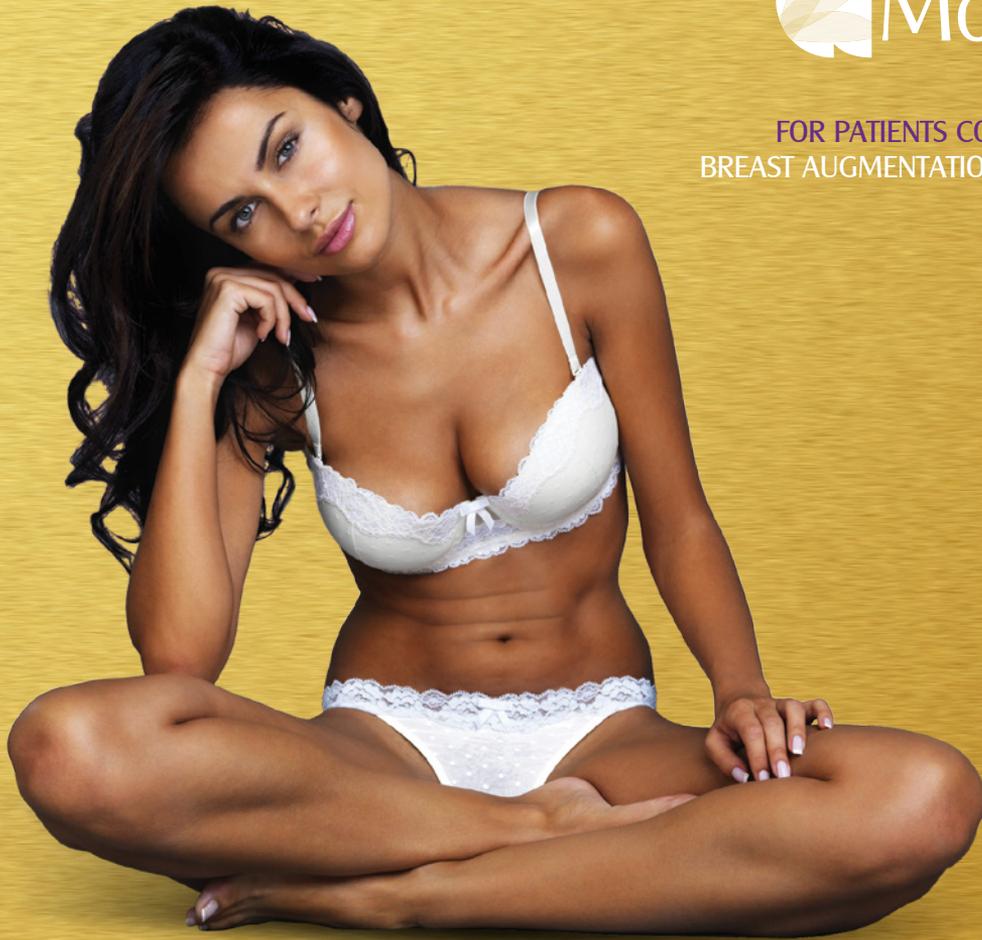




FOR PATIENTS CONSIDERING
BREAST AUGMENTATION SURGERY



INTRODUCTION | BREAST IMPLANT CHOICES | WHY SHOULD YOU CHOOSE MOTIVA? | GLOBAL AESTHETIC COMPANY
REGULATORY APPROVALS | ABOUT YOUR SURGERY | FACTORS TO CONSIDER | ABOUT OUR PATIENT SERVICES

Safety Through Innovation

www.motivaimplants.com



Safety Through Innovation

TABLE OF CONTENTS

Introduction	4
Breast Implant Choices	5
Why Should You Choose Motiva?.....	7
Global Aesthetic Company.....	11
Regulatory Approvals	12
About Your Surgery.....	15
Factors to Consider.....	18
About Our Patient Services	19



Safety Through Innovation

INTRODUCTION

It's important that you are able to make an informed decision when choosing to have breast augmentation surgery, a decision that takes into account your motivation behind having surgery, your options and expectations, as well as any potential risks and side effects.

Learning about the breast enhancement procedure is the first step on this journey. This booklet will guide you through all of the steps involved in the process, so you can make an informed decision and have realistic expectations about the results. We recommend that you take your time to read the information provided in this booklet and please note that this information is not intended to replace the consultation with your Plastic Surgeon, where you will have the opportunity to discuss your preferences for the size, feel and overall appearance of your breasts. Your surgeon will describe the specific types of implants, as well as options for surgical techniques.

Reasons for Breast Augmentation

Breast augmentation is an aspect of breast enhancement and consists of the surgical placement of implants to increase fullness and projection of the breasts, or to improve their symmetry.

A breast augmentation procedure is used cosmetically to:

- Enlarge a naturally small breast.
- Restore breast volume lost following pregnancy, as a result of breast-feeding or due to weight loss.
- Achieve better symmetry when breasts are moderately disproportionate in size and shape.
- Enhance your self-image and self-confidence.

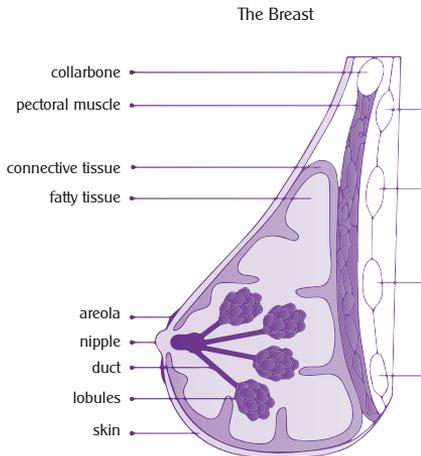
Your reason for considering breast augmentation is unique. Your motivations are distinctive and private, and when embracing them, it is essential that you receive the assurance that you're making an informed and excellent breast implant choice.

BREAST IMPLANT CHOICES

Your Breasts

Female breasts are formed by fat and glandular tissue, blood vessels, nerves, milk lobules and ducts and lymph ducts. Fat tissue makes up a large proportion; often the majority of tissue within the breasts. Differences in breast size are due primarily to differences in the amount of fat tissue, as opposed to differences in duct or lobule volume. It is the fat tissue, together with the skin elasticity that makes your breasts feel soft and gives them their shape.

Each breast lies over a muscle of the chest called the pectoral muscle. A breast implant can be placed over, under or partially under this muscle.



Breast Implants

Breast implants consist of a filler material (silicone gel or saline solution) inside a silicone elastomer shell. Breast implants can have different types of surfaces and shapes.

Filler Choices

There are two main types of implant fillers: saline solution and silicone gel, both having an outer silicone shell.

Saline Filled: Saline implants are filled with sterile saline water solution. They're inserted empty, and then filled once they're in place and typically require a smaller incision. However, visible wrinkling or rippling of the skin over the implant may be more likely to occur. Deflation of the implant is another possible complication of this type of filling. Establishment Labs does not manufacture saline-filled breast implants.

Silicone Filled: Silicone implants are pre-filled with silicone gel. Newer implants are filled with form-stable silicone gels because most women feel that silicone breast implants look and feel more like natural breast tissue. Additionally, silicone has been extensively studied and proven safe in the medical devices, pharmaceutical and food industries for decades.



BREAST IMPLANTS CHOICES

Surface Choices

Traditionally, breast implant surfaces have been either smooth or textured. Textured surfaces have been manufactured by projecting salt, sugar or other particles on the implant shell. Lately, several studies have shown that aggressive textures, such as the ones obtained with the use of these materials, may have secondary effects,^{1,2} including in women with active lifestyles.

Motiva Implant Matrix® SilkSurface® and VelvetSurface® are unique surfaces obtained without the use of foreign materials like salt or sugar, with a controlled process designed for a better biocompatibility^{3,4}. Additionally, these nano-surfaces promote a more natural interaction between the implant and the surrounding tissues, accommodating the implant to the normal movement of the breast.^{3,4}

Shape Choices

Breast implants have either a round, oval or contoured shape and come in several different sizes and projections.

Historically, round implants have been used to increase fullness of the breast upper-pole, while oval or teardrop shaped implants were designed to best mimic the natural breast shape, with more fullness in the lower pole. The placement of these teardrop implants requires a more advanced technique and can have complications like implant rotation and undesired aesthetic results.^{5,6}

A novel development for women who seek the most natural look and feel can be found in the **Motiva Implant Matrix®** Ergonomix™ line.

Size, Base and Projection Choices

Additionally to implant shape, you must consider size, base and projection in order to achieve the desired breast aesthetic outcome.

The base of the implant will define the resulting cleavage, the fullness is determined by the implant projection and the cup by the implant volume.

Breast Implant Developments

Prior to the advent of Motiva Implant Matrix® Silicone Breast Implants, innovation and technology advancement in the breast implants industry had been relatively stationary. Originally, breast implant shells were particularly “thin” to achieve a more natural feel, but their durability was limited. Early implants were also traditionally underfilled, which could result in more frequent implant ruptures.

Aggressive implant texturing was developed to maximize implant positioning and address the sometimes painful hardening of the implant, that when occurs requires revision surgery called “capsular contracture”. However, aggressive texturing has been associated with seroma and double capsule formation, which are highly undesirable adverse events.^{1,2} A variety of implant filling materials were also developed, including saline. Saline was an alternative to silicone, but lacked the natural feel, could leak and could produce unsightly “wrinkling and rippling” on the breasts.

WHY SHOULD YOU CHOOSE MOTIVA?

Due to Establishment Lab's experience and success in advanced product design and development, technological manufacturing and product support, **Motiva Implant Matrix®** Silicone Breast Implants represent the most innovative implants available today:

- State-of-the-art shell design that results in a stronger and more durable breast implant.
- Exceptional elasticity for ease of insertion and smaller incisions.
- Ultra soft, form-stable filling gel for optimal shape retention and feel.
- The most comprehensive range of implant projections to meet patient's and surgeon's expectations.
- Specialized choice of surface texturing, with no foreign materials that can damage the implant shell.

- Q Inside Safety Technology™ offers unique traceability that allows you and your physician to access specific information about your implants anytime, anywhere.
- Outstanding patient support.

Innovation plays a key role in safety

Better manufacturing practices, adherence to US and European Standards and patented technologies all contribute to the surgical safety and in times of uncertainty, the goal of innovation must be patient safety.

At Establishment Labs, innovation is our daily routine. Engineers and executive staff have been in the breast aesthetics industry for more than 30 years both in the US and abroad.



Safety Through Innovation

Motiva Implant Matrix® Breast Implants are Designed to Help Reduce Patient Risks

- Our implants incorporate BluSeal®, which is a color indicator to assure the presence of the barrier layer that prevents potential gel diffusion.
- Establishment Labs offers the world's first and only externally identifiable silicone-filled breast implant through the use of an Electronic Serial Number (ESN).
- Our TrueMonobloc® design increases the strength of the implant for ease of surgical insertion and enhanced durability.
- Exclusive 100% filled with ultra soft, form-stable ProgressiveGel™, ProgressiveGel™ PLUS and ProgressiveGel™ Ultima, designed to resist breaking during insertion, silicone leakage, and unwanted migration.

Motiva Implant Matrix® Breast Implants are Designed to Help Improve Patient Breast Aesthetics

Widest range of filling gel choices in a breast implant family.

- ProgressiveGel™ is a very firm gel that will give you upper-pole fullness and a round look.
- ProgressiveGel™ PLUS adapts to the natural breast contour, due to its ideal balance between firmness and elasticity.
- ProgressiveGel™ Ultima is a very elastic soft gel for the look and feel of a natural breast.

Motiva provides the ideal patient choice for desired volume, cleavage and breast fullness.



MOTIVA IMPLANT MATRIX®
A CHOICE TO SUIT EVERY NEED

Different Gel Type Options

ProgressiveGel™

Maintains the Upper-Pole Fullness



ProgressiveGel™ PLUS

A More Natural Look

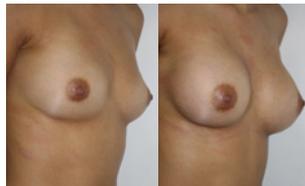


ProgressiveGel™ Ultima™

The Look and Feel of a Natural Breast



Firm gel	Balanced gel elasticity and firmness	Elastic and soft gel
Upper-pole fullness	Lower-pole fullness	Adapts to the natural breast shape
Round look	Younger active look	The most natural look and feel
Notorious profile	Medium profile	Natural profile



Motiva Implant Matrix® Silicone Breast Implants comply with the Highest Quality Standards

- Medical grade, long-term implantable silicones with extensive chemical, physical and biological testing, filed with the FDA.
- Raw materials provided by the largest and most reputed medical grade silicone manufacturer in the US, with a safety record of more than 30 years in the medical industry.
- Mechanical testing results that exceed the requirements of the American Society for Testing and Materials (ASTM) F703-07 and ISO 14607:2007 Standards.
- Enhanced safety profile, as demonstrated by the biological testing results, in accordance to the US and European Pharmacopoeias as well as the ISO standard 11737-1:2006 Standard.⁷
- Establishment Labs offers the world's first breast implant containing Q Inside Safety Technology that enables your breast implant to be identified externally in your physician's office with a proprietary handheld reader.

Do the math on safety and performance: Outstanding!

- Shell elongation of twice the minimum value of 350%, required by the FDA.^{8,9}
- Force at breaking four times above the FDA requirement.⁸
- 100 times less bacterial endotoxins than allowed by the US Pharmacopeia (USP), 31st Revision and the European Pharmacopeia (Ph.Eur.) 7th Edition.^{7,10}
- Rupture rates below 0.1%¹¹
- 94.5% Satisfaction rates.¹²



ESTABLISHMENT LABS: AN ENVIRONMENTALLY FRIENDLY GLOBAL AESTHETIC COMPANY

With regulatory offices in the United States, a European distribution center in Belgium and a manufacturing facility in Costa Rica, Establishment Labs is the next generation breast implant company, with regulatory approvals worldwide. We create the most advanced levels of safety for women seeking to improve their appearance, through Motiva's proprietary and exclusive technologies and higher quality standards.

The Costa Rican central valley, where Establishment Lab's manufacturing unit is located, has become the success story of the technology and life industries, with "more than 50 medical devices companies operating there, including Baxter, St. Jude Medical, Hologic, Arthrocare, Allergan, Boston Scientific, Hospira, De Royal, Establishment Labs, Abbott Vascular and others."¹³

Our state-of-the-art manufacturing process has significantly reduced our environmental impact by eliminating the use of water and other materials such as salt and sugar, traditionally employed in the texturing process.

Additionally, we are continuously seeking to minimize our carbon footprint by reducing the amount of materials used in our packaging and by utilizing vegetable-source inks and responsible forest management (Forest Stewardship Council) source materials.

"As a boutique manufacturer of next generation breast implants, we have partnered with the best minds in the industry to bring you Safety through Innovation."

-Olivier Tourniaire,
Sales Manager EMEA

COSTA RICA: HIGH-TECH GREEN MANUFACTURING



Safety Through Innovation

MOTIVA IMPLANT MATRIX® SILICONE BREAST IMPLANTS REGULATORY STATUS

Regulatory Approvals

Motiva Implant Matrix® has been awarded the prestigious CE Mark designation, which means the products and company conform to rigorous safety and health performance standards. In addition to utilizing only FDA filed, medical grade silicone materials, Establishment Labs has also created a world-class Quality Management System, certified by the distinguished British Standard Institution (BSI) notified body, that complies with ISO 9001:2008¹⁴ and ISO 13485:2003¹⁵ medical standards. All of our implants undergo several strict quality inspections using the latest technological advancements available.

CE
1014



“Our quality standards for breast implants are the strictest in the industry and our production process is continually inspected by health authorities from high vigilance countries, resulting in more than 60 countries with regulatory approval worldwide.”

-Robert De Mezerville,
Quality and Regulatory Affairs Manager



ABOUT YOUR SURGERY

Planning Your Aesthetic Result

Volume

When selecting the right breast implant for you, breast sizing is essential in achieving the desired breast aesthetic outcome. Accurate measurement of the baseline breast size is a basic starting point in selecting the right implant volume or cup size that will suit you best.

Moderate Volume



Medium Volume



High Volume



Cleavage

Another important consideration for your satisfaction, is an open dialogue with your surgeon regarding the desired cleavage.

Modest Cleavage



Noticeable Cleavage



Pronounced Cleavage



Upper-Pole

There may also be a discussion about desired "upper breast fullness" or the way your breasts will look in certain clothing or swimwear. Breast symmetry as well as various nipple considerations, may also be discussed.

Moderate Upper-Pole



Full Upper-Pole



Fullest Upper-Pole



Motiva Implant Matrix® helps facilitate and support the discussion between patients and surgeons, in order to help you select the implant that will give you the desired aesthetic result you are hoping to achieve.

ABOUT YOUR SURGERY

Basics About Your Surgery

Breast Augmentation is a very common procedure worldwide and is usually associated with a high degree of patient satisfaction. However, like all surgical procedures, it is important that you discuss any potential risks directly with your surgeon.

Depending on the specific type of breast augmentation procedure you undergo, surgery typically takes between 1-2 hours. Breast augmentation is usually performed as an outpatient procedure, which means that you are permitted to return home on the same day as your surgery.

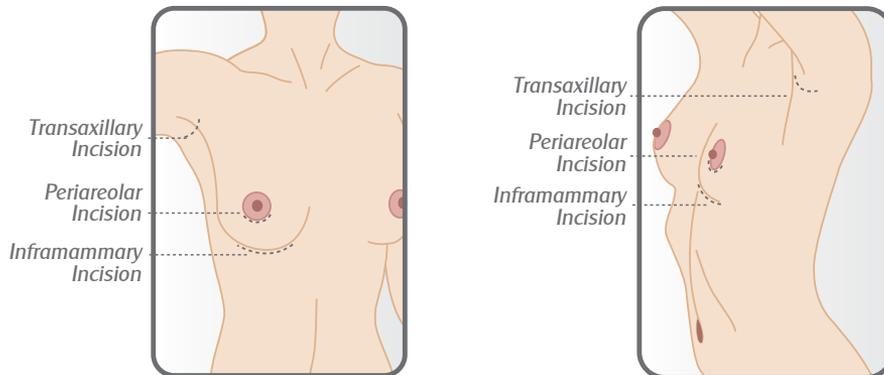
Surgeons most commonly use general anaesthesia during surgery, though your surgeon may talk to you about the possibility of conscious sedation.

Regarding the post-operative period, the recovery process depends on the individual patient profile and other variable factors. During the first 48 hours, it's possible that you could have an elevated body temperature and swelling, but both fade away over time.

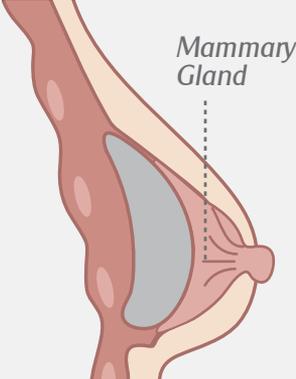
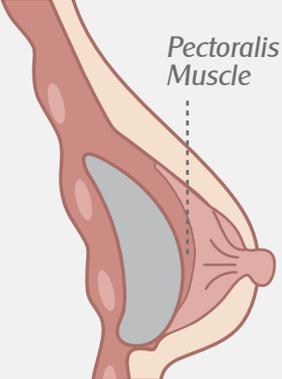
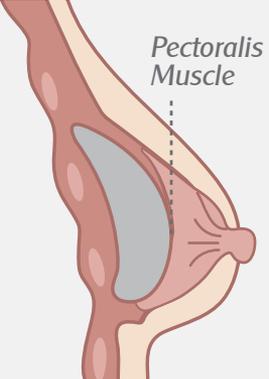


Possible Options for Incision Location

1. Inframammary Incision	2. Periareolar Incision	3. Transaxillary Incision
May result in a more rapid post-op recovery.	May result in a more rapid post-op recovery.	Patient recovery time could be longer.
Same incision may be used in the event of revision surgery.	May facilitate explantation in the event of replacement surgery.	Alternate incision site would be required in the event of revision surgery.
The scar may be visible when patient lays horizontally.	Scar may be visible as it is located around the areola.	Does not produce a visible scar directly on the breast.
Less risk of nipple hypersensitivity.	Higher risk of nipple hypersensitivity or loss of sensitivity.	Less risk of nipple hypersensitivity or loss of sensitivity.
May accommodate most styles of implants; better for larger implants.	May allow a mastopexy or breast lift in conjunction with breast augmentation.	May result in more difficult implant pocket creation.



Different Options and Considerations for Implant Placement

<i>Subglandular Placement</i>	<i>Subpectoral Placement</i>	<i>Dual Plane Placement</i>
Shorter surgical procedure.	More complex surgical procedure.	Surgical procedure might take longer.
Quicker recovery time and possibly less painful.	Longer and possibly more painful recovery time.	Longer and possibly more painful recovery time.
Recommended placement for textured implants.	Not recommended for textured implants because of a higher risk of abrasion-related seroma.	A more natural slope to the breast shape; hides rippling in the upper pole.
Improved control of the upper breast shape.	Better protection of the implants and more natural shape.	Accuracy of implant placement and best shaping of the inferior part of the breast.
Higher risk of capsular contracture.	Lower risk of capsular contracture.	Lower risk of capsular contracture.
Implant may become more noticeable in patients with thin skin.	Implant may be less noticeable and less palpable.	Less likely to feel or see implant edge.
Potential for mammogram interference.	Lowest potential for mammogram interference.	Low potential for mammogram interference.
 <p><i>Mammary Gland</i></p>	 <p><i>Pectoralis Muscle</i></p>	 <p><i>Pectoralis Muscle</i></p>

POST-OPERATIVE CARE

Breast augmentation recovery includes a post-surgical recovery period of 24 to 48 hours and an additional reduced-activity period of a few days. You will likely experience soreness and swelling for a few weeks.

Exercise and normal activity can resume at the direction of your plastic surgeon. Over time, post-surgical swelling will decrease and incision lines will become less visible.

GENERAL ADVICE

- Sleep or rest with your head slightly elