PATIENT INFORMATION:
TISSUE EXPANDER-BASED BREAST RECONSTRUCTION WITH MOTIVA FLORA®

Only surgeons with qualified training and certification by their region's corresponding national medical board(s) 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/INDICATIONS FOR USE

The Motiva Flora® Tissue Expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond 6 months. The Motiva Flora® Tissue Expander is used for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures.

2. CONDITIONS FOR USE

Motiva Flora® is intended to be used by certified plastic surgeons within an operating room under sterile conditions, in compliance with good aseptic practices.

3. OVERVIEW

- Alternative treatments are available for breast reconstruction, including tissue flap procedures to rebuild the shape of your breast after surgery.
- Women who are appropriate candidates for breast reconstruction may consider the use of a tissue expander in immediate or delayed breast reconstruction following a prophylactic (preventative) or therapeutic mastectomy.
- Breast reconstruction with tissue expansion is a two-stage process. The first stage involves the use of a silicone rubber balloon-like tissue expander that is inserted under or over the pectoral muscle. Saline solution is injected gradually into the tissue expander to fill it over a period of weeks or months. This process allows the skin on the chest to be stretched over the expander, creating a breast mound. Once the skin has been stretched to the desired volume or size, the tissue expander is surgically removed and replaced with a breast implant.
- Please refer to section 4 ("**COMPONENTS**") for information about the materials and substances used in Motiva Flora® Tissue Expander.
  SmoothSilk®/SilkSurface®, the surface used in Motiva Flora®, is classified as a smooth surface per ISO 14607:2018 (Non-active surgical implants - Mammary implants - Particular Requirements). Its outer shell is comprised of standard layers and a barrier layer. Both types of layers are made from medical-grade, silicone-based elastomer (silicones have been tested for biocompatibility and are appropriate for medical applications).

- A radiofrequency identification device (RFID) signal from a built-in microtransponder is used to identify the center of the injection port for accurate injection of saline solution. There are no magnetic components in the design of the Motiva Flora® Tissue Expander. Therefore, the device can be used with magnetic resonance imaging (MRI) and computerized axial tomography (CAT) without negatively affecting the images and/or its interpretation.
- The safe use of Motiva Flora® cannot be guaranteed in patients who have implanted devices that could be affected by a magnetic field (e.g., pacemakers, drug infusion devices, artificial sensing devices).
- The decision to use a tissue expander as part of breast reconstruction is a personal one. The important information in this document is meant to help you understand the risks and benefits of breast reconstruction surgery with Motiva Flora® in order to make the most informed decisions possible.
- Motiva Flora® is a temporary device and is only meant to stay implanted until the expansion process is finished. It is not meant to be implanted for more than 6 months. The total expansion period will vary depending on patient tolerance, tissue behavior, and desired tissue expansion.

4. DEVICE COMPONENTS

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

Implant Component	Description
Shell: Standard Layers	Medical-grade, silicone-based elastomer
Shell: Barrier Layer	Medical-grade, silicone-based elastomer (it is referred to as the "barrier" layer due to its specific chemical composition)
Barrier Layer Indicator	Medical-grade, biocompatible blue colorant pigments the barrier layer so that the surgeon may visually verify its integrity and homogeneity across the shell
Patch Assembly	Medical-grade, silicone-based elastomer sheet
RFID coil	This RFID transponder is a metallic micro-antenna that receives reader signal and transmits its specific information.

NOTE: There are no known manufacturing residuals that could pose a risk to the patient**.** The materials used in the manufacture of Motiva Implants are medical grade and have been tested by international toxicity standards.

5. CONTRAINDICATIONS

Tissue expander-based breast reconstruction is contraindicated in the presence of the following situations or conditions:

- Patients who have implanted devices that could be affected by a magnetic field (e.g., pacemakers, drug

infusion devices, artificial sensing devices)
- Active infection anywhere in the body
- Existing malignant or premalignant breast cancer without adequate treatment

6. RELEVANT TOPICS

6.1. INFORMED CONSENT

Establishment Labs, the manufacturer of Motiva Flora®, 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 "Information for the patient: Tissue expander-based breast reconstruction with Motiva Flora®" (i.e. this document) 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 tissue expander implantation surgery with Motiva Flora®.

