Breast Reconstruction Options

MENTOR

the power to transform®
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INTRODUCTION

There are many decisions and choices involved in the process of breast reconstruction, but perhaps the most important question to ask is the following: Is breast reconstruction right for you? For tens of thousands of breast cancer survivors, the answer has been yes.

Not every woman facing a mastectomy may feel the need for breast reconstruction, but for many women it is an important part of their recovery. There are many options available today for women who decide that reconstruction is right for them. The more you know about the procedure and the options involved, the better equipped you will be to make a decision that is best for you.

There are many factors to consider about breast reconstruction and a great deal of information to learn and understand. The purpose of this brochure is to help you in making an informed decision about having breast implants for reconstruction (restoration) or breast revision-reconstruction (replacement) surgery. This brochure is not intended to replace consultation with your surgeon. This educational brochure is set up to provide you with information about the risks and benefits of Mentor saline and MemoryGel™ breast implants.

Choosing Breast Reconstruction

Today, most women who have mastectomies are good candidates for breast reconstruction. Women choose to have their breast(s) reconstructed for many different reasons. Following a mastectomy, some women feel a lack of wholeness or a loss of femininity, while others simply don’t like the hassle or worry associated with wearing a breast prosthesis.

Whatever the reason for reconstruction, every woman’s decision is different and must ultimately be made by her, based on her needs, desires and expectations. The breast reconstruction procedure that is best for you will vary depending on the results you desire, your particular situation and other physical and mental determinations. Whatever procedure is decided upon, it’s important that you take part in making the necessary decisions.

Keep in mind that any breast reconstruction process will require multiple procedures. Because each patient and procedure is different, the actual number of surgeries and recovery time will vary. Be sure you select a surgeon who is experienced in breast reconstruction. If your general surgeon works closely with your
plastic surgeon, your aesthetic outcome may be enhanced. Your decision to have breast reconstruction surgery is an important personal choice involving both risks and benefits. There are other options for breast reconstruction that do not involve breast implants. Be sure to ask your surgeon for a detailed explanation of each alternative to help you decide which reconstruction option is most suitable for you and your lifestyle.

This brochure is intended to provide general information about saline and MemoryGel™ breast implants and surgery, but it is not a substitute for a thorough consultation with your surgeon. You are advised to carefully review and consider all the information you have received before deciding whether to have reconstruction surgery. Prepare a list of questions after reading this brochure, and discuss them with your surgeon.

Patient and Medical Professional Services

As you learn about breast reconstruction and face important decisions, it’s normal to have questions. To help answer those questions and provide you with objective and straightforward information, Mentor offers a free, person-to-person service called Patient and Medical Professional Services.

Patient and Medical Professional Services is led by an experienced team of nursing professionals who are available to answer your questions through a toll-free number. The service is intended to
provide you with balanced, honest information and to encourage you to be fully informed so you can discuss your options with your physician before making a decision. Contacting Patient and Medical Professional Services is easy. Just call (800) MENTOR – 8.

WHO’S INVOLVED WITH YOUR TREATMENT?

Physicians’ roles

During the course of your treatment for breast cancer, there will be several different physicians working together to plan your mastectomy and reconstruction procedure to give you the best possible result. They are:

- **Surgeon** – Performs the biopsy of the breast tumor and the mastectomy
- **Pathologist** – Studies the tumor to determine the degree of malignancy
- **Medical oncologist** – Administers anticancer drugs or chemotherapy
- **Radiation oncologist** – Administers radiation therapy
- **Plastic surgeon** – Performs your breast reconstruction

The following list of questions may help remind you of topics to discuss with your doctor. While many of these topics are covered in this booklet, it is important to have a discussion with your surgeon about them because he or she may be able to provide you with additional information and answer any questions. The page can be removed from this booklet so you can bring the list of questions with you to your consultation.

QUESTIONS TO ASK YOUR PLASTIC SURGEON

- What are all my options for breast reconstruction?
- What are the possible risks and complications for each type of breast implant surgery, and how common are they?
- What if my cancer recurs or occurs in the other breast?
- Will reconstruction interfere with my cancer treatment?
- How many steps are there in each procedure, and what are they?
- How long will it take to complete my reconstruction?
- How much experience do you have with each procedure?
• Do you have before-and-after photos I can look at for each procedure? What results are reasonable for me?
• What will my scars look like?
• What kind of changes in my implanted breast can I expect over time?
• What kind of changes in my implanted breast can I expect with pregnancy?
• What are my options if I’m dissatisfied with the cosmetic outcome of my implanted breast?
• Can I talk with other patients about their experience?
• For staged reconstruction, what is the estimated total cost of each procedure?
• How much will my health insurance carrier cover, especially any complication that may require surgery?
• How much pain or discomfort will I feel, and for how long?
• How long will I be in the hospital?
• Will I need blood transfusions, and can I donate my own blood?
• When will I be able to resume my normal activity (sexual activity or athletic activity)?
• Who is the manufacturer of my breast implant?
• Does the manufacturer have a product warranty?

BREAST RECONSTRUCTIVE SURGERY

Anatomy of the Breast

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. The chest muscle (pectoralis major muscle) is located beneath the breast. Factors such as pregnancy (when milk glands are temporarily enlarged), rapid weight loss and the effects of gravity as you age combine to stretch your skin, which may cause your breast to droop or sag.

Breast cancer surgery can significantly change the shape of the breast to a greater or lesser degree, depending on:

• How much breast tissue is removed in a partial or complete mastectomy;
• How much skin is removed at the time of your surgery; and
• How much tissue reaction or scarring there is in the remaining breast and skin in response to chemotherapy or radiation therapy.

What is a mastectomy?
When cancer is discovered in a woman’s breast, a common form of treatment is a mastectomy. A mastectomy is the removal of breast tissue due to the presence of a cancerous or precancerous growth. The amount of tissue removed during a mastectomy procedure varies. There are several types of mastectomies that can be performed. The type that is best for you depends on many factors, including the size and stage of your cancer, your particular anatomy and your preferences.

Two of the most common mastectomy procedures are the modified radical mastectomy and the simple mastectomy. The modified radical mastectomy entails removing the breast, its tissues, the nipple-areola and the lymph nodes found in the armpit. This procedure leaves the pectoralis major (the large muscle located on the chest wall) intact.

The simple mastectomy involves the removal of only the breast tissue and sometimes the lymph nodes. Breast reconstruction can be performed after the modified radical mastectomy or the simple mastectomy.

A lumpectomy is the most conservative surgical procedure. It calls for the removal of only
the tumor itself and some of the normal tissue that surrounds it, preserving the majority of the breast and its tissues. The cosmetic result of a lumpectomy will vary depending on the size and location of the tumor and the size of the breast.

**RECONSTRUCTION OPTIONS**

Your first decision regarding breast reconstruction is whether to have *immediate reconstruction*, which is performed at the time of the mastectomy; or *delayed reconstruction*, which is performed weeks, months or even years after your mastectomy. You and your doctor can decide which of these options is best for you.

The type of breast reconstruction procedure available to you depends on your medical situation, breast shape and size, general health, lifestyle and goals.

Breast reconstruction can be accomplished by the use of a prosthesis (a breast implant, either silicone gel or saline-filled), your own tissues (a tissue flap), or a combination of the two. A tissue flap is a combination of skin, fat, and/or muscle that is moved from your stomach, back, or other area of your body to the chest, where it is shaped into a new breast. A tissue flap also may be used to provide skin or other tissue needed to make up for what was removed at the time of surgery, or changed following radiation treatment. Your surgeon can help you decide what method of breast reconstruction is most suitable for your particular situation.

Whether or not you have reconstruction with or without breast implants, you will probably undergo additional surgeries to improve symmetry and appearance. These additional surgeries may be part of a several-stage reconstruction of the removed breast, or may be to shape the remaining breast to bring it into better balance with the reconstructed one. Most commonly, breast implants are placed after a space has been created for them using a temporary soft tissue expander that can be placed at the time of your mastectomy, or at a later time.

 Portions of your reconstruction may be done in two stages. For example, because the nipple and areola are usually removed with the breast tissue during a mastectomy, the nipple is usually reconstructed by using a skin graft from another area of the body or from the opposite breast. The area also may be tattooed to obtain a better color match. Nipple reconstruction is normally done as a
separate outpatient procedure after the initial reconstruction surgery is complete.

**BREAST RECONSTRUCTION WITHOUT IMPLANTS**

In some patients, the breast may be reconstructed by surgically moving an area of skin, fat and muscle from one area of your body to another. The section of tissue may be taken from such areas as your abdomen, upper back, upper hip or buttocks. This may be required to provide enough tissue to match a large remaining breast, or to replace tissue removed or damaged at the time of your mastectomy or following radiation therapy.

The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicle flap), or it may be removed completely and reattached to the breast area by microsurgical techniques to reconnect the tiny blood vessels from the flap to vessels on the chest area (a free flap). Operating time is generally longer with free flaps due to the microsurgical requirements.

Flap surgery requires a hospital stay of several days and generally a longer recovery time than implant reconstruction. Flap surgery also creates scars at the site where the flap was taken and on the reconstructed breast. However, flap surgery has the advantage of being able to replace tissue in the chest area. This may be useful when the chest tissues have been damaged and are not suitable for tissue expansion. Another advantage of flap procedures over implantation is that alteration of the unaffected breast is generally not needed to improve symmetry.

The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap), which uses tissue from the abdomen; and the latissimus dorsi flap, which uses tissue from the upper back. In most patients, the TRAM flap can provide enough tissue to completely rebuild the breast mound. However, breast implants are frequently needed to complete breast reconstruction for patients having latissimus flaps. This is because there is rarely enough fatty tissue in the flap to completely rebuild the breast mound.

It is important for you to be aware that flap surgery, particularly the TRAM flap, is a major operation, and more extensive than your
A mastectomy operation. It requires good general health and strong emotional motivation. If you are very overweight, smoke cigarettes, have had previous surgery at the flap site, or have any circulatory problems, you may not be a good candidate for a tissue flap procedure. In addition, if you are very thin, you may not have enough tissue in your abdomen or back to create a breast mound with this method. You should discuss with your surgeon whether you would be a candidate for either of these procedures. There potentially are complications associated with flap procedures that you should also discuss with your surgeon.

The TRAM Flap (pedicle or Free)

During a TRAM flap procedure, the surgeon removes a section of tissue from your abdomen and moves it to your chest to reconstruct the breast. The TRAM flap is sometimes referred to as a “tummy tuck” reconstruction because it may leave the stomach area flatter.

A pedicle TRAM flap procedure typically takes three to six hours of surgery under general anesthesia. A free TRAM flap procedure generally takes longer. The TRAM procedure may require a blood transfusion. Typically, the hospital stay is two to five days. You can resume normal daily activity after six to eight weeks.

Some women, however, report that it takes up to one year to resume a normal lifestyle. You may have temporary or permanent muscle weakness in the abdominal area. If you are considering pregnancy after your reconstruction, you should discuss it with your surgeon. You will have a large scar on your abdomen and may also have additional scars on your reconstructed breast.
During a latissimus dorsi flap procedure, the surgeon moves a section of tissue from your back to your chest to reconstruct the breast. Because the latissimus dorsi flap is usually thinner and smaller than the TRAM flap, this procedure may be more appropriate for reconstructing a smaller breast. This flap is frequently used when there is not enough skin available to use a soft tissue expander alone, or when there is too much tightness after the mastectomy, or when radiation therapy has been used. Latissimus flaps may be combined with soft tissue expanders in a variation of the two-stage breast reconstruction technique.

The latissimus dorsi flap procedure typically takes two to four hours of surgery under general anesthesia. The hospital stay is normally two to three days. You can resume daily activity after two to three weeks. You may have some temporary or permanent muscle weakness and difficulty with movement in your back and shoulder. You will have a scar on your back, which can usually be hidden in the bra line. You may also have additional scars on your reconstructed breast.

The Buttocks Flap

The Buttocks Flap is a less common method of reconstruction that removes skin and tissue from the buttocks or thigh area and transfers it to the breast area. This method requires microsurgery to reattach blood vessels, which creates a blood supply for the newly formed breast mound.

A breast implant can be used in conjunction with any of these three techniques if the transferred tissue does not provide enough mass or produce the desired results. Depending on the type of mastectomy.
performed, sometimes a breast implant can be placed without flap reconstruction or the use of a tissue expander. This is possible only in cases where adequate tissue is left intact and the implant to be placed is relatively small.

In cases where breast cancer only affects a single breast, women with ptosis (sagging breasts) may choose to have a mastopexy (breast lift) of the opposite breast. This will help to achieve symmetry with the reconstructed breast. Small- or large-breasted women may elect to have the opposite breast enlarged or reduced.

