WARNING: Breast implants have been associated with the development of cancer of the immune system called Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). More detailed information can be found inside on BIA-ALCL section.

Patients with breast implants should have regular clinical follow-up with their surgeon.

DIRECTIONS FOR USE

ESTABLISHMENT LABS
STERILE SILICONE BREAST IMPLANTS
MOTIVA IMPLANT MATRIX®

Motiva® implants

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Directions For Use
Sterile Silicone Breast Implants
Motiva Implant Matrix®
Establishment Labs

INTRODUCTION
The aim of this Product Insert is to provide an overview of essential information about Establishment Labs Sterile Silicone Breast Implants Motiva Implant Matrix®, including device description, indications for use, contraindications, warnings, precautions, relevant topics that must be discussed with the patient, adverse events, other reported conditions, returned goods policy, product evaluation, warranty and medical device reporting.

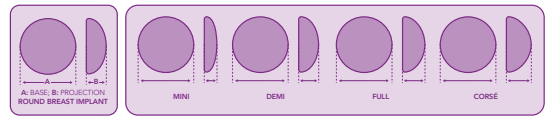
DEVICE DESCRIPTION
Establishment Labs Sterile Silicone Breast Implants Motiva Implant Matrix® are mammary augmentation/ reconstruction devices constructed of successive cross-linked layers of silicone elastomer and a low diffusion barrier shell technology that provide these implants their elasticity and integrity. All implants are composed of the above described shell, a patch, and silicone gel fill. The shell is filled with ProgressiveGel™ PLUS or ProgressiveGel™ ULTIMA®, an Establishment Labs silicone gel proprietary formula. All silicone raw materials are supplied by a FDA approved source in the USA.

The following are the reference ranges of Establishment Labs Sterile Silicone Breast Implants Motiva Implant Matrix®:

Motiva Implant Matrix® - Round

	MINI		DEMI		FULL		CORSÉ	
Base (cm)	P(cm)	V (cc)	P(cm)	V (cc)	P (cm)	V (cc)	P (cm)	V (cc)
8.5	2.2	105	3.1	135	3.5	145	4.0	180
9	2.3	125	3.3	155	3.7	175	4.2	210
9.5	2.4	140	3.4	180	3.9	205	4.5	240
9.75	2.4	150	3.4	190	4.0	220	4.6	260
10	2.5	160	3.5	205	4.1	235	4.8	280
10.25	2.5	170	3.5	215	4.2	255	4.9	300
10.5	2.6	185	3.6	230	4.3	275	5.1	325
10.75	2.6	205	3.7	245	4.4	295	5.2	350
11	2.7	220	3.8	265	4.5	315	5.4	380
11.25	2.7	230	3.8	285	4.6	335	5.5	410
11.5	2.8	245	3.9	300	4.7	355	5.7	440
11.75	2.8	260	3.9	320	4.8	375	5.8	475
12	2.9	275	4.0	340	4.9	400	6.0	510
12.25	2.9	290	4.0	360	5.0	425	6.1	550
12.5	3.0	310	4.1	380	5.1	450	6.3	590
13	3.1	360	4.3	425	5.3	500	6.6	650
13.5	3.2	400	4.4	475	5.5	550	6.9	725
14	3.3	430	4.5	525	5.7	625	7.2	825
14.5	3.4	475	4.6	575	5.9	700	7.5	925
15	3.5	525	4.8	625	6.1	775	7.8	1050

P=Projection
V=Volume



INDICATIONS
Establishment Labs Sterile Silicone Breast Implants Motiva Implant Matrix® are indicated for the following procedures in female patients:

- **Breast augmentation for women of at least 18 years old,** including previous augmentation to increase the breast size and revision surgery to correct or improve the result of a previous breast augmentation surgery.
- **Breast Reconstruction.** Breast reconstruction, including previous reconstruction to replace breast tissue that has been removed due to cancer or trauma, or that has failed to develop properly due to a severe breast anomaly, as well as revision surgery to correct or improve the results of a previous breast reconstruction surgery.

CONTRAINDICATIONS
Breast augmentation with implants is contraindicated in:

- Women with existing carcinoma of the breast, without mastectomy.
- Women with advanced fibrocystic disease considered premalignant, without accompanying subcutaneous mastectomy.
- Women with active infections.
- Women who are currently pregnant or nursing.
- Women with any disease, including uncontrolled diabetes, which is clinically known to impact wound-healing ability.
- Women who show tissue characteristics clinically incompatible with mammoplasty, such as tissue damage resulting from radiation, inadequate tissue, compromised vascularity or ulceration.
- Women with any condition – or treatment – determined by the surgeon to constitute an unjustifiable surgical risk (e.g., unstable cardiovascular disease, coagulopathies, chronic pulmonary problems, etc).

WARNINGS
Care during surgical insertion and subsequent procedures:

- Do not allow sharp instruments, such as scalpels or needles, to come in contact with the device during the implantation or other surgical procedures. Patients should be instructed to inform other treating physicians to also observe this warning.
- Do not immerse the implant in iodine solution. If iodine solution is used in the pocket, make sure that it is rinsed thoroughly with deionized water so that no residual solution remains in the pocket.
- Do not allow the implant to come in contact with cauterization devices.
- Do not alter the implant or attempt to repair or insert a damaged implant.
- Ensure no excessive force is applied to a very small area of the shell during insertion of the device throughout the incision. Instead, apply force over as large an area of the implant as possible during insertion. Excessive forces can lead to implant failure by either gel fracture or implant rupture.
- The incision should be of appropriate length to accommodate the volume and profile of the implant. This will reduce the potential for creating excessive stress to the implant when inserting it. Forcing implants through a very small opening may result in local weakening of the breast implant shell potentially

leading to shell damage, gel fracture and possible implant rupture.
- Periareolar and axillary incision sites may make the insertion more difficult, increasing the risk of damage to the implant. Periareolar incision may considerably reduce the possibility of future breastfeeding.
- Do not use the periumbilical approach to place the implant.
- Avoid creating wrinkles or folds in the device during the insertion. It is recommended to run a finger around the implant before closing to make sure the implant is flat.
- Do not place more than one implant per breast pocket.
- Do not treat capsular contracture by closed capsulotomy or forceful external compression, which will likely produce implant damage, rupture, folds, and/or hematoma.
- Procedures such as open capsulotomy, breast pocket revision, hematoma/seroma aspiration, biopsy, and lumpectomy might result in damage to the implant shell, so they must be carefully performed. Care should be taken when re-positioning the implant during subsequent procedures to avoid contamination of the implant. Use of excessive force during any subsequent procedure can contribute to local weakening of the breast implant shell, potentially leading to shell damage and possible implant rupture.
- Do not re-use or re-sterilize any product that has been previously implanted. Breast implants are intended for single use only.
- Do not use microwave diathermy in patients with breast implants, as it has been associated with tissue necrosis, skin erosion, and implant extrusion.

PRECAUTIONS

1. Specific Populations

Safety and effectiveness of breast augmentation surgery have not been established for the following populations and/or conditions:
- Patients with autoimmune diseases (e.g., lupus, scleroderma).
- Patients whose immune system is compromised (e.g., currently receiving immunosuppressive therapy such as steroids).
- Patients with conditions or medications that may interfere with wound healing ability (e.g., poorly controlled diabetes, or corticosteroid therapy) or blood clotting (e.g., concomitant Warfarin therapy).
- Patients with reduced blood supply to breast or overlying tissue.
- Patients undergoing radiation therapy.
- Women with ptotic breasts where nipples fall below the inframammary fold, without concurrent mastopexia.
- Previous repeated contour correction failures.
- Patients with clinical diagnosis of depression or other mental health disorders, including BDD (body dysmorphic disorder) and eating disorders. The patient should be advised to discuss any history of mental health disorders with her surgeon prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until stabilization of these conditions prior to undergoing breast implant surgery.
- There may be other patients with complicated medical histories, who are judged to present risk factors that might interfere with the safety and effectiveness of the breast implant surgery. As with any surgical procedure, the patient's medical history should be carefully reviewed to ensure that she is an appropriate candidate for breast implant surgery.

2. Surgical Precautions

Preliminary product examination– Immediately before insertion, examine the device by gently manipulating it while carefully checking for rupture, gel fracture, leakage sites or particulate contamination.

Surgical technique and implant selection– There are several surgical techniques that can be used to perform the implantation of a silicone gel-filled breast implant. Therefore, the surgeon is advised to use his/her clinical judgment in choosing the procedure that is best for the patient, consistent with this product insert. The incision should be of appropriate length to accommodate the volume and profile of the implant with highly cohesive gel. This will reduce the potential for creating excessive stress to the implant when inserting it. Forcing implants through a very small opening may result in damage to the implants gel and possible ruptures or gel fractures. After setting realistic aesthetic goals that assure mutual understanding between doctor and patient, the surgeon must choose from current and accepted surgical techniques to minimize the incidence of adverse reactions and achieve the best results.
The implant size should be consistent with the patient's chest wall dimensions, including base width measurements, characteristics of the tissue and projection of the implant.
Textured implants, larger implants, subglandular placement, and an insufficient amount of tissue available to cover the implant may cause them to be more palpable.
Implants of larger sizes may increase the risk of complications such as extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling.

CAUTION: Only surgeons with qualified training and certified by the corresponding national medical board of their countries should use this product. The use of this product by unqualified practitioners may result in extremely poor aesthetic outcomes and serious adverse effects.

RELEVANT TOPICS THAT MUST BE DISCUSSED WITH THE PATIENT

Patient Counseling Information

This document and the information for the patient must be carefully reviewed before counseling a patient about Establishment Labs Sterile Silicone Breast Implants Motiva Implant Matrix® and breast augmentation surgery. Doctors must thoroughly read and understand the contents of these document and make sure that any questions or concerns have been resolved prior to proceeding with use of the device. Breast implant surgery is an elective procedure, and the patient must understand its potential risks and benefits in order to make an informed decision. For this reason, the patient should be instructed to read the document called **"DOC-001004 Information for the patient breast augmentation and reconstruction with Motiva Implants®".** The doctor must discuss with the patients sections on warnings, contraindications, precautions, important factors to consider, complications and all other aspects of the document. The physician should inform the patient about the potential complications and that medical management of serious complications may include additional surgery and explanation.

Informed Consent

Each patient should be given the Establishment Labs **"DOC-001004 Information for the patient breast augmentation and reconstruction with Motiva Implants®"** during her surgical consultation. It is the surgeons´ responsibility to ensure this happens and it is a requirement for the use of the device. The patient must be given enough time to read and completely understand the information regarding the risks, benefits and recommendations associated with silicone gel-filled breast implant surgery.
In order to document a successful informed decision process, the patient, a witness and the surgeon should sign the **"Informed Consent Document"**, which will be part of the patient's medical file.

Some of the relevant topics patients need to be aware of when considering the use of silicone gel-filled breast implants are:

Rupture– Breast implants can rupture when the shell develops a tear or hole. Rupture can occur at any time after implantation, but it is more likely to happen when the implant has been in place for a long time. Rupture of a silicone gel-filled breast implant is most often silent (the patient does not experience any symptoms and there are no physical signs of changes with the implant) rather than symptomatic. Therefore, patients should be advised to have regular MRIs over their lifetime to screen for silent rupture even if they are not having any apparent problems. The first MRI should be performed at 3 years postoperatively, then regularly at 2-year intervals, and the images submitted to the treating surgeon. Patients should be provided with a list of radiology centers with experience with breast implant MRI to scan for signs of rupture. The importance of these MRI evaluations should be emphasized. If rupture is noted on an MRI, the patient should be strongly encouraged to have her implant removed.

Gel Fracture– Gel fracture can occur with cohesive silicone and occur most frequently as a consequence of subjecting the implant to excessive compression forces during the implantation. Alternatively, gel fracture can occur due to the development of capsular contracture and may result in device distortion.

Mammography– Patients should be advised to have routine mammography performed according to their surgeon's recommendations. The importance of these exams should be emphasized. Patients should be instructed to inform their examiners about the presence, type, and placement of their implants, and to request a diagnostic mammography, rather than a screening 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 examining patients with breast implants and the use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast. Pre and post-surgical mammographies may be performed to determine a baseline for routine future studies in augmentation patients.

Explantation– Implants are not lifetime devices, and there is a possibility that patients will undergo implant removal(s), with or without replacement, over the course of their life. When implants are explanted without replacement, changes to the patient's breasts may be irreversible. Complication rates are higher following revision surgery (removal with replacement).

Reoperation– Rupture, unacceptable cosmetic outcomes (dimpling, wrinkling, and other potentially permanent cosmetic changes of the breast) and other complications may require additional surgeries to the patient´s breasts. Patients should be advised that their risk of future complications increases with revision surgery as compared to primary augmentation or reconstruction surgery. For example, the risk of severe capsular contracture doubles for both augmentation and reconstruction patients with implant replacement compared to first time implantation. There is a risk of an accidental compromise of implant shell integrity during reoperation, potentially leading to product failure.

Infection– Signs of acute infection reported in association with breast implants include edema, erythema, tenderness, pain, and fever. As with other invasive surgeries, Toxic Shock Syndrome (TSS), a life-threatening condition, has been reported in rare instances following breast implant surgery. Symptoms of TSS occur suddenly and can include high fever (102°F, 38.8°C or higher), vomiting, diarrhea, sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches and drops in blood pressure, which may cause fainting. Patients should immediately contact their physician for diagnosis and treatment if any of these symptoms occur.

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 implant excessively. The patient should be told that the presence of lumps, persistent pain, swelling, hardening, or change in the implant shape could suggest symptomatic rupture of the implant. If the patient has any of these signs, she should be advised to report them, and possibly have an MRI evaluation to screen for rupture.