Section 10 details all potential complications associated with breast tissue expander-based breast reconstruction surgery. 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:

Radiation therapy: If required, radiation therapy may be administered from prior to mastectomy until the completion of tissue expansion. Radiation therapy to the chest region before or after breast reconstruction with a tissue expander can produce unacceptable firmness or other long-term complications. Establishment Labs has not tested the effects of Motiva Flora® Tissue Expander during radiation therapy and cannot warrant the safety of such use. There is always a risk associated with radiotherapy procedures which must be assessed by the physician. In addition, tests have been performed on the device during the radiation planning with computed tomography (CT) that show there is minimal impact on the calculation of the radiation dose. However, there is always a risk associated with radiotherapy procedures, which your surgeon and radiation oncologist must assess.

Reoperation: Deflation, unacceptable cosmetic outcomes (dimpling, wrinkling, failure in tissue expansion and other potentially permanent cosmetic changes of the breast), and other complications may require additional surgeries. There is a risk that the expander's shell integrity could accidentally be compromised during reoperation, potentially leading to product failure.

Surgical setting and anesthesia: General anesthesia is commonly used, while local anesthesia with sedation is also an option. You should confirm with your surgeon and surgical facility the pre-surgery conditions that you must meet, such as food, medicine, or any other necessary preparations.

Topical medications: You should consult a physician or a pharmacist before the use of any topical medication (e.g. steroids) around the breast area.

Trauma: If you have suffered any trauma or compression around the breast area (e.g. injuries caused by sports, seat belts, motor vehicle accidents) or suspect any complication due to trauma, you must consult your surgeon.

Smoking: Smoking may interfere with the healing process. Delayed wound healing may increase the risk of infection, extrusion and necrosis.

Insurance coverage: Before undergoing surgery, you should check with your insurance company about insurance benefits and coverage issues.

Mental health: It is up to the surgeon to consider whether you are a suitable candidate to undergo surgery. Your mental health may be carefully assessed and evaluated prior to surgery. You should disclose any current and/or prior mental health illness(es) to your surgeon during your consultation visit.

7. GENERAL POST-OPERATIVE CARE

The recovery process is different for every patient, but the following points should be considered:

- You might have an elevated body temperature.
- You are likely to feel tired and sore for several days following the operation.
- Your breast(s) may remain swollen and sensitive to physical contact during the expansion period.
- You may experience a feeling of tightness in the breast area as the skin adjusts to the new breast size, which may increase following each expansion.
- Drains should remain in place until the output is less than 30 ml in 24 hours; this typically takes 7 to 10 days.
- Take all post-operative prophylactic antibiotics and other medications as your surgeon prescribes.
- Avoid any strenuous or vigorous activity for at least a couple of weeks (or until your surgeon clears you to do so), though you should be able to return to work within a few days if your surgeon approves.
- Sleep or rest with your head slightly elevated, avoiding lateral positions.
- Keep your arms close to your body and avoid lifting weights until your surgeon allows it.
- Do not drive for at least 2 days after your surgery and do not exercise until your surgeon clears you to do so.
- Your surgeon may recommend topical products.
- The average recovery for tissue expander insertion is 3 to 4 weeks.
- You will be unable to do any heavy lifting of more than 10 lbs for 4 to 6 weeks after your operation.
- As well, you will be unable to lift anything over 10 lbs for the first 24 hours after each tissue expander inflation.

- Don't use deodorant or other cosmetic products until after you have put your bra on. This will prevent deodorant from getting on your incision and causing an infection. Don't use deodorant on the side of your surgery if there is any break in the skin there.
- Do not expose your breasts directly to sunlight until you are cleared to do so 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 or post-operative bra, *without underwires.* Your surgeon will provide or recommend the best bra to use after your surgery, along with instructions on how long you must wear it. Most patients wear their medical compression garment day and night for 1 to 2 weeks, after which they can transition to a supportive sports bra.

Your tissue expander will likely be over-expanded. As you near the end of the expansion, your reconstructed breast may look larger than your other breast, if only one breast was operated on. During the different stages of your breast reconstruction, your bra can be padded to help balance your appearance. One way to fill the bra is to use a soft breast form. This breast form is a lightweight nylon pouch. The size can be adjusted to match your opposite breast by adding or removing the cotton fluff inside. This is especially useful as your breast mound becomes larger during expansion.