Any breast reconstruction process will require multiple procedures. Because each patient and procedure is different, the actual number of surgeries and recovery time will vary. If your reconstruction involves breast implants or tissue expanders, you need to know about the products described in this booklet.

**BREAST RECONSTRUCTION WITH IMPLANTS**

Your surgeon will decide whether your health and medical condition make you an appropriate candidate for breast reconstruction. He or she also may recommend breast implantation of the opposite, uninolved breast in order to make them more alike, or he may suggest breast reduction (*reduction mammoplasty*) or a breast lift (*mastopexy*) to improve the symmetry between your breasts.

Mastopexy involves removing a strip of skin from under the breast or around the nipple to lift the nipple and breast location and tighten the skin over the breast. Reduction mammoplasty involves the removal of breast and skin. If it is important to you not to alter the unaffected breast, you should discuss this with your surgeon, as it may affect the breast reconstruction methods considered for your case.

**Tissue expansion**

One method of breast reconstruction involves the use of a tissue expander and a breast implant.

*Stage 1: Placing the expander*

During a mastectomy, the general surgeon removes skin as well as breast tissue, leaving the chest tissues flat and tight. To create a breast-shaped space for the breast implant, a tissue expander is placed under the remaining chest tissues.

A tissue expander is a balloon-like device made from elastic
silicone rubber. It is inserted unfilled, and over time sterile saline fluid is added by inserting a small needle through the skin and into the tissue expander’s filling port. As the tissue expander fills, the tissues over the expander begin to stretch, similar to the gradual expansion of a woman’s abdomen during pregnancy. The tissue expander creates a new breast-shaped pocket for a breast implant.

Tissue expander placement usually occurs under general anesthesia in an operating room. The procedure may require a brief hospital stay, or be done on an outpatient basis. Typically, you can resume normal daily activities after two to three weeks.

Because the chest skin is usually numb from the mastectomy surgery, it is possible that you may not experience much pain from the placement of the tissue expander or the needle sticks that follow to fill it with saline solution. However, you may experience feelings of pressure, tightness and discomfort after each filling of the expander. These feelings stop after several days, once the tissue expands, but they may last for a week or more. The tissue expansion process typically lasts four to six months.
Stage 2: Placing the breast implant

After the tissue expander is removed, the breast implant is placed in the pocket. In reconstruction following a mastectomy, a breast implant is most often placed submuscularly. The surgery to replace the tissue expander with a breast implant (implant exchange) is usually done under general anesthesia in an operating room. It may require a brief hospital stay or be done on an outpatient basis.

Mentor tissue expanders

Contour Profile® Tissue Expander

The Contour Profile® Tissue Expander is used to expand the skin and create a shaped pocket for implantation. This product is designed to expand primarily in the lower portion of the breast, so the resulting pocket will accommodate the implant and slope like a mature breast. It also has an integral injection dome that allows your surgeon to add saline solution to the expander and gradually stretch the breast tissue over several months. Expansion is typically performed in an office procedure.

For some patients, the secondary surgery for the expander/breast implant exchange can be avoided by using an implant that is postoperatively adjustable, or is a combination type expander/mammary implant. In a simple office procedure after your surgery, the fluid volume of postoperatively adjustable implants can be increased or reduced. This helps you to achieve the final breast size you desire.

Smooth and Siltex® Spectrum® Expander/Breast Implants

The Spectrum® functions as both a tissue expander and a long-term saline breast implant. It can be placed with minimal volume during your initial surgery, with the fluid volume gradually being increased over time, which expands the breast’s tissues. This implant contains a fill tube and remote injection dome that can be removed when the final volume is reached. They are then left in place as the long-term breast implant.
IMPLANT CHOICES

If you decide to have breast reconstruction with implants, you also will need to decide what kind of tissue expander and/or implant will help you and your physician achieve the result you want. Breast implants and tissue expanders come in many shapes and sizes. Together, you and your physician will select the options that are best suited for you.

Breast implant defined

A breast implant is a sac (implant shell) of silicone elastomer filled with silicone gel or saline, which is surgically implanted under your breast tissue or under your chest muscle. Mentor makes two basic types: saline and MemoryGel™ breast implants.

MemoryGel™ Breast Implants

MemoryGel™ implants feature a unique cohesive gel, which is not a liquid or semi-liquid. It holds together uniformly while retaining the natural give that resembles breast tissue. Mentor’s MemoryGel™ breast implants have either a textured or smooth surface shell, and are available in a wide range of sizes and profiles to fit different body types.

Saline breast implants

Saline breast implants are inflated with saline (a saltwater solution) through a valve. Saline is much like the fluid that makes up most of the human body. There are two types/families of implants filled with saline. One is referred to as saline-filled and the other is called Spectrum® implants.

The saline-filled family of implants has a self-sealing valve located on the front (anterior) of the implant that is used for filling the device. The Spectrum® family of implants have a valve on the back (posterior) of the implant that allows saline to be added after surgery (referred to as postoperative adjustability). Put simply, Mentor’s Spectrum® implant is a saline-filled implant that lets your physician adjust the size of your breasts after your surgery.
Implant shapes and sizes

Depending on the desired shape you wish to achieve, you and your surgeon have implants with three different round profiles, or styles, from which to choose. Generally, the larger you want your cup size, the larger the breast implant your surgeon will consider. Breast implants are measured in cubic centimeters, or cc’s, not in cup sizes. This is because the size of the implant used depends on the size and shape of the individual woman’s chest.

Your surgeon will also evaluate your existing breast and skin tissue to determine if you have enough to cover the breast implant you are considering, or, in some cases such as after pregnancy, too much extra skin. If you desire a breast implant size that is too large for your tissue, your surgeon may warn you that the breast implant edges may be visible or palpable following your surgery. Also, excessively large breast implants may speed up the effects of gravity on the breast, and can result in droop or sag at an earlier age.

A recent report indicates that larger sized implants (greater than 350 cc) may be too large for many women, increasing the risk of developing complications such as extrusion, hematoma, infection, palpable implant folds and visible skin wrinkling. Surgical intervention could be required to correct these complications.

Implant surfaces

Breast implants are available with either a smooth or textured surface. Mentor’s textured breast implant surface is called Siltex®. It was originally designed to help reduce capsular contracture, which is the hardening of scar tissue around an implant.

Some studies suggest that surface texturing reduces the chance of severe capsular contracture, while other studies do not. Mentor’s Core Study did not show a difference in the likelihood of developing capsular contracture with textured implants compared to smooth-surfaced implants.

Smooth-surfaced implants have a slightly softer shell and are less likely to be felt through the skin and tissue. Choosing the implant surface that is right for you should be discussed by you and your physician.
MENTOR BREAST IMPLANTS

Options for every body

Mentor offers a number of specialized saline-filled and MemoryGel™ breast implant products that are designed to meet your unique, personal needs. Mentor implants are available in a wide variety of sizes, profiles and surface texture choices, which provides surgeons with more options to help you achieve the best match for your body type.

Below is a closer look at some of the features of our saline-filled and MemoryGel™ breast implants. Your physician can further explain their different benefits, and discuss which type of implant is the right choice for you.

MemoryGel® Breast Implants

- FDA approved
- Filled with Mentor’s proprietary cohesive gel
- Gel filler uniformly holds together and retains a natural give that resembles breast tissue
- Set fill volume
- Three projection options: Moderate, Moderate Plus and High Profile
- Two shell surface options: smooth and textured
- Covered by Mentor’s Standard or Enhanced limited warranty and lifetime replacement policy
Saline Breast Implants

- FDA approved
- Filled with a saltwater solution similar to the fluid that makes up most of the human body
- Slightly firmer feel than gel
- Flexible fill volume that can be adjusted by surgeon during procedure
- Three projection options: Moderate, Moderate Plus and High Profile
- Two shell surface options: smooth and textured
- Covered by Mentor’s Standard or Enhanced limited warranty and lifetime replacement policy

Contour Profile® Tissue Expanders

- Siltex® Low Height, Style 6100
- Siltex® Medium Height, Style 6200
- Siltex® Tall Height, Style 6300
SPECIAL CONSIDERATIONS FOR BREAST RECONSTRUCTION

Should you have breast reconstruction?

Whether you decide to have breast reconstruction depends on your own individual case, medical condition, general health, lifestyle, emotional state, and breast size and shape. You should consult your surgeon to discuss your personal goals for breast reconstruction. You may also consider consulting your family, friends, breast implant support groups, and breast cancer support groups to help you make this decision.

If you are considering breast reconstruction and do not have a reconstructive surgeon, ask your general surgeon for a referral. He or she can give you the names of experienced, board-certified surgeons in your area. Your general surgeon, breast reconstruction surgeon, and oncologist should work together to plan your mastectomy and reconstruction procedure, and advise you based on your specific clinical needs and desired outcome.

What are the alternatives to breast reconstruction?

After considering your options with your physician, you may choose not to undergo breast reconstruction. In this case, you may or may not decide to wear an external breast form (prosthesis) inside your bra. Breast forms are available in a variety of shapes, sizes and materials, such as foam, cotton and silicone. Custom prostheses are also available to match the size and shape of your breast.

The timing of your breast implant reconstruction

The following description applies to reconstruction following mastectomy, but similar considerations apply to reconstruction following breast trauma or reconstruction for congenital anomalies. The breast reconstruction process may begin at the time of your mastectomy (immediate reconstruction) or months to years afterwards (delayed reconstruction). This decision is made after consultation with your cancer treatment team based on your individual situation.

Immediate reconstruction may involve placement of a breast implant, but typically involves placement of a tissue expander, which is used to recreate skin that was removed during your cancer surgery. The tissue expander is then eventually replaced with a breast implant.
It is important to know that any type of surgical breast reconstruction may take several steps to complete.

A potential advantage to immediate breast reconstruction is that it begins at the time of your mastectomy. The result may be a savings in cost and potentially fewer days in the hospital when you combine your mastectomy procedure with the first stage of your breast reconstruction. However, there may be a higher risk of capsular contracture, extrusion, and other complications associated with immediate reconstruction as a result of postoperative radiation and chemotherapy treatment. Your initial operative time and recovery period may also be longer.

A potential advantage to delayed reconstruction is that you can delay your reconstruction decision and surgery until other treatments, such as radiation therapy and chemotherapy, are completed. Delayed reconstruction may be advisable if your surgeon anticipates healing problems with your mastectomy, or if you just need more time to consider your options.

There are medical, financial and emotional considerations in choosing between immediate and delayed reconstruction. You should discuss with your general surgeon, reconstructive surgeon and oncologist, the pros and cons of the options available in your individual case.

Surgical considerations to discuss with your doctor

Discuss the advantages and disadvantages of the following options with your surgeon and your oncologist.

**Immediate reconstruction**

- One-stage reconstruction with a breast implant or a combination expander/mammary implant (implant only).
- Two-stage immediate reconstruction with a tissue expander followed by delayed reconstruction several months later with a breast implant.

**Delayed reconstruction**

- Two-stage delayed reconstruction with a tissue expander followed several months later with a breast implant.

**One-stage immediate breast implant reconstruction**

Immediate one-stage breast reconstruction may be done at the time
of your mastectomy. After the general surgeon removes your breast tissue, the reconstructive surgeon will then place a breast implant that completes the one-stage reconstruction. In reconstruction following a mastectomy, a breast implant is most often placed submuscularly, which is underneath the muscle of the chest wall.

**Two-stage (immediate or delayed) breast implant reconstruction**

Breast reconstruction usually occurs as a two-stage procedure, starting with the placement of a breast tissue expander, which is replaced several months later with a breast implant after enough new skin has been created to obtain the best result. The tissue expander placement may be done immediately at the time of your mastectomy, or be delayed until months or years later.

**THE SURGICAL PROCEDURE**

There are many important factors that may have an effect on your particular implant procedure, your recovery and your results. They should be well understood and carefully discussed with your doctor. Some of these factors are:

- The type of mastectomy you have had
- The stage of development of the cancer when it was discovered
- The follow-up treatment that you will require
- Your overall health
- Your chest structure and overall body shape
- Your healing capabilities (which can be affected by smoking, alcohol and various medications)
- Prior breast surgeries
- Bleeding tendencies
- Infections
- Shifting of implant
- Scarring from the incision
- Predisposition to develop a hardened capsule around the implant

Reconstruction surgery is usually performed on an inpatient basis in an operating room when it begins at the same time as your mastectomy. Some of the stages, such as nipple reconstruction, or
placement of the implant after soft tissue expansion, can be done as an outpatient procedure. General anesthesia is most often used.

Reconstruction incision sites
In reconstructive surgery, the incision placement and length is decided by your surgeon, and largely influenced by the type of cancer surgery that is planned for you.

Recovery period
Depending on the type of surgery you have (i.e., immediate or delayed), your postoperative recovery period will vary. Possible complications that may occur have been described throughout this booklet. Ask your surgeon to advise you on your specific postoperative care instructions.

