Information for the Patient

Breast Augmentation with Motiva Implants® SmoothSilk® Round Ergonomix® and SmoothSilk® Round Silicone Gel-Filled Breast Implants

The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Motiva USA and Establishment Labs. Federal (USA) law restricts this device to sale by, or on the order of a physician.

WARNING:

- Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery.
- Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.
- Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

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Glossary	
Abdomen	Part of the body between the upper chest (breasts) and the pelvis (hips); often called the stomach.
Areola	Pigmented or darker colored area of the skin surrounding the nipple.
Asymmetry	Uneven appearance between the left and right breasts in terms of size, shape, or breast level.
Atrophy	Thinning or diminishing of tissue or muscle.
Autoimmune Disease	An autoimmune disease is a disease in which the body's immune system attacks its own cells or tissues by mistake, causing damage and dysfunction. Autoimmune diseases can affect connective tissue in the body (the tissue that binds together body tissues and organs). Autoimmune diseases can affect many parts of the body, like nerves, muscles, glands, and the digestive system.
Axillary	Related to the armpit area.
Bilateral	Relating to both the left and right side.
Biocompatible	Ability to exist along with living tissues or systems without causing harm.
Biopsy	Removal and examination of tissue from the body.
Body Dysmorphic Disorder	A psychological condition characterized by excessive worry about an imagined or minor physical flaw to the point that it can interfere with normal daily activities.
Body Esteem Scale	A series of questions asking about a person's feelings about his or her body.
Breast Augmentation	Surgical procedure to increase breast size and to treat such conditions as sagging or drooping of the breast (ptosis) or breast of different size, shape, or placement (asymmetry); the first time a breast implant is placed to increase breast size or treat such conditions as ptosis or asymmetry, it is referred to as "primary augmentation." Any time there is another surgery to replace the implant, it is referred to as "revision-augmentation."
Breast Implant	Any surgically implanted artificial device intended to replace missing breast tissue or to enhance a breast.
Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL)	A rare type of non-Hodgkin's lymphoma (cancer of the immune system); BIA-ALCL is not breast cancer.

Breast Mass	A lump in the breast.
Breast Reconstruction	Surgical procedure to replace breast tissue or reconstruct a breast after tissue was taken out because of cancer or injury; breast reconstruction also includes the surgical correction of a breast that has failed to develop properly due to a severe abnormality or congenital defect. The first time a breast implant is placed to replace breast tissue is referred to as "primary reconstruction." Any time there is another surgery to replace the implant, it is referred to as "revision-reconstruction".
Calcification/Calcium Deposits	The process of a soft tissue hardening when the mineral calcium builds up in a certain place.
Capsular Contracture	The tightening of the scar tissue (also called a capsule) that normally forms around the breast implant during the healing process after surgery; in some women, the scar tissue (capsule) squeezes the implant. When this occurs, it is called capsular contracture. This results in firmness or hardening of the breast. Capsular contracture is classified by a scale named Baker Grade.
Capsule	The scar tissue that forms around the breast implant.
Capsulotomy (Closed)	An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast; this method does not require surgery but may rupture the implant and is contraindicated and should not be performed.
Capsulotomy (Open)	A surgery to create an incision or opening in the capsule (scar tissue).
Chest Wall	The system of structures outside the lungs that move as a part of breathing, including bones (the rib cage) and muscles (diaphragm and abdomen).
Congenital Anomaly	An abnormal body part that existed at birth, also called a congenital malformation or congenital deformity.
Connective Tissue Disease/Disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system; connective tissue diseases ("CTDs") that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.
Contraindication	A use that is improper and should not be followed; failure to follow contraindications identified in the labeling could cause serious harm.
Delayed Wound Healing	Unusually slow progress in the healing of a wound; surgical incision site fails to heal normally or takes longer to heal.
Displacement	Movement of the implant from the usual or proper place.
Dual Plane Placement	Placement partly underneath the chest muscle and partly underneath the breast tissue.

Extrusion	Skin breakdown with the implant pressing through the skin or surgical incision.
Fibrocystic Breast Disease	Common, benign (noncancerous) changes in the tissues of the breast; the term "disease" is misleading, and many doctors prefer the term "change." The condition is so commonly found in breasts that it is believed to be a variation of normal. Other related terms include "mammary dysplasia," "benign breast disease," and "diffuse cystic mastopathy."
Fibromyalgia	A chronic condition characterized by widespread pain in muscles and joints that may include fatigue, difficulty sleeping, and morning stiffness.
Fibrous Tissues	Connective tissue composed mostly of fibers (for example, tendons).
Gel Bleed/Gel Diffusion	When silicone gel leaks or "bleeds" or "diffuses" through the implant shell.
Granuloma	Noncancerous lumps that can form around foreign material, such as silicone; like any lump, it should be evaluated to distinguish it from a lump that might be cancerous.
Groin	The fold where the lower abdomen meets the inner part of the thigh.
Hematoma	A collection of blood inside the body, for example in skin tissue, breast, or other areas.
Hypertrophic Scarring	An enlarged scar that remains after a wound heals.
Infection	The growth in the human body of microorganisms such as bacteria, viruses, or fungi; an infection can occur as a result of any surgery.
Inflammation/ Irritation	The response of the body to infection or injury resulting in swelling, redness, warmth and/or pain.
Inframammary Fold	Incision made in the fold below the breast.
Lactation	The production and secretion of milk by the breast glands.
Local Complications	Complications that occur in the breast or chest area.
Lymph Nodes	Lymph nodes are glands that play an important part in the body's defense against infection. They produce lymph, which travels throughout the body in the lymph system, and filters impurities from the body. Common areas where the lymph nodes can be felt with the fingers include: groin, armpit, neck, under the jaw and chin, behind the ears, and on the back of the head.
Lymphadenopathy	Enlarged lymph node(s).

Malposition	When the implant is placed incorrectly during the initial surgery or when the implant has moved/shifted from its original position; shifting can be caused by many factors, such as gravity, trauma, poor initial placement, and capsular contracture.
Mammary	Pertaining to the breast.
Mammography	A type of x-ray examination of the breasts used for detection of cancer.
Mammoplasty	Plastic surgery of the breast.
Mastitis	Inflammation or infection of the breast, usually associated with breastfeeding.
Mastopexy	Surgical procedure to raise and reshape sagging breasts.
Migration/Gel Migration	Movement of silicone material outside the breast implant to other areas of the body.
Motiva Implants® CORE Clinical Study	The clinical study that supports the approval of a medical product (such as breast implants); for Motiva breast implants, the CORE Study includes primary augmentation and revision augmentation patients. Information on the safety and effectiveness of the implants are collected every year for 10 years after study participants get their implants.
MRI (Magnetic Resonance Imaging)	A radiographic technology that uses a magnetic field to create a 3-dimensional picture of a body part or organ; this imaging method currently has the best ability to detect rupture of silicone gel breast implants.
Necrosis	Death of cells or tissues.
Palpability/Visibility	Palpability is when the implant can be felt through the skin; visibility is when the implant can be seen through the skin.
Patch Assembly	Silicone component located on the posterior side of the breast implant used to seal the implant shell.
Pectoralis	Major muscle of the chest.
Periareolar	The areola is the pigmented or darker colored area of skin surrounding the nipple. Periareolar refers to the area just around the areola.
Periumbilical	Around the belly button.
Plastic Surgery	Surgery intended to enhance or improve the appearance of the body.
Platinum	A metallic element used to help make both silicone elastomer (the rubbery material of the breast implant shell) and silicone gel.

Postoperative	After surgery.
Precautions	Information that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
Prosthesis	Any artificial device used to replace or represent a body part.
Ptosis	Sagging or drooping of the breast.
Redness/Bruising	Bleeding at the surgical site causes discoloration and varies in degree and length of time. This is expected following breast implant surgery or other breast procedures.
Removal	Removal of the implant, with or without replacement using another implant.
Reoperation	Any additional surgery performed to the breast or chest area after the first breast implantation.
Risks	The chance or likelihood that an undesirable effect will occur.
Rosenberg Self-Esteem Scale	A questionnaire that measures overall self-esteem.
Rupture	A hole or tear in the shell of the implant that allows silicone gel filler material to leak from the shell.
Saline	Salt water (solution made of water and a small amount of salt).
Scar Revision	A surgical procedure to improve the appearance of a scar.
Scarring	Formation of tissue at an incision site; all wounds heal by the formation of a scar.
Seroma	Similar to a bruise, a seroma occurs when the watery portion of the blood collects around a surgical incision or around a breast implant.
SF-36 Scale	Thirty-six item survey that examines eight health concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions.
Silent Rupture	A breast implant rupture without symptoms or a visible change; silent rupture cannot be felt by the woman or detected by a doctor through physical examination. Silent rupture can only be discovered through appropriate imaging techniques such as MRI.

Silicone	Silicone is a man-made material that can be found in several forms such as oil, gel, or rubber (elastomer). The exact make-up of silicone will be different depending on its use.
Silicone Elastomer	A type of silicone that has elastic properties similar to rubber.
Silicones - Low Molecular Weight ("Low Molecular Weight (LMW) Silicones")	Small silicone molecules that may be present in gel bleed/gel diffusion.
Squamous Cell Carcinoma (SCC)	There have been rare, reported cases of SCC (a cancer) located in the capsule or scar tissue around breast implants.
Subfascial Placement	Placement above the chest muscle and underneath the chest muscle fascia (connective tissue).
Subglandular Placement	When the implant is placed under and within the breast glands (breast tissue) but on top of the chest muscles.
Submuscular Placement	When the implant is placed underneath the chest muscles.
Surgical Incision	A cut made to body tissue during surgery.
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Symptomatic	Experiencing symptoms; any evidence or sign of disease or disorder.
Symptomatic Rupture	A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape).
Systemic	Pertaining to or affecting the body as a whole.
Toxic Shock Syndrome (TSS)	A rare, but life-threatening bacterial infection that may occur after surgery; symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment if TSS is suspected.
Transaxillary	Placement of the incision for the breast implant in the armpit.
Warnings	A statement that alerts the reader about a situation which, if not avoided, could result in serious injury or death.
Wrinkling/Rippling	Wrinkling of the implant that can be felt or seen through the skin.

INFORMATION FOR THE PATIENT: BREAST AUGMENTATION WITH MOTIVA IMPLANTS® SILICONE GEL BREAST IMPLANTS

1. HOW TO USE THIS EDUCATIONAL BROCHURE

Motiva USA, the company that sells Motiva Round and Round Ergonomix Breast Implants, has designed this educational brochure to help you understand breast augmentation and talk with your doctor(s) about breast augmentation. A "Patient Decision Checklist", which highlights key information regarding risks of breast implant surgery, is provided in Section 28 of this brochure, located at the Motiva® webpage (www.motivausa.com), and also discussed further below. You should also be aware that there is a Boxed Warning for all breast implants. It is critical for you to understand these warnings. The Boxed Warning is located in Section 9 Boxed Warnings of this brochure. Additional information regarding the risks listed in the Boxed Warning and other risks are discussed below in Section 11 Risks of Breast Surgery with Silicone Gel Implants.

Motiva USA sponsored a large clinical study of Motiva Implants® (the CORE Study; also referred to in this brochure as the "Study") that gathered data about these breast implants. The Study collected data from the primary augmentation and revision augmentation cohorts (groups). There are 560 patients participating in the Study. A total of 451 patients had primary augmentation and 109 patients had revision augmentation. The results from the Study are presented in Section 18 Clinical Study Results.

After you receive this information, give yourself time to read and think about the information. Because breast implants will require monitoring and care for the rest of your life, you should wait 1-2 weeks after reviewing and considering this information before deciding whether to have the surgery. If you are having revision-augmentation surgery, your surgeon may advise you to have the surgery sooner.

If you decide to have the surgery, you will be asked to review and sign a Patient Decision Checklist (See Section 28) before the surgery. This document will be part of your patient medical file. It is important that you read and understand this checklist as it highlights key information regarding risks and complications of receiving silicone gel filled breast implants, including:

- Situations in which the device should not be used or implanted;
- Considerations for a successful breast implant candidate;
- Risks of undergoing breast implant surgery;
- Importance of appropriate physician education, training and experience;
- Risk of breast implant associated-anaplastic large cell lymphoma (BIA-ALCL);
- Risk of systemic symptoms; and
- Discussion of options other than breast implants, as appropriate.

Make sure all of your questions have been answered and you understand the information in this brochure.

2. OVERVIEW

The information in this section provides general information about breast augmentation with breast implants.

2.1 What gives the breast its shape?

As shown in Figure 1, your breast consists of milk ducts, glands, blood vessels, and nerves that are surrounded by fatty tissue. Glandular tissue is firm and gives the breast its shape. The fatty tissue gives the breast its soft feel. The chest muscle (the pectoralis major muscle) is located underneath all this breast tissue but does not have much effect on the shape or feel of the breast.

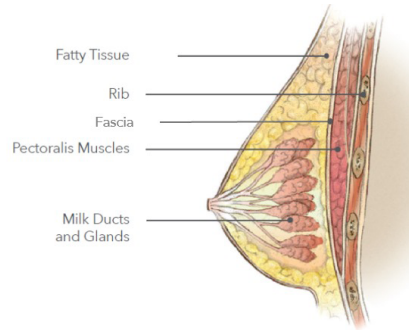


Figure 1. Anatomy of the Breast

2.2 What is a silicone gel breast implant?

A silicone gel breast implant is a sac (implant shell) made of silicone elastomer (rubber), which is filled with clear silicone gel. Information on the materials in Motiva Implants® is presented in Section 5 Components of Motiva Silicone Breast Implants.

2.3 How do breast implants work in breast augmentation?

Breast implants are used to make the breasts larger. They may be surgically implanted beneath your breast tissue in different locations, such as:

- Subglandular placement – on top of the chest muscle
- Submuscular placement – underneath the chest muscle
- Dual plane placement – partly underneath the chest muscle and partly underneath the breast tissue.
- Sub-fascial placement – above the chest muscle and underneath the chest muscle fascia (connective tissue)

3. DECIDING WHETHER TO HAVE BREAST AUGMENTATION SURGERY WITH IMPLANTS

The information in this section will help you to decide whether breast augmentation surgery with implants is right for you.

3.1 Am I eligible for augmentation with silicone gel breast implants?

Breast implants have been approved for use in augmentation in:

i. Primary Augmentation to increase the size of the breast in women at least 22 years old
ii. Revision Augmentation to correct or improve the result of a primary augmentation. Revision augmentation includes replacing an existing implant.

- Alternative treatments are available for the above conditions, including external breast prostheses or padding, or the transfer of other body tissues to enlarge breast size. For details on alternative treatments, please see Section 10. The decision to have breast implants is a personal choice that has both benefits and risks. The information provided in this document is intended to give you information about the benefits and risks of surgery using silicone gel breast implants to help you make an informed decision about your breast augmentation (primary or revision) surgery. You should decide whether it is a right choice for you after discussing all the options with your plastic surgeon and any other doctors who are treating you.

- Motiva Implants® breast implants are available in a round shape, and come in two different gel types and several sizes and projections. Motiva Implants also have the option of a microtransponder, (RFID), in your breast implants which provide device identification information. Your surgeon should talk to you about the different possible outcomes based on your physical characteristics and personal expectations.

- When choosing breast augmentation with implants, you should be aware that you may require additional procedures and further consultations with your surgeon. Breast implants are not lifetime devices and are subject to wear and tear like any other implantable device. Your implants may have to be removed or replaced, which may imply revision surgery. Many of the changes to your breasts following implantation are irreversible (cannot be undone). If you choose to have your implants removed and not replaced, you may experience unsatisfactory aesthetic results, which can be permanent.