8. EXPECTED BENEFITS OF TISSUE EXPANDER-BASED BREAST RECONSTRUCTION

Tissue expander-based breast reconstruction aims to stretch the breast skin and soft tissue in order to create space for future long-term implant placement. Mastectomy is a mutilating operation that, without reconstruction, causes deformity in women. The general goals of breast reconstruction are to restore the missing form of the female breast as well as the location and size of the breast, so that women no longer need to wear an external prosthesis[1]. The loss of a breast can be a traumatic experience, with serious effects on quality of life. For women who have undergone a mastectomy, breast reconstruction provides psychosocial as well as aesthetic benefits. Breast reconstruction has therefore come to be regarded as not just a cosmetic procedure but an integral part of the management of breast cancer.[2]

Tissue expander- and implant-based reconstruction have proved to be safe, cost-effective, and reliable techniques that can be performed in women with various comorbidities. Short operative time, fast recovery, and absence of donor site morbidity are other advantages over autologous breast reconstruction[2]. The advantages of expander-implant techniques for breast reconstruction also include minimal morbidity compared with the donor site damage with autologous flap reconstruction techniques and the saving of surrounding skin tissue flaps, which remain available for use in different reconstruction techniques[1].

[1] Elisa Bellini,Marianna Pesce,PierLuigi Santi,and Edoardo Raposio. Two-Stage Tissue-Expander Breast Reconstruction: A Focus on the Surgical Technique. *BioMed Research International* 2017; Volume 2017(Article ID 1791546).
[2] Nicolo Bertozzi, Marianna Pesce, PierLuigi Santi, Edoardo Raposio. Tissue expansion for breast reconstruction: Methods and techniques. *Annals of Medicine and Surgery* 2017; 21().

9. RISKS AND POTENTIAL COMPLICATIONS

9.1. 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 via inhalation by an anesthesiologist. Under general anesthesia, the patient is unable to feel pain and may also have amnesia. There are several potential side effects from 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, and a sore throat due to the breathing tube.

9.2. RELATED TO THE SURGICAL PROCEDURE AND EXPANSION SESSIONS

After tissue expander-based breast reconstruction surgery, patients might experience swelling, hardness, discomfort, itching, allergies, bruising, twinges, and/or pain over the first few weeks and after each expansion session.

9.3. RELATED TO TISSUE EXPANDERS

Potential adverse events that may occur with tissue expander-based reconstruction surgery include:

9.3.1. Capsular Contracture

The formation of a capsule of collagen fibers around a foreign body (with the aim of isolating it) is a normal immune response by 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 tissue expander itself.

9.3.2. Rupture/Deflation

Tissue expander rupture/deflation occurs when the shell develops a tear or a hole. Rupture/deflation can occur at any time after implantation but is more likely to occur the longer the expander is in place. The following may cause expanders to rupture/deflate: damage by surgical instruments, implant stress and weakening during implantation, age, design of the device, location, occurrence of post-operatory hematomas or seromas, folding or wrinkling of the expander shell, trauma, and severe capsular contracture. Expander deflation may also occur when there is leakage of saline solution when removing

the needle out of the injection area during filling. Another possible cause is a damaged breast tissue expander shell.

9.3.3. 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.

9.3.4. 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 expander present are harder to treat than infections in tissue without an expander present. If an infection does not respond to antibiotics, the expander 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.

9.3.5. Hematoma

Hematoma is a collection of blood within the space around the expander. The majority of hematomas occur in the immediate postoperative period, however, there are some reports of hematomas with a delayed presentation. The blood that causes a hematoma is usually reabsorbed back into your body, in some cases, the blood may need to be surgically drained, usually by reopening the incision made during breast surgery.

The risk of postoperative hematoma after mastectomy with reconstruction is not affected by any measurable preoperative, operative, or oncologic factors. With no definitive risk factor for bleeding, surgeons should remain meticulous and vigilant throughout the operation.[3]

Gross postoperative hematoma, manifested by enlargement, tenderness and discoloration of tissue may, if untreated, lead to device extrusion.

[3] Seth AK, Hirsch EM, Kim JY, Dumanian GA, Mustoe TA, Galiano RD, Fine NA. 2013. Hematoma after mastectomy with immediate reconstruction: an analysis of risk factors in 883 patients. Ann Plast Surg. 2013 Jul;71(1):20-3.

