

FACTS about  
MENTOR® MemoryGel®  
Silicone Gel Filled Breast Implants





ARE YOU CONSIDERING  
BREAST IMPLANT SURGERY  
BUT NOT CERTAIN WHICH  
TYPE OF IMPLANT TO  
CHOOSE?

YOU'RE NOT ALONE.

## Science-based information to empower good choices

This brochure was created by Mentor Worldwide LLC to give you the facts you need regarding the new generation of silicone gel filled breast implants. When it comes to a decision as important as this, knowing all the facts will lead to the most successful outcome. As you read through this brochure you will learn about the science, technology, choices, and the commitment behind the products available; as well as where to research further if you choose.

## Quality first

First and foremost, you want the peace of mind that you're choosing breast augmentation products with a long, proven history of high quality. Next, you want implants from a company with a continual commitment to improving the patient experience. For over 20 years, Mentor has been recognized worldwide as a leading manufacturer of the highest quality breast implants. After decades of research with surgeons and patients, MENTOR® MemoryGel® Silicone Gel Filled Breast Implants, exclusively from Mentor, are available in the US.



# THE HISTORY OF SILICONE

Did you know silicone has been used in hundreds of thousands of medical devices for over 50 years?

Catheters, heart valves, pacemakers, artificial joints and tissue expanders...just to name a few you are familiar with. Surgeons have trusted silicone for years because they know it is reliable, easy to sterilize, biocompatible, and flexible when used in both implantable and nonimplantable medical devices.

MENTOR® Silicone Gel Filled Breast Implants first became available in the United States in April 1984. In 1992, the Food and Drug Administration called for a moratorium (removal from the marketplace) to the sale and use of silicone filled breast implants, limiting patient access to silicone filled breast implants and requiring implant manufacturers to collect clinical study data. Shortly following the moratorium the FDA decided to allow breast restoration patients as well as women who already had existing breast implants the option to receive silicone filled breast implants through a clinical study—the Mentor Adjunct Study.

The Mentor Adjunct Study has been one of the largest clinical device studies conducted in the world, with more than 150,000 patients participating. The data collected in the Mentor Adjunct Study was used as supplemental clinical data in support of the MENTOR® MemoryGel® PMA (Pre-market Application per the FDA website) for approval.

The MENTOR® MemoryGel® Breast Implants that were approved by the FDA in 2006 contain the same silicone breast implant material as those that, prior to this approval, were manufactured and available to patients participating in the Mentor Adjunct Study.

## A major study of silicone breast implants sponsored by the US Government found: “No evidence for health concerns”

In 1997, the Department of Health and Human Services requested the Institute of Medicine (IOM) of the National Academy of Sciences to conduct a comprehensive evaluation of the safety of breast implants. The IOM panel of independent scientific experts included members of the medical, scientific and educational communities with experience in radiology, women’s health, neurology, oncology, silicone chemistry, rheumatology, immunology, epidemiology internal medicine and plastic surgery.

### The Results

After reviewing years of evidence and research concerning silicone gel filled breast implants, the IOM found that “Evidence suggests diseases or conditions such as connective tissue diseases, cancer, neurological diseases or other systemic complaints or conditions are no more common in women with breast implants than in women without implants.”

The complete IOM report is available online at <http://books.nap.edu/catalog/9602.html>.



AN APPROVAL  
BASED ON SCIENCE:  
*THE FDA SAID “APPROVED”*

In November of 2006, the FDA approved MENTOR® MemoryGel® Breast Implants for breast augmentation and restoration.

After nearly two decades of research and testing with surgeons and patients all over the world, MENTOR® MemoryGel® Breast Implants became available to women in the US.

**MENTOR® MemoryGel® Breast Implants—A trusted choice**

MENTOR® MemoryGel® Breast Implants have been successfully used and trusted for over 20 years by millions of women worldwide. Why? Our implants feel more like natural breast tissue without compromising reliability or safety. Mentor currently has seven silicone gel breast implant clinical studies in progress. Over 200,000 women have participated in our studies in order to provide a significant body of clinical evidence demonstrating the safety and effectiveness of silicone filled breast implants. As we have to date, Mentor will remain committed to providing objective, clinical information about breast implant safety.

## Silicone used today versus silicone of the past

Silicone gel filled breast implants have undergone changes over time to meet increasingly sophisticated consumer expectations. The very first silicone breast implants used thick shells and contained firm gel. The second generation of implants introduced in the late 1970's had thinner shells and used less firm gel to address concerns of patients and surgeons who believed that implants were too firm, palpable and visible.

In the mid 1980s, concerns related to rupture rates of the second generation thinner-shelled implants led manufacturers to introduce a third generation of implants. The shell and gel of these third generation implants are slightly thicker but still soft.

Today these third generation silicone gel-filled breast implants are typically referred to as cohesive gel implants.

Mentor products have kept pace with the ever-evolving expectations of surgeons and patients who desire a soft gel to retain the natural feel that resembles actual breast tissue.





## A Picture is Worth A Thousand Words

We have cut a MENTOR® MemoryGel® Breast Implant in half to demonstrate how the gel material holds together uniformly. MemoryGel® is a cohesive, gelatin-like substance that acts as a solid rather than a liquid thereby maintaining its shape.

Our adherence to strict quality manufacturing requirements has resulted in silicone shells that have been tested and shown to possess excellent strength, resilience and elasticity.



**FACT:** The amount of silicone released from MENTOR® MemoryGel® Breast Implants is extremely minute... less than is absorbed from daily consumer products containing silicone. It is equal to approximately 1/1000th the weight of the head of a straight pin and more than a million fold below established safety limits, based on the results of studies presented to the FDA\*. These levels are also more than a hundred-fold below absorbed daily exposures to the same materials from commonly used consumer products, such as antiperspirants, skin care lotions and hair care products.