- When you have your implants replaced (revision augmentation), your risk of future complications increases compared to that associated with first-time augmentation surgery. For example, the risk of capsular contracture is higher for augmentation patients with implant replacement compared to the first-time implantations.

The styles and characteristics of Round and Round Ergonomix® implants are shown in Table 1.

Table 1. The Motiva Implant Matrix

Motiva Implant Matrix			
Style	**Volume**	**Base Width**	**Projection**
Round			
Mini	245cc - 400cc	11.5cm - 13.5cm	2.8cm - 3.2cm
Demi	205cc - 525cc	10.0cm - 14.0cm	3.5cm – 4.5cm
Full	255cc - 625cc	10.25cm - 14.0cm	4.2cm – 5.7cm
Round Ergonomix			
Mini	150cc - 475cc	9.75cm - 14.5cm	2.4cm – 3.4cm
Demi	155cc - 575cc	9.0cm - 14.5cm	3.3cm – 4.6cm
Full	255cc – 625cc	10.25cm - 14.0cm	4.2cm – 5.7cm
Projection Styles	Low (Mini or 'M'), Moderate (Demi or 'D'), High (Full or 'F')		

A passive radio frequency identification device (referred to as RFID, microtransponder, or Qid) that is placed in the Gel at the Shell/Patch area is an optional feature for all implant styles. This microtransponder provides each implant with a unique electronic serial number for device identification. The RFID is embedded inside the gel, located near the Implant patch system and is 9 mm in length and 2 mm in diameter.

4. INDICATION FOR USE

Motiva Round and Round Ergonomix breast implants are indicated for breast augmentation for women of at least 22 years old. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of an original primary breast augmentation surgery (i.e., revision-augmentation).

5. COMPONENTS OF MOTIVA SILICONE BREAST IMPLANTS

Information on the materials to which you can be exposed is detailed in Table 2 below.

Table 2. Motiva Implants® Materials to Which You Can be Exposed

Component	Material
Shell: Standard Layers	Standard Silicone Elastomer Dispersion based on a mix of dimethyl and diphenyl
Shell: Barrier Layer	Barrier Silicone Elastomer Dispersion based on a mix of dimethyl and diphenyl
Shell: Barrier Layer Pigment	Biocompatible blue pigment dispersed in silicone polymer
Patch Assembly	Standard silicone elastomer plus uncatalyzed, vinyl-functional, high consistency silicone elastomer
Filling Gel	Silicone gel: Base and crosslinker; platinum-cured siloxane polymer
Microtransponder*	Copper polystermide estersol 180 wire, nickel-zinc ferrite core, Photobond 4442 acrylate adhesive, 4305 Application Specific Integrated Circuit (ASIC), and soda-lime silicate glass

**Optional feature*

The potential toxicity of the chemicals and metals listed in Tables 3 and 4 below have been evaluated with toxicity testing and risk assessments to evaluate the exposure levels compared to the amount determined to likely be safe. However, individual responses to substances may vary, and all reactions cannot be predicted.

Table 3. Heavy Metals Found in Motiva Implants®

	Motiva® SmoothSilk® Round Ergonomix® Breast Implants		Motiva® SmoothSilk® Round Breast Implants	
Element	**Shell Concentration (µg/g)**	**Gel Concentration (µg/g)**	**Shell Concentration (µg/g)**	**Gel Concentration (µg/g)**
Beryllium	<0.5	<0.5	<0.5	<0.5
Magnesium	<0.5	<0.5	<0.5	<0.5
Titanium	<0.5	<0.5	<0.5	<0.5
Vanadium	<0.5	<0.5	<0.5	<0.5
Chromium	<0.5	<0.5	0.9	<0.5
Cobalt	<0.5	<0.5	<0.5	<0.5
Nickel	<0.5	<0.5	0.6	<0.5
Copper	1.1	<0.5	0.8	<0.5
Zinc	<0.5	<0.5	<0.5	<0.5
Arsenic	<0.5	<0.5	<0.5	<0.5
Selenium	<0.5	<0.5	<0.5	<0.5
Molybdenum	<0.5	<0.5	<0.5	<0.5
Silver	<0.5	<0.5	<0.5	<0.5
Cadmium	<0.5	<0.5	<0.5	<0.5
Tin	<0.5	<0.5	<0.5	<0.5
Antimony	<0.5	<0.5	<0.5	<0.5
Barium	<0.5	<0.5	<0.5	<0.5
Platinum	4.6	3.0	4.3	3.0
Mercury	<0.5	<0.5	<0.5	<0.5
Lead	<0.5	<0.5	<0.5	<0.5

**Limit of detection for all compounds = 0.5 µg/g*
µg/g, microgram/gram of implant material

Table 4. Chemicals That Might be Released by Motiva Implants®

	Motiva® SmoothSilk® Round Ergonomix® Breast Implants			Motiva® SmoothSilk® Round Breast Implants		
Cyclic Siloxane	**Total Concentration (µg/g)**	**Shell and Patch (µg/g)**	**Gel and Qid (µg/g)**	**Total Concentration (µg/g)**	**Shell and Patch (µg/g)**	**Gel and Qid (µg/g)**
D3	ND	ND	ND	ND	ND	ND
D4	0.37	ND	0.37	0.32	ND	0.32
D5	0.96	0.74	0.22	1.11	0.61	0.50
D6	2.65	1.57	1.08	4.30	0.98	3.32
D7	2.19	1.37	0.82	9.39	7.15	2.24
D8	3.96	3.73	0.22	43.86	43.48	0.39
D9	15.76	15.46	0.30	17.56	17.33	0.23
D10	44.84	44.13	0.71	48.44	48.02	0.41
D11	100.30	99.07	1.23	100.10	99.30	0.81
D12	1037.19	1035.29	1.90	144.47	142.88	1.59
D13	235.71	232.40	3.31	202.03	198.38	3.65
D14	275.50	269.55	5.94	247.29	237.74	9.55
D15	305.85	296.55	9.30	269.40	255.98	13.42
D16	326.56	312.29	14.27	287.59	267.14	20.45
D17	355.74	335.38	20.36	287.63	259.29	28.34
D18	1145.67	1102.79	42.88	806.93	770.38	36.54
D19	630.42	590.78	39.64	494.92	447.32	47.60
D20	1311.49	1277.19	34.30	192.12	147.59	44.53
Total cyclic siloxanes	5795	5618	177	3157	2944	214

ND, not detected; µg/g, microgram/gram of implant material

Volatiles
The Shell was tested for volatile using Gas Chromatography/Mass Spectrometry (GC/MS). Isopropyl alcohol, Trimethyl silanol, Xylene (m or p), 2,2-dimethylpropanoic acid, 2-ethyl-hexanol, D5, and D6 were detected in the Round Ergonomix shells. Trimethyl silanol, Xylene (m or p), dimethylpropanoic acid, D5, D6, and D8 were detected in the Round shells. All volatile compounds were at concentrations below 1 µg/g test article; a toxicological risk assessment determined that the concentrations of all volatile compounds were below the threshold of toxicological concern. No other volatile compounds were detected.

Gel Bleed Testing
Intact implants were extracted in bovine serum albumin to model the natural condition of the breast implant. The test methods described in FDA Guidance, Saline, Silicone Gel, and Alternative Breast Implants, Guidance for Industry and Food and Drug Administration Staff, September, 2020, ASTM F703-18 [1], and ISO 14607:2018 were used to measure the gel bleed of Round and Round Ergonomix® implants by measuring concentration of low molecular weight siloxanes and platinum at 1 hour, and every 10 days out to 70 days. At each time point, no cyclic/linear siloxanes were detected above the detection limit (LOD) of 0.6 µg/test article for Round and 0.9 – 2.0 µg/test article for Round Ergonomix; similarly, the platinum concentration measured in the serum extract was below the limit of detection of 0.0001 µg/test article for both implants.

Most of these chemicals stay inside the shell of the implant but small quantities have been found to diffuse (migrate) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking.

6. CONTRAINDICATIONS

A contraindication is a medical condition that, if present, means a procedure should not be performed. Breast implant surgery is contraindicated in women

A. With active infections anywhere in their body,
B. With existing cancer or precancerous conditions who have not received adequate treatment for those conditions, or
C. Who are currently pregnant or nursing.

Surgery in general is not recommended in patients with an active infection, existing cancer, or pre-cancer and existing pregnancy (unless the surgery is to treat the infection, cancer or pregnancy as recommended by your doctor), as it may interfere with the treatment of the infection or the cancer and safety of the pregnancy/nursing. In addition, these conditions may interfere with the healing after surgery.

Adequate studies have not been performed to demonstrate the safety of breast implant surgery in women with these conditions or under these circumstances; therefore, if you have any of the above conditions or circumstances, breast augmentation surgery with implants should not be performed at this time. Failure to take into consideration these contraindications may increase the risks involved with the surgery and could cause harm.

7. PRECAUTIONS

The safety and effectiveness of this device have not been established in patients with:

i. An autoimmune disease (for example, rheumatoid arthritis, systemic lupus erythematosus, discoid lupus, scleroderma),
ii. A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease),
iii. Conditions that interfere with wound healing and/or blood clotting,
iv. Reduced blood supply to breast tissue,
v. Chemotherapy or radiation therapy to the breast following implantation, and

vi. Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. If you have been diagnosed with or treated for depression, an anxiety disorder, or another mental health condition, you should wait until your condition has resolved or stabilized before having breast implant surgery. Discuss any history of mental health disorders with your doctor(s) prior to surgery.

Before you have surgery, you should have a detailed conversation with all of your doctors (general practitioner, any surgeons, and any specialists you see) about breast implant surgery in consideration of your medical history.

CAUTION: In order to avoid possible injury or damage to your incision site(s), you should avoid the following for the first month after your surgery:

vii. Direct sun exposure,
viii. Busy, abrupt movements or activities that stretch the skin at your incision site(s),
ix. Participating in sports or other activities that increase your heartrate or blood pressure, and
x. Extra physical or emotional stress.

Motiva USA has not tested the in vivo effects of radiation therapy in patients who have breast implants. Scientific literature suggests that radiation therapy may increase the likelihood of breast implant complications, such as capsular contracture, necrosis, and implant extrusion.

8. WARNINGS

There is a boxed warning on all breast implants (See Section 9).

Read this entire brochure before having breast implant surgery so that you will understand the risks and benefits and have realistic expectations of the outcome of your surgery. Breast implants are associated with many short-term and long-term risks. Additional information regarding other warnings you should be aware of and understand before deciding to have augmentation with breast implants are provided below and in Section 9 Boxed Warning.

WARNING – The following is a list of possible complications associated with breast implant surgery. Make sure you read and understand these before deciding whether to have breast implant surgery. Please refer to the following sections in this document for more detail on these factors: Section 11 Risks of Breast Surgery with Silicone Gel Implants, Section 17 Post-operative Care, and Section 18 Motiva Implants® Core Clinical Study Results.

i. Breast implants are not expected to last for the rest of your life, and breast implantation may not be a one-time surgery. It is likely that you will need other surgery related to your breast implants over the course of your life. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures.
ii. Many of the changes to your breast that may occur as a result of breast implant surgery will be permanent and cannot be undone. If you have your implants removed, your skin may be permanently dimpled, puckered, or wrinkled.
iii. Breast implants may interfere with your ability to produce milk (lactate) for breast feeding. If you are planning to breast feed your infant, be prepared to use formula and bottle-feed your baby in the event you have difficulty breast feeding.
iv. Mammography for detecting breast cancer (or cancer recurrence) may be more difficult with breast implants in place. You will need more views captured than during a routine mammogram. Therefore, the procedure will take more time and you will be exposed to more radiation than during a standard routine screening mammogram. However, the benefits of mammograms outweigh this risk. You must tell the technologist that you have silicone gel breast implants before the procedure. The technologist can then use special techniques to get the best possible views of your breast tissue. Under mammography, the optional RFID within the Motiva Implants is not visible and produces no artifact, allowing for visualization and screening of all visualized breast tissues.
v. Your implants could rupture without you feeling the rupture or noticing any change in your breasts. In some of these instances even your

doctor might not be able to tell that a rupture has occurred. A rupture that has no symptoms is called a "silent" rupture. Because silent ruptures can occur and because they are difficult to detect, it is recommended that you have periodic imaging (e.g., MRI, ultrasound) of your silicone gel-filled breast implants to screen for implant rupture.

vi. These recommendations do not replace other additional imaging that may be required depending on your medical history or circumstances (i.e., screening mammography for breast cancer).

vii. Even if you have no symptoms, you should have your first ultrasound or MRI at 5-6 years after your initial breast implant surgery and then every 2-3 years thereafter for as long as you have your breast implants. If you have symptoms at any time or uncertain ultrasound results for breast implant rupture, an MRI is recommended. The RFID that is placed in the gel is an optional feature for all implant styles. This microtransponder provides each device with a unique electronic serial number for device identification purposes. Implants with RFID are MR Conditional. During MRI, a small susceptibility artifact can be observed around the RFID, see Section 19 Interference with Magnetic Resonance Imaging (MRI), for additional information.

viii. Routine self-examination of your breasts may be more difficult with implants. However, you should still perform an examination of your breasts every month for cancer screening. 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, swelling, hardening, or change in implant shape, which may be signs of rupture of the implant. Report any of these symptoms or persistent pain to your doctor. Your surgeon may recommend an evaluation via MRI to check for rupture.

ix. After undergoing breast augmentation surgery, you may experience changes in your healthcare insurance. Your health insurance premiums may increase; your coverage may be dropped or discontinued; you may not be able to get health insurance coverage in the future; and/or insurance may not cover treatment of complications associated with your breast implants. Be sure to check with your insurance company about these potential issues and understand the complete extent of your health coverage before having breast augmentation with implants.

x. A closed capsulotomy, external pressure on the capsule to break up the tissue capsule is contraindicated (should not be performed), because it can cause implant rupture, bleeding, and pain.

9. BOXED WARNING

WARNING:

- Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery.
- Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.
- Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

10. WHAT ARE ALTERNATIVES TO IMPLANTATION WITH SILICONE GEL-FILLED BREAST IMPLANTS?

If this is your first (primary) breast augmentation surgery, there are other options for you to consider:

- Electing to not have surgery,
- Wearing a padded bra or external shaping (prosthesis),
- Having a breast lift surgery (mastopexy) without implant(s),

- Having breast augmentation with saline-filled implants, or
- Using your own tissue

If you are considering a revision surgery, your alternatives may include:
- Not undergoing a revision surgery,
- Removing your implants without replacing them,
- Wearing a padded bra or external shaping (prosthesis),
- Having your revision breast surgery with saline-filled implants, or
- Using your own tissue

11. RISKS OF BREAST IMPLANTS SURGERY WITH SILICONE GEL IMPLANTS

Motiva Implants® share the same intended use and mechanism of action as other similar breast implants available in the market.

Breast implants are not lifetime devices, and there is a possibility that you will undergo implant removal(s), with or without replacement, throughout your lifetime. The longer you have your implants, the more likely it will be for you to have them removed or replaced, and the more likely you are to experience local complications (complications caused by or associated with breast implants) and adverse outcomes (any unwanted medical occurrence). The most common local complications and adverse outcomes are capsular contractures, reoperation, and rupture. Other complications include wrinkling, asymmetry, scarring, pain, and infection. You should assume that you will likely need to have additional surgeries (reoperations) in the future. Many of the changes to your breast(s) following implantation may be cosmetically undesirable and irreversible. For example, if you have your implants removed but not replaced, you may experience changes to your natural breasts such as dimpling, puckering, wrinkling, breast tissue loss, appearance that the breast is empty or deflated, or other undesirable cosmetic changes. If you have breast implants, you will need to monitor your breasts for the rest of your life. If you notice any abnormal changes in your breasts, you will need to see a doctor promptly. If you have silicone gel-filled breast implants, you will need to undergo periodic MRI examinations or ultrasounds to detect implant ruptures that do not cause symptoms ("silent ruptures").

