Patient Information Leaflet for Mentor Textured and Smooth Gel Breast Implants

Breast implantation is an elective procedure and you may wish to explore alternatives to breast impanation with your physician. Your physician should counsel you on the risks and benefits of breast implant surgery. If you are considering breast implant surgery with Mentor's Textured or Smooth silicone gel breast implants, you should review the information in this Patient Information Leaflet, associated patient education materials and discuss any questions and concerns you have with your surgeon.

Reasons for Considering Breast Implants

Implants are to be used for the following indications:

- Breast Augmentation – This procedure is performed to increase the size and proportions of a woman's breasts. The European Parliament "recommends that implants in women under 18 years of age should be authorized only on medical grounds."
- Breast Reconstruction – This procedure is performed to restore a woman's breast shape after a mastectomy or injury that resulted in either partial or total loss of the breast(s), or to correct a birth defect.
- Replacement or Revision – This procedure is performed as replacement or revision surgery for patients with previous augmentation or reconstruction with silicone gel-filled or saline-filled implants.

Device Models and Name

Model Numbers	**Textured Breast Implant Description**
354-XXX1; 354-XXX7; 354-4XXX; 354-5XXX	Mentor Siltex Round Gel breast implant Family Cohesive I (Moderate Plus, High, Ultra High profile)
324-4XXX; 324-5XXX; 354-XXX9	Mentor Siltex Round Gel breast implant Family Cohesive II (High, Moderate Profile)
334-0901 to 334-1651 354-0908 to 354-1708	Mentor Siltex Contour Gel breast Implants Cohesive III (Various profiles)
354-1500 to 354-8000	Mentor Siltex Round Becker Gel breast implants Family (Cohesive I)
324-0955 to 324-1605	Mentor Siltex Contour Becker Gel breast implants Family (Cohesive II)
THPX-XXX and TMPX- XXX	Mentor MemoryGel Xtra Siltex breast implants Family
Model Numbers	**Smooth Breast Implants Description**
SHPX-XXX; and SMPX-XXX	Mentor MemoryGel Xtra Smooth Breast Implant Family
310JSP1100 to 310JSP1600; 350-1001BC to 350-8004BC	Mentor Smooth Round Gel breast implant Family (Cohesive I)

Note: XXX represents the different volumes of the implants. For example, model 354-1751 is an implant with a volume of 175cc (cubic centimeters). Family product ranges have been indicated by the use of the word "to". For example, 334-0901 "to" 334-1651 mean all models in this range belong to the same family of breast implants. Your Physician should provide you with the patient implant card containing the model number related to your breast implants. Keep the Patient ID Card provided by your physician (with the style and lot number of your breast implant[s]) to facilitate medical care.

Device Description

All Mentor Textured and Smooth Gel Breast Implants contain silicone gel which is cohesive, meaning the gel stay together. The breast implants are offered with three degrees of cohesive filling material: Cohesive I (standard), Cohesive II (moderate) and Cohesive III (high). The implants come in a variety of shapes and sizes. Breast implants are available with either a smooth or textured surface. Mentor has a textured breast implant surface called SILTEX™. Mentor's gel-filled implants are available with a single silicone shell filled with cohesive silicone gel (MemoryGel) or as expander/breast implants with an inner silicone shell filled with saline and an outer silicone shell filled with cohesive silicone gel (Becker Expander/Gel Implant).

Device Materials

Mentor Textured and Smooth Gel-Filled Breast Implants have been tested according to international standards. Mentor Textured and Smooth Gel breast implants are made of 100% medical implant grade silicone polymers. To date, there are not known manufacturing residuals from gel breast implants that could pose a risk to patients.

Information for Post-Operative Care of Your Implants

Considerations for Mammography

In consultation with your personal physician you may consider establishing a baseline mammogram reference by obtaining mammograms pre-operation and another one six months to one year after implantation.

The implant may interfere with finding breast cancer during mammography and also may make it difficult to perform mammography. Therefore, it is essential that you tell your mammography technologist that you have an implant before the procedure. The technologist can use special techniques to minimize the possibility of rupture and to get the best possible views of the breast tissue. Because the breast is squeezed during mammography, it is possible for an implant to rupture during the procedure. More x-ray views are necessary with these special techniques; therefore, women with breast implants will receive more radiation. However, the benefit of the mammogram in finding cancer outweighs the risk of the additional x-rays.

Magnetic Fields/MRI Compatibility

You should discuss impact to MRI testing with your physician prior to breast implantation. MRI scans may be used to determine if your implant has raptured. MRIs are not suitable for patients that have metal devices in their bodies. If you have a metal device implanted, please advise your physician.

Distinguishing the implant from breast tissue during breast self-examination

You should ask your physician to help you distinguish the implant from your breast tissue. If a biopsy is performed, care must be taken to avoid puncturing the implant.

Capsule Procedures

You should be aware that closed capsulotomy, the practice of forcible squeezing or pressing on the fibrous capsule around the implant to break the scar capsule, is not recommended as this may result in rupture or breakage of the implant.

Radiation

You should be aware that testing has not been done to show the effects of radiation therapy on tissues of patients who have breast implants; however, the literature suggests that radiation therapy may increase the likelihood of experiencing capsular contracture. The decision regarding the use of radiation therapy following breast implantation should be made by your physician and radiation oncologist.

General X-Ray

There are not known risks with having general X-rays and breast implants. You should discuss impact to X-rays exposure with your physician and X-rays technician.

Distinguishing the implant from breast tissue during breast self-examination

You should consult your physician how frequently you should perform breast self-examination. Your physician can show you how to distinguish the breast implant from your breast tissue. If you find any abnormalities during your slef-examinations, you should consult your physician. If a biopsy is performed, care must be taken to avoid puncturing the breast implant.

Warnings and Precautions

In addition to risk related to any type of surgical procedures, there are potential complications specific to breast implant surgery and breast implants, some of these complications are listed below. If you experience any symptoms related to your breast implants, you should consult a health care provider.

- **Rupture.** Breast Implants are not lifetime devices. Rupture (a hole or break in the shell) can occur at any time after implantation, but it is more likely to occur the longer the implanted is implanted. Your implants could rupture without noticing any change in your breasts. In some of these instances even your doctor might not be able to tell that a rupture has occurred, the best way to diagnose a rupture is with an MRI examination. You should discuss MRI screening with your physician.
- **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 revision-reconstruction than in primary reconstruction. Because you may have your initial implants replaced, you should be aware that your risk of capsular contracture increases with revision-reconstruction. Capsular contracture is a risk factor for implant rupture, and it is one of the most common reasons for reoperation.
- **Pain.** Pain of varying intensity and duration may occur and persist following breast implant surgery. Areas where you may experience pain include the breast, chest wall and axilla. In

addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should tell your physician about severe pain.

- **Changes in Nipple and Breast Sensation**. Feeling in the nipple and breast can increase or decrease following breast implantation.
- **Delayed Wound Healing.** In some cases, the incision site fails to heal normally. Infection, radiation, chemotherapy, smoking, diabetes, taking steroids, anti-coagulants, and excessive heat or cold therapy can cause necrosis and delayed wound healing.
- **Dissatisfaction with Cosmetic Results.** Dissatisfying results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, hypertrophic (irregular, raised) scarring, and/or sloshing (with implants containing saline) may occur**.** Careful surgical planning and technique can minimize but not always prevent such results.
- **Inflammation** see Pain and Infection.
- **Ptosis.** Breast sagging as a result of normal ageing, pregnancy, or weight loss.
- **Infection.** Infection is a possible consequence of any kind of surgery. Signs that you have an infection include: skin redness or rash, tenderness or pain, fluid accumulation in or around the breast(s), and fever.
- **Active Infection.** If you have active infections anywhere in your body you should consult your physician before breast implantation.
- **Hematoma/Seroma.** Hematoma is a collection of blood within the space around the implant and seroma is a build up of fluid around the implant**.**
- **Impact to Breastfeeding -** Some women with breast implants have reported difficulty breastfeeding.
- **Extrusion of the implant/Interruption of Wound Healing -** Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin. Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.
- **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 (cancer of the immune system). If you have breast implants, you have a very small, but increased risk of developing Breast Implant Associated ALCL (BIA-ALCL). In most cases, BIA-ALCL is found in the scar tissue (capsule) and fluid near the implant, with documented potential for local, regional, and distant spread of the cancer throughout the body. In the cases that have spread beyond the scar tissue and fluid near the implant, rare cases of death have been reported. Most patients were diagnosed with BIA-ALCL when they sought medical treatment for implant-related symptoms such as swelling, pain, lumps or asymmetry that developed after their initial surgical site were fully healed. In the cases known to US Food and Drug Administration (FDA) to date, BIA-ALCL was diagnosed years after the breast implant was placed.
- 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. Reports in the 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 texture implants. Several journal articles explore the risk factors for BIA-ALCL, including the varied methods used to create surface texture of the implant and the role of biofilm in causing

disease, among others. Mentor is currently undertaking non-clinical testing to further understand these potential risks and their possible association with breast implants.

