PATIENT INFORMATION:
BREAST AUGMENTATION AND RECONSTRUCTION WITH MOTIVA IMPLANTS® (Australia)

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.

This patient information leaflet is relevant for all Motiva Breast Implants supplied in Australia including Motiva® Round and Motiva Ergonomix® Breast Implants (please refer to pages 20-25 for all models).

1. INTENDED USE.

Motiva® breast implants are intended to be used in female patients to increase the breast size in a breast augmentation surgery, or to correct/improve the result of a previous breast implant procedure. Motiva® breast implants are also indicated for 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. GENERAL INFORMATION.

- Breast augmentation and breast reconstruction are elective (personal choice) surgical procedures 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 the 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.

- Motiva® breast implants are classified as smooth surface implants 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 (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.

- 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 breast 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 breast 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 undesirable aesthetic results which can be permanent.

3. SILICONE BREAST IMPLANT COMPONENTS.

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

Table 1. Motiva Implants® Round SilkSurface® Plus components.

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, built by a ferrite core to strengthen the data transmission distance and sealed in a biocompatible glass capsule.

NOTE: The manufacturing materials used to manufacture Motiva Implants® pose minimal risk to the patient. The materials used in the manufacture of Motiva Implants are medical grade and have been tested by international toxicity standards.

4. CONTRAINDICATIONS.

The use of silicone breast implants is contraindicated in women with the folowings conditions:

- Existing breast carcinoma that has not been treated with mastectomy.
- Advanced fibrocystic disease considered precancerous that has not been treated with accompanying subcutaneous mastectomy.
- Active infections.
- 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
- Unjustifiable surgical risk factor determined by the surgeon.

5. RELEVANT TOPICS.

5.1. Informed Consent.

Establishment Labs, the manufacturer of Motiva Implants®, relies on your surgeon to explain to you the existing risks and benefits of breast 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 provided with this document titled "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 this document.

5.2 Additional Relevant Topics.

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 medical examiner of the presence of your breast 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: Breast 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 breast implants are explanted without replacement, changes to the breasts may be irreversible.

Reoperation: 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 breast implant from breast tissue. Therefore, it is important to take into consideration the following recommendations:

- Never manipulate or squeeze the breast implant excessively. The presence of lumps, persistent pain, swelling, hardening, or change in the breast implant shape could suggest symptomatic

rupture of the breast implant. If you have any of these signs, report it to your surgeon immediately and if possible, receive an evaluation through MR or High Resolution Ultra Sound

Trauma: You should consult with 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.

6. 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 could experience an elevated body temperature.
- Your breasts may remain swollen and sensitive to physical contact for a month or a longer period of time.
- You may 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 once your surgeon approves it.
- 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.

7. RISK/BENEFITS ANALYSIS.

7.1. 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 in particular, breast cancer survivors, includes dissatisfaction with appearance, perceived lack of femininity and body wholeness, reluctance to look at one's self while nude, feeling less sexually attractive, and self-consciousness about appearance.[1]

If your breasts never developed, if they shrank as a result of weight loss or pregnancy, or if your breasts are not the size or shape you desire, you may benefit from breast augmentation. Beyond improving your appearance, sense of youthfulness 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.[2]

With respect to breast reconstruction surgeries, women have reported that breast reconstruction has assisted in their recovery from breast cancer and 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).

7.2. Risks of Breast Augmentation Surgery with Silicone Implants.

[1] Koçan, s, K, Gürsoy, a, G. Body Image of Women with Breast Cancer After Mastectomy: A Qualitative Research. J Breast Health. [Online] 2016;12(4): 145-150. Available from: https://www.ncbi.nlm.nih.gov/pubmed/28331752 [Accessed 29 January 2020].

[2] Spear, sl, S, Murphy, dk, M, Slicton, a, S, Walker, ps, W. Inamed silicone breast implant core study results at 6 years. Plast Reconstr Surg. [Online] 2007;120(7 Suppl 1): 8S-16S; discussion 17S-18S. Available from: https://www.ncbi.nlm.nih.gov/pubmed/18090808?report=docsum [Accessed 29 January 2020].

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 breast 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 breast implantation may be cosmetically undesirable and irreversible. If you have your breast 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 breast implant that do not cause symptoms ("silent ruptures").

7.3. Risks of Breast Reconstruction Surgery with Silicone Implants.

Using an implant to rebuild the breast requires less surgery than flap reconstruction, since it only involves the chest area (and not a tissue donor site). Still, it may require more than one procedure, as implants can wear out and develop other issues, such as tightness of scar tissue around the implant.[3] Overall reconstruction process can take longer (multiple steps, multiple office visits to receive tissue expander injections) and generally not a good option if skin has undergone radiation. The most common local complications and adverse outcomes are rupture, deflation, capsular contracture, Breasts that don't match each other in size or appearance (asymmetry) and less likely to feel, look, or move like a natural breast.

8. RISKS AND POTENTIAL COMPLICATIONS DURING BREAST AUGMENTATION OR RECONSTRUCTION SURGERY.

Please consult your surgeon or healthcare professional if you are concerned about any of the following potential complications listed below:

8.1. Related to general anesthesia.

Under general anesthesia, the patient is unable to feel pain and may also have amnesia.

[3] Breastcancer.org. (2019). Implant Reconstruction. Retrieved February 24, 2020, from https://www.breastcancer.org/treatment/surgery/reconstruction/types/implants

There are a number of potential side effects of anesthesia. Some individuals may experience no side effects and others may experience a few side effects. Typically, the side effects last temporarily and tend to occur immediately after the anesthesia wear off. 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.

8.2. 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 course of the first few weeks.

8.3. Related to breast implants.

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

8.3.1. 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 breast implant, which makes the breast implant feel hardened (from slightly firm to quite hard). This 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 and reconstruction surgery for breast implants than in patients undergoing primary breast implantation surgery. Capsular contracture is a risk factor for breast 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 breast implant itself.

8.3.2. Rupture

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

Typically when a silicone gel-filled breast implant ruptures, the patient does not experience any apparent symptoms and there are no externally physical signs of changes with the implant rather

than visibly symptomatic. If displacement and/or rupture is suspected, you will need a screening MR (magnetic resonance imaging) examination or High Resolution Ultra Sound to determine whether the breast implant ruptured. If breast implant rupture is confirmed with the MR, you should have the breast implant removed (with or without replacement).

The United States Food & Drug Administration (US FDA) recommends having the first MR performed 3 years after the surgical breast implantation and in 2-year intervals regularly after the first MR performed; however, 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 breast implant(s) removed and replaced.
Concerns have been raised over whether ruptured breast 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 are not conclusive in associating breast implants with rheumatic disease.

8.3.3. Gel fracture.

Gel fracture can occur with cohesive silicone and occurs most frequently as a result of subjecting the breast implant to excessive compressive forces during the breast implantation operation(?). As a result, the shape of the breast implant is irrevocably lost, requiring breast 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.

8.3.4. 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 breast implant rupture. You must immediately report to your surgeon or physician if you experience significant and/or persistent pain.

8.3.5. 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.

8.3.6. 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. 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 breast 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.

8.3.7. Hematoma/Seroma.

Hematoma is a buildup of blood within the space around the breast implant, and a seroma is a buildup of fluid around the breast 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 typically occur soon after surgery but they can also occur at any time after injury to the breast. While the body absorbs small hematomas, some seromas 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.

8.3.8. 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.

8.3.9. 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 lead to successful resolution. In some cases, breast implant removal is required for complete symptom relief.

8.3.10. Breastfeeding.

Although most women with breast implants who attempt to nurse 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."[4] However, the American Academy of Pediatrics has stated that there is no reason why a woman with breast implants should refrain from nursing.

8.3.11. Calcification.

Calcification refers to the accumulation of calcium salts in the body's tissues. Calcium deposits can form in scar tissue surrounding the breast 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.

8.3.12. 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.

[4] 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.

8.3.13. Implant Extrusion.

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

8.3.14. Necrosis.

Necrosis is the formation of dead tissue around the breast implant. This may prevent wound healing and require surgical correction and/or breast 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.

8.3.15. Granulomas.

Granulomas 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. Clinically apparent silicone granulomas are a relatively rare complication of breast implant placement and surgical resection is indicated when they are symptomatic or of diagnostic concern.

8.3.16. 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 breast implants are still in place or following breast implant removal without replacement. Either of these conditions may result in the need for additional surgeries and/or undesireable dimpling/creasing of the breast.

8.3.17. 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 breast implant surface remains intact (Lee, 2017)[5].

[5] 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.

8.3.18. Undesirable Results.

Unsatisfactory results such as wrinkling, asymmetry, breast implant displacement/migration, incorrect size, breast 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 breast 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.

8.3.19. Gel Diffusion.

Small quantities of silicone may diffuse through the elastomer envelope of silicone gel-filled breast 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 breast implants have been reported in the literature and have suggested that gel-bleed may contribute to the development of capsular contracture and lymphadenopathy.

8.3.20. 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 breast implant.

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 avoid) the risk of malposition. Malposition may lead to patient dissatisfaction with aesthetic outcomes.

The clinical symptoms manifested by 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.

8.3.21. 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 breast implant placement during surgery. The clinical symptoms resulting from breast implant(s) bottoming out include asymmetry, upward-pointing nipples, a sagging breast, palpable breast 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.

8.3.22. 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 breast implant is positioned anteriorly, deforming the breast of the patient. Some scientific literature have reported that the interaction between breast envelopes, physical characteristics of the breast implant, and pocket dissection is the cause of malposition. Other theories include the involution of the breast tissue. Regarding breast implant characteristics, flipping has been associated with the presence or absence of texturing, the shape/profile of the breast 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 breast 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.

8.3.23. Implant Rotation.

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

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

BIA-ALCL is a rare type of T-cell lymphoma, a cancer of the lymphatic system involving cells of the immune system. **The lymphatic system** is a **network** of tissues and organs that help rid the **body** of toxins, waste and other unwanted materials. The primary function of **the lymphatic system** is to transport **lymph**, a fluid containing infection-fighting white blood cells, throughout the **body.**. 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 breast 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), a French government agency with jurisdiction over pharmaceuticals, biological products, medical devices and cosmetics, 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 breast implant and its surrounding capsule. Some cases have been treated by chemotherapy and radiation.

The following are considerations from the US FDA regarding BIA-ALCL[6]:

BIA-ALCL is a very rare condition; when it occurs, it has been identified most frequently in patients undergoing breast 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 breast implants, as well as provide educational materials before surgery.
- If you have late-onset, persistent peri-implant (i.e. surrounding the breast 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.

9. OTHER REPORTED CONDITIONS.

There have been reports in medical literature of other conditions in women with silicone breast implants.

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

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.

9.1. Connective Tissue Disease (CTD).

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.

9.2. 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.

9.3. 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 breast implants. However, there is no evidence in published literature of a causal relationship between breast implants and neurological disease.

9.4. Interference with Mammography.

You should have routine mammography exams performed according to your surgeon's recommendations and the importance of these exams should be explained by your surgeon. It is important to inform your medical examiners about the presence, type, and placement of your breast 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 breast implants.

9.5. Interference with MR.

Sterile silicone breast implants with a microtransponder are considered MR (magnetic resonance) conditional, which means that during a MR exam, the microtransponder can create an imaging void immediately around it (known as an artifact), which can obscure the view of parts of the breast 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 breast implant shell for the detection of rupture or a missed diagnosis of cancer (should it obscure a cancer

in the artifact area). It is important that you inform your medical examiner about the presence, type and placement of your breast implant(s). Further information regarding this topic is described in Section 10 of this document.

9.6. General X-ray interaction.

Silicone gel breast implants obscure partially or entire parts of an x-ray image during an X-ray procedure, depending on the size and the thickness of the breast implant as well the energy used[7]. It is important that you inform your medical examiner about the presence, type and placement of your breast implant(s).

9.7. Biopsy's interaction.

A breast biopsy involves removing a sample of breast tissue to determine whether it is cancerous or benign (non-cancerous). Since the breast implant will always be placed in a retromamamarial position, a biopsy could be performed normally if required. The precision and directional abilities of vacuum-assisted biopsy make it the most viable percutaenous ("through the skin") biopsy option for women with breast implants. Conventional core needle biopsy is typically less precise in locating breast abnormalities (lesions) and requires multiple needle insertions in order to obtain adequate breast tissue samples. It is important that you inform your medical examiner about the presence, type and placement of your breast implant(s) in order to avoid a rupture due to a puncture of the breast implant.[8]

10. 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 breast implant´s 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.

[7] Daskalaki A, Bliznakova K, Pallikarakis N. Evaluation of the effect of silicone breast inserts on X-ray mammography and breast tomosynthesis images: A Monte Carlo simulation study. Phys Med. 2016 Feb;32(2):353-61. doi: 10.1016/j.ejmp.2016.01.478. Epub 2016 Jan 25.

[8] Imaginis. Breast Implant Imaging. [Online]. Available from: https://www.imaginis.com/mammography/breast-implant-imaging-2 [Accessed 29 January 2020].

Motiva Implants® with Qid® are MR conditional. The patient may 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.

11. FOLLOW-UP EXAMINATIONS.

For safety, as well as the most optimal aesthetic outcomes, it is important that you return to your surgeon's office for all follow-up evaluations s/he prescribes. Establishment Labs recommends yearly visits to verify a breast implant's integrity. The evaluation for possible ruptures should be assessed in every follow-up visit.

11.1. Symptomatic Rupture.

Symptoms associated with rupture may include hard knots or lumps surrounding the breast 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 breast implant(s) for rupture and determine whether you need to have an MR examination to find out if your symptoms are due to breast implant rupture. If rupture has occurred, you should have your breast implant removed/replaced.

12. ADDITIONAL INFORMATION AND REPORTING.

12.1. Life expectancy.

Breast implants are not lifetime devices. However, the life expectancy of a silicone breast implant cannot be precisely estimated, as there are many factors beyond the manufacturer's control that can affect a breast implant's longevity. A breast implant's life expectancy varies from patient to patient depending on many factors that affect the durability and efficiency of breast implants, including your lifestyle, your body's response to the implanted breast implants, and the expertise of your surgeon.

Average life expectancy of breast implants in the market has been indicated as 10 years (US FDA reference)[9], but as long as the breast implants are not ruptured or subject to any complication, there is no need to remove or replace them.

Towards the end of the expected lifetime of the device, it is important for a patient to consult their healthcare professional for a follow up examination. Establishment Labs does not have a recommendation regarding the exact time after implantation at which the breast implants must be removed and replaced. Such decision must be based on the results of the periodic MRI recommended by the manufacturer in their Directions for Use[10].

12.2. Device traceability.

Motiva Implants® are subject to device tracking via the MotivaImagine® registration system. You can register your breast implants at https://register.motivaimagine.com/. If you have difficulty registering your breast implant, you may contact Establishment Labs to receive assistance.
Breast implant registration will help ensure that Establishment Labs has a record of each breast implant's 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 breast implant that patients should be made aware of.

12.3. Patient ID.

It is imperative that you have a record of your surgical procedure in case of future consultations or additional surgeries. A patient ID card must be given to you by your surgeon for personal reference. This card is for patients' permanent records and should always be kept safely.

[9] 5 Things to Know About Breast Implants
Office Commissioner - https://www.fda.gov/consumers/consumer-updates/5-things-know-about-breast-implants
[10] Establishment Labs (2019). RTL-001020 Rational for Motiva Implants® Lifespan.

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

ESTABLISHMENT LABS HEADQUARTERS
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www.lifehealthcare.com.au

IMPORTANT:
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/
All patients in Australia can participate in the Australian Breast Device Registry (ABDR). The ABDR is a Commonwealth Government initiative established to monitor the safety and quality of procedures involving implantable breast devices. For more information, please speak with your surgeon or visit www.abdr.org.au

Motiva Breast Implants supplied in Australia including Motiva® Round and Motiva Ergonomix® Breast Implants are listed in the tables below.

Product Name	Surface	Profile	Volume (cc)	Base Width (cm)	Product Code
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	155	9	RSD-155+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	180	9.5	RSD-180+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	205	10	RSD-205+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	215	10.25	RSD-215+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	230	10.5	RSD-230+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	245	10.75	RSD-245+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	265	11	RSD-265+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	285	11.25	RSD-285+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	300	11.5	RSD-300+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	320	11.75	RSD-320+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	340	12	RSD-340+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	360	12.25	RSD-360+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	380	12.5	RSD-380+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	425	13	RSD-425+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	475	13.5	RSD-475+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	525	14	RSD-525+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	575	14.5	RSD-575+Q

Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Demi	625	15	RSD-625+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	145	8.5	RSF-145+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	175	9	RSF-175+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	205	9.5	RSF-205+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	220	9.75	RSF-220+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	235	10	RSF-235+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	255	10.25	RSF-255+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	275	10.5	RSF-275+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	295	10.75	RSF-295+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	315	11	RSF-315+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	335	11.25	RSF-335+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	355	11.5	RSF-355+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	375	11.75	RSF-375+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	400	12	RSF-400+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	425	12.25	RSF-425+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	450	12.5	RSF-450+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	500	13	RSF-500+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	550	13.5	RSF-550+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	625	14	RSF-625+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	700	14.5	RSF-700+Q

Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Full	775	15	RSF-775+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	240	9.5	RSC-240+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	160	9.75	RSC-260+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	280	10	RSC-280+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	300	10.25	RSC-300+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	325	10.5	RSC-325+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	350	10.75	RSC-350+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	380	11	RSC-380+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	410	11.25	RSC-410+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	440	11.5	RSC-440+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	475	11.75	RSC-475+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	510	12	RSC-510+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	550	12.25	RSC-550+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	590	12.5	RSC-590+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	650	13	RSC-650+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	725	13.5	RSC-725+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	825	14	RSC-825+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	925	14.5	RSC-925+Q
Motiva® Round ProgressiveGel® Plus + QiD®	SmoothSilk®/SilkSurface®	Corse	1050	15	RSC-1050+Q

Product Name	Surface	Profile	Volume (cc)	Base Width (cm)	Product Code
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	155	9	RSD-155
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	180	9.5	RSD-180
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	205	10	RSD-205
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	215	10.25	RSD-215
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	230	10.5	RSD-230
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	245	10.75	RSD-245
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	265	11	RSD-265
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	285	11.25	RSD-285
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	300	11.5	RSD-300
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	320	11.75	RSD-320
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	340	12	RSD-340
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	360	12.25	RSD-360
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	380	12.5	RSD-380
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	425	13	RSD-425
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	475	13.5	RSD-475
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	525	14	RSD-525
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	575	14.5	RSD-575
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Demi	625	15	RSD-625
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	145	8.5	RSF-145
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	175	9	RSF-175
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	205	9.5	RSF-205
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	220	9.75	RSF-220
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	235	10	RSF-235
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	255	10.25	RSF-255
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	275	10.5	RSF-275
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	295	10.75	RSF-295
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	315	11	RSF-315
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	335	11.25	RSF-335
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	355	11.5	RSF-355
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	375	11.75	RSF-375
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	400	12	RSF-400
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	425	12.25	RSF-425
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	450	12.5	RSF-450
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	500	13	RSF-500

Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	550	13.5	RSF-550
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	625	14	RSF-625
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	700	14.5	RSF-700
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Full	775	15	RSF-775
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	240	9.5	RSC-240
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	160	9.75	RSC-260
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	280	10	RSC-280
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	300	10.25	RSC-300
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	325	10.5	RSC-325
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	350	10.75	RSC-350
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	380	11	RSC-380
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	410	11.25	RSC-410
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	440	11.5	RSC-440
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	475	11.75	RSC-475
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	510	12	RSC-510
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	550	12.25	RSC-550
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	590	12.5	RSC-590
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	650	13	RSC-650
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	725	13.5	RSC-725
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	825	14	RSC-825
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	925	14.5	RSC-925
Motiva® Round ProgressiveGel® Plus	SmoothSilk®/SilkSurface®	Corse	1050	15	RSC-1050

Product Name	**Surface**	**Profile**	**Volume (cc)**	**Base Width (cm)**	**Product Code**
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	125	9	ERSM-125Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	140	9.5	ERSM-140Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	160	10	ERSM-160Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	185	10.5	ERSM-185Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	205	10.75	ERSM-205Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	220	11	ERSM-220Q

Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	230	11.25	ERSM-230Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	245	11.5	ERSM-245Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	260	11.75	ERSM-260Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	275	12	ERSM-275Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	290	12.25	ERSM-290Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	310	12.5	ERSM-310Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	360	13	ERSM-360Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	400	13.5	ERSM-400Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	430	14	ERSM-430Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	475	14.5	ERSM-475Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Mini	525	15	ERSM-525Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	155	9	ERSD-155Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	180	9.5	ERSD-180Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	205	10	ERSD-205Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	215	10.25	ERSD-215Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	230	10.5	ERSD-230Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	245	10.75	ERSD-245Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	265	11	ERSD-265Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	285	11.25	ERSD-285Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	300	11.5	ERSD-300Q

Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	320	11.75	ERSD-320Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	340	12	ERSD-340Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	360	12.25	ERSD-360Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	380	12.5	ERSD-380Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	425	13	ERSD-425Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	475	13.5	ERSD-475Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	525	14	ERSD-525Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	575	14.5	ERSD-575Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Demi	625	15	ERSD-625Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	145	8.5	ERSF-145Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	175	9	ERSF-175Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	205	9.5	ERSF-205Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	220	9.75	ERSF-220Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	235	10	ERSF-235Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	255	10.25	ERSF-255Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	275	10.5	ERSF-275Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	295	1.75	ERSF-295Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	315	11	ERSF-315Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	335	11.25	ERSF-335Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	355	11.5	ERSF-355Q

Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	375	11.75	ERSF-375Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	400	12	ERSF-400Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	425	12.25	ERSF-425Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	450	12.5	ERSF-450Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	500	13	ERSF-500Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	550	13.5	ERSF-550Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	625	14	ERSF-625Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	700	14.5	ERSF-700Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Full	775	15	ERSF-775Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	240	9.5	ERSC-240Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	260	9.75	ERSC-260Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	280	10	ERSC-280Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	300	10.25	ERSC-300Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	325	10.5	ERSC-325Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	350	10.75	ERSC-350Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	380	11	ERSC-380Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	410	11.25	ERSC-410Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	440	11.5	ERSC-440Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	475	11.75	ERSC-475Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	510	12	ERSC-510Q

Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	550	12.25	ERSC-550Q
Motiva Ergonomix® ProgressiveGel Ultima®	SmoothSilk®/SilkSurface®	Corse	590	12.5	ERSC-590Q