**INFORMATION FOR THE PATIENT**
**BREAST AUGMENTATION AND RECONSTRUCTION WITH MOTIVA IMPLANTS®**

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

## 1. INTENDED USE

Motiva breast implants are intended to increase the breast size in a breast augmentation surgery, or to correct/improve the result of a previous procedure. It is also indicate in breast 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.

## 2. INDICATIONS.

Motiva® breast implants are indicated for the following procedures in female patients:

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

## 3. INTENDED CONDITIONS FOR USE.

Motiva Implants® are intended to be used by certified plastic surgeons within an operating room under sterile conditions, in compliance with Good Aseptical Practices.

## 4. OVERVIEW.

- Breast augmentation/reconstruction is an elective surgical procedure for enhancing and/or rebuilding the breast area in women of at least 18 years of age, using silicone implants.

- Alternative treatments are available, including external breast prostheses or padding, or the transfer of other body tissues to enlarge breast size. The use of other synthetic filling materials (such as liquid silicone or other fillers) is not recommended and can provoke serious health problems.

- The decision to have breast implants is a personal choice. The important information provided in this document is intended to raise your awareness about the risks and benefits of surgery using breast implants, to help you make a better informed decision about your breast augmentation/reconstruction (primary or replacement) surgery.

- Motiva® breast implants are classified as smooth surface implants per ISO 14607:2018 (Non-active surgical implants - Mammary implants - Particular Requirements). It's outer shell is comprised of standard layers and a barrier layer. Both types of layers are made from medical-grade (silicones tested for biocompatibility and are appropriate to be used for medical applications), silicone-based elastomer. The implant is filled with a medical-grade, highly cohesive silicone gel, and is surgically implanted above or below your pectoral muscle.

- Please refer to section 4 ("**SILICONE BREAST IMPLANT COMPONENTS**") for information about the materials and substances used in Motiva® breast implants.

- Breast implants are available in different shapes: round, oval, or contoured; and come in several different sizes and projections. Your surgeon should talk to you about the different possible outcomes based on your individual characteristics and personal expectations.

- You should be aware, when choosing breast augmentation/reconstruction with implants, that you may require additional procedures as well as further consultations with your surgeon. Breast implants are not lifetime devices and are subject to wear and tear like any other implant device. Breast implantation might not be a one-time surgery. Your implant(s) may have to be removed or replaced, which may imply revision surgery. Many of the changes to your breasts following implantation are irreversible (cannot be undone). If you choose to have your implant(s) removed and not replaced, you may experience unacceptable aesthetic results which can be permanent.

- When you have your implants replaced (for revision augmentation or reconstruction), your risk of future complications increases compared to that associated with first-time (primary) augmentation or reconstruction surgery. For example, the risk of severe capsular contracture is doubled for both augmentation and reconstruction patients with implant replacement compared that associated with first-time implantation.

- Rupture of a silicone gel-filled breast implant is typically silent. This means that neither you nor your surgeon can tell via visual or touch-based inspection that your implants have ruptured. If displacement and/or rupture is suspected, you will need a screening MR (magnetic resonance imaging) examination or High Resolution Ultra Sound to confirm. If implant rupture is confirmed with MR, you should have the implant removed (with or without replacement).

**5. SILICONE BREAST IMPLANT COMPONENTS.**

The components of Motiva® breast implants are outlined in the table below:

| Implant Component | Materials and/or substances. |
|---|---|
| Shell: Standard Layers | Medical-grade, silicone-based elastomer. |
| Shell: Barrier Layer | Medical-grade, silicone-based elastomer. It is called the barrier layer due to its specific chemical composition, which is intended to prevent leakage of the internal silicone gel filling. |
| Barrier Layer Indicator | Medical-grade, biocompatible blue colorant that pigments the barrier layer so that its integrity may be visually verified by the surgeon. |
| Patch Assembly | Medical-grade, silicone-based elastomer sheet. |
| Internal Gel | Medical-grade, cohesive silicone gel. |
| Microtransponder | RFID transponder is a metallic micro-antenna that receives reader signal and transmits the specific information, builded by a ferrite core to strenghten the data transmision distance and sealed in a biocompatible glass capsule. |

6. **CONTRAINDICATIONS**.

The use of silicone breast implants is contraindicated in women:

- With existing breast carcinoma that has not been treated with mastectomy
- With advanced fibrocystic disease considered premalignant (precancerous) that has not been treated with accompanying subcutaneous mastectomy
- With active infections
- Who are currently pregnant or nursing
- With any disease (including uncontrolled diabetes) that is clinically known to impact wound-healing ability

- Who show tissue characteristics clinically incompatible with a breast implant surgery, such as tissue damage resulting from radiation, inadequate tissue, and/or compromised vascularity or ulceration
- With any condition or treatment the surgeon determines to be an unjustifiable surgical risk factor (e.g. unstable cardiovascular disease, coagulopathies, chronic pulmonary problems etc.)