Tables 5 and 6 present the potential risks associated with primary augmentation and revision augmentation breast implant surgery and the likelihood of the risks based on the results from Motiva Implants® CORE Clinical Study through 3 years.

Table 5. Potential Risks Associated with Primary Breast Augmentation

Event	Likelihood of the Event Occurring*	Possible Effects of the Event
Any Complication including Reoperation	6 of 100 (6%)	• Infection • Scarring • Hematoma or seroma • Delayed wound healing • Necrosis • Pain or discomfort • Anesthesia related complications • Loss of breast tissue • Undesirable cosmetic results

Implant Removal with Replacement	1 of 100 (1%)	• Infection • Scarring • Hematoma or seroma • Delayed wound healing • Necrosis • Pain or discomfort • Anesthesia related complications • Loss of breast tissue • Undesirable cosmetic results
Implant Removal without Replacement	1 of 100 (1%)	• Infection • Scarring • Hematoma or seroma • Delayed wound healing • Necrosis • Pain or discomfort • Anesthesia related complications • Loss of breast tissue • Undesirable cosmetic results
Capsular Contracture (Baker Grade III/IV)	1 of 100 (1%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal • Undesirable cosmetic results
Implant Rupture (confirmed and suspected)	1 of 100 (1%)	• Implant removal • Reoperation
Infection	<1 of 100 (0.9%)	• Swelling • Pain or tenderness • Redness • Fever • Implant removal • Reoperation
Other Risks occurring in 1% or more of patients		
Implant Malposition	3 of 100 (3%)	• Implant visibility • Asymmetry • Reoperation • Implant removal • Undesirable cosmetic results

**Based on the results of the Motiva Implants® Core Clinical Study within the first 3 years after implant surgery*

Table 6. Potential Risks Associated with Revision Augmentation

Event	Likelihood of the Event Occurring*	Possible Effects of the Event
Any Complication including Reoperation	28 of 100 (28%)	• Infection • Scarring • Hematoma or seroma • Delayed wound healing • Necrosis • Pain or discomfort • Anesthesia related complications • Loss of breast tissue • Undesirable cosmetic results
Implant Removal with Replacement	14 of 100 (14%)	• Infection • Scarring • Hematoma or seroma • Delayed wound healing • Necrosis • Pain or discomfort • Anesthesia related complications • Loss of breast tissue • Undesirable cosmetic results
Implant Removal without Replacement	3 of 100 (3%)	• Infection • Scarring • Hematoma or seroma • Delayed wound healing • Necrosis • Pain or discomfort • Anesthesia related complications • Loss of breast tissue • Undesirable cosmetic results
Capsular Contracture (Baker Grade III/IV)	7 of 100 (7%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal • Undesirable cosmetic results
Implant Rupture (confirmed and suspected)	0 of 100 (0.0%)	• Implant removal • Reoperation
Infection	<1 of 100 (0.9%)	• Swelling • Pain or tenderness • Redness • Fever • Implant removal • Reoperation

Other Risks occurring in 1% or more of patients		
Double Capsule	1 of 100 (1%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal
Breast Pain	1 of 100 (1%)	• Increased or decreased nipple sensitivity • Breastfeeding difficulties • May affect sexual response
Implant Malposition	5 of 100 (5%)	• Implant visibility • Asymmetry • Reoperation • Implant removal • Undesirable cosmetic results
Asymmetry	4 of 100 (4%)	• Undesirable cosmetic result • Reoperation • Implant removal
Hematoma	2 of 100 (2%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
Implant Extrusion	1 of 100 (1%)	• Swelling • Pain or discomfort • Infection • Reoperation • Implant removal
Mass/Cyst	2 of 100 (2%)	• Implant visibility • Asymmetry • Reoperation • Implant removal • Undesirable cosmetic results
Ptosis	5 of 100 (5%)	• Undesirable cosmetic result • Reoperation • Implant removal • Wrinkling or rippling

**Based on the results of the Motiva Implants® Core Clinical Study within the first 3 years after implant surgery*

11.1 Potential complications of breast augmentation surgery

- **Pain.** Most women undergoing augmentation with a breast implant will experience post-operative breast pain. This pain usually resolves in most women as they heal after surgery, but it can become a long-term problem in other women. Hematoma, implant migration, infection, implants that are too large, placement or surgical technique or capsular contracture can also cause pain. Sudden, severe pain may be associated with implant rupture. Tell your surgeon immediately if there is significant pain or if pain does not go away.

- **Swelling.** Swelling is build-up of fluid or inflammation of a body part and can occur any time after surgery, however, it usually peaks at 3-5 days after surgery.

- **Hypertrophic Scarring.** Scarring is a natural healing process and can take time to see improvements. Hypertrophic scars may happen when there is excessive production of tissue, which forms the scar. Scars may also be caused because the wound takes too long to heal. Biologically, some people tend to be more susceptible to hypertrophic scars due to their genetic make-up[1].

- **Seroma.** Seroma is an accumulation of fluid. Similar to a bruise, a seroma occurs when the watery portion of the blood collects around a surgical incision or around a breast implant. Seromas can be reabsorbed by the body over several weeks, however, some will require surgery. While seromas do not increase breast cancer risk, they sometimes heal with scar tissue or calcifications that can raise a concern about the interpretation of mammograms in the future. This is because calcifications can lead to a false positive reading[2]. Seroma symptoms most often appear a week to 10 days after surgery; the area may feel tender and swollen, with a discrete lump and redness arising within a day or two. In addition to causing pain, a seroma increases the risk of developing an infection in the breast. Depending on the location, it may also increase pressure over the surgical site and sometimes cause wound dehiscence (wound opening).

- **Hematoma.** A hematoma is a collection of blood within the breast tissue. Symptoms of hematomas generally include swelling, bruising, and pain around the incision area[3]. Small hematomas may resolve on their own or will only require drainage. Drains are small surgical tubes that lead out of the breast, with a small bulb attached to collect blood and other fluids. If a hematoma is larger or continues to grow, your surgeon may decide to perform an operation to remove the hematoma.

- **Enlarged Lymph Nodes.** There are many lymph nodes in the body. The lymph nodes in the armpit drain the breast area of body fluid. Some patients with breast implants have been found to have swollen or enlarged lymph nodes in the armpits[3]. This is referred to as lymphadenopathy. It has been reported to occur in women with both ruptured and intact silicone gel breast implants. If a swollen lymph node becomes painful, it may need to be surgically removed. You should report any swollen or painful lymph nodes to your doctor.

- **Undesirable Cosmetic Results.** Unsatisfactory results such as stretch marks, wrinkling, visibility, and dissatisfaction with the implant volume or breast shape may occur. Some of these results may cause discomfort. Pre-existing asymmetry may not be entirely correctable by implant surgery. Revision surgery could be indicated to increase patient satisfaction, but this involves additional considerations and risks. Careful preoperative planning and surgical technique can minimize, but not always prevent, unsatisfactory results.

- **Breastfeeding Difficulties.** Some women who undergo breast augmentation can successfully breastfeed, and some cannot or may have difficulties doing so. Please talk to your surgeon about breastfeeding and options for incisions used for breast implant placement.

- **Infection.** Infection can occur with any surgery or breast implant. Most infections resulting from surgery appear within a few days to weeks after the operation[4]. Symptoms of infection may include pain, fever, redness or swelling. However, infection is possible at any time after surgery. In addition, breast and nipple piercing procedures may increase the possibility of infection. If an infection does not respond to antibiotics, the implant may have to be removed, with replacement. As with other surgical procedures, Toxic Shock Syndrome (TSS), a life-threatening condition, has been reported in rare instances following breast implant surgery. TSS symptoms occur suddenly and can include high fever (102° F/38.8° C or higher), vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. Patients should contact their doctor immediately for diagnosis and treatment if they experience these symptoms[5].

- **Delayed Wound Healing.** Some patients may take a long to time heal. Smoking causes a decrease in the blood's oxygen levels, directly affecting surgical wounds' healing process. Delayed wound healing may increase the risk of infection, extrusion (skin breakdown with exposure of the breast implant), and necrosis (tissue death) and may vary depending on the type of surgery or incision or medical history. Be sure to ask your surgeon about how long it takes to heal after surgery and report to your surgeon if you do not heal in that time frame.

- **Visibility/Palpability.** Palpability is when the implant can be felt through the skin; visibility is when the implant can be seen through the skin. Visibility and palpability of the implant can occur because the skin or tissue is thin. This can be due to several causes, including excessive implant size, previous surgery, and general skin aging.

- **Changes in Nipple and Breast Sensation.** Breast surgery can increase or decrease breast and/or nipple sensitivity. The range of changes can vary from intense sensitivity to no feeling in the nipple or breast. While some of these changes can be temporary, they can also be permanent and may affect your sexual response or breastfeeding ability[6]. For some patients, additional sensitivity in the nipple area may be noticed days or weeks after breast implant surgery. This is normal and is due to the stretching of the area near your nerves during the surgery. Fortunately, this extra sensitivity may go away as the tissues continue healing.

- **Ptosis.** Ptosis is the sagging or drooping of the breast. Sagging of breast tissue over the implant can also occur. Certain breast implants (and implant locations) may be more prone to contribute to this problem, such as implants that are placed high, especially in women whose body is less symmetrical[7]. Pregnancy and nursing after breast implant surgery may cause breast tissue and muscle changes that could lead to ptosis (drooping).

- **Malposition.** Malposition, or displacement of the breast implant, occurs when the implant has moved/shifted from its original position. The shifting of the breast implant can be caused by many factors, such as aging/gravity, chest injury/impact, capsular contracture, or poor initial placement.

- **Inflammation/Irritation.** Breast implants, like any foreign material implanted into the human body, can trigger a host's (the patient) protective immune reaction. A foreign body response may be indicated by redness, swelling, warmth, and pain. This foreign body response is the body's natural reaction and attempts to remove or surround the "foreign body material" with fibrous tissue to protect the immune system. Granulomas are noncancerous lumps that can form around foreign material, such as silicone (like any lump, it should be evaluated to distinguish it from a lump that might be cancerous).

- **Gel Diffusion.** Small quantities of silicone may diffuse or bleed through the implant shell of silicone gel-filled implants. The detection of small quantities of silicone in the tissue around the implant, the axillary lymph nodes, and other parts of the body with intact breast implants has been reported in the literature. Some studies on long-term implants have suggested that gel bleed may contribute to capsular contracture and lymph node reaction. However, there is evidence that gel bleed may not be a large contributing factor to capsular contracture. This is supported by data showing that capsular contracture rates are similar or lower for silicone gel-filled breast implants than for saline-filled (salt water) breast implants[8].

- **Capsular Contracture.** Capsular contracture is the tightening of the scar tissue (also called a capsule) that normally forms around the breast implant during the healing process after surgery; in some women, the scar tissue (capsule) squeezes the implant. When this occurs, it is called capsular contracture. This results in firmness or hardening of the breast. This can impact the aesthetic outcome, resulting in pain, breast deformity, and can require additional operations[9]. 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 patients undergoing revision augmentation surgery than in patients undergoing primary augmentation surgery. Capsular contracture is one of the most common reasons for reoperation[9,10].

Capsular contracture is graded into four (4) levels depending on its severity:

- 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.

Additional surgery might be needed in cases where pain and/or firmness are severe (Baker Grades III or IV) and that capsular contracture may happen again after additional surgeries. A closed capsulotomy, external pressure on the capsule to break up the tissue capsule, is contraindicated (should not be performed) because it can cause implant rupture, bleeding, and pain.

- **Rupture.** Breast implants rupture when the implant shell develops a tear or hole. Rupture can occur at any time after implantation but is more likely to occur the longer the implant is in the patient. The following reasons may cause implants to rupture: damage by surgical instruments, implant/shell stress and weakening during implantation, normal use over time, the occurrence of post-operative hematomas or seromas, folding or wrinkling of the implant shell, excessive force to the chest, trauma, compression during mammographic imaging, and severe capsular contracture[11].

  Silicone gel implant ruptures are most often silent; this means that most of the time, you may not experience symptoms and neither the doctor nor you can determine with the physical examination if the implant has a tear or hole in the shell. For this reason, it is recommended that you have periodic imaging (ultrasound or magnetic resonance imaging (MRI)) of your silicone gel-filled breast implants to screen for implant rupture. These recommendations do not replace other additional imaging that may be required depending on your medical history or circumstances (i.e., screening mammography for breast cancer). Even if you have no symptoms, you should have your first ultrasound or MRI at 5-6 years after your initial implant surgery and then every 2-3 years thereafter. If you have symptoms at any time or uncertain ultrasound results, an MRI is recommended[12].

  Symptoms associated with rupture may include 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 the breast. These symptoms are not specific to rupture and may also be experienced by patients who have capsular contracture or other complications[13].

- **Extrusion.** Breast implant extrusion or exposure occurs when the breast skin and tissue holding the implant break down, causing the implant to protrude through the skin and become exposed. It can occur soon after breast augmentation or can occur well after surgery. Breast implant extrusion can occur for various reasons: infection, trauma, too little skin tissue to cover the incision/implant, larger implant combined with too little tissue/skin coverage, or lack of blood supply. Breast implant extrusion generally requires surgery and may include removal of the implant[14].

- **Double Capsule.** A "double capsule" refers to the finding of two separate capsular (scar tissue) layers, separated by a space, around a breast implant. Although rare, double capsules can occur after breast implant surgery. Clinical signs may vary from having no symptoms to firmness of the implant, discomfort, change in shape or position of the implant, and pain.

- **Rippling/Wrinkling.** Wrinkling/rippling of the implant that can be felt or seen through the skin. Rippling is the skin complication, visible or palpable, of the implant ripples and edge that are typically most apparent when the patient bends forward. In situations where the implants soft tissue coverage (skin) is insufficient, rippling may become more apparent. Adequate skin and body tissue coverage over the implant is important to prevent rippling or implant edge visibility.

- **Calcification/Calcium Deposits.** Calcium deposits in the breast can occur in women who undergo breast reduction procedures, in patients who have experienced hematoma(s) and/or seroma(s), and even in the breasts of women who have not had any breast surgery. Calcium deposits can form in the scar tissue surrounding the implant and cause pain and firmness. Calcium deposits are visible on mammography.

As these deposits must be differentiated from calcium deposits that are a sign of breast cancer, additional surgery may be necessary to remove and examine calcifications. The occurrence of calcium deposits increases with age.

- **Reoperation (Explantation).** Breast implants are not lifetime devices, and there is a possibility that patients will undergo implant removal(s), with or without replacement, throughout their life. When implants are explanted without replacement, changes to the patient's breasts may not be reversible. Future complications increase with revision augmentation surgery compared to primary augmentation surgery. For example, the risk of capsular contracture is higher for augmentation patients with implant replacement compared to first time implantation. Radiation therapy may cause premature removal because of skin damage/extrusion, capsular contracture, and recurrent seroma/hematoma. Rupture, unacceptable cosmetic outcomes (dimpling, wrinkling, and other potentially permanent cosmetic changes of the breast), and other complications may require additional surgeries to the patient´s breasts. Explantation is the removal of the breast implant.

