As a leading global manufacturer of the highest quality breast implants, we – Mentor and our 1,200 worldwide employee associates – strive to provide high-quality products and services to health care professionals and women.
THE MENTOR PLEDGE

To our Mentor Customers and Patients, we pledge to you our commitment to excellence.

We abide by the following guiding principles:

• Our primary concern is always for the health and safety of our patients.
• Mentor is dedicated to effectively inform and reassure the patient about her decision to have breast augmentation with MENTOR® Breast Implants.
• We also provide women with comprehensive education that highlights our commitment to breast cancer awareness and the reconstruction solutions that restore patients’ self-esteem and quality of life.
• Mentor, the #1 worldwide leader in breast aesthetics, offers MENTOR® and PERTHESÉ™ Breast Implants, providing our customers and patients with the broadest range of breast implant sizes and styles.
• MENTOR® and PERTHESÉ™ Breast Implants are CE-Marked. MENTOR® MemoryGel™ Breast Implants are also approved by the FDA (United Food and Drug Administration) (Round-Shaped only). We are committed to maintaining vigilant reporting. These procedures continuously monitor the safe and effective use of our products in active partnership with Global Regulatory Authorities.
• We offer professional education to the healthcare community to ensure that our products are used correctly and in a compliant manner.

At Mentor, we are committed to making safe products that offer high quality, reliability and state-of-the-art design to enhance aesthetic and reconstructive procedures.
Mentor founded in Minneapolis and goes public.
1969 - 1970

Mentor acquires Heyer-Schulte of AHSC.
1984 - 1985

Mentor launches its SILTEX™ Technology.
1987

Mentor introduces the BECKER™ Expander/Breast Implant.
1985

Mentor became the first breast implant manufacturer to achieve CE-Marking.
1995

Mentor launches the CONTOUR PROFILE™ Gel Breast Implant.
2001

2000 - 2006

Johnson & Johnson acquires Mentor.
2009

A VALUED HISTORY, A PROMISING FUTURE.

Our Future
The trusted global leader in Aesthetic Medicine

1971 - 1980
Growth driven by focus in urology.

1985
Mentor introduces the BECKER™ Expander/Breast Implant.

1995
Mentor became the first breast implant manufacturer to achieve CE-Marking.

2001
Mentor launches the CONTOUR PROFILE™ Gel Breast Implant.

2006 - MemoryGel™ Breast Implant’s receives FDA approval.


2008 - PREVELLE® Silk receives FDA approval.

Our History Speaks for Itself
Mentor and Perthese - We have over 40 years of combined breast aesthetics excellence. Our years of experience result in reliable products for use in both breast augmentation and breast reconstruction. Made under strict standards of design and testing, Mentor has achieved a tremendous level of respect in the medical community and is consistently recognized by physicians for outstanding product integrity.

In January 2009, Mentor was acquired by Johnson & Johnson. Joining forces, we aspire to provide a broad range of innovative, science and clinical-based solutions to maintain, enhance, and restore self-esteem and quality of life. Simply said, our goal is to make life more beautiful.
SCIENCE YOU CAN TRUST - SCIENCE BASED MEDICINE

When faced with such an important decision, knowing all the facts will lead to the most successful outcome. MENTOR® and PERTHES™ Breast Implants have been successfully used and trusted by surgeons worldwide. Mentor remains committed to providing objective, clinical information about breast implant safety. We currently have seven breast implant clinical studies in progress. Over 200,000 women have participated in these studies, in order to provide a significant body of clinical evidence demonstrating the safety and effectiveness of our saline and silicone-filled breast implants.

WHAT YOU SHOULD KNOW ABOUT THE QUALITY OF MENTOR® BREAST IMPLANTS

Gel Cohesiveness
MENTOR® Silicone Gels are cohesive polymers. Although soft and fluid feeling, the gel acts as a unit. Our gels hold together uniformly, while retaining the natural “give” that resembles breast tissue.

Silicone Quality
At Mentor, we only use high-quality, medical-grade silicone gel in our gel-filled implants.

Addressing Gel Bleed
The amount of material released from MemoryGel™ Breast Implants is extremely minimal, more than a million fold below established safety limits. Studies presented to the US FDA show that MENTOR® Breast Implants are safe and reliable.

Rupture Rates
The MENTOR® Breast Implants are constructed using strong material and shell thickness has been optimized for strength.