## 7. RELEVANT TOPICS.

### 6.1 Informed consent .

Establishment Labs relies on your surgeon to explain to you the existing risks and benefits of the implantation. It is also the surgeon's responsibility to obtain your formal informed consent to perform the surgical procedure.

As a patient, you will be given Establishment Labs' document on "Breast Augmentation and Reconstruction with Motiva Implants® Information for the Patient" during your surgical consultation. You must have enough time to read and fully understand the information provided in the document regarding the risks, benefits, and recommendations associated with silicone gel-filled breast implant surgery.

To document a successful informed decision process, you, a witness, and your surgeon should sign the "Informed Consent Document", which will be part of your medical file.

Section 8 details identified potential complications associated with breast augmentation or reconstruction surgery with silicone breast implants. Please review them all in detail. Additional relevant topics you need to be aware of when considering the use of silicone gel-filled breast implants include:

**Mammography:** Routine mammography should be performed per your surgeon's recommendations. You should inform the examiner of the presence of your implants, including type and placement, as well as 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 an implanted breast.

**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 breasts may be irreversible.

**Reoperation/Explantation:** Rupture, unacceptable cosmetic outcomes, and other clinical complications may require additional surgeries. You should be advised that the risk of future complications increases with revision surgery as compared to primary augmentation or reconstruction surgery.

**Lactation:** Breast implant surgery may interfere with the ability to successfully breastfeed, either by reducing or eliminating milk production. Particularly, the periareolar incision may considerably reduce the possibility of breastfeeding.

**Topical Medications**: You should consult a physician or a pharmacist before using topical medicines (e.g. steroids) in the breast area.

**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. Scientific literature suggests that radiation therapy may increase the likelihood of breast implant complications, such as capsular contracture, necrosis, and implant extrusion.

**Insurance Coverage**: Before undergoing surgery, you should check with your insurance company regarding coverage issues.

**Breast Examination Techniques**: You should perform breast self-examinations monthly and be shown how to distinguish the implant from breast tissue. Therefore, it is important to take into consideration the following recommendations:

- Never manipulate or squeeze the implant excessively. The presence of lumps, persistent pain, swelling, hardening, or change in the implant shape could suggest symptomatic rupture of the implant. If you have any of these signs, report it to your surgeon and if possible, receive an evaluation through MR or High Resolution Ultra Sound

**Trauma**: You should consult your surgeon or physician if any complications are suspected – in particular, in cases of trauma or compression caused, for example, by extreme massaging of the breast region, by some sports activities, or by using seat belts.

**Mental Health and Elective Surgery:** It is up to the surgeon to consider whether you are mentally ready for breast augmentation/reconstruction surgery. Be sure to let your surgeon know if you have a history and/or current occurrence of depression or other mental health issues.

**Surgical Setting and Anesthesia**: General anesthesia is commonly used and local anesthesia with sedation is also an option. Be sure to ask about the length of time you need to stay without food or any other pre-surgical indication that must be followed before your surgery day. Don't forget to inform your surgeon about any medications you are taking.

**8. POSTOPERATIVE CARE.**

The recovery process depends on your individual profile and other variables. Below, we have detailed some general instructions and possibilities to expect:

- You might have an elevated body temperature.
- Your breasts may remain swollen and sensitive to physical contact for a month or longer .
- You are likely to feel tired and sore for several days following the operation.
- You could experience a feeling of tightness in the breast area as your skin adjusts to your new breast size.
- Avoid any strenuous activities for at least a couple of weeks, though you may be able to return to work within a few days.
- Breast massage may also be recommended as appropriate.
- Sleep or rest with your head slightly elevated, avoiding lateral positions.
- Keep your arms close to your body and avoid lifting weights until allowed by your surgeon.
- Do not drive for at least 2 days after your surgery and do not exercise until approved by your surgeon.
- Do not expose your breasts directly to sunlight until approved by your surgeon.
- Topical cream may be recommended by your surgeon.
- Immediately after surgery, your breasts will be swollen and tender, so you will likely need to wear a medical compression bra, also called a surgical bra, *without underwires. Y*our surgeon will provide or recommend the best bra after breast augmentation or reconstruction, along with instructions on how long you must wear it. Most patients wear

their medical compression garment day and night for one to two weeks, after which they can transition to a supportive sports bra.

- Pregnancy and nursing after breast implant surgery may cause breast tissue and muscle changes that could lead to ptosis (drooping) and flipping.

