

motiva.health

The decision to undergo a breast enhancement is one made by more than a million women like you around the world every year. As a highly personalized procedure, there are various motivations that might drive that decision, such as:

- · Filling out upper pole of breasts and cleavage
- · Restoring volume lost from pregnancy and nursing
- · Wanting a more youthful appearance
- · Feeling beautiful in a variety of clothing
- · Simply wanting to boost naturally petite breasts

This information has been designed to help you become familiar with some of the topics you'll be discussing with your surgeon, and to introduce you to Motiva Implants®, created by Establishment Labs. Our aim is to help you feel confident and empowered to make informed decisions throughout your breast enhancement journey.



"Safety through innovation" perfectly captures the commitment of Establishment Labs. Years of research, development, and innovation have yielded a product line that meets the needs of even the most discerning patients and surgeons.

We are committed to rigorous manufacturing practices in compliance with US, European, and other international standards.

We have established safety and performance in our products through consistently positive post-operative outcomes and patient satisfaction observed across a variety of studies, with patients reporting few to no device-related complications with Motiva Implants[®]. 1, 2, 3, 4

SMOOTHSILK®: A NEW, ADVANCED SMOOTH SURFACE

Over the last decade, a body of extensive clinical and scientific research has demonstrated that the overall risks associated with macrotextured implants outweigh their benefits.^{5,6}

Establishment Labs has never produced aggressively textured implants, instead focusing our development on a novel, cell-friendly smooth surface, designed to maximize compatibility with the body's own tissue and minimize inflammation.

As a result, Establishment Labs and it's revolutionary Motiva® breast implants remain unaffected by the global recalls of certain types of textured implants issued by medical device regulators, who now recognize their association with chronic inflammatory conditions.

Our new, advanced smooth surface is present in all Motiva Implants®. Women can be confident that the Motiva SmoothSilk® surface (also known as SilkSurface®) does not pose the risks associated with macrotextured implants, as it is classified as a smooth surface per the latest international standard (ISO-14607:2018).

- 1. Sforza M, Zaccheddu R, Alleruzzo A et al. Preliminary 3-year evaluation of experience with SilkSurface and VelvetSurface Motiva silicone breast implants: a single-center experience with 5813 consecutive breast augmentation cases. Aesthet Surg J. 2018; 38(Suppl 2):S62-S73.
- 2. Chacón M, Chacón M, Fassero J. Six-Year Prospective Outcomes of Primary Breast Augmentation with Nano-Surface Implants. Aesthet Surg J. 2018; doi: 10.1093/asj/sjy196.
- 3. Huemer GM, Wenny R, Aitzetmüller MM, Duscher D. Motiva Ergonomix Round SilkSurface Silicone Breast Implants: Outcome Analysis of 100 Primary Breast Augmentations over 3 Years and Technical Considerations. Plast Reconstr Surg. 2018; 141(6):831e-842e.
- 4. Sim HB. Revisiting Prepectoral Breast Augmentation: Indications and Refinements, Aesthet Surg J. sjy294, https://doi.org/10.1093/asj/sjy294.
- 5. Hall-Findlay EJ. Breast implant complication review: double capsules and late seromas. Plast Reconstr Surg. 2011;127:56–66.
- Van Slyke AC, Carr M, Carr NJ. Not all breast implants are equal: a 13-year re- view of implant longevity and reasons for explantation. Plast Reconstr Surg. 2018;142:281e–289e.

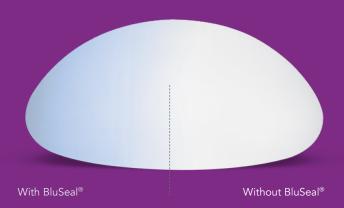
SAFETY & AESTHETICS

Motiva® has introduced first-of-its-kind safety technology into the breast aesthetics field that experts consider an entire generation ahead of the industry at large.⁷

BluSeal®: The World's Only Barrier Layer Indicator in a Breast Implant

Motiva Implants® appear to have a very light blue tint, and with good reason. With traditional implants, surgeons have no way to check if an implant's barrier layer (which is meant to prevent gel bleed into surrounding tissue) is intact before using it.

BluSeal®, made with biocompatible dyes, BluSeal® effectively eliminates this blind spot and thus allows the surgeons to visually confirm the vital barrier layer of a Motiva® implant is 100% intact before they use it.



TrueMonobloc®: For a More Durable, Flexible Implant

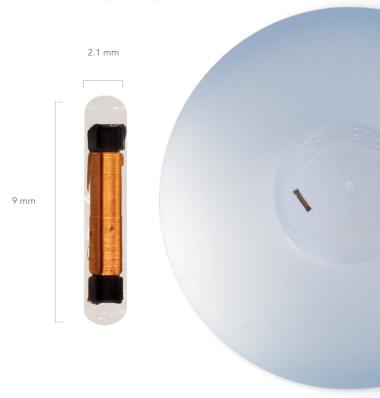
TrueMonobloc® refers to our flexible, multilayer system that links all individual parts of a Motiva® implant (i.e. its gel, shell, and patch seal) so they possess as a single, unified structure that provides flexibility and durability, and allows for easier implant insertion by your surgeon.

Qid®/Q Inside® Safety Technology: A Digital Passport for Instant Verification

While you may lose cards or documents containing your implant's information, you can never lose a digital passport.

As an optional feature only available with Motiva Implants®, Qid® or Q Inside® Safety Technology is an FDA-cleared radiofrequency identification device (RFID) microtransponder. It is battery free, passive, and is only activated externally by a handheld reader.

By storing an electronic serial number (ESN), Qid® is an instant, non-invasive way to retrieve important implant information (such as manufacturing details and implant features) and provide peace of mind.



ProgressiveGel®: For the Shape & Feel You Want

While most implants are only partially filled, Motiva Implants® are filled with silicone gel to 100% of their capacity to minimize visible rippling or wrinkling.

The properties of the gel used to fill your implant affects how the implant will look, feel, and behave. For instance, a gel with greater cohesivity is more likely to retain its shape (and not migrate throughout the body) if the outer shell or surface becomes damaged.

^{7.} Sforza M, Hammond DC, Botti G et al. Expert Consensus on the Use of a New Bioengineered, Cell-Friendly, Smooth Surface Breast Implant. Aesth Surg. J. 2019 May, 39(3):S95-S102.

Elasticity and flexibility can also determine the size of the incision required to insert an implant.

The most common gel type in the industry today is often referred to as "gummy bear" filling. But patients have complained about gummy bear implants looking and feeling stiff and unnatural, especially when lying down or moving.

To fulfil women's unmet desires for an implant with both structure and softness, Motiva® created its own proprietary gel family: ProgressiveGel®.

Motiva® breast implants are available in two different types of ProgressiveGel®, each with unique cohesive and elastic properties.

ProgressiveGel® PLUS	ProgressiveGel ULTIMA®
Motiva® Round	Motiva Ergonomix®
Creating shape with a natural feel	The look and feel of a natural breast
Balanced gel elasticity and firmeness	Elastic and soft gel
Upper-pole fullness	Adapts to the natural breast shape
Younger active look	A more natural look and feel
Fullness profile	Natural profile

MOTIVA® SAFETY & AESTHETICS PERFORMANCE

Safety and performance data collected through a post-market surveillance system and other extensive clinical research confirm that SmoothSilk®/SilkSurface® contributes to improved post-operative outcomes, with patients reporting fewer high-risk and low-risk complications.9

A three-year evaluation of 5,813 patients has associated SilkSurface® implants with overall complication and revision rates of under 1 percent.1

That same study also reported no cases of rupture due to implant failure, capsular contracture (Baker Grades III and IV), double capsules, or late seromas.

Bacterial biofilm accumulates on breast implant surfaces over time and has been associated with complications such as capsular contracture and breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

A comparative in-vitro evaluation of SmoothSilk®,

textured, and traditional smooth implants showed that bacterial attachment and biofilm formation were the lowest in SmoothSilk® implants, and highest in the textured implants.8



Lisa O.

*Real Motiva® Patient

8. James GA, Boegli L, Hancock J, Bowersock L, Parker A, Kinney BM. Bacterial Adhesion and Biofilm Formation on Textured Breast Implant Shell Materials. Aesthetic Plast Surg. 2019 Apr;43(2):490-497. doi: 10.1007/s00266-018-1234-7.

9. Establishment Labs Post-Market Surveillance Report Q1-2020

THE MOST COMPREHENSIVE RANGE OF

ADVANCED SMOOTH IMPLANTS

With our cell-friendly, advanced smooth surface Motiva® offers women a range of implant options to suit their unique body proportions and aesthetic goals.





Ergonomics – the science behind designing products to be as user friendly as possible – is a paramount part of our patient-centric mandate. We applied these principles to our implant design, challenging ourselves to come up with an implant that behaves as naturally as possible.

The unique gel characteristics of ProgressiveGel Ultima® allow Ergonomix® implants to be naturally dynamic in behaviour by adapting to the movements of a woman's body – holding a round shape when she is lying down and assuming a natural-look teardrop shape when she is standing. As a result, Ergonomix® can mimic how real breast tissue looks, feels, and moves.

Ergonomix® is available in a variety of base widths to complement individual chest lengths and widths.

MOTIVA® ROUND: YOUTHFUL SHAPE WITH A FULL UPPER BREAST

As its name suggests, Motiva® Round is a uniformly round-shaped implant. Filled with ProgressiveGel® Plus to hold its round shape with soft, balanced firmness, Motiva® Round is designed to provide a complete filling of the upper pole of the breast.

Patients often choose round implants to experience fuller upper breasts for a perkier, more youthful appearance.



MOTIVA® DESIGNED SURGERIES

Each of us come in a variety of sizes and shapes, and so do our aesthetic goals. We're focused on providing each patient with solutions as unique as they are, which is why we've collaborated with world-renowned plastic surgeons to pioneer customizable designed surgeries.



MOTIVAHYBRID®

MotivaHybrid® is an innovative, specialized surgical procedure that combines the use of smaller Motiva Implants® with strategically placed, high-quality fat grafts derived from your own body.

Larger implants can lead to potential risk and strain to your body's surrounding tissues. The use of your own fat allows you to choose a smaller, lighter – and therefore less risky – implant that is kinder to your breast and the body.

The use of fat grafts also allows for more customization or precise corrections, such as balancing asymmetrical breasts, rounding out the sides of your breasts, or providing more coverage over an implant in certain areas that may lack quality tissue.

In addition to getting beautifully enhanced, natural-looking breasts, MotivaHybrid® patients enjoy the opportunity to remove fat from places they wish to slim down, such as the thighs or abdomen — all during the same operation.

MOTIVA® MINIMALSCAR

The principle behind Motiva MinimalScar® is modern and straightforward: **smaller incisions equal smaller scars**. Motiva MinimalScar® is a minimal-incision breast augmentation in which our proprietary Ergonomix® implant is placed into the breast pocket through an incision that is roughly half the standard size of a traditional incision – thus leaving patients with very small scars (as small as 2.5 cm).

While the final length of the incision and scar vary from patient to patient, part of what determines the length of the incision needed to insert an implant is the implant's rigidity and durability under stress (such as pressing or squeezing).

Compared to other implants on the market Ergonomix[®] implants are designed to be durable under stress yet less rigid (i.e. more elastic or flexible), allowing them to be inserted through much smaller incisions for easier insertion and a less traumatic surgery - which in turn can promote enhanced recovery).

DISCUSSING

BREAST AUGMENTATION

WITH YOUR SURGEON

Each combination of incision and implant placement option comes with its own advantages to be considered in conjunction with physical characteristics, lifestyle, and aesthetic goals. Your surgeon will discuss which options may be right for you during a detailed consultation.

INCISION LOCATION



Inframammary (in the fold under your breast)



Periareolar (around the areola)



Transaxillary (in the axilla or armpits)

IMPLANT PLACEMENT

Subpectoral (under the chest muscle)



PECTORALIS MUSCLE

Subglandular

(under your mammary tissue but over the fascia* layer)



FASCIA MAMMARY GLAND

Subfascialboth the mammary

(under both the mammary tissue and the fascia* layer)



PECTORALIS FASCIA MUSCLE

Dual Plane

(partly under both the pectoral muscle and mammary gland)



PECTORALIS MUSCLE

GENERAL ADVICE FOR POST-OP RECOVERY

- 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 two days after your surgery and do not exercise until it has been cleared by your surgeon.
- Do not expose your breasts directly to sunlight until approved by your surgeon.
- Wear a non-wire supportive post-operative bra for at least 12 weeks following your surgery.
- Healing cream may be recommended by your surgeon, to be used per their exact instructions.
- Do not massage or manipulate your breasts in any way unless specifically advised by your surgeon.

RISK ASSOCIATED

WITH BREAST IMPLANTS AND BREAST IMPLANT SURGERY

Undergoing any type of surgery involves risks. There are a number of local complications (problems at or near the breast/surgical incision site) that may occur after you have silicone gel breast implant surgery. There are general, surgery related complications and implant related complications.

Some potential risks and complications associated with breast implants include:

- Capsular contracture
- Rupture
- Gel fracture
- Pain
- Changes in nipple and breast sensation
- Infection
- Irritations / inflammation

- Hematoma / seroma
- Implant malposition
- Bottoming out
- Flipping
- Wrinkling / rippling

We recommend that patients read the full patient information leaflet called "Information for the Patient – Breast Augmentation and Reconstruction with Motiva Implants®" prior to surgery to understand the risks and benefits associated with breast implant surgery.

This can be accessed via your surgeon or at www.motiva.health/patients/

COMMITMENT TO BREAST HEALTH

Establishment Labs encourages every woman to be diligent in scheduling yearly breast exams. Technology used in breast evaluation is generally compatible with breast implants, though it's important to let your health care provider know that you have breast implants.

If Magnetic Resonance Imaging (MRI) is used as part of your exam, be sure to let the imaging technician know that you have Motiva Implants with Q Inside® Safety Technology (an MRI safe ID Chip)

AUSTRALIAN BREAST DEVICE REGISTRY

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

ALWAYS CONFIDENT WARRANTY®

& EXTENDED WARRANTY PROGRAMS

We care about your safety, which is why Motiva Implants® are covered against rupture by our Always Confident Warranty® for the lifetime of the device and our Product Replacement Policy against capsular contracture (Baker Grades III and IV) for a period of 10 years.

Furthermore, we offer optional Extended Warranty Programs that you may participate in based on your personal case:

24 Motiva® Program

For Motiva Implants®

without Q Inside® Safety Technology

Sy Motiva® Program

For Motiva Implants®

with Q Inside® Safety Technology

In addition to the replacement product, these programs will support you with financial assistance applicable to the cost of one revision surgery in the event of a warranty claim for rupture or capsular contracture (Baker Grades III and IV).

REGISTER YOUR MOTIVA IMPLANTS®

To take advantage of our extended warranty, use the information from your Patient ID card (which your surgical team will provide you on the day of your procedure) to register your implants, within 90 days after surgery,

within 90 days after surgery, with their serial numbers to the Motivalmagine® app or website: (register.motivaimagine.com)





GENERAL BREAST AUGMENTATION **FAQ**

Is breast augmentation surgery safe?

Breast enhancement is one of the most commonly performed plastic surgeries in the world, with a high patient satisfaction rate. However, as with all surgeries, you should always discuss the potential risks with your plastic surgeon.

Am I a candidate for breast augmentation?

Besides patient-specific circumstances, there are some basic considerations that determine whether a patient may be ready for a breast augmentation/enhancement:

- You can clearly define the goals you would like to achieve with a breast augmentation
- You understand what the procedure realistically can and cannot accomplish
- You accept the risks of breast augmentation surgery
- You clearly understand your responsibilities as a patient in ensuring your procedure is safe and your results are maintained
- You are physically and mentally healthy
- You understand breast implants are not lifetime devices and will need to be replaced at some point to maintain safe and long-term results, and that you will require follow-up appointments with your plastic surgeon and radiologist

How long is a breast augmentation surgery?

Depending on the specifics of your procedure, surgery can typically last between 30 minutes to two hours.

Will I require general anesthesia?

Plastic surgeons most commonly use general anesthesia during surgery, but yours may talk to you about the possibility of conscious sedation.

When can I go home after surgery?

While breast enhancement is often an outpatient procedure, your plastic surgeon will ultimately determine when you are ready to be discharged.

What is recovery time for breast augmentation?

During the first 48 hours, you may have an elevated body temperature and swelling. Both should return to normal over time, though the recovery process can vary from patient to patient.

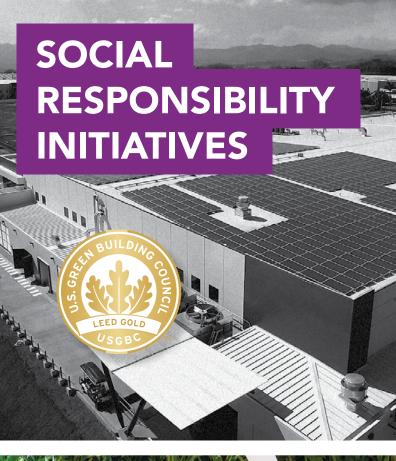
When might I need to replace my breast implants?

Any form of implant failure or a clinical condition (such as capsular contracture) could potentially create the need for implant replacement. Patients should be mindful of the consensus that breast implants have a limited lifetime, although a patient could keep her implants for 10-20 years without the need to replace them (provided she attends all required post-operative checkups and follows aftercare instructions).



COMMITMENT TO WOMEN'S HEALTH

Establishment Labs encourages every woman to be diligent in scheduling yearly breast exams. Technology used in breast evaluation is generally compatible with breast implants, though it's important to let your healthcare provider know that you do have breast implants.







LEED-CERTIFIED

MANUFACTURING FACILITIES

LEED (Leadership for Energy and Environmental Design) certification is the world's preeminent program that acknowledges environmentally sustainable, high-performance design, construction, and operation of green buildings.

Establishment Labs is proud to to hold LEED Gold certification for its headquarters, which houses its state-of-the-art manufacturing facilities; research, development, and innovation labs; and corporate offices.



Establishment Labs is an active supporter of Las Pumas Rescue Center and the Magical Trees Foundation in their efforts to safeguard Costa Rica's flora and fauna. In relation to this mission, Establishment Labs showcases the work of Costa Rican photographer and founder of the Magical Trees Foundation, Giancarlo Pucci, in our product packaging.













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