Lactation– Breast implant surgery may interfere with the ability to successfully breast feed, either by reducing or eliminating milk production. Particularly, periareolar incision may considerably reduce the possibility of breast-feeding.

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

Topical Medications– The patient should consult a physician or a pharmacist before the use of topical medicines (e.g. steroids) in the breast area.

Trauma– The patient should consult the surgeon or physician if any complications are suspected, in particular in the case of trauma or compression caused, for example, by extreme massaging of the breast region, by some sport activities or by using seat belts.

Smoking– Smoking may interfere with the healing process.

Radiation to the Breast– Establishment Labs 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, necrosis, and implant extrusion.

Insurance Coverage– Patients should check with their insurance company regarding coverage issues before undergoing surgery.

Mental Health and Elective Surgery– It is important that all patients seeking an elective procedure such as breast augmentation have realistic expectations that focus on improvement rather than perfection. Ask the patient to openly discuss, prior to surgery, any history of depression or other mental health disorders.

Postoperative Care:

The patient should be advised that she will likely feel tired and sore for several days following the operation, and that her breasts may remain swollen and sensitive to physical contact for a month or longer. She also could experience a feeling of tightness in the breast area as the skin adjusts to the new breast size. The patient should avoid any strenuous activities for at least a couple of weeks but should be able to return to work within a few days. Breast massage may also be recommended as appropriate.

Life expectancy of the breast implant:
Breast implants are not lifetime devices. However, the life expectancy of a silicone breast implant cannot be precisely estimated, as there are many factors beyond the manufacturer´s control that can affect the longevity of a device. The time period varies from woman to woman. Some women could need replacement surgery few years after the augmentation procedure while others can have their implants intact for 10-20 years. Therefore, the life expectancy of the implant cannot be guaranteed.

ADVERSE EVENTS

If any of the following or other adverse events occurs fill out a complaint notification form, providing all available information on patients, product information, a reason for the complaint and a summary of the event and send it to https://motiva.health/support/.

Because breast implant surgery is more often performed using general anesthesia, it is associated with the same risks as other invasive surgical procedures. After breast implant surgery, patients might experience swelling, hardness, discomfort, itching, allergies, bruising, twinges and pain over the first few weeks. Potential adverse events that may occur with silicone gel-filled breast implant surgery include:

Capsular Contracture

Normally, capsules of collagen fibers form as an immune response around a foreign body, such as a breast implant, tending to isolate it. Capsular contracture occurs when the capsule tightens and squeezes the implant. This can cause the implant to turn rigid (from slightly firm to quite hard) and the firmest ones can cause varying degrees of discomfort, pain and palpability. In addition to the firmness, capsular contracture can result in a deformed breast, visible surface wrinkling and/or displacement of the implant. Detection of breast cancer by mammography may also be more difficult. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in patients undergoing revision surgery than in patients undergoing primary implantation surgery. Capsular contracture is a risk factor for implant rupture, and it is the most common reason for reoperation in augmentation and reconstruction patients.
Capsular contracture is graded into 4 levels depending on its severity. Baker Grade I: the breast is normally soft and looks natural; Baker Grade II: the breast is a little firm but looks normal; Baker Grade III: the breast is firm and looks abnormal; Baker Grade IV: the breast is hard, painful, and looks abnormal. Patients should also be advised that additional surgery might be needed in cases where pain and/or firmness are severe (Baker Grades III or IV) and that capsular contracture may happen again after additional surgeries.
Correction of capsular contracture may require surgical removal or release of the capsule, or removal and possible replacement of the implant itself. Closed capsulotomy (external manipulation of the capsule in order to “pop” the tissue capsule and open it up) used to be a common procedure for treating capsular contracture, but most manufacturers, including Establishment Labs, contraindicate it because it can cause implant rupture.

Rupture

Breast implants can potentially remain intact for decades in the body, but all such devices will fail at some point.
Breast implants rupture when the shell develops a tear or hole. Rupture can occur at any time after implantation, but it is more likely to occur the longer the implant is in place. The following may cause implants to rupture: damage by surgical instruments, implant stress and weakening during implantation, age and design of the implant, submuscular rather than subglandular location, occurrence of post-operatory hematomas or seromas, folding or wrinkling of the implant shell, excessive force to the chest (e.g., during closed capsulotomy, which is contraindicated), trauma, compression during mammographic imaging, and severe capsular contracture.
Silicone gel-filled implant ruptures are most often silent. (MRI examination is currently the best screen method for silent rupture.) This means that most of the time neither doctor nor patient will know if the implant has a tear or hole in the shell. This is why a first MRI is recommended after 3 years, and then at regular intervals every 2 years thereafter, to screen for ruptures. Sometimes there are symptoms associated with gel implant rupture, such as lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.
When MRI findings of rupture are found, or if there are signs or symptoms of rupture, the implant should be removed, with or without replacing it. If the patient develops symptoms that suggest implant rupture, she should be told to have an MRI evaluation to screen for rupture.
If rupture occurs, silicone gel may either remain within the scar tissue capsule surrounding the implant (intracapsular rupture), move outside the capsule (extracapsular rupture), or move beyond the breast (migrated gel). There is also a possibility that rupture may progress from intracapsular to extracapsular and beyond.
Below is a summary of information related to the health consequences of implant rupture, which **have not been fully established**, in women who had a variety of implant models from different manufacturers.

- Local breast complications that were associated with rupture in the literature include breast firmness, a change in breast shape or size, and breast pain. These symptoms are not specific to rupture and may be also experienced by women who have capsular contracture.
- There have been rare reports of gel migration to nearby tissues such as the chest wall, armpit, or abdominal wall, and to more distant locations down the arm or into the groin. This has led to nerve damage, granuloma formation and/or breakdown of tissues in direct contact with the gel in a few cases. There have been reports of silicone presence in the liver of patients with silicone breast implants. Movement of silicone gel material to lymph nodes in the armpit also has been reported, even in women without evidence of rupture, leading to lymphadenopathy.
- Concerns have been raised over whether ruptured implants are associated with the development of connective tissue or rheumatic diseases and/ or symptoms such as fatigue and fibromyalgia. A number of epidemiology studies have evaluated large populations of women with breast implants from a variety of manufacturers and implant models. These studies do not support an association of breast implants and rheumatic disease.

Gel Fracture

Gel fracture is defined as a fissure or crack in the gel that occurs when the filler is forcibly separated by exceeded intrinsic forces. As a result, the shape is irrevocably lost requiring replacement. (Jill Baker et all,2016).

Gel fractures can occur with cohesive silicone and occur most frequently as a consequence of subjecting the implant to excessive compression forces during the implantation. Alternatively, gel fracture can occur due to the development of capsular contracture and may result in device distortion.