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

- **Interference with Mammography/Mammograms.** Motiva USA emphasizes the importance of mammography (x-ray images of the breast). Mammography is used to detect breast cancer. You should inform your examiners in an accredited mammography center that you have implants and provide the implant type and location (over or under your chest muscle). Your ordering physician may request a "diagnostic" mammography rather than "screening" mammography[15]. Breast implants may complicate the interpretation of mammographic images by blocking underlying breast tissue and/or compressing overlying tissue. Pre- and post-surgical mammography may be performed to determine a baseline for routine future studies in augmentation patients.

- **Interference with Magnetic Resonance Imaging (MRI).** Motiva Implants provide the option of a microtransponder (radio frequency identification device that contains the manufacture date, serial number, volume and size) that is included in the Breast implant gel. It is optional to have an implant with a microtransponder. It is up to you and your surgeon to decide on which Motiva implant is best for you. Motiva Implants® with the optional microtransponder are considered MR Conditional (can safely undergo an MRI under specific MR conditions). During the MRI procedure, the microtransponder can create an MRI artifact (blurring) directly around the microtransponder that can prevent the radiologist from seeing parts of the implant's shell edge/side and parts of the patient's tissue, including breast. Therefore, there are potential added MRI risks associated with this artifact, including, but not limited to, an inadequate evaluation of the implant shell for the detection of rupture or miss a diagnosis of cancer if it is blocked by the artifact area.

11.2 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. Furthermore, it is possible that other risks, yet unknown, could be determined to be associated with breast implants in the future.

Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

- **Neurological Signs and Symptoms.** Some women with breast implants have experienced neurological disturbances (e.g., visual symptoms or alterations in sensation, muscle strength, walking, balance, thinking, or memory) or diseases (e.g., multiple sclerosis), and they believe those symptoms are related to their implants.

- **Breast Cancer.** Published studies indicate that patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer[16–25]. 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 indicated that breast implants neither significantly delay breast cancer detection nor adversely affect cancer survival of women with breast implants[17,20,25–28].

- **Breast Mass/Cyst.** A breast cyst is a fluid-filled sac that develops within the breast tissue. These sacs form when normal fluid-producing glands in the breast enlarge or become blocked. The development of a breast cyst may be due to the implant or implant placement. Breast cysts are usually found on a self-breast exam. When they are small, they often go unnoticed or may instead be seen on a mammogram. A breast mass is a lump in the breast. It can be found during a self-exam or by a clinician during a physical exam.

- **Breast Tissue Atrophy.** Breast tissue atrophy (thinning or diminishing of tissue) may result from aging or the pressure exerted by the weight from breast implant around the patients breast and chest wall size.

- **Chest Wall Deformity.** The breast implants pressure may cause the breast tissue/skin to thin and shrink (with increased implant visibility and palpability), potentially leading to chest wall deformity. This can occur while implants are still in place or following implant removal without replacement.

- **Breast Implant Illness (BII).** Some patients who have received breast implants have reported a variety of systemic symptoms including joint pain, fatigue, rash, memory loss, and "brain fog" that some patients have called breast implant illness. While the causes of these symptoms are unclear, some patients have reported relief of these symptoms with removal of their implants and surrounding scar tissue capsule, however not all patients may experience improvement in their symptoms. Some patients with BII also get diagnosed with a specific autoimmune or connective tissue disorder[29], but many do not. Researchers are investigating the symptoms to understand their cause(s) better. These symptoms and what causes them are poorly understood. In some cases, removing breast implants without replacement is reported to improve or resolve these symptoms. More information on systemic symptoms in patients with breast implants can be found at Medical Device Reports for Systemic Symptoms in Women with Breast Implants | FDA (https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-systemic-symptoms-women-breast-implants).

  Symptoms can include central nervous system disorders (brain fog, memory loss, tinnitus, vertigo, headaches, blurred vision, migraines), musculoskeletal disorders (fibromyalgia, muscle pain, hand discoloration, numbness, headaches, migraines), psychological disorders (anxiety, panic attack, feeling of imminent death), immune/inflammatory disorders (Raynaud's Syndrome, scleroderma, Hashimoto's Thyroiditis, Sjögren's syndrome, autoimmune disease, recurrent infections, rheumatoid arthritis, night sweats, toxic shock, chronic fatigue, dry eye, sudden food intolerance, systemic lupus erythematosus, multiple sclerosis), as well as anemia and symptoms related to the cardiorespiratory and genitourinary systems.

- **Connective Tissue Disease (CTD).** Connective tissue disease is a disease, group of diseases, or conditions affecting connective tissue, such as muscle, ligaments, skin, etc., and/or the immune system, and include diseases such as lupus, scleroderma, rheumatoid arthritis, and fibromyalgia. There have been a number of published studies, meta-analyses, and "weight-of-the-evidence" or reviews that have looked at whether having a breast implant is associated with having a connective tissue disease. The study size needed to conclusively rule out a risk of connective tissue disease among women with silicone gel breast implants would need to be very large[26,30–34]. Some published studies taken together show that breast implants are either not significantly associated with a risk of developing a typical or defined connective tissue disease, or if a significance was detected, based on limitations of the studies, a causative relationship with breast implants could not be determined[16,30,32–43]. These studies do not distinguish between women with intact and ruptured implants. Some independent scientific panels and review groups have concluded that there is no evidence to support an association between breast implants and connective tissue disease, or at least if a risk cannot be absolutely excluded, it is too small to be measured[30,34].

- **CTD Signs and Symptoms.** Some women (with or without breast implants) may have some of the signs or symptoms of connective tissue diseases, without having the actual disease. Patients receiving breast implants have reported a variety of signs and symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well-established. Some patients report complete resolution of symptoms when the implants are removed without replacement. If you have any of these signs or symptoms, you should contact your doctor.

- **Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL).** If you have breast implants, you have a very small, but increased risk of developing breast implant associated anaplastic large cell lymphoma, or BIA-ALCL. BIA-ALCL is not breast cancer—it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases it can spread throughout the body. In the cases that have spread beyond the scar tissue and fluid near the implant, rare cases of death have been reported. Most patients were diagnosed with BIA-ALCL when they sought medical treatment for implant related symptoms such as swelling, pain, lumps, or asymmetry that developed after their initial surgical sites were fully healed. In the cases known to FDA to date (as of June 30, 2023, FDA Report), the earliest report of BIA-ALCL was diagnosed less than one year after implant placement and the latest was 40 years after the implant surgery. About half the cases occurred within the first 8 years after implant. BIA-ALCL was most often diagnosed in women who had textured implants. The textured implant may have been placed at the most recent surgery or at any other prior breast implant operation.

  If you develop swelling or pain around your breast implants, be sure to talk to your health care provider. Your health care provider should consider the possibility of BIA-ALCL if after you have recovered from your breast implant operation, you later notice changes in the way your breast looks or feels—including swelling or pain around the implant. If your health care provider suspects BIA-ALCL, they will refer you to an appropriate specialist for evaluation which may involve obtaining fluid and tissue samples from around your breast implant. If a diagnosis of BIA-ALCL is confirmed, the doctor will develop an individualized treatment plan for you. Because of the small number of cases worldwide and the variety of available treatment options, there is no single defined treatment. However, if you are diagnosed with BIA-ALCL, the National Comprehensive Cancer Network (NCCN) recommends removing the implant and the surrounding tissue.

  If you have breast implants, you should monitor them and follow your routine medical care. You do not need to take any additional steps. It is not necessary to remove your breast implants if you have no symptoms and you have not been diagnosed with BIA-ALCL. If you are diagnosed with BIA-ALCL, you can help the FDA understand the disease and the effectiveness of treatment. You or your doctor should report all con-firmed cases of BIA-ALCL to the FDA (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program). In some cases, the FDA may contact you for additional information. The FDA will keep the identities of the reporter and the patient confidential. In addition, if you are diagnosed with BIA-ALCL, talk to your doctor about reporting it to the PROFILE Registry (https://www.thepsf.org/research/clinical-impact/profile.htm). Every case of BIA-ALCL should be reported to the PROFILE Registry because this helps provide a better understanding of the disease. If you are considering breast implant surgery, you should discuss the risks and benefits with your health care provider.

  You may also visit the FDA's Breast Implants website for additional information https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants

  For additional information on FDA's analysis and review of BIA-ALCL, please visit:
  https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma

- **Effects on children.** It is not known if a small amount of silicone may move through the breast implant shell and pass into breast milk. There is no test for detecting silicone in breast milk that is considered accurate. There has been a study (2000) that measured silicon levels (one component of silicone). It did not indicate higher levels of silicon in breast milk from women with silicone gel breast implants when compared to women without implants[44].

- **Brain Cancer.** Most studies of brain cancer in women with silicone gel breast implants have found no increased risk[19,21–25,45,46]. There is one study that reported a higher rate of brain cancer in women with breast implants compared to the general population[18]. However, rates of brain cancer were not significantly higher in women with breast implants when compared to women who had other non-breast implant plastic surgeries.

- **Lympho-Hematopoietic Cancers.** Lympho-hematopoietic cancers are cancers that develop in the lymph nodes or certain blood cells. Lymph nodes and the affected cells are part of the body's immune system to fight infection. These kinds of cancers include non-Hodgkin's lymphoma, Hodgkin's disease, multiple myeloma, and leukemia. Most studies have found no increased risk of these cancers for women with silicone gel breast implants [19,21–25,45]. However, there have been reports of various lymphomas, in the scar tissue (capsule) that forms around breast implants. The various lymphomas reported are not the same as the Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). The occurrence of various lymphomas in the capsule around the breast implant may be rare and the cause, incidence, and risk factors remain unknown.

- **Respiratory/Lung Cancer.** Several studies have found that women with silicone gel breast implants are not at greater risk for lung cancer[19,21–25,45]. One study found an increased risk of respiratory/ lung cancer in women with breast implants compared to women who had other kinds of plastic surgery (non-breast implant). However, the risk of lung cancer was not higher than national lung cancer rates for the general population. Studies of women in Sweden and Denmark 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[47–49]; this may increase their risk for lung cancer.

- **Reproductive System Cancer.** Reproductive system cancers in women are cancers of the cervix, ovaries, uterus, vulva, vagina, and other female genital organs. Most studies [19,21–25,45,46] found that women with silicone gel breast implants have no greater risk of these cancers than women without implants. One study reported an increased incidence of cervical/vulvar cancer in women with breast implants [18].

- **Squamous Cell Carcinoma.** There have been reported cases of squamous cell carcinoma (SCC), a cancer, in the scar tissue (capsule) that forms around the breast implant[50]. The occurrence of SCC in the capsule around the breast implant may be rare and the cause, incidence, and risk factors remain unknown.

- **Other Cancers**. Studies have examined other types of cancer including eye, urinary tract (related to the bladder and urethra), connective tissue (fibrous tissues like tendons, cartilage, and bone that provide structure and support throughout the body), and endocrine system (the parts of the body that make hormones). Studies show that women with silicone gel breast implants have no greater risk of these types of cancers compared to the general population[18,51,52].

- **Suicide.** Some studies have reported a higher incidence of suicide in women with breast implants, but it is not clear whether these suicides were associated with having silicone gel breast implants or some other underlying condition that can lead to suicide, depression and/or anxiety[18,23,25,45,53–58]. One researcher believes that some women who want cosmetic surgery suffer from a disorder, called body dysmorphic disorder, which may cause them to think about suicide or attempt suicide[59]. One study found that women with breast implants were admitted to the hospital more often because of psychiatric problems before they even had their implant surgery, compared to women in the general population[53]. This may be a contributing factor of the higher incidence of suicide in women with breast implants reported.

- **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[30,60] The evidence is inconclusive 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[30] and lymphadenopathy[61,62]. However, evidence against gel bleed being a significant contributing factor to capsular contracture and other local complications is supported by the studies of similar or lower complication rates for silicone gel breast implants than for saline breast implants. Saline breast implants do not contain silicone gel; therefore, gel bleed is not a factor for those implants.

For the latest statistical data on reported cases, refer to:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breast-implants-certain-labeling-recommendations-improve-patient-communication

12. CLINICAL BENEFITS OF BREAST IMPLANTS

The following benefits are expected from Motiva Implants®:

- Increase the breast size and/or
- Correct or improve the results of previous breast augmentation surgery, known as revision-augmentation surgery

13. PREPARING FOR BREAST AUGMENTATION WITH SILICONE GEL BREAST IMPLANTS

Deciding to have breast augmentation with implants is an important personal decision that has both benefits and risks. You should decide whether it is the right choice for you after discussing all the options with your plastic surgeon and any other doctors who are treating you. This section will give you the information needed to make an informed choice and help you make a number of decisions that have to be made before your surgery. If you decide to have the surgery, before the surgery you will be asked to read, initial each section, and sign a Patient Decision Checklist that highlights key information regarding risks of breast implant surgery. The Checklist says you have read and understood the information in this brochure and in the Boxed Warning, and that you have been informed of the benefits and risks of breast implants. Your surgeon will also sign this Checklist indicating that they have reviewed all of the information in this brochure with you and addressed all of your questions. There is a copy of the Patient Decision Checklist at the end of this brochure in Section 28. Make sure all of your questions have been answered and you understand the information in this brochure before you sign the Patient Decision Checklist.

13.1 Should I have breast augmentation?

Breast augmentation with silicone gel breast implants is one option that may be available to you if you wish to enhance the appearance of your breasts. A breast revision-augmentation surgery may be appropriate if you have had a breast augmentation with implants but need to complete, improve upon, or correct a part of that first surgery (called the primary augmentation). Whether breast augmentation is right for you, depends on many things, some of them are personal. You should take into account your medical condition, general health, lifestyle, how you feel emotionally, and your breast size and shape before surgery, as well as your hopes for breast size and shape after surgery. All of these things will affect the outcome of your surgery. Discuss your goals for breast augmentation with your doctors. You may also wish to consult your family and friends and breast implant support groups to help you learn about the options and decide. Many women who choose implants as part of their augmentation say their augmented breast(s) help them feel more self-confident, feel better about their bodies, and/or give them a greater feeling of well-being. Some women are not satisfied with their implants because of complications, like capsular contracture, rupture, or pain.

14. SURGICAL PROCEDURE

Breast Augmentation with Implants – Understanding the Procedure
The surgical procedure for breast augmentation consists of choices you and your surgical team (surgeon(s), nurses, anesthetist, etc.) will make as you plan your surgery. These choices include:

i. The surgical setting (where the surgery will be performed, for example, in a hospital, surgery center, or doctor's office),
ii. The type of anesthesia used,

iii. The location of the incisions made to insert the Implants,
iv. How the Implants may be placed in your breasts:
    1. Subglandular placement – on top of the chest muscle
    2. Submuscular placement – underneath the chest muscle
    3. Dual plane placement –partly underneath the chest muscle and partly underneath the breast tissue
    4. Sub-fascial placement – above the chest muscle and underneath the chest muscle fascia (connective tissue)
    5. Whether your existing skin and/or breast tissue can cover implants.

Each of these is discussed in the sections that follow. The procedure available to you depends on your medical situation, breast shape and size, general health, lifestyle, and goals for the augmentation. Breast augmentation with silicone gel breast implants can usually be completed in a single surgery.

14.1 General anesthesia

General anesthesia is commonly used for breast augmentation surgery. You should be sure to check with your surgeon and with the facility where the surgery will take place to be prepared for the tests, pre-surgical examinations, and length of time you need to be without food or your routine medications before the surgical procedure. Please discuss the risks and benefits of the anesthesia with your surgeon and anesthetist.

14.2 Surgical technique

Breast implants may be positioned in several different tissue/chest locations, described as the pocket location and discussed below in Section 14.6 Placement. The selection of this pocket is an important process in obtaining the desired outcome.

