

# UNSURPASSED PORTFOLIO

INTRODUCING MENTOR'S ADVANCED RECONSTRUCTION  
PRODUCT OFFERINGS

#1

GLOBAL BRAND



**RIGHT FROM THE START. MADE TO MATCH**  
MENTOR® CPX™4 Breast Tissue Expander

**GIVING YOU GREATER CONTROL OVER  
THE DESIRED BREAST SHAPE**  
MENTOR® CPG™ Breast Implants



**POST-OPERATIVELY ADJUSTABLE  
EXPANDER AND BREAST IMPLANT  
ALL IN ONE DEVICE**

BECKER™ Expander/Breast Implants



**PROVEN**

WITH

**MENTOR®**

PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

## SILTEX™ BECKER™ EXPANDER/BREAST IMPLANT

# PROVEN INNOVATION

## The ability to adjust the implant size postoperatively

- **TISSUE EXPANDER** that uniquely converts into a long-term implant
- **TWO INDEPENDENT SHELLS** - silicone gel outer lumen and adjustable saline- fillable inner lumen, allowing for a tactile advantage of gel with the volume flexibility of saline
- **TWO STYLES AND WIDE RANGE OF FINAL FILL VOLUMES** - optimizes ability to provide custom sized implants
- **FLEXIBLE USE** - can be used as a long-term implant in a single stage procedure or as part of a two stage reconstruction
- **POSTOPERATIVELY ADJUSTABLE** - provides control over implant volume
- **PATENTED VALVE TECHNOLOGY** - unique dual self-sealing valves after desired fill volume has been achieved allowing for adjustability and aiding symmetry in bilateral and unilateral cases
- **MRI COMPATIBLE**
- **REMOTE INJECTION DOME**
- **SILTEX® TEXTURED SURFACE**
- **MEMORYGEL™ COHESIVE SILICONE GEL CHOICE** - meet your needs with two dome sizes, with two connector styles to choose from too



### SILTEX® Contour Profile BECKER™ 35

Shaped outer lumen is 35% pre-filled with silicone gel. Shaped inner lumen is connected on the backside of the outer lumen to prevent rotation. The empty inner lumen constitutes 65% of the final nominal volume. Over- expansion is possible to 25% beyond nominal fill volume.



### SILTEX® Round BECKER™ 25

Outer lumen is 25% pre-filled with silicone gel. The empty inner lumen can be filled with saline to constitute 75% of the final nominal volume.

Over-expansion is possible to 50% beyond nominal fill volume.

# CPX™4 BREAST TISSUE EXPANDER

## PROVEN EXPANSION

The only company to offer a breast tissue expander with proven directional lower pole expansion<sup>1</sup>

### PATIENT COMFORT

Incorporates two principle innovations that were designed to enhance patient comfort while maintaining the same expansion profile<sup>\*\*</sup>

### EASY TO DETECT

The **CENTRESCOPE® Magnetic Detection Device** locates the magnetic injection dome for absolute ease and accuracy

The injection dome contains a rare earth magnet that is 48% stronger than previous expanders<sup>3\*</sup>

### EASE OF USE

More pliant proprietary BufferZone™ Patch, smooth injection dome and enhanced shell pliability<sup>‡</sup>, designed for easier insertion and removal<sup>5</sup>

### NATURAL SHAPE

The combination of the **BufferZone™ Self-Sealing Patch** and the posterior **Dacron® Patch** provides directionally focused expansion to maximise lower pole projection, creating a natural shape<sup>4</sup>

### 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<sup>6\*\*</sup>

### TEXTURED SURFACE

SILTEX™ Texture provides consistent coefficient throughout the device to minimise implant rotation

The patented SILTEX™ Texture has a surface substantially free of pores and interstices<sup>7</sup>



\*The third-party trademarks used herein are trademarks of their respective owners

‡Compared with the MENTOR® CPX™2 Tissue Expander

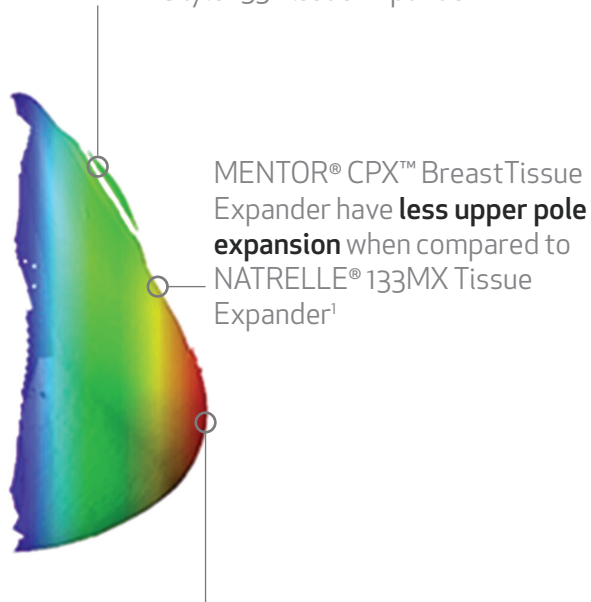
\*\*Design Validation Report, Mentor Worldwide LLC, January 2013

