# THE MENTOR WARRANTY

for MENTOR<sup>®</sup> MemoryGel<sup>®</sup> Breast Implants and MemoryShape<sup>®</sup> Breast Implants

Implanted in the United States (including Puerto Rico) on or after **October 06, 2014** 



### YOUR **PEACE-OF-MIND** COMES FIRST

Partnering with the right surgeon and choosing the best implants are your core choices when it comes to breast surgery and what drives your overall experience. The best implants should come with a generous product warranty to ensure you are supported long after the surgery. Mentor stands firmly behind the integrity of our products with our lifetime replacement policy so you can have complete confidence when making MENTOR<sup>®</sup> MemoryGel<sup>®</sup> Breast Implants and MENTOR<sup>®</sup> MemoryShape<sup>®</sup> Breast Implants your choice.

# **Mentor** is committed to your long-term well-being

Our relationship with you does not end with your surgery. We are here before your surgery to answer questions and provide perspective. And importantly, we are there after your surgery —with a long-term commitment.

# The **first company** to offer patients a limited warranty on all our breast implants

Clinically tested. FDA approved. The choice by millions of women for over 25 years. Our faith in our breast implants is based on results and this is why we can so confidently offer the **Mentor** and **Mentor** Enhanced Warranties.

# COULD **NOW** BE THE TIME?

# First and foremost: MENTOR® Breast Implants are **guaranteed for your lifetime**

All recipients of MENTOR<sup>®</sup> MemoryGel<sup>®</sup> Breast Implants and MENTOR<sup>®</sup> MemoryShape<sup>®</sup> Breast Implants are automatically enrolled in the **Mentor Product Replacement Policy**.<sup>1</sup>

What this means to you is that should a confirmed rupture occur, you are eligible for up to two replacement breast implants of any size in the same style...at no charge.

<sup>1</sup>Product Replacement Policy: In the event of unexpected rupture (loss of shell integrity), Mentor will provide replacement of a MENTOR® Product of any size in the same style as the originally implanted product free of charge for the lifetime of the patient. Upon the surgeon's request, a different implant style may be selected (subject to a charge of the difference between product list prices).

Please read the appropriate patient brochures: For MemoryGel® Implants: Important Information for Augmentation Patients about MENTOR® MemoryGel® Breast Implants. For MemoryShape® Implants: Patient Educational Brochure – Breast Augmentation with MENTOR® MemoryShape® Breast Implants and Quick Facts about Breast Augmentation & Reconstruction with MENTOR® MemoryShape® Breast Implants. These educational brochures provide you with information about the risks and benefits of silicone breast implants. It is very important that you take the time to read and fully understand the brochure, consult with your surgeon, and ask any questions you may have. For gel filled breast implants, you will also be asked to sign the Acknowledgement of Informed Decision Form in the brochure. You should then wait at least one to two weeks prior to deciding on surgery. After reading and signing the Informed Decision Form in your brochure, your surgeon will help you decide which implant is the right choice for you.

# HERE'S WHERE TO BEGIN: **BECOME INFORMED**

SUMMARY OF WARRANTY OPTIONS	MENTOR WARRANTY	MENTOR ENHANCED WARRANTY
Enrollment in our Product Replacement Policy <sup>1</sup>	Automatic	Automatic
Financial assistance for rupture <sup>3</sup>	Up to \$3,500	Up to \$3,500
An additional product replacement policy covering capsular contracture Baker Grade III & IV, double capsule, and late-forming seroma <sup>2</sup>	First 3 years	Up to 10 years
Financial assistance for capsular contracture Baker Grade III/IV <sup>2,3,4</sup>		Up to \$3, 500
Financial assistance for double capsule <sup>2, 3, 4</sup>		Up to \$3, 500
Financial assistance for late-forming seroma <sup>2, 3, 4</sup>		Up to \$3, 500
Contralateral (opposite side) implant replacement upon surgeon request	FREE	FREE
Enrollment Fee	FREE	Purchase for \$200 within 45 days from implantation

#### The **MENTOR ENHANCED WARRANTY** offers more than any previous breast implant warranty. **Check out the advantages:**

- → Automatic enrollment in our Product Replacement Policy<sup>1</sup> for any MENTOR<sup>®</sup> MemoryGel<sup>®</sup> Breast Implants or MemoryShape<sup>®</sup> Breast Implants
- → For a \$200 enrollment fee, pays up to \$3,500<sup>3</sup> financial assistance for operating room, anesthesia, and surgeon fees not covered by insurance for

replacement surgery resulting from a Baker Grade III capsular contracture, Baker Grade IV capsular contracture, double capsule, or late-forming seroma for up to 10 years from the date of primary<sup>5</sup> implant surgery **occuring on or after date of implant October 6, 2014** 

- ⇒ Free contralateral (opposite side) implant replacement upon surgeon request
- ⇒ For surgeries occuring on or after October 6, 2014

<sup>2</sup>Applies only to primary<sup>5</sup> implant surgeries, whether augmentation or reconstruction, conducted on or after October 6, 2014. If you had breast surgery prior to Oct 6, 2014, your warranty coverage is what was offered at the time of your original surgery.

<sup>3</sup>Operating room and anesthesia charges to be given payment priority. In order to qualify for financial assistance, you will need to sign a Release before Mentor will make payment to you or on your behalf.