14.3 Implant selection

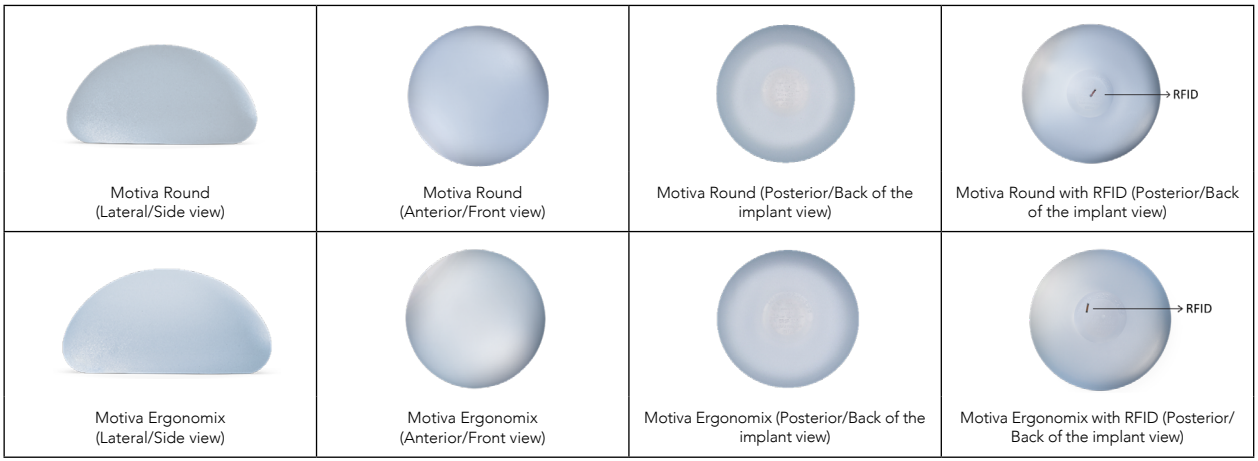
Motiva Implants® come in various widths, heights, projections, and volumes to offer you the most appropriate device for your specific needs. The implant size should be consistent with your chest wall dimensions, including base width measurements, tissue characteristics, and implant projection. Therefore, this decision should be made in consultation with your surgeon to avoid choosing an implant that is too large for your tissue or chest and avoid post-operative implant visibility and palpability.

The following factors may cause implants to be more palpable: larger implants, subglandular placement, and insufficient tissue available to cover the implant. Larger implants may speed up the effects of gravity on the breast tissue/skin. This can result in drooping or sagging, or aesthetically undesirable results, which may require surgical intervention for correction.

14.4 Device description

The Motiva Round and Round Ergonomix® silicone breast implants are comprised of a shell made of silicone elastomer (rubber) which is filled with silicone gel. The shell contains a lightly tinted blue biocompatible barrier layer that allows for visual inspection confirming the implant shell is intact. The materials of the Round and Round Ergonomix® devices are identical although there are differences in the construction of each device type; the Round Ergonomix® implant contains one less shell layer and a gel that is slightly less firm than the Round implant.

The shell of both style implants has a SmoothSilk® controlled surface architecture produced by the mandrel imprinting technique with an average roughness of 4 microns. This means that the implant surface is controlled by a dipping mold (mandrel) during manufacturing. When the shell is removed from the mandrel, the controlled features of the mandrel create the silicone shell surface.



Motiva Round (Lateral/Side view) | Motiva Round (Anterior/Front view) | Motiva Round (Posterior/Back of the implant view) | Motiva Round with RFID (Posterior/Back of the implant view)

Motiva Ergonomix (Lateral/Side view) | Motiva Ergonomix (Anterior/Front view) | Motiva Ergonomix (Posterior/Back of the implant view) | Motiva Ergonomix with RFID (Posterior/Back of the implant view)

Figure 2. Images of Round and Round Ergonomix Implants With and Without RFID

A passive radio frequency identification device (referred to as RFID, microtransponder, or Qid) that is placed in the Gel at the Shell/Patch area is an optional feature for all implant styles. This microtransponder provides each implant with a unique electronic serial number for device identification.

Motiva Round and Round Ergonomix SmoothSilk Breast Implants are available in the following styles and sizes (Table 7).

Table 7. Motiva Round® and Ergonomix® Round Implants

Style	Profile	Base Width (cm)	Implant Gel	Size Range (Volume)
Round Style				
RSM	Mini	2.8-3.2	ProgressiveGel® Plus	245cc-400cc
RSD	Demi	3.5-4.5	ProgressiveGel® Plus	205cc-525cc
RSF	Full	4.2-5.7	ProgressiveGel® Plus	255cc-625cc
Round Ergonomix Style				
ERSM	Mini	2.4-3.4	ProgressiveGel® Ultima®	150cc-475cc
ERSD	Demi	3.3-4.6	ProgressiveGel® Ultima®	155cc-575cc
ERSF	Full	4.2-5.7	ProgressiveGel® Ultima®	255cc-625cc

**Optional microtransponder available for all styles; see Section 15.3 Microtransponder below*

14.5 Incision

The incision should be of sufficient length to place the implant inside the breast without damaging the implant. Table 8 describes the common incision locations for the placement of breast implants.

Table 8. Types of Incisions for Breast Augmentation with Silicone Gel Implants

Incision Type	Characteristics
Periareolar	• Incision is made around the nipple • Better concealed • May reduce the possibility of future breastfeeding • Associated with a higher risk of changes in nipple sensation
Inframammary	• Incision is made under the breast at/near the crease • Less concealed than the periareolar incision • Associated with fewer breastfeeding and nipple sensation difficulties
Transaxillary	• Incision is made underneath the armpit • Allows surgeon easier access to the chest muscle • Less concealed incision site (when the arm is lifted) • May limit the size of implant used

For a better understanding of the anatomical location where different incisions are made, refer to the images in Figure 3, below:

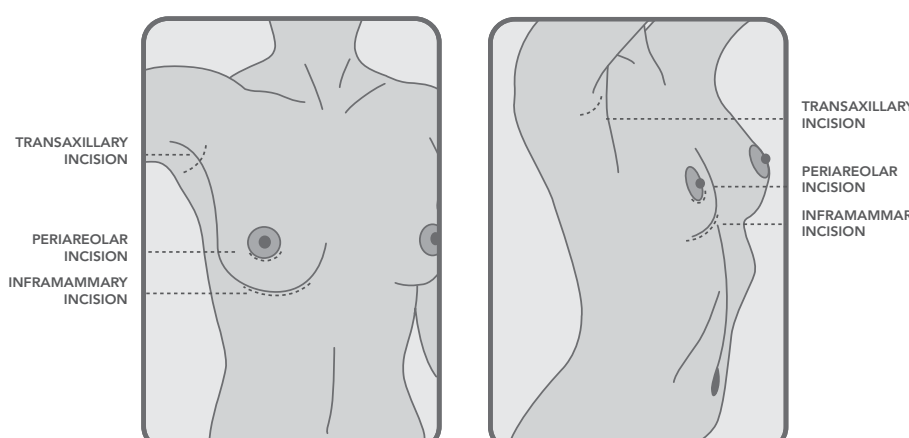


Figure 3. Anatomical Location of Incision Site Options for Breast Implants

14.6 Placement

Table 9 describes the differences between placement locations for silicone gel breast implants.

Table 9. Placement for Breast Augmentation With Silicone Gel Implants

Placement	Characteristics
Submuscular/Subpectoral (under the chest muscle)	• Implants may be less palpable • It may be easier to image breast with mammography • Surgery time may be longer • Recovery may be longer • May be more painful • May increase difficulty in performing some reoperation procedures
Subglandular (under the breast tissue but over the chest muscle fascia* layer)	• May reduce surgery and recovery time • May be less painful • Implants may be more palpable and visible • It may be harder to image breast with mammography
Dual Plane (partly underneath the chest muscle and partly underneath the breast tissue)	• Possible greater expansion of the lower portion of the breast • May provide a more natural looking appearance than fully under the muscle (submuscular) • Surgery time may be longer • Recovery may be longer • May be more painful
Subfascial (above the chest muscle and underneath the chest muscle fascia)	• May be similar to subglandular characteristics • Please discuss with your surgeon regarding specific advantages or disadvantages

**Fascia* *refers to a thin layer of connective tissue that lies on top of the chest muscle*

For a visual understanding of the anatomical locations where the implants could be placed, please see the images in Figure 4, below:

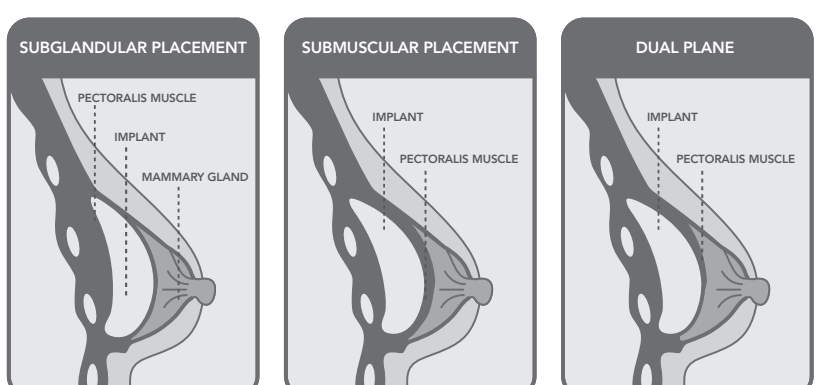


Figure 4. Anatomical Locations of Placement Options for Breast Implants

14.7 Choosing a surgeon

The following are types of questions you should consider when choosing a surgeon:

- In which state(s) are they licensed to practice surgery?
- Have they completed residency requirements in plastic surgery from a recognized and accredited academic program?
- Are they board certified in plastic surgery in the United States? If so, which board?
- How many breast augmentation surgeries do they perform each year?
- How many years have they been doing breast augmentation surgeries?
- What is the most common complication they encounter with breast augmentation patients?
- What is their reoperation rate for augmentation patients? And what is the most common type of reoperation that they perform?
- Will they perform all of my surgery in a hospital?

15. SPECIFIC BREAST IMPLANT CHARACTERISTICS OF MOTIVA BREAST IMPLANTS

15.1 Blue barrier layer

Motiva Implants® have a lightly tinted blue barrier layer, made with biocompatible coloring (called "BluSeal®"). This layer allows for visual inspection to ensure the implant shell is intact after manufacturing. The BluSeal® pigment contains a small amount of copper of which trace amounts may diffuse from the implant.

15.2 Microtransponder

Motiva Implants® are available with an optional microtransponder, a radio frequency identification device (RFID), embedded in the breast implant filler material. Your surgeon can use a scanner to read the microtransponder and access a database containing the breast implant information (serial and lot numbers, the reference number, volume, size, and projection, model, manufacturing date, etc.). This assures full traceability to implant specific identification.

Unlike product and warranty cards that are provided to a patient undergoing breast augmentation, a microtransponder can never be lost or misplaced. This authentication system does not include any patient information.

It is the patient's choice to select implants containing the RFID microtransponder. The RFID microtransponder creates an imaging void during breast implant MRI (known as artifact effect) that can block visualization of a small area around the RFID microtransponder. Patients implanted with an RFID microtransponder can safely undergo MRI under the conditions listed in Section 10.

16. OTHER PROCEDURES AT THE TIME OF THE BREAST AUGMENTATION

Your surgeon may recommend having other cosmetic procedures during the same surgery to get the best results from your breast implants. In some cases, breast implants alone may not give you the results you want. If, in the past, you have lost a lot of weight, been pregnant, or breastfed, you may have sagging, stretched, or extra skin that is not completely filled out by breast tissue. In this case, your doctor may recommend doing a breast lift (mastopexy) to remove extra skin from the rest of the breast tissue in one or both breasts.

Your surgeon will discuss the potential use of other implanted products during your breast implant surgery. Your surgeon will also discuss the risks and benefits of using these implanted products and their planned surgical approach.

17. POST-OPERATIVE CARE

The recovery process depends on many variables. Your surgeon will give you specific instructions about what to do after surgery. Follow your surgeon's directions.

Below are some general instructions and what you may expect after surgery:

a. Immediately after surgery, your breasts will be swollen and tender, so you will likely need to wear a compression bra, also called a surgical bra, without underwires. Most patients wear their medical compression garments day and night for one to two weeks, and then transition to a supportive sports bra. Your surgeon will provide or recommend the best bra after breast augmentation, along with instructions on how long you must wear it.
b. Your breasts may remain swollen and sensitive to physical contact for a month or longer.
c. You are likely to feel tired and sore for several days following the operation.
d. You may experience a feeling of tightness in the breast area as your skin adjusts to your new breast size.
e. You should avoid any strenuous activities for at least a couple of weeks, please follow your surgeons instructions.
f. Sleep or rest with your head slightly elevated, avoiding fully flat positions.
g. Keep your arms close to your body and avoid lifting weights until allowed by your surgeon.
h. Do not drive and do not exercise until approved by your surgeon.
i. Do not expose your breasts directly to sunlight until approved by your surgeon.
j. Your surgeon may recommend a topical cream.
k. After breast implant surgery, you might experience swelling, hardness, discomfort, itching, bruising, twinges, and pain over the first few weeks.
l. Topical Medications: You should consult a physician before using topical medicines (e.g., steroids) in the breast area.

17.1 Follow-up examinations

There are some things you should do to make sure your breasts stay healthy and to take care of your implants: mammograms, breast exams, and protecting your implants from certain types of damage. It will be important to monitor your breasts for breast cancer. Also monitor regularly for breast implant rupture.

17.1.1 Mammograms

A mammogram is a special way of x-raying the breast. Whether or not you have breast implants, having a mammogram is considered the best way to detect breast cancer. However, there are some special considerations for women with breast implants:

- Breast implants can make it harder to see breast cancer on a mammogram.
- Breast implants can make it harder for the technologist to perform the mammogram.

The machine that does a mammogram squeezes the breast to make it as flat as possible while taking a picture. The pressure from this squeezing could make your implant rupture or cause gel bleed. You must tell the technologist that you have silicone gel breast implants before the procedure. The technologist can then use special techniques to get the best possible views of your breast tissue. They can also take steps to reduce the likelihood that your implants will be damaged from the mammogram.

It is a good idea to have a mammogram before your breast implant surgery. This establishes a baseline to which future mammograms can be compared. You are also encouraged to have another mammogram 6 months to 1 year after your implant surgery to establish a baseline with the implant present. After that, the recommendations for mammograms are the same as for women without implants; have a mammogram every 1 to 2 years, starting at age 40[48], or as advised by your doctor. When you go for a mammogram, do the following things to get the most reliable pictures of your breast(s):

- When you schedule a mammogram, tell the office that you have breast implants. Find a mammographer who is experienced with imaging implanted breasts. Your doctor should be able to help you find a qualified mammographer.
- Your doctor may request a "diagnostic" mammogram instead of a "screening" mammogram because more pictures are taken for a diagnostic mammogram.
- Make sure your mammographer knows what type of implants you have and how they are placed (for example, on top of the chest muscle or underneath).
- Carry your Patient Device Implant Card (that you will receive after surgery) with you and show it to the mammographer.

17.1.2 Other breast exams

Perform self-breast exams regularly, approximately at the same time every month.

You can find brochures about how to perform breast self-exams through your doctor, a women's health clinic, or online. Your doctor can show you how to do a self-breast exam. Ask your doctor to help you learn to tell the difference between your breast implant and breast tissue. This will help you do your self-breast exams without squeezing your implant too much. If you see or feel that something has changed, talk to your doctor promptly.

It is important to have regular exams by a doctor as well. It may be hard for you to feel changes in your breast because the implant is there, especially if you have capsular contracture. The doctor will look at your breasts and palpate your breasts like in a self-exam to feel for any changes. If your doctor finds anything, they may refer you for a mammogram to help diagnose the change. Your doctor may also ask for an MRI if they suspect a rupture.

