Establishment Labs S.A. / Motiva USA

Directions for Use

Motiva® 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.

Caution:
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.

Table of Contents

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.

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.

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

INTRODUCTION

Directions to the Physician

The information contained in this Directions for Use (DFU) is intended to provide an overview of essential information about Motiva Implants® Silicone Gel-Filled Breast Implants (also referred to as "Motiva Implants®" or the "Implants"), including a device description, indications for use, contraindications, warnings, precautions, important factors for a patient to consider, adverse effects, other reported conditions, and a summary of the Motiva Implants® Core Clinical Study (also referred to as the "Study"). There is a ***Boxed Warning*** for all breast implants (see Cover Page).

Patient Counseling Information

As with any surgical procedure, breast implantation is not without risks. Breast implantation is an elective procedure, and the patient must be well counseled and understand the risk/benefit relationship. You should review this document and the patient labeling, including the Patient Decision Checklist highlighting key information regarding the risks of breast implant surgery, before counseling the patient about Motiva Implants® and breast implant surgery. Please familiarize yourself with the content of this document and resolve any questions or concerns before proceeding with the use of this device. You should thoroughly review all risk information with the patient and address all questions prior to signing the checklist along with the patient.

Before deciding to proceed with surgery, you should instruct the patient to read the document titled: Motiva Implants® Information for the Patient: Breast Augmentation with Motiva Implants® Silicone Gel-Filled Breast Implants and discuss with the patient the warnings, precautions, important factors to consider, complications, and the Study results listed in the patient labeling. You should advise the patient of the potential complications and that medical management of serious complications may include additional surgery and explantation. Please refer to this document's INFORMATION TO BE DISCUSSED WITH THE PATIENT section for additional patient counseling information.

Informed Decision

Each patient should receive the Motiva Implants® Information for the Patient brochure during their initial visit/consultation to allow the patient sufficient time to read and adequately understand the risks, follow-up recommendations, and benefits associated with silicone gel breast implant surgery.

Allow the patient at least 1-2 weeks to review and consider this information before deciding to have primary breast surgery. In the case of revision surgery, it may be necessary to perform surgery sooner.

To document a successful informed decision process, the Motiva Implants® Information for the Patient brochure includes a Patient Decision Checklist, which should be signed by both the patient and the surgeon and then retained in the patient's file. A copy should also be provided to the patient.

Device Tracking

Silicone Gel-Filled Breast Implants are subject to device tracking per United States Food and Drug Administration (FDA) regulation. Tracking is intended to facilitate notifying patients in the event that important new information about a device becomes available. The laws that govern device tracking require physicians to report certain information relating to their practice, the breast implants used, and the patients who receive breast implants (21 CFR §821.30).[1] A physician prescribing Silicone Gel-Filled Breast Implants is required, by federal regulation, to comply with Device Tracking Regulations, and report the following to Motiva USA:

- The serial number of the implanted device(s),
- The date of the implant surgery,
- Patient's name,
- The patient's personal contact information (including address, telephone number, and date of birth),

- Contact information for the prescribing physician's practice and the physician who regularly sees the patient for primary care, and
- When applicable, the date the device was:
  - Explanted, with the name, mailing address, and telephone number of the explanting physician;
  - Out of use due to patient death (date of death);
  - Returned to the manufacturer;
  - Permanently disposed of.

Tracking continues until the Implant is returned, destroyed, explanted, or the patient becomes deceased. Tracking information will be recorded on the Device Tracking Form supplied by Motiva USA with each Implant. The form should then be returned to Motiva USA at www.motivausa.com/instructions.

Motiva USA strongly recommends that all patients receiving Motiva Implants® participate in the Motiva Implants® Device Tracking program.

Patients are not required by law to enroll themselves in any tracking program or device registry. However, participation in the Motiva Implants® Device Tracking program is necessary to activate the Motiva Implants® Warranty section of this DFU. Patients must allow their physicians to share contact information and information about the Implant to activate the warranty.

The National Breast Implant Registry

The Plastic Surgery Foundation has developed the National Breast Implant Registry (NBIR) in collaboration with the FDA, patients, and breast implant manufacturers to strengthen the post-market surveillance of breast implant devices in the United States. The NBIR, first launched in 2018, is a quality improvement initiative and safety surveillance registry that collects clinical, procedural, and outcomes data at the time of operation and any subsequent reoperations for all US patients receiving breast implants. NBIR allows surgeons to register implants with the manufacturers for the purpose of device tracking while also submitting data to the registry.
Go to thepsf.org/NBIR to register and start data entry.

Device Description

Motiva® SmoothSilk® Round and SmoothSilk® Round Ergonomix® Silicone Gel-Filled Breast Implants are comprised of a single-lumen silicone elastomer shell and a filler made of silicone gel. The Shell is constructed of successive cross-linked layers of silicone elastomer (standard dispersion) and a low diffusion barrier layer (barrier dispersion) containing a blue pigment, which together provide the mechanical characteristics and integrity of the device. The material components of the Shell and the Gel of the SmoothSilk® Round and SmoothSilk® Round Ergonomix® devices are identical although there are differences in the construction of each device type; the SmoothSilk® Round Ergonomix® implant contains one less layer of standard dispersion and a gel that is slightly less firm than the SmoothSilk® 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.

A passive radio frequency identification device (RFID) that is placed in the gel at the shell/patch area is an optional feature for all implant styles. This optional microtransponder provides each Implant with a unique electronic serial number for traceability.

For implant styles, the base range is 9.0 cm to 14.5 cm, the projection range is 2.4 cm to 5.7 cm (mini, demi and full projection styles), and the volume range is 150 cc to 625 cc. The Implants are dry heat sterilized and are available in various, gel types, shapes, profiles, and sizes. Tables 1 and 2 provide the available styles and sizes of the Motiva® SmoothSilk® Round and SmoothSilk® Round Ergonomix® Breast Implants. Figure 1 provides visuals of the SmoothSilk® Round and SmoothSilk® Round Ergonomix® Implants.

Table 1. Available Styles and Sizes of Motiva® SmoothSilk® Round Implants*

Motiva® SmoothSilk® Round Implants						
Base Width (cm)	MINI		DEMI		FULL	
	Projection (cm)	Volume (cc)	Projection (cm)	Volume (cc)	Projection (cm)	Volume (cc)
10.0			3.5	205		
10.25			3.5	215	4.2	255
10.5			3.6	230	4.3	275
10.75			3.7	245	4.4	295
11.0			3.8	265	4.5	315
11.25			3.8	285	4.6	335
11.5	2.8	245	3.9	300	4.7	355
11.75	2.8	260	3.9	320	4.8	375
12.0	2.9	275	4.0	340	4.9	400
12.25	2.9	290	4.0	360	5.0	425
12.5	3.0	310	4.1	380	5.1	450
13.0	3.1	360	4.3	425	5.3	500
13.5	3.2	400	4.4	475	5.5	550
14.0			4.5	525	5.7	625

**All Round Styles available with an optional microtransponder*

Table 2. Available Styles and Sizes of Motiva® SmoothSilk® Round Ergonomix® Implants*

Motiva® SmoothSilk® Round Ergonomix® Implants						
Base Width (cm)	MINI		DEMI		FULL	
	Projection (cm)	Volume (cc)	Projection (cm)	Volume (cc)	Projection (cm)	Volume (cc)
9.0			3.3	155		
9.5			3.4	180		
9.75	2.4	150	3.4	190		
10.0	2.5	160	3.5	205		
10.25	2.5	170	3.5	215	4.2	255
10.5	2.6	185	3.6	230	4.3	275
10.75	2.6	205	3.7	245	4.4	295
11.0	2.7	220	3.8	265	4.5	315
11.25	2.7	230	3.8	285	4.6	335
11.5	2.8	245	3.9	300	4.7	355
11.75	2.8	260	3.9	320	4.8	375
12.0	2.9	275	4.0	340	4.9	400
12.25	2.9	290	4.0	360	5.0	425
12.5	3.0	310	4.1	380	5.1	450
13.0	3.1	360	4.3	425	5.3	500
13.5	3.2	400	4.4	475	5.5	550
14.0	3.3	430	4.5	525	5.7	625
14.5	3.4	475	4.6	575		

**All Motiva® SmoothSilk® Round Ergonomix® Styles available with an optional microtransponder*

Figure 1: Anterior, side, and lateral views of a Motiva® SmoothSilk® Round (top) and SmoothSilk® Round Ergonomix® (bottom) breast implant. Both SmoothSilk® Round and SmoothSilk® Round Ergonomix® are round in shape. However, the SmoothSilk® Round Ergonomix® has one less shell layer and a softer gel versus the SmoothSilk® Round breast implants. The differences in the gel type and the number of shell layers result in a softer feel and may allow for more gel movement with gravity for SmoothSilk® Round Ergonomix® versus the SmoothSilk® Round implants.

INDICATIONS FOR USE

The Motiva® SmoothSilk® Round and SmoothSilk® 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).

CONTRAINDICATIONS

Breast implant surgery is contraindicated in women:

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

WARNINGS

Boxed Warning

There is a Boxed warning on all breast implants:

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.

AVOID DAMAGING THE IMPLANT

The most common causes of implant rupture include damage to the Implant that occurs during the surgical implantation or other related medical procedures. Accordingly, physicians should not use excessive force and should minimize the handling of the Implant during surgical insertion.

- Do not allow cautery devices or sharp instruments, such as scalpels, suture needles, hypodermic needles, hemostats, Adson forceps, or scissors to contact the Implant during the implantation procedures.
- Use an appropriate length incision to accommodate the style, size, and profile of the Implant.