# PROVEN EXPANSION

Two added Benefits: one feature for Safety and one for Shape<sup>4\*\*</sup>

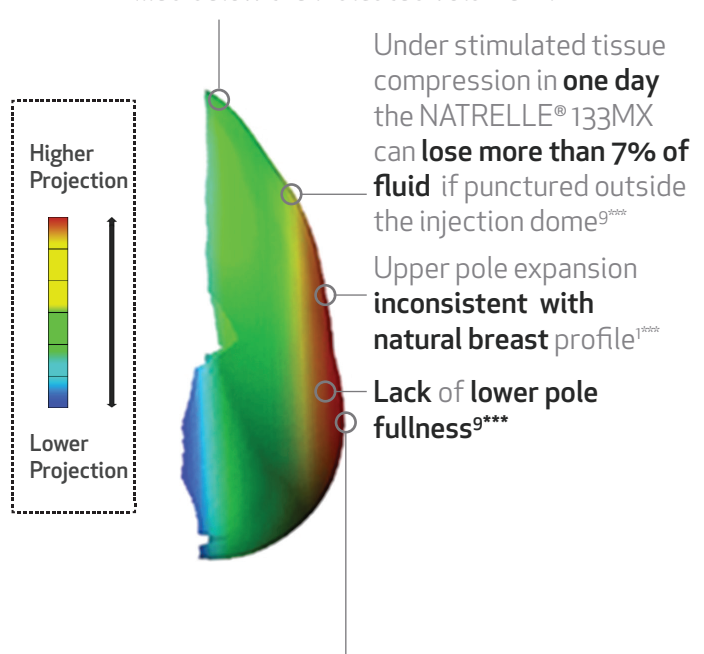
Photographs and 3D Image Analysis of Mentor and Allergan Expanders showing tissue expanders compare under simulated pressurised conditions

**MENTOR® CPX™ 4** Breast Tissue Expander offers a **47% greater target area** as compared to the NATRELLE® Style 133 Tissue Expander<sup>\*\*8</sup>



Under simulated tissue compression, CPX™ 4 Expander has **greater lower pole projection** than NATRELLE® 133MX<sup>1</sup>

**NATRELLE® 133MX\*** had **average base expansions greater than 10mm** even when filled below the indicated volume<sup>9\*\*\*</sup>.



The **profile and shape** of the NATRELLE® 133 Tissue Expander become **round** at all expansion levels<sup>9</sup>

**Mentor is the only company to offer a breast tissue expander with proven directional lower pole expansion<sup>1</sup>**

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

\*\* Natrelle® Two Stage Reconstruction Catalogue. January, 2013.

