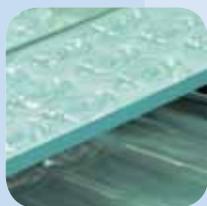


The beauty of trust.



MemoryGel® Breast Implants

NOT FOR DISTRIBUTION IN THE U.S.

Brought to you by  **MENTOR**®



Implants as precise as you are.

Choosing Mentor gel implants not only reflects your own high standards, but also affirms the premium you place on a patient's care. When you invest a bit more on implants recognized for their quality, the reassurance to patients is priceless.

Our history speaks for itself.

As the world's leading maker of high quality breast implants, our years of experience result in quality products that you can rely on.



- . . . has been making breast implants since 1984.
- . . . meets the strictest quality control standards in the world.
- . . . offers a lifetime product replacement policy on all gel and saline implants.
- . . . has the only automated breast implant dipping machine, ensuring consistently uniform implant shells.
- . . . became the first breast implant manufacturer to achieve CE-marking in 1995.

Innovation across 5 continents.

Mentor is a leading supplier of medical products to more than 100 countries, including the US. Our success comes from the pursuit of a single philosophy: Advancing technology not only improves our products, but also the potential of everyone who uses them.

Scientific research and development have always been key to our long-term goals. Mentor has consistently invested in pre-clinical and clinical studies vital to product innovation. Through educational tours, Mentor offers the opportunity to witness first hand our state-of-the-art production facility in Leiden, including insights into the development of new materials and upcoming technological advancements.

Much more than a manufacturer of medical products, Mentor has become a global resource to invent, develop, and test new solutions for aesthetic medicine.

Quality is always the wisest investment.

We've been making breast implants for over 20 years. Those two decades have provided a wealth of experience and a global reputation for integrity. Our manufacturing expertise, structural excellence, and safety record speak for themselves.



Advancing technology not only improves our products, but also the potential of everyone who uses them.

Quality is a necessity, not a luxury.



Cohesion Testing



Elongation Testing

Three levels of testing.

Safety:

- Biocompatibility Tests
- Toxicity
- Endotoxins
- Sensitisation
- Implantation
- Carcinogenicity/Chronic Toxicity

Shell/Device Physical Properties:

- Elongation
- Tension Set
- Fatigue
- Impact
- Static Rupture

Device Testing:

- Chemical Analysis
- Gel Cohesion
- Packaging
- Sterility
- Stability

The world's most evolved breast implant.

- Highly compliant shell for ease of placement
- Strict US and EU manufacturing standards
- Lifetime product replacement policy
- Low, Moderate, Moderate *Plus*, High, and Ultra High projections
- Proprietary silicone gel formula for a natural give that resembles breast tissue



Common gel myths:

Cohesion confusion.

There is still a misconception among some patients and surgeons concerning silicone gel. All of Mentor's gels are cohesive polymers, not liquids. 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.

The myth of bleed.

There has been ongoing discussion concerning small molecules of silicone gel fluid, which may pass through an implant shell and into the body. Minute amounts of "bleed" occur in all silicone breast implants. It is important to note that all Mentor gel implants are low bleed.

*"The total amount of siloxanes detected in "gel bleed" from MemoryGel® devices was 4.7 micrograms (...) and more than a million-fold below no-effect levels."*¹ World-wide studies on the subject of bleed have not linked it to illness in patients.

It's the chemistry that counts.

The key factor in construction of a shell is in its chemical make-up. The amount of shell layers is of little relevance, what does matter is the strength of the material and optimal total thickness of the shell. Mentor's shell wall is consistently strong with proven physical properties.

1. Roger Wixtrom Ph.D., DABT



Round Low Profile



Round Moderate Profile



Round Moderate *Plus* Profile



Round High Profile



Ultra High Profile



More cohesion levels. More styles. More choices.

The following descriptions of our three cohesion levels, five styles of implants, and the variations within each style, will give you a brief overview of the options available to you. Your understanding of our implant style options will assist you in your patient consultations and in determining the product best suited for the needs of your patients.

All Cohesive, All the Time.[™]

All of Mentor's gel implants use gel that is cohesive, safe, and aesthetically pleasing.

Cohesive I[™]

The standard cohesive level gel used in Mentor's implants. This is Mentor's softest gel and has been preferred for years in textured and smooth Round Low, Moderate, Moderate *Plus*, High, Ultra High Profile gel breast implants, Round Spectra[™], and Becker implants.