- Do not treat capsular contracture by closed capsulotomy or forceful external compression, which could likely result in implant damage, rupture, folds, and/or hematoma.
- Use care in subsequent procedures, such as open capsulotomy, breast pocket revision, hematoma/seroma aspiration, and biopsy/ lumpectomy to avoid damage to the Implant. Repositioning of the Implant during surgical procedures should be carefully evaluated by the medical team, and care taken to avoid contamination of the Implant. Excessive force during any subsequent procedure can contribute to localized weakening of the breast implant shell, potentially leading to decreased device performance.
- Do not immerse the Implant in liquid such as Betadine or other iodine solution. If Betadine is used in the pocket, ensure that it is rinsed thoroughly so that no residual solution remains in the pocket.
- Do not alter the implants or attempt to repair or insert a damaged implant.
- Do not reuse or re-sterilize any implant that has been previously implanted.
- Breast implants are intended for single use only.
- Do not place more than one Implant per breast.
- Do not use the periumbilical approach to place this Implant.

RFID and Imaging

The Motiva Implant® styles that contain an optional RFID microtransponder for Device Identification are labeled MR Conditional. Patients implanted with these devices may safely undergo MRI under specific conditions. 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 increase diagnostic accuracy when Motiva Implants® with microtransponder are present. During MRI, a small susceptibility artifact can be observed around the RFID that projects into the lumen of the breast implant and can be visualized in the images (Figures 2 and 3). 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.

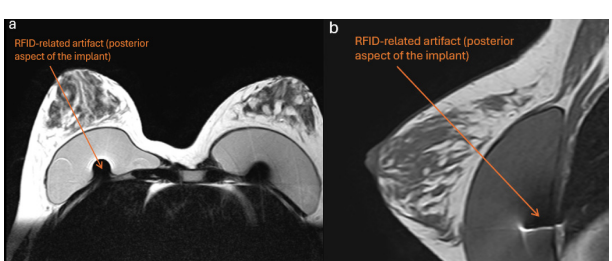

Figure 2. a) Axial and b) sagittal view of MRI scans of a SmoothSilk® Round Ergonomix® implant (ERSD-285Q) using a 1.5 Tesla MR machine. The image shows the RFID-related susceptibility artifact in the posterior aspect of the implant. Source: Establishment Labs, Medical Imaging and Patient Reported Outcomes-Study of the Long-Term Effectiveness of the Motiva® Implants® SmoothSilk® Round and SmoothSilk® Round Ergonomix® in Primary and Revision Breast Augmentation (MIRO) Study.

For MR Safety information see section INSTRUCTIONS WHEN PATIENTS UNDERGO MAGNETIC RESONANCE IMAGING (MRI).

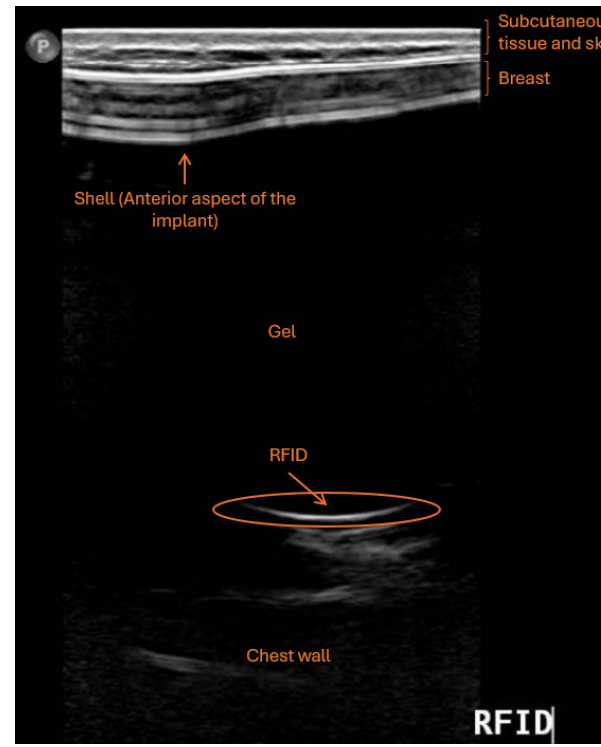

Figure 3. Ultrasound image of the left breast at the site of the RFID with visualization of the posterior wall without artifact. The curvilinear increased echogenicity represents the RFID (where arrow points). Source: Nelson MT, Meisamy S. High Risk Breast Cancer Patient with Silicone Breast Implant and Q Inside Safety Micro Transponder. OJMI. Dec 2019;9: 52-57. Doi: 10.4236/ojmi.2019.94005

Microwave Diathermy

Do not use microwave diathermy in patients with breast implants, as it has been reported to cause tissue necrosis, skin erosion, and implant extrusion.

PRECAUTIONS

Specific Populations, Surgical Precautions, and Implant Considerations

- A thorough discussion should be conducted with the patient, employing appropriate visual aids to clarify her objectives and manage expectations in order to reduce the incidence of reoperation for size change.

- The following may cause implants to be more palpable: larger implants, subglandular placement, and insufficient skin/tissue available to cover the Implant.
- Available tissue must provide adequate coverage of the Implant.

Incision Site Selection

You should choose one of the following incision sites based on your patient's particular needs, (Figure 4):

- Inframammary incision
- Periareolar incision
- Transaxillary incision

The periumbilical approach has not been studied in the Motiva Implants® Study and should not be used for various reasons, including potential damage to the implant shell.

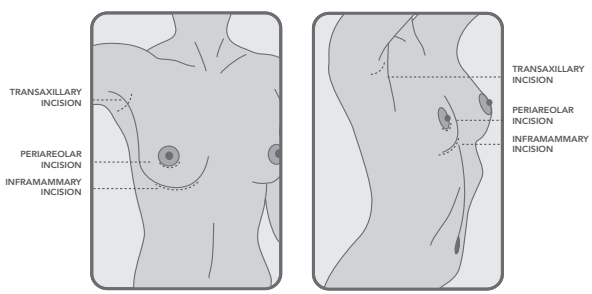

Figure 4. Anatomical Location of Incision Site Options for Breast Implants

Specific Populations

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

- Autoimmune diseases,
- A compromised immune system (for example, currently receiving immunosuppressive therapy),
- Conditions that interfere with wound healing and blood clotting,
- Reduced blood supply to breast tissue,
- Chemotherapy or radiation to the breast following implantation, and
- Clinical diagnosis of depression or other mental disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders with your patient prior to surgery. Patients with a diagnosis of depression or other mental disorders should wait until the resolution or stabilization of these conditions before undergoing breast implantation surgery

Implant Selection

To avoid possible injury or damage to the incision site(s), you should advise your patients to avoid the following for the first month after surgery:

- Sun exposure
- Jerky movements or activities that stretch the skin incision site(s),
- Participating in sports or other activities that raise the pulse or blood pressure, and
- Unnecessary physical or emotional stress.

Surgical Precautions

Surgical precautions, such as those described below, should be undertaken to maximize a successful aesthetic result and the long-term performance of the device.

Surgical Technique

The implantation of Motiva Implants® involves various surgical techniques. Therefore, you should use the method that, in your own best medical judgment, will provide the patient with the desired outcome consistent with these Directions for Use.

Implant Selection and Placement

To properly select the correct Implant, the following considerations should be considered and, as appropriate, discussed with the patient, (Figure 5):

- The Implant should be consistent in size with the patient's chest-wall dimensions, including base width measurements, laxity of the tissue, and projection.

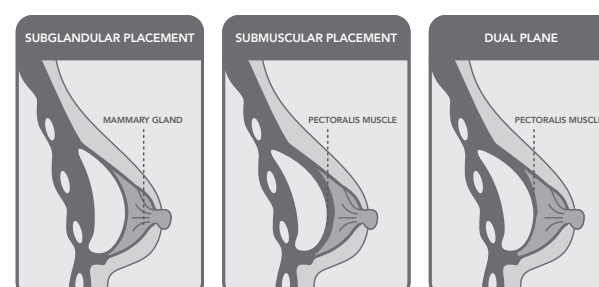

Figure 5. Anatomical Locations of Placement Options for Breast Implants

A well-defined, dry pocket of adequate size and symmetry must be created for implant placement.

Possible benefits of sub-muscular placement are that it may result in less palpable implants, less likelihood of capsular contracture (2000)[2], and more accessible imaging of the breast for mammography. Also, submuscular placement may be preferable if the patient has thin or weakened breast tissue. Subglandular placement may result in more palpable implants, greater likelihood of capsular contracture (2004-2005),[3,4] and increased difficulty in imaging the breast with mammography. The benefits of subglandular placement include easier and quicker recovery than submuscular, less

animation deformity during physical activity, and may provide a more natural look and feel. Alternatively, dual plane placement includes placing the upper portion of the implant under the pectoral muscle, and the lower half is directly under the mammary/glandular tissue. Subfascial placement, placing the implant above the pectoral muscle but underneath the fascia, has also been used.

INFORMATION TO BE DISCUSSED WITH THE PATIENT

Breast implantation is an elective procedure, and the patient must be thoroughly counseled on the risks and benefits of these products and procedures. You should advise your patient that she must read the patient labeling for augmentation.

The patient labeling is intended as the primary means to provide consistent risk and benefit information to assist your patient in making an informed decision about primary breast augmentation and revision-augmentation but is not intended to replace consultation with you. The patient should be advised to wait at least 1-2 weeks after reviewing and considering this information before deciding whether to have this surgery unless an earlier surgery is deemed medically necessary.

Both you and your patient will be required to sign the Patient Decision Checklist form before surgery. The form, once signed, acknowledges the patient's full understanding of the information provided in the brochure. The form should be retained in the patient's permanent medical record.

Below are some of the important factors your patients need to be aware of when using Motiva Implants®:

Rupture
Rupture of a silicone gel breast Implant may be silent/asymptomatic (i.e., there are no symptoms experienced by the patient and no physical signs of changes with the Implant) rather than symptomatic. You should advise your patient to undergo regular breast ultrasound or magnetic resonance imaging (MRI) to screen for silent rupture, even if she is asymptomatic. For asymptomatic patients, the first ultrasound or MRI should be performed at 5-6 years postoperatively, then every 2-3 years thereafter. An MRI is recommended for symptomatic patients or patients with equivocal ultrasound results for rupture at any time postoperatively. If a rupture is noted on imaging, then you should advise your patient to have her Implant removed. You should provide her with a list of MRI facilities in her area that have at least a 1.5 Tesla magnet, a dedicated breast coil, and a radiologist experienced with reading breast implant MRIs to diagnose a silent rupture. Diagnostic procedures will add to the cost of having implants, and patients should be aware or advised that these costs may exceed the cost of their initial surgery over their lifetime and that their insurance carrier may not cover these costs.