Please note:
If you experience fever or noticeable swelling and/or redness in your implanted breast(s), you should contact your surgeon immediately.

FACTORS TO CONSIDER BEFORE RECONSTRUCTION OR IMPLANTATION
You should familiarize yourself with the following options in breast implant surgery and be prepared to discuss with your surgeon the following issues:

Surgical experience and training
When choosing a surgeon who is experienced with breast reconstruction, you should know the answers to the following questions:

- How many breast reconstruction implantation procedures does he/she perform per year?
- How many years has he/she performed breast reconstruction procedures?
- Has he/she obtained training certification from Mentor to use its MemoryGel™ breast implants?
- Is he/she board certified, and if so, with which board?
- In which state(s) is he/she licensed to practice surgery? Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients, either by request or on the Internet.
• What is the most common complication he/she encounters with breast reconstruction?
• What is his/her reoperation rate with breast reconstruction, and what is the most common type of reoperation he/she performs?

**Palpability**

Implants may be more palpable or noticeable if there is an insufficient amount of skin/tissue available to cover the implant and/or when the implant is placed subglandularly.

**Health insurance coverage**

In general, private insurance that covers medically necessary mastectomies will also cover breast reconstructive surgery. Insurance coverage for reoperation procedures or additional surgeon visits following reconstruction may not be covered, depending on the policy. For example, a reoperation may include temporary removal of the implant to facilitate the oncologist’s ongoing surveillance for breast cancer recurrence.

Because coverage policies vary and can change over time, no guidance can be given with respect to coverage under any particular health plan. It is therefore recommended that you contact your health plan provider to obtain specific information regarding its coverage policies before deciding to proceed with reconstructive surgery.
Mentor’s Lifetime Product Replacement Policy provides for the free lifetime product replacement of its saline-filled and MemoryGel™ breast implants, world wide. When implant replacement is required, and the Mentor Product Replacement Policy applies, Mentor will provide, throughout the patient’s lifetime, the same or similar Mentor breast implant at no cost. If a more expensive product is requested, Mentor will invoice your surgeon for the price difference.

The Mentor Standard Advantage Limited Warranty is free of charge to all patients who are implanted with Mentor saline-filled or MemoryGel™ breast implants in the United States and Puerto Rico.

The Mentor Enhanced Advantage Limited Warranty is an optional limited warranty available for women who are implanted with Mentor saline-filled or MemoryGel™ breast implants in the United States and Puerto Rico. You must pay a $100.00 enrollment fee within 45 days of your breast implantation.

Your surgeon will provide you with a copy of Mentor’s product replacement and limited warranty program for breast implants. However, it is not intended to replace any discussion between you and your physician. Prior to your surgery, your physician should advise you about possible risks and complications associated with breast implant surgery, including deflation or rupture.

With both the Mentor Standard Advantage and Mentor Enhanced Advantage Limited warranties, it’s important for you to also maintain your own records to ensure validation of your enrollment. This is necessary because it’s possible your doctor may only be required to retain your records for a limited period of time depending upon the laws of your state.

* When undergoing breast reconstruction, be aware that breast implantation may not be a one-time surgery. You should read and fully understand “Important Information for Reconstruction Patients about Mentor MemoryGel™ Silicone Gel-Filled Breast Implants.”
Upon request, you’ll be provided with a copy of the package insert (Directions For Use). You can request a copy from your surgeon or from Mentor. The package insert has many undefined medical and technical terms because it contains information directed only to the surgeon.

For more detailed information on the preclinical and clinical studies conducted by Mentor, please refer to the Summary of Safety and Effectiveness Data (SSED) for this product at www.fda.gov/cdrh/breastimplants/.

If you should decide to get breast implants, you will be given a device identification card with the style and serial number of your breast implant(s). This will be given to you right after your surgery. It is important that you keep a copy of this card because you may need to refer to the information at a later date.

For additional information or questions about Mentor breast implants, please call 1-800-MENTOR-8. The following list of resources may help you obtain additional information so you can make an informed decision about breast augmentation.

**Mentor Corporation**
1-800-MENTOR-8
www.mentorcorp.com
www.mentor4me.com

**Institute of Medicine Report on the Safety of Silicone Implants**
www.nap.edu/catalog/9618.html

**Food and Drug Administration**
1-888-INFO-FDA or 301-827-3990
www.fda.gov/cdrh/breastimplants/

You can find important information in the FDA breast implant consumer handbook, which is available through the phone number or web site provided above.

**American Society of Plastic Surgeons**
www.plasticsurgery.org/publiceducation/silicone-breast-implant-surgery.cfm

**Breast Reconstruction Resources**

**National Cancer Institute**
1-800-4-CANCER
www.cancernet.nci.nih.gov
American Cancer Society
(Reach to Recovery)
1-800-ACS-2345)
www.cancer.org

Women’s Information Network Against Breast Cancer
866-2WINABC (866-294-6222)
www.winabc.org

Y-ME National Organization for Breast Cancer Information and Support
(800) 221-2141
www.y-me.org

Books


Upon request, you will be provided with a copy of the Direction for Use device package insert.

Sources of additional information
The following resources are available for more information about breast implants: the package insert and the FDA consumer handbook.

Mentor’s saline-filled breast implants have been demonstrated to be effective for reconstruction patients in a prospective 36-month study of 416 patients. The study included immediate postmastectomy (IPM), delayed postmastectomy (DPM) and congenital deformity (CD) patients. Along with restoring breast size, these implants also demonstrated several statistically significant additional benefits, including:

- Increased ability to cope with day-to-day living (IPM, DPM).\(^5\)
- Decreased level of depression (IPM, CD).\(^6\)
- Improved satisfaction with physical appearance (CD).\(^7\)
COMPLICATIONS, PRECAUTIONS AND WARNINGS FOR SALINE-FILLED BREAST IMPLANTS

SALINE-FILLED & SPECTRUM® MAMMARY PROSTHESES PRODUCT DISCLOSURE

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Device Description
A breast implant is a sac (implant shell) of silicone elastomer (rubber), which is surgically implanted under your chest tissues and then filled with saline, a saltwater solution, through a valve.

Are You Eligible for Saline-Filled Breast Implants?
Implants are to be used for females for the following indications (procedures):

- **Breast Reconstruction** – This procedure is done to restore a woman’s breast shape after a mastectomy or injury that resulted in either partial or total loss of the breast(s), or to correct a birth defect.

What Are Important Factors for You to Consider When Deciding to Have Saline-Filled Implants?

- Whether you are undergoing augmentation or reconstruction, be aware that breast implantation may not be a one-time surgery. You are likely to need additional surgery and surgeon visits over the course of your life.
- Breast implants are not considered lifetime devices. You will likely undergo implant removal with or without replacement over the course of your life.
- Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed, you may experience unacceptable dimpling, puckering, wrinkling or other cosmetic changes of the breast.
- Breast implants may affect your ability to produce milk for breast-feeding. Also, breast implants will not prevent your breasts from sagging after pregnancy.
- With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.
- For patients who have undergone breast implantation either as a cosmetic or a reconstructive procedure, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should check with your insurance company regarding these coverage issues.

**Reconstruction** – Most insurance covers the first breast reconstruction operation. Insurance coverage for reoperation procedures or additional surgeon’s visits following reconstruction may not be covered, depending on the policy.

Who Is Not Eligible for Breast Implants?

Implants are not to be used for

- Women with existing malignant or premalignant cancer of your breast without adequate treatment
- Women with active infection anywhere in your body
- Augmentation in women who are currently pregnant or nursing
What are contraindications,Warnings and Precautions for You to Consider?

Surgical practices that are contraindicated in breast implantation because they may damage the shell and cause deflation/rupture:

- Placement of drugs/substances inside the implant other than sterile saline
- Any contact of the implant with Betadine®*
- Injection through implant shell
- Alteration of the implant
- Stacking of implants: more than one implant per breast per breast pocket

Safety and effectiveness have not been established in patients with the following conditions:

- Autoimmune diseases such as lupus and scleroderma
- Conditions that interfere with wound healing and blood clotting
- A weakened immune system (for example, currently receiving immunosuppressive therapy)
- Reduced blood supply to breast tissue

Further considerations:

- Preimplantation Mammography – You may wish to undergo a preoperative mammogram and another 6 months to 1 year after implantation to establish a baseline.
- Interference with Mammography – The implant may interfere with finding breast cancer during mammography and also may make it difficult to perform mammography. Therefore, it is essential that you tell your mammography technologist that you have an implant before the procedure. The technologist can use special techniques to minimize the possibility of rupture and to get the best possible views of the breast tissue. Because the breast is squeezed during mammography, it is impossible for an implant to rupture during the procedure. More x-ray views are necessary with these special techniques; therefore, women with breast implants will receive more radiation. However, the benefit of the mammogram in finding cancer outweighs the risk of the additional x-rays.
- Distinguishing the Implant From Breast Tissue During Breast Self-Examination – You should perform a breast self-examination monthly on your implanted breast. In order to do this effectively, you should ask your surgeon to help you distinguish the implant from your breast tissue. Any new lumps should be evaluated with a biopsy. If a biopsy is performed, care must be taken to avoid puncturing the implant.
- Long-Term Effects – The long-term safety and effectiveness of breast implants have not been studied; however, Mentor is monitoring the long-term (i.e., 10-year) chance of implant rupture, reoperation, implant removal and capsular contracture (hardening of the tissues around the implant). Mentor is also conducting mechanical testing to assess the long-term likelihood of implant rupture. Mentor will update this brochure with this information and time frames later.
- Capsule Procedures – You should be aware that closed capsulotomy, the practice of forcible squeezing or pressing on the fibrous capsule around the implant to break the scar capsule, is not recommended, as this may result in breakage of the implant.

What Are Potential Breast Implant Complications?

Undergoing any surgical procedure may involve the risk of complications such as the effects of anesthesia, infection, swelling, redness, bleeding, and pain. In addition, there are potential complications specific to breast implants. These complications include:

- Deflation/Rupture – Breast implants deflate when the saline solution

*Betadine is a registered trademark of Purdue Frederick Company.
leaks either through an unsealed or damaged valve or through a break in the implant shell. Implant deflation can occur immediately or slowly over a period of days and is noticed by loss of size or shape of your breast. Some implants deflate (or rupture) in the first few months after being implanted and some deflate after several years. Causes of deflation include damage by surgical instruments during surgery, overfilling or underfilling of the implant with saline solution, capsular contracture, closed capsulotomy, stresses such as trauma or intense physical manipulation, excessive compression during mammographic imaging, umbilical incision placement, and unknown/unexplained reasons. You should also be aware that the breast implant may wear out over time and deflate/rupture. Deflated implants require additional surgery to remove and to possibly replace the implant.

- Capsular Contracture – The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant and is called capsular contracture. Capsular contracture is more common following infection, hematoma and seroma. It is also more common with subglandular placement (behind the mammary gland and on top of the chest muscle). Symptoms range from mild firmness and mild discomfort to severe pain, distorted shape, palpability of the implant and/or movement of the implant. Additional surgery is needed in cases where pain and/or firmness is severe. This surgery ranges from removal of the implant capsule tissue to removal and possibly replacement of the implant itself. Capsular contracture may happen again after these additional surgeries.

- Pain – Pain of varying intensity and duration may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should tell your surgeon about severe pain.

- Additional Surgeries – You should understand there is a high chance that you will need to have additional surgery at some point to replace or remove the implant. Also, problems such as deflation, capsular contracture, infection, shifting and calcium deposits can require removal of the implants. Many women decide to have the implants replaced, but some women do not. If you choose not to, you may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.

- Dissatisfaction with Cosmetic Results – Dissatisfying results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, hypertrophic (irregular, raised scar) scarring and/or sloshing may occur. Careful surgical planning and technique can minimize but not always prevent such results.

- Infection – Infection can occur with any surgery. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. Infections with an implant present are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved. In rare instances, toxic shock syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness and/or sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment for this condition.

- Hematoma/Seroma – Hematoma is a collection of blood inside a body cavity, and a seroma is a collection of the watery portion of the blood (in this case, around the implant or around the incision). Postoperative hematoma and seroma may contribute to infection and/or capsular contracture. Swelling, pain and bruising may result. If a hematoma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, large ones will
require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation/rupture can occur from surgical draining if damage to the implant occurs during the draining procedure.

- **Changes in Nipple and Breast Sensation** – Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. Changes in feeling can be temporary or permanent and may affect your sexual response or your ability to nurse a baby. (See the paragraph on breast-feeding below.)

- **Breast-Feeding** – At this time it is not known if a small amount of silicone may diffuse (pass through) from the saline-filled breast implant silicone shell and may find its way into breast milk. If this occurs, it is not known what effect it may have on the nursing infant. Although there are no current methods for detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone-filled gel implants when compared to women without implants.