\* US Food and Drug Administration Web site. [www.fda.gov/cdrh/breastimplants/platinum.html](http://www.fda.gov/cdrh/breastimplants/platinum.html)

## WE'RE PROUD OF OUR MEMORYGEL® BREAST IMPLANTS AND IT'S EASY TO SEE WHY:

- We conduct rigorous, multi-level testing at every step of manufacturing
- MENTOR® MemoryGel® Breast Implants offer optimized structural integrity
- The outer shell is highly compliant for ease of placement
- Premier Advantage Limited Warranty and a lifetime replacement policy come with all MENTOR® MemoryGel® Breast Implants and Saline Filled Breast Implants
- We also offer an optional extended Enhanced Advantage Limited Warranty



## Another important reason to trust *Mentor*:

*MENTOR® MemoryGel® Implants are the only silicone implants made in the US under the strictest US and EU manufacturing standards.*

## Nothing could be more important than the quality of the breast implant that you and your surgeon choose

Mentor is the world leader in breast implant manufacturing, research and testing. For over 35 years, we have adhered to the highest standards of safety in manufacturing, testing and clinical trials for saline and silicone breast implants for use in both breast augmentation and breast restoration. Because of this, we are consistently recognized by surgeons for outstanding product integrity. Over 2 million women worldwide have used MENTOR® MemoryGel® Breast Implants.

## Rigorous Studies Continue...

In addition to FDA evaluations, Mentor is committed to conducting its own long-term, far-reaching clinical studies. Throughout the years, Mentor has done extensive safety evaluations of both saline filled breast implants and gel filled breast implants. Mentor is and will remain committed to providing objective, clinical information about breast implant safety.



# TRUSTED INSTITUTIONS IN THE SCIENTIFIC COMMUNITY **AGREE:**

**That silicone gel breast implants are safe.** For the past several years, many respected medical professionals and institutions have conducted scientific studies about the safety of breast implants. Mentor is committed to providing the public with up-to-date information about silicone breast implants.

## The National Cancer Institute

**Their Findings:** “No significant increase in breast cancer incidence.”

The National Cancer Institute recently published their findings from a study of 13,500 women who received silicone gel implants for cosmetic reasons prior to 1989. Researchers found no significant increase in breast cancer incidence. More information on this study is available online at [www.cancer.gov/newscenter/pressreleases/2000/siliconebreast](http://www.cancer.gov/newscenter/pressreleases/2000/siliconebreast)

## Institute of Medicine

**Their Findings:** “Evidence suggests that such diseases or conditions are no more common in women with breast implants than in women without implants.”

The full text of the publication, *Information for Women About the Safety of Silicone Breast Implants—A Report of a Study by the Institute of Medicine*, is available online at [www.nap.edu](http://www.nap.edu).

## National Science Panel

**Their Findings:** “No identifiable associations between the use of silicone implants and disease.”

In October 1996, Judge Sam C. Pointer Jr., the coordinating judge for federal breast implant litigation, established the Rule 706 National Science Panel. The purpose of this panel was to investigate scientific data about breast implants and their possible relation to connective tissue diseases and immune system dysfunction. The panel reviewed over 2,000 medical documents and heard testimony under oath from legal, medical and scientific experts. The panel released their findings in November 1998, and concluded that there are no identifiable associations between the use of silicone implants and disease.

## Independent Review Group

**Their Findings:** “No scientific evidence of an association between silicone gel-filled breast implants and any established connective tissue disease.”

The Independent Review Group (IRG) on Silicone Breast Implants was assembled by the Chief Medical Officer of the UK to review the possible health issues associated with silicone gel-filled breast implants. Members of the IRG were selected for their independent views, their knowledge and understanding of the issues, and lack of any financial interest in the conclusions they reached.

Led by Professor Roger D. Sturrock, MD, FRCP, the IRG reported in 1998 that there is no scientific evidence of an association between silicone gel-filled breast implants and any established connective tissue disease. The complete report is available online at [www.silicone-review.gov.uk](http://www.silicone-review.gov.uk).

# MENTOR IS HERE FOR YOU.

Visit [www.LoveYourLook.com](http://www.LoveYourLook.com)  
for more information and to find  
a qualified surgeon in your area.

Important Safety Information:

MENTOR® MemoryGel® and Saline Filled Breast Implants are indicated for breast augmentation—in women who are at least 22 years old for MemoryGel® Implants and at least 18 years old for Saline Implants—or for breast restoration.

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
- Who are currently pregnant or nursing.

Safety and effectiveness have not been established in patients with autoimmune diseases (for example lupus and scleroderma), a weakened immune system, conditions that interfere with wound healing and blood clotting, or reduced blood supply to breast tissue. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implant surgery.

There are risks associated with breast implant surgery. You should be aware that breast implants are not lifetime devices and breast implantation is likely not a one-time surgery. You may need additional unplanned surgeries on your breasts because of complications or unacceptable cosmetic outcomes. Many of the changes to your breast(s) following implantation are irreversible (cannot be undone) and breast implants may affect your ability to breastfeed, either by reducing or eliminating milk production.

The most common complications with MemoryGel® Breast Implants include reoperation, 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). 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 Breast Implants include reoperation, implant removal, capsular contracture, wrinkling, breast pain and deflation.

Detailed information regarding the risks and benefits associated with MENTOR® Breast Implants is provided in two brochures, *Important Information for Augmentation Patients about MENTOR® MemoryGel® Silicone Gel-Filled Breast Implants* or *Saline-Filled Breast Implants, Making an Informed Decision* available from your surgeon or on line at [www.mentorwwllc.com](http://www.mentorwwllc.com). It is important that you read and understand these brochures when considering MENTOR® Breast Implants.



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