## 9. RISK/BENEFITS ANALYSIS.

### 9.1. Benefits of Breast Surgery with Silicone Implants.

Body image is defined as the mental picture of one's body, an attitude about the physical self, appearance, and state of health, wholeness, normal function, and sexuality. Negative body image elements among general female population and specially breast cancer survivors, includes dissatisfaction with appearance, perceived lack of femininity and body wholeness, reluctance to look at one's self nude, feeling less sexually attractive, and self-consciousness about appearance (Koçan, S., & Gürsoy, A, 2016).

In case of cosmetic augmentation, if your breasts never developed, if they shrank as a result of weight loss or pregnancy, or if your breasts just do not have the size or shape you desire, you may benefit from breast augmentation. Beyond improving your appearance, sense of youthful and being able to wear new or different clothes, many women report additional benefits in terms of improved self-esteem and social or professional opportunities. (Spear, et al., 2007).

In case of breast reconstruction, women have reported that breast reconstruction has been an aid in their recovery from breast cancer and has reduced emotional stress by helping them to return their bodies to a more natural appearance, as opposed to not having reconstructive surgery or wearing an external prosthesis. (US Core Studies).

### 9.2. Risks of Breast Surgery with Silicone Implants.

Breast implants are not lifetime devices; the longer you have your implants, the more likely it will be for you to have them removed/replaced and the more likely you are to experience local complications and adverse outcomes. The most common local complications and adverse outcomes are capsular contracture, reoperation, implant removal, and rupture or deflation of the implant. Other complications include wrinkling, asymmetry, scarring, pain, and infection at the incision site. You should assume that you will need to have additional surgeries (reoperations). Many of the changes to your breast following implantation may be cosmetically undesirable and irreversible. If you have your implants removed but not replaced, you may experience changes to your natural breasts such as dimpling, puckering, wrinkling, breast tissue loss or other undesirable cosmetic changes. If you have breast implants, you will need to monitor your breasts for the rest of your life. If you notice any abnormal changes in your breasts, you will need to see a doctor promptly. If you

have silicone gel-filled breast implants, you will need to undergo periodic MR examinations in order to detect ruptures of the implant that do not cause symptoms ("silent ruptures").

For early detection of silent rupture, the FDA and breast implant manufacturers recommend that women with silicone gel-filled breast implants receive MRI screenings 3 years after they receive a new implant and every 2 years after that. MRI screening for implant rupture is costly and may not be covered by your insurance. If you have breast implants, you have a low risk of developing a rare type of cancer called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) in the breast tissue surrounding the implant. BIA-ALCL is not breast cancer. Women diagnosed with BIA-ALCL may need to be treated with surgery, chemotherapy and/or radiation therapy (www.fda.gov/breastimplants).

## 10. RISKS AND POTENCIAL COMPLICATIONS

### 10.1. Related to general anesthesia.

There are some risks associated with taking general anesthetics, but they are relatively safe when administered correctly, they are normally administered intravenously (IV) or inhaled by an anesthesiologist. Under general anesthesia, the patient is unable to feel pain and may also have amnesia.

There are a number of potential side effects of anesthesia. Some individuals may experience none, others a few. None of the side effects are particularly long-lasting and tend to occur straight after the anesthesia.

Side effects of general anesthesia include temporary confusion and memory loss, although this is more common in the elderly, dizziness, difficulty passing urine, bruising or soreness from the IV drip, nausea and vomiting, shivering and feeling cold sore throat, due to the breathing tube.

### 10.2. General adverse events related to a surgical procedure.

After breast implant surgery, patients might experience swelling, hardness, discomfort, itching, allergies, bruising, twinges, and/or pain over the first few weeks.

### 10.3. Related to breast implants.

If any of the following or other adverse events occur, contact your surgeon as soon as possible:

#### 10.3.1. Capsular Contracture

The formation of a capsule of collagen fibers around a foreign body with the aim of isolating it is a normal reaction of the body. Capsular contracture occurs when this capsule hardens, tightens, and squeezes the implant, which makes the implant feel hardened (from slightly firm to quite hard). The

firmest ones can cause varying degrees of discomfort, pain, and palpability. In addition to firmness, capsular contracture can result in undesirable aesthetic results.

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 is the most common reason for reoperation in augmentation and reconstruction patients. Based on the severity/grade of the capsular contracture diagnosed, the correction may require surgical removal or release of the capsule, or removal and possible replacement of the implant itself.

#### 10.3.2. Rupture

Breast implants can rupture when the shell develops a tear or hole. Rupture can occur at any time during/after implantation, but is more likely to happen due to an intraoperative puncture or excessive force exerted when placing the implant into the surgical pocket. It can also be associated with inadequate positioning or ulterior displacement (folded envelope), trauma, implant aging, etc.