With respect to the ability to successfully breast-feed after breast implantation, one study reported up to 64% of women with implants who were unable to breast-feed compared to 7% without implants. The periareolar incision site may significantly reduce the ability to successfully breast-feed.

- **Calcium Deposits in the Tissue Around the Implant** – Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer.

- **Delayed Wound Healing** – In some instances, the incision site takes longer to heal than normal.

- **Extrusion** – Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.

- **Necrosis** – Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

- **Breast Tissue Atrophy/Chest Wall Deformity** – The pressure of the breast implant may cause the breast tissue to thin out and shrink. This can occur while implants are still in place or following implant removal without replacement.

In addition to these common complications, there have been concerns with rarer diseases, of which you should be aware:

- **Connective Tissue Disease** – Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature of small numbers of women with implants. A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants. However, a lot of women with breast implants believe that their implants caused a connective tissue disease.

- **Cancer** – Published studies indicate that breast cancer is no more common in women with implants than those without implants.

- **Second Generation Effects** – There have been concerns raised regarding potential damaging effects on children born of mothers with implants. A review of the published literature on this issue suggests that the information is insufficient to draw definitive conclusions.
MENTOR’S CLINICAL STUDIES

Although you will experience your own risks (complications) and benefits following breast implant surgery, this section describes the specific complications and benefits of Mentor’s saline-filled breast implants. Mentor’s clinical studies indicate, for example, that while most women can expect to experience at least one complication at some point through 3 years after implant surgery, most women were satisfied with their implants. The studies also indicate that the chance of additional surgery is 1 in 2.5 for reconstruction patients (with the most common type of additional surgery being capsule-related). The information below provides more details about the complications and benefits you may experience.

Description of Studies

Mentor conducted clinical testing of its saline-filled breast implants to determine the short-term and most common complications, as well as benefits, of their implants. These were assessed in the following studies:

- The Large Simple Trial (LST)
- Saline Prospective Study (SPS)

The LST was designed to determine the 1-year rates of capsular contracture, infection, deflation and implant removal. There were 104 reconstruction patients enrolled. Of these enrolled patients, 47% returned for their 1-year visit.

The SPS was designed as a 3-year study to assess all complications with breast implants as well as patient satisfaction, body image and self-concept. Patients were followed annually and data through 3 years are available. The SPS enrolled 428 reconstruction patients. Seventy-eight (78%) percent of reconstruction patients returned for their 3-year visit. The outcomes of the patients lost to follow-up are not known. The SPS results in this brochure represent data through 3 years.

After product approval, Mentor switched data collection to a post-approval study. The post-approval study involves the collection of some safety data from SPS patients through their 10-year postimplantation timepoint. The data are collected from questionnaires that are mailed out to the patients each year. The post-approval data presented includes earlier data shown in the SPS tables with new information added to it. The 5-year post-approval data are shown in the “Reconstruction Results from Post-Approval Study” section which follows.

What Were the 1-Year Complication Rates from the LST?

The table below shows the complication rates for augmentation, reconstruction and revision patients through 1 year. The rates reflect the number of patients out of 100 who experienced the listed complication. For example, 5% or 5 out of 100 augmentation patients experienced capsular contracture at some time within 1 year after implantation. However, this does not mean that 5% of the patients still have capsular contracture at 1 year.

<table>
<thead>
<tr>
<th>COMPLICATIONS</th>
<th>1-YEAR COMPLICATION RATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsular Contracture</td>
<td>29%</td>
</tr>
<tr>
<td>Implant Removal</td>
<td>10%</td>
</tr>
<tr>
<td>Implant Leakage/Deflation</td>
<td>NA</td>
</tr>
<tr>
<td>Infection</td>
<td>NA</td>
</tr>
</tbody>
</table>

NA: Not Available or insufficient data to perform an analysis of risk of the complication.

Data on 47% of the 2385 patients enrolled in the study.
What Were the 3-Year Complication Rates from the SPS for Reconstruction Patients?

The 3-year complication rates (including all levels of severity, from mild to severe) are shown from the most common to the least common in the table below. The rates reflect the number of reconstruction patients out of 100 who experienced the listed complication at least once within the first 3 years after implantation. Some complications occurred more than once for some patients. The most common complication experienced within the first 3 years of implantation was wrinkling (40% or 40 patients out of 100).

<table>
<thead>
<tr>
<th>Reconstruction Complications</th>
<th>3-Year Complication Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Operation (Reoperation)</td>
<td>40%</td>
</tr>
<tr>
<td>Loss of Nipple Sensation</td>
<td>35%</td>
</tr>
<tr>
<td>Capsular Contracture III/IV or grade unknown</td>
<td>30%</td>
</tr>
<tr>
<td>Asymmetry</td>
<td>28%</td>
</tr>
<tr>
<td>Implant Removal</td>
<td>27%</td>
</tr>
<tr>
<td>Wrinkling</td>
<td>20%</td>
</tr>
<tr>
<td>Breast Pain</td>
<td>17%</td>
</tr>
<tr>
<td>Infection</td>
<td>9%</td>
</tr>
<tr>
<td>Leakage/Deflation</td>
<td>9%</td>
</tr>
<tr>
<td>Irritation/Inflammation</td>
<td>8%</td>
</tr>
<tr>
<td>Delayed Wound Healing</td>
<td>6%</td>
</tr>
<tr>
<td>Seroma</td>
<td>6%</td>
</tr>
<tr>
<td>Scarring</td>
<td>5%</td>
</tr>
<tr>
<td>Extrusion</td>
<td>2%</td>
</tr>
<tr>
<td>Necrosis</td>
<td>2%</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1%</td>
</tr>
<tr>
<td>Position Change</td>
<td>1%</td>
</tr>
</tbody>
</table>

What Were the Types of Additional Surgical Procedures Performed for Reconstruction Patients?

The following table provides a breakdown of the types of surgical procedures that were performed through the 3 years after the initial implantation. There were a total of 353 additional surgical procedures in 149 reconstruction patients (excluding those that were planned reconstruction such as nipple reconstruction). Of these 149 patients, most reported multiple surgical procedures during a single reoperation. The most common type of additional surgical procedure was capsule related (28% of the 353 procedures).
What Were the reasons for implant removal for reconstruction patients?

The main reasons for implant removal among reconstruction patients in the SPS over the 3 years are shown in the table below. There were 116 implants removed in 97 patients.

Of the 116 implants removed among reconstruction patients, 60% were replaced. The most common reasons for implant removal were correction of capsular contracture and infection (26% of the 116 implants removed).

<table>
<thead>
<tr>
<th>Main Reason for Augmentation Implant Removal through 3 Years</th>
<th>N=116 Implants Removed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsular Contracture</td>
<td>30%</td>
</tr>
<tr>
<td>Infection</td>
<td>24%</td>
</tr>
<tr>
<td>Leakage/Deflation</td>
<td>22%</td>
</tr>
<tr>
<td>Patient Request for Size/Shape Change</td>
<td>6%</td>
</tr>
<tr>
<td>Necrosis/Extrusion</td>
<td>5%</td>
</tr>
<tr>
<td>Asymmetry</td>
<td>4%</td>
</tr>
<tr>
<td>Breast Pain</td>
<td>3%</td>
</tr>
<tr>
<td>Delayed Wound Healing</td>
<td>2%</td>
</tr>
<tr>
<td>Cosmetic Revision</td>
<td>1%</td>
</tr>
<tr>
<td>Wrinkling</td>
<td>1%</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

1Corrections to some rates reported at 3 years. Total number of implants removed did not change.

What Were the Complication Rates After Implant Replacement for Reconstruction Patients?

There were 66 reconstruction patients who had 76 implants removed and replaced with Mentor implants. The table below reflects the number of replaced implants (not patients) out of 100 implants associated with the listed complications within 3 years following replacement. For example, there was a reoperation in 31% or 31 out of 100 implants at some time within the 3 years after replacement.

<table>
<thead>
<tr>
<th>Type of Additional Surgical Treatment</th>
<th>N=353 Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsule Related</td>
<td>28%</td>
</tr>
<tr>
<td>Implant Removal with Replacement</td>
<td>19%</td>
</tr>
<tr>
<td>Scar or Wound Revision</td>
<td>13%</td>
</tr>
<tr>
<td>Implant Removal without Replacement</td>
<td>11%</td>
</tr>
<tr>
<td>Nipple Related (unplanned)</td>
<td>8%</td>
</tr>
<tr>
<td>Saline Adjustment</td>
<td>7%</td>
</tr>
<tr>
<td>Reposition Implant</td>
<td>6%</td>
</tr>
<tr>
<td>Biopsy/Cyst Removal</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Breast Reduction or Mastectomy</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Mastopexy</td>
<td>&lt;1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
What Were the Breast Disease and CTD Events in Reconstruction Patients?

Breast disease and connective tissue disease (CTD) were reported in some patients through 3 years after implantation in the SPS. Although there were 416 reconstruction patients enrolled in the SPS, not every patient returned for each follow-up visit. Therefore, the percentage of patients with these events cannot be determined. Only the number of events can be provided. There were no new cases of breast disease. The table below shows the number of reports of CTD through 3 years after implantation. Some patients may have reported more than one CTD. Confirmed reports were based on a diagnosis by a doctor. Unconfirmed reports were based on self-reports by the patients.

Without a comparison group of women with similar characteristics (age, race, etc.) and without breast implants, no conclusions can be made about the relationship between breast implants and these CTD events.

<table>
<thead>
<tr>
<th>Complication Following Replacement of Reconstruction Implant</th>
<th>3-Year Complication Rate N=76 implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Operations (Reoperation)</td>
<td>31%</td>
</tr>
<tr>
<td>Leakage/Deflation</td>
<td>23%</td>
</tr>
<tr>
<td>Implant Removal</td>
<td>21%</td>
</tr>
<tr>
<td>Capsular Contracture III/IV or grade unknown</td>
<td>19%</td>
</tr>
<tr>
<td>Asymmetry</td>
<td>17%</td>
</tr>
<tr>
<td>Wrinkling</td>
<td>16%</td>
</tr>
<tr>
<td>Breast Pain</td>
<td>13%</td>
</tr>
<tr>
<td>Infection</td>
<td>5%</td>
</tr>
<tr>
<td>Irritation/Inflammation</td>
<td>3%</td>
</tr>
<tr>
<td>Seroma</td>
<td>3%</td>
</tr>
<tr>
<td>Extrusion</td>
<td>2%</td>
</tr>
<tr>
<td>Hematoma</td>
<td>2%</td>
</tr>
<tr>
<td>Scarring</td>
<td>2%</td>
</tr>
<tr>
<td>Necrosis</td>
<td>1%</td>
</tr>
</tbody>
</table>

Number of Reports of CTD in RECONSTRUCTION Patients in the SPS Study

<table>
<thead>
<tr>
<th>Connective Tissue Disease</th>
<th>No. of Confirmed Reports</th>
<th>No. of Unconfirmed Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoarthritis</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Arthritis (type unknown)</td>
<td>1</td>
<td>19</td>
</tr>
<tr>
<td>Ankylosing Spondylitis</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>4</td>
<td>28(^1)</td>
</tr>
</tbody>
</table>

\(^1\)Seven reconstruction patients had 2 unconfirmed CTDs.

What Were the Benefits of the SPS for Reconstruction Patients?

The SPS measured a variety of outcomes that assessed the benefits of the implants. For reconstruction, these outcomes included breast size change. These outcomes were assessed before implantation and at 3 years after surgery for those patients who still had their original implants.
For reconstruction patients, 283 out of the original 416 patients (68%) still had implants and were in the study after 3 years. Of these 283 patients, the average increase in chest circumference was 1.5 inches.

**RECONSTRUCTION RESULTS FROM POST-APPROVAL STUDY**

In terms of patient accountability, of the 335 reconstruction patients expected for follow-up at 5 years, data were collected for 52%. Please note that the follow-up rate at 3 years was 78%, which makes the 3-year data more reliable than the 5-year data or 7-year data. There was some 5-year data reported for 73% of the 335 reconstruction patients at some time from 3 to 10 years postoperatively. There was some 7-year data reported for 79% of the reconstruction patients at some time from 3 to 10 years postoperatively. It is assumed that information obtained at a later time (for example, at 7 years) applies to an earlier time (for example, at 5 years), which counts on patient memory over time. This is not as reliable as information obtained at an earlier time.

The 5-year and 7-year complication rates are shown in the table below. The rates reflect the number of reconstruction patients out of 100 who experienced the listed complication at least once within the first 5 years or 7 years after implantation. The most common complication experienced through 5 years was reoperation (43% or 43 patients out of 100).

