The guide to Breast Reconstruction

Breast Teamwork that changes lives

breastTeam

CARE + ADVISE + RESTORE + EMPOWER

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MENTOR
Make life more beautiful™
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YourBreastOptions.com
Breast Anatomy
Breast Anatomy

- Pectoralis Major Muscle
- Pectoralis Minor Muscle
- Fatty Tissue
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- Milk Ducts
- Nipple and Areola
- Soft Tissue
- Ribs

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Mastectomy
A mastectomy is when breast tissue is removed due to the presence of a cancerous or pre-cancerous growth.

The amount of tissue removed varies based on the size and stage of your cancer, your body type and your personal preferences.
Nipple/Areola and Skin Sparing Mastectomy

• Nipple/Areola and skin sparing mastectomy is a way to treat cancer, and save the nipple/areola and the breast skin.
• The procedure involves removing the cancerous breast tissue through a small incision usually around the areola area of the nipple.
• The surgeon leaves most of the breast skin, creating a pocket, that is filled with a breast implant or with the patient’s own tissue from another part of her body.
What is Breast Reconstruction
Breast reconstruction is a type of surgery for women who have had a breast removed (mastectomy), usually after breast cancer. The surgery rebuilds the breast so that it is about the same size and shape as it was before.
Nipple and Areola Reconstruction
Nipple and areola reconstruction is optional. The reconstruction is usually the final phase of breast reconstruction. Separate surgery is done to make the reconstructed breast look more like the original breast. It can be done as an outpatient procedure. It is usually done after the new breast has had time to heal.
Breast Reconstruction Timing
Immediate breast reconstruction takes place during the same operation as your mastectomy, meaning that you only have **one operation** and **one recovery period**, therefore you avoid the experience of having only one breast.
Delayed breast reconstruction is done **after** the mastectomy and allows you to first focus on your recovery from cancer and rebuild your strength. You will also have more time to consider your options and to make a well-informed decision.
Breast Implant Reconstruction Choices
One-Stage Breast Reconstruction

Breast reconstruction procedure

1. The expander/breast implant is placed in position.

2. The expander/breast implant is then expanded by injecting saline through the dome for up to 6 months.

3. Final volume is achieved.

4. The dome is then removed in an office procedure.

5. Nipple reconstruction is performed and final result is achieved.

MENTOR® SILTEX™ Round BECKER™ 25 Expander/Breast Implant

Breast Implant Reconstruction Choices
Adjustable Implants

• The MENTOR® SPECTRUM™ Implant can be used to expand the breast tissue and as a long-term saline breast implant.
• The MENTOR® SPECTRUM™ Implant is also available in SILTEX™ Round Texture and in SILTEX™ CONTOUR PROFILE™ Shape.

• The MENTOR® BECKER™ Expander/Breast Implant can be used to expand the breast tissue and as a long-term breast implant.
• The MENTOR® BECKER™ Expander/Breast Implant has an inner lumen containing saline that allows for tissue expansion and an outer lumen of gel that is designed to provide a softer feeling implant.
• The MENTOR® BECKER™ Expander/Implant is also available in SILTEX™ CONTOUR PROFILE™ Shape.

Both products:
• Can be used for both immediate and delayed breast reconstruction
• Can be used as part of a two-stage breast reconstruction or as the long-term implant in a one-stage procedure
Two-Stage Breast Reconstruction

Breast reconstruction procedure with a tissue expander, followed by a breast implant.

First Surgery

1. The tissue expander is placed in position.

2. The injection dome is located. Expansion begins by injecting saline through the dome.

3. After the skin over the breast area has stretched enough, the tissue expander is removed.

MENTOR® CPX™ Breast Tissue Expander

Breast Implant Reconstruction Choices
Second Surgery

1. The implant is then placed in the expanded pocket.

2. Nipple reconstruction is performed and final result is achieved.

MENTOR® CPG™ Gel Breast Implant

MENTOR® Smooth Round MemoryGel™ Breast Implant
Breast implant is a sac (implant shell) of silicone elastomer, filled with silicone gel or saline, that is surgically implanted under the patient’s breast tissue or under her chest muscle.
We have cut a MENTOR® MemoryGel™ Breast Implant in half to demonstrate how the gel material can hold together uniformly. It does this because of a cohesive, gelatin-like substance that acts as a solid rather than a liquid.
Breast Reconstruction with Autologous Tissue
1. Donor site is marked.
2. Mastectomy is performed. Skin, fat and blood vessels are removed from the abdominal area. **No muscle is removed.**
3. Abdominal skin and fat are shaped into a natural looking breast and reattached to the chest area to form the breast mound. Blood vessels are reattached in the chest under microsurgery.
4. Final results.
TRAM Flap

The TRAM Flap (Pedicle or Free)
(Transverse Rectus Abdominus Musculocutaneous)

1. Donor site is marked.
2. Mastectomy is performed. Skin, fat, muscles and blood vessels are removed from the abdominal area.
3. a. **Pedicle Flap:** Abdominal skin, fat, muscles and blood vessels are moved through a tunnel under the skin, up to the chest area to form the breast mound. The blood vessels remain attached to the lower abdominal tissue.
   
   b. **Free Flap:** Abdominal skin, fat, muscles and blood vessels are removed from the abdominal area and reattached in the chest area to form the breast mound. Blood vessels are reattached in the chest under microsurgery.