Rupture of a silicone gel-filled breast implant is most often silent (i.e. the patient does not experience any apparent symptoms and there are no externally physical signs of changes with the implant) rather than visibly symptomatic. Therefore, patients should be advised to have regular MRs over their lifetime to screen for silent rupture even if they are not having any apparent problems.

The US FDA (United States Food & Drug Administration) recommends having the first MR performed 3 years after the surgical implantation, then regularly in 2-year intervals after that, but such recommendations vary between regions, taking into account the availability and accessibility of different imaging modalities and healthcare guidelines.

A list of radiology centers experienced in breast implant MR films to scan for signs of rupture should be provided to you. If a rupture is noted on an MR, you will likely be strongly encouraged to have your implant(s) removed and replaced.

Concerns have been raised over whether ruptured implants are associated with the development of connective tissue-related 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 between breast implants and rheumatic disease.

**10.3.3. Gel fracture.**

Gel fracture can occur with cohesive silicone and occurs most frequently because of subjecting the implant to excessive compressive forces during the implantation. As a result, its shape is irrevocably lost, requiring implant replacement. Gel fracture can be detected by ultrasound or MR. Most gel fractures are clinically undetectable and can occur due to the development of capsular contracture, which may result in device distortion.

**10.3.4. Pain.**

Most women undergoing augmentation or reconstruction with a mammary (breast) implant will experience post-operative pain in the chest or breast area, which can sometimes become a chronic problem. Hematoma, migration, infection, overly large implants, and/or capsular contracture can cause chronic pain. Sudden, severe pain may be associated with implant rupture. You must immediately report to your surgeon or physician if you experience significant and/or persistent pain.

**10.3.5. Changes in Nipple and Breast Sensation.**

Breast surgery can result in increased/decreased breast and/or nipple sensitivity. Typically, sensation is lost after complete mastectomy where the nipple itself is removed and can be severely lessened after partial mastectomy. The range of changes varies from intense sensitivity to no feeling in the nipple and/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 and/or ability to nurse.

**10.3.6. 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 present. If an infection does not respond to antibiotics, the implant may have to be removed, with replacement occurring only after the infection is resolved. As with other surgical procedures, 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, fainting, dizziness, and/or sunburn-like rash. Patients should contact their doctor immediately for diagnosis and treatment if they have these symptoms.

**10.3.7. Hematoma/Seroma.**

Hematoma is a buildup of blood within the space around the implant, and a seroma is a buildup of fluid around the implant. Having a hematoma and/or seroma following surgery may result in

infection and/or capsular contracture later. 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.

**10.3.8. Irritation/Inflammation.**

Breast implants prompt the development of a fibrous or periprosthetic capsule. Breast implants are no different from any foreign material implanted into the human body in terms of triggering a protective immune reaction in the host. This foreign body response is universal and ideally removes or otherwise surrounds the "irritant material" with fibrous tissue to prevent unwanted immune consequences. A capsule around a breast implant is, therefore, a necessary mechanism of body defense, but if excessive, can lead to pain and deformity of the breast.

**10.3.9. Silicone reaction.**

In general, cutaneous risks with breast implants seem to be low. However, several reports have documented the presence of cutaneous hypersensitivity-like reactions to breast implants, despite their biological compatibility (i.e. biocompatibility) and presumed inertness of their compounds.

Topical and systemic medications may relieve symptoms and led to successful resolution. In some cases, implant removal is required for complete symptom relief.

**10.3.10. Breastfeeding.**

Although most women with breast implants who attempt nursing have successfully breastfed their babies, it is not known if there are increased risks for women with breast implants or if their children are more likely to experience 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, though a 2018 meta-analysis of multiple studies concluded that "(p)eriareolar incision does not appear to reduce

the exclusive breastfeeding rate."[1] However, the American Academy of Pediatrics has stated that there is no reason why a woman with implants should refrain from nursing.

**10.3.11. Calcification.**

Calcification refers to the accumulation of calcium salts in the body's tissues. 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.

**10.3.12. 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.

**10.3.13. 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.

**10.3.14. 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.

**10.3.15. Granulomas.**

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

[1] Cheng, Fengrui, Shuiping Dai, Chiyi Wang, Shaoxue Zeng, Junjie Chen, and Ying Cen. "Do Breast Implants Influence Breastfeeding? A Meta-Analysis of Comparative Studies - Fengrui Cheng, Shuiping Dai, Chiyi Wang, Shaoxue Zeng, Junjie Chen, Ying Cen, 2018." SAGE Journals. June 22, 2018. Accessed May 16, 2019. https://journals.sagepub.com/doi/abs/10.1177/0890334418776654?journalCode=jhla.