Cohesive II[™]

A slightly firmer gel for surgeons wanting a firmer feeling implant. This gel is used in textured Round Moderate, Moderate *Plus*, High Profile gel breast implants, and Contour Profile[®] Becker implants.

Cohesive III[™]

Mentor's most cohesive gel, providing shape retention with a pleasing level of firmness for optimal aesthetic results. This gel is used in Mentor's Contour Profile[®] Gel implant Family.

Tailored to the patient.

Successful procedures strike a unique balance between selecting an implant most appropriate to body type and addressing patient expectations. By offering diversity in firmness, size, profile and texture, Mentor provides surgeons more options to achieve the best fit.

Round Gel Breast Implant Family

Currently the most popular choice for augmentation procedures. The round shape is available in a wide array of sizes to accommodate various body types. Mentor's gel-filled round implants come in five different profiles (Low, Moderate, Moderate *Plus*, High and Ultra High Profile) and two different cohesion levels (Cohesive I and II). In addition, the round shapes come in smooth and Siltex™ textured.



Contour Profile® Gel Breast Implant Family

These implants feature an anatomic shape that closely resembles the outline of a natural breast. This style is often preferred by women looking for a gently sloping breast silhouette. All CPG™ implants feature Cohesive III gel, providing the optimal stability for aesthetic results.



Spectra™ and Becker Expander Implant Family

Spectra™ Adjustable Gel Implant

Double lumen implant with adjustable saline inner lumen (10% - 30%) and silicone gel outer lumen (~ 80%). By adding saline, the projection of the implant can be increased without base width being compromised. Also, as projection is increased the soft feel of the gel is not altered. Available with Cohesive I™ gel, in High Profile, with smooth or textured surface shell, and posterior self-sealing valve system.

Siltext™ Contour Profile® Becker 35

Shaped outer lumen 35% pre-filled with silicone gel. Shaped inner lumen connected on the backside of the outer lumen to prevent rotation. Empty inner lumen constitutes 65% of the final nominal volume, which can be adjusted over a suggested six-month fill period. Expansion possible to 25% beyond nominal fill volume.

Siltext™ Round Becker 25

Outer lumen 25% pre-filled with silicone gel. Empty inner lumen can be filled with saline to constitute 75% of the final nominal volume. Can be expanded 50% beyond nominal fill volume.

Siltext™ Round Becker 50

The only 50% gel, 50% saline expander/implant on the market. Outer lumen is 50% pre-filled with silicone gel while the inner saline lumen is empty, again allowing gradual fill for modification to size and dimensions. A true adjustable implant that also features a range of saline volumes per device.



Our sales representatives are an exceptional resource for addressing technical product issues. For questions, additional information, or to order, please contact your local Mentor representative.

Mentor Statement

The approved Mentor breast implant products have been reviewed and approved by the regulatory agencies confirming that the products satisfy applicable safety and health standards:

- CE marking of conformity, the prerequisite for marketing the products in the European Economic Area (EEA)¹.
- United States Food and Drug Administration (US FDA) premarket approval (PMA)².
- Independent, in conjunction with, or predicated upon other approvals, Mentor breast implants are officially accepted in more than 60 countries, commonwealths and principalities including the major population centers on all continents.

The approved Mentor breast implant products satisfy the applicable standards, specifications and guidance documents, including but not limited to:

- ISO 10993 "Biological Evaluation of Medical Devices"³
- ISO 14607 "Non-active surgical implants – Mammary Implants – Particular requirements"⁴
- ASTM F-703 "Standard Specification for Implantable Breast Prostheses"⁵
- "Guidance for Industry and FDA Staff – Saline, Silicone Gel, and Alternative Breast Implants"⁶

The approved Mentor breast implants are manufactured in compliance with:

- ISO 13485, "Medical devices – Quality management systems – Requirements for regulatory purposes"⁷

The approved Mentor breast implant products conform to the applicable directives, codes and regulations:

- MDD 93/42/EEC "Medical Device Directive 93/42/EEC"⁸
- 21 CFR Part 820 "Quality System Regulation" including current good manufacturing practice (cGMP) requirements⁹

1. The Saline-filled, gel-filled, Becker and Spectra breast implant products are CE-Marked.

2. The Mentor breast implant products approved by the FDA are the saline-filled breast implant and the gelfilled round profile cohesive I breast implant.

3. International Organization for Standardization, Geneva, Switzerland.

4. Ibid

5. ASTM International, West Conshohocken, PA, United States.

6. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Plastic and Reconstructive Surgery Devices Branch, Rockville, MD, United States.