9.3.6. Seroma

Seroma is a build-up of fluid around the expander and is a known entity linked to complications in TE/ADM reconstructive course. The breast area involved in the surgery may have a spot that's swollen and feels like there is liquid under the skin. Seromas can appear about 7 to 10 days after surgery, after the drainage tubes have been removed.
Most seromas are reabsorbed back into your body in about a month, but in some cases it can take up to a year, when it becomes clinically significant, current methods for its management consist of repeated needle aspiration[4].

Having a 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.

The presence of seroma after breast tissue expander (TE) insertion for a long duration can cause infection and purulency; thus, obvious fluid collection around TEs should be drained as early as possible. However, due to the risk of puncture (rupture), it may not be possible to completely drain the fluid if it is located above the TE[5] and explantation may be required.

9.3.7. 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 the breasts of women who undergo breast reduction procedures, who have experienced hematoma formation, and even those who have not undergone any breast surgery. The occurrence of calcium deposits significantly increases with age.

9.3.8. 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.

9.3.9. Extrusion

Lack of adequate tissue coverage, local trauma, or infection may result in exposure and extrusion (i.e. forced out of the normal position) of the expander. This has been reported with the use of steroid drugs

[4] Marcasciano M, Kaciulyte J, Marcasciano F, Lo Torto F, Ribuffo D, Casella D.2019. No Drain, No Gain": Simultaneous Seroma Drainage and Tissue Expansion in Pre-pectoral Tissue Expander-Based Breast Reconstruction. Aesthetic Plast Surg. 2019 Aug;43(4):1118-1119

[5] Kagaya Y, Arikawa M, Kageyama D, Sekiyama T, Akazawa S. 2018. Simple-safe-sure Fluid Drainage Just above Breast Tissue Expander using 18-Gauge Blunt Cannula. Plast Reconstr Surg Glob Open. 2018 Oct 16;6(10):e1983

or after radiation therapy of breast tissue. If tissue breakdown occurs and the expander becomes exposed, device removal may be necessary, which may result in additional scarring and/or loss of breast tissue.

9.3.10. Necrosis

Necrosis is the formation of dead tissue around the device. 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.

9.3.11. Tissue Damage

Vascularization (i.e. development or extension of blood vessels) of the overlying tissue may become compromised when an excessively rapid tissue expansion is performed. If you notice any signs of tissue damage, wound dehiscence/separation, abnormal skin pallor (e.g., blanching), erythema (i.e. redness), edema (abnormal fluid accumulation), pain, or tenderness, notify your surgeon as soon as possible. In the absence of other signs, some temporary erythema may occur as a normal tissue response to expansion. Radiotherapy, steroid use in the surgical pocket, excessive heat or cold therapy, and smoking may affect tissue viability.

9.3.12. Skin Flap Necrosis

Necrosis is the premature death of cells in living tissue due to an interruption of blood supply to a specific region. If skin flap necrosis occurs in a small area, it may be treated with topical antibiotics and local wound care. However, if the area of necrosis is large, a more aggressive approach with advanced wound care is necessary. In non-nipple-sparing cases, limiting expansion to a maximum of two thirds of the expected final volume may minimize the possibility of mastectomy flap necrosis. Salvage surgery, with local advancement of the remaining envelope after excision of the necrotic area or distant flap, may also be performed.

9.3.13. Inflammatory Reaction

The introduction of foreign materials can prompt the development of a fibrous or periprosthetic (i.e. surrounding the prosthetic) capsule. Tissue expanders are no different from any foreign material implanted into the human body in terms of triggering this protective immune reaction. This foreign body response is universal and ideally removes or otherwise isolates the “irritant material” with fibrous tissue to prevent unwanted immune consequences. A capsule around a tissue expander is, therefore, a necessary mechanism of body defense – but if excessive, can lead to pain and deformity of the breast.

9.3.14. Silicone Reaction

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

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

9.3.15. Rotation

Rotation of a tissue expander may occur, though proper placement and pocket dissection reduce its risk. Revision surgery may be necessary to correct rotation.

9.3.16. Distortion

Tissue expansion may cause temporary discomfort and distortion. Patients should be psychologically suitable, well informed, and motivated to complete the expansion process. Negative reactions may include depression and withdrawal.

9.3.17. Inadequate Tissue Flap

If you do not have adequate tissue flap, additional surgery and expansion may be required. As part of the original surgical plan, sequential expansion may be included in cases with limited viable donor site tissue.

