentor breast implants that are implanted in Canada after May 1, 2005,† provided implants have been:

- Implanted in accordance with the Mentor package insert, current to the date of implantation, and other notifications or instructions published by Mentor; and
- Used by appropriately qualified, licensed surgeons, in accordance with accepted surgical procedures.

Events Covered

The Mentor Advantage coverage applies to the following:

- Deflation due to crease fold failure, patient trauma, or unknown cause
- Loss of valve integrity
- Other loss-of-shell-integrity events also may be covered by this program. Mentor reserves the right to determine if specific, additional, events should be covered.

Events Not Covered

The Mentor Advantage coverage does not apply to the following:

- Removal of intact implants due to capsular contracture, wrinkling, or rippling.
- Loss of implant shell integrity resulting from reoperative procedures, open capsulotomy, or closed compression capsulotomy procedures.
- Removal of intact implants for size alteration.

Filing for Financial Assistance

- To file a Mentor Advantage claim for product replacement and/or financial assistance, the surgeon must contact Mentor, a unit of Johnson & Johnson Medical Products, a division of Johnson & Johnson Inc. prior to replacement surgery.

- For financial assistance claims, a patient-specific Release form will be generated that the patient must sign and return.
- For either replacement or financial assistance claims, the surgeon must send the explanted, decontaminated Mentor breast implant(s) within six months of the date of explantation to:
  Mentor, a unit of Johnson & Johnson Medical Products, a division of Johnson & Johnson Inc. 200 Whitehall Drive Markham, ON Canada L3R 0T5
- Upon receipt, review and approval of the completed claim, including receipt of the explanted product and the patient's completion of a full general release, financial assistance will be issued.

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* Lifetime Product Replacement Policy: Mentor will provide replacement Mentor product of any size in the same or similar style as the originally implanted product free of charge for the lifetime of the patient. Upon surgeon's request, a different implant style maybe selected (subject to a charge of the difference between product list prices). Refer to the Mentor Advantage Limited Warranty for eligibility and program details

** Operating room and anesthesia charges to be given payment priority. In order to qualify for financial assistance, you will need to sign a Release form.

† For breast implants implanted prior to this date, contact Mentor Worldwide for information regarding any applicable warranty terms.

This is a summary of the coverage of the Mentor Advantage Limited Warranty. It is an overview only and not a complete statement of the program. A copy of the complete Mentor Advantage Limited Warranty for saline-filled and silicone gel-filled breast implants may be obtained by writing or calling:

Mentor, a unit of Johnson & Johnson Medical Products, a division of Johnson & Johnson Inc.
200 Whitehall Drive
Markham, ON
Canada L3R 0T5
+1 (800) 668-6069

A copy of the complete programs may also be obtained by going to www.mentorwwllc.com.

THESE ARE LIMITED WARRANTIES ONLY AND ARE SUBJECT TO THE TERMS AND CONDITIONS SET FORTH AND EXPLAINED IN THE APPLICABLE MENTOR LIMITED WARRANTIES. ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS ARE EXCLUDED.

Mentor reserves the right to cancel, change, or modify the terms of the Mentor Advantage coverage. Any such cancellation, change, or modification will not affect the currently stated terms of the Mentor Advantage coverage for those already enrolled.

MENTOR

For customer service call Mentor, a unit of
Johnson & Johnson Medical Products, a division of
Johnson & Johnson Inc., **at** +1 (800) 668-6069
or contact your local Mentor representative.

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DEFINITIONS OF SYMBOLS ON LABELLING:

QTY 1	**Quantity One**
Left Breast	**Left Breast is the location of the implanted breast implant**
Right Breast	**Right Breast is the location of the implanted breast implant**
Date of Implant	**Date of the implant surgery**
Patient Name	**Patient Name**
Surgeon Name	**Surgeon Name**
Address	**Surgeon's Address**
Phone	**Surgeon's Telephone Number**

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