7. Ibid

8. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, updated 2007.

9. United States Code of Federal Regulations Title 21 Food and Drugs, Part 820 Quality System Regulation. Mentor Medical Systems final product implants are not marketed in the United States and are not required to be in compliance with 21 CFR Part 820

Perthese® Statement

Perthese® cohesive silicone gel-filled breast implant products have been reviewed and approved by regulatory agencies to satisfy applicable safety and health standards.

Among the approvals are:

- CE marking of conformity, the prerequisite for marketing regulated products in the European Economic Area (EEA).
- Independent, in conjunction with, or predicated upon other approvals, Perthese breast implants are officially approved for import to more than 50 countries.

Perthese® breast implant products satisfy the applicable standards and specifications, including but not limited to:

- ISO 10993 "Biological Evaluation of Medical Devices"¹
- ISO 14607 "Non-active surgical implants – Mammary Implants – Particular requirements"²

Perthese® breast implant products are manufactured in compliance with:

- ISO 13485, "Medical devices – Quality management systems – Requirements for regulatory purposes"³

Perthese® breast implant products conform to the applicable directives, codes and regulations including:

- MDD 93/42/EEC "Medical Device Directive"⁴

1. International Organization for Standardization, Geneva, Switzerland.

2. Ibid

3. Ibid

4. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, updated 2007.

Lifetime Product Replacement Policy for Mentor® Breast Implants

Mentor will offer free replacement of its breast implants that experience rupture/deflation due to loss of shell or valve integrity during the lifetime of the patient-recipient upon request. Requests for replacement product should be made by the patient's surgeon to the local Mentor representative. Mentor will then provide a replacement product free of charge. To take advantage of this policy, any MENTOR® breast implants so replaced must be returned to Mentor and shall then become the property of Mentor. This replacement policy is limited to replacement of the MENTOR® breast implants and Mentor shall not be responsible for any incidental or consequential damages of any kind, directly or indirectly, arising from the use of this product, including without limitation, medical, surgical and hospital costs or the reimbursement for the cost of breast implants not manufactured by Mentor. This replacement policy shall only be effective provided that Mentor manufactures breast implants at the time the request for replacement is made. This policy is not a warranty or guarantee. Mentor expressly disclaims all warranties, whether express or implied by operation of law or otherwise, whether written or oral, including without limitation, any implied warranties of merchantability, fitness, or design. Mentor shall have no responsibility for any statements or representations, whether oral or written, made by any other person or entity.

Mentor makes no representation as to the life expectancy of a breast implant. There are conditions which may cause these devices to wear out or malfunction and require replacement. These devices should not be considered lifetime implants.



PatientSafe Coverage Limited Warranty For Silicone Gel Filled Breast Implants

Choose well. Choose wisely. Choose Mentor.

Learn about our PatientSafe Coverage Limited Warranty for peace of mind.

Make sure the breast implants that will become part of your body are made by a company with the highest level of quality and experience in the world.

This is a limited warranty only and is subject to the terms and conditions set forth in this document and explained in greater detail in the applicable mentor limited warranty. All other warranties, whether expressed or implied, by operation of law or otherwise, including but not limited to, implied warranties of merchantability and fitness, are excluded, to the extent permitted by law.

The terms in effect when original implantation occurs will apply at the time of claim.

This brochure provides an overview of the MENTOR® PatientSafe Coverage limited warranty for silicone gel-filled breast implants. However, it is not intended to replace any discussion between you and your surgeon.

Thank you for selecting MENTOR® silicone gel-filled breast implants. Our relationship with you does not end with your surgery. We make a long-term commitment to our patients and we stand behind the integrity of our products.

PatientSafe Coverage. Reassurance that lasts.

- ✓ Automatic enrollment
- ✓ Free of charge
- ✓ Lifetime product replacement
- ✓ Up to 1000 € of financial assistance up to 10 years from the date of implant

All MENTOR® breast implants come with a Lifetime Product Replacement Policy¹ at no additional charge. Also, once you receive MENTOR® silicone gel-filled breast implants, you are automatically enrolled in the MENTOR® PatientSafe Coverage.

Lifetime Product Replacement Policy

- Automatically applies to all recipients of MENTOR® breast implant products
- Provides that regardless of the age of the implant, when confirmed rupture occurs, you are eligible for a no-charge replacement breast implant product of any size in a similar style

Additional Benefits with PatientSafe Coverage

The MENTOR® PatientSafe Coverage is free of charge to all patients who are implanted with MENTOR® silicone gel-filled breast implant products.

