

Restoring a body
Restoring a life



MENTOR® Breast Reconstruction Product Portfolio



NOT FOR DISTRIBUTION IN USA.
APPROVED FOR EMEA REGION.

REBUILDING BEAUTY.

Breast cancer is a reality in our world today – it is by far the most frequent cancer among women across the world and it still has the highest mortality rate.¹

Survival rates are very promising if the cancer is detected early enough.² Breast cancer screening programmes based on mammography and organised at the population level help to achieve an effective decrease of breast cancer mortality.³

Once diagnosed with breast cancer, a number of difficult decisions are related to finding the best treatment option – and breast reconstruction should be offered as an integral part of the treatment planning. However, a US study states that whereas decisions on treatments were associated with patient's goals and concerns, women treated with mastectomy in this study were NOT well-informed about breast reconstruction options.⁴

But breast reconstruction is part of the restoration of a woman's self-assurance. The positive effects of breast reconstruction on the mental well-being of women with breast cancer, leading to less mental distress of losing a breast and better overall quality has among others been shown by a study conducted in Italy.⁵

Helping YOU in making that journey as smooth as possible for the patient is Mentor's goal.

You need a partner that combines best in class products, unbiased advice, professional education and resources for each unique and complex breast reconstruction procedure.



CONTOUR PROFILE™ Tissue Expanders

START WITH INNOVATIVE WAYS TO EXPAND SURGICAL POTENTIAL.

Expansion performance you are accustomed to — MENTOR® CPX™2 Tissue Expander

SECURITY — Only MENTOR® Expanders offer the proprietary BufferZone™ Self-Sealing Patch to minimize the potential for leakage in the event of accidental needle puncture.

EASY TO DETECT —

The CENTERSCOPE™ Magnetic Detection Device locates the magnetic injection dome** for absolute ease and accuracy; the palpation ring*** offers tactile means of locating the injection site.



NATURAL SHAPE — The combination of the BufferZone™ Self-Sealing Patch and the posterior Dacron® Patch* provides directionally focused expansion to maximize lower pole projection creating a natural shape.⁶

TEXTURED SURFACE — the SILTEX™ Texture shell provides a disruptive surface for collagen interface.⁷

ABOUT SILTEX™ TEXTURE

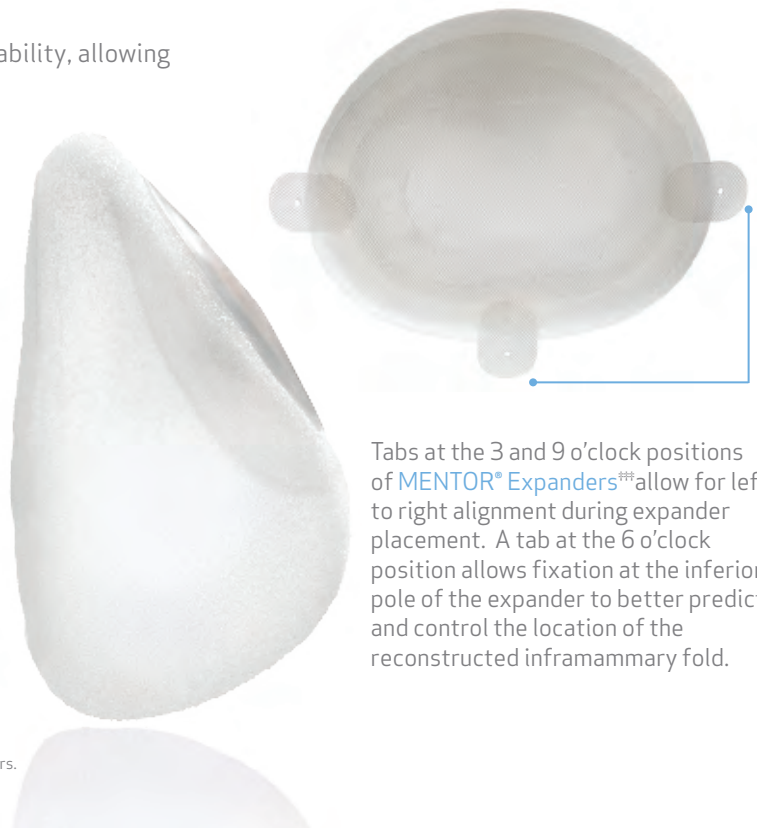
The SILTEX™ Texture is produced by an imprinting process in which a textured sheet of silicone material is impressed upon the outer layer of the tissue expander or breast implant shell, leaving a textured pattern behind. No salt or sugar crystals are used in the process.