9.3.18. Displacement

The tissue expander may become displaced, especially if the surgical pocket is too large. Tissue expander displacement may make location of the integrated valve difficult or impossible without surgical correction.

9.3.19. Malposition

Malposition of a tissue expander refers to either its incorrect placement during surgery or a shift from its original position. Malposition has been frequently reported due to its multifactorial causes and can occur during the lifetime of the device.

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

Clinical symptoms of malposition can include changes in breast shape, displacement, or sensation of firmness. Revision surgery may be indicated to achieve patient satisfaction. New risks need to be considered before performing a revision surgery.

9.3.20. Breast Tissue Atrophy/Chest Wall Deformity

The pressure of the tissue expander during the expansion process may cause the breast tissue to thin and shrink (with increased expander visibility and palpability), potentially leading to chest wall deformity. This can occur while expanders are still in place, or after the expander is removed.

9.3.21. Premature Explantation

Adverse reactions may require premature explantation, which may affect desired flap size. Irradiation may be a cause of premature removal because of extrusion, capsular contracture, and recurrent seroma.

9.3.22. Unsatisfactory Result

Insufficient expansion can lead to the placement of a longer-term implant of the wrong size or shape. During the expansion process, displacement or migration of the device; rotation; wrong size choice; and/or capsular contracture could impact final aesthetic results. In some cases, there may be device wrinkling that the patient may find aesthetically unappealing, though this should resolve once the expansion process has been completed.

9.4. OTHER REPORTED CONDITIONS

There have been reports in medical literature of other conditions in women with silicone breast tissue expanders. Many of these conditions have been studied to assess their possible association with tissue expanders, though a causal relationship between expanders and the conditions listed below has not been established. None of the investigations have been directly related to tissue expanders, since their use is temporary.

9.4.1. Connective Tissue Disease (CTD)

While recent studies suggest a possible association between silicone breast implants and CTDs (given that silicone in breast implants acts as a foreign body that can elicit an inflammatory response), no conclusive data is available to support this theory.

9.4.2. 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.

9.4.3. 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) that they believe are related to their implants. However, there is no evidence in published literature of a causal relationship between breast implants and neurological disease.

9.4.4. Interference with Mammography

Patients who have undergone a complete mastectomy followed by reconstruction with tissue expanders are not required to undergo a mammography since no breast tissue remains after the mastectomy. However, it is important that the patient, along with the surgeon, carries out a frequent physical examination of the breast area.

9.4.5. Interference with Magnetic Resonance Imaging (MRI)

The Motiva Flora® tissue expander is considered MR (magnetic resonance) conditional, which means that during an MRI study, the microtransponder can create an imaging void immediately around it (known as an artifact), which can obscure the view of parts of the device's footprint and parts of the patient's tissue. Such effects can be overcome with appropriate imaging techniques.

Motiva Flora® comes with an integrated port whose center can be located using an external Motiva Flora® Port Locator. The use of a copper ring instead of other metal components is an innovative technology not available in other tissue expanders on the market. As the component (also known as the air wound coil) does not contain any ferromagnetic materials, it provides minimal interference with the MRI process.

An ultrasound (US) may complement MRI by allowing the radiologist to visualize the area within the product artifact. In the event of an MRI evaluation, you must inform your radiologist of the presence of the Motiva Flora® tissue expander(s), along with its microtransponder and integrated port. Further information regarding this topic is described in section 15 of this document.

10. STERILE PRODUCT

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

11. SURGICAL PROCEDURE

11.1. SURGICAL TECHNIQUE

There are several surgical techniques for tissue expander insertion. 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, the surgeon must choose from current and accepted surgical techniques to minimize the incidence of adverse reactions and achieve the best possible results. The surgeon must carefully choose the appropriate expander size and projection according to your anatomy, any pre-existing surgical incisions, tissue viability, and desired expansion outcomes.

11.2. EXPANDER SELECTION

Motiva Flora® Tissue Expanders come in various widths, heights, projections, and volumes to offer you the most appropriate device for your specific needs. The base diameter and desired volume of the longer-term implant informs the choice of the tissue expander. The plan for the contralateral breast (if present), your personal wishes, and the surgeon's medical criteria all play an important role in choosing the right tissue expander.

Full-projection tissue expanders help utilize upper pole tissue to further expand the lower pole, giving a naturally ptotic (lowered) appearance to the reconstructed breast.