Be advised that during device insertion excessive force should not be applied to a small area of the shell. Instead, apply force over as large an area of the implant as possible.

The incision should be of appropriate length to accommodate the volume and profile of the implant with highly cohesive gel. This will reduce the potential for creating excessive stress to the implant when inserting it. Forcing implants through a very small opening may result in damage to the implants gel and possible ruptures or gel fractures.

Gel fracture can be detected by ultrasound or magnetic resonance imaging (MRI). The majority of gel fractures are clinically undetectable.

Pain

Most women undergoing augmentation or reconstruction with a mammary implant will experience some post-operatory breast and/or chest pain. While this pain normally recedes in most women as they heal after surgery, it can become a chronic problem in other women.
Hematoma, migration, infection, implants that are too large, or capsular contracture can cause chronic pain. Sudden, severe pain may be associated with implant rupture. The surgeon should instruct the patient to immediately report if there is significant pain or if pain persists.

Changes in Nipple and Breast Sensation

Breast surgery can result in an increased/decreased breast and/or nipple sensitivity. Typically the sensation is lost after complete mastectomy where the nipple itself is removed, and can be severely lessened by partial mastectomy. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. While some of these changes can be temporary, they can also be permanent, and may affect the patient's sexual response or ability to nurse.

Infection

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

Hematoma/Seroma

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

EN (AUS)

Breast-feeding

Although most women with breast implants who attempt nursing have successfully breastfed their babies, it is not known if there are increased risks for a woman with breast implants or if the children of women with breast implants are more likely to have health problems. At this time, it is not known if it is possible for a small amount of silicone to pass from the breast implant silicone shell into breast milk during breastfeeding, or what the potential consequences might be.
A periareolar surgical approach may further increase the chance of breastfeeding difficulties. However, the American Academy of Pediatrics has stated that there is no reason why a woman with implants should refrain from nursing.

Calcification

Calcium deposits can form in scar tissue surrounding the implant and may cause pain and firmness, and be visible on a mammography. These deposits must be identified as different from calcium deposits that are a sign of breast cancer. Additional surgery may be necessary to remove and examine calcifications. Calcium deposits also occur in women who undergo breast reduction procedures, in patients who have had hematoma formation, and even in the breasts of women who have not undergone any breast surgery. The occurrence of calcium deposits significantly increases with age.

Delayed Wound Healing

Some patients may experience a prolonged wound healing time. Smoking may interfere with the healing process. Delayed wound healing may increase the risk of infection, extrusion, and necrosis. Wound healing times may vary depending on the type of surgery or incision.

Implant Extrusion

Lack of adequate tissue coverage, local trauma or infection may result in exposure and extrusion of the implant. This has been reported with the use of steroid drugs or after radiation therapy of breast tissue. If tissue breakdown occurs and the implant becomes exposed, implant removal may be necessary, which may result in additional scarring and/or loss of breast tissue.

Necrosis

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

Granulomas

These are benign lumps that can form when body cells surround foreign material such as silicone. Like any lump, it should be further evaluated to rule out a malignancy.

Breast Tissue Atrophy/Chest Wall Deformity

The pressure of the breast implant may cause the breast tissue to thin and shrink (with increased implant visibility and palpability), potentially leading to chest wall deformity. This can occur while implants are still in place or following implant removal without replacement. Either of these conditions may result in additional surgeries and/or unacceptable dimpling/creasing of the breast.

Lymphadenopathy

Literature reports associate lymphadenopathy with both intact and ruptured silicone breast implants. One study reported that armpit lymph nodes from women with both intact and ruptured silicone gel implants had abnormal tissue reactions, granulomas, and the presence of silicone.

These reports occurred in cases of women who had implants from a variety of manufacturers and implant models.

Unsatisfactory Results

Unsatisfactory results such as wrinkling, asymmetry, implant displacement/ migration, incorrect size, implant palpability/visibility, scar deformity, and/or hypertrophic scarring, may occur. Some of these results may cause discomfort. Pre-existing asymmetry may not be entirely correctable by implant surgery. Revision surgery could be indicated to increase patient satisfaction, but this involves additional considerations and risks. Careful preoperative planning and surgical technique can minimize but not always prevent unsatisfactory results.

Other Reported Conditions

There have been reports in the literature of other conditions in women with silicone breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. However, no causal relationship has been established between breast implants and the conditions listed below.

Connective Tissue Disease (CTD)

Since the early 1990s, nearly a dozen comprehensive systemic reviews have been commissioned by government health ministries in several countries to examine the alleged links between silicone gel breast implants and systemic diseases. A clear consensus has emerged from these independent scientific reviews that there is no clear evidence of a causal link between the implantation of silicone breast implants and connective tissue disease.

Cancer

Breast cancer reports in the medical literature reveal that patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer. 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 medical literature indicate that breast implants do not significantly delay breast cancer detection or adversely affect cancer survival prognosis in implanted women. Some studies even suggest lower rates of breast cancer in women with breast implants.

Neurological Disease, Signs, and Symptoms

Some women with breast implants have experienced neurological disturbances (e.g., visual symptoms or alterations in sensation, muscle strength, walking, balance, thinking or memory) or diseases (e.g., multiple sclerosis) and they believe those symptoms are related to their implants. However, there is no evidence in published literature of a causal relationship between breast implants and neurological disease.

Gel Diffusion

Small quantities of silicone may diffuse through the elastomer envelope of silicone gel-filled implants. The detection of small quantities of silicone in the periprosthetic capsule, axillary lymph nodes and other distal regions in patients with apparently intact gel-filled implants has been reported in the literature. Some studies on long-term implants have suggested that gel-bleed may contribute to the development of capsular contracture and lymphadenopathy. On the other hand, evidence against gel-bleed being a significant contributing factor to capsular contracture and other local complications is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast implants than for saline-filled breast implants.

Malposition

Malposition of a breast implant is defined as an incorrect placement during surgery or the shifting of the implant from its original position. Malposition has been a frequent event reported due to its multifactorial causes and it can be expected during the lifetime of the device.

The shifting of the implants can be produced by trauma, capsular contracture, gravity, or initial wrong placement. The surgeon must plan the operation carefully and conduct the surgery with a technique that can minimize, but not completely evade the risk of malposition. The risk associated with this event is dissatisfaction with aesthetic outcomes.

The clinical symptoms manifested by the patients are change in breast shape, displacement or sensation of firmness. Revision surgery may be indicated to achieve patient satisfaction. New considerations and risks need to be taken into account before performing a revision surgery.

Bottoming-out

The inferior displacement of a breast implant, increasing the distance between the nipple-areolar complex and the inframammary fold, after breast implant surgery. Risk factors reported in the literature are, but not limited to the quality of the preexisting breast tissue (thin subcutaneous tissue, defective dermal elements, breast tuberosity), the breast implant selection (larger implants), the IMF dissection and the placement of the implant during surgery (submuscular and subglandular planes). The clinical symptoms resulting from a bottoming out implant are asymmetry, upward-pointing nipples, sagging breast, palpable implant, among others. Prevention of this complication is based on the anticipation of the possible causes, for example: a careful and individual assessment of the mammary soft-tissues, a careful implant selection, preparation with a technique that can minimize the risk, and to provide adequate breast support after the surgery. The treatments may vary depending on the severity of the complication and go from a simple sub mammary fixation to the use of additional supporting materials.