Introducing our latest innovation designed to enhance patient comfort —

MENTOR® CPX™4 Tissue Expander and CPX™4 with Suture Tabs Tissue Expander

In designing the MENTOR® CPX™4 Tissue Expander, patient comfort and ease of use were our priorities.

- **OPTIONAL SUTURING TABS** — offers additional stability, allowing expansion to occur where it is intended.
- **EASE OF USE** — more pliant proprietary BufferZone™ Patch, smooth injection dome and enhanced shell pliability* designed for easier device insertion and removal.
 - 48% stronger magnet.*
- **UNMATCHED SAFETY FEATURES** — The proprietary BufferZone™ Self-Sealing Patch has at least 1.5 times - and at most 5.7 times - the surface area of the injection dome, reducing the risk of device leakage from inadvertent needle puncture.
 - The target area for injection is 47% greater than the Natrelle®** Style 133 Tissue Expander.



Tabs at the 3 and 9 o'clock positions of MENTOR® Expanders*** allow for left to right alignment during expander placement. A tab at the 6 o'clock position allows fixation at the inferior pole of the expander to better predict and control the location of the reconstructed inframammary fold.

* Dacron is a registered trademark of Invista, Inc.

** Injection dome is not MRI compatible.

*** Palpation ring available on CPX™2 Tissue Expander.

‡ Compared with the MENTOR® CPX2™ Tissue Expander.

†† The third-party trademarks used herein are trademarks of their respective owners.

††† Suture tabs available on CPX™4 with Suture Tabs Tissue Expander.

CPG™ Gel Breast Implants

SHAPE AESTHETIC POSSIBILITIES TO REPLICATE NATURE.

As a pioneer in cohesive gel technology, it is no surprise that MENTOR® Breast Implants have led the way to a new level of excellence in breast reconstruction results. With the CPG™ Breast Implant family, Mentor offers an anatomic product range, which uniquely suits the CONTOUR PROFILE™ Tissue Expander results in size, shape and volume.

- **MEMORYGEL™ BREAST IMPLANTS** — Mentor's proprietary cohesive silicone gel, which holds together uniformly, and has the natural 'give' of breast tissue⁸
- **COHESIVE III™** — Mentor's most cohesive, form stabilising gel⁹
- **LOW BLEED SHELL** — the shell is designed to minimize silicone gel bleed⁹
- **UNIQUE SHAPE** — a projection point designed to maximize visual outcome
- **EASE OF PLACEMENT** — anterior and posterior orientation marks to facilitate surgical placement¹⁰
- **DIVERSITY IN PROFILE, HEIGHT AND SIZE** — 9 styles with 3 projections and 3 heights
- **TEXTURED SURFACE** — the SILTEX™ Texture provides a disruptive surface for collagen interface¹⁰



MENTOR® CPG™ Breast Implant 8-Year Data 95% CI: Primary Reconstruction¹¹

Rupture Rate MRI Sub-Cohort by patient	Capsular Contracture Rate	Satisfaction Rate	Rotation Rate
0%	10.1%	98.0%	5.1%

- Mentor data source is the 6-year Core Study Clinical Report that was submitted to FDA and Canada in 2010.
- Rupture and Capsular Contracture rates are Kaplan-Meier estimated cumulative incidence rates.
- Please note that Rupture Rate data includes suspected and confirmed ruptures based upon MRI cohort patients receiving MRIs at 6 years.

MEMORYGEL™ Breast Implants

Mentor also offers MemoryGel™ Round Breast Implants in five different profiles (Low, Moderate, Moderate Plus, High and Ultra High Profile) and two different cohesion levels (Cohesive I™ and Cohesive II™). In addition, the round shapes come in smooth and SILTEX™ Texture. For more information please refer to MENTOR® Implant Catalogue, 0907007 Rev E.

SILTEX™ BECKER™ Expander/Breast Implants

COMBINE EXPANDER AND BREAST IMPLANT

The SILTEX™ BECKER™ Expander/Breast Implant family combines a tissue expander and long-term breast implant into a single device. BECKER™ Expander/Breast Implants are a technological advancement in terms of the surgeon's ability to create exact outcomes in size, shape and fill, without compromising silicone gel's natural give.