Explantation
Implants are not considered lifetime devices and patients will likely undergo implant removal(s), with or without replacement, over the course of their life. When implants are removed without replacement, changes to the patient's breasts may be irreversible. Complication rates are typically higher following revision surgery (removal with replacement).

Reoperation
Additional surgeries to the patient's breasts will likely be required, whether because of implant rupture, unacceptable size/cosmetic outcomes, or other complications. Patients should be advised that their risk of future complications increases with revision surgery compared to primary augmentation surgery. Further, in a reoperation in which the Implant is not removed (such as open capsulotomies or scar revision), there is a risk that the integrity of the Implant shell could be compromised inadvertently, potentially leading to product failure.

Breast Examination Techniques
Patients should perform breast self-examinations monthly and be shown how to distinguish the Implant from their breast tissue. The patient should not manipulate or squeeze the implants excessively. The patient should be told that the presence of lumps, persistent pain, swelling, hardening, or change in the implant shape might be symptoms of rupture of the Implant. If the patient has any of these signs, the patient should be told to report them to her surgeon and possibly have an MRI evaluation to screen for rupture.

Mammography
Patients should be instructed to undergo routine mammography exams as per their primary care physician's recommendations. The importance of having these exams should be emphasized. Patients should be instructed to inform their mammography technologist about the presence, type (including whether RFID chip is present or not in the implant), and placement of their implants. Patients should request a diagnostic mammography rather than a screening mammography because more pictures are taken with diagnostic mammography. Breast implants may complicate the interpretation of mammographic images by obscuring underlying breast tissue and/or by compressing overlying tissue.

Accredited mammography centers, technicians with experience in imaging patients with breast implants, and the use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast. The current recommendations for preoperative/screening mammograms are no different for women with breast implants than for those women without implants. Pre-surgical mammography with a follow-up mammogram after implantation may be performed to establish a baseline for routine future mammography in augmentation patients.

Lactation
Breast implant surgery may interfere with the ability to breastfeed by reducing or eliminating milk production. The Institute of Medicine (IOM), in its 1999 report on the safety of silicone breast implants, encourages mothers with silicone gel breast implants to breastfeed, stating that while breast implantation may increase the risk of lactation difficulties, there is no evidence of a hazard to the infant "beyond the loss of breastfeeding itself", (2000). Other professional medical associations and independent scientific panels have echoed these conclusions and recommendations (1996,1998, 2001).[5-7]

Avoiding Damage During Other Treatment
Patients should inform other treating physicians of the presence of implants to minimize the risk of damage to the implants.

Smoking
As with any surgery, smoking may interfere with the healing process after breast implant surgery.

Radiation to the Breast
Motiva Implants® has not tested the in vivo effects of radiation therapy in patients who have breast implants. The literature suggests that radiation therapy may increase the likelihood of capsular contracture (2006, 2009),[8,9] necrosis, and implant extrusion (2009).[10]

Insurance Coverage
Patients should be advised that health insurance premiums may increase, insurance coverage may be dropped, and/or future coverage may be denied based on the presence of breast implants. Treatment of complications of breast implantation may not be covered as well. Patients should check with their insurance company regarding coverage questions before undergoing surgery.

Mental Health and Elective Surgery
It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Request that your patient openly discusses with you, prior to surgery, any history that she may have of depression or other mental health disorders.

Long-Term Effects
Motiva USA will continue its Core Study through the end of each patient's 10-year study term. The endpoints in the long-term 10-year follow-up include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and results. Motiva USA will update its labeling as appropriate with the long-term results. It is important that new safety information is relayed to your patients as soon as the information is provided to you.

GENERAL ADVERSE EFFECTS ASSOCIATED WITH BREAST IMPLANT SURGERY

Potential adverse events that may occur with silicone gel breast implant surgery include rupture, capsular contracture, reoperation, implant removal, pain, changes in nipple and breast sensation, infection, hematoma/ seroma, unsatisfactory results, breastfeeding complications, and additional complications.

Below is a description of these adverse events. For specific adverse event rates/out- comes for Motiva Implants®, refer to the Study section that follows.

Rupture
Breast implants are not lifetime devices. Breast implants rupture when the shell develops a tear or hole. Rupture can occur any time after implantation, but rupture is more likely to occur the longer the Implant is implanted. The following things may cause Implants to rupture: damage by surgical instruments; stressing the Implant during implantation and weakening it; folding or wrinkling of the Implant shell; excessive force to the chest; trauma; compression during mammographic imaging; and severe capsular contracture. Breast implants may also wear out over time.

Silicone gel breast implant ruptures may be silent. This means that neither you nor your patient may know if the Implant has ruptured. Asymptomatic patients should have their first ultrasound, or MRI performed at 5-6 years postoperatively, then every 2-3 years thereafter. An MRI is recommended for symptomatic patients or patients with equivocal ultrasound results for rupture at any time postoperatively.

Some published studies (1992, 1995, 1996) suggest that silent rupture is relatively uncommon.[11-13]

Sometimes there may be local symptoms associated with silicone gel implant rupture. The symptoms of rupture can include hard knots or lumps surrounding the Implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast (2001-2003).[14-17]

When MRI findings indicate a rupture (such as subcapsular lines, characteristic folded wavy lines, teardrop sign, keyhole sign, noose sign), or ultrasound findings of rupture or if there are signs or symptoms of rupture, you should remove the Implant (with or without replacement), and any gel you determine is present. It also may be necessary to remove the tissue capsule, which will involve additional surgery with associated costs. If your patient has symptoms, such as breast hardness, a change in breast shape or size, and/or breast pain, you should recommend that she have an MRI to determine whether rupture is present (2000, 2004).[2,18]

There may also be consequences of rupture. If a rupture occurs, silicone may remain within the scar tissue surrounding the Implant (intracapsular rupture) or move outside the capsule (extracapsular rupture), or gel may move beyond the breast (migrated gel). There is also a possibility that a rupture that initially occurs as an intracapsular rupture may progress to extracapsular and beyond.

Studies of Danish women evaluated with MRI involving a variety of manufacturers, and implant models showed that about three-fourths of implant ruptures are intracapsular, and the remaining one-fourth are extracapsular (2001).[19] Additional studies of Danish women indicate that over 2 years, about 10% of the implants with intracapsular rupture progressed to extracapsular rupture as detected by MRI (2004).[18] Approximately half of the women whose ruptures had progressed from intracapsular to extracapsular reported that they experienced trauma to the affected breast during this period or had undergone mammography. In the other half, no cause was given. In women with extra-capsular rupture, after 2 years, the amount of silicone that has migrated outside of the scar tissue capsule increased in approximately 14% of these women. These studies pertain to a variety of silicone implants from various manufacturers and implant models and is not specific to Motiva Implants®.

There have been reports of silicone gel in areas outside the breast capsule; the commonly reported sites of silicone gel migration are the axilla, regional lymph nodes, and upper arm (2005, 2006, 2016, 2021).[20-24] Moyer and others have stated that there are case reports of silicone gel migration in women with intact (i.e., non-ruptured) breast implants that identified silicone using localized spectroscopy in the livers of such women (1994, 1995, 2012).[25, 26, 27]

Capsular Contracture

Patients should be advised that capsular contracture might be more common following infection, hematoma, seroma, and the chance of it occurring may increase over time. Capsular contracture is also a risk factor for implant rupture (2001),[15] and it is one of the most common reasons for reoperation. Patients should be advised that additional surgery might be needed in cases where pain and/or firmness are severe. This surgery ranges from removing the Implant capsule tissue to removing and possibly replacing the Implant itself. This surgery may result in the loss of breast tissue. Capsular contracture may recur after these additional surgeries.

Reoperation

Patients should be advised that additional surgery to their breast and/or Implant will likely be necessary over the course of their life. Reoperations can be required for many reasons, including a patient's decision to change the size or type of her implants, or improve her breast surgery outcome.

Implant Removal

Patients should be advised that Implants are not considered lifetime devices, and they will potentially undergo Implant removal, with or without replacement, throughout their life. Patients should also be advised that the changes to their breasts following explantation might be irreversible.

Pain

Pain of varying intensities and lengths of time may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain. Surgeons should instruct their patients to inform them if there is significant pain or if it persists.

Changes in Nipple Sensation

Sensation in the nipple and breast can increase or decrease after implant surgery.

Infection

In rare instances, an acute infection may occur in a breast with Implants. The signs of acute infection include erythema, tenderness, fluid accumulation, pain, and fever. Very rarely, Toxic Shock Syndrome, a potentially life-threatening condition, has been reported in women after breast implant surgery. It is characterized by symptoms that occur suddenly and include high fever (102 °F, 38.8 °C), vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches, and drops in blood pressure, which may cause fainting. Patients should be instructed to contact a physician immediately for diagnosis and treatment for any of these symptoms.

Hematoma/Seroma

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

Unsatisfactory Results

Patients should be informed that dissatisfaction with cosmetic results related to incorrect size, scar deformity, hypertrophic scarring, capsular contracture, asymmetry, wrinkling, Implant displacement/migration, and Implant palpability/visibility might occur. Careful surgical planning or technique can minimize, but not preclude the risk of such results. Pre-existing asymmetry may not be entirely correctable. Revision surgery may be indicated to maintain patient satisfaction but carries additional considerations and risks.

Breastfeeding Complications
Difficulties with breastfeeding have been reported following both breast reduction and breast augmentation surgeries. A periareolar surgical approach may further increase the chance of breastfeeding difficulties.