If you develop swelling or pain around your breast implants, be sure to talk to your health care provider. Your health care provider should consider the possibility of BIA-ALCL if after you have recovered from your breast implant operation, you later notice change in the way your breast looks or feels – including swelling or pain around the implant. If your health care provider suspects BIA-ALCL, they will refer you to an appropriate specialist for evaluation which may involve obtaining fluid and tissue samples around your breast implant. If a diagnosis is confirmed, the doctor will develop an individualized treatment plan for you. If you are diagnosed with BIA-ALCL, the National Comprehensive Cancer Network (NCCN) recommends removing the implant and the surrounding tissue.

- **Necrosis (formation of dead tissue around the implant).** This may prevent wound healing and require surgical correction and/or implant removal.
- **Connective Tissue Disease (CTD), Signs, and Symptoms -** Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature in small numbers of women with implants. A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than in women without implants.
- **Wrinkling of the implant/Dissatisfaction with Cosmetic Results/Asymmetry**
- **Calcium Deposits in the Tissue Around the Implants**

  Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery to biopsy and/or removal of the implants to distinguish them from cancer.
- **Breast Tissue Atrophy/Chest Wall Deformity-** The pressure of the breast implants may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement.
- **Additional Surgeries** - You should understand there is a high chance that you will need to have additional surgery at some point to replace or remove the implant. Also, problems such as rupture, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. Many women decide to have the implants replaced, but some women do not. If you choose not to, you may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant**.**
- **Autoimmune Diseases such as lupus and scleroderma.** If you have these conditions you should consult your physician before breast implantation.
- **Blood coagulation diseases.** If you have conditions that interfere with wound healing and blood clotting, you should consult your physician before breast implantation.
- **Tissue characteristics.** If you have tissue characteristics, which are clinically incompatible with breast implantation (e.g. tissue damage resulting from radiation, inadequate tissue, or compromised vascularity, you should consult your physician before breast implantation.

Expected Device Lifetime and Follow-up

Breast implants are not considered lifetime devices and complications are more likely the longer the implants remain. Although rupture can occur at any time following implantation, a number of studies examining rupture of current generation, single-lumen, round and shaped silicone gel-filled breast implants of various manufacturers over time (using MRI evaluations) have consistently reported similar results indicating the average expected lifetime exceeds 10 years.

The functional life of the device implanted in an individual patient is unknown. It is dependent on

interactions between the patient, physician, the procedure, and the device, and therefore, the performance of devices can vary. The physician is best placed to explain the risks of surgery to the patient based on the physician's previous results. There can be no minimum device lifetime for a specific device in an individual patient.

Follow-up with physician

You should discuss with your physician what post-operative follow-up is needed to care for your breast implants including frequency of self-examination.

Patient ID Card

Enclosed with each gel-filled breast implant is a Patient ID Card. Information specific to the implant, including the product code, serial number, unique device identifier, etc. are included on the implant card as well as within patient records as kept by the health care provider. Your physician should provide you with the patient card containing information to identify the product-specific information related to your breast implants. Keep the Patient ID Card provided by your physician (with the style and lot number of your breast implant[s]) to facilitate medical care.

The Australian Breast Device Registry

(ABDR) is a Commonwealth-funded Monash University-led health initiative that records health data relating to breast device surgery. The registry tracks patient health outcomes, monitors the long-term safety and performance of breast devices and benchmarks the quality of surgery involving breast implants and breast tissue expanders. For more information, please visit https://www.abdr.org.au/patients/

Problem Reporting and Additional Information for Australian and New Zealand Patients

If you wish to report any adverse effects you believe are a result of your implanted medical device, please talk with your physician or report the information to Johnson & Johnson Medical Product Safety Department on: **Email**: RA-JNJAU-Complaint@ITS.JNJ.COM

Reports may also be made directly to the Therapeutic Goods Administration via the website http://www.tga.gov.au/reporting-problems

Or

If you are based in New Zealand, Medsafe via the website https://www.medsafe.govt.nz/regulatory/DevicesNew/9AdverseEvent.asp

This Patient Information Leaflet is available at https://www.jnjmedicaldevices.com/en-AU/patient-information-leaflets.