- **TWO INDEPENDENT SHELLS** — silicone gel outer lumen and adjustable saline-fillable inner lumen¹²
- **THREE STYLES AND WIDE RANGE OF FINAL FILL VOLUMES** — optimises ability to provide custom-sized implants
- **FLEXIBLE USE** — can be used as long-term implant in a single stage procedure or as part of a two-stage reconstruction¹²
- **POSTOPERATIVELY ADJUSTABLE** — provides discreet control over implant volume, making attaining symmetry more consistent¹²
- **PROPRIETARY VALVE TECHNOLOGY** — unique dual self-sealing valves after desired fill volume has been achieved¹²
- **MRI COMPATIBLE REMOTE INJECTION DOME**¹²
- **TEXTURED SURFACE** — the SILTEX™ Texture provides a disruptive surface for collagen interface¹²



SILTEX™ ROUND
BECKER™ Expander/Implant 25



SILTEX™ ROUND
BECKER™ Expander/Implant 50



SILTEX™ CONTOUR PROFILE™
BECKER™ Expander/Implant 35

SPECTRUM™ Post-Operatively Adjustable Saline Breast Implants

INTRODUCE REFINEMENTS SIMPLY AND BEAUTIFULLY.

This unique offering from Mentor, like the BECKER™ Expander/Breast Implants, combines tissue expansion with a longterm saline breast implant. Accessible through the skin and self-sealing after desired proportions have been achieved¹³, SPECTRUM™ Implants provide similar features to the BECKER™ Expander/Implants.



SMOOTH ROUND
SPECTRUM™ Implant



SILTEX™ ROUND
SPECTRUM™ Implant



SILTEX™ CONTOUR PROFILE™
SPECTRUM™ Implant

PERTHESE™ ESTHEA Breast Implants

RESEMBLE BEAUTY AESTHETICALLY AND NATURALLY.

The PERTHESE™ Esthea Breast Implant family completes Mentor's range of anatomical breast implants, giving surgeons the broadest choice of implant sizes and styles and patients natural results. In two-stage reconstruction procedures, PERTHESE™ Esthea Breast Implants represent an additional choice for a longterm implant after expansion with a CONTOUR PROFILE™ Tissue Expander.

- **PERTHESE™ BREAST IMPLANTS** — made of cohesive and soft silicone gel, resembling the normal breast's consistency¹⁴
- **LOW BLEED SHELL** — the silicone envelope consists of an internal and external layer made with a medical grade silicone elastomer and an intermediate silicone barrier layer designed to reduce gel bleed¹⁵
- **NATURAL SHAPE** — respects the curves of the breast giving it a very natural appearance
- **EASE OF PLACEMENT** — anterior and posterior orientation marks to facilitate surgical placement¹⁵
- **WIDE CHOICE** — 7 models in various sizes
- **MICRO-TEXTURED SHELL** — provides a soft envelope while allowing a non-aggressive disorganisation of the collagen structure¹⁵



PERTHESE™ Breast Implants are also available as Microtextured Round Silicone Gel Breast Implants in five different profiles (Low, Moderate, Moderate Plus, High and Ultra High Profile). For more information please refer to MENTOR® Implant Catalogue, 0907007 Rev E.

PROFESSIONAL SUPPORT

Mentor Breast Team (MBT) — A Patient Centric Reconstruction Approach.



THE GOAL— Bringing together medical professionals from Oncology and Reconstructive specialties to fully implement the principles of a multi-disciplinary team approach in breast cancer care for improved patient outcomes.

HOW — Pre-surgical patient consultation, joint decisions of the best alternative for the patient and full treatment offering should be the standard of care in every medical setting.

Mentor supports interested teams/hospitals in building their own MBT setting by offering access to a Center of Excellence.

Breast Teamwork that changes lives

Driving patient awareness of breast reconstruction

When your patients are considering their options for breast cancer surgery, they need to know what is available. Our patient focused website YourBreastOptions™ is available in multiple languages to give patients access to information related to their reconstruction options and other resources to help them make an informed decision.

ENCOURAGE YOUR PATIENTS TO VISIT:

YOURBREASTOPTIONS.COM

YourBreastOptions.co.uk

YourBreastOptions.de

YourBreastOptions.fr

YourBreastOptions.ru

YourBreastOptions.es

YourBreastOptions.pl

PROFESSIONAL EDUCATION

Mentor offers a comprehensive range of Professional Education opportunities to support surgeons throughout their career. Our range of courses includes:

PRACTICAL COURSES IN BREAST RECONSTRUCTION SURGERY WITH IMPLANTS— Designed for a small group of participants, this course consists of lectures and surgery observation in the OR that demonstrate expander/implant selection and surgical technique in a variety of breast reconstruction cases.

• **TARGET AUDIENCE:** Reconstruction surgeons looking to increase their procedural expertise in using expanders and implants in reconstruction.