4. Final results.
Latissimus Dorsi Flap

With or Without Breast Implants

1. A skin flap and muscle are taken from the donor site in the back.
2. The tissue is tunneled to the mastectomy and used to create a breast mound.
3. An implant can also be used to create the breast mound.
Advantages and disadvantages of tissue flap breast reconstruction

Advantages:
- Symmetry can be improved without altering the unaffected breast.
  - Adipocutaneous tissue from lower abdomen mimics the breast
  - Big amount of well perfused tissue
  - Preserving integrity of the abdominal muscle wall
  - Relatively acceptable scars
  - Acceptable results without using implants

Disadvantages:
- A flap operation requires a hospital stay of several days and generally takes a longer recovery time than implant reconstruction.

- A flap operation also creates noticeable scars at the site where the flap was taken and on the reconstructed breast.

A tissue flap operation requires good general health and strong emotional motivation. Potential delay of adjuvant therapy (due to postoperative complications).
Important Information
You Need to Know
Regulatory Standards & Approvals of MENTOR® Memory Gel™ Breast Implants

- The approved MENTOR® Breast Implant products have been reviewed and approved by the regulatory agencies confirming that the products satisfy applicable safety and health standards:
  - United States Food and Drug Administration (U.S. FDA) premarket approval (PMA)
  - CE mark approval under the Medical Device Directive 93/42/EEC
- US FDA approval for MENTOR® MemoryGel™ Breast Implants, MemoryShape™ Breast Implants (CPG™ Gel Breast Implants), and Saline Breast Implants
- MENTOR® Breast Implants currently manufactured and marketed in EMEA are not approved by the FDA but do comply with CE-Mark requirements
- Mentor became the first breast implant manufacturer to achieve CE-Marking in 1995

Warranty Information MENTOR® Breast Implants

• Any MENTOR® Breast Implant, implanted prior to March 1st 2013, is covered by the following respective product replacement policies; **Mentor Lifetime Product Replacement Policy**.

• Any MENTOR® Silicone Gel-Filled Breast Implant, implanted prior to March 1st 2013, is covered by the following respective warranty plans; **Mentor Lifetime Product Replacement Policy or Mentor PatientSafe Limited Warranty**.

• Any MENTOR® Breast Implant, implanted After March 1st 2013, is covered by the **Mentor Lifetime Product Replacement Policy**.¹

• Any MENTOR® Silicone Gel-filled Breast Implant, implanted after March 1st 2013, is covered by **Mentor PatientCare Promise Limited Warranty**.¹

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¹ Patients may also obtain a copy of the warranties by writing to: Mentor Medical Systems CV, Zernikedreef 2, 2333 CL, Leiden - The Netherlands. Phone +31-71-7513600.
Safety Information for Breast Implants

• In 1999, the U.S. Institute of Medicine issued a report including the following conclusions: “Evidence suggests that 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.”

• In November 2006, FDA approved silicone gel-filled breast implants. In June 2011, almost 5 years later, the FDA continues to support the safety and effectiveness of these implants when used as intended.

• In its 2011 findings, the FDA indicated that studies to date do not indicate that silicone gel-filled breast implants cause breast cancer, reproductive problems, or connective tissue disease, such as rheumatoid arthritis.

• The U.S. National Science Panel found no evidence that silicone implants are responsible for any connective tissue diseases.

• Silicone polymers are commonly found in consumer care products, like anti-perspirant, hand lotion, makeup, haircare products, etc.

MENTOR® 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. Patient 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 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. The most common complications with MENTOR® Saline-Filled Breast Implants include re-operation, implant removal, capsular contracture, wrinkling, deflation, asymmetry, and breast pain.

MENTOR® CPX™2 Tissue Expanders can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The device is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

MENTOR® Smooth Round Tissue Expanders with Remote Dome can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The expander and remote injection dome are for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

MENTOR® CPX™4 Tissue Expanders can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. These expanders are intended for temporary subcutaneous or submuscular implantation; they should be used within a time frame determined by the physician to achieve the clinically desired degree of tissue expansion.*

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 patients understand the risks associated with breast implant surgery when considering MENTOR® Breast Implants.

* Note: CPX™4 Expander is available with two separate Indications for Use. One that is limited to use not more than six months, and the other with the indications shown here. This is dependent upon which CPX™ 4 Expander product code is ordered. Please refer to the Product Insert Data Sheet to determine which product codes are at your customer’s availability.
Mentor’s Commitment
Mentor’s Commitment

For over 30 years, Mentor Worldwide LLC has been recognised throughout the world as a leading manufacturer of the highest quality breast implants.

Mentor has been committed to developing and delivering safe and effective aesthetic medical products that give patients the power to transform their lives.

In addition to its commitment to provide superior quality products, Mentor has also been dedicated to educating patients about breast cancer - specifically about their breast reconstruction options - to help them make an informed decision.