Flipping

Anterior/posterior malposition, also called flipping, has been described to occur more frequently with cohesive gel implants. The shape of the breast is lost because the flat base of the implant is positioned anteriorly, deforming the breast of the patient. It has been reported in the literature that the interaction between breast envelopes, physical characteristics of the implant, and the pocket dissection is the cause of malposition. Other theories include the involution of the breast tissue. Regarding the implant characteristics, it has been associated with the presence or absence of texturing, the shape/profile of the implant, and the gel-filling ratio. Other factors such as infection, hematoma, capsular contracture, dissection, surgeon´s experience, physical activity, and external manipulation of the implant could potentially contribute to the development of this complication. The diagnosis is based on clinical evidence: the patient complaints of loss of breast shape, which is confirmed by the inspection of the affected area. MRI or CT imaging to validate the diagnosis can be useful but are not necessary. Flipping can be treated with bimanual manipulation in the office and can be repeated in recurrent cases. However, in some cases, it may be necessary a revision surgery to reduce pocket dimensions.

Interference with Mammography

Breast implants (especially in subglandular placement) may complicate the interpretation of mammographic images by obscuring the underlying breast tissue and/or by compressing overlying tissue. Despite of the fact that the presence of breast implants lessens tissue compression range during mammography, a number of studies looking at breast cancers in women with

implants have found no significant difference in stage of disease at time of diagnosis, and prognosis appears to be similar in implanted and nonimplanted patients. Accredited mammography centers, technicians with experience in imaging patients with breast implants, and use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast. Anterior breast tissue is best visualized with displacement views and posterior breast tissue with compression views. The decrease in visible area of 35% with compression views is improved to 25% with displacement views.

Interference with Magnetic Resonance Imaging (MRI)

Sterile Silicone Breast Implants Motiva Implant Matrix® with a *microtransponder* are considered MRI conditional. The *microtransponder*, during an MRI study, can create an MRI image immediately around the *microtransponder* (known as an artifact) that can prevent radiologists from being able to see parts of the implant's footprint and parts of the patient's tissue.

Therefore, there are potential added MRI risks associated with this artifact including, but not limited to, an inadequate evaluation of the implant shell for the detection of rupture or missing a diagnosis of cancer should it obscure a cancer in the artifact area.

Calculated risk of missing a shell rupture due to the artifact is 1 for every 166,000 units of Motiva Implants® with Qid® (*microtransponder*).

Risk of missing breast cancer detection due to the artifact has been determined to be 1 high-risk patient with a cancer recurrence for every 596 high-risk patient MRI screening exams performed on patients with Qid Motiva Implants®. When MRI is used in combination with US, to screen the high-risk patient group, it would take 17,892 MRI and US combination screening exams before a patient with cancer recurrence is likely to be missed (false negative).

Reduction of these risks can be achieved by performing an Ultrasound (US) in addition to the MRI thereby allowing the radiologist to see the area within the artifact produced in the MRI. As such, the radiologist should be informed of the presence of the *microtransponder* and that it is embedded near the patch area inside the breast implant. The presence of an MRI imaging void artifact should be anticipated along with its expected size.

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

BIA-ALCL is a rare type of T-cell lymphoma involving cells of the immune system. The World Health Organization in the year 2016 recognized it as a breast implant-associated disease. The exact number of cases remains difficult to determine due to significant limitations in worldwide reporting and lack of global implant sales data. It has been reported that most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces.

The French National Agency for Medicines and Health Products Safety (ANSM) has requested manufacturers of textured breast implants to perform biocompatibility testing. Establishment Labs has complied with this request.

There is a significant body of medical literature relating to breast implants and the risk of developing ALCL. According to the FDA, all of the information reviewed as of the date of FDA's March 2017 notice, suggests that "women with breast implants have a very low but increased risk of developing ALCL compared to women who do not have breast implants". Most cases of breast implant associated ALCL are treated by removal of the implant and the capsule surrounding the implant and some cases have been treated by chemotherapy and radiation.

The following are considerations from the FDA to the investigators regarding BIA-ALCL:

If you have patients with breast implants, you should continue to provide them routine care and support including regular clinical follow-up. BIA-ALCL is a very rare condition; when it occurs, it has been identified most frequently in patients undergoing implant revision operations for late onset persistent seroma. Because it has generally only been identified in patients with late onset of symptoms such as pain, lumps, swelling, or asymmetry, prophylactic breast implant removal in patients without symptoms or other abnormality is not recommended.

Current recommendations include the steps below:

Be aware that most confirmed cases of BIA-ALCL have occurred in women with textured breast implants. Provide the manufacturers labeling as well as any other educational materials to your patients before surgery and discuss with them the benefits and risks of the different types of implants.

Consider the possibility of BIA-ALCL when you have a patient with late onset, persistent peri-implant seroma. In some cases, patients presented with capsular contracture or masses adjacent to the breast implant. If you have a patient with suspected BIA-ALCL, refer the patient to an appropriate specialist for evaluation. When testing for BIA-ALCL, collect fresh seroma fluid and representative portions of the capsule and send for pathology tests to rule out BIA-ALCL. Diagnostic evaluation should include cytological evaluation of seroma fluid with Wright Giemsa stained smears and cell block immunohistochemistry testing for cluster of differentiation (CD) and Anaplastic Lymphoma Kinase (ALK) markers. Develop an individualized treatment plan in coordination with the patient's multi-disciplinary care team. Consider current clinical practice guidelines, such as those from the Plastic Surgery Foundation or the National Comprehensive Cancer Network (NCCN) when choosing your treatment approach.

For the latest statistical data on reported cases refer to:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm

INSTRUCTIONS FOR USE

Single Use

This product is intended to be used only in one patient for a single procedure. DO NOT reuse explanted implants. To reuse a single-use device could expose patients and staff to risks which outweigh the perceived benefits of using such devices. This product is not intended to be reprocessed in any way and/or used again, not even on the same patient. The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk, such as infection, the inability to assure the proper cleaning and decontamination, the presence of residues of cleaning agents, reaction to endotoxins, exposure to other bio-hazards and/ or device failure. This practice may also have legal implications that vary according to each jurisdiction.

Product Traceability

The product traceability stickers, provided with each device and located within the internal product packaging, provide product specific information and should be attached to the patient's chart for identification purposes. Stickers are also available for the Patient ID Card and the hospital files, if applicable. The surgeon should encourage the patient to participate in the Establishment Labs device-tracking program, entering their implant(s) information at www.motivaimplants.com.