\*\*\* Mentor\_100316549 3D Benchtop Imaging of Ar DOF RPT, April 2015

# CPG™ GEL BREAST IMPLANTS

## PROVEN PERFORMANCE\*

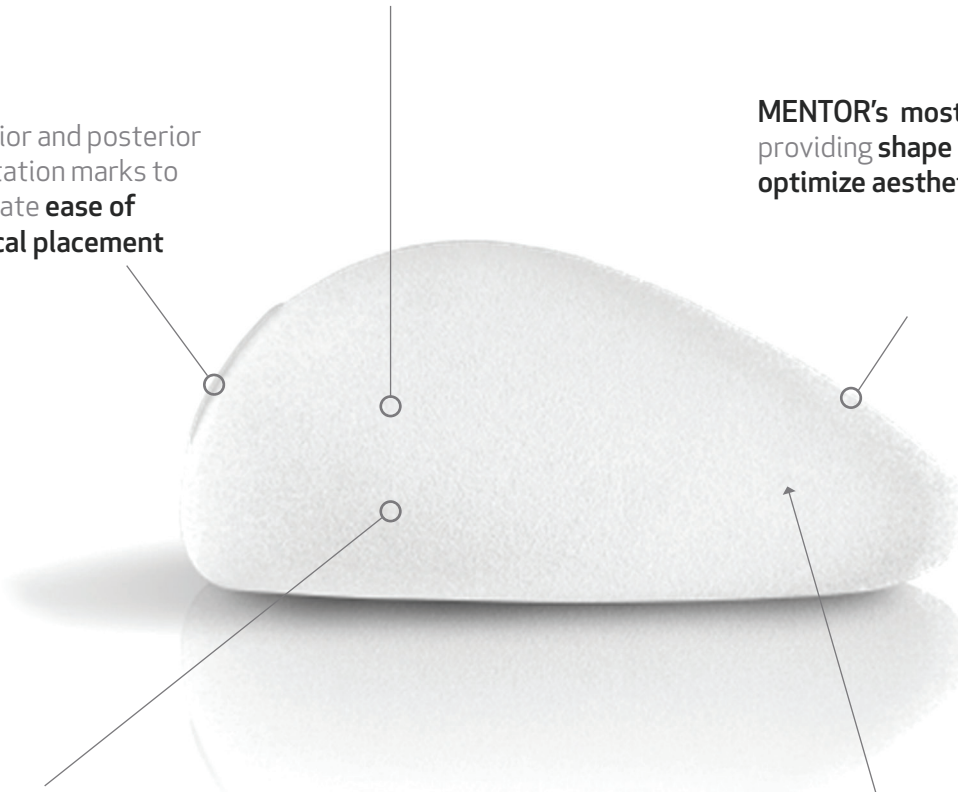
With MENTOR® CPG™ Gel Breast Implants, the implant shapes the breast,  
not the breast shaping the implant

### **MOST PROJECTING SHAPED IMPLANT\*\***

Tapered shape, with a **gradually sloping upper pole** and more projecting lower pole\*\*\*

Anterior and posterior orientation marks to facilitate **ease of surgical placement**

MENTOR's most cohesive gel, providing **shape retention** to help **optimize aesthetic results**



### **TEXTURE YOU CAN TRUST**

MENTOR® CPG™ Gel Breast Implants incorporate **SILTEX™ Texture** to help **reduce** the risk of **capsular contraction** and **rotation**

**SILTEX™ Texture** provides **consistent coefficient of friction** throughout the device to **minimize implant rotation**

### **PERFORMANCE\***

The **lowest reported capsular contracture rate** in primary breast reconstruction at 10 years<sup>11</sup>

\*Not a head to head study. Based on the comparison of key complication rates reported in the 10 year Core Studies for MemoryShape®/ CPG™ Gel Breast Implants, NATRELLE™ 410 TruForm™ 3 Gel Breast Implants, NATRELLE™ Round TruForm™ 1 Gel Breast Implants, and MemoryGel™ Breast Implants.

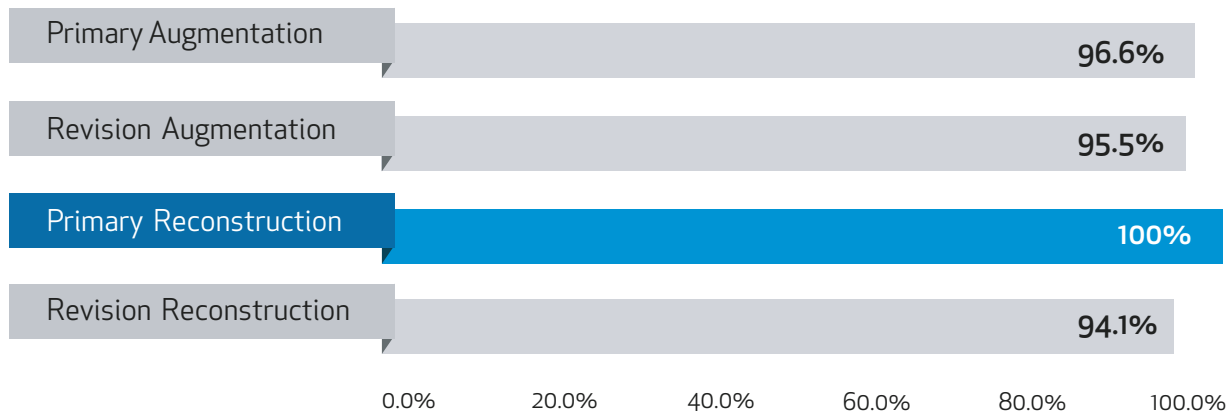
\*\*Most projection based on projection and base width comparisons of the following textured shaped silicone gel breast implants: CPG™ Gel Breast Implants, NATRELLE™ 410 TruForm™2 Breast Implants, NATRELLE™ 410 TruForm™3 Breast Implants, NATRELLE™ 510 Dual Gel Anatomical Implants, Silimed BIODESIGN™ Matrix Textured Breast Implants, The Matrix Breast Implants by EUROSILICONE™, NAGOR™ CoGel System® Breast Implants, SEBBIN Naturgel™ Anatomical Breast Implants, CEREPLAS® Anatomical Breasts Implants and POLYTECH SublimeLine®. NATRELLE™ Product Catalogue 11-2008, Silimed Catalogue 2012, EUROSILICONE™ Product Catalogue 2013, NAGOR™ Product Catalogue 2013, SEBBIN Naturgel™ Anatomical Implants Catalog, CEREPLAS® Anatomical Breast Implants, and POLYTECH SublimeLine® Catalogs all accessed 11/4/2014