Breast Examination Techniques: It is important to take into consideration the following recommendations: Never manipulate or squeeze the implant excessively. The presence of lumps, persistent pain, swelling, hardening, or change in the implant shape could suggest symptomatic rupture of the implant. If you have any of these signs, report it to your surgeon.

17.1.3 Protecting your implants

To protect your implants, you should make sure that any healthcare practitioners (doctors, emergency medical technologists, nurses, massage therapists, acupuncturists, chiropractors, physical therapists, etc.) treating you know that you have silicone gel breast implants. If they do not know about your implants, they may damage them by accident. Carry your Patient Device Implant Card with you and show it to healthcare practitioners before receiving treatment. You should also protect your implants by guarding against any strong or repeated pressure on your breasts.

17.1.4 Things to call your doctor about right away

Call your doctor immediately if you have:

- Signs of an infection,
- Pain
- A lump,
- Skin around the nipple that has become dimpled or drawn in,
- Discharge from the nipple,
- Change in the position or shape of your implant, or
- Injury to your breast(s).

If your implant becomes damaged, it may have to be removed.

17.1.5 Physical limitations

After you have healed from surgery, you should be able to carry on normal activities, including sports. Avoid situations that put a lot of pressure on your breasts or may cause trauma to your breast. Ask your doctor if there are any activities they do not recommend.

17.2 Symptomatic rupture

Symptoms associated with rupture may include hard knots or lumps surrounding the implant, change of size/shape, pain, tingling, swelling, numbness, burning, or hardening of the breast area. If you notice any of these changes, consult your plastic surgeon so that they can examine your implant(s) for rupture and determine whether you need to have an MRI examination to check if your symptoms are due to implant rupture. If rupture has occurred, you should have your implant removed and/or replaced.

Additionally, the US FDA recommends that you have periodic imaging (MRI or ultrasound) of your silicone gel-filled breast implants to screen for implant rupture. These recommendations do not replace other additional imaging that may be required depending on your medical history or circumstances (i.e., screening mammography for breast cancer). Even if you have no symptoms, you should have your first ultrasound or MRI at 5-6 years after your initial implant surgery and then every 2-3 years thereafter. If you have symptoms at any time or uncertain ultrasound results for breast implant rupture, an MRI is recommended.

17.2.1 What to do if you suspect an implant rupture

If you suspect that an implant has ruptured, call your doctor right away and schedule an exam. Your doctor may recommend an MRI or other kinds of tests to help diagnose possible rupture. MRI is currently considered the best way to diagnose rupture.

17.2.2 What to do if the implant rupture is confirmed

If your doctor confirms that you have a ruptured implant or that silicone gel has bled (moved) out of your implant shell, they will talk with you about your options. As a precaution, Motiva USA recommends that ruptured implants be taken out permanently and either replaced with a new implant or not replaced, depending on your preference or medical need. If your implant is taken out, your surgeon may also have to remove some of your breast tissue (the tissue capsule that forms around the breast implant), which will involve surgery, with associated risks and costs. In some cases, it may not be possible to replace your implants.

18. MOTIVA IMPLANTS® CORE CLINICAL STUDY RESULTS

As part of the marketing approval requirements for the Motiva® SmoothSilk® Round and Motiva SmoothSilk® Round Ergonomix Silicone Gel-Filled Breast Implants, Motiva USA conducted a Clinical Study (the Study) with subjects who received the Implants for augmentation (primary and revision-augmentation). The Study collected data from the primary augmentation and revision augmentation groups (cohorts). The results of the Study will provide you with useful information on the experience of other women who have received these Motiva silicone gel breast implants. The results of the Study should not be used to predict your own experience with the Motiva Implant, but the information can be used as a general guide about what you may expect. Your own benefits and complications depend on many individual factors. The Study is a prospective, 10-year, multicenter (many different surgeons) clinical study conducted to examine the safety and effectiveness of the Motiva Silicone Gel Breast Implants (referred to as Motiva Implants® or Implants) in patients undergoing primary augmentation and revision-augmentation of the breast. The study began in 2018.

Summary of Study subjects: Demographic information with regards to race was: 86.6% of the subjects were Caucasian, 5.7% were Asian, 1.6% were African American, and 6.1% were other. Average age at surgery was 33.5 years for primary augmentation subjects and 44.5 years for revision-augmentation subjects. Table 10 presents information regarding patient incision site and implant placement in the Study.

Table 10. Incision Site and Implant Placement, Primary and Revision Augmentation Patients

Incision Site and Placement of Implants in the MOTIVA Core Study	By-Implant (n = Number of implants)	
	Primary Augmentation n (% of 901)	Revision Augmentation n (% of 218)
Incision Site		
Inframammary	769 (85.3%)	178 (81.7%)
Mastopexy	20 (2.2%)	14 (6.4%)
Periareolar	26 (2.9%)	22 (10.1%)
Transaxillary	86 (9.5%)	4 (1.8%)
Placement		
Complete muscle coverage	24 (2.7%)	4 (1.8%)
Partial sub-muscular/Dual Plane	852 (94.6%)	172 (78.9%)
Sub-fascial	5 (0.6%)	4 (1.8%)
Subglandular	20 (2.2%)	38 (17.4%)

18.1 Overview of the study

Motiva Implants® Core Clinical Study (The Study) is a prospective, 10-year, multicenter clinical study conducted to examine the safety and effectivness of Motiva Implants® in subjects (study patients) undergoing primary augmentation and revision augmentation. A total of 23 sites (20 sites in the United States and 3 in Europe) enrolled 560 primary and revision augmentation subjects. The study was conducted in US (511 subjects) and outside of the US (OUS) (49 subjects). A total of 451 subjects underwent primary augmentation and 109 subjects had revision augmentation surgery. Of these, 176 primary augmentation subjects and 42 revision augmentation subjects are assessed for silent rupture with MRI evaluations at years 1, 2, 3, 5, 7, and 10 after receiving implants.

The assessment of safety was based on the total adverse event rate ("any complication") through three years of follow-up. The study collected data to support the assessments of effectiveness based on patient satisfaction (5-point Likert scale and BREAST-Q©), physician satisfaction (5-point Likert scale), changes in breast measurements (primary augmentation only), and the subject's quality of life with their overall health, self-esteem, and body esteem. The questionnaires used to collect this information included the BREAST-Q© Augmentation Module (pre/post-operative) vesion 2.0: Satisfaction With Breasts, Rosenberg Self-Esteem Scale, SF-36v2SF® Health Survey, and Body Esteem Scales.

The Study will continue to follow subjects through 10 years after their breast implant surgery. Results provided here represent the first 3 years of data. This document will be updated as more information becomes available. You should also ask your surgeon if they have received any udated clinical information. The following sections provide more information about the complications and benefits you may experience following augmentation with Motiva Silicone Gel Breast Implants, based on the experiences of the augmentation patients in the Study.

18.2 What are the 3-year follow-up rates?

The 3-year follow up rates are 92.4% (415/449) for the primary augmentation cohort, 88.7% (94/106) for the revision augmentation cohort, and 91.7% overall (509/555). Compliance was calculated by visit type and based on the number of subjects who followed up divided by the number of subjects expected for a visit. There were 11 patients in the Primary Augmentation cohort and 7 in the Revision Augmentation cohort who followed up late outside the target follow-up visit window.

18.3 What are the benefits?

Subject satisfaction across both primary augmentation and revision augmentation subjects at Year 3 is 95.4% (475 out of 498 responses) and the overall physician satisfaction is 98.4% (out of 490 out of 498 responses).

Primary Augmentation

At the 3-year follow-up, the majority of primary augmentation subjects (97.1%) and physicians (99.0%) were satisfied with their results based on the 5-point Likert Scale.

For the BREAST-Q© Augmentation Module version 2.0 Satisfaction with Breasts questionnaire, 156 participants completed the questionnaire at baseline with a mean score of 37.4. Of the participants (n=141 subjects) who completed questionnaires at baseline and the Year-3 visit, there was a mean increase for individual patients of 41.6 points. There was a total of 383 participants who completed the BREAST-Q© questionnaire at Year 3 (regardless of baseline completion) with a mean satisfaction score of 82.0 points. The questionnaire is a 100-point scale, with higher numbers being better.

Many subjects (90.6%) in the primary augmentation cohort reported increased bra size by at least one cup size. The majority (57.8%) of the subjects increased by two to five cup sizes. 3.9% decreased or did not report the change in bra size (e.g., sports bra with different sizing or no bra).

For primary augmentation subjects, comparisons of Baseline SF-36 QOL scores to scores at Year 3 showed some changes; there were a number of decreases in the quality of life scales. However, effect sizes were small, so the observed changes may not be clinically relevant.

For the primary augmentation cohort, the measures and mean scores from baseline to Year 3 were:

Rosenberg Self-Esteem Scale (30-point scale)

- 25.8 to 25.8

Body Esteem survey (5-point scale)

- Overall, 3.9 to 3.9
- Physical Condition, 4.2 to 4.0
- Sexual Attractiveness, 3.9 to 4.0
- Weight Concern, 3.7 to 3.6

SF-36 survey (100-point scale)

- Bodily Pain, 92.5 to 86.9
- General Health, 88.6 to 85.2
- Mental Health, 83.3 to 79.6
- Physical Functioning, 97.1 to 96.2
- Role Emotional, 95.3 to 91.8
- Role Physical, 96.5 to 94.3
- Social Functioning, 95.0 to 90.6
- Vitality, 72.9 to 66.5

Revision Augmentation

Most revision-augmentation subjects (over 87.5%) and physicians (95.5%) were satisfied with their results of their revision implant surgery based on the 5-point Likert Scale.

For the BREAST-Q© Augmentation Module version 2.0 Satisfaction with Breasts question-aire, 13 participants completed the questionnaire at baseline with mean a score of 54.2 points. Of the participants (n=12 subjects) who completed questionnaires at baseline and the Year-3 visit, there was a mean increase for individual patients of 27.1 points. There was a total of 78 participants who completed the BREAST-Q© questionnaire at Year 3 (regardless of baseline completion) with a mean satisfaction score of 78.2 points. The questionnaire is a 100-point scale, with higher numbers being better.

Bra size changes were not analyzed for revision augmentation subjects. For revision augmentation subjects, comparisons of Baseline SF-36v2® scores to scores at Year 3 showed some changes. Only one of the six (i.e., Role Emotional) may be considered clinically relevant because the effect size was greater than 0.50 though the mean score at Year 3 (93.7) was higher/better than the national norm (79.5).[3]

For the revision augmentation cohort, the measures and mean scores from baseline to Year 3 were:

Rosenberg Self-Esteem Scale (30-point scale)

- 26.2 to 25.8

Body Esteem survey (5-point scale)

- Overall, 3.9 to 3.9
- Physical Condition, 4.2 to 4.1
- Sexual Attractiveness, 3.9 to 4.0
- Weight Concern, 3.8 to 3.7

SF-36 survey (100-point scale)

- Bodily Pain, 90.2 to 83.8
- General Health, 88.0 to 84.4
- Mental Health, 83.8 to 80.3
- Physical Functioning, 95.4 to 95.7
- Role Emotional, 97.1 to 93.7
- Role Physical, 95.6 to 94.7
- Social Functioning, 96.2 to 92.2
- Vitality, 75.6 to 70.3

For revision augmentation subjects, mean total self-esteem scores on the Rosenberg Self-Esteem Scale at Baseline and Year 3 reported high self-esteem responses (mean values greater than 25 points) at all time points, including baseline. No significant changes were found between baseline and Year 3.

Mean scores on the Body Esteem Scale and subscales showed no clinically significant change from Baseline to Year 3.

18.4 What are the 3-year complication rates?

Primary Augmentation
The complications observed in women who had primary augmentation through 3 years are presented in Table 11. The most common reported complication within the first 3 years after augmentation surgery was reoperation (6.1% or approximately 6 out of 100 subjects).

Table 11. Kaplan-Meier Risk Rates of Key Complications Reported Through 3 Years for Primary Augmentation Subjects

	By-Subject
Key Event[1-2]	**Primary Augmentation N=451 (95% CI)**
Any Complication (including reoperation)	8.4% (6.1%, 11.4%)
Reoperation	6.1% (4.3%, 8.8%)
Explantation with/without replacement	1.6% (0.8%, 3.3%)
Capsular Contracture III/IV	0.5% (0.1%, 1.8%)
Rupture – Suspected/Confirmed	0.6% (0.1%, 4.4%)
Rupture (MRI-Cohort)	0.6% (0.1%, 4.4%)
Rupture (Non-MRI-Cohort)	0
Infection	0.9% (0.3%, 2.4%)
RFID Failure	0
Other Complications Occurring at a Kaplan-Meier Risk Rate ≥ 1%	
Implant Malposition	3.2% (1.9%, 5.3%)

[1] The following complications were reported at a risk rate of less than 1%: animation deformity, asymmetry, breast pain, breast tissue atrophy, capsular contracture II with surgical intervention, delayed wound healing, hematoma, hypertrophic/abnormal scarring, implant palpability/visibility, infection, mass/cyst/lump, ptosis, nipple complications, skin rash, wrinkling/rippling.

[2] None of the following complications occurred: Breast Implant-Associated ALCL, breast/skin sensation changes, calcification, breast cancer new or recurrent, double capsule, fibrocystic disease, galactorrhea, granuloma, implant extrusion, implant rotation, inflammation, irritation, redness, seroma, nipple sensation changes, skin related, swelling, necrosis, upper pole fullness.

Revision Augmentation

The complications observed in women who had revision augmentation through 3 years are presented in Table 12. The most common reported complication within the first 3 years after revision-augmentation surgery was reoperation (25.8% or approximately 26 out of 100 subjects).

Table 12. Kaplan-Meier Risk Rates of Key Complications Reported Through 3 Years for Revision Augmentation Subjects

	By-Subject
Key Event[1-2]	**Revision Augmentation N=109 (95% CI)**
Any Complication (including reoperation)	28.4% (20.8%, 38.0%)
Reoperation	25.8% (18.5%, 35.4%)
Explantation with/without replacement	16.5% (10.6%, 25.1%)
Capsular Contracture III/IV	6.7% (3.2%, 13.5%)
Rupture – Suspected/Confirmed	0
Rupture (MRI-Cohort)	0
Rupture (Non-MRI-Cohort)	0
Infection	0.9% (0.1%, 6.4%)
RFID Failure	0
Other Complications Occurring at a Kaplan-Meier Risk Rate ≥1%	
Breast Pain	1.0% (0.1%, 6.6%)
Capsular Contracture II with surgical intervention	1.9% (0.5%, 7.4%)
Hematoma	1.8% (0.5%, 7.1%)
Implant Extrusion	1.0% (0.1%, 6.6%)
Implant Malposition	4.9% (2.1%, 11.3%)
Mass/Cyst/Lump	2.4% (0.6%, 9.4%)
Ptosis	4.8% (2.0%, 11.2%)
Asymmetry	3.9% (1.5%, 10.0%)
Double Capsule	1.0% (0.1%,6.6%)

[1] The following complications were reported at a risk rate of less than 1%: Infection.

[2] None of the following complications occurred: Animation Deformity, Breast Implant-Associated ALCL, breast tissue atrophy, breast/skin sensation changes, calcification, breast cancer new or recurrent, delayed wound healing, fibrocystic disease, galactorrhea, granuloma, hypertrophic/abnormal scarring, implant palpability/visibility, implant rotation, inflammation, irritation, redness, rupture, seroma, nipple complications, RFID failure, skin rash, skin related, swelling, necrosis, upper pole fullness, wrinkling/rippling.