SCIENCE OF BREAST IMPLANTS — Focuses on clinical evidence of breast implant safety, discussion of key complications and how to prevent them as well as manufacturing & quality controls designed to ensure product quality.

• **TARGET AUDIENCE:** Health Care Providers interested in deepening their knowledge of clinical evidence, safety and quality of breast implants.

MENTOR BREASTTEAM (MBT) PATIENT CENTRIC RECONSTRUCTION APPROACH

— Designed to share experience, know-how and tools through team discussions, lectures, case studies and interaction with breast cancer patients.

• **TARGET AUDIENCE:** Surgical teams from hospitals who would like to apply or advance their multi-disciplinary Breast Cancer Treatment concept through team learning.





A beautiful outcome from products made to work in concert.

Choosing our integrated system of reconstruction-oriented products is choosing a combination of technological excellence and thorough product support. You are also collaborating in an ongoing effort to help women transition with more confidence from trauma to wholeness. Through research, science and a sustained partnership with our surgeons, Mentor continues to develop reconstruction innovations that play a rejuvenating role in a woman's recovery from cancer. We are indebted to the surgeons whose work helps make our products make the difference.

For more information visit www.mentorwllc.eu

Important Safety Information:

MENTOR® 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 who are pregnant or nursing.

There are risks associated with breast implant surgery. Breast implants are not lifetime devices and breast implantation is not necessarily a one-time surgery.

The most common complications with MENTOR® MemoryGel™ Breast Implants and PERTHESE™ Breast Implants include re-operation, implant removal, capsular contracture, asymmetry, and breast pain. A lower risk of complication is implant rupture, which is most often silent. 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 Implants include re-operation, implant removal, capsular contracture, wrinkling, deflation, asymmetry, and breast pain.

The MENTOR® CONTOUR PROFILE™ Tissue Expander are used for breast reconstruction following 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. CONTOUR PROFILE™ Tissue Expanders are devices that contain magnetic injection domes and are NOT MRI compatible. Do not use the CONTOUR PROFILE™ Tissue Expander in patients where an MRI may be needed. DO NOT use the CONTOUR PROFILE™ Tissue Expander in patients that have a previously implanted device that could be affected by a magnetic field. 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.

Your patient needs to be informed and understand the risks and benefits of breast implants and breast tissue expanders, and provided with an opportunity to consult with you prior to deciding on surgery.

For detailed indications, contraindications, warning and precautions associated with the use of all MENTOR® Implantable Devices, please refer to the Product Insert Data Sheet provided with each product, or review the Important Safety Information provided at www.mentorwllc.eu

References: 1. GLOBOCAN 2008 (IARC) *Section of Cancer Information* (11/4/2013) <http://globocan.iarc.fr/> 2. American Cancer Society, <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-survival-by-stage> (Accessed on 11 April, 2013) 3. ECHI INDICATOR DEVELOPMENT AND DOCUMENTATION, Joint Action for ECHIM Final Report Part II 4. C.N. Lee et al "Are Patients Making High-Quality Decisions about Breast Reconstruction after Mastectomy?" *PRSJournal*, Volume 127, Number 1 5. S. Bellino et al "Quality of Life of Patients Who Undergo Breast Reconstruction after Mastectomy: Effects of Personality Characteristics", *PRSJournal*, Volume 127, Number 1r ECHIM 6. CPX™ 510k notification May 2001. 7. CONTOUR PROFILE™ Tissue Expander with BUFFERZONE™ Area Product Insert Data Sheet 102811-001 Rev. B Effective June 2003. 8. IOM Expert Panel Report (Bondurant et al. 2000) page 58. 9. Data on File at Mentor Worldwide LLC. 10. Gel Breast Implants Product Insert Data Sheet 10605-04. 11. D.C. Hammond et al "Mentor Contour Profile Gel Implants: Clinical Outcomes at 6 Years" *PRSJournal*, Volume 129, Number 6 12. SILTEX™ BECKER™ Expander/Breast Implant Product Insert Data Sheet 10202-07 13. Saline-Filled & SPECTRUM™ Post-Operatively Adjustable Saline Breast Implants Product Insert Data Sheet 10210-001 Rev. A Effective March 2009. 14. Psillakis J., Facchina P., Kharmandayan P., Trillo L., Canzi W., Aguiar H. eds. (2009). Review of 1,447 Breast Augmentation Patients Using PERTHESE Silicone Implants. *Aesthetic Plastic Surgery*. 15. PERTHESE™ Silicone Gel-Filled Breast Implant Instructions and Indications 12-09/014.

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