### 10.3.16. 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 the need for additional surgeries and/or unacceptable dimpling/creasing of the breast.

### 10.3.17. Lymphadenopathy.

Lymphadenopathy or adenopathy is a disease of the lymph nodes (small, round structures that operate as part of the body's immune system), in which they become abnormal in size or consistency (most commonly producing swollen or enlarged lymph nodes).

Literature reports associate lymphadenopathy with both intact and ruptured silicone breast implants since microscopic silicone droplets can migrate to body tissues even when the implant surface remains intact (Lee, 2017)[2].

### 10.3.18. 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.

### 10.3.19. 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 have been reported in the literature and have suggested that gel-bleed may contribute to the development of capsular contracture and lymphadenopathy.

[2] Lee Y, Song SE, Yoon ES, Bae JW, Jung SP. Extensive silicone lymphadenopathy after breast implant insertion mimicking malignant lymphadenopathy. Ann Surg Treat Res. Ann Surg Treat Res. 2017 Dec;93(6):331-335. doi: 10.4174/astr.2017.93.6.331. Epub 2017 Dec 1.

**10.3.20. Malposition.**

Malposition of a breast implant refers to either its incorrect placement during surgery or a shift from its original position. Malposition has reportedly been a frequent event due to its multifactorial causes, and can be expected during the lifetime of the device.

Trauma, capsular contracture, gravity, or initial incorrect placement may cause malposition. The surgeon must plan the operation carefully and use techniques that can minimize (though they may not completely evade) the risk of malposition. Malposition may lead to patient dissatisfaction with aesthetic outcomes.

The clinical symptoms manifested by the patients include 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 considered before performing a revision surgery.

**10.3.21. Bottoming out.**

“Bottoming out” refers to when a breast implant slides down along the chest wall to a lower position after breast implant surgery, increasing the distance between the nipple-areolar complex and the inframammary fold (IMF) (i.e. making the nipple and areola look unusually high relative to the rest of the breast).

Risk factors reported in literature include, but are not limited to, the quality of pre-existing breast tissue, larger volume and/or higher projection in the selected implant(s); dissection through the IMF; and implant placement during surgery. The clinical symptoms resulting from implant(s) bottoming out include asymmetry, upward-pointing nipples, a sagging breast, palpable implant, and others. The treatments may vary depending on the severity of the complication, ranging from a simple sub-mammary fixation to the use of additional supporting materials.

**10.3.22. Flipping.**

Anterior/posterior malposition, also called flipping, has been said 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. Some scientific literature has reported that 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 implant characteristics, flipping 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.

Diagnosis is based on clinical evidence, MR or CT (computed tomography) imaging to validate the diagnosis may 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 to undergo a revision surgery to reduce pocket dimensions.

#### 10.3.23. Implant Rotation.

Rotation of an implant may occur, though proper placement and pocket dissection reduce the risk of occurrence. Revision surgery may be necessary to correct rotation.

## 11. OTHER REPORTED CONDITIONS.

There have been reports in medical 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.

### 11.1. Connective Tissue Disease (CTD).

No conclusive evidence has been found to support an association between silicone breast implants and CTDs. Recent studies suggest that this association is possible given that silicone in breast implants act as a foreign body that can elicit an inflammatory response. Nevertheless, no conclusive data is available in this regard.

### 11.2. Cancer.

Breast cancer reports in medical literature reveal that patients with breast implants are not at a greater risk for developing breast cancer than those without breast implants.

### 11.3. 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.

### 11.4. Interference with Mammography.

You should be advised to have routine mammography exams performed according to your surgeon's recommendations. The importance of these exams should be emphasized. It is important to inform your examiners about the presence, type, and placement of your implant(s) and to request a diagnostic mammography, rather than a screening mammography. The current recommendations for preoperative/screening mammograms are no different for women with breast implants than for those women without implants. Pre and post-surgical mammographies may be performed to determine a baseline for routine future studies in augmentation patients.

### 11.5. Interference with MR.

Sterile silicone breast implants with a microtransponder are considered MR (magnetic resonance) conditional, which means that during a MR study, the microtransponder can create an imaging void immediately around it (known as an artifact), which can obscure the view of parts of the implant's footprint and parts of the patient's tissue. Therefore, there are added potential MR risks associated with this artifact, including, but not limited to, an inadequate evaluation of the implant shell for the detection of rupture or a missed 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 ultrasound (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).

The risks can be reduced by performing an ultrasound (US) in addition to the MR, thereby allowing the radiologist to visualize the area within the product artifact. In the event of an MR evaluation, you must inform your radiologist about the presence of the breast implants and microtransponder (if present). Further information regarding this topic is described in section 16 of this document.