18.5 What are the main reasons for reoperation?

Subjects may require a reoperation for a number of reasons, including size and/or style change, implant removal (with or without replacement), capsular contracture, incision and drainage, implant repositioning, scar revision, etc. In addition, patients may require more than one surgical procedure.

Primary Augmentation

In the Study, 27 (6.0%) of the subjects had at least one reoperation through 3 years (a total of 29 reoperations performed in 451 patients). Table 13 provides the main reasons for reoperation. The most common reasons for reoperation through 3 years in these subjects were Implant Malposition, Capsular Contracture, and Hematoma.

Table 13. Main reasons for Reoperation through 3 Years: Primary Augmentation Subjects (N=29 Reoperations)

Reasons for Reoperation through 3 Years	n (%)
Implant Malposition	13 (44.8%)
Capsular Contracture	3 (10.3%)
Hematoma	3 (10.3%)
Infection	2 (6.9%)
Hypertrophic/Abnormal Scarring	2 (6.9%)
Size Change/Subject Choice	2 (6.9%)
Animation Deformity	1 (3.4%)
Asymmetry	1 (3.4%)
Ptosis	1 (3.4%)
Mass/Cyst/Lump	1 (3.4%)

[1] Some reoperations were performed for multiple reasons; only the primary reason is provided in the table.

Revision Augmentation
In the Study, 27 (24.8%) of the subjects had at least one reoperation through 3 years (a total of 29 reoperations performed in 109 revision augmentation patients). Table 14 provides the main reasons for reoperation. The most common reasons for reoperation through 3 years were subject request for Size/Style Change of their implants, Capsular Contracture, and Ptosis.

Table 14. Main Reasons for Reoperation through 3 Years: Revision Augmentation Subjects (N=29 Reoperations)

Reasons for Reoperation through 3 Years	n (%)
Size Change/Subject Choice	6 (20.7%)
Capsular contracture	6 (20.7%)
Ptosis	5 (17.2%)
Hematoma	4 (13.8%)
Implant Malposition	2 (6.9%)
Implant Extrusion	1 (3.4%)
Breast Pain	1 (3.4%)
Upper Pole Fullness	1 (3.4%)
Asymmetry	1 (3.4%)
Infection	1 (3.4%)
Hypertrophic/Abnormal Scarring	1 (3.4%)

[1] Some reoperations were performed for multiple reasons; only the primary reason is provided in the table.

18.6 What are the main reasons for implant removal?
Breast implants may be removed (with or without replacement) to treat a complication or to improve the cosmetic result.

Primary Augmentation
In the Study, 1.6% of the subjects had at least one removal (a total of 13 implants from 7 patients). Table 15 shows that the most common reason for implant removal was subject request for implant size/ style change.

Table 15. Main Reasons for Implant Removal through 3 Years: Primary Augmentation Subjects (7 subjects with 13 implants removed)

Reason for Implant Removal	n (%)
Size Change/Subject Choice	6 (46.2%)
Capsular Contracture	5 (38.5%)
Implant Malposition	1 (7.7%)
Infection	1 (7.7%)

Revision Augmentation

In the Study, 16.5% of subjects had at least one removal (a total of 28 implants removed from 17 patients). As Table 16 shows, the most common reason for implant removal was due to patient request for implant size/style change.

Table 16. Main Reasons for Implant Removal through 3 Years: Revision Augmentation Subjects (17 subjects with 28 implants removed)

Reason for Implant Removal	n (%)
Size Change/Subject Choice	12 (42.9%)
Capsular Contracture	7 (25.0%)
Breast Pain	2 (7.1%)
Asymmetry	2 (7.1%)
Ptosis	2 (7.1%)
Infection	1 (3.6%)
Implant Extrusion	1 (3.6%)
Implant Malposition	1 (3.6%)

18.7 What are other clinical data findings?

The Study evaluated several possible long-term health effects that have been reported in breast implant patients. These include rupture, cancer, Connective Tissue Disorder (CTD), CTD signs and symptoms, complications with lactation, reproductive complications, and suicide.

Rupture. Out of a total 1,119 implants in 560 subjects in the primary and revision augmentation, there has been one suspected rupture in one patient through Year 3.

There is a total of 33 patients with 66 implants with RFID enrolled in the MRI Cohort.

There are 176 primary augmentation subjects enrolled in the MRI cohort study who have routine MRI screening of their implants to assess for rupture. Through 3 years, 99.4% of these patients (99.7% of implants) had no evidence of rupture. Through Year 3, there has been 1 suspected implant rupture occurring in one subject. Overall, the 3-year risk of rupture was 0.6% per patient in the primary augmentation cohort. This means that after receiving Motiva Implants®, less than 1 out of 100 women may experience a rupture during the first 3 years.

There are 42 revision augmentation subjects enrolled in the MRI cohort who have routine MRI screening of their implants to assess for rupture. Through 3 years, zero (0) subjects had evidence of rupture. Of the revision augmentation subjects in the study who were not evaluated by MRI, there were no (0) implant ruptures. Overall, the 3-year risk of rupture was 0.0% per patient in the revision augmentation cohort. This means that after receiving Motiva Implants®, 0 out of 100 women may experience a rupture during the first 3 years.

Cancer. Through 3 years for all subjects there were no reports of breast cancer, BIA-ALCL, and fibrocystic breast disease. There were two reports (less than 1%) of non-breast cancer (Gastrointestinal in one primary augmentation subject and Leukemia in one revision augmentation subject). No other cases of cancer were reported in any subjects.

Connective Tissue Disease (CTD) Signs and Symptoms. The study collected information on CTD signs and symptoms (that did not result in a diagnosis of a CTD) in augmentation and revision augmentation subjects every year during the follow-up visit. Thirty-three (33) patient-reported signs and symptoms were collected at the follow-up visits. The individual symptoms were combined into 7 categories for analysis including General/Other, Hematologic, Joint, Muscle, Neurological, Respiratory and Skin.

For primary augmentation subjects, through 3 years, the risk of experiencing any of the symptoms after implantation is 6.1%. For revision augmentation subjects, through 3 years, the risk of experiencing any of the symptoms after implantation is 5.3%. For both, general (depression, unexplained fever, dizziness, dry eyes, dry mouth, fatigue, generalized pain) and skin-related (e.g., hair loss, facial rash, photosensitivity, skin rash, urticaria, telangiectasia, pruritis) signs and symptoms were the most common.

Of note, CTD signs/symptoms were not collected at the initial visit for all subjects (prior to implantation); therefore, the risk estimates for symptoms may be potentially high because they also include signs/symptoms that were present before the subjects had the surgery.

The 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 or not these increases were due to the implants.

However, patients should be aware that there is a potential risk they may experience an increase in some general and skin symptoms after receiving breast implants.

Lactation Complications. Lactation complications including difficulties with breast feeding breast infection (mastitis), and pain were examined in the study.

For the primary augmentation subjects, 48.6% attempted breastfeeding with no difficulties, 42.6% never attempted to breastfeed, 7.8% had preoperative difficulties, and 1.1% had postoperative difficulties (e.g., inadequate milk production, mastitis), through 3 years.

For the revision augmentation subjects, 49.5% attempted breastfeeding with no difficulty, 41.3% never attempted breastfeeding, 9.2% reported preoperative difficulties, and 0.9% had postoperative difficulties through 3 years.

Reproduction Complications. Reproduction complications that were collected in the Study include, preeclampsia, endocrine disease (e.g. hypo- or hyperthyroidism, gestational diabetes), infertility, miscarriage, termination of pregnancy (due to medical reasons), and other reasons (such as ovarian cyst).

For primary augmentation, 2.4% of subjects reported at least 1 reproductive complication through 3 years. Complications reported include infertility (0.4%), miscarriage (1.6%), termination due to medical reasons (0.2%), and others, e.g. ovarian cyst, hysterectomy (0.4%).

For revision augmentation, 1.8% of subjects through 3 years reported reproductive issues. The reproductive issues include both preeclampsia and termination due to medical reasons, each at 0.9%.

Suicide. There were no reports of suicide in primary augmentation or revision augmentation patients in the study through 3 years.

Other Deaths. In the primary augmentation cohort, there was one reported death through 3 years due to rectal cancer complications. In the Revision Augmentation cohort, there was one reported death through 3 years due to a brain hemorrhage, as the result of a fall.

18.8 Study strengths and weaknesses

The Core Study includes a variety of strengths. The Study is a prospective and long-term (10-year) study and collects health related outcome data collected during surgeon office visits from multiple sites. Data collected also include patient reported outcomes. The overall follow-up rates at office visits was 91.7% at Year 3. Additionally, the study enrolled a variety of Motiva's Implant Styles (various volumes and projections).

Weaknesses of the study include: the lack of control group, enrollment not separated to enroll implant styles equally across the study, lack of baseline collection of CTD signs and symptoms.

19. INSTRUCTIONS FOR PATIENTS UNDERGOING MAGNETIC RESONANCE IMAGING (MRI)

You should be monitored continuously throughout the lifetime of your breast implant(s). It is important to have regular MRIs and/or ultrasounds (US) over the implants lifetime to screen for silent rupture, even if there appear to be no problems with them (as described earlier in this document).

Motiva Implants® without an RFID microtransponder for device identification do not require special MRI instructions.

For Motiva implants with RFID microtransponder:
During MRI, a small susceptibility artifact can be observed around the RFID. In bench testing, the image artifact extended approximately 15 mm out from the RFID microtransponder when imaged (The imaging was done using a gradient echo (GRE) pulse sequence and a 3-Tesla MR system). This is illustrated in Figure 5 below.

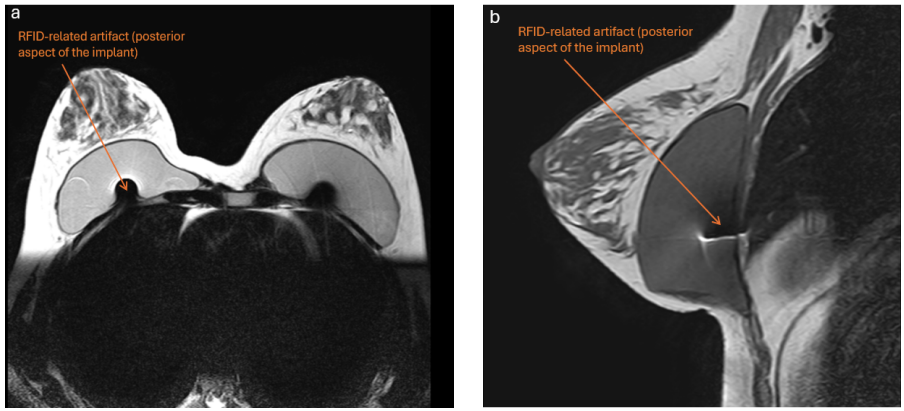


Figure 5. a) Axial and b) Sagittal views of MRI scan showing the RFID-related susceptibility artifact in the posterior aspect of the implant

Motiva Implants® containing an optional RFID microtransponder for Device Identification are labeled "MR Conditional". Patients implanted with Motiva Implants with a RFID microtransponder can safely undergo MRI under the following MR conditions:

MR Conditional

MRI SAFETY INFORMATION
A person with the Motiva Silicone Gel-Filled Smoothsilk Breast Implants® with a RFID microtransponder may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	**Motiva Silicone Gel-Filled Smoothsilk® Breast Implants with a RFID microtransponder**
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularity Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode
	3.2 W/kg head average SAR for 60 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode
MR Image Artifact	The presence of this implant may produce an image artifact

There is potential for decreased sensitivity of breast MRI in the evaluation of silicone implant integrity and potential for impact on visualization of surrounding tissue, including breast tissue.

Studies conducted by Motiva USA indicate that the use of "combined" or "dual" modality imaging techniques (i.e., MRI with another imaging method such as ultrasound) to detect silent rupture may considerably increase diagnostic accuracy when Motiva Implants® with microtransponder are present.

20. ADDITIONAL INFORMATION

20.1. Life expectancy

Motiva Implants® are not lifetime devices.

The longer you have breast implants, the greater the chances are that you will develop complications, some of which will require more surgery. According to the FDA[67] , the life of breast implants varies by person and cannot be predicted. That means everyone with breast implants may need additional surgeries, but no one can predict when. Patients can also request additional surgeries to modify the size or shape of their breasts.

21. BREAST IMPLANT TRACKING

Federal regulations require MOTIVA to track Motiva Round and Round Ergonomix silicone gel breast implants.

Motiva Implants® are subject to device tracking via the Motiva Device Tracking registration system. Your surgeon will register your implants at www.motivausa.com/instructions. They may contact Motiva USA customer service to receive assistance.

Implant registration will help ensure that Motiva USA has a record of each device's related information (such as ID, reference number, and serial number), surgery date, and patient and surgeon contact information, so that they can be contacted in the event of situations related to the device that patients should be made aware of.

22. PATIENT DEVICE IMPLANT CARD

Each implant comes with a Patient Device Implant Card, which should be given to you by your surgeon. It is important for you to keep a record of your surgical procedure in case of future consultations or additional surgeries.
The Patient Device Implant Card includes the following information:

- information documented on the patient record label (which should come affixed to the back of the card),
- your name (patient identification),
- the location position of the implant,
- date of implantation (surgery date),
- the name of the treating surgeon (healthcare center or doctor),
- Toll-free phone number to Motiva, and
- Web link to access the most current patient decision checklist, and labeling for the Motiva Implants®

This Patient Device Implant Card is for your permanent records and should always be kept safe.

Below are symbols that are used in Motiva product labeling and what they mean.

SYMBOLS IN PRODUCT LABELING					
	Patient Identification		Manufacturer	MD	Medical device
	Health care center or doctor	REF	Catalogue number	SN	Serial Number
	Date	VOL	Implant Volume		MR conditional, the device can be imaged safely under the tested specifications described in Directions for Use
	Position of the implant	UDI	Unique Device Identifier		

23. PRODUCT EVALUATION

Motiva USA requires that complications resulting from the use of Motiva Implants® be reported immediately to your doctor. Your doctor must fill out all the necessary information using the Motiva Implants® Complaint Form available at the following webpage: www.motiva.health/support/

24. REPORTING AND ADDITIONAL INFORMATION

If you need additional information related to Motiva Implants®, contact Customer Care at 1 (800) 924-5072. If any serious incident occurs, immediately contact your surgeon and report the event to www.motivausa.com/support/ or the Motiva USA Customer Care number listed above.

Motiva USA contact office location:

CONTACT INFORMATION

Motiva USA LLC
125 East De La Guerra Suite 203A
Santa Barbara, CA 93101
Phone: 1 (800) 924-5072
Email:customercare@motivausa.com

In addition to informing your doctor, you can report a problem to Motiva Implants® and/or to the U.S. Food and Drug Administration (FDA). Your doctor or other healthcare provider may do this or you may report it yourself.

You can report any serious problem directly to the FDA through its voluntary reporting program called MedWatch. (See http://www.fda.gov/medwatch). There is a special form to use for voluntary reporting (FDA Form 3500). You can obtain it several ways:

- Complete Form 3500 and submit it online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm,
- Download Form 3500 from the website (https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm) and print it out, fill it in, and send it to FDA, or
- Call FDA to get a reporting package at 1-800-FDA-1088 (1-800-332- 1088).

If you need to complete a Form 3500, FDA recommends that you take Form 3500 to your doctor, who can help you to complete it.

25. WHERE TO FIND MORE INFORMATION

Motiva USA has more information about its silicone gel breast implants that is available to you. You may request a copy of the package insert given to surgeons that describes how to use the Implant. It also discusses safety information and research performed on implants in general and on Motiva Implants® in particular. Note that this document is intended only for surgeons, so it has a large amount of medical and technical language.

