

# MENTOR® MemoryShape® Breast Implants

**PROVEN** PROJECTION  
PERFORMANCE  
PEACE of MIND



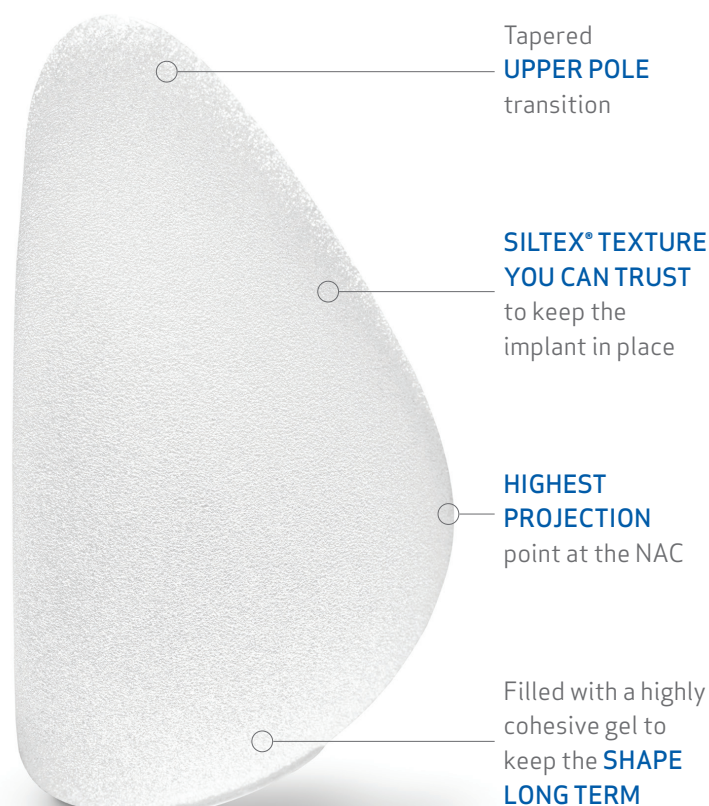
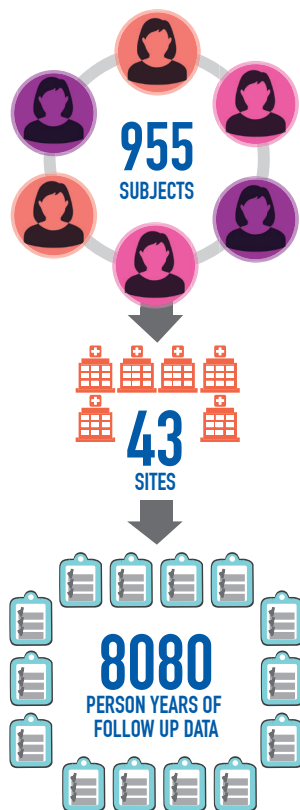
# PROVEN DESIGN

Designed to help you create your patient's desired look with long lasting results.

Based on a decade of research into the safety and efficacy of breast implants, our Mentor Core Study<sup>1</sup> provides evidence to support the **UNSURPASSED DESIGN** of MENTOR® MemoryShape® Breast Implants.

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.

## Multi-center Core Study



**Clinical data reveals the lowest reported incidence of key complications in primary augmentation at 10 years.<sup>1</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.

For further information about MENTOR® MemoryShape® Implants or any other MENTOR® Products, talk to your Mentor sales representative today or visit [mentordirect.com](http://mentordirect.com).

# PROVEN PERFORMANCE

Reliable implants continuously delivering world class clinical results.

The lowest reported risk of key complications in primary breast augmentation at 10 years<sup>1</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.

Each Mentor® MemoryShape® Breast Implant undergoes a stringent quality inspection and rigorous testing to ensure quality, performance and shell integrity.