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

BIA-ALCL is a rare type of T-cell lymphoma involving cells of the immune system. In 2016, the World Health Organization recognized ALCL 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. 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. Most cases of BIA-ALCL are treated by removal of the implant and its surrounding capsule. Some cases have been treated by chemotherapy and radiation.

The following are considerations from the FDA regarding BIA-ALCL[3]:

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. Your surgeon should discuss with you the benefits and risks of different types of implants, as well as provide educational materials before surgery.
- If you have late-onset, persistent peri-implant (i.e. surrounding the implant) seroma, your surgeon should consider the possibility of BIA-ALCL and refer you to an appropriate specialist for evaluation. Collecting fresh seroma fluid and representative portions of the capsule to be sent for pathology tests is part of ruling out BIA-ALCL. The diagnostic evaluation must include cytological evaluation of seroma.
- A patient's multidisciplinary care team plan must be developed to meet an individual treatment according to your surgeon’s criteria.

**12. STERILE PRODUCT.**

Motiva Implants® are sterilized during manufacturing by using a dry heat sterilization method. An implant is intended to be used only in one patient for a single procedure, and supplied in a sealed, double sterile barrier primary package.

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

## 13. SURGICAL PROCEDURE.

### 13.1. Surgical technique.

There are several surgical techniques that can be used to perform the insertion of a silicone implant. The surgeon is advised to use his/her clinical judgment in choosing the procedure that is best for you. After setting realistic goals that assure mutual understanding between you and your surgeon, your surgeon must choose from current and accepted surgical techniques to minimize the incidence of adverse reactions and to achieve the best possible results. Your surgeon must carefully choose the appropriate implant size and projection according to your anatomy and desired expansion outcomes. S/he will choose the surgical technique of her/his choice that fits your individual characteristics and properly places the sterile silicone breast implant.

In some cases, it is possible to use intraoperative, single-use, sterile, silicone breast sizers from the Motiva Implant Matrix®, which are single-use devices designed for temporary intraoperative placement, to assist in determining the appropriate breast implant volume and shape for each patient prior to implantation of a Motiva® implant.

### 13.2. Implant selection.

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

The following conditions may cause implants to be more palpable: textured implants, larger implants, subglandular placement, and an insufficient amount of tissue available to cover the implant. Excessively large implants may speed up the effects of gravity on the breasts and can result in drooping or sagging, the risk of developing clinical complications, or aesthetically undesirable results, which sometimes require surgical intervention for correction.

### 13.3. Incision.

The incision should be of sufficient length to place the implant inside the breast without risking damage to the implant.
In the table below, the differences between different incisions for placement of breast implants are detailed.

Table 1.

*Types of incision for breast augmentation with silicone implants.*

| **Incision type** | **Characteristics** |
|---|---|
| Periareolar | Better concealed.<br>May reduce the possibility of future breastfeeding.<br>Associated with a higher risk of changes in nipple sensation. |
| Inframammary | Less concealed than the periareolar incision.<br>Associated with fewer breastfeeding difficulties. |
| Axillary | Least concealed of all incision sites (when the arm is lifted). |

For a better understanding of the anatomical position where different incisions are made, refer to the image below:

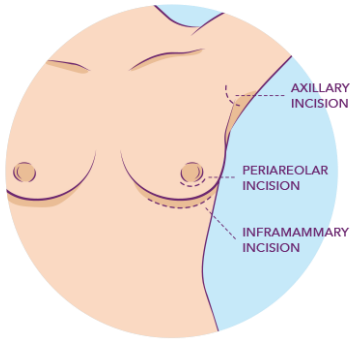


*Figure 1.* Anatomical location of possible incision sites for breast augmentation with silicone implants.

### 13.4. Placement.

One of the most important factors in a successful breast augmentation is the proper placement of the implant.

In the table below, the differences between different placement pockets for silicone breast implants are detailed.

Table 2.