11.3. INCISION.

The incision should be long enough to place the tissue expander into the breast pocket without risking damage to the implant.

The image illustrates different incisions for breast tissue expander placement.

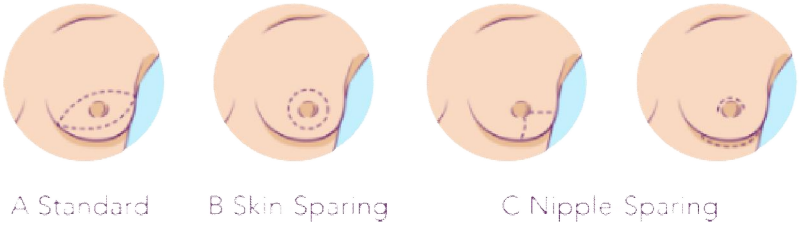

Figure 1. *Anatomical location of possible incision sites for breast augmentation with silicone tissue expanders.*

11.4. PLACEMENT

The pre-operative plan should be made the day before the operation by the oncologic surgeon along with the plastic surgeon. Pre-operative markings should favorably locate the mastectomy scar while preserving the required skin envelope. When both matching surgery for the contralateral breast and mastectomy for the cancerous one are to be performed within the same operation, the pre-operative markings for the contralateral breast should also be made; breast augmentation, breast reduction, and mastopexy are the usual procedures required.

At this stage, your surgeon should already have a clear picture in mind of the final result of the reconstructed breast to be able to select the best tissue expander dimensions and location accordingly. The base diameter and volume of the eventually placed implant determines the choice of the tissue expander, while your lifestyle guides the selection of the contour profile of the final implant. The choice is also influenced by the surgeon's preferences, the plan for the contralateral breast, and your wishes. Your surgeon must be aware that your main concern is the final aesthetic result, and that the final breast size complements the rest of your body. If you choose to receive a two-staged reconstruction, your plastic surgeon will place the tissue expander between the skin and chest muscle after your oncological surgeon removes the breast tissue.

SPECIFIC MOTIVA FLORA® TISSUE EXPANDER CHARACTERISTICS

11.5. BluSeal® technology

Motiva Flora® is the only breast tissue expander in the world that comes 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.

11.6. RADIOPAQUE ORIENTATION LINES

Motiva Flora® possess blue orientation lines 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 the device. 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.

11.7. TRUEFIXATION® SYSTEM

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

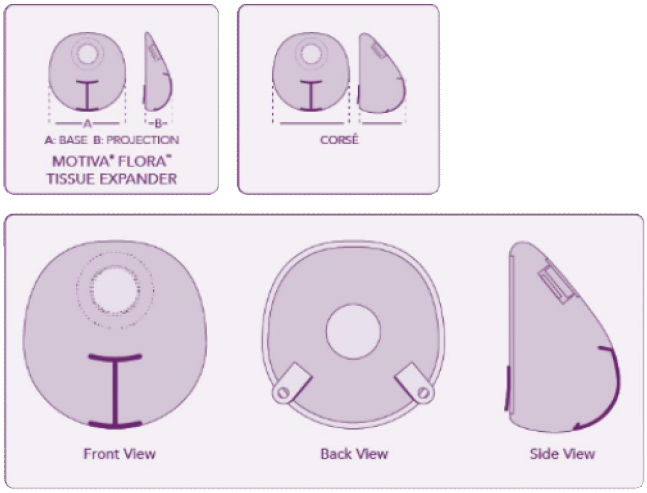

***Figure 2**. Different views of Motiva Flora® Tissue Expander design.*

11.8. RADIOFREQUENCY IDENTIFICATION DEVICE (RFID)

Motiva Flora® is filled via an integrated port, whose location is found by using an external Motiva Flora® Port Locator through the RFID signal emitted by the air wound coil placed inside the needle stop (internal component). The air wound coil is intended to interact with the port locator to identify the location of the injection port. The use of an RFID signal to identify the center of the injection port is an innovative technology not currently available in other tissue expanders on the market.

Motiva Flora® contains a RFID 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.

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 reconstruction, the information provided via this technology can never be lost or misplaced. This authentication system prevents association to any personal patient information and is compliant will all governmental regulations.

Figure 3. *Motiva Flora® Port Locator.*

12. SPECIFIC INSTRUCTIONS

12.1. INSTRUCTIONS FOR PATIENTS UNDERGOING MRI

In some cases, it is necessary to perform an MRI during the expansion period. It is up to the specialist to perform the test as required by the clinical condition of each patient.

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 operator can immediately terminate the procedure. Provide the patient with the means to alert the operator of any unusual sensations or problems.

Motiva Flora® Tissue Expander contains a RFID air wound coil 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.

MRI quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Non-clinical testing has demonstrated that the Motiva Flora® Tissue Expander is MR conditional. It can be imaged safely under the following tested 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 in *a* 1.5-Tesla/64-MHz and 3-Tesla/128-MHz MR conditions

- Under the scan defined conditions, the Motiva Flora® Tissue Expander is expected to produce a maximum temperature rise of 1.6° C after 15 minutes of continuous scanning (i.e. per pulse sequence)

Recent studies suggest the use of a "combined" or "dual" modality, which refers to using additional imaging technologies (i.e. MRI with ultrasound, tomosynthesis etc.), may considerably increase the diagnostic accuracy of procedures involving Motiva Flora® Tissue Expander with RFID. The addition of other imaging modalities, using standard practices, allows for the complete radiological survey of the breasts.

13. FIRST FOLLOW-UP APPOINTMENT.

Your first follow-up appointment will be 1 to 2 weeks after your surgery. Call your plastic surgeon's office to make the appointment (if not already scheduled) once you've been discharged from the hospital.

13.1. FILLING

For patients with tissue expanders, serial expansions should be initiated after the incision has healed, which is typically 2-3 weeks after the surgery. Volumes of serial tissue expansions and the intervals between them are determined by the surgeon on a per-patient basis. Patient discomfort and tissue tightness are the primary concerns taken into consideration.
Your surgeon should carefully monitor during each session for any signs of adverse reactions. If any signs of tissue damage, abnormal skin pallor (e.g., blanching), erythema, edema, pain, or tenderness are observed, filling should immediately stop until the cause is determined, and the problem solved. If signs persist, the device must be removed.
Filling volumes during each session, intervals between filling sessions, and total expansion time may vary because they are highly dependent on patient and procedure.

13.2. RECORDING TISSUE EXPANDERS' IMPLANTATION.

A Patient Fill Volume Record form is provided in this document. It is recommended that you take the sheet to each filling session that your surgeon schedules to document the volume added to the device.

14. ADDITIONAL INFORMATION

14.1. INFORMATION OF DEVICE LIFE EXPECTANCY

Motiva Flora® is intended for temporary sub-cutaneous or sub-muscular implantation for up to 6 months and requires periodic filling sessions with sterile saline solution until the desired volume is achieved per the surgeon's criteria. Establishment Labs does not recommend its use for longer than the necessary time required for tissue expansion based on the surgeon's criteria. The time required for complete tissue expansion varies from woman to woman. The life expectancy of the expander cannot be guaranteed beyond 6 months of implantation.

15. DEVICE TRACEABILITY

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

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.

16. PRODUCT EVALUATION.

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

17. PATIENT ID.

It is imperative that you keep a record of your surgical procedure in case of future consultations or additional surgeries. Each Motiva Flora® tissue expander comes with a Patient ID card, which your surgeon must give you 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 expander, date of implantation (surgery), and the name of the treating surgeon. This card is for patients' permanent records and should always be kept safely.

18. REPORTING AND ADDITIONAL INFORMATION

If you need additional information related to Motiva Flora® or Motiva Implants®, do not hesitate to contact Establishment Labs. If any serious adverse incident occurs in relation to Motiva Flora®, see your surgeon immediately 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
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

EUROPEAN IMPORTER
EDC Motiva® BVBA
Nijverheidsstraat 96, Wommelgem
Antwerp, 2160 Belgium

Applicable to patients in EU member states:
Any serious incident that occurs in relation to Motiva Flora® or Motiva Implants® should be reported to Establishment Labs and to the competent authority of the EU member state in which the patient is established.

MOTIVA FLORA® TISSUE EXPANDER FILLING RECORD

For better control of your reconstruction process, ask your surgeon to complete the information below for your Motiva Flora® Tissue Expander.

PATIENT NAME: _____ ID NUMBER: _____

DEVICE SERIAL NUMBER: _____ VOLUME (CC): _____

DATE OF IMPLANTATION: ____ / ____ / ____

DATE	VOLUME (CC)	CUMULATIVE TOTAL