The 5-year and 7-year complication rates are shown in the table below. The rates reflect the number of reconstruction patients out of 100 who experienced the listed complication at least once within the first 5 years or 7 years after implantation. The most common complication experienced through 5 years was reoperation (43% or 43 patients out of 100).

| Reoperation | 43% | 50% |
| Implant Removal | 30% | 39% |
| Capsular Contracture III/IV or unknown | 29% | 49% |
| Implant Deflation | 16% | 29% |
| Breast Pain | 18% | 27% |

The most common complication experienced through 7 years was reoperation or capsular contracture (50% or 50 patients out of 100).

The reasons for reoperation through 3, 5 and 7 years are shown below. The reasons for reoperation at 3 years are included below because the original labeling only reported the types of surgical procedures. While there may be some overlap of these two, they are different sets of data. An example of a type of additional surgical procedure is saline adjustment; an example of a reason for reoperation is infection. There were 209 reoperations performed in 149 patients through 3 years. There were 232 reoperations performed in 162 patients through 5 years. There were 279 reoperations performed in 185 patients through 7 years. There may have been multiple reasons for one reoperation; therefore, the percentages in the table below do not add up to 100%. The most common reason for reoperation through 5 years was capsular contracture (29% of the 232 reoperations).

The most common reason for reoperation through 7 years was capsular contracture (31% of the 279 reoperations). Note that the percentages are smaller for some of the reasons for reoperation because the number of reoperations has gotten bigger. The main reasons for implant removal through 5 years and 7 years are shown below. There were 135 implants removed in 112 patients at 5 years, and 180 implants removed in 142 patients at 7 years. The most common reason for removal through 5 years and 7 years was capsular contracture (29% of the 135 implants removed at 5 years, and 29% of the 180 implants removed at 7 years). Note that the percentages are smaller for some of the reasons for removal because the number of removals has gotten bigger.
The main reasons for implant removal through 5 years and 7 years are shown below. There were 135 implants removed in 112 patients at 5 years, and 180 implants removed in 142 patients at 7 years. The most common reason for removal through 5 years and 7 years was capsular contracture (29% of the 135 implants removed at 5 years, and 29% of the 180 implants removed at 7 years). Note that the percentages are smaller for some of the reasons for removal because the number of removals has gotten bigger.

<table>
<thead>
<tr>
<th>Reason for Reoperation</th>
<th>3-Years N=209 Reoperations</th>
<th>5-Years N=232 Reoperations</th>
<th>7-Years N=279 Reoperations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsular Contracture</td>
<td>30%</td>
<td>29%</td>
<td>30%</td>
</tr>
<tr>
<td>Asymmetry</td>
<td>22%</td>
<td>20%</td>
<td>17%</td>
</tr>
<tr>
<td>Patient Request for Size/Shape Change</td>
<td>16%</td>
<td>16%</td>
<td>15%</td>
</tr>
<tr>
<td>Leakage/Deflation</td>
<td>13%</td>
<td>15%</td>
<td>19%</td>
</tr>
<tr>
<td>Staged Reconstruction</td>
<td>16%</td>
<td>15%</td>
<td>12%</td>
</tr>
<tr>
<td>Infection</td>
<td>16%</td>
<td>15%</td>
<td>12%</td>
</tr>
<tr>
<td>Delayed Wound Healing</td>
<td>9%</td>
<td>8%</td>
<td>7%</td>
</tr>
<tr>
<td>Breast Pain</td>
<td>8%</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>Hematoma/Seroma</td>
<td>8%</td>
<td>7%</td>
<td>6%</td>
</tr>
<tr>
<td>Scarring</td>
<td>6%</td>
<td>6%</td>
<td>5%</td>
</tr>
<tr>
<td>Wrinkling</td>
<td>6%</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Extrusion</td>
<td>4%</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>Necrosis</td>
<td>4%</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Cosmetic Revision</td>
<td>4%</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Irritation/Inflammation</td>
<td>4%</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Breast Mass or Cancer</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Sagging</td>
<td>0%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Valve Malposition</td>
<td>1%</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Lymphadenopathy</td>
<td>1%</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Contralateral Replacement</td>
<td>0%</td>
<td>0%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Position Change</td>
<td>0%</td>
<td>0%</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

1If there was more than one reason reported per patient, all reasons are included in this table. This table excludes patients in which staged reconstruction was the only reason for reoperation.
COMPLICATIONS, PRECAUTIONS AND WARNINGS FOR MEMORYGEL™ SILICONE GEL-FILLED BREAST IMPLANTS

What Is a Silicone Gel-Filled Breast Implant?
A breast implant is a sac (implant shell) of silicone elastomer (rubber) filled with silicone gel, which is surgically implanted either under your breast tissue or under your chest muscle.

Are You Eligible for Silicone Gel-Filled Breast Implants?
Mentor MemoryGel Silicone Gel-Filled Breast Implants are indicated for females for the following uses (procedures):

- **Breast reconstruction.** Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

Contraindications
Breast implant surgery should not be performed in:

- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions.
- Women with active infection anywhere in their body.
- Women who are currently pregnant or nursing.

Precautions
Safety and effectiveness have not been established in patients with the following:

- **Main Reason for Removal** | **5-Years N=135 Implants Removed** | **7-Years N=180 Implants Removed**
- Capsular Contracture | 29% | 29%
- Leakage/Deflation | 25% | 28%
- Infection | 21% | 16%
- Patient Request for Size/Style Change | 8% | 9%
- Necrosis Extrusion | 5% | 4%
- Asymmetry | 4% | 4%
- Breast Pain | 3% | 2%
- Breast Mass or Cancer | 1% | 2%
- Delayed Wound Healing | 1% | 1%
- Wrinkling | 1% | 1%
- Cosmetic Revision | 1% | 1%
- Contralateral Replacement | 0% | 2%
- Position Change | 0% | 1%
- Hypertrophic Scarring | 0% | 1%
- Irritation/Scarring | 0% | 1%
Autoimmune diseases (for example, lupus and scleroderma).

A weakened immune system (for example, currently taking drugs that weaken the body’s natural resistance to disease).

Conditions that interfere with wound healing and blood clotting.

Reduced blood supply to breast tissue.

Radiation to the breast following implantation.

Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders with your surgeon prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

**Important Factors You Should Consider When Choosing Silicone Gel-Filled Implants.**

- You should be aware that there are many factors that will affect the outcome and timing of your reconstruction with breast implants, such as the stage of your disease, the type and extent of cancer removal surgery you have had, the amount of skin and soft tissue available for the reconstruction, and additional treatments such as chemotherapy and radiation, which you may require.

- Breast implants are not lifetime devices, and breast implantation is likely not a one-time surgery. You will likely need additional unplanned surgeries on your reconstructed and/or contralateral augmented breasts because of complications or unacceptable cosmetic outcomes. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures. When you have your implants replaced (revision-reconstruction), your risk of future complications increases compared to first time (primary) reconstruction surgery, so you should review the complication rates for revision-reconstruction patients to see what future risks you may experience.

- Many of the changes to your breast and chest wall following preparation and implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed and not replaced, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast.

- If you undergo a mastectomy, removal of the breast tissue eliminates the ability to breast feed with the removed breast. In addition, contralateral breast augmentation may affect your ability to breast feed, either by reducing or eliminating milk production.

- Rupture of a silicone gel-filled breast implant is most often silent. This means that neither you nor your surgeon will know that your implants have a rupture most of the time. In fact, the ability of a physical examination by a plastic surgeon who is familiar with breast implants to detect silicone breast implant rupture is 30%8 compared to 89% for MRI.9 You will need to have regular screening MRI examinations over your lifetime in order to determine if silent rupture is present. You should have your first MRI at 3 years after your initial implant surgery and then every 2 years, thereafter. The cost of MRI screening may exceed the cost of your initial surgery over your lifetime. This cost, which may not be covered by your insurance, should be considered in making your decision.

- If implant rupture is noted on by MRI, you should have the implant removed, with or without replacement.

- With breast implants, routine screening mammography for breast cancer will be more difficult. You should continue to undergo routine mammography screening as recommended by your primary care physician. The implant may interfere with finding breast cancer during mammography. Because the breast and implant are squeezed during mammography, an implant may rupture during the procedure. More x-ray views are necessary for women with breast...
implants; therefore, you will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays. Be sure to inform the mammography technologist that you have implants.

• You should perform an examination of your breasts every month for cancer screening; however, this may be more difficult with implants. You should ask your surgeon to help you distinguish the implant from your breast tissue.

• You should perform an examination of your breasts for the presence of lumps, persistent pain, swelling, hardening, or change in implant shape, which may be signs of symptomatic rupture of the implant. These should be reported to your surgeon and possibly evaluated with an MRI to screen for rupture.

• The timing for any revision following reconstruction surgery should be discussed with your surgeon so that all issues such as the potential effects of radiation, chemotherapy, and additional cancer surgery or treatments can be fully discussed.

• After undergoing cancer treatment and/or reconstructive breast surgery (either primary or revision), your health insurance premiums may increase, your insurance coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should discuss the complete extent of your insurance coverage with your insurance company before undergoing reconstructive surgery with breast implants.

• You should inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.

• Mentor will continue its ongoing Core Study through 10 years to further evaluate the long-term safety and effectiveness of these products. In addition, Mentor has initiated a separate, 10-year post-approval study to address specific issues for which the Mentor Core Study was not designed to fully answer, as well as to provide a real-world assessment of some endpoints. The endpoints in the large post-approval study include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and results. Mentor will update its labeling as appropriate with the results of these two studies. You should also ask your surgeon if he/she has any available updated clinical information.

• It is important that you read this entire brochure because you need to understand the risks and benefits and to have realistic expectations of the outcome of your surgery.

POTENTIAL BREAST IMPLANT COMPLICATIONS
Undergoing any type of surgical procedure involves risks (some serious) such as the effects of anesthesia, infection, swelling, redness, bleeding, pain, and even death, which need to be balanced against the benefits of the breast reconstruction surgery. There are potential complications specific to breast implant surgery and breast implants, as described below. It should also be noted that the cited references include data from augmentation and/or reconstruction patients, as well as from a variety of manufacturers and implant models.

Rupture
Breast implants are not lifetime devices. Breast implants rupture when the shell develops a tear or hole. Rupture can occur at any time after implantation, but they are more likely to occur the longer the implant is implanted. The following things may cause your implant to rupture: damage by surgical instruments; stressing the implant during implantation and weakening it; folding or wrinkling of the implant shell; excessive force to the chest (for example, during closed capsulotomy, which is contraindicated); trauma; compression during mammographic imaging; and severe capsular contracture. Breast implants may also simply wear out over time.
Laboratory studies have identified some of the types of rupture for Mentor’s product; however, it is not known whether these tests have identified all causes of rupture. These laboratory studies will continue post-approval.

Silicone gel-filled implant ruptures are most often silent. (MRI examination is currently the best method to screen for silent rupture.) This means that most of the time neither you nor your plastic surgeon will know if the implant has a tear or hole in the shell. This is why MRI is recommended at 3 years and then every 2 years, thereafter, to screen for rupture. However, sometimes there are symptoms associated with gel implant rupture. These symptoms include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.

When MRI findings of rupture are found, or if your surgeon determines you have signs or symptoms of rupture, you should have the implant and any gel removed, with or without replacement of the implant. It also may be necessary to remove the tissue capsule as well as the implant, which will involve additional surgery, with associated costs. If you have symptoms such as breast hardness, a change in breast shape or size, and/or breast pain, you should have an MRI to determine whether rupture is present.\(^\text{10,11}\)

There are also consequences of rupture. If rupture occurs, silicone gel may either remain within the scar tissue capsule surrounding the implant (intracapsular rupture), move outside the capsule (extracapsular rupture), or gel may move beyond the breast (migrated gel). There is also a possibility that rupture may progress from intracapsular to extracapsular and beyond. There have also been health consequences reported in the literature. See below for details.

**Rupture Information on Mentor Implants**

In Mentor’s Core study, rupture was assessed for patients who had scheduled MRIs to screen for rupture (i.e., part of the MRI cohort) and those who were not assessed for rupture by MRI (i.e., part of the non-MRI cohort). For primary reconstruction patients in the MRI cohort, the rupture rate was approximately 1% through 3 years. This means that through 3 years, 1 of every 100 primary reconstruction women had at least one ruptured breast implant. There was one primary reconstruction patient in the Mentor Core study with a suspected implant rupture that was silent and only detected with MRI. Rupture has not been confirmed with examination of the implant following removal. For revision-reconstruction patients in the MRI cohort, the rupture rate was 0% through 3 years. There were no ruptures reported in the non-MRI cohorts for either the primary reconstruction or revision-reconstruction patients through 3 years. Across all patients in the Mentor Core Study, of the 8 implants reported as ruptured, 4 showed intracapsular gel and 4 showed extracapsular gel on MRI (3 implants with extracapsular gel were in 2 revision-augmentation patients and 1 was in a primary reconstruction patient). For one of these implants with extracapsular gel, this was a confirmed case in which the device was explanted and the intracapsular gel rupture progressed into an extracapsular gel rupture as shown by MRIs at approximately 10 months and approximately 2 years. There were no cases of migrated gel.

