WARNING:
- Breast implants are not lifetime devices. The longer people have them, the greater chances are that they will develop complications, some will require more surgery.
- Breast implants have been with the development of a cancer of the immune system breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.
- Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

Caution: US law restricts this device to sale by or on the order of a physician.

The sale and distribution of Mentor Breast Implant Devices are restricted to users and/or user facilities that provide information to patients about the risks and benefits of the device prior to its use in the form and manner specified in approved labeling to be provided by Mentor Worldwide LLC.

Important Safety Information:
The MENTOR® Collection of Breast Implants are indicated for breast augmentation - in women who are at least 22 years old for MENTOR® MemoryGel® Breast Implants or MENTOR® MemoryShape® Breast Implants, and at least 18 years old for MENTOR® Saline Breast Implants. MENTOR® Breast Implants are also indicated for breast reconstruction.

Breast implant surgery should not be performed in women:
- With active infection anywhere in their body
- With existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions
- Who are currently pregnant or nursing

Safety and effectiveness have not been established in patients with autoimmune diseases (for example lupus and scleroderma), a weakened immune system, conditions that interfere with wound healing and blood clotting, or reduced blood supply to breast tissue. 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 are risks associated with breast implant surgery. You should be aware that breast implants are not lifetime devices and breast implantation may not be a one-time surgery. You may need additional unplanned surgeries on your breasts because of complications or unacceptable cosmetic outcomes. Many of the changes to your breast following implantation are irreversible (cannot be undone) and breast implants may affect your ability to breastfeed, either by reducing or eliminating milk production.

Breast implants are not lifetime devices and breast implantation may not be a one-time surgery. The most common complications for breast augmentation with MemoryGel® Implants include any reoperation, capsular contracture, nipple sensation changes, and implant removal with or without replacement. The most common complications with MemoryShape® Implants for breast augmentation include reoperation for any reason, implant removal with or without replacement, and ptosis.

The most common complications for breast reconstruction with MENTOR® MemoryGel® Breast Implants include any reoperation, implant removal with or without replacement, and capsular contracture. The most common complications with MENTOR® MemoryShape® Breast Implants for breast reconstruction include reoperation for any reason, implant removal with or without replacement, and capsular contracture. A lower risk of complication is rupture. The health consequences of a ruptured silicone gel breast implant have not been fully established. MRI screenings are recommended three years after initial implant surgery and then every two years after to detect silent rupture. Breast implants are also associated with the risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), an uncommon type of lymphoma. An individual's risk of developing BIA-ALCL with MENTOR® Breast Implants is low based on the incidence of worldwide cases.

Detailed information regarding the risks and benefits associated with MENTOR® Breast Implants is provided in several educational brochures for both augmentation and reconstruction:
- For Augmentation: Important Information for Augmentation Patients about MENTOR® MemoryGel® Breast Implants. Patient Educational Brochure – Breast Augmentation with MENTOR® MemoryShape® Breast Implants and Quick Facts about Breast Augmentation & Reconstruction with MENTOR® MemoryShape® Breast Implants.
- For Reconstruction: For MemoryGel® Implants: Important Information for Reconstruction Patients about MENTOR® MemoryGel® Breast Implants. For MemoryShape® Implants: Patient Educational Brochure – Breast Reconstruction with MENTOR® MemoryShape® Breast Implants and Quick Facts about Breast Augmentation & Reconstruction with MENTOR® MemoryShape® Breast Implants.
- Saline-filled Implants: Making an Informed Decision.

These brochures are available from your surgeon or visit www.mentorwwllc.com. It is important that you read and understand these brochures when considering MENTOR® Breast Implants.

ARTOURA® Breast Tissue Expanders and CONTOUR PROFILE® Breast Tissue Expanders are used for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision, and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months. ARTOURA® Breast Tissue Expanders and CONTOUR PROFILE® Tissue Expanders contain a magnet within the internal injection domes and are NOT MRI compatible. The device could be moved by the MRI causing pain or displacement, potentially resulting in a revision surgery. DO NOT use the ARTOURA® Breast Tissue Expander and CONTOUR PROFILE® Tissue Expander in patients that have a previously implanted device such as pacemakers, drug infusion devices, artificial sensing devices, etc. that could be affected by a magnetic field. Mentor has not tested the effects of radiation therapy with ARTOURA® Breast Tissue Expanders and CONTOUR PROFILE® Expander devices. The incidence of extrusion of the expander has been shown to increase when the expander has been placed in injured areas: scarred, heavily irradiated or burned tissue, crushed bone areas, where severe surgical reduction of the area has previously been performed; and where steroids are used in the surgical pocket. Detailed information about indications, contraindications, warnings, and precautions associated with the use of ARTOURA® Breast Tissue Expanders CONTOUR PROFILE® Expanders are provided in the Instructions for Use (IFU) available online at www.mentorwwllc.com.