The outcomes of the study speak for themselves, with beautiful, long-lasting results and high patient satisfaction.<sup>2</sup>



## Results that instill confidence in your patients:

Primary Augmentation	MENTOR® MemoryShape® Breast Implant Core Study, Long term 10 years <sup>2</sup>	Allergan® Natrelle® 410 Breast Implant Core Study, Long term 10 years <sup>7</sup>	Allergan® Natrelle® Breast Implant <sup>8*</sup>
Capsular Contracture (Baker III/IV)	3.6%	9.2%	18.9%
Suspected or Confirmed Rupture (MRI Cohort)	6.6%	17.7%	9.3%
Device Removal (with or without replacement)	9.2%	19.6%	20.9%

Kaplan-Meier estimated risk of first occurrence, %

\* The Allergan NATRELLE® Silicone-Filled Breast Implant core study is the primary set of clinical data used to establish a reasonable assurance of safety and effectiveness of the NATRELLE INSPIRA® Breast Implants for breast augmentation.

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.

Give your patients the confidence and reassurance they need. Talk to your Mentor sales representative today or visit [mentordirect.com](http://mentordirect.com) for more information.

# PROVEN TEXTURE YOU CAN TRUST

**SILTEX™ Texture providing you and your patients with peace of mind.**

MENTOR® MemoryShape®/CPG™ Implants are proven to have a low risk of capsular contracture and rotation in primary augmentation patients at 10 years and are covered by the most comprehensive warranty in the market.<sup>2</sup>

By manufacturing an implant with our proprietary SILTEX™ Imprinted Texture, we have created a surface substantially free of pores and interstices which can contribute to a reduction in key complications related to breast augmentation.<sup>3</sup>

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

As a result, MENTOR® MemoryShape®/CPG™ Implants are proven to have a low risk of capsular contracture and rotation in primary augmentation patients at 10 years.<sup>2</sup>

## Proven results that you can trust:

### LOWEST

Reported incidence of the following complication at 10 years

**3.6%**

Capsular contracture in primary augmentation<sup>1</sup>

### LOWEST

Reported incidence of the following complication at 10 years

**1.3%**

Rotation in primary augmentation<sup>1</sup>

### NO

Silicone particulates left behind

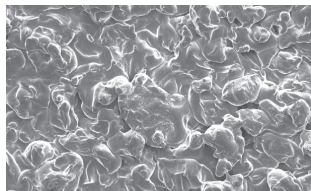
**0 out of 5**

No (0) particles suspected to be silicone globules were found in the capsular tissue of 5 patients implanted with SILTEX™ Texture devices<sup>4</sup>

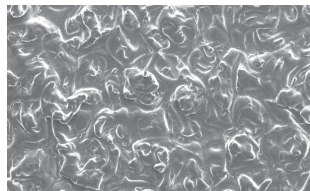
Not a head to head study. Based on the comparison of key complication rates reported in the 10 year Core Studies for MemoryShape®/CPG™ Gel Breast Implants, NATRELLE™ 410 TruForm™ 3 Gel Breast Implants, NATRELLE™ Round TruForm™ 1 Gel Breast Implants, and MemoryGel™ Breast Implants.