Additional Complications
After breast implant surgery, the following may occur and/or persist, with varying intensity and/or varying length of time: implant extrusion, necrosis, delayed wound healing, and breast tissue atrophy/chest wall deformity. Calcium deposits can form in the tissue capsule surrounding the Implant, with symptoms that may include pain and firmness. Lymphadenopathy has also been reported in some women with implants.

OTHER REPORTED CONDITIONS

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.

There have been reports in the literature of other conditions in women with silicone gel breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants.

Furthermore, there is the possibility of risks, yet unknown, which could be determined to be associated with breast implants in the future. It should be noted that the cited references include data from augmentation and/or reconstruction patients, as well as from a variety of manufacturers and implant models.

Connective Tissue Disease Diagnoses or Syndromes
Connective tissue diseases include diseases such as lupus, scleroderma, rheumatoid arthritis, and fibromyalgia. There have been a number of published epidemiological studies, meta-analyses, and "weight-of-the-evidence" or critical reviews that have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease. The study size needed to conclusively rule out a smaller risk of connective tissue disease among women with silicone gel breast implants would need to be very large (1999-2001, 2003-2004).[2,28-33] Some published studies (1996-2002, 2004, 2007) 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.[2,14,15,30-32,34-42] These studies do not distinguish between women with intact and ruptured implants. One study (2003) evaluated specific connective tissue disease diagnoses, and symptoms in women with silent ruptured versus intact implants, but it was too small to rule out a small risk.[29] Another study (2003) in a small group of women concluded that significantly more women with ruptured implants than intact implants reported debilitating chronic fatigue;[43] the women reported their symptoms after learning whether or not they had a ruptured implant.

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 quantified (1998, 2000-2001).[2,7,32]

Connective Tissue Disease Signs and Symptoms
Some literature reports have also been made associating silicone gel breast implants with various rheumatological signs and symptoms, such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. Having these rheumatological signs and symptoms does not necessarily mean that a patient has a connective tissue disease. Some scientific expert panels (2000) and literature reports (2001-2002 and 2004) have found no evidence of a consistent pattern of signs and symptoms in women with silicone gel breast implants.[2,44-47] If a patient has an increase in these signs or symptoms, you should refer her to a rheumatologist to determine whether these signs or symptoms are due to a connective tissue disorder or autoimmune disease.

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.

Cancer

Breast Cancer
Many reports in the medical literature indicate that patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer (2000-2002, 2006-2007).[35,48-56] 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 (2000, 2002-2004).[29,48,51,56-58]

Brain and Nervous System Cancers
One study reported an increased risk of brain cancer in women with breast implants as compared to the general population (2001).[49] The incidence of brain cancer, however, was not significantly increased in women with breast

implants when compared to women who had other types of plastic surgeries; the study relied on very few cases, and the authors relied upon death certificates for brain cancer diagnoses, which may reflect other cancers that have metastasized. Other large studies (2000, 2002, 2004, 2006-2007) and a published review of four large studies in women with cosmetic implants concluded that the evidence does not support an association between brain cancer and breast Implants.[31,50,52-56]

Lympho-Hematopoietic Cancers

One study (2001) reported an increased risk of leukemia in women with breast implants as compared to the general population.[41] However, there was no increased risk when compared to women who had other types of plastic surgery. Other recent large studies (2000, 2002, 2004, 2006-2007) concluded that the evidence does not support an association between lympho-hematopoietic cancers and breast implants. [29,50,52-56]

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

Based on information reported to global regulatory agencies and found in medical literature, an association has been identified between breast implants and the development of anaplastic large cell lymphoma (BIA-ALCL), a type of non-Hodgkin's lymphoma (2008).[59] Women with breast implants have a very small but increased risk of developing ALCL (BIA-ALCL) in the fluid or scar capsule adjacent to the Implant, with documented potential for local, regional, and distant spread of the cancer with mortality reported in rare cases.

BIA-ALCL has been reported globally in patients with an implant history that includes various manufacturers' breast implants with various surface properties, styles, and shapes. The majority of cases in the literature reports describe a history of using textured implants.

You should consider the possibility of BIA-ALCL when a patient presents with late-onset, persistent peri-implant seroma. In some cases, patients presented with capsular contracture or masses adjacent to the breast implant. When testing for BIA-ALCL, collect fresh seroma fluid and representative portions of the capsule, and send them to a laboratory with appropriate expertise for pathology tests to rule out BIA-ALCL, including immunohistochemistry testing for CD30 and ALK (anaplastic lymphoma kinase). If your patient is diagnosed with peri-implant BIA-ALCL, develop an individualized treatment plan in coordination with a multidisciplinary care team. Because of the small number of cases, there is no worldwide consensus on the treatment regimen for peri-implant BIA- ALCL. However, the National Comprehensive Cancer Network (NCCN) recommends a surgical treatment that includes implant removal and complete capsulectomy ipsilaterally and contralaterally, where applicable.

Report all confirmed 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.

FDA also recommends reporting cases of BIA-ALCL to the PROFILE Registry (https://www.thepsf.org/research/clinical-impact/profile.htm), where you can submit more com- prehensive case data. This will help provide a better understanding of the etiology of BIA-ALCL.

For additional information on the FDA's analysis and review of BIA-ALCL, please visit: Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma | FDA (https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma)

Respiratory/Lung Cancer

One study (2001) has reported an increased incidence of respiratory/lung cancer in women with breast implants.[41] Other research (2006) on women in Sweden and Denmark has 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.[46] Several large studies (2002, 2006-2007) have found no association between breast implants and respiratory/lung cancer.[50,52,53,55,56]

Reproductive System Cancers

One study (2001) has reported an increased incidence of cervical/vulvar cancer in women with breast implants.[49] However, there was no increased risk compared to women with other types of plastic surgery. Another study (2007) reported an increased incidence of vulvar cancer that has not been explained.[52] Other recent large studies (2000, 2002, 2004, 2006) concluded that the evidence does not support an association between reproductive system cancers and breast implants.[31,50,53-56]

Squamous Cell Carcinoma and Various Lymphomas

Based on information reported by the FDA and published in literature, there are reports of cancers, including squamous cell carcinoma (SCC) and various lymphomas, in the scar tissue (capsule) that forms around breast implants. The various lymphomas reported are not the same as the as Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) (2023).[60] As of March 2023, the limited global published data includes 19 reported cases of SCC and less than 30 cases of various lymphomas reported in the breast capsule of patients implanted with breast implants. The occurrence of SCC or various lymphomas in the capsule around the breast implant is considered rare and the cause, incidence, and risk factors remain unknown. The FDA recommends reporting all cases of cancers including SCC and various lymphomas in the capsule around breast implants to MedWatch, the FDA Safety Information, and Adverse Event Reporting program at https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

FDA also recommends reporting cases of cancers including SCC and various lymphomas to the PROFILE Registry (https://www.thepsf.org/research/clinical-impact/profile.htm), where you can submit more comprehensive case data.

Other Cancers

Several studies have examined the risk of other types of cancers, e.g., thyroid, urinary system, sarcoma, endocrine, connective tissue, cancer of the eye, and unspecified cancers in women with breast implants. These studies found no increased risk in women with breast implants (2000-2001, 2003-2004, 2006-2007).[25,45,49,50,52-55]

Neurological Disease, Signs, and Symptoms

Some women with breast implants have complained of neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking, or remembering things) or neurological diseases (such as multiple sclerosis), which they believe are related to their implants. One scientific expert panel (2000) found that the evidence for neurological disease or syndrome caused by or associated with breast implants is insufficient or flawed.[2] Subsequent to that report, one epidemiological study (2001)[61] and one cohort study (2001)[35] examined a variety of neurological diseases in women with breast implants and found no significantly increased risk.

Suicide

Several studies (2001-2004) observed a higher incidence of suicide, depression, and/ or anxiety in women with breast implants.[62-66] The reason for the observed increase is unknown, but it was found that women with breast implants had higher rates of hospital admissions due to psychiatric causes before surgery, as compared with women who had breast reduction or in the general population of Danish women.[66]

Effects on Children

It is unknown if a small amount of silicone may pass through from the breast implant silicone shell into breast milk during breastfeeding.

Although there are no established methods for accurately detecting silicone levels in breast milk, one study (2000) measuring silicon (one component of silicone) levels did not indicate higher levels in breast milk from women with silicone gel breast implants when compared to women without implants (based on literature published from 2000).[67]

In addition, concerns have been raised regarding potential damaging effects on children born to mothers with implants. Several studies (2001-2002, 2006) in humans have found that the risk of birth defects or other adverse health effects overall is not increased in children born after breast implant surgery.[68-70] Although low birth weight was reported in one study (2004), other factors (for example, lower pre-pregnancy weight) may explain this finding.[71] This author recommended further research on infant health.

Potential Health Consequences of Gel Bleed

Small quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse ("bleed") through an intact implant shell (2000, 2003).[2,72] The evidence is inconclusive as to whether there are any clinical consequences associated with gel bleed. For instance, studies on implanted women over a long duration have suggested that such bleed may be a contributing factor in the development of capsular contracture (2000)[2] and lymphadenopathy (2005).[73] However, the evidence against gel bleed being a significant contributing factor to capsular contracture, and other local complications is provided by the fact that there are similar or lower complication rates for silicone gel breast implants than for saline-filled breast implants. Saline-filled breast implants do not contain silicone gel, and, therefore, gel bleed is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in the studied implants does not cause toxic reactions when large amounts are administered to test animals. It should also be noted that studies reported in the literature (1987, 1995, 1999) have demonstrated that the low concentration of platinum in breast implants is in the most biocompatible state (zero oxidation).[74-77]

Gel bleed of Motiva® SmoothSilk® Round and SmoothSilk® Round Ergonomix® Implants was measured by examining the 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 SmoothSilk® Round and 0.9 – 2.0 µg/test article for SmoothSilk® 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.

MOTIVA IMPLANTS® CORE CLINICAL STUDY

Overview

Motiva's Silicone Gel Core Clinical Study (The Study) is a prospective, 10-year, multi-center clinical study conducted to examine the safety and effectiveness of Motiva Implants® in subjects undergoing primary augmentation and revision augmentation. Subjects were treated between April 17, 2018 and August 26, 2019. Five hundred sixty (560) subjects are participating in the study. Of these, 49 subjects were implanted at one of the three sites outside of the United States.