\*\*\*As compared to MENTOR® MemoryGel® Breast Implants

# PROVEN PEACE OF MIND

At MENTOR® we put patient safety as our number one priority

100% Patient Satisfaction in Primary Reconstruction at 10 years<sup>11</sup>



MENTOR® CPG™ Gel Breast Implants Core Study at 10 years<sup>11</sup>

#### 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 those women with active infection anywhere in their body, those with existing cancer or pre-cancer of their breast(s), those who have not received adequate treatment for these conditions or those 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. Patients may require additional unplanned surgeries on the breast(s) because of complications or unacceptable cosmetic outcomes. Many of the changes to the breast(s) following implantation are irreversible (cannot be undone) and breast implants may affect the ability to breastfeed, either by reducing or eliminating milk production. The most common complications with MENTOR® MemoryGel™ 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 (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, deflation, asymmetry, and breast pain. MENTOR® CPX™4 Breast Tissue Expanders can be utilized 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; CPX™ Breast Tissue Expanders are devices that contain magnetic injection domes and are NOT MRI compatible. Do not use the CPX™ Tissue Expander in patients where an MRI may be needed. DO NOT use the CPX™ 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. Patients are reminded to discuss the indications, contraindications, warnings, precautions and the risks and benefits associated with MENTOR® Breast Implants with their surgeon and review the Important Safety Information provided at [www.mentorwllc.eu](http://www.mentorwllc.eu). It is important that patients understand the risks associated with breast implant surgery when considering MENTOR® Breast Implants.

#### REFERENCES:

- Hoffman\_CP529\_530Interim\_Report\_for\_CP529\_DOF\_PR\_20131007 (PDF)
- Source 6: Design Requirements Matrix. Source 9: Patient Comfort VOC. Source 16: Design Verification Report. Source 17: Design Validation Report. Design Fact: Fluid travels the path of least resistance. The reinforced anterior and posterior patches drive fluid towards the lower pole of the expander. Source 14 AST-2012-0176 3D Imaging Study
- Source 13 Magnet Strength Memo CPX2-3 vs CPX4. Source 18: IUPAC Nomenclature
- Design Fact: Fluid travels the path of least resistance. The reinforced anterior and posterior patches drive fluid towards the lower pole of the expander. Lower pole expansion more closely mimics the female breast (which is tapered in appearance). Source 14 AST-2012-0176 3D Imaging Study
- Source 6: Design Requirements Matrix. Source 9: Patient Comfort VOC. Source 16: Design Verification Report. Source 17: Design Validation Report
- Source 15: Surface Area Memo
- Source 22 Siltex US4960425(A)
- Source 11a: Larger Target Area Rationale. Source 11b: Natrelle® Reconstruction Brochure
- Allergan® 133MV-13 Tissue Expander in a benchtop study under simulated compression.
- Mentor Worldwide, LLC. MemoryShape® Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015 Mentor Worldwide LLC. Data on File. MemoryGel® Core Gel Clinical Study Final Report, April 2013 Maxwell, G. Patrick; Van Natta, Bruce W.; Bengtson, Bradley P.; and Murphy, Diane K., "Ten-Year Results from the Natrelle™ 410 Anatomical Form-Stable Silicone Breast Implant Core Study" (2015). Public Health Resources.  
Health Canada: Summary Basis of Decision (SBD) for Natrelle™ Highly Cohesive Silicone-Filled Breast Implants. Application No. 88573. License No.72262. Date Issued: 2014/01/17.  
Health Canada: Summary Basis of Decision (SBD) for Natrelle™ Silicone-Filled Breast Implants-Smooth Shell with Barrier and Natrelle™ Silicone Filled Breast Implants - Textured Shell with Barrier Layer. Application No. 61865 and 60524 License No License No 72264 and 72263. Date Issued: 2012/09/25.
- Mentor Worldwide, LLC. MemoryShape® Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015



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