## A closer look at Mentor's proprietary SILTEX™ Texture<sup>5</sup>

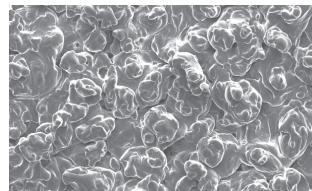
SEM images of SILTEX™ Texture



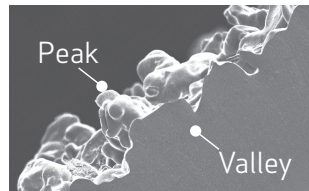
Anterior View



Radius View



Posterior View



Cross Section

# PROVEN PROJECTION

## Most projecting implant per base width.

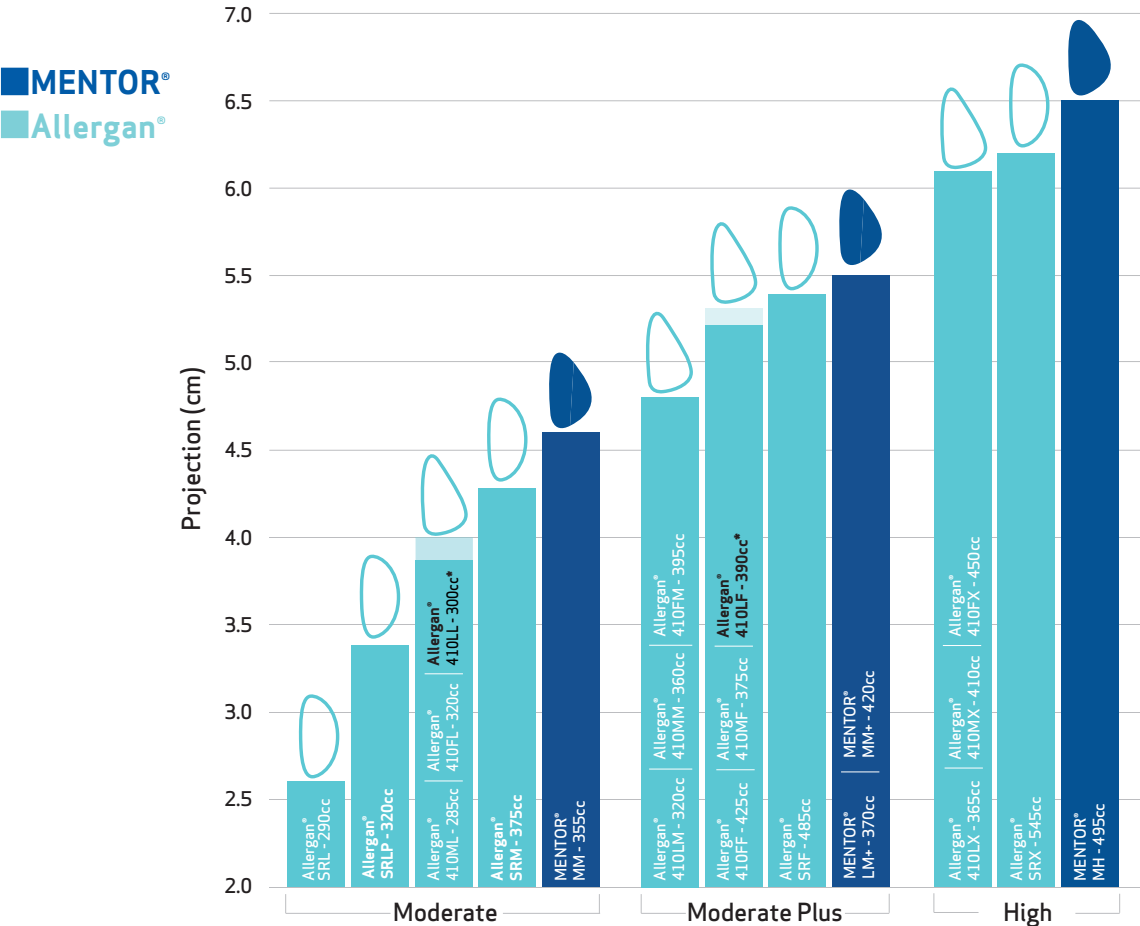
As compared with Allergan Natrelle® 410 Breast Implants, Allergan Natrelle® Inspira implants, and Sientra Breast Implants®

**MENTOR® MemoryShape® Breast Implant's unique, tapered shape provides more projection at the lower pole offering maximum projection when needed.**

As compared to MENTOR® MemoryGel® Breast Implants

With a uniquely formulated form stable highly cohesive gel that holds together uniformly, Mentor® MemoryShape® Breast Implants shape the breast, not the breast shaping the implant, helping you create your patient's desired look with long lasting results.<sup>2</sup>

### COMPARISON CHART: MENTOR® MemoryShape® Breast Implants versus other gel implants with approximate base width of 13CM



All implants compared have base width of 13cm unless noted. Implants with \* are 13.5cm.

