

MENTOR® CPG™ Gel Breast Implants

10 YEARS

THAT SHAPED BREAST
AESTHETICS

A ten year multicentre FDA Core Study.¹



 **MENTOR®**
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

A significant milestone in the design and performance of the MENTOR® CPG™ Gel Breast Implant

Based on a decade of research into the safety and efficacy of breast implants, our Mentor Core Study¹ provides evidence to support the UNSURPASSED PERFORMANCE* of MENTOR® CPG™ Implants.

This rigorous clinical data reveals the lowest reported incidence of key complications in primary augmentation at 10 years.^{1*}

Furthermore, the MENTOR® CPG™ Implant offers you TEXTURE YOU CAN TRUST, supported by long-term clinical data, and the MOST PROJECTING SHAPED IMPLANT² on the market.

This brochure summarises the latest findings on these three areas.



For further information about MENTOR® CPG™ Implants or any other MENTOR® Products, talk to your Mentor Sales Representative today or visit mentorwllc.eu.

* Not a head to head comparison. Based on 10 year core clinical study reported data of CPG™ Gel Breast Implants, NATRELLE™ 410 TruForm™ 3 Gel Breast Implants, NATRELLE™ Round TruForm™ 1 Gel Breast Implants, and MemoryGel™ Breast Implants. These core clinical studies DID NOT include NATRELLE™ Inspira Round TruForm™ 1 Gel Breast Implants, NATRELLE™ 410 TruForm™ 2 Gel Breast Implants, or NATRELLE™ 510 Dual Gel Anatomical Breast Implants. Only clinical studies with 10 year data were considered.

UNSURPASSED PERFORMANCE*

Reliable implants continuously delivering world class clinical results

THE LOWEST REPORTED RISK OF KEY COMPLICATIONS IN PRIMARY BREAST AUGMENTATION AT 10 YEARS^{1*}

* Not a head to head comparison. Based on 10 year core clinical study reported data of CPG™ Gel Breast Implants, NATRELLE™ 410 TruForm™ 3 Gel Breast Implants, NATRELLE™ Round TruForm™ 1 Gel Breast Implants, and MemoryGel™ Breast Implants. These core clinical studies DID NOT include NATRELLE™ Inspira Round TruForm™ 1 Gel Breast Implants, NATRELLE™ 410 TruForm™ 2 Gel Breast Implants, or NATRELLE™ 510 Dual Gel Anatomical Breast Implants. Only clinical studies with 10 year data were considered.

Each MENTOR® CPG™ Gel 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 increased patient satisfaction.¹



Results that instill confidence in your patients:

Primary Augmentation	MENTOR® CPG™ Gel Breast Implant Core Study, Long term 10 years ¹	Allergan® Natrelle® 410 Breast Implant Core Study, Long term 10 years ³
Capsular Contracture (Baker III/IV)	3.8%	9.2%
Suspected or Confirmed Rupture (MRI Cohort)	6.4%	17.7%
ANY Reoperation	23.0%	29.7%
Device Removal (with or without replacement)	9.5%	19.6%

Kaplan-Meier estimated risk of first occurrence. Data presented in table is not based on a head to head comparison of the Mentor® CPG™ Gel Breast Implant and the Allergan® Natrelle® 410 Breast Implant Core Studies.

Give your patients the confidence and reassurance they need. Talk to your Mentor Sales Representative today or visit mentorwllc.eu for more information.

