Patient Information Leaflet for Mentor Smooth Saline 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 Smooth saline-filled breast implants, you are advised to review the information in this Patient Information Leaflet, associated patient education materials and discuss any questions and concerns you have with your physician.

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.
- 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 implants.

Device Models and Name

Model Number	Smooth Saline Breast Implant Description
3501610 to 3501695	Mentor Smooth Saline breast implant family (Moderate Profile)
350-2175 to 350-2800	Mentor Smooth Saline breast implant family (Moderate Plus Profile)
350-3170 to 350-3630	Mentor Smooth Saline breast implant family (High Profile)

Note: Family product ranges have been indicated by the use of the word "to". For example, 350-1610 "to" 334-1695 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

Breast implants come in a variety of shapes and sizes. A saline-filled breast implant is a sac (implant shell) of silicone elastomer (rubber), which is surgically implanted under your chest tissues, and then filled with saline, a saltwater solution, through a valve. The Mentor Smooth Saline-Filled implants has a self-sealing valve located on the front of the implant that is used for filling the device. The implants are available with smooth surface shells.

Device Materials

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

Information for Post-Operative Care of Your Implants

- Vigorous body movement (e.g. physical exercise) or excessive manipulation or trauma in the region of the expander may cause stress to the device and result in subsequent deflation.

- **Interference with 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. With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation. You should inform the health care provider of your implants and care should be taken to avoid deflation of the implant.

- **Breast self-examination**
  You should perform a breast self-examination monthly on your implanted breast. 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.

- **Magnetic Resonance Imaging (MRI)**
  Magnetic Resonance Imaging (MRI) is a commonly accepted and widely used diagnostic medical procedure that can be used in patients with saline breast implants. You should inform your healthcare provider about your implants.

- **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

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.

- **Deflation** - Saline-filled breast implants deflate when the saline solution leaks either through

an unsealed or damaged valve or through a break in the implant shell. Implant deflation can occur immediately or slowly over a period of days and is noticed by loss of size or shape of your breast. Some implants can deflate in the first few months, after several years, or at any time in between. Causes of deflation include damage by surgical instruments during surgery, overfilling or underfilling of the implant with saline solution, capsular contracture, closed capsulotomy, stresses such as trauma or intense physical manipulation, excessive compression during mammographic imaging, umbilical incision placement, and unknown/unexplained reasons. You should also be aware that the breast implant may wear out over time and deflate. Deflated implants require additional surgery to remove and to possibly replace the implant.

- **Capsular Contracture -** The scar tissue or capsule that normally forms around the implant may tighten over time and squeeze/compress the implant, making it feel firm and leading to what is called capsular contracture. Capsular contracture may be more common following infection, hematoma (a collection of blood), and seroma (a build-up of the water portion of the blood). It is also more common with subglandular placement (behind the mammary gland and on top of the chest muscle). Symptoms range from mild firmness and mild discomfort to severe pain, distorted shape, palpability of the implant, and/or movement of the implant. Additional surgery is needed in cases where pain and/or firmness is severe. This surgery ranges from removal of the implant capsule tissue to removal and possibly replacement of the implant itself. Capsular contracture may happen again after these additional surgeries
- **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.

- **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.

- **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 buildup 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) –** If you have breast implants, you have a very small, but increased risk of developing BIA-ALCL, a rare 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. 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. 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.

  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 deflation, 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. Patients should be advised that they will likely undergo implant removal with or without replacement over the course of the patient's life. Mentor has completed a 10-year study of its Saline-filled Breast Implants. Based on study data available from the Mentor Saline Breast Implant Study, it is estimated that between 22% and 28% of augmentation patients and between 27% and 39% of reconstruction patients will experience implant deflation 10 years after placement of the implants.

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.

Patient ID Card

Enclosed with each saline-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, it 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.