MENTOR® CPG™ Gel Breast Implants

# 10 YEARS THAT SHAPED BREAST AESTHETICS

A ten year multicentre FDA Core Study.1





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

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 PERFORMANCE\*.<sup>2</sup> of MENTOR\* CPG\*\* Gel Breast Implants.

This clinical data reveals MENTOR® CPG™ Gel Breast Implants have the lowest reported incidence of key complications in primary augmentation at 10 years.\*.2

Furthermore, the MENTOR® CPG™ Gel Breast Implant offers you TEXTURE YOU CAN TRUST, supported by long-term clinical data,³ and the MOST PROJECTING SHAPED IMPLANT on the market.†

This brochure summarises the latest findings on these three areas.



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

<sup>\*</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<sup>TM</sup> Gel Breast Implants, NATRELLE<sup>TM</sup> 410 TruForm<sup>TM</sup> 3 Gel Breast Implants, NATRELLE<sup>TM</sup> Round TruForm<sup>TM</sup> 1 Gel Breast Implants, and MemoryGel<sup>TM</sup> Breast Implants

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

# 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\*,1 and the lowest reported incidence of rotation and capsular contracture in the Core study at 10 years.\*,2

By manufacturing an implant with our unique SILTEX™ Imprinted Texture, we have created a surface substantially free of pores and interstices which can contribute to a reduction in key complications of breast augmentation.⁴

Proven results that you can trust:

#### LOWEST

Reported incidence of the following complications at 10 years

3.6%

Capsular contracture in primary augmentation\*,2

1.3%

Rotation in primary augmention\*,2

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

MENTOR® CPG™ Gel Breast Implants are proven to have a low risk of capsular contracture and rotation in primary augmentation patients at 10 years.¹

#### LOW

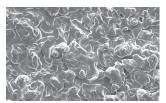
Complication risk in over 9000 SILTEX™ Texture Implants \*.6

0%

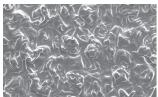
Reported double capsule \*,1

#### A closer look at MENTOR® patented SILTEX™ Texture

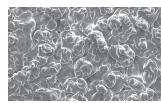
SEM images of SILTEX™ Texture



Anterior View



Radius View



Posterior View



**Cross Section** 

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

<sup>\*</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<sup>TM</sup> Gel Breast Implants, NATRELLE 410 TruForm<sup>TM</sup> 3 Gel Breast Implants, NATRELLE<sup>TM</sup> Round TruForm<sup>TM</sup> 1 Gel Breast Implants, and MemoryGel<sup>TM</sup> Breast Implants

Based on the MENTOR® CPG™ Gel Breast Implants Core study report of 955 patients

<sup>\*</sup> Based on Key Complications of Capsular Contracture, Infection, Explantation and any Reoperation.

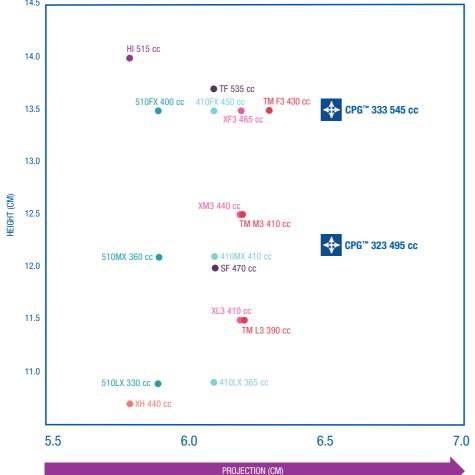
# MOST PROJECTION SHAPED IMPLANT

#### 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 Gel vs MENTOR® CPG™ Gel Breast Implants Projection Comparison – Shaped Implants 13 – 13.5 cm diameter



Allergan® Dual Gel
Allergan®
Sebbin®
Silimed® Enhance
Nagor®
Silimed® Nuance
Eurosilicone®

**♦** MENTOR®

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

†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



# UNSURPASSED PERFORMANCE\*,2

#### Reliable implants continuously delivering world class clinical results<sup>1</sup>

Based on clinical study results for primary augmentation patients, MENTOR® CPG™ Gel Breast Implants have the LOWEST REPORTED INCIDENCE OF KEY COMPLICATIONS IN PRIMARY BREAST AUGMENTATION AT 10 YEARS\*,2

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 Core Study speak for themselves, with beautiful, long-lasting results and high patient satisfaction.<sup>1</sup>



## Results that instil confidence in your patients:

Primary Augmentation	MENTOR® CPG™ Gel Breast Implant Core Study, Long term 10 years¹ (N = 572)	Allergan° Natrelle° 410 Breast Implant Core Study Long term 10 years <sup>5</sup> (N = 492)
Capsular Contracture (Baker III/IV)	3.6%	9.2%
Suspected or Confirmed Rupture (MRI Cohort)	6.6%	17.7%
ANY Reoperation	22.3%	29.7%
Device Removal (with or without replacement)	9.2%	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.

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

<sup>\*</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<sup>TM</sup> Gel Breast Implants, NATRELLE<sup>TM</sup> 410 TruForm<sup>TM</sup> 3 Gel Breast Implants, NATRELLE<sup>TM</sup> Round TruForm<sup>TM</sup> 1 Gel Breast Implants, and MemoryGel<sup>TM</sup> Breast Implants

# 10 YEARS OF COMMITMENT TO EXCELLENCE

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.

### Most Comprehensive Warranty on the Market-MentorPromise

The confidence we have in our products speaks for itself. That's why every MENTOR® CPG™ Gel Breast Implant comes with a FREE MentorPromise with automatic patient enrollment.

The MentorPromise assures that all our implants are made to a high level of quality and service.

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

#### Important Safety Information

MENTOR® MemoryGel™ 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. 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. 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.

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

For detailed indications, contraindications, warnings 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.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.

- Mentor Worldwide, LLC. MemoryShape® Post-Approval Cohort Study (formerly Contour Profile Gel Core Study) Final Clinical Study Report. 02 June 2015.
- 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.

- Health Canada: Summary Basis of Decision (SBD) for Mentor MemoryGel (TM) CPG Breast Implants Cohesive III. Application No. 86150 License No.72270. Date Issued: 2016/05/09
- 4. 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
- Ten-year results from the Natrelle 410 anatomical form-stable silicone breast implant core study. Maxwell GP, Van Natta BW, Bengston BP, Murphy DK.
- 6. MemoryShape™ Post-Approval Continued Access Study (formerly Contour Profile Gel Continued Access Study), Final Report October 2014. MemoryShape™ Post-Approval Cohort Study (formerly Contour Profile Gel Core Study), Final Report 02 June 2015. CPG Styles Study: A Study of the Safety of the Contour Profile Gel Breast Implants in Subjects who are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction, or Revision, Final Clinical Study Report 20 October 2015

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