Further rupture rate information on Mentor implants in augmentation patients is provided from an unpublished European study known as the U.K. Sharpe and Collis Study. Silent rupture was assessed by a single MRI on 101 augmentation patients implanted with textured Mentor implants by one surgeon. The average age of the implants was approximately 9 years. Silent rupture was found in approximately 10% of these augmentation patients, which includes one patient for which the device was not explanted to confirm rupture. There were no cases of extracapsular rupture or migrated gel.

Additional information on rupture will be collected through Mentor’s post-approval Core study and large post-approval study.

**Additional Information on Consequences of Rupture from Literature**

Studies of Danish women evaluated with MRI involving a variety of manufacturers
and implant models showed that about three-fourths of implant ruptures are intracapsular and the remaining one-fourth is extracapsular. Additional studies of Danish women indicate that over a 2-year period, about 10% of the implants with intracapsular rupture progressed to extracapsular rupture as detected by MRI. This means that for women with silicone gel rupture within the scar tissue capsule detected via MRI after 2 years, 1 in 10 of these women had progression of the gel outside the scar tissue capsule. Approximately half of the women whose ruptures had progressed from intracapsular to extracapsular reported that they experienced trauma to the affected breast during this time period or had undergone mammography. In the other half, no cause was given. In the women with extracapsular rupture, after 2 years, the amount of silicone seepage outside the scar tissue capsule increased for about 14% of these women. This means that for 100 women with silicone gel rupture outside the scar tissue capsule, the amount of gel outside the scar tissue capsule increased for 14 women 2 years later. This type of information pertains to a variety of silicone implants from a variety of manufacturers and implant models, and it is not specific to Mentor implants.

Below is a summary of information related to the health consequences of implant rupture, which have not been fully established. These reports were in women who had implants from a variety of manufacturers and implant models.

- Local breast complications reported in the published literature that were associated with rupture include breast hardness, a change in breast shape or size, and breast pain. These symptoms experienced by women who have capsular contracture.

- Concerns have been raised over whether ruptured implants are associated with the development of connective tissue or rheumatic diseases and/or symptoms such as fatigue and fibromyalgia. A number of epidemiology studies have evaluated large populations of women with breast implants from a variety of manufacturers and implant models. These studies do not, taken together, support a significant association of breast implants with a typical, diagnosed rheumatic disease. Other than one small study, these studies do not distinguish whether the women had ruptured or intact implants.

- Capsular Contracture – The scar tissue (capsule) that normally forms around the implant may tighten over time and compress the implant, making it feel firm and leading to what is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in revision-reconstruction than in primary reconstruction. Because you may have your initial implants replaced, you should be aware that your risk of capsular contracture increases with revision-reconstruction. Capsular contracture is a risk factor for implant rupture, and it is the most common reason for reoperation in primary reconstruction patients. Symptoms of capsular contracture range from mild firmness and mild discomfort to severe pain, distorted shape of the implant, and palpability (ability to feel the implant). Capsular contracture is graded into 4 levels depending on its severity. Baker Grades III or IV are considered severe and often additional surgery is needed to correct these grades:
  - **Baker Grade I**: the breast is normally soft and looks natural
  - **Baker Grade II**: the breast is a little firm but looks normal
  - **Baker Grade III**: the breast is firm and looks abnormal
  - **Baker Grade IV**: the breast is hard, painful, and looks abnormal
In Mentor’s Core Study, for women receiving reconstruction implants for the first time, the risk of severe capsular contracture was 8% through 3 years. This means 8 out of every 100 women who received Mentor implants for primary breast reconstruction had severe capsular contracture at least once during the first 3 years after receiving the implants.

For women receiving revision-reconstruction implants, the risk of severe capsular contracture was 16% through 3 years. This means 16 out of every 100 women who received Mentor implants for breast revision-reconstruction had severe capsular contracture at least once during the first 3 years after receiving the implants.

Additional surgery may be needed in cases where pain and/or firmness are severe. This surgery ranges from removal of the implant capsule tissue, to removal and possible replacement of the implant itself. This surgery may result in loss of your breast tissue. Capsular contracture may happen again after these additional surgeries. Capsular contracture may increase the risk of rupture.\textsuperscript{10}

- **Additional Surgeries (Reoperations)** – You should assume that you will need to have additional surgeries (reoperations). In the Mentor Core Study, the reoperation rate was 27% for primary reconstruction patients, which means that 27 out of every 100 women who received Mentor implants for primary reconstruction had a reoperation during the first 3 years after receiving the implants. The reoperation rate was 29% for revision-reconstruction patients, which means that 29 out of every 100 women who received mentor implants for revision-reconstruction had a reoperation during the first 3 years after receiving the implants.

Patients may decide to change the size or type of their implants, requiring additional surgery. Problems such as rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional surgery. Summary tables are provided on pages 47-51 that describe the reasons for performing additional surgeries experienced in the Mentor Core Study. For women receiving primary reconstruction implants, the three most common reasons for reoperation were asymmetry, patient request for style/size change and implant malposition. For women receiving revision-reconstruction implants, the three most common reasons for additional surgery were biopsy, severe capsular contracture and implant malposition.

- **Implant Removal** – Because these are not lifetime devices, the longer you have your implants, the more likely it will be for you to have them removed for any reason, either because of dissatisfaction, an unacceptable cosmetic result, or a complication such as severe capsular contracture. Having your implants removed and replaced increases your chances of getting future complications.

For women receiving primary reconstruction implants in Mentor’s Core Study, 12% had their implants removed at least once through 3 years. Patient choice and asymmetry were the most common reasons for implant removal. For women receiving revision-reconstruction implants in Mentor’s Core Study, 14% had their implants removed at least once through 3 years. The most common reason was severe capsular contracture.

Most women who have their implants removed, have them replaced with new implants, but some women do not. If you choose not to replace your implants, you may have cosmetically unacceptable dimpling, puckering, wrinkling, and/or other potentially permanent cosmetic changes of the breast following removal of the implant. Even if you have your implants replaced, implant removal may result in loss of your breast tissue. Also, implant replacement increases your risks of future complications. For example, the risks of severe capsular contracture increase for patients with implant replacement compared to first time replacement. You should consider the possibility of having your implants replaced and its consequences when making your decision to have implants.
• **Unsatisfactory Results** — Unsatisfactory results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, and/or hypertrophic scarring, may occur. Some of these results may cause discomfort. Pre-existing asymmetry may not be entirely correctable by implant surgery. Revision surgery may be recommended to maintain patient satisfaction, but carries additional considerations and risks. Selecting an experienced plastic surgeon may minimize, but not necessarily prevent, unsatisfactory results.

• **Pain** — Pain of varying intensity and length of time may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain. You should tell your surgeon about significant pain or if your pain persists.

• **Changes in Nipple and Breast Sensation** — Feeling in the nipple and breast are typically lost after complete mastectomy where the nipple itself is removed, and can be severely lessened by partial mastectomy. Radiation therapy also can significantly reduce sensation in the remaining portions of the breast or chest wall. The placement of breast implants for reconstruction may further lessen the sensation in the remaining skin or breast tissue. While some of these changes can be temporary, they can also be permanent, and may affect your sexual response or your ability to nurse a baby with the remaining breast.

• **Infection** — Infection can occur with any surgery or implant. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. In addition, breast and nipple piercing procedures may increase the possibility of infection. Infections in tissue with an implant present are harder to treat than infections in tissue without an implant. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved (cleared up). As with many other surgical procedures, in rare instances, toxic shock syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. You should contact your doctor immediately for diagnosis and treatment if you have these symptoms.

• **Hematoma/Seroma** — Hematoma is a collection of blood within the space around the implant, and a seroma is a build-up of fluid around the implant. Having a hematoma and/or seroma following surgery may result in infection and/or capsular contracture later on. Symptoms from a hematoma or seroma may include swelling, pain, and bruising. If a hematoma or seroma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, some will require surgery, typically involving draining and potentially placing a surgical drain in the wound temporarily for proper healing. A small scar can result from surgical draining. Implant rupture also can occur from surgical draining if there is damage to the implant during the draining procedure.

• **Breast Feeding** — Breast feeding difficulties have been reported following breast surgery, including breast reduction and breast augmentation. If your surgeon uses a periareolar surgical approach (an incision around the colored portion surrounding the nipple), it may further increase the chance of breast feeding difficulties in the remaining breast.

• **Calcium Deposits in the Tissue Around the Implant** — Calcium deposits can form in the tissue capsule surrounding the implant. Symptoms may include pain and firmness. Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer. If additional surgery is necessary to examine and/or remove calcifications, this may cause damage to the implants. Calcium deposits also occur in women who undergo breast reduction procedures, in patients who have
had hematoma formation, and even in the breasts of women who have not undergone any breast surgery. The occurrence of calcium deposits increases significantly with age.

- **Extrusion** – Extrusion is when the breast implant comes through your skin. This may occur, for example, when your wound has not closed or when breast tissue covering your implants weakens. Radiation therapy has been reported to increase the likelihood of extrusion. Extrusion requires additional surgery and possible removal of the implant, which may result in additional scarring and/or loss of your breast tissue.

- **Necrosis** – Necrosis is the death of cells or tissues. This may prevent or delay wound healing and require surgical correction, which may result in additional scarring and/or loss of your breast tissue. Implant removal may also be necessary. Factors associated with increased necrosis include infection, use of steroids, smoking, chemotherapy, radiation, and excessive heat or cold therapy.

- **Delayed Wound Healing** – Some patients may experience a prolonged wound healing time. Delayed wound healing may increase the risk of infection, extrusion, and necrosis. Depending on the type of surgery or the incision, wound healing times may vary. Smoking may interfere with the healing process. You should contact your surgeon immediately if your wound does not heal within the period of time he/she has discussed with you.

- **Breast Tissue Atrophy/Chest Wall Deformity** – The pressure of the breast implant may cause breast tissue thinning (with increased implant visibility and palpability) and chest wall deformity. This can occur while implants are still in place or following implant removal without replacement. Either of these conditions may result in additional surgeries and/or unacceptable dimpling/puckering of the breast.

- **Lymphadenopathy** – Lymphadenopathy is a chronic enlargement of the lymph nodes. A lymph node is a round mass of tissue which makes cells as part of your immune system. The lymph nodes in the armpit (axilla) drain the breast area of fluid. Sometimes the enlarged lymph nodes are painful. If they become too large or painful, the lymph node(s) may need to be surgically removed. Painful and/or enlarged lymph nodes should be reported to your doctor. Literature reports associate lymphadenopathy with both intact and ruptured silicone breast implants. One study reported that armpit lymph nodes from women with both intact and ruptured silicone gel implants had abnormal tissue reactions, granulomas, and the presence of silicone.13 These reports were in women who had implants from a variety of manufacturers and implant models.

### Other Reported Conditions

There have been reports in the literature of other conditions in women with silicone gel-filled breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. Although no cause and effect relationship has been established between breast implants and the conditions listed below, you should be aware of these reports. Furthermore, there is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants.

- **Connective Tissue Disease (CTD)** – Connective tissue diseases include diseases such as lupus, scleroderma, and rheumatoid arthritis. Fibromyalgia is a disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue. There have been a number of published epidemiological studies which have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease. The study size needed to conclusively rule out a smaller risk of connective tissue disease among women with silicone gel-filled breast implants would need to
be very large.10,15,16,17,18,19,20,21,22,23 The published studies taken together show that breast implants are not significantly associated with a risk of developing a typical or defined connective tissue disease.10,19,20,21 These studies do not distinguish between women with intact and ruptured implants. Only one study evaluated specific connective tissue disease diagnoses and symptoms in women with silent ruptured versus intact implants, but it was too small to rule out a small risk.16

• **CTD Signs and Symptoms** — Literature reports have also been made associating silicone breast implants with various rheumatological signs and symptoms such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. Scientific expert panels and literature reports have found no evidence of a consistent pattern of signs and symptoms in women with silicone breast implants.10,14,24,25,26 Having these rheumatological signs and symptoms does not necessarily mean you have a connective tissue disease; however, you should be aware that you may experience these signs and symptoms after undergoing breast implantation. If you notice an increase in these signs or symptoms, you should consider seeing a rheumatologist to determine whether these signs or symptoms are due to a connective tissue disorder or autoimmune disease.