MOST PROJECTING SHAPED IMPLANT²

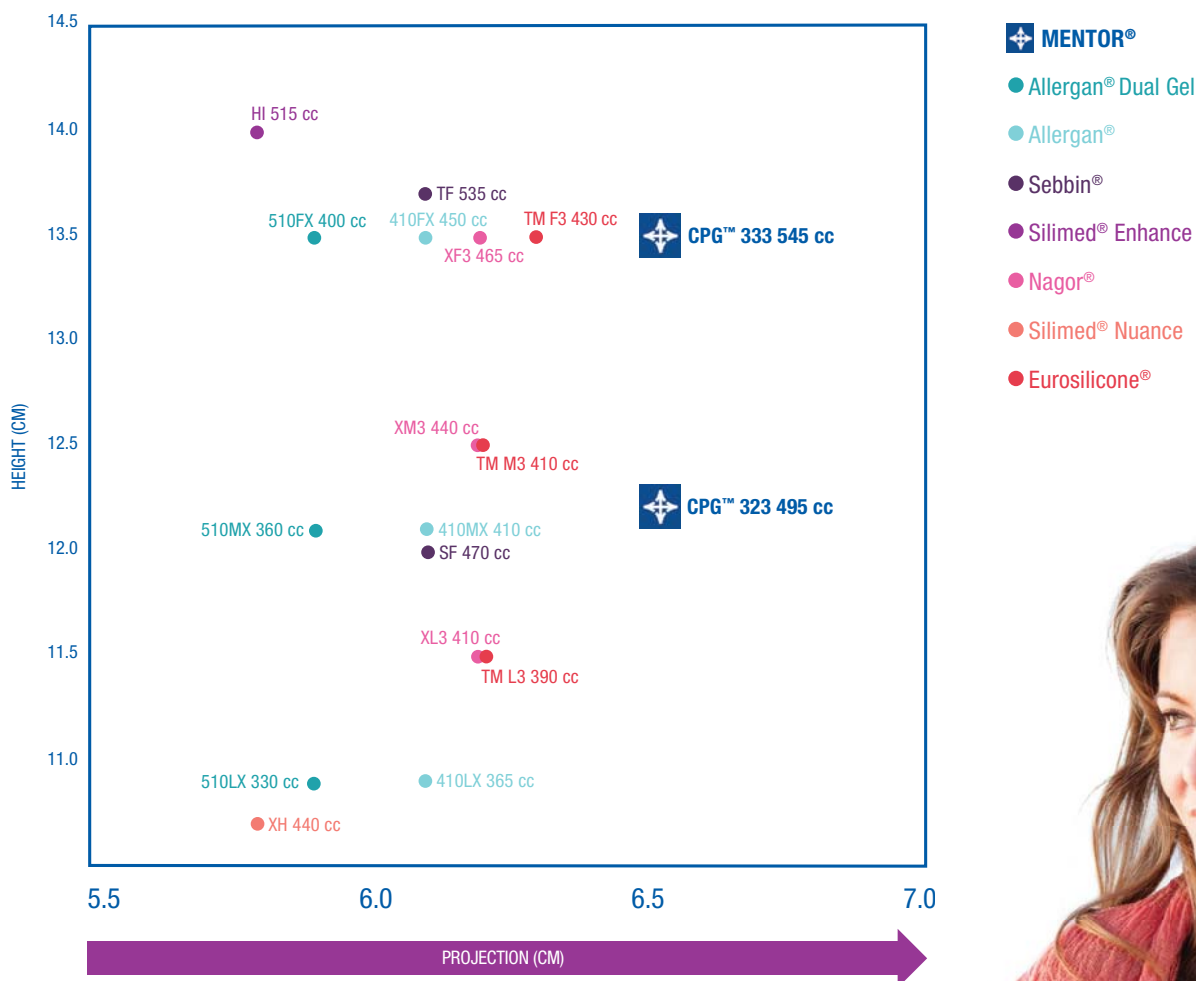
Projection without compromising the feel

With a uniquely formulated cohesive gel that holds together uniformly, the MENTOR® CPG™ Gel Breast Implant offers maximum

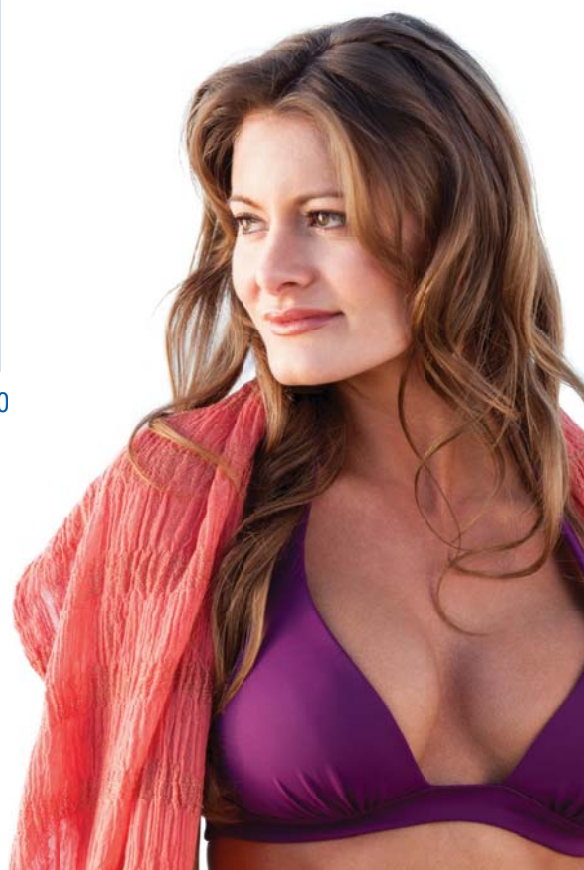
projection when needed, whilst giving your patients a natural shape and feel.

Natural shape and projection that lasts:

COMPARISON CHARTS: Shaped Gels vs MENTOR® CPG™ Gel Implants Projection Comparison - Shaped Implants 13 - 13.5 cm diameter



Give your patients maximum projection with a soft, natural feel. Talk to your Mentor Sales Representative today or visit mentorwwllc.eu for more information.