This will help ensure that Establishment Labs has a record of each patient's contact information so that they can be contacted in the event of a field action or other problems with the implants of which they should be made aware.

Sterile Product

Product is sterilized by the manufacturer using Dry Heat Sterilization method, each sterile silicone breast implant is supplied in a sealed, double sterile barrier primary package. Use standard procedures to maintain sterility during transfer of the breast implant to the sterile field. Remove the breast implant from their packages in an aseptic environment, using talc-free gloved hands.

Sterility of the implant is maintained only if the thermoform packages, including the package seals, are intact.

DO NOT use the product if the thermoform packages or seals have been damaged.

DO NOT re-sterilize the product.

Avoid prolonged exposure to extreme storage conditions. We recommend keeping these devices at room temperature, at atmospheric pressure, in dry conditions and away from direct sunlight.

DO NOT implant any device that may appear to have particulate contamination, damage, or loss of shell integrity. A sterile back-up implant must be readily available at the time of surgery.

DO NOT implant any device that may appear to have leaks or scratches.

How to Open Sterile Product Package

DO NOT expose the breast implant to talc, sponges, towels, or other contaminants.

1. A non-sterile team member should open the outer package.
2. Remove the inner package and invert it over the sterile field, allowing the sealed inner thermoform package to gently slide into the field.
3. Use the pull-tab to open the lid of the inner thermoform package.
4. Retrieve the breast implant and examine it for any particulate contamination, damage, or loss of shell integrity. If satisfactory, return the breast implant to the inner thermoform tray. At this point, you might slightly rinse the implant with a small amount of saline to remove the static and cover the tray whit the lid until implantation to prevent contact with airborne and surgical field particulate contaminants.

Surgical Technique and Implant Selection

There are several surgical techniques that can be used to perform the implantation of silicone gel-filled breast implants. Therefore, the surgeon is advised to use his/her clinical judgment in choosing the procedure that is best for the patient, consistent with this product insert. After setting realistic aesthetic goals that assure mutual understanding between doctor and patient, the surgeon must choose from current and accepted surgical techniques to minimize the incidence of adverse reactions and achieve the best results.

The surgeon must carefully assess the implant size, projection and surface, as well as the incision placement, pocket dissection and implant placement criteria according to the patients' anatomy and desired aesthetic outcomes.

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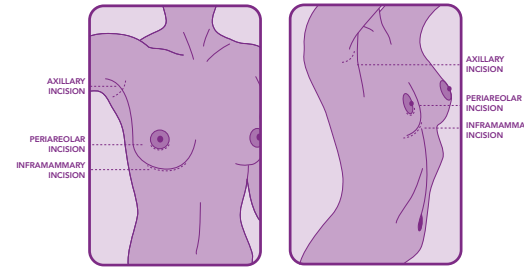
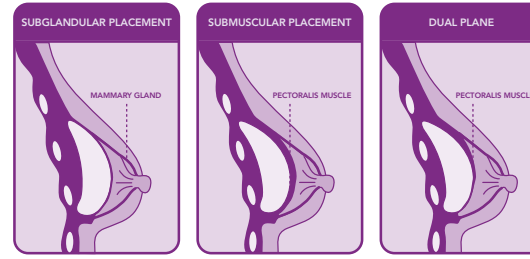


Incision Site Selection

- The periareolar incision is usually more concealed but may considerably reduce the possibility of future breastfeeding as compared to other incision sites. A periareolar incision may be associated with a higher risk of changes in nipple sensation.
- The inframammary incision is generally less concealed than the periareolar, but it is associated with less breast-feeding difficulties.
- The axillary incision is the least concealed of all incision sites.
- The periumbilical approach should not be used with Sterile Silicone Breast Implants Motiva Implant Matrix® for a number of reasons, including potential damage to the implant shell.



Implant Placement Selection

- The possible benefits of submuscular placement are that it may result in less palpable implants, less likelihood of capsular contracture, and easier mammographies. This placement may be preferable if the patient has thin or weakened breast tissue. However, submuscular placement is associated with a longer surgical procedure, a more prolonged recovery period and more pain. Also, it may make it more difficult to perform some reoperation procedures.
- Subglandular placement may make surgery and recovery shorter, be less painful, and provide easier access for reoperation than the submuscular placement. However, this placement may result in more palpable implants, greater risk of capsular contracture, ptosis and increased difficulty in imaging the breast with mammography.

- Dual plane placement has been associated by some authors with the benefits of submuscular placement with the advantages of a faster recovery and less pain and postoperative discomfort.

During the Surgical Procedure:

- It is advisable to have more than one size of breast implant in the operating room at the time of surgery to allow for flexibility in determining the appropriate size to be used.
- A backup implant should also be available.
- Be advised that during device insertion excessive force should not be applied to a small area of the shell. Instead, apply force over an area of the implant as large as possible.
- The incision should be of appropriate length to accommodate the volume and profile of the implant with highly cohesive gel. This will reduce the potential for creating excessive stress to the implant when inserting it. Forcing implants through a very small opening may result in damage to the implants gel and possible ruptures or gel fractures. In the event of gel fracture during implantation, do not insert the implant in to the patient's body and replace it with a new one
- Insufficient pocket dissection increases the risk of rupture and incorrect positioning of the implant. A well-defined, dry pocket of adequate size and symmetry must be created to allow the implant to be placed flat on a smooth surface.
- During breast implant surgery, all devices should be thoroughly assessed for gel fracture, gel bubbles or any other device failures before being inserted into the patient's body. Do not insert an implant with gel fractures at any point, instead replace the implant with a new one.
- During explantation, surgeons must assess intraoperatively the integrity of the breast implant to identify presence or absence of rupture, gel fracture and gel migration. In the case of a device failure the implant should be returned to Establishment Labs for revision.
- **DO NOT** use lubricants during placement since they increase the risk of pocket contamination and may also affect the tissue-capsule interface.
- **DO NOT** damage the breast implant with sharp surgical instruments such as needles and scalpels, blunt instruments such as clamps and forceps, or by over-handling and manipulation during introduction into the surgical pocket.
- **DO NOT** use excessive force during breast implant placement.
- **DO NOT** manipulate the implant for radial expansion, compression or dissection of the pocket.
- **DO NOT** use more than one implant per breast pocket.

Maintaining Hemostasis/Avoiding Fluid Accumulation

The risk of postoperative hematoma and seroma may be reduced by carefully The risk of postoperative hematoma and seroma may be reduced by carefully handling the hemostasis during surgery, and possibly also by postoperative use of a closed drainage system. Persistent or excessive bleeding must be controlled before implantation.

Any postoperative evacuation of hematoma or seroma must be conducted with care to avoid contamination or damage to the breast implant.

Instructions and precautions for removal

Among the most common reasons for breast implant removal are complications such as capsular contracture, implant rupture and implant malposition, as well as the patient´s desire to change the implant size or shape. The surgeon is advised to use his/her clinical judgment in choosing from current and accepted breast implants removal and replacement surgical techniques to minimize the incidence of adverse reactions and achieve the best results for the patient.

