MENTOR Promise

A highly comprehensive protection plan assured by Johnson & Johnson, a global leader in Healthcare with over 130 years of experience[1]

ONLY WITH MENTOR® BREAST IMPLANTS

Protection beyond compare

Mentor is committed to your long term well-being

Before your surgery, we are here for you to answer your questions, and most importantly, we are here for you after your procedure, with a long term commitment to your well-being.

Whether you've decided to look or feel better, knowing your surgeon has selected high-quality implants can offer you peace of mind[2] with your decision long after your surgery.

As one of the world's leading maker of high-quality breast implants for over 30 years, our experience results in quality products that you can rely on,[3] Mentor has been the trusted choice by millions of women worldwide.[3,4]

MENTOR® Breast Implants go through a series of controlled tests to insure that only products that meet or exceed our standards leave our facility.[2] Our products are backed by a highly comprehensive protection plan assured by Johnson & Johnson, a global leader in Healthcare with over 130 years of experience[1]— the MENTORPromise.

MENTORPromise

MENTORPromise Protection Plan Overview[1]

FREE AND **AUTOMATIC** ENROLLMENT[Δ]

FREE LIFETIME PRODUCT REPLACEMENT FOR RUPTURE[*Δ]

UP TO **€1000** FINANCIAL ASSISTANCE COVERAGE FOR RUPTURE[†§]

FREE PRODUCT REPLACEMENT IN THE EVENTS OF CAPSULAR CONTRACTURE (Baker III/IV), DOUBLE CAPSULE AND LATE STAGE SEROMA[‡π]

FREE CONTRALATERAL IMPLANT at your surgeon's request[**]

* In the event of a confirmed rupture or deflation (leaking) of any MENTOR® Breast Implant due to wear or delamination requiring surgical intervention, regardless of the age of the implant, Mentor will provide a free replacement of a MENTOR® Breast Implant of any size in the same or similar style as the originally implanted product.

† When a replacement surgery of a MENTOR® Gel-Filled Breast Implant is required due to confirmed rupture occurs within ten (10) years from the date of implantation, provided that eligibility is proven and confirmed by Mentor based on its assessment and evaluation, Mentor will pay uninsured, out-of-pocket costs for operating room, anesthesia and/or surgical expenses directly related to revision surgery up to a maximum aggregate amount of €1000. Operating room and anesthesia charges shall be given payment priority. In such cases, the request for financial assistance under the MentorPromise Protection Plan must be made to your surgeon. Financial assistance does not imply a loan to you.

‡ In the events of capsular contracture (Baker III/IV), double capsule or late-stage seroma in augmentation surgery of a MENTOR® Gel-Filled Breast Implant, Mentor will provide a replacement of a MENTOR® Gel-Filled Breast Implant, free of charge for the period of ten (10) years from the date of implantation, provided that eligibility is proven and confirmed by Mentor based on its evaluation of explanted product and assessment of all required documentation. Mentor will provide a replacement MENTOR® Product of any size in the same or similar style as the originally implanted product.

[Δ] Applicable to all MENTOR® Breast Implants, as of December 2002 (In primary Augmentation and Reconstruction).

[§] Applicable to MENTOR® Gel Breast Implants for 10 years, as of October 2005 (In primary Augmentation and Reconstruction).

[π] Applicable to MENTOR® Gel Breast Implants, for 10 years CC – as of May 2013/ DC LSS – as of July 2017 (In primary Augmentation).

** Applicable to all MENTOR® Breast Implants in cases of rupture, CC, DC, LSS - as of July 2017.

REFERENCES

1. MENTORPROMISE PROTECTION PLAN FOR MENTOR® BREAST IMPLANTS, Legal Document, 2021.
2. MENTOR Worldwide LLC. PROC400623 2.2. MENTOR Worldwide LLC. TX330.070411.01 , TX330.070213.03, TX330.070213. 2.3. FDA Website, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071228.htm. Accessed 04/12/18.
3. Bondurant, S., Ernster, V., and Herdman, R. Safety of Silicone Implants. Washington, DC: National Academy Press. 1999.
4. Mentor Worldwide LLC. Mentor Worldwide Historical Implant Data 1985 - May 2018.

IMPORTANT SAFETY INFORMATION

The MENTOR® Collection of Breast Implants are indicated for breast reconstruction and breast augmentation - in women who are at least 18 years old for MENTOR® MemoryGel® Breast Implants, MENTOR® CPG™ Breast Implants, or MENTOR® Saline Breast Implants.

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. The chance of developing complications increases over time. 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 CPG™ Breast Implants for breast augmentation include reoperation for any reason, implant removal with or without replacement, and ptosis. 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 data currently available on the incidence of worldwide cases.

Detailed information regarding the risks and benefits associated with MENTOR® Breast Implants is provided in several educational brochures, including the 'Important Information for Woman Considering Breast Implants' brochure, and the 'Making an Informed Decision' brochure. These brochures are available from your surgeon or visit https://breastimplantsbymentor.net/safety/mentor-safety. It is important that you read and understand these brochures when considering MENTOR® Breast Implants.

MENTOR® CONTOUR PROFILE™ Breast Tissue Expanders are used for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision, and tissue defect procedures. These expanders are intended for temporary subcutaneous or submuscular implantation; they should be used within a time frame determined by the physician to achieve the clinically desired degree of tissue expansion.

DO NOT use the MENTOR® 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 the MENTOR® 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 MENTOR® CONTOUR PROFILE™ Expanders are provided in the Instructions for Use (IFU) available online at www.mentorwwllc.eu

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