• **Cancer**

  - **Breast cancer** — Reports in the medical literature indicate that patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer.27,28,29,30,31 Some reports have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy; however, other reports in the published medical literature indicate that breast implants neither significantly delay breast cancer detection nor adversely affect cancer survival of women with breast implants.31,32,33,34,35 You should discuss this with your surgeon if you are thinking about placing a breast implant in the remaining breast to balance it with the reconstructed breast.

  - **Brain cancer** — One recent study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population.36 The incidence of brain cancer, however, was not significantly increased in women with breast implants when compared to women who had other plastic surgeries. Another recently published review of four large studies in women with cosmetic implants concluded that the evidence does not support an association between brain cancer and breast implants.37

  - **Respiratory/lung cancer** — One study has reported an increased incidence of respiratory/lung cancer in women with breast implants.36 Other studies of women in Sweden and Denmark have found that women who get breast implants are more likely to be current smokers than women who get breast reduction surgery or other types of cosmetic surgery.38,39,40

  - **Cervical/vulvar cancer** — One study has reported an increased incidence of cervical/vulvar cancer in women with breast implants.36 The cause of this increase is unknown.

  - **Other cancers** — One study has reported an increased incidence of stomach cancer and leukemia in women with breast implants compared to the general population.36 This increase was not significant when compared to women who had other types of plastic surgeries.

• **Neurological Disease, Signs, and Symptoms** — Some women with breast implants have complained of neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking or remembering things) or diseases (such as multiple sclerosis), which they believe are related to their implants. A scientific expert panel report found that the evidence for a neurological disease or syndrome caused by or associated with breast implants is insufficient or flawed.10

• **Suicide** — In several studies, a higher incidence of suicide was observed in
women with breast implants. The reason for this increase is unknown, but it was found that women with breast implants had higher rates of hospital admission due to psychiatric causes prior to surgery, as compared with women who had breast reduction or in the general population of Danish women.

- Effects on Children – At this time, it is not known if a small amount of silicone may pass through from the breast implant silicone shell into breast milk. Although there are no current established methods for accurately detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone gel-filled implants when compared to women without implants.

In addition, concerns have been raised regarding potential damaging effects on children born to mothers with implants. Two studies in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery. Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding. This author recommended further research on infant health.

- Potential Health Consequences of Gel Bleed – Small quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse (“bleed”) through an intact implant shell. The evidence is mixed as to whether there are any clinical consequences associated with gel bleed. For instance, studies on implants implanted for a long duration have suggested that such bleed may be a contributing factor in the development of capsular contracture and lymphadenopathy. However, evidence against gel bleed being a significant contributing factor to capsular contracture and other local complications, is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast implants than for saline-filled breast implants. Saline-filled breast implants do not contain silicone gel and, therefore, gel bleed is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in the Mentor implants does not cause toxic reactions when large amounts are administered to test animals. It also should be noted that studies reported in the literature have demonstrated that the low concentration of platinum contained in breast implants is in the zero oxidation (most biocompatible) state. In addition, two separate studies sponsored by Mentor have demonstrated that the low concentration of platinum contained in its breast implants is in the zero oxidation (most biocompatible) state.

Mentor performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact implants into the body. Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence.

MENTOR CORE STUDY RESULTS FOR RECONSTRUCTION
AND REVISION-RECONSTRUCTION

This section of this brochure summarizes the results of the Mentor Core Study conducted on Mentor’s silicone breast implants for primary reconstruction and revision-reconstruction. The Mentor Core Study is the primary clinical study for this product. The results of the Mentor Core Study give you useful information on the experience of other women with Mentor silicone gel-filled implants. While the results cannot be used to predict your individual outcome, they can be used as a rough guide of what you may expect. Your own complications and benefits depend on many individual factors.

As a note, supplemental safety information was also obtained from the Mentor Adjunct Study, the U.K. Sharpe/Collis Study, and the literature to help assess long-
term rupture rate and the consequences of rupture for this product. The literature, which had the most available information on the consequences of rupture, was also used to assess other potential complications associated with silicone gel-filled breast implants. The key literature information is referenced throughout the Breast Implant Complications section above.

Overview of Mentor Core Study
The Mentor Core Study is a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients. Patient follow-up is at 6 months, 12 months, 24 months, and annually through 10 years. Safety is assessed by complications, such as implant rupture, capsular contracture, and reoperation. Benefit (effectiveness) is assessed by patient satisfaction and measures of quality of life (QoL).

The Mentor Core Study consists of 1,007 patients, including 551 primary augmentation patients, 146 revision-augmentation patients, 251 primary reconstruction patients, and 59 revision-reconstruction patients. Of these patients, 202 primary augmentation patients, 57 revision-augmentation patients, 134 primary reconstruction patients, and 27 revision-reconstruction patients are in the MRI cohort, which means that they are assessed for silent rupture by MRI at years 1, 2, 4, 6, 8, and 10. The study is currently ongoing, with the results through 3 years reported in this brochure. Mentor will periodically update this brochure as more information becomes available. You should also ask your surgeon if he/she has any available updated clinical information.

Mentor’s Core study results indicate that the risk of at least one occurrence of any complication (including reoperation) at some point through 3 years after implant surgery is 49% for primary reconstruction patients and 48% for revision-reconstruction patients. The information below provides more details about the complications and benefits you may experience.

Described below are benefits and complications reported in the Mentor Core Study for reconstruction patients. The findings are described separately for primary reconstruction and revision-reconstruction patients.

What Was the 3-Year Follow-Up Rate in Reconstruction Patients?
At the 3-year follow-up visit, data are reported for 82% of the eligible primary reconstruction patients, and 86% of the eligible revision-reconstruction patients.

What Were the Benefits for Reconstruction Patients?
The Mentor Core Study measured a variety of outcomes that assessed the benefits of the implants. For reconstruction, these outcomes included circumferential chest size, satisfaction, and quality of life (QoL) measures. These outcomes were assessed before implantation and at 1, 2, and 3 years after surgery for those patients who still had their original implants and came back for follow-up visits.

- **Primary Reconstruction Patients:** For primary reconstruction patients, 183 (73%) out of the original 251 patients were included in the analysis of circumferential chest size at 3 years. Of these 183 patients, the average increase in circumferential chest size was 1.3 inches.

  Mentor’s satisfaction assessment was based on a single question of “Would the patient have this breast surgery again?” At 3 years, 189 (75%) out of 251 primary reconstruction patients enrolled answered that question. Of these 189 patients, 185 (98%) stated to their surgeon that they would have the breast implant surgery again.

  With regard to QoL measures at 3 years for primary reconstruction patients, a significant improvement in functioning was observed as measured by the Functional Living Index of Cancer. No change was observed on Rosenberg Self Esteem Scale. The Tennessee Self Concept Scale (TSCS) is a survey completed by the patient that evaluates how the patient sees herself and what she does, likes, and feels. There was no change in the overall score for the TSCS. There was no change on the overall score of the Body Esteem Scale. The Sexual
The Attractiveness Subscale of the Body Esteem Scale significantly improved. The SF-36 is a collection of scales assessing mental and physical health. There was no change in any of the 10 SF-36 scales.

**Revision-Reconstruction Patients:** For revision-reconstruction patients, 45 (76%) out of the original 59 patients were included in the analysis of circumferential chest size at 3 years. Of these patients, the average increase in circumferential chest size was 0.9 inches.

Mentor’s patient satisfaction was based on a single question of “Would the patient have this breast surgery again?” At 3 years, 48 (81%) out of 59 revision-reconstruction patients enrolled answered that question. Of these 48 patients, 47 (98%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years for revision-reconstruction patients, no change was observed on the Rosenberg Self Esteem Scale nor on the Tennessee Self Concept Scale. For the Body Esteem Scale, 2 of 6 scales worsened over time, but, after adjusting for the aging effect, none of the changes were significant. The Sexual Attractiveness Subscale of the Body Esteem Scale significantly improved over time. The SF-36 is a collection of scales assessing mental and physical health. Although some of the SF-36 scales showed decreases over time, after adjusting for the aging effect, changes in 7 of 10 SF-36 scales were not statistically significant.

**What Were the 3-Year Complication Rates in Reconstruction Patients?**

The 3-year complication rates are shown from the most common to the least common in Table 1 (reconstruction) and Table 2 (revision-reconstruction) below. The rates reflect the percentage of reconstruction patients who experienced the listed complication at least once within the first 3 years after implantation. Some complications occurred more than once for some patients. The two most common complications experienced by primary reconstruction patients within the first 3 years of implantation were reoperation (27.0%) and capsular contracture Baker Grade III/IV (8.3%).
the two most common complications experienced by patients within the first 3 years of revision-reconstruction surgery were reoperation (29.1%) and capsular contracture Baker Grade III/IV (16.3%). Notice that the rates for capsular contracture are higher than for primary reconstruction. (For primary reconstruction, reoperation was 27.0% and capsular contracture Baker Grade III/IV was 8.3%.)

<table>
<thead>
<tr>
<th>Key Complications</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reoperation</td>
<td>27.0</td>
</tr>
<tr>
<td>Capsular Contracture Baker Grade III/IV</td>
<td>8.3</td>
</tr>
<tr>
<td>Implant Removal with Replacement with Study Device</td>
<td>7.4</td>
</tr>
<tr>
<td>Implant Removal without Replacement</td>
<td>5.7</td>
</tr>
<tr>
<td>Infection</td>
<td>5.7</td>
</tr>
<tr>
<td>Rupture (MRI Cohort)</td>
<td>0.9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other Complications occurring in ≥ 1% of patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ptosis (sagging)</td>
<td>6.9</td>
</tr>
<tr>
<td>Scarring/Hypertrophic Scarring</td>
<td>6.8</td>
</tr>
<tr>
<td>Asymmetry</td>
<td>6.7</td>
</tr>
<tr>
<td>Seroma</td>
<td>4.9</td>
</tr>
<tr>
<td>Breast Mass</td>
<td>3.6</td>
</tr>
<tr>
<td>Nipple Complications</td>
<td>3.3</td>
</tr>
<tr>
<td>Wrinkling</td>
<td>2.6</td>
</tr>
<tr>
<td>Breast Pain</td>
<td>2.2</td>
</tr>
<tr>
<td>Metastatic Disease</td>
<td>1.8</td>
</tr>
<tr>
<td>Implant Malposition</td>
<td>1.7</td>
</tr>
<tr>
<td>Recurrent Breast Cancer</td>
<td>1.7</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1.3</td>
</tr>
<tr>
<td>Extrusion of Intact Implant</td>
<td>1.2</td>
</tr>
<tr>
<td>Breast Sensation Changes</td>
<td>1.0</td>
</tr>
<tr>
<td>Rash</td>
<td>1.0</td>
</tr>
</tbody>
</table>

1 There was 1 patient with signs of rupture by MRI of one of her implants through the 3-year timepoint. This has not been confirmed with removal and visual inspection of the implant.
2 The following complications were reported at a rate less than 1%: deep vein thrombosis, delayed wound healing, lymphadenopathy, miscarriage, muscle spasm, necrosis, new diagnosis of breast cancer, new diagnosis of rheumatic disease (1 patient with fibromyalgia), redness, stitch abscess, tight benillli suture, and trauma to breast due to car accident.
3 Mild occurrences were excluded.
4 The general recurrence rate for breast cancer reported in the medical literature ranges from 5 to 25%. 51,52,53

The two most common complications experienced by patients within the first 3 years of revision-reconstruction surgery were reoperation (29.1%) and capsular contracture Baker Grade III/IV (16.3%). Notice that the rates for capsular contracture are higher than for primary reconstruction. (For primary reconstruction, reoperation was 27.0% and capsular contracture Baker Grade III/IV was 8.3%).
What Were the main reasons for reoperation in augmentation patients?

There may be one or more reasons identified for having a reoperation (additional surgery after the primary or revision breast reconstruction). Furthermore, there may be multiple surgical procedures (for example, implant removal with or without...