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Disposal Method

Treat product that is not returned to the manufacturer as bio hazardous infectious material. Used device can be disposed in suitable disposal unit and subsequently be incinerated by a specialized collection service or in accordance with local regulations.

SPECIFIC INSTRUCTIONS FOR USE

APPLICABLE TO BREAST IMPLANTS CONTAINING A *MICROTRANSPONDER*

Description

Sterile Silicone Breast Implants Motiva Implant Matrix® with Q Inside® Safety Technology (*microtransponder*) include a miniaturized, implantable, radio frequency identification device (RFID), which is safely embedded in the breast implant filler material. Scanners to scan and read the information in the *microtransponders* are purchased separately. The *microtransponder* is a passive device that contains an electronic circuit that is activated externally by a low-power electromagnetic field, emitted by a handheld battery powered scanner. The *microtransponder* is used to store an electronic serial number (ESN). The ESN number is used by patient-approved physicians and other health professionals.

Indications

The *microtransponder* is indicated for use as a miniature, long-term implantable device that is inserted into the breast implant. The *microtransponder* in the breast implant provides the patient an electronic serial number that may be used to access a database containing the breast implant information (serial and lot numbers; reference number; volume, size and projection, model, surface type, manufacturing date, etc.).

Contraindications

Breast implants containing a *microtransponder* should not be used in patients known to have allergies or sensitivity to the composition of the *microtransponder* (USP Type III glass).

Precautions

Patients with breast implants containing a *microtransponder* may safely undergo MRI diagnostics in up to 3 Tesla cylindrical systems. See section below: INSTRUCTIONS FOR PATIENTS UNDERGOING MRI for detailed instructions.

Instructions For Patients Undergoing MRI

The patient should be monitored continuously throughout the MRI procedure using visual and audio means (e.g. intercom system). Instruct the patient to alert the MRI system operator of any unusual sensations or problems so that, if necessary, the MRI system operator can immediately terminate the procedure. Provide the patient with a means to alert the MRI system of any unusual sensations or problems.

Do not perform the MRI if the patient is sedated, anesthetized, confused, or otherwise unable to communicate with the MRI system operator.

Patients should be advised to have regular MRIs over their lifetime to screen for silent rupture even if they are not having any apparent problems. As mentioned before, it is advised by the FDA to have the first MRI 3 years postoperatively, then regularly at 2-year intervals.

Sterile Silicone Breast Implants Motiva Implant Matrix® are MRI conditional. The patient implanted with Sterile Silicone Breast Implants Motiva Implant Matrix® can undergo MRI scan under the following conditions:

- Static magnetic field of 1.5-Tesla and 3 -Tesla only.
- Maximum spatial gradient magnetic field of 4.000-gauss/cm (40-T/m) (extrapolated).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.
- Under the scan defined conditions, the Sterile Silicone Breast Implants Motiva Implant Matrix® with Q Inside® Safety Technology is expected to produce a maximum temperature rise of 1.5ºC after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the magnetically induced displacement force and magnetically induced torque were tested, and no clinically significant displacement or torque was detected. Sterile Silicone Breast Implants Motiva Implant Matrix® with Q Inside® Safety Technology contains a *microtransponder* that creates an imaging void during breast implant MRI (known as artifact effect) that can block visualization of a small area around the *microtransponder*. In non-clinical testing, the image artifact caused by Sterile Silicone Breast Implants Motiva Implant Matrix® extends approximately 15 mm radially from the RFID when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

In selected cases, additional imaging techniques such as ultrasound, tomosynthesis, digital compression mammogram, subtraction contrast mammography and scintimammography are recommended to complement the visualization of the region affected by the artifact and improve the overall diagnosis.

Studies conducted by the manufacturer indicate that the use of a “combined” or “dual” modality, using additional imaging technologies (i.e. MRI with: Ultrasound, Mammography, Tomosynthesis, etc.), may considerably increase the diagnostic accuracy of procedures involving Sterile Silicone Breast Implants Motiva Implant Matrix® with Q Inside® Safety Technology. The addition of other imaging modalities, using standard practices, allows for the complete radiological survey of the breasts

Additional Instructions For Use

Additional Directions for Use for breast implants which include a *microtransponder*:

- Verify the *microtransponder* in the implant before opening the sterile barriers, using the corresponding scanner, if available.
- Re-verify the *microtransponder* in the implant after implantation using the corresponding scanner, if available.

Caution

If the breast area is subsequently subjected to physical trauma as a result of accident or injury, the patient shall consult her physician to ensure that the *microtransponder* is properly functioning. If for any reason the *microtransponder* would stop being scannable by the appropriate scanner, this sole situation will not impair the breast implant to continue fulfilling its function appropriately and does not constitute a complication.

SPECIFIC INSTRUCTIONS FOR USE

DEVICE TRACKING

Silicone gel-filled breast implants are subject to device tracking. Compliance with this requirement is mandatory. This means that it is required to report to

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Establishment Labs, either directly or through a representative, the lot and serial numbers of the device(s) implanted in a patient, the date of the surgery, the ID number and personal contact information, and information related to the surgeon’s practice.

Establishment Labs strongly recommends that all patients receiving silicone gel-filled breast implants participate in the Establishment Labs device-tracking program, entering their implant information at www.motivaimplants.com/#implantRegistration. This will help ensure that Establishment Labs has a record of each patient’s contact information so that they can be contacted in the event of a field action or other situations with the implants of which they should be made aware

PROCEDURE RECORDING AND DEVICE ID CARD

Each breast implant is supplied with five Patient Record Labels showing the reference number, lot number, serial number, side (left or right), and volume of the implant. Patient Record Labels are located on the internal product packaging attached to the main label. To complete the Patient ID Card, adhere one Patient Record Label for each implant on the back of each patient’s ID Card. Another label should be affixed to the patient’s chart. A third label should be attached to the practitioner’s records and the fourth label is provided for hospital records when applicable. A spare label is also provided. If a Patient Record Label is unavailable, the appropriate information may be copied by hand from the device label.

PATIENT ID CARD

Every patient must have a record of her surgical procedure in case of future consultations or additional surgeries. Each implant is provided with a Patient ID card, which must be given to the patient for personal reference. Apart from the information stated on the Record Labels that should be affixed to the back of the card, the Patient ID card includes the patient’s name, position of the implant (submuscular, subglandular, dual plane, other), date of implantation and name of the treating surgeon.

INFORMATION ON EXPECTED LIFETIME

In practice, it is not possible to predict accurately the actual lifetime of an individual implant. It is well understood that several factors are beyond the control of the manufacture. These factors might have a significant effect on the lifetime of an individual device. These factors include the actual implantation procedure, the anatomy and state of health of the patient and regular activities (for example sporting activities), as well predictable and unpredictable external mechanical influences.