- Automatic enrollment
- In the case of confirmed implant rupture up to €1000 of financial assistance for operating room, anesthesia, and surgical charges incurred in any revision surgery carried out within 10 years of the date of the original implant not covered by insurance will be provided.²

Products Covered

The MENTOR® PatientSafe Coverage applies to MENTOR® silicone gel-filled breast implants that are implanted in the UK after October 1st, 2005 and implanted in Ireland, Malta and South Africa after June 1st, 2011, provided implants have been:

- Implanted in accordance with the Mentor package insert, current to the date of implantation, and other notifications or instructions published by Mentor
- Used by appropriately qualified, licensed surgeons, in accordance with accepted surgical procedures

1. Lifetime Product Replacement Policy: Mentor will provide replacement MENTOR® breast implant of any size in the same or similar style as the originally implanted product free of charge for the lifetime of the patient. Upon surgeon's request, a different implant style may be selected (subject to a charge of the difference between product list prices).

2. Operating room and anesthesia charges to be given payment priority. In order to qualify for financial assistance, you will need to sign a Release form and the Patient claimform. Financial assistance does not imply a loan to the patient.

a personal commitment to your wellbeing

Events Covered

The MENTOR® Lifetime Replacement policy and PatientSafe Coverage only apply to:

- Cases of loss of shell integrity resulting in implant rupture that require surgical intervention

Mentor reserves the right to determine if specific, additional events should be covered.

Events Not Covered

The MENTOR® Lifetime Replacement policy and PatientSafe Coverage do not apply to the following:

- Removal of intact implants due to capsular contracture, wrinkling, or rippling
- Loss of implant shell integrity resulting from reoperative procedures, open capsulotomy, or closed compression capsulotomy procedures
- Removal of intact implants for size alteration
- Surgery on the opposite breast to replace an intact implant

Data Protection

In order to assess your eligibility for PatientSafe Coverage for silicone gel-filled breast implants, and to provide replacement product and financial assistance, Mentor Medical Systems CV will, through its local operations, collect the following information about you: name, address, date of implantation, product serial number and other product details, as well as other personal details that you may wish to provide. Mentor will not share the information with parties other than your medical health or insurance providers, except where required for legal or regulatory compliance or litigation. Mentor will retain the information for the duration of your use of the silicone gel-filled breast implants, unless a longer retention period is required or permitted by law.

You may also obtain a copy of the complete MENTOR® PatientSafe Coverage limited warranty by writing to Mentor Medical Systems CV, Zernikedreef 2, 2333 CL, Leiden, The Netherlands.

MENTOR
A division of Johnson & Johnson Medical Limited
PO Box 1988, Simpson Parkway, Kirkton Campus,
Livingston, Scotland, EH54 0AB
Registration No. SC132162
Customer Service 0800 937 082

© December 2008 Mentor 0602004. TOR 2 Rev September 2011

OUR CREDO

We believe our first responsibility is to the doctors, nurses and patients,
to mothers and fathers and all others who use our products and services.

In meeting their needs everything we do must be of high quality.

We must constantly strive to reduce our costs
in order to maintain reasonable prices.

Customers' orders must be serviced promptly and accurately.

Our suppliers and distributors must have an opportunity
to make a fair profit.

We are responsible to our employees,
the men and women who work with us throughout the world.

Everyone must be considered as an individual.

We must respect their dignity and recognize their merit.

They must have a sense of security in their jobs.

Compensation must be fair and adequate,
and working conditions clean, orderly and safe.

We must be mindful of ways to help our employees fulfill
their family responsibilities.

Employees must feel free to make suggestions and complaints.

There must be equal opportunity for employment, development
and advancement for those qualified.

We must provide competent management,
and their actions must be just and ethical.

We are responsible to the communities in which we live and work
and to the world community as well.

We must be good citizens – support good works and charities
and bear our fair share of taxes.

We must encourage civic improvements and better health and education.

We must maintain in good order
the property we are privileged to use,
protecting the environment and natural resources.

Our final responsibility is to our stockholders.

Business must make a sound profit.

We must experiment with new ideas.

Research must be carried on, innovative programs developed
and mistakes paid for.

New equipment must be purchased, new facilities provided
and new products launched.

Reserves must be created to provide for adverse times.

When we operate according to these principles,
the stockholders should realize a fair return.

The logo for Johnson & Johnson, featuring the company name in a red, cursive script font.