You can find more detailed information on the studies (in animals and humans or other laboratory testing) done on these Implants in Motiva Implants® Summary of Safety and Effectiveness Document (SSED) on FDA's website at: http://www.fda.gov/breastimplants.

You can find these resources on Motiva Implants® website at http://www.motivausa.com/support/ or through Motiva Implants® Customer Care at:
Phone: 1 (800) 924-5072 or
Email:customercare@motivausa.com

There are several other sources of information about breast implants and breast implant surgery.

The U.S. Food and Drug Administration (FDA) has a website for information on breast implants as well as things to consider before getting breast implants. It contains descriptions of the risks of having breast implants (similar to this brochure) and links to more information. FDA website is at: http://www.fda.gov/breastimplants.

Professional organizations for surgeons offer helpful information on their websites about making decisions about plastic/cosmetic surgery and about choosing a surgeon. You can find this information at the following websites:

The American Society for Aesthetic Plastic Surgery - http://www.surgery.org
American Society of Plastic Surgeons - http://www.plasticsurgery.org

In 2000, the Institute of Medicine (IOM) published a comprehensive review of studies that have looked at the safety of silicone gel breast implants. The report is available on the website: https://www.ncbi.nlm.nih.gov/books/NBK44776/.

Patient groups offer support and information to women who have had problems with their breast implants. Several such websites are listed at: http://www.fda.gov/breastimplants.

26. BREAST IMPLANT REGISTRY

In collaboration with the U.S. Food and Drug Administration (FDA), breast implant device manufacturers, and patients, The Plastic Surgery Foundation (PSF) has developed the National Breast Implant Registry (NBIR) for the purpose of strengthening national surveillance for breast implant devices in the United States. The NBIR is a database that collects information on breast implant procedures and devices. Collecting this information will allow the NBIR, plastic surgeons, and breast implant manufacturers to identify trends and other helpful safety information that can be used to improve the safety of breast implants for you and future patients. You are encouraged to ask if your surgeon is participating in this registry. The surgeons may access it through registering at https://www.thepsf.org/research/registries/nbir.

The NBIR collects clinical data including outcomes data at the time of surgery and reoperation including demographic information, procedural and complications data related to breast implants. It also collects information about you and your procedure, including your contact information for future follow-up, information about your medical history, your breast implant operation and the implant itself, and any other complications or adverse events that may have occurred from your breast implant operation. The NBIR is open to all patients who undergo breast implant procedures in the United States, the information collected in the NBIR is used to improve the quality of care for all patients who undergo a breast implant procedure. Information from the NBIR can be analyzed to find trends in breast implant procedures, as well as identify potential complications that occur.

To learn more about the NBIR visit the following link: https://www.thepsf.org/documents/Research/Registries/NBIR/nbir-patient-faq.PDF

27. WARRANTY INFORMATION

Motiva USA warrants that this product is manufactured to meet approved specifications and is free of manufacturing defects at the time of shipment. To the extent permitted by applicable law, Motiva USA shall not be responsible for any damages or expenses directly or indirectly arising from the use of this product. In the event Motiva USA determines that the product contains a manufacturing defect, its sole responsibility to you shall be outlined in the warranty program terms and conditions. The complete terms and conditions of the Motiva USA warranty Program can be reviewed on the website www.motivausa.com, or can be provided by your implanting surgeon or local Motiva USA representative. This warranty is in lieu of and excludes all other warranties not expressly set forth there-in, whether express or implied by operation of law, or otherwise, including, but not limited to, any implied warranties of merchantability, suitability for use or performance.

28. PATIENT DECISION CHECKLIST

To the patient considering breast implants filled with silicone gel intended for breast augmentation:

The review and understanding of this document is a critical step in making the decision whether you should choose breast implant surgery. You should learn about breast implants and then carefully consider the benefits and risks associated with breast implants and breast implant surgery before you make that decision. This form lists important risks, including those known or reported to be associated with the use of the device based on information from clinical trials, scientific literature, and reports from patients who have undergone device placement.

This patient decision checklist is intended to supplement the additional patient labeling that should be provided to you by your physician. You should receive a patient booklet/brochure that includes important information about your specific breast implant, as well as a boxed warning and patient decision checklist. After reviewing the information in the patient information booklet/brochure for the specific implant that will be used, please read and discuss the items in this checklist carefully in consultation with your physician. You should place your initials in the location provided next to each item to indicate that you have read and understood the item. Your full signature at the end of this document means that you have read the materials and that your physician has answered all questions to your satisfaction.

Considerations for a Candidate for Successful Breast Implantation

I understand that I am not a candidate for breast implants if any of the following situations applies to me:

- I have an active infection anywhere in my body;
- I have an existing cancer or pre-cancer of my breast tissue that has not been adequately treated; or
- I am pregnant or nursing.

I understand that if I have any of the following conditions, I may be at a higher risk for a poor surgical outcome:

- Medical condition that affects my body's ability to heal (e.g., diabetes, connective tissue disorder);
- Active smoker or a former smoker;
- Currently taking drugs that weaken the body's natural resistance to disease, such as steroids and chemotherapy drugs (e.g., prednisone, tacrolimus, sirolimus, mycophenolate, azathioprine, cyclosporine, methotrexate, chlorambucil, leflunomide, or cyclophosphamide);
- History of chemotherapy or planned chemotherapy following breast implant placement;
- History of radiation therapy or planned radiation following breast implant placement;
- Conditions that interfere with wound healing or blood clotting (e.g., hemophilia, von Willebrand disease, factor V Leiden, hyperhomocysteinemia, protein C deficiency, anti-thrombin III deficiency, or systemic lupus erythematosus); or
- Reduced blood supply to the breast tissue

I understand the following conditions have not been adequately studied to determine whether the conditions put me at higher risk:

- Autoimmune disease (e.g., Hashimoto's, Lupus, Rheumatoid Arthritis) or family history of autoimmune disease (breast implant premarket clinical studies have not evaluated the safety of breast implants in patients with autoimmune disease);
- Clinical diagnosis of depression or other mental health disorder (including body dysmorphic disorder or eating disorder); or
- Have other products permanently implanted in the breast.

Patient Initials: _____

Risks of Breast Implant Surgery

I understand that there are risks of undergoing breast implant surgery. The percentages specified below were reported in the 3-year Core Study for Motiva Implants®. Each rate represents the largest percentage reported for Motiva implants in Augmentation or Revision-Augmentation

through 3 years. I understand that risks of undergoing breast implant surgery with Motiva Implants® may include:

- breast pain (reported in up to 1.0% of patients),
- skin or nipple sensitivity changes or loss (may occur but was not reported in any patients through 3 years),
- asymmetry (reported in up to 3.9% of patients),
- impact of aging or weight change on size and shape of breast (ptosis) (reported in up to 4.8% of patients),
- infection requiring possible removal of implant (reported in up to 0.9% of patients),
- swelling (was not reported in any patients through 3 years, but may occur with other reported risks)
- scarring (reported in up to 0.2% of patients),
- fluid collections (seroma) (may occur but was not reported in any patients through 3 years),
- hematoma (reported in up to 1.8% of patients),
- tissue death of breast skin or nipple (may occur but was not reported in any patients through 3 years),
- breast feeding difficulties (reported in up to 1.1% of patients),
- complications of anesthesia (may occur but was not reported in any patients through 3 years),
- bleeding (was not reported in any patients through 3 years, but may occur with other reported risks such as hematoma),
- chronic pain (may occur but was not reported in any patients through 3 years),
- damage to surrounding tissue, such as muscle, nerves, and blood vessels (may occur but was not reported in any patients through 3 years), and
- impact on imaging of breast tissue (may occur but was not reported in any patients through 3 years).

My physician has discussed these risks and has provided me with the patient information booklet/brochure (including the boxed warning) with information on the types of risks that are possible and expected rates of occurrence.

My physician has discussed the potential use of other implanted products during my breast implant surgery. My physician has also discussed the risks and benefits of using these implanted products and their planned surgical approach.

Patient Initials: _____

Risk of Cancer - Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA- ALCL)

I understand that breast implants are associated with the development of a type of cancer of the immune system called Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Information regarding the number of medical device reports of BIA-ALCL can be found on FDA's website[63]. I have received information regarding the overall incidence rates of BIA- ALCL and the rates as they pertain to my specific breast implant.

I understand that this cancer has been reported more frequently for textured breast implants, but that patients with smooth surfaced implants have also been diagnosed.

I understand that patients with breast implants have a risk of developing BIA-ALCL within the scar tissue and fluid surrounding the breast implant.

I understand that BIA-ALCL typically takes several years to develop after implantation, but cases have been reported as early as within one year. Typical symptoms to be aware of include: swelling, breast tightness, pain, lumps, or swelling of the breast months or years after I receive my implants.

I understand that treatment for BIA-ALCL involves an operation to remove the implants and the surrounding scar tissue capsule. Based on the stage of the cancer at diagnosis, some patients have required chemotherapy or radiation. While BIA-ALCL typically responds well to therapy, some patients have died from BIA-ALCL. Diagnosis and treatment may be at my own expense and is not always covered by insurance.

Patient Initials: _____

Systemic Symptoms
I understand that some patients who have received breast implants have reported a variety of systemic symptoms including joint pain, fatigue, rash, memory loss, and "brain fog" that some patients have called breast implant illness. While the causes of these symptoms are unclear, some patients have reported relief of these symptoms with removal of their implants and surrounding scar tissue capsule, however not all patients may experience improvement in their symptoms. Researchers are working to better understand the possible link between breast implants and these symptoms.

I also understand that some patients with breast implants have reported health problems in their children after birth or breastfeeding. While a causal link between breast implants and these reported health problems in children has not been demonstrated, more research is needed. I understand that breast implants and breast surgery may interfere with my ability to successfully breastfeed.

Patient Initials: _____

Breast Implant-Specific Risks
I understand that a breast implant is NOT a lifetime device and the longer I have my implants, the more likely I am to experience a complication and the more likely I am to require a reoperation requiring the replacement or removal of my breast implant. As many as 16.5 percent of women who receive breast implants for augmentation have to have their implants removed within 3 years as reported in the 3 year MOTIVA Core Study, but my implants may last for a shorter or longer time.

I understand that my breast implant may rupture or leak at any time, and that the longer I have my implants, the more likely I am to experience a complication such as rupture. I understand that gel bleed (small quantities of chemicals diffusing from the implant shell) of silicone gel-filled implants may occur. I understand that if I have a saline-filled implant, my breast may deflate in appearance if there is a rupture or leakage of the saline.

I understand that if I have a silicone gel-filled breast implant, I or the physician may not be able to tell on physical exam whether my implant has ruptured or is leaking silicone gel. Because rupture or leakage of silicone gel-filled breast implants is difficult to detect, I understand that periodic imaging evaluation is recommended for screening of silicone gel-filled breast implant rupture. It is recommended that I have periodic imaging of my silicone gel-filled breast implants to screen for implant rupture regardless of whether my implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on my medical history or circumstances (i.e., screening mammography for breast cancer).

Even if I have no symptoms, I should have regular imaging evaluations as described in the "Recommended Follow-Up" section below. These imaging evaluations may not detect all ruptures or leaks, be costly, and the expense may not be covered by my medical insurance.

I understand that silicone can migrate from my implant into nearby tissues (e.g., chest wall, lymph nodes under the arm) and organs (e.g., liver, lungs) where it may not be possible to remove.

I understand that all breast implants can interfere with mammography and breast exams, which could delay the diagnosis of breast cancer. Mammography can also cause the breast implant to rupture or leak. I should tell the mammography technician if I have breast implants.

I understand that the long-term risks of breast implants may include (Each rate represents the largest percentage reported for Motiva implants in Augmentation or Revision-Augmentation through 3 years) painful or tightening of scar tissue (capsule) around my implant (capsular contracture) (reported in up to 6.7% of patients),

- rupture or leaking of the implant (reported in up to 0.6% of patients),
- wrinkling (rippling) of the implant (reported in up to 0.5% of patients),
- visibility of the implant edges (reported in up to 0.2% of patients),

- shifting of the implant (reported in up to 4.9% of patients), or
- need for reoperation (reported in up to 25.8% of patients).

I understand that I will receive a "Patient Device Implant Card" after my surgery that has information on each of my specific implants. I understand that it is important for me to keep each card in case I or my physician need to know what kind of implant I have many years later.

I understand that all breast implants contain chemicals and heavy metals. I understand that most of these chemicals stay inside the shell of the implant, but small quantities have been found to diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking. A list of the components, chemicals, and heavy metals is available in the patient information booklet/ brochure.

Patient Initials: _____

Recommended Follow-up
Even if I have no symptoms, I should have my first ultrasound or MRI at 5-6 years after my initial implant surgery and then every 2-3 years thereafter. If I have symptoms or uncertain ultrasound results for breast implant rupture at any time, an MRI is recommended.

I understand that I will need routine and regular follow-up with my physician as long as I have a breast implant for examination of my breast implant as well as to discuss any updates regarding breast implant issues.

National Breast Implant Registry (NBIR): I understand and have discussed with my physician that there is a National Breast Implant Registry where information regarding my health and breast implant information can be entered. The NBIR may help understand the long-term safety and performance of breast implants.

Patient Registry and Outcomes For breast Implants and Anaplastic Large Cell Lymphoma (ALCL) etiology and Epidemiology (PROFILE): I understand and have discussed with my physician that there is a registry (PROFILE) where information is collected to better understand BIA-ALCL in patients with breast implants.

Patient Initials: _____

Questions for My Physician
I have had the opportunity to ask my physician questions about their experience, medical degree, specialty of training, and credentials. I understand that breast implants have associated procedural risks and should only be used by physicians who are appropriately trained.

Patient Initials: _____

Options Following Mastectomy (If applicable)
I understand that breast reconstruction is an elective procedure which I can choose to do or not.

I understand that I may choose not to have breast reconstruction ("going flat") and may choose to use an external prosthesis in my bra to look like I have a breast when wearing clothes.

I understand the surgical options for breast reconstruction, including the use of a breast implant and the use of my own tissue ("autologous reconstruction").

I understand that if my breast implants are ever removed, I may be left with dimpling, chest wall concavity, puckering, or sagging of my breasts or skin.

I understand that more surgeries may be necessary in the future due to complications or to remove or replace the breast implants.

I have discussed all of the options for breast reconstruction with my provider, including whether I am a candidate and the benefits and risks of each, and I believe that breast reconstruction with a breast implant is the best option for me.

Patient Initials: _____

Breast Augmentation Options

I understand that breast augmentation is an elective procedure to increase the size of my breasts. I understand that breast augmentation may result in permanent changes to my breast tissue and if my implants are ever removed, I may be left with unsatisfactory appearance, changes to the size and shape of my breasts, including but not limited to dimpling, chest-wall concavity, puckering, sagging, or different incision size or location.

If I am an augmentation patient, any additional surgeries or medical procedures will likely be at my own expense.

Patient Initials: _____

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the patient information booklet/brochure for the specific implant that will be used during my surgery and that I have had time to discuss the information in it and on this document with my physician. I have had the opportunity to ask questions and understand the benefits and risks of breast implants for me, given my specific health conditions. I have considered alternatives to breast implants, including reconstruction without breast implants, no reconstruction/augmentation, and their benefits and risks.

Patient Signature and Date

_____

Physician: I acknowledge that I have discussed the benefits and risks of breast implants as described elsewhere in the patient information booklet/brochure and in this checklist. I have also explained the benefits and risks of the alternatives. I have encouraged the patient to ask questions, and I have addressed all questions.

Physician Signature and Date

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