REPORTING AND DEVICE RETURN EFFORTS

In the event of an explantation, the reason for explantation should be reported on the Establishment Labs Complaint Notification Form and the explanted device returned to the local Establishment Labs representative. In case there is no local representative available, report directly at Establishment Labs Coyol Free Zone and Business Park Building 4th Street, Building B-15, Alajuela, Costa Rica; Phone: +506 2434-2400 or https://motiva.health/support/.

The explanted device must be decontaminated and properly packaged before returning it according to the Establishment Labs Explanted Implants Return Protocol. In case local health codes do not allow for the implant to be returned, please contact us directly at https://motiva.health/support/ for specific instructions.

PRODUCT EVALUATION

Establishment Labs requires that any complications resulting from the use of this device be brought to the immediate attention of the company through the Sterile Silicone Breast Implants Motiva Implant Matrix® complaint notification form addressed to Establishment Labs Coyol Free Zone and Business Park Building 4th Street, Building B-15, Alajuela, Costa Rica; Phone: +506 2434-2400 or https://motiva.health/support/.

RETURNED GOODS POLICY

Product returns should be handled through the local Establishment Labs representative. In case there is no local representative available, report directly at Establishment Labs Coyol Free Zone and Business Park Building 4th Street, Building B-15, Alajuela, Costa Rica; Phone: +506 2434-2400 or customerservice@establishmentlabs.com.

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

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ESTABLISHMENT LABS ALWAYS CONFIDENT WARRANTY® LIMITED WARRANTY, LIMITATION OF LIABILITY, AND DISCLAIMER OF OTHER WARRANTIES

The complete terms, conditions and limitations of the Establishment Labs Always Confident Warranty® can be reviewed in the website www.motivaimplants.com or can be provided by the local Establishment Labs representative. No warranty or program of Establishment Labs covers any costs, fees or expenses related to any medical treatment and/or the surgical replacement of the implants. Establishment Labs warrants that this product is free of manufacture defects at the time of its shipment. Establishment Labs shall not be responsible for any incidental or consequential loss, damage or expenses directly or indirectly arising from the use of this product. Establishment Labs's sole responsibility in the event that Establishment Labs determines the product was defective when shipped by Establishment Labs, shall be the replacement of the product. Establishment Labs S.A assumes no further liability. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, 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.

MANUFACTURER

Establishment Labs S.A.: Coyol Free Zone & Business Park Building 4th Street, Building B-15, Alajuela, Costa Rica. Phone: +506 2434-2400
customerservice@establishmentlabs.com
www.establishmentlabs.com
www.motiva.health

EUROPEAN REPRESENTATIVE

Emergo Europe: Prinsessegracht 20, 2514 AP The Hague, The Netherlands.

EDC Motiva BVBA
Nijverheidsstraat 96, Wommelgem
Antwerp 2160, Belgium

QTY = Quantity

MR
MR Conditional

CE
2797

MOTIVA IMPLANTS FEEDBACK FORM

This survey provides valuable customer input that helps us offer the best possible service. **Thank you** for completing and returning the Motiva Implants® Feedback Form by mail to Establishment Labs Coyol Free Zone & Business Park Building 4th Street, Building B-15, Alajuela, Costa Rica, or by email: customerservice@establishmentlabs.com. You can also fill in the form on-line at www.motivaimplants.com.

Name:	**Implant Information**
Gender: ..... Age:	Reference Number: .....
Address:	Serial Number: .....
City:	Product: .....
Country:	Lot Number: .....

Please rate your satisfaction level with each of the following statements:

1 = very satisfied **2** = somewhat satisfied **3** = neutral	**4** = somewhat dissatisfied **5** = very dissatisfied Leave blank if not applicable

PACKAGING	1	2	3	4	5
1. How satisfied are you with the presentation of the external product packaging?	◯	◯	◯	◯	◯
2. Do you find the packaging easy to open?	◯	◯	◯	◯	◯
3. How satisfied are you with the presentation of the internal packaging (thermoforms)?	◯	◯	◯	◯	◯
4. Do you find the device easy to retrieve from its packaging?	◯	◯	◯	◯	◯

5. Please suggest any packaging improvements: .....

.....

PATIENT ID CARD	1	2	3	4	5
1. How satisfied are you with the presentation of the Patient ID Card?	◯	◯	◯	◯	◯
2. Do you think the Patient ID Card is easy to find inside the box?	◯	◯	◯	◯	◯
3. How satisfied are you with the information collected on the Patient ID Card?	◯	◯	◯	◯	◯

4. Please suggest any Patient ID Card improvements: .....

.....

PRODUCT INSERT	1	2	3	4	5
1. How satisfied are you with the presentation of the Product Insert?	◯	◯	◯	◯	◯
2. How satisfied are you with the information provided in the Product Insert?	◯	◯	◯	◯	◯

3. Please suggest any Product Insert improvements: .....

.....

LABELING	1	2	3	4	5
1. Rate your satisfaction with the information provided on the external packaging labels.	◯	◯	◯	◯	◯
2. Rate your satisfaction with the information provided on the internal packaging labels.	◯	◯	◯	◯	◯

3. Please suggest any Product Labeling improvements: .....

.....

PRODUCT	1	2	3	4	5
1. Rate your satisfaction with the product range available inside Motiva Implants®.	◯	◯	◯	◯	◯
2. How satisfying is the appearance of the implant?	◯	◯	◯	◯	◯
3. How satisfying is the feel of the implant?	◯	◯	◯	◯	◯
4. Rate your satisfaction with the implant ease of insertion into the surgical pocket.	◯	◯	◯	◯	◯
5. How satisfying is the quality of the product?	◯	◯	◯	◯	◯
6. Rate your overall satisfaction with the product.	◯	◯	◯	◯	◯

7. Please rate Motiva Implants® to similar products on the market.

◯ Much better ◯ Somewhat better ◯ Average
◯ Somewhat worse ◯ Much worse

If your answer is “somewhat worse”, or “much worse”, please explain:

.....

8. Would you use Motiva Implants® again in the future?

◯ Definitely ◯ Probably ◯ Probably not
◯ Definitely not ◯ Not sure

If your answer is “probably not”, “definitely not” or “not sure”, please explain:

.....

9. Would you recommend Motiva breast Implants® to a colleague?

◯ Definitely ◯ Probably ◯ Probably not
◯ Definitely not ◯ Not sure

If your answer is “probably not”, “definitely not” or “not sure”, please explain:

.....

SUPPORT	1	2	3	4	5
How satisfied are you with delivery of the products?	◯	◯	◯	◯	◯
How satisfied are you with the support provided by your distributor?	◯	◯	◯	◯	◯

Please suggest how Establishment Labs can improve your customer experience:

.....

.....

Motiva implants

www.motiva.health

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Date: 022013

STERILE

MR MR Conditional

CE 2797

Establishment Labs

EC REP

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

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