

Important Safety Information

MENTOR® MemoryGel® and MENTOR® Saline-Filled Breast Implants are indicated for breast augmentation — in women who are at least 18 years old — or 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(s) who have not received adequate treatment for those conditions or are pregnant or nursing.

There are risks associated with breast implant surgery. Breast implants are not lifetime devices and breast implantation is likely not a one-time surgery. You may need additional unplanned surgeries on your breast(s) because of complications or unacceptable cosmetic outcomes. Many of the changes to your breast(s) following implantation are irreversible (cannot be undone) and breast implants may affect your ability to breastfeed, either by reducing or eliminating milk production.

The most common complications with MemoryGel® Breast Implants include re-operation, capsular contracture, asymmetry, and breast pain. A lower risk of complication is implant rupture, which is most often silent (meaning neither you nor your doctor will know you have a rupture). The health consequences of a ruptured silicone gel-filled breast implant have not been fully established. Screenings such as mammography, MRI, or ultrasound are recommended after initial implant surgery to assist in detecting implant rupture.

The most common complications with MENTOR® Saline-Filled Breast Implants include re-operation, implant removal, capsular contracture, wrinkling, breast pain and deflation.

CONTOUR PROFILE® Tissue Expanders and Smooth Round Tissue Expanders with Remote Dome are used for breast reconstruction following mastectomy. These expanders are intended for temporary subcutaneous or submuscular implantation and are not intended for use beyond six months. You should not have an MRI while the CONTOUR PROFILE® Tissue Expander or Smooth Tissue Expander with Remote Dome is implanted. The device could be moved by the MRI causing pain or displacement, potentially resulting in a revision surgery. 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 or where severe surgical reduction of the area has previously been performed.

Patients are reminded to discuss the indications, contraindications, warnings, precautions and the risks and benefits associated with MENTOR® Breast Implants with their surgeons and review the Important Safety Information provided at www.mentorwllc.com.

It is important that you understand the risks associated with breast implant surgery when considering MENTOR® Breast Implants.