<sup>4</sup> Pays up to \$3,500<sup>3</sup> financial assistance for operating room, anesthesia, and surgeon fees not covered by insurance for replacement surgery resulting from capsular contracture Baker Grade III & IV, double capsule, and late-forming seroma for up to 10

years from the date of primary<sup>5</sup> implant surgery occurring on or after date of implant October 6, 2014. Your surgeon must diagnose these events and provide documentation to Mentor to support your date of implant, product implanted, and event experienced in order to qualify.

<sup>5</sup> primary means the very first original implantation of the MENTOR® MemoryGel or MemoryShape® Implant. Prior implant(s), regardless of type, style, or manufacturer, preclude inclusion in the Mentor Enhanced Warranty for both replacement product and financial assistance. In the event of primary reconstruction with use of a tissue expander, the temporary tissue expander does not qualify as an implant.

## HOW THE CLAIM PROCESS WORKS

To file a claim for product replacement and/or financial assistance, your surgeon must contact the Mentor Customer Quality Department at 1-866-250-5115 prior to replacement surgery.

#### Required paperwork:

For financial assistance claims, a patient-specific Release will be generated by Mentor that you must sign and return.

# What your surgeon must send to **Mentor** and by when:

For either replacement or financial assistance claims, the surgeon must send the explanted (removed), decontaminated MENTOR® Breast Implant(s) within 60 days of the date of explantation to:

> Mentor Worldwide LLC Attn: Product Evaluation Department 3041 Skyway Circle North Irving, TX 75038

Upon receipt, review, and approval of the completed claim, including receipt of the explanted product and patient completion of a full general Release, financial assistance will be issued.

# Get your questions answered at the consultation with your surgeon.

This brochure only provides a brief overview of the **Mentor Warranties** and is not intended to replace any discussion between you and your surgeon.

Please refer to **www.mentorwwllc.com** for full warranty coverage details.

# A SPECIAL NOTE

Please be sure to maintain your own records to ensure validation of your enrollment, as it is possible your surgeon may not retain your records for the entire duration of the warranty. This is a summary of coverage. It is an overview only and not a complete statement of the program. You may obtain a copy of the complete Mentor Warranty and Enhanced Warranty for MemoryGel® Breast Implants and MemoryShape® Breast Implants by going to www.mentorwwllc.com.

Mentor reserves the right to cancel, change, or modify the terms of The Mentor Warranty and Enhanced Warranty coverages. Any such cancellation, change, or modification will not affect the currently stated terms of the Mentor Warranty and Enhanced Warranty coverages for those already enrolled.

#### Important Safety Information:

MENTOR® MemoryGel® Breast Implants, MENTOR® MemoryShape® Breast Implants, and MENTOR® Saline-filled Breast Implants are indicated for breast augmentation in women (at least 22 years old for MemoryGel® and MemoryShape® Implants, and 18 years old for Saline Implants) 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 currently pregnant or nursing.

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

The most common complications with MENTOR® Saline-filled Implants include reoperation, implant removal, capsular contracture, breast pain, and implant deflation.

For MemoryGel® Implants, patients should receive a copy of Important Information for Augmentation Patients about MENTOR® MemoryGel® Breast Implants or Important Information for Reconstruction Patients about MENTOR® MemoryGel® Breast Implants. For MemoryShape® Implants, 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, and a copy of Quick Facts about Breast Augmentation & Reconstruction with MENTOR® MemoryShape® Breast Implants. For MENTOR® MemoryShape® Breast Implants, and a copy of Saline-Filled Breast Implants. For MENTOR® Saline-filled Implants, Patients should receive a copy of Saline-Filled Breast Implants. Making an Informed Decision. 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.

The MENTOR® CONTOUR PROFILE® Tissue Expanders can be utilized for breast reconstruction after 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. Do not use the CONTOUR PROFILE® Expander in patients where an MRI may be needed. 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.

For detailed indications, contraindications, warnings, and precautions associated with the use of all MENTOR® implantable devices, which include MENTOR® Saline-filled Breast Implants, MemoryGel® Implants, MemoryShape® Implants, and CONTOUR PROFILE® Expanders, please refer to the Product Insert Data Sheet provided with each product or visit www.mentorwwllc.com.

#### MENTOR WARRANTY REGISTRATION

#### **REGISTER ONLINE for peace of mind.**

Even though you automatically qualify for the MENTOR WARRANTY, by completing the online registration form located at **www.mentorwwllc.com** we can better serve you in the future.

#### MENTOR ENHANCED WARRANTY ENROLLMENT

#### **REGISTER AND PAY ONLINE**

To enroll in the MENTOR ENHANCED WARRANTY, complete the online registration form located at **www.mentorwwllc.com** within 45 days of your surgery.

THIS IS A LIMITED WARRANTY ONLY AND IS SUBJECT TO THE TERMS AND CONDITIONS SET FORTH IN THIS DOCUMENT AND EXPLAINED IN GREATER DETAIL IN THE APPLICABLE MENTOR LIMITED WARRANTY. ALL OTHER WARRANTIES, WHETHER EXPRESSED OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS ARE EXCLUDED.

THIS REMEDY IS THE SOLE AND EXCLUSIVE REMEDY AVAILABLE. MENTOR SHALL NOT BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL LOSS, DAMAGE OR EXPENSE ARISING DIRECTLY OR INDIRECTLY FROM THE USE OF THESE PRODUCTS. MENTOR NEITHER ASSUMES NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

THE TERMS IN EFFECT WHEN ORIGINAL IMPLANTATION OCCURS WILL APPLY AT THE TIME OF CLAIM.

201 Mentor Drive Santa Barbara, CA 93111 USA (805) 879-6000 www.mentorwwllc.com



© Mentor Worldwide LLC 2014 022384-141013