*Placements for breast augmentation with silicone implants.*

| **Placements** | **Characteristics** |
|---|---|
| Submuscular (under the chest muscle) | Less palpable implants.<br>Lower likelihood of capsular contracture.<br>Easier mammographies. |

| | |
|---|---|
| | Associated with a longer surgical procedure, longer recovery period, and more pain. It can influence the degree of difficulty in performing some reoperation procedures. |
| Subglandular (under your Mammary/glandular tissue but over the fascia* layer | May reduce surgery and recovery duration.<br>Less painful.<br>Easier access for reoperation than submuscular placement. May result in increased implant palpability.<br>Greater risk of capsular contracture and ptosis (sagging).<br>Increased difficulty in performing mammographies. |
| Subfascial (under both the mammary tissue and the fascia* layer) | Natural-looking shape.<br>Associated with a longer procedure and more challenging dissection.<br>Less painful than submuscular/dual plane.<br>Better lower-pole coverage but less upper-pole coverage.<br>Minimal muscular distortion with arm movement.<br>More predictable results. |
| Dual plane | Associated with the benefits of submuscular placement, along with the advantages of a faster recovery and less pain and postoperative discomfort. |

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

For a better understanding of the anatomical place where the implants could be placed according to the surgeon's criteria, observe the image below:

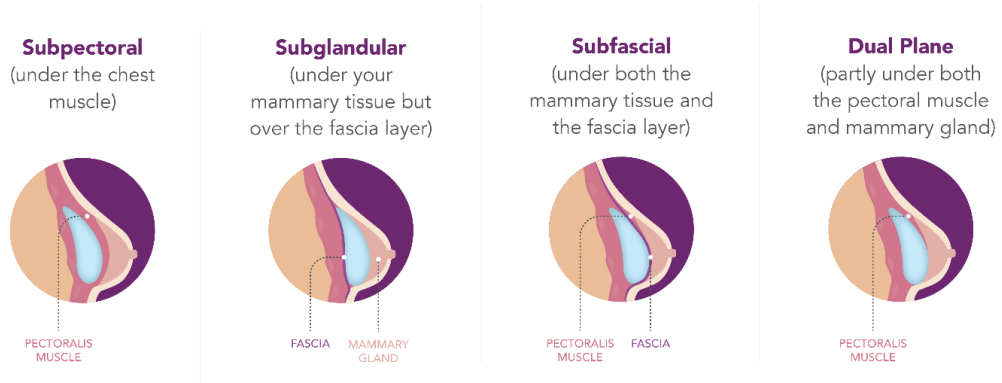


*Figure 2.* Anatomical locations of the placement pockets of breast implants.

## 14. SPECIFIC BREAST IMPLANTS CHARACTERISTICS.

### 14.1. TrueFixation® tabs.

**(exclusively in Motiva Anatomical TrueFixation® breast implant)**

The Anatomical TrueFixation® system includes two fixation tabs made from reinforced silicone, which are to be sutured to adjacent tissue to prevent possible rotation and/or displacement after surgery, with the subsequent distortion in the expected results.

### 14.2. Radiopaque orientation lines.

**(exclusively in Ergonomix® Oval and Anatomical TrueFixation® breast implants)**

Some breast implants of the Motiva® family possess blue orientation lines and/or dots made of radiopaque material to identify potential post-surgical malposition of the device during an X-ray procedure.

The radiopaque lines and dots are designed to act as guides for the surgeon when implanting a breast implant. They also act as indicators when determining via X-ray whether the implant has been displaced/malpositioned, to justify if additional measures are needed for correction.

### 14.3. BluSeal® technology.

Motiva Implants® are the only breast implants in the world that come with a lightly tinted blue barrier layer, made with biocompatible dyes to allow for pre-surgical visual inspection by your surgeon, to ensure the integrity of the entire implant shell. Thus, the BluSeal® barrier layer prevents the use of defective products and prevents silicone gel leakage into the body after implantation.

### 14.4. Q Inside® Safety Technology (also known as Qid®).

Motiva Implants® are available with an optional digital passport. Q Inside® Safety Technology is a passive radiofrequency identification device (RFID); the world's first FDA cleared microtransponder for use in humans.

Q Inside® Safety Technology consists of a biocompatible microtransponder, programmed with a unique electronic serial number (ESN) that is accessed by a proprietary handheld reader when waved over the breast area. The 15-digit ESN corresponds to a unique identification number which provides access to the product information kept in a secured data base accessible only by authorized personnel. By utilizing Q Inside® Safety Technology, physicians and patients have access to a secure, non-invasive verification of implant-specific data (such as serial, reference, and lot numbers; volume, size, and projection; model; surface type; manufacturing date).

The RFID is safely embedded in the implant during its manufacturing. It is located near the patch area of the implant and suspended in the cross-linked, highly viscoelastic silicone gel filling.

This innovative technology has been proven to be both safe and effective because it tolerates all conditions to which it will be exposed and is activated externally by the reader. Because it doesn't require a battery, its life expectancy is indefinite.

Unlike product and warranty cards that are typically provided to a patient undergoing breast augmentation or reconstruction, Q Inside® Safety Technology can never be lost or misplaced. This authentication system does not include any personal patient information and is compliant will all governmental regulations.