Based on product comparisons of the following MENTOR® MemoryShape® Breast Implants: [http://www.mentorwllc.com/pdf/Product\\_Ref\\_Guide.pdf](http://www.mentorwllc.com/pdf/Product_Ref_Guide.pdf); Natrelle Product Catalog accessed 28/10/2016 from <http://www.natrellesurgeon.com>

# PROVEN PEACE of MIND

To our Mentor customers and patients, we pledge our commitment to excellence. That is why we back our MemoryShape® Breast Implants with the most comprehensive warranty in the industry.

Our MENTOR® MemoryShape® Breast Implants 10 year data demonstrates our passion to deliver safe products that offer high quality, reliable and state-of-the-art

design to enhance breast aesthetic procedures. We are determined to continue to provide objective, clinical information about breast implant safety.

## Mentor Warranties & Product Replacement Policy

### MENTOR® MemoryGel® Breast Implants and Memory Shape® Breast Implants

We have the industry's most comprehensive warranty for our full line of MemoryShape® Breast Implants and MemoryGel® Breast Implants and are proud to offer The Mentor & Mentor Enhanced Warranty. For full program details, qualifications and enrollment, visit [www.mentorwllc.com](http://www.mentorwllc.com).



MENTOR® BREAST IMPLANTS  
ARE PROUDLY  
MADE IN THE USA

For further information, talk to your Mentor sales representative or visit [mentorwllc.com](http://mentorwllc.com)



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#### Important Safety Information

MENTOR® MemoryShape® Breast Implants are indicated for breast augmentation in women at least 22 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 who have not received adequate treatment for those conditions, or who are pregnant or nursing.

Breast implants are not lifetime devices and breast implantation may not be a one-time surgery. The most common complications with MENTOR® MemoryShape® Breast Implants for breast reconstruction include reoperation for any reason, implant removal with or without replacement, and capsular contracture. 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.

Patients should receive a copy of *Patient Educational Brochure – Breast Augmentation with MENTOR® MemoryShape® Breast Implants* or *Patient Educational Brochure – Breast Reconstruction with MENTOR® MemoryShape® Breast Implants*, and a copy of *Quick Facts about Breast Augmentation & Reconstruction with MENTOR® MemoryShape® Breast Implants*. Your patient needs to read and understand the information regarding the risks and benefits of breast implants, with an opportunity to consult with you prior to deciding on surgery.

For detailed indications, contraindications, warnings, and precautions associated with the use of MENTOR® MemoryShape® Breast Implants please refer to the Product Insert Data Sheet provided with each product, or visit [www.mentorwllc.com](http://www.mentorwllc.com).

1. 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 Narelle(TM) 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.
2. Mentor Worldwide, LLC. MemoryShape® Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015.
3. Textured Silicone Breast Implant Use in Primary Augmentation: Core Data Update and Review, Derby, B., Codner, M. Wixtrom R, Vargo J, Canady J, Controversies in Breast Implant Texturing: New evidence on friction, rotation, double capsules and interactive effect of device placement on contracture in primary augmentation. Paper presented at IQUAM Congress and Consensus Conference. 10 April 2014. Budapest
4. Danino, A.M. Basmacioglu, P, Saito, S, et al. PRSJ, 2001; 108:2047-2052.
5. Mentor Worldwide, LLC, Data on File.
6. Mentor Product Reference Guide, Santa Barbara, CA 2015.  
Sientra Product Catalogue, Santa Barbara, CA: Sientra; 2015.  
NATRELLE® Breast Implants Product Catalogue, Irvine, CA: Allergan; APC04EQQ15 2015.
7. 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.
8. Directions for Use: Natrelle® Silicone-Filled Breast Implants and NATRELLE INSPIRA™ Breast Implants - L034 Rev. 08 2015