A total of 451 subjects underwent primary augmentation and 109 revision augmentation surgery. Of these, 176 primary augmentation subjects and 42 revision augmentation subjects are assessed for silent ruptures with MRI evaluations at years 1, 2, 3, 5, 7, and 10 after receiving implants.

Study Inclusion and Exclusion Criteria

Enrollment in the study was limited to subjects who met the following inclusion criteria:

- Genetic female
- Subject is seeking one of the following procedures:
    - Primary Breast Augmentation: age 22 and over, indicated to increase breast size
    - Breast Implant Revision Surgery (removal and replacement of breast implants): revision surgery to correct or improve the results of a previous breast augmentation
- Subject has adequate tissue available to cover implant(s)
- Willingness to follow all study requirements including agreeing to attend all required follow-up visits and signs the informed consent
- Agrees to have device returned to the Sponsor, if explanted
- Willing to undergo Magnetic Resonance Imaging (MRI) evaluation if medically advised

Subjects were not permitted to enroll in the study if they met any of the following exclusion criteria:

- Has any breast disease considered to be pre-malignant in one or both breasts or is reporting mutations in BRCA1 or BRCA2 without a previous bilateral mastectomy or an untreated cancer of any type
- Has inadequate or unsuitable tissue (e.g., due to radiation damage, ulceration, compromised vascularity, history of compromised wound healing)
- Has an abscess or infection
- Is pregnant or nursing or has had a full-term pregnancy or lactated within 6 months of enrollment
- Is taking any drugs that would interfere with blood clotting, or that might result in elevated risk and/or significant postoperative complications
- Has any medical condition such as obesity (BMI >40), diabetes, autoimmune disease, chronic lung or severe cardiovascular disease that might result in unduly high surgical risk and/or significant postoperative complications
- Has any connective tissue/autoimmune disorder or rheumatoid disease, such as systemic lupus erythematosus, discoid lupus, scleroderma, or rheumatoid arthritis, among others
- Has any condition that impedes the use of MRI including implanted metal device, claustrophobia, or other conditions that would make MRI scan prohibited
- Has a history of psychological characteristics that are unrealistic or unreasonable given the risks involved with the surgical procedure
- Has been implanted with any non-FDA approved breast implant
- Has been implanted with any silicone implant other than breast implants
- HIV positive (based on medical history)
- Has been diagnosed with anaplastic large cell lymphoma (ALCL)
- Works for the Sponsor or any of their subsidiaries, the study surgeon, or ICON the Contract Research Organization (CRO) that is helping to conduct the study or are directly related to anyone that works for the Sponsor or any of their subsidiaries, the study surgeon, or the CRO

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) version 2.0: Satisfaction with Breasts, Rosenberg Self-Esteem Scale, SF-36v2SF® Health Survey, and Body Esteem Scales.

The results provided here represent three years of data. This DFU will be updated as additional information becomes available. The following sections provide more information about the complications and benefits that patients may experience following augmentation with Motiva Implants® based on the experiences of the subjects in the study.

Follow-up Rates

Data are available through 3 years post-implantation. Through 3 years, the study visit follow-up rates were 92.4% for the primary augmentation cohort and 88.7% for the revision augmentation cohort. The overall follow-up rate was 91.7%. However, 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. The MRI visit follow-up rates through 3 years was 81.6% overall.

Demographics and Surgical Characteristics

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. The median age at surgery was 33.0 years for primary augmentation subjects and 44.0 years for revision-augmentation subjects. Half of the subjects were married and 90% had a college education. Table 3 presents the population demographics at baseline by cohort.

Table 3. Demographics

Accounting by Window	By-Subject	
	Primary Augmentation n (% of 451)	Revision Augmentation n (% of 109)
Age Group		
22-29 years	155 (34.4%)	6 (5.5%)
30-39 years	207 (45.9%)	35 (32.1%)
40-49 years	75 (16.6%)	28 (25.7%)
50-59 years	13 (2.9%)	33 (30.3%)
60-69 years	1 (0.2%)	7 (6.4%)
70+ years	0	0
Age (years)		
Mean (SD)	33.5 (7.49)	44.5 (10.52)
Median (Min-Max)	33.0 (22-60)	44.0 (24-68)
Body Mass Index (kg/m²)		
Mean (SD)	22.0 (2.84)	22.5 (2.91)
Median (Min-Max)	21.5 (17-35)	22.1 (18-35)
Race		
American Indian or Alaska Native	1 (0.2%)	0
Asian	28 (6.2%)	4 (3.7%)
Black	9 (2.0%)	0
Native Hawaiian or Other Pacific Islander	1 (0.2%)	2 (1.8%)
White	389 (86.3%)	96 (88.1%)
Other	23 (5.1%)	7 (6.4%)
Education		
Less than high school	2 (0.4%)	2 (1.8%)
High School/GED	38 (8.4%)	14 (12.8%)
Some College/Vocational School	113 (25.1%)	22 (20.2%)
College Graduate	202 (44.8%)	52 (47.7%)
Post-Graduate Education	96 (21.3%)	19 (17.4%)
Marital Status		
Divorced	49 (10.9%)	18 (16.5%)
Married	218 (48.3%)	60 (55.0%)
Separated	5 (1.1%)	1 (0.9%)
Single	176 (39.0%)	27 (24.8%)
Widowed	3 (0.7%)	3 (2.8%)

With respect to the surgical approach, for primary augmentation subjects, the surgical approaches used were 85.3% inframammary, 9.5% transaxillary, 2.9% periareolar and 2.2% via mastopexy incision. The submuscular/dual plane placement was the most common approach in 94.6% of subjects, followed by complete muscle coverage, subglandular, and subfascial placements (2.7%, 2.2%, and 0.6% respectively).

For revision augmentation subjects, the majority of implants (81.7%) were placed through an inframammary incision, 10.1% of implants were placed through a periareolar incision, 6.4% via a mastopexy incision, and 1.8% were transaxillary. The placement was submuscular/dual plane in 78.9% of implants, subglandular in 17.4% of implants, and 1.8% in each subfascial and complete muscle coverage approaches.

Motiva® SmoothSilk® Round and SmoothSilk® Round Ergonomix breast implants represented 100% of total implants for both cohorts, with SmoothSilk® Round comprising 11.6% and SmoothSilk® Round Ergonomix comprising 88.4% of all devices implanted.

The following two tables present breast implant placement by cohort (Table 4) and breast implant style by cohort (Table 5).

Table 4. Breast Implant Placement

Incision Site and Placement	By-Implant	
	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%)

Table 5. Breast Implant Style

Characteristic	By-Implant	
	Primary Augmentation n (% of 901)	Revision Augmentation n (% of 218)
Device Style		
SmoothSilk® Round	102 (11.3%)	28 (12.8%)
SmoothSilk® Round Ergonomix®	799 (88.7%)	190 (87.2%)
Radiofrequency Identification Device (RFID)		
With RFID	270 (30.0%)	38 (17.4%)
Without RFID	631 (70.0%)	180 (82.6%)

The Study is currently ongoing and results available through 3 years are presented in this DFU. Motiva USA will periodically update this document as more information becomes available. Information on the safety and benefits of the implants are presented below and organized by indications, Augmentation and Revision-Augmentation.

RUPTURE

Out of a total study cohort of 1,119 implants in 560 subjects in the primary and revision cohorts combined, there has been one (1) suspected rupture in one subject through Year 3. There are 176 primary augmentation subjects with 352 implants enrolled in the MRI cohort study who have routine MRI screening of their implants to assess for rupture with a 3 year follow-up compliance rate of 81.6%. Through 3 years, 99.4% of these subjects (99.7% of implants) had no evidence of rupture. Through Year 3, there was 1 suspected implant rupture occurring in one subject. Therefore, the 3-year risk of rupture was 0.6% (95% CI, 0.1%- 4.4%) per subject in the primary augmentation cohort.

There are 42 revision augmentation subjects with 84 implants enrolled in the MRI cohort who have routine MRI screening of their implants to assess for rupture with a 3-year follow-up compliance rate of 81.1%. Through 3 years, all of these subjects (100%) had no evidence of rupture. Of the revision augmentation subjects in the study who were not evaluated by MRI, there were no (0) implant ruptures. Overall, through 3 years, zero subjects had evidence of rupture in the revision augmentation cohort.

EFFECTIVENESS OUTCOMES

The benefits reported in the Study for primary and revision augmentation subjects are described below. Effectiveness included an analysis of subject satisfaction based on the 5-point Likert scale and two secondary effectiveness endpoints, patient's satisfaction with their breasts based on the BREAST-Q® Augmentation Module version 2.0 Satisfaction with Breasts questionnaire, and Physician Satisfaction with the implant based on the 5-Point Likert Scale. If the patient responded satisfied or very satisfied, they were considered satisfied. The overall patient satisfaction across both primary augmentation and revision augmentation subjects at Year 3 is 95.4% (out of 498 responses) and the overall physician satisfaction is 98.4% (out of 498 responses).

Effectiveness: Primary Augmentation Subjects

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

For primary 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 timepoints, 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 among women in the primary

augmentation cohort. There were a number of decreases in the quality of life scales. However, effect sizes were small, so the observed changes were judged not clinically relevant.

Effectiveness: Revision Augmentation Subjects

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 questionnaire, 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 even though the mean score at Year 3 (93.7) was higher/better than the national norm (79.5).[78]

For the revision augmentation cohort, the measures and means 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.

SAFETY OUTCOMES

The complications reported in the Study for primary and revision augmentation subjects are described below.

Safety: Primary Augmentation Subjects

The Kaplan-Meier (KM) risk rates of complications observed in women who had primary augmentation through 3 years are presented in Table 6.