## 15. SPECIFIC INSTRUCTIONS.

### 15.1. Instructions for Patients Undergoing MR.

You should be monitored continuously throughout the lifetime of your breast implant(s). It is important to have regular MRs over the devices´ lifetime to screen for silent rupture, even if there appear to be no problems with them (as mentioned earlier in this document).

Motiva Implants® with Q Inside® Safety Technology contain a microtransponder that 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 caused extends approximately 15 mm radially from the microtransponder when imaged using a gradient echo (GRE) pulse sequence and a 3-Tesla MR system.

Motiva Implants® with Qid® are MR conditional. The patient implanted can undergo MR 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)
- Maximum MR system reported whole body average specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Control Operating Mode.
- Under the scan's defined conditions, Motiva Implants® with Qid® are expected to produce a maximum temperature rise of 1.5° C after 15 minutes of continuous scanning (i.e., per pulse sequence).

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 Establishment Labs indicate that the use of "combined" or "dual" modality imaging techniques (i.e. MR with another imaging method such as ultrasound, mammography, tomosynthesis etc.), may considerably increase diagnostic accuracy when Motiva Implants® with Q Inside® Safety Technology are present. The addition of other imaging modalities, using standard practices, allows for the complete radiological survey of the breasts.

## 16. FOLLOW-UP EXAMINATIONS.

### 16.1. Symptomatic Rupture.

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

## 17. ADDITIONAL INFORMATION.

### 17.1. Life expectancy

Silicone breast implants are not lifetime devices. For safety, as well as the best possible aesthetic outcomes, it is important that you return to your plastic surgeon's office for all follow-up evaluations s/he prescribes. Establishment Labs recommends yearly visits to verify an implant's integrity. The evaluation for posible ruptures should be assesed everytime the doctor follows up. Average life expectancy of implants in the market has been indicated as 10 years (FDA reference)[4], but as long as the implants are not ruptured or subject of any complication, there is no need to remove or replace them.

## 18. DEVICE TRACEABILITY.

Motiva Implants® are subject to device tracking via the MotivaImagine® registration system. You can register your implants at https://register.motivaimagine.com/. If you have difficulty registering your implant, you can contact Establishment Labs to receive assistance.

[4] 5 Things to Know About Breast Implants
Office Commissioner - https://www.fda.gov/consumers/consumer-updates/5-things-know-about-breast-implants

Implant registration will help ensure that Establishment Labs has a record of each device's related information (such as ID, lot, and serial numbers), surgery date, and patient and surgeon contact information, so that they can be contacted in the event of a field action or other situations related to the device that patients should be made aware of.

**19. PRODUCT EVALUATION.**

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

**20. PATIENT ID.**

It is imperative that you have a record of your surgical procedure in case of future consultations or additional surgeries. Each implant comes with a Patient ID card, which must be given to you by your surgeon for personal reference. Besides the information stated on the Patient Record Label (which should come affixed to the back of the card), the Patient ID card also includes your name, position of the implant, date of implantation (surgery), and the name of the treating surgeon. This card is for patients' permanent records and should always be kept safely.

**21. REPORTING AND ADDITIONAL INFORMATION**

If you need additional information related to Motiva Implants®, do not hesitate to contact us. If any serious incident occurs, go immediately to your surgeon and report the event to the closest Establishment Labs office:

ESTABLISHMENT LABS HEADQUARTERS
Coyol Free Zone and Business Park,
Building B25, Alajuela, Costa Rica
Phone: +506 2434-2400 Fax: +506 2434-2450
customerservice@establishmentlabs.com
www.motiva.health/support/
www.establishmentlabs.com

MANUFACTURING SITES
ESTABLISHMENT LABS
Coyol Free Zone & Business Park, 4th Street
Building B15, Alajuela, Costa Rica
ESTABLISHMENT LABS
Coyol Free Zone & Business Park
Building B25, Alajuela, Costa Rica

EUROPEAN REPRESENTATIVE
Emergo Europe: Prinsessegracht 20, 2514 AP
The Hague, The Netherlands

EDC Motiva BVBA (European Distribution Center)
Nijverheidsstraat 96, Wommelgem
Antwerp, 2160 Belgium
Phone: +32 34324170

MOTIVA USA LLC
(Establishment Labs subsidiary)
712 Fifth Avenue, 14th Floor,
New York, NY 10019-4108, USA
Phone: 888-846-2915

**Applicable to patients in EU Members States**:
Any serious incident that occurs in relation to Motiva Implants® should be reported to Establishment Labs and to the competent authority of the EU Member State in which the patient is established.

**Applicable to patients in Australia only**:
Any serious incident that occurs in relation to Motiva Implants® should be reported to Establishment Labs and to the Therapeutic Goods Administration (TGA): http://www.tga.gov.au/