MemoryGel™ Breast Implants have a 3-layer construct:
- Methyl (inner layer) confers structural integrity
- Phenyl a hydrophobic layer (impedes diffusion)
- Methyl (outer layer) confers structural integrity
- Gel

For important safety information about our family of silicone and saline breast implants, please visit: http://www.mentorwwllc.com/global-us/SafetyInformation.aspx.
OUR COMMITMENT TO YOU

Our Family of Implants
Mentor is committed to developing unparalleled products for the most discerning physicians and patients. We understand that every woman has different goals driven by personal preference, anatomy, health and even geography. That’s why we offer so many options, making it easy to help women reach the outcome they envision. Understanding of our implant style options will assist in determining the product best suited for each woman. Mentor is your complete source for some of the finest silicone and saline breast implants, along with other products associated with breast augmentation and breast reconstruction.

We Stand Behind Our Products
Our relationship doesn’t end with surgery. We’re committed to supporting the patient throughout her decision-making journey, providing educational resources each step of the way. More importantly, we are there with her after her surgery with a long-term commitment. All MENTOR® Breast Implants are covered by the Mentor Lifetime Product Replacement Policy at no additional charge. Also, once the patient receives MENTOR® Silicone Gel-Filled Breast Implants, she is automatically enrolled in Mentor PatientSafe Coverage Limited Warranty.

All PERTHESE™ Silicone Gel-Filled Breast Implants are covered by the Quality Assurance Program.

For more information, please visit:
http://www.mentorwwllc.eu/warranty-info
SILICONE GEL EVOLUTION

Silicone Gel-filled Breast Implants have undergone changes over time to meet increasingly sophisticated consumer expectations. The first silicone breast implants used thick shells and contained firm gel. The second generation of implants (introduced in the late 1970’s) had thinner shells and used less firm gel to address concerns of patients and surgeons who believed that implants were too firm, palpable, and visible.

In the mid 1980’s, concerns related to rupture rates of the second generation thinner-shelled implants led manufacturers to introduce a third generation of implants. The shell and gel of these implants are slightly thicker but still soft.

Today these third generation silicone gel filled breast implants are typically referred to as cohesive gel implants. Mentor’s products have kept pace with the ever-evolving expectations of surgeons and women who desire a safe, soft gel to retain the natural feel that resembles actual breast tissue.

Watch a video demonstrating the cohesiveness of Mentor’s third generation silicone breast implants: http://www.mentorwwllc.eu/videos.html?m=cutting

Proprietary, cohesive gel acts as a solid rather than a liquid.
QUALITY IS A NECESSITY, NOT A LUXURY

An Investment in Quality
Our decades of experience have provided a wealth of experience and a global reputation for integrity. Our manufacturing expertise, structural excellence, and safety record speak for themselves.

Manufacturing
At Mentor, we understand the importance of maintaining the highest standards. In fact, we believe that what distinguishes Mentor as the world leader in breast implant manufacturing is a dedication to advanced technology, quality, value and service rivaled by none. Our commitment is evident each and every step of the way, from research and development, to quality-controlled production striving to provide exceptional customer service.

Supply Chain
Mentor is proud of its long-term relationships with its suppliers. For decades, Mentor has worked with select suppliers to procure the highest quality silicone materials for use in critical long-term implants and medical products. In addition, every supplier undergoes routine audits by Mentor in compliance with Good Manufacturing Practices (GMP) regulations.

Testing
Mentor considers quality a necessity, not a luxury. Our products are put through three-levels of testing to ensure the integrity of every breast implant we manufacture.

SAFETY:
Biocompatibility Tests
Toxicity
Endotoxins
Sensitization
Implantation
Carcinogenicity/Chronic Toxicity

SHELL/DEVICE PHYSICAL PROPERTIES:
Elongation Tension Set
Fatigue
Impact
Static Rupture

DEVICE TESTING:
Chemical Analysis
Gel Cohesion
Packaging
Sterility
Stability

Regulations
Our breast implants conform to applicable standards and regulations:
- CE-Marking for MENTOR® and PERTHES® Breast Implants
- US FDA approval for MENTOR® MemoryGel™ and Saline Breast Implants
- ISO 10993 “Biological Evaluation of Medical Devices”
- ISO 14607 “Non-active surgical implants – Mammary Implants – Particular requirements”
- ISO 13485 “Medical devices – Quality management systems – Requirements for regulatory purposes”
- 93/42/EEC Medical Device Directive

1. The MENTOR® Breast Implant products approved by the FDA are the MENTOR® MemoryGel™ Round Profile Cohesive I™ Breast Implants and the MENTOR® Saline-Filled Breast Implants.
3. Ibid
4. Ibid
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.

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