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Table 2 – 3-Year Complication Rates for Revision-Reconstruction Patients (N=59 Patients)

<table>
<thead>
<tr>
<th>Key Complications</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reoperation</td>
<td>29.1</td>
</tr>
<tr>
<td>Capsular Contracture Baker Grade III/IV</td>
<td>16.3</td>
</tr>
<tr>
<td>Implant Removal with Replacement with Study Device</td>
<td>8.8</td>
</tr>
<tr>
<td>Implant Removal without Replacement</td>
<td>5.2</td>
</tr>
<tr>
<td>Infection</td>
<td>0</td>
</tr>
<tr>
<td>Rupture (MRI Cohort)</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other Complications occurring in ≥ 1% of patients¹</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymmetry²</td>
<td>8.9</td>
</tr>
<tr>
<td>Implant Malposition²</td>
<td>8.5</td>
</tr>
<tr>
<td>Wrinkling²</td>
<td>7.0</td>
</tr>
<tr>
<td>Breast Mass²</td>
<td>7.0</td>
</tr>
<tr>
<td>Granuloma</td>
<td>5.1</td>
</tr>
<tr>
<td>Scarring/Hypertrophic Scarring²</td>
<td>3.6</td>
</tr>
<tr>
<td>Breast Pain²</td>
<td>3.5</td>
</tr>
<tr>
<td>Hematoma²</td>
<td>3.5</td>
</tr>
<tr>
<td>New Diagnosis of Rheumatic Disease³</td>
<td>3.5</td>
</tr>
<tr>
<td>Ptosis (sagging)²</td>
<td>3.4</td>
</tr>
<tr>
<td>Breast Sensation Changes²</td>
<td>1.9</td>
</tr>
<tr>
<td>Numbness in Both Hands at Night</td>
<td>1.8</td>
</tr>
<tr>
<td>Seroma</td>
<td>1.7</td>
</tr>
<tr>
<td>Nipple Complications²</td>
<td>1.7</td>
</tr>
<tr>
<td>Inflammation</td>
<td>1.7</td>
</tr>
<tr>
<td>Recurrent Breast Cancer⁴</td>
<td>1.7</td>
</tr>
<tr>
<td>New Diagnosis of Breast Cancer</td>
<td>1.7</td>
</tr>
<tr>
<td>Delayed Wound Healing³</td>
<td>1.7</td>
</tr>
<tr>
<td>Trauma⁵</td>
<td>1.7</td>
</tr>
<tr>
<td>Capsule Tear</td>
<td>1.7</td>
</tr>
<tr>
<td>Extrusion of Intact Implant</td>
<td>1.7</td>
</tr>
</tbody>
</table>

¹No complications were reported at a rate of <1%.
²Mild occurrences were excluded.
³These rheumatic diagnoses were fibromyalgia (1 patient) and pyoderma gangrenosum (1 patient).
⁴The general recurrence rate for breast cancer reported in the medical literature ranges from 5 to 25%.⁵,⁶,⁷,⁸,⁹
⁵Trauma to breast from fall.

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What Were the Main Reasons for Reoperation in Augmentation Patients?

There may be one or more reasons identified for having a reoperation (additional surgery after the primary or revision breast reconstruction). Furthermore, there may be multiple surgical procedures (for example, implant removal with or without...
replacement, capsule procedures, incision and drainage, implant reposition, scar revision, etc.) performed during a reoperation. In Mentor’s Core Study, there were 143 additional surgical procedures performed in 79 reoperations involving 66 primary reconstruction patients.

Table 3 below provides the main reason for each reoperation in primary reconstruction patients following initial implantation that were performed through 3 years. The most common reason for reoperation through 3 years was because of asymmetry (16 of 79 reoperations).

**TABLE 3 – MAIN REASONS FOR REOPERATION IN PRIMARY RECONSTRUCTION PATIENTS THROUGH 3 YEARS**

<table>
<thead>
<tr>
<th>Reason for Reoperation</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymmetry</td>
<td>16</td>
</tr>
<tr>
<td>Biopsy</td>
<td>11</td>
</tr>
<tr>
<td>Capsular Contracture Baker Grade II, III, IV</td>
<td>10</td>
</tr>
<tr>
<td>Implant Malposition</td>
<td>9</td>
</tr>
<tr>
<td>Patient Request for Style/Size Change</td>
<td>9</td>
</tr>
<tr>
<td>Infection</td>
<td>4</td>
</tr>
<tr>
<td>Scarring/Hypertrophic Scarring</td>
<td>3</td>
</tr>
<tr>
<td>Ptosis (sagging)</td>
<td>3</td>
</tr>
<tr>
<td>Hematoma/Seroma</td>
<td>3</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>3</td>
</tr>
<tr>
<td>Extrusion of Intact Implant</td>
<td>2</td>
</tr>
<tr>
<td>Nipple Complications (unplanned)</td>
<td>3</td>
</tr>
<tr>
<td>Delayed Wound Healing</td>
<td>1</td>
</tr>
<tr>
<td>Breast Pain</td>
<td>1</td>
</tr>
<tr>
<td>Implant Palpabilit/Visibility</td>
<td>1</td>
</tr>
<tr>
<td>Muscle Spasm</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>79</strong></td>
</tr>
</tbody>
</table>

In Mentor’s Core Study, there were 54 additional surgical procedures performed in 24 reoperations involving 17 revision-reconstruction patients. Table 4 below provides the main reason for each reoperation in revision-reconstruction patients following initial implantation that were performed through 3 years. The most common reason for reoperation through 3 years was because of biopsy (7 of 24 reoperations).
What Were the Reasons for Implant Removal in Reconstruction Patients?
The main reasons for implant removal among primary reconstruction patients in the Mentor Core Study over the 3 years are shown in Table 5 below. There were 41 implants removed in 31 patients. Of these 41 implants, 23 were replaced. The most common reason for implant removal was patient request (15 of the 41 implants removed).

TABLE 5 – MAIN REASONS FOR IMPLANT REMOVAL IN PRIMARY RECONSTRUCTION PATIENTS THROUGH 3 YEARS

<table>
<thead>
<tr>
<th>Reason for Removal</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Request for Style/Size Change</td>
<td>15</td>
</tr>
<tr>
<td>Asymmetry</td>
<td>10</td>
</tr>
<tr>
<td>Capsular Contracture Baker Grade II, III, IV</td>
<td>5</td>
</tr>
<tr>
<td>Implant Malposition</td>
<td>3</td>
</tr>
<tr>
<td>Extrusion of Intact Implant</td>
<td>2</td>
</tr>
<tr>
<td>Infection</td>
<td>2</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1</td>
</tr>
<tr>
<td>Lack of Projection</td>
<td>1</td>
</tr>
<tr>
<td>Muscle Spasm</td>
<td>1</td>
</tr>
<tr>
<td>Recurrent Breast Cancer</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>41</strong></td>
</tr>
</tbody>
</table>

The main reasons for implant removal among revision-reconstruction patients in the Mentor Core Study over the 3 years are shown in Table 6 below. There were 11 implants removed in 8 patients. Of these 11 implants, 7 were replaced. The most common reason for implant removal was patient request (15 of the 41 implants removed).

TABLE 4 — MAIN REASONS FOR REOPERATION IN REVISION-RECONSTRUCTION PATIENTS THROUGH 3 YEARS

<table>
<thead>
<tr>
<th>Reason for Reoperation</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopsy</td>
<td>23</td>
</tr>
<tr>
<td>Capsular Contracture Baker Grade III/IV</td>
<td>7</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
</tr>
<tr>
<td>Implant Malposition</td>
<td>5</td>
</tr>
<tr>
<td>Suspected Rupture</td>
<td>5</td>
</tr>
<tr>
<td>Asymmetry</td>
<td>3</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>2</td>
</tr>
<tr>
<td>Extrusion of Intact Implant</td>
<td>2</td>
</tr>
<tr>
<td>Hematoma/Seroma</td>
<td>1</td>
</tr>
<tr>
<td>Nipple Complications (unplanned)</td>
<td>1</td>
</tr>
<tr>
<td>Patient Request for Style/Size Change</td>
<td>1</td>
</tr>
<tr>
<td>Ptosis (sagging)</td>
<td>1</td>
</tr>
<tr>
<td>Wrinkling</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>58</strong></td>
</tr>
</tbody>
</table>

1Includes 1 follicular cyst palpable nodule, 1 palpable nodule, and 1 pocket tear.
2The device was removed and found to be intact (not ruptured).
common reason for implant removal was capsular contracture Baker Grade III/IV (3 of the 11 implants removed).

### TABLE 6 – MAIN REASONS FOR IMPLANT REMOVAL FOR REVISION-RECONSTRUCTION PATIENTS THROUGH 3 YEARS

<table>
<thead>
<tr>
<th>Reason for Removal</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsular Contracture Baker Grade III/IV</td>
<td>3</td>
</tr>
<tr>
<td>Asymmetry</td>
<td>2</td>
</tr>
<tr>
<td>Patient Request for Style/Size Change</td>
<td>2</td>
</tr>
<tr>
<td>Symmastia</td>
<td>2</td>
</tr>
<tr>
<td>Extrusion of Intact Implants</td>
<td>1</td>
</tr>
<tr>
<td>Pocket Tear</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>11</strong></td>
</tr>
</tbody>
</table>

What Were Other Clinical Data Findings in Reconstruction Patients?
Below is a summary of clinical findings from Mentor’s Core Study with regard to connective tissue disease (CTD); CTD signs and symptoms; cancer; lactation complications, reproduction complications; and suicide. These issues, along with others, are being further evaluated as part of a Mentor post-approval study involving patients followed through 10 years.

- **CTD Diagnoses** – One primary reconstruction patient and two revision-reconstruction patients in the Mentor Core Study were reported to have a new diagnosis of CTD according to a rheumatologist. These diagnoses were two cases of fibromyalgia, both at 1 year, and pyoderma gangrenosum at 1 year. It cannot be concluded that these CTD diagnoses were caused by the implants because there was no comparison group of similar women without implants.

- **CTD Signs and Symptoms** – In Mentor’s Core Study, data on over 100 self-reported signs and symptoms, including 50 self-reported rheumatological symptoms, were collected. Compared to before having the implants, a significant increase was found for joint pain in the primary reconstruction patients, and no significant increases were found for any individual signs and symptoms in the revision-reconstruction patients. The increase in joint pain seen in the primary reconstruction patients was not found to be related to simply getting older. The Mentor Core Study was not designed to evaluate cause and effect associations because there is no comparison group of women without implants, and because other contributing factors, such as medications and lifestyle/exercise, were not studied. Therefore, it cannot be determined whether this increase was due to the implants or not, based on the Mentor Core Study. However, you should be aware that you may experience an increase in these symptoms after receiving breast implants.

- **Cancer** – For primary reconstruction patients, 1 (0.5%) patient had a new diagnosis of breast cancer and 4 (1.7%) patients had a recurrence of breast cancer. For revision-reconstruction, 1 (1.7%) patient had a new diagnosis of breast cancer and 1 (1.7%) patient had a recurrence of breast cancer. There were no reports of other cancers, such as brain, respiratory, or cervical/vulvar.

- **Lactation Complications** – For primary reconstruction patients, of the 3 women who attempted to breastfeed, none experienced lactation difficulties. None of the revision-reconstruction patients attempted to breast feed.

- **Reproduction Complications** – For primary reconstruction patients, 2 (0.9%) patients reported a miscarriage. None of the revision-reconstruction patients suffered a miscarriage.
• Suicide – There were no reports of suicide in either the primary reconstruction or revision-reconstruction indications in Mentor’s Core Study through 3 years.

HOW TO REPORT PROBLEMS WITH YOUR IMPLANT

The Food and Drug Administration (FDA) requires that serious injuries (defined as those that need medical or surgical intervention to prevent permanent damage) be reported by hospitals if they are aware of the serious injuries. If you believe that you have experienced one or more serious problems related to your breast implants, you are encouraged to report the serious problem(s) through your health professional to the FDA. Although reporting by doctors or other health professionals is preferred, women may also report any serious problem directly through FDA’s MedWatch voluntary reporting system. You can report by telephone to 1-800-FDA-1088; by FAX, use Form 3500 to 1-800-FDA-0178; electronically at http://www.fda.gov/medwatch/index.html; or by mail to:

MedWatch Food and Drug Administration
HF-2, 5600 Fishers Lane
Rockville, MD 20857-9787.

Keep a copy of the MedWatch form completed by your doctor for your records. The information reported to MedWatch is entered into databases to be used to follow safety trends (patterns) of a device and to determine whether further follow-up of any potential safety issues related to the device is needed.
MENTOR —
A COMPANY THAT CARES

Founded in 1969, Mentor is a leading supplier of medical products in over 60 countries throughout the world. With over 20 years of experience making breast implants, our exceptional record of quality and longevity has gained us a tremendous level of respect in the medical community.

Mentor breast implants are made at our U.S. based state-of-the-art manufacturing plant in Dallas, Texas. This advanced manufacturing facility features many groundbreaking engineering advances that are new to the breast implant industry.

Mentor conducts research, development and manufacturing at several facilities throughout Europe and the United States. The company also has sales and distribution outlets around the world.

Mentor is proud of the quality built into each of our breast implants, and you can be assured that behind your decision to use our products is a company that understands your hopes and desires, and a company that truly cares.
49 Flassbeck, D.B., et al. 2003. Determination of siloxanes, silicon, and platinum in tissues of women with silicone gel-filled implants. 375(3):356-62 (for example, data from Patients B & C).
The purpose of this brochure is to help you in making an informed decision about having breast implants for reconstruction (restoration) or breast revision-reconstruction (replacement) surgery. This brochure is not intended to replace consultation with your surgeon.