TEXTURE YOU CAN TRUST

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

MENTOR® CPG™ Gel Breast Implants with SILTEX™ Texture have 0% reported incidence of double capsule, and the lowest reported risk of rotation and capsular contracture.^{1*}

By manufacturing an implant with our unique SILTEX™ Imprinted Texture, we have created a surface substantially free of pores and interstices⁵ which can contribute to a reduction in key complications during breast augmentation.^{6,7}

Our SILTEX™ Texture provides consistent coefficient of friction to minimise implant rotation.⁶

MENTOR® CPG™ Implants are proven to have a low risk of capsular contracture and rotation.¹

Proven results that you can trust:

LOWEST

Reported incidence of the following complications at 10 years^{1*}

3.8%

Capsular contracture in primary augmentation¹

1.5%

Rotation in primary augmentation¹

LOW

Complication risk in over 9000 SILTEX™ Texture Implants⁴

0%

Reported double capsule¹

NO

Silicone globules left behind⁸

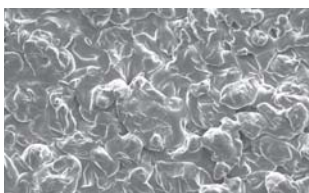
0 out of 5

Capsules had silicone globules in a published study⁸

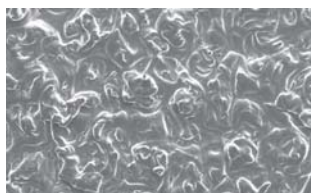
* Not a head to head comparison. Based on 10 year core clinical study reported data of CPG™ Gel Breast Implants, NATRELLE™ 410 TruForm™ 3 Gel Breast Implants, NATRELLE™ Round TruForm™ 1 Gel Breast Implants, and MemoryGel™ Breast Implants. These core clinical studies DID NOT include NATRELLE™ Inspira Round TruForm™ 1 Gel Breast Implants, NATRELLE™ 410 TruForm™ 2 Gel Breast Implants, or NATRELLE™ 510 Dual Gel Anatomical Breast Implants. Only clinical studies with 10 year data were considered.

A closer look at MENTOR® patented SILTEX™ Texture⁵

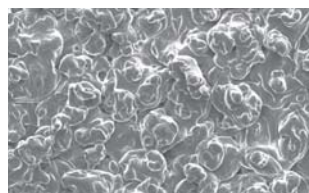
SEM images of SILTEX™ Texture



Anterior View



Radius View



Posterior View



Cross Section

Uncover the unique SILTEX™ Texture of MENTOR® CPG™ Implants today. Talk to your Mentor Sales Representative or visit mentorwllc.eu for more information.

10 YEARS OF COMMITMENT TO EXCELLENCE¹

This 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.

**To our Mentor customers and patients, we pledge our
commitment to excellence.**

Our PatientCare Promise Warranty is our promise to you

The confidence we have in our products speaks for itself. That's why every MENTOR[®] CPG[™] Gel Breast Implant comes with a Lifetime Product Replacement Policy with automatic patient enrolment.

The Mentor PatientCare Promise is a comprehensive warranty, assuring that all our implants are made to the highest level of quality and service.

For further information, talk to your Mentor Sales Representative or visit mentorwwllc.eu.



As a member of the Johnson & Johnson family of companies, patient safety is our priority at Mentor. That's why we're committed to delivering the highest standards of quality and increased patient outcomes.

Important Safety Information

MENTOR[®] MemoryGel[™] Breast Implants and PERTHESE[™] 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. Patients may need 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 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 (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.

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.mentorwwllc.eu.

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

1. Mentor Worldwide, LLC. MemoryShape[®] Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Annual Report. June 2014.
2. Based on product comparisons of the following textured shaped silicone gel breast implants:
http://www.mentorwwllc.com/pdf/Produwct_Ref_Guide.pdf
<http://www.sebbin.com/en/women.html>
<http://www.eurosurgical.co.uk/wp-content/uploads/2011/12/2012-Silimed-catalogue-breast.pdf>
http://eurosilicone.com/pdf/Eurosilicone_Product_Catalogue_2013.pdf
http://nagor.com/pdf/Nagor_Product_Catalogue_2013.pdf
Allergan Natrelle Product Catalogue 11-2008
Access Date 09-12-2014
3. Health Canada. Summary Basis of Decision (SBD) for Natrelle[™] Highly Cohesive Silicone-Filled Breast Implants, 2014. Application No: 88573, Licence No: 72262. Canada: Device Licensing, Health Canada; January 17, 2014.
4. Mentor's Core and Continued Access studies for round and shaped breast implants.
5. United States Patent Number 4, 960, 425. Yan et al
6. Textured Silicone Breast Implant Use in Primary Augmentation: Core Data Update and Review, Derby, B., Codner, M.
7. 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
8. Danino, A.M. Basmacioglu, P, Saito, S, et al. PRSJ, 2001; 108:2047-2052.

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