Patient Information Leaflet for Mentor CPX 4 Textured Breast Tissue Expanders

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 reconstruction surgery. If you are considering breast reconstruction with a Mentor CPX4 Textured Breast Tissue Expander, you are advised to review the information in this Patient Information Leaflet and discuss any questions and concerns you have with your physician.

Device Models and Name

Model Number	CPX 4 Mentor Textured Tissue Expander Description
3548111 to 3548116	Mentor CPX4 Low Height Breast Tissue Expander
3548211 to 3548216	Mentor CPX4 Medium Height Breast Tissue Expander
3548311 to 3548317	Mentor CPX4 Tall Height Breast Tissue Expander
3549111 to 3549116	Mentor CPX4 with Suture Tabs, Low Height Breast Tissue Expander
3549211 to 3549216	Mentor CPX4 with Suture Tabs, Medium Height Breast Tissue Expander
3549311 to 3549317	Mentor CPX4 with Suture Tabs, Tall Height Breast Tissue Expander

Note: Family product ranges have been indicated by the use of the word "to". For example, 3548111 "to" 3548116 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

The MENTOR CPX4 Textured Breast Tissue Expander is a sac (implant shell) of silicone elastomer (rubber), which is surgically implanted under your chest tissues. After the implantation surgery, the expander is gradually filled with saline, a saltwater solution, through the injection dome. A magnetic accessory (CENTERSCOPE Magnetic Injection Port Locator) can be used by your physician to locate the port to inject saline into the expander during office visits.

The filled tissue expander creates a pocket suitably sized and shaped to later receive a long-term breast implant after the Tissue Expander is removed.

Picture of CPX4 Expander (left) and CENTERSCOPE Injection Port Detector (right)

Intended Use of the Expander

Mentor's CPX4 Breast Tissue Expanders can be used for 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. A two-stage or "delayed reconstruction" consist of the use of a temporary tissue expander followed several months later by replacement with a long-term breast implant.

Device Materials

Mentor CPX4 Textured Breast Tissue Expanders have been tested in accordance with international standards. Materials to which patients can come into contact with from the Mentor CPX4 Breast Tissue Expanders are 100% medical implant grade silicone polymers. The patient-contacting material of the CENTERSCOPE Magnetic Injection Port Locator provided with the Tissue Expander is 100% Nylon.

Additional non-patient contact material include the stainless steel needle guard to help prevent inadvertent needle puncture within the injection dome. The injection dome also incorporates a magnet to facilitate use with the CENTERSCOPE magnetic detection device.

To date, there are not known manufacturing residuals from CPX4 expanders that could pose a risk to patients

Information for Safe use

- 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. You should discuss your exercise routine with your physician.
- **Magnetic Fields/MRI Compatibility**- You should discuss impact to MRI testing with your physician prior to tissue expansion. MRIs is not recommended while you are implanted with the CPX4 tissue expander because movement could occur causing patient pain or expander displacement that could require revision surgery.
- **Considerations for Mammography -** 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.
  The frequency of mammographies should be discussed with your physician.
- **Radiation Therapy** - 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 expanders. 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 ask your physician to help you distinguish the expander from your breast tissue. If a biopsy is performed, care must be taken to avoid puncturing the expander.

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 tissue expander, you should consult a health care provider.

- **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.
- **Deflation –** Breast tissue expanders 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. Additional surgery is needed to remove or replace the expander.
- **Extrusion of the implant/Interruption of Wound Healing -** Extrusion is when the breast expander comes through the skin. This can happen if your surgical wound has not healed properly or if the skin over your breast weakens. Radiation therapy has been reported to increase the chances of implant extrusion.
- **Hematoma/Seroma.** A hematoma is a collection of blood inside a body cavity, and a seroma is a collection of the watery portion of the blood (in this case, around the implant or around the incision). Postoperative hematoma and seroma may contribute to infection and/ or capsular contracture. Swelling, pain, and bruising may result. If a hematoma 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, large ones will require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation can occur from surgical draining if damage to the implant occurs during the draining procedure.
- **Inflammation** see Infection and Pain.
- **Infection -** Infection is a possible consequence of any kind of surgery. Signs that you have an infection include: redness or rash, tenderness or pain, fluid accumulation in or around the breast(s), and fever.
- **Pain –** Pain may be felt of varying severity (degrees) and duration (length of time) during the expansion process. Areas where you may experience pain include the breast, chest wall and axilla. 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 expander implantation.

- **Ptosis.** Breast sagging as a result of normal ageing, pregnancy, or weight loss.

- **Active Infection.** If you have active infections anywhere in your body you should consult your physician before breast implantation

- **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.

  Tissue expanders are intended for temporary use only. The potential risk of BIA-ALCL associated with these devices is not known.

- **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.** Wrinkling of the implant that can be felt or seen through the skin.

- **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 expander implantation (e.g. tissue damage resulting from radiation, inadequate tissue, or compromised vascularity, you should consult your physician before breast expander implantation.

Complications related to long-term implantation of Breast Implants

In addition to potential complications that may be experienced during tissue expansion with an expander, there are additional risks related to long-term effects of breast implants, you should consult your physician and review safety information related to the implant you choose after tissue expansion.

Expected Device Lifetime

The CPX4 Textured Breast Tissue Expander is a device implanted typically for four to six months to expand the tissue in the breast pocket. The lifetime of the CPX4 Textured Breast Tissue Expander is the amount of time required to attain the desired breast tissue pocket and for the patient to be ready to have an additional surgery to exchange the expander for a long-term breast implant, as determined by the healthcare provider and the patient.

In some cases additional surgery is needed to remove or replace the expander as described in the Warnings and Precautions Section.

Follow-up with physician

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

Patient ID Card

Enclosed with each breast tissue expander is a Patient ID Card. Information specific to the expander, 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 expander. Keep the Patient ID Card provided by your physician (with the style and lot number of your breast expander 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.