Table 6. Primary Augmentation: Kaplan-Meier Risk of Key Events at Year 3, By Subject

Key Event[1-2]	By-Subject
	Primary Augmentation (N=451) % (95% Confidence Interval)
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%)
Explantation with replacement	1.4% (0.6%, 3.0%)
Explantation without replacement	0.2% (0.0%, 1.6%)
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 KM Risk ≥ 1%	
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, RFID failure, skin related, swelling, necrosis, upper pole fullness, RFID failure.

Safety: Revision Augmentation Subjects

The Kaplan-Meier risk rates of complications observed in revision augmentation subjects through 3 years are presented in Table 7.

Table 7. Revision Augmentation: Kaplan-Meier Risk of Key Events at Year 3, By Subject

Key Event[1-2]	By-Subject
	Revision Augmentation (N=109) % (95% Confidence Interval)
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%)
Explantation with replacement	13.8% (8.4%, 22.2%)
Explantation without replacement	2.9% (0.9%, 8.7%)
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 KM Risk ≥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%)
Asymmetry	3.9% (1.5%, 10.0%)
Double Capsule	1.0% (0.1%, 6.6%)
Iatrogenic Injury to Implant	1.0% (0.1%, 6.6%)
Mass/Cyst/Lump	2.4% (0.6%, 9.4%)
Ptosis	4.8% (2.0%, 11.2%)

[1] The following complication was 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.

Reasons for Reoperation: Primary Augmentation Subjects

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 subjects). Table 8 provides the main reasons for reoperation. The two most common reasons for reoperation through 3 years in these subjects were Implant Malposition and Capsular Contracture.

Table 8. 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%)

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

Reasons for Reoperation: Revision Augmentation Subjects

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 subjects). Table 9 provides the main reasons for reoperation. The two most common reasons for reoperation through 3 years were Subject Request for Size/Style Change and Capsular Contracture.

Table 9. Main Reasons for Reoperation Through 3 Years: Revision Augmentation Subjects (N=29 Reoperations)

Reasons for Reoperation through 3 Years	n (%)
Subject Request for Size/Style Change	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%)

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

Reasons for Implant Removal: Primary Augmentation Subjects

In the Study, 1.6% of the subjects had at least one removal (a total of 13 implants from 7 subjects). Table 10 shows that the most common reason for implant removal was Subject Request for Size/Style Change.

Table 10. Main Reasons for Implant Removal Through 3 Years: Primary Augmentation Subjects

Reason for Implant Removal	n (% of 13)
Subject Request for Size/Style Change	6 (46.2%)
Capsular Contracture	5 (38.5%)
Implant Malposition	1 (7.7%)
Infection	1 (7.7%)

Reasons for Implant Removal: Revision Augmentation Subjects

In the Study, 16.5% of subjects had at least one removal (a total of 28 implants removed from 17 subjects). As Table 11 shows, the most common reason for implant removal was due to Subject Request for Size/Style Change

Table 11. Main Reasons for Implant Removal Through 3 Years: Revision Augmentation Subjects

Reason for Implant Removal	n (% of 28)
Subject Request for Size/Style Change	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%)

OTHER CLINICAL FINDINGS

The study evaluated several possible long-term health effects through 3 years that have been reported in breast implant subjects. These include rupture, cancer, CTD, CTD signs and symptoms, complications with lactation, reproductive complications, and suicide.

Cancer

Through 3 years (in both cohorts), 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).

CTD Signs and Symptoms

The study collected information on CTD signs and symptoms in all subjects every year during the follow-up visit. No patients received a CTD diagnosis through 3 years. Thirty-three (33) subject-reported signs and symptoms were collected at the follow-up visits. The individual symptoms were combined into 7 categories for prevalence analysis, (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 cohorts, the most common signs and symptoms were 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).

Of note, CTD sign/symptoms were not collected at baseline (prior to implantation); therefore, the risk estimates for symptoms may be biased upwards because they also include signs/symptoms that may have been present prior to implantation.

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, your 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 breastfeeding (e.g., inadequate milk production, mastitis), 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 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 examined in the Study include preeclampsia, disease (endocrine), infertility, miscarriage, termination of pregnancy (due to medical reasons), and other reasons.

For the primary augmentation subjects, 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 (0.4%).

For the revision augmentation subjects, 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.

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.

Risk Factor Analysis
A risk factor analysis was performed to determine whether there were any risk factors associated with the reported complications.

In the primary augmentation cohort, four adverse event types with at least 10 events were reported and examined (Any Complication, Reoperation, Explantation, and Implant Malposition).

- Implant projection was identified as a risk factor for Explantation, Reoperation, and Any Complication; subjects who received implants with Corsé or Full projections were more likely to undergo reoperation than those who received implants with Demi or Mini projections.
- In addition, pre-operative medication use was also found to be a risk factor for reoperation; subjects who reported taking at least one medication in the 3 months prior to implantation were more likely to undergo reoperation.
- Regarding implant malposition, no significant factors were found.

In the revision augmentation cohort, four adverse event types with at least 10 events were reported and examined (Any Complication, Reoperation, Explantation, and Ptosis).

- Implant placement was identified as a significant factor for three of the event types (i.e., the composite Any Complication endpoint, Ptosis, and Reoperation).
- For all three, implants placed in the sub-fascial or subglandular positions were found more likely to have a complication, experience ptosis, and/or undergo reoperation than implants placed in the complete or partial/dual plane submuscular position.
- Additionally, for Ptosis, subject age was identified as a significant risk factor, with risk of ptosis decreasing as implantation age increases.
- Regarding Explantation, no significant factors were found.

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.

INSTRUCTIONS FOR USE
Back-up Implants should be available during the procedure. Do not use more than one Implant per breast.
The product is intended for single use only. Do not reuse explanted implants.

Preoperative Patient Procedures
Motiva USA relies on the surgeon to know and follow proper surgical procedures when implanting, explanting, or performing revision surgery with Motiva Implants®. Proper surgical planning, such as allowance for adequate tissue coverage, implant placement, incision site, implant size, shape, style, and texture, should be made preoperatively. The surgeon should consider the contraindications, warnings and precautions described in this document, the patient's medical history, preferences, expectations, and physical condition.

Informed Decision
In order to document a successful informed decision process as discussed above, the patient labeling includes a Patient Decision Checklist, which should be signed by both the patient and the surgeon and then retained in the patient's file. A copy should also be provided to the patient.

Instructions for Opening and Inspecting the Sterile Inner and Outer Thermoform Package
DO NOT expose the Implant to talc, sponges, towels, or other contaminants.

1. A non-sterile operative team member should open the Implant box carton and examine the implant's sealed outer thermoform barrier system before entering the surgical area to verify package integrity.
2. Separate the product accessories, such as the Directions for Use, the Patient Device Implant Card , Tracking Form, and the adhesive labels.
3. Attach the adhesive labels with the product data to the patient's operative report and Patient Device Implant Card. Make sure to provide the Patient Device Implant Card to the patient after surgery.
4. Remove the lid of the outer thermoform barrier system and invert it over the sterile field, allowing the sealed inner thermoform barrier system to carefully enter the surgical field.
5. Use the pull-tab to open the lid of the inner thermoform barrier system.
6. Remove the breast implant and examine it for any particulate contamination, damage or loss of shell integrity. You will note in the Implant shell layer the presence of a blue pigment used for quality control during manufacturing . If satisfactory, return the breast implant to the inner thermoform tray.
    - Recover the tray with the lid until implantation to prevent contact with airborne and surgical-field particulate contaminants.
    - If not satisfactory, replace the device with a sterile backup implant.

7. For breast implants with the RFID, verify the microtransponder in the implant before opening the sterile barrier, and reverify the microtransponder in the implant after implantation, using the Motiva Reader.

Do not implant any device that

- Appears to have particulate contamination, damage, or loss of shell integrity,
- Appears to have leaks or nicks, or is damaged or contaminated.

Motiva Implants® are sterilized by dry heat. Do not re-sterilize the product.

Intraoperative Considerations

Take note of the following intraoperative considerations:

- Have a spare Implant available during the surgical procedure, and all follow-up procedures and revisions.
- The periumbilical approach has not been studied in Motiva Implants® Core Clinical Study and should not be used for various reasons, including potential damage to the implant shell.
- To avoid damaging the device, ensure that the incision is sufficiently large to facilitate insertion without excessive manipulation and handling of the device.
- Do not use lubricants to facilitate placement.
- Use extreme care to avoid damaging the breast implant with sharp surgical instruments such as needles and scalpels, cautery devices, blunt instruments such as clamps or forceps, or by over-handling and manipulation during introduction into the surgical pocket.
- Do not use excessive force during breast implant placement.

Please refer to the Warnings and Precautions sections in this document for additional information about intraoperative considerations.

Postoperative Considerations

Postoperative hematoma and seroma may be minimized by meticulous attention to hemostasis during surgery. Persistent, excessive bleeding must be controlled before implantation. Any postoperative evacuation of hematoma or seroma must be performed with care to avoid damage to the Implant from sharp instruments.

Silicone gel breast implant ruptures may be silent. This means that neither you nor your patient may know if the Implant has ruptured. Asymptomatic patients should have their first ultrasound, or MRI performed at 5-6 years postoperatively, then every 2-3 years thereafter. An MRI is recommended for symptomatic patients or patients with equivocal ultrasound results for rupture at any time postoperatively.

MANAGING A RUPTURED IMPLANT

Physicians should recommend implant removal to their patients if a rupture is confirmed.

In the event of a breast implant rupture, the following technique may be helpful to remove the silicone mass (implant). Wearing double talc-free surgical gloves on one hand, use the index finger to penetrate the silicone mass. With the other hand, exert pressure on the breast area to facilitate removal of the silicone mass into the double-gloved hand. Once the silicone is removed from the patient, remove and wrap the outer glove over the silicone mass. If any residual silicone remains, carefully clean/absorb the surgical pocket with gauze sponges. Avoid contact between surgical instruments and the ruptured silicone. If contact occurs, use isopropyl alcohol to remove the silicone from the instruments. Ruptured breast implants must be reported and should be returned to Motiva USA. In the event of breast implant rupture, contact Motiva USA at 1 (800) 924-5072.

MRI SAFETY INFORMATION

The Motiva® SmoothSilk® Round and SmoothSilk® Round Ergonomix® Implants without the RFID microtransponder are MR Safe.

Motiva Implants® containing an optional RFID microtransponder for Device Identification are MR Conditional. Patients implanted with Motiva Implants with RFID microtransponders 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

A microtransponder creates an imaging void during breast implant MR (known as artifact effect) that can block visualization of a small area around the microtransponder. In non-clinical testing, the image artifact extends approximately 15 mm radially from the microtransponder when imaged using a gradient echo (GRE) pulse sequence and a 3-Tesla MR system.

During MRI, a small susceptibility artifact can be observed around the RFID that projects into the lumen of the breast implant and can be visualized in the images (Figure 1). 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.

FDA Guidance recommendation for rupture screening for silicone gel-filled breast implants states[79] "For asymptomatic patients, the first ultrasound or magnetic resonance imaging (MRI) should be performed at 5-6 years postoperatively, then every 2-3 years thereafter. For symptomatic patients

or patients with equivocal ultrasound results for rupture at any time postoperatively, an MRI is recommended."

ADDITIONAL PRODUCT-SPECIFIC INFORMATION

Returned Merchandise Policy
Product returns should be handled through the local Motiva USA representative. If no local representative is available, please contact Customer Care at 1 (800) 924-5072 or email at customercare@motivausa.com or USPMS@motivausa.com.

All package seals must be intact for product to be eligible for return. Returned products may be subject to a restocking charge. For more information, please contact the local Motiva USA representative.

Explanted Device Returns and Reporting
Explanted devices must be returned to Motiva USA, and the reason for explantation must be provided. All explanted devices must be returned in a Motiva Return Kit. Please contact the Motiva USA Customer Care Team at 1 (800) 355-4164 or email at customercare@motivausa.com or USPMS@motivausa.com for a Return Kit and instructions.

Product Warranty
The complete terms, conditions, and limitations of the Motiva USA Warranty Program can be reviewed on the website www.motivausa.com or can be provided by a local Motiva USA representative. Motiva USA warrants that this product is free of manufacturing defects at the time of its shipment. Motiva USA shall not be responsible for any incidental or consequential loss, damage, or expenses directly or indirectly arising from the use of this product. Motiva's sole responsibility, in the event of a determined manufacturing defect, shall be outlined in the warranty program terms and conditions and Motiva USA assumes no further liability. The warranty program is in lieu of and excludes all other warranties not expressly set forth therein, 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.

Product Ordering
To order directly in the U.S.A. or for product information, please contact Motiva USA LLC at 1 (800) 924-5072 or email at customercare@motivausa.com

Access to Electronic Information
The Information for the Patient, the Device Tracking Form, and the electronic version of this DFU can be found on the QR code provided on the box label and the Motiva Implants® website at www.motivausa.com/support/

Reporting Problems
The FDA requires manufacturers, device user facilities (such as hospitals), and importers to report serious injuries involving medical devices (defined as those that need medical or surgical intervention to prevent permanent damage) to the FDA. In addition, the FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety. In addition, the patient can voluntarily report injuries or complications directly to FDA's MedWatch.

You can report by telephone to 1-800-FDA-1088 (1-800-332- 1088); by FAX, use Form 3500 to 1-800-FDA-0178 (1-800-332-0178); electronically at https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program ; or by mail to MedWatch Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857- 9787. Keep a copy of the completed MedWatch form for your records.

This information reported to MedWatch is entered into databases to be used to follow safety trends and to determine whether further follow-up of any potential safety issues related to the device is needed.

You are also required to report any product problem or serious adverse effect to Motiva USA. Deaths must be reported to Motiva USA.

Device Manufacturer
Motiva Implants® Silicone Gel-Filled Breast Implants are manufactured by Establishment Labs and imported to the US by Motiva USA LLC.

CONTACT INFORMATION

Motiva USA LLC
125 East De La Guerra Street Suite 203A
Santa Barbara, California, 93101
Phone: US Customer Care 1 (800) 924-5072
Email: customercare@motivausa.com
Website: www.motivausa.com/support/

LEGAL MANUFACTURER

Establishment Labs S.A.:
Coyol Free Zone & Business Park Building
4th Street, Building B15, Alajuela, Costa Rica
Zip Code: 20113
Phone: +506 2434-2400
www.motivausa.com/support/

MANUFACTURING SITE

Coyol Free Zone & Business Park Building
0 Street, Building B25, Alajuela, Costa Rica
Zip Code: 20113
www.motivausa.com/support/

REFERENCES

1. FDA. Tracking obligations of persons other than device manufacturers: distributor requirements 21 Code of Federal Regulations (CFR) §821.30 (2022).
2. Bondurant, S., Ernster, V., & Herdman, R. (eds.). (National Academy Press, 2000).
3. Henriksen, T. F. et al. Surgical intervention and capsular contracture after breast augmentation: a prospective study of risk factors. Ann Plast Surg 54, 343-351 (2005).
4. Kulmala, I. et al. Local complications after cosmetic breast implant surgery in Finland. Ann Plast Surg 53, 413-419 (2004).
5. Bleiweiss, I. J., Klein, M. J. & Copeland, M. Breast prosthesis reaction. Am J Surg Pathol 20, 505-507 (1996).
6. American Academy of Pediatrics (AAP) Committee on Drugs. (2001) Transfer of drugs and other chemicals into human milk. Pediatrics 108, 776-789.
7. Independent Review Group (IRG). (1998). Silicone Gel Breast Implants: Report of the IRG (United Kingdom).
8. Pinsolle, V., Grinfeder, C., Mathoulin-Pelissier, S. & Faucher, A. Complications analysis of 266 immediate breast reconstructions. J Plast Reconstr Aesthet Surg 56, 1017-1024 (2006).
9. Whitfield, G. A. et al. Incidence of severe capsular contracture following implant-based immediate breast reconstruction with or without postoperative chest wall radiotherapy using 40 Gray in 15 fractions. Radiother Oncol 90, 141-147 (2009).
10. Kronowitz, S. J. & Robb, G. L. Radiation therapy and breast reconstruction: a critical review of the literature. Plast Reconstr Surg 124, 395-408 (2009).
11. Destouet, J. M. et al. Screening mammography in 350 women with breast implants: prevalence and findings of implant complications. AJR Am J Roentgenol 159, 973-978; discussion 979-981 (1992).
12. Park, A. J., Walsh, J., Reddy, P. S., Chetty, U. & Watson, A. C. The detection of breast implant rupture using ultrasound. Br J Plast Surg 49, 299-301 (1996).
13. Berg, W. A. et al. Single- and double- lumen silicone breast implant integrity: prospective evaluation of MR and US criteria. Radiology 197, 45-52 (1995).
14. Brown, S. L., Duggirala, H. J. & Pennello, G. An association of silicone-gel breast implant rupture and fibromyalgia. Curr Rheumatol Rep 4, 293-298 (2002).
15. Brown, S. L., Pennello, G., Berg, W. A., Soo, M. S. & Middleton, M. S. Silicone gel breast implant rupture, extracapsular silicone, and health status in a population of women. J Rheumatol 28, 996-1003 (2001).
16. Gaubitz, M., Jackisch, C., Domschke, W., Heindel, W. & Pfleiderer, B. Silicone breast implants: correlation between implant ruptures, magnetic resonance spectroscopically estimated silicone presence in the liver, antibody status and clinical symptoms. Rheumatology (Oxford) 41, 129- 135; discussion 123-124 (2002).
17. Hölmich, L. R. et al. Self-reported diseases and symptoms by rupture status among unselected Danish women with cosmetic silicone breast implants. Plast Reconstr Surg 111, 723-732; discussion 733-724 (2003).
18. Holmich, L. R. et al. Untreated silicone breast implant rupture. Plast Reconstr Surg 114, 204-214; discussion 215-206 (2004).
19. Holmich, L. R. et al. Prevalence of silicone breast implant rupture among Danish women. Plast Reconstr Surg 108, 848-858; discussion 859-863 (2001).
20. Katzin, W.E., et al., Pathology of lymph nodes from subjects with breast implants: a histologic and spectroscopic evaluation. Am J Surg Pathol 29(4),506-11 (2005).
21. Lahiri, A. and Waters, R., Locoregional silicone spread after high cohesive gel silicone implant rupture. J Plast Reconstr Aesthet Surg, 59(8): 885-886 (2006).
22. Kappel, R., et al., Gel bleed and rupture of silicone breast implants investigated by light-, electron microscopy and energy dispersive x-ray analysis of internal organs and nervous tissue. Clin Med Rev Case Report. 3:1 (2016). doi:10.23937/2378-3656/1410087
23. Dijkman, H. B. P. M., et al., Assessment of Silicone Particle Migration Among Women Undergoing Removal or Revision of Silicone Breast Implants in the Netherlands. JAMA Netw Open (2021). 4(9):e2125381. doi:10.1001/jamanetworkopen.2021.25381
24. Todorov, T. I., et al., A Case of Silicone and Sarcoid Granulomas in a Patient with "Highly Cohesive" Silicone Breast Implants: A Histopathologic and Laser Raman Microprobe Analysis. Int J Environ Res Public Health 18(9):4526 (2021). https://doi.org/10.3390/ijerph1809452
25. Pfleiderer B, Garrido L. Migration and accumulation of silicone in the liver of women with silicone gel-filled breast implants. Magn Reson Med 33(1):8-17 (1995).
26. Garrido L, Pfleiderer B, Jenkins BG, Hulka CA, Kopans, DB. Migration and chemical modification of silicone in women with breast prostheses. Magn Reson Med 31(3):328-30 (1994).
27. Moyer HR, Ghazi BH, Losken A. The effect of silicone gel bleed on capsular contracture: a generational study. Plast Reconstr Surg 130(4):793-800 (2012).
28. Brinton, L. A. et al. Risk of connective tissue disorders among breast implant patients. Am J Epidemiol 160, 619-627 (2004).
29. Hölmich, L. R. et al. Stage of breast cancer at diagnosis among women with cosmetic breast implants. Br J Cancer 88, 832-838 (2003).
30. Janowsky, E. C., Kupper, L. L. & Hulka, B. S. Meta-analyses of the relation between silicone breast implants and the risk of connective-tissue diseases. N Engl J Med 342, 781-790 (2000).
31. McLaughlin, J. K. & Lipworth, L. Brain cancer and cosmetic breast implants: a review of the epidemiologic evidence. Ann Plast Surg 52, 115-117 (2004).
32. Tugwell, P. et al. Do silicone breast implants cause rheumatologic disorders? A systematic review for a court appointed national science panel. Arthritis Rheum 44, 2477-2484 (2001).
33. Wolfe, F. & Anderson, J. Silicone filled breast implants and the risk of fibromyalgia and rheumatoid arthritis. J Rheumatol 26, 2025-2028 (1999).
34. Blackburn, W. D., Jr. & Everson, M. P. Silicone-associated rheumatic disease: an unsupported myth. Plast Reconstr Surg 99, 1362-1367 (1997).
35. Englert, H. et al. Women's health after plastic surgery. Intern Med J 31, 77- 89 (2001).
36. Fryzek, J. P. et al. A nationwide study of connective tissue disease and other rheumatic conditions among Danish women with long-term cosmetic breast implantation. Ann Epidemiol 17, 374-379 (2007).
37. Hochberg, M. C. & Perlmutter, D. L. The association of augmentation mammoplasty with connective tissue disease, including systematic sclerosis (scleroderma): a meta-analysis. Curr Top Microbiol Immunol 210, 411-417 (1996).
38. Kjoller, K. et al. Connective tissue disease and other rheumatic conditions following cosmetic breast implantation in Denmark. Arch Intern Med 161, 973-979 (2001).
39. Lamm, S. H. Silicone breast implants, breast cancer and specific connective tissue diseases: A systematic review of the data in the epidemiological literature Int. J. Toxicol. 17, 497-457 (1998).
40. Lewin, S. L. & Miller, T. A. A review of epidemiologic studies analyzing the relationship between breast implants and connective tissue diseases. Plast Reconstr Surg 100, 1309-1313 (1997).
41. Silverman, B. G. et al. Reported complications of silicone gel breast implants: an epidemiologic review. Ann Intern Med 124, 744-756 (1996).
42. Wong, O. A critical assessment of the relationship between silicone breast implants and connective tissue diseases. Regul Toxicol Pharmacol 23, 74- 85 (1996).
43. Vermeulen, R. C. & Scholte, H. R. Rupture of silicone gel breast implants and symptoms of pain and fatigue. J Rheumatol 30, 2263-2267 (2003).
44. Berner, I., Gaubitz, M., Jackisch, C. & Pfleiderer, B. Comparative examination of complaints of patients with breast-cancer with and without silicone implants. Eur J Obstet Gynecol Reprod Biol 102, 61-66 (2002).
45. Breiting, V. B. et al. Long-term health status of Danish women with silicone breast implants. Plast Reconstr Surg 114, 217-226; discussion 227-218 (2004).
46. Fryzek, J. P. et al. Self-reported symptoms among women after cosmetic breast implant and breast reduction surgery. Plast Reconstr Surg 107, 206- 213 (2001).
47. Kjoller, K. et al. Self-reported musculoskeletal symptoms among Danish women with cosmetic breast implants. Ann Plast Surg 52, 1-7 (2004).
48. Brinton, L. A. et al. Breast cancer following augmentation mammoplasty (United States). Cancer Causes Control 11, 819-827 (2000).
49. Brinton, L. A. et al. Cancer risk at sites other than the breast following augmentation mammoplasty. Ann Epidemiol 11, 248-256 (2001).
50. Brisson, J. et al. Cancer incidence in a cohort of Ontario and Quebec women having bilateral breast augmentation. Int J Cancer 118, 2854-2862 (2006).

51. Deapen, D., Hamilton, A., Bernstein, L. & Brody, G. S. Breast cancer stage at diagnosis and survival among patients with prior breast implants. Plast Reconstr Surg 105, 535-540 (2000).

52. Deapen, D. M., Hirsch, E. M. & Brody, G. S. Cancer risk among Los Angeles women with cosmetic breast implants. Plast Reconstr Surg 119, 1987-1992 (2007).

53. Friis, S. et al. Cancer risk among Danish women with cosmetic breast implants. Int J Cancer 118, 998-1003 (2006).

54. McLaughlin, J. K. et al. Long-term cancer risk among Swedish women with cosmetic breast implants: an update of a nationwide study. J Natl Cancer Inst 98, 557-560 (2006).

55. Mellemkjaer, L. et al. Cancer occurrence after cosmetic breast implantation in Denmark. Int J Cancer 88, 301-306 (2000).

56. Pukkala, E. et al. Incidence of breast and other cancers among Finnish women with cosmetic breast implants, 1970-1999. J Long Term Eff Med Implants 12, 271-279 (2002).

57. Jakub, J. W. et al. Breast cancer in patients with prior augmentation: presentation, stage, and lymphatic mapping. Plast Reconstr Surg 114, 1737-1742 (2004).

58. Miglioretti, D. L. et al. Effect of breast augmentation on the accuracy of mammography and cancer characteristics. Jama 291, 442-450 (2004).

59. de Jong, D. et al. Anaplastic large-cell lymphoma in women with breast implants. Jama 300, 2030-2035 (2008).

60. FDA, 2023. Breast Implants: Reports of Squamous Cell Carcinoma and Various Lymphomas in Capsule Around Implants: FDA Safety Communication. https://www.fda.gov/medical-devices/safety-communications/update-reports-squamous-cell-carcinoma-scc-capsule-around-breast-implants-fda-safety-communication

61. Winther, J. F. et al. Neurological disease among women with silicone breast implants in Denmark. Acta Neurol Scand 103, 93-96 (2001).

62. Ahern, M., Smith, M., Chua, H. & Youssef, P. Breast implants and illness: a model of psychological illness. Ann Rheum Dis 61, 659 (2002).

63. Brinton, L. A., Lubin, J. H., Burich, M. C., Colton, T. & Hoover, R. N. Mortality among augmentation mammoplasty patients. Epidemiology 12, 321-326 (2001).

64. Jacobsen, P. H. et al. Mortality and suicide among Danish women with cosmetic breast implants. Arch Intern Med 164, 2450-2455 (2004).

65. Koot, V. C., Peeters, P. H., Granath, F., Grobbee, D. E. & Nyren, O. Total and cause specific mortality among Swedish women with cosmetic breast implants: prospective study. BMJ 326, 527-528 (2003).

66. Pukkala, E. et al. Causes of death among Finnish women with cosmetic breast implants, 1971-2001. Ann Plast Surg 51, 339-342; discussion 343-334 (2003).

67. Lugowski, S. J. et al. Analysis of silicon in human tissues with special reference to silicone breast implants. J Trace Elem Med Biol 14, 31-42 (2000).

68. Brown, S. L., Todd, J. F., Cope, J. U. & Sachs, H. C. Breast implant surveillance reports to the U.S. Food and Drug Administration: maternal- child health problems. J Long Term Eff Med Implants 16, 281-290 (2006).

69. Kjoller, K. et al. Health outcomes in offspring of Danish mothers with cosmetic breast implants. Ann Plast Surg 48, 238-245 (2002).

70. Signorello, L. B., Fryzek, J. P., Blot, W. J., McLaughlin, J. K. & Nyren, O. Offspring health risk after cosmetic breast implantation in Sweden. Ann Plast Surg 46, 279-286 (2001).

71. Hemminki, E., Hovi, S. L., Sevon, T. & Asko-Seljavaara, S. Births and perinatal health of infants among women who have had silicone breast implantation in Finland, 1967-2000. Acta Obstet Gynecol Scand 83, 1135- 1140 (2004).

72. Flassbeck, D. et al. Determination of siloxanes, silicon, and platinum in tissues of women with silicone gel-filled implants. Anal Bioanal Chem 375, 356-362 (2003).

73. Katzin, W. E., Centeno, J. A., Feng, L. J., Kiley, M. & Mullick, F. G. Pathology of lymph nodes from patients with breast implants: a histologic and spectroscopic evaluation. Am J Surg Pathol 29, 506-511 (2005).

74. Chandra, G., Lo, P. Y., Hitchcock, P. & Lappert, M. F. A convenient and novel route to bis(alkyne)platinum(0) and other platinum(0) complexes from Speier's hydrosilylation catalyst. Organometallics, 191-192 (1987).

75. Lappert, M. F. & Scott, F. P. A. The reaction pathway from Speier's to Karstedt's hydrosilylation catalyst. J. Organomet. Chem. 492, C11-C13 (1995).

76. Lewis, L. N. et al. Mechanism of Formation of Platinum(0) Complexes Containing Silicon-Vinyl Ligands. Organometallics 14, 2202-2213 (1995).

77. Stein, J., Lewis, L.N., Gao, Y., & Scott, R.A. . In situ determination of the active catalyst in hydrosilylation reactions using highly reactive Pt(0) catalyst precursors. J. Am. Chem. Soc. 121, 3693-3703 (1999).

78. Ware Ware, J.E. SF-36 Health survey. Manual and interpretation guide. The Health Institute (1993): 6-1.

79. FDA Guidance for Industry and Food and Drug Administration Staff, Breast Implants-Certain Labeling Recommendations to Improve Patient Communication (September 29, 2020).

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		

Motiva®

www.motivausa.com

DOC-001045 Rev.3
P/N: 110-BIS-0115
Date: 092024

Establishment Labs®

Establishment Labs S.A.
Coyol Free Zone & Business Park Building
0 Street, Building, B25,
Alajuela, Costa Rica.
Phone: +506 2434-2400
Zip code: 20113
customercare@motivausa.com
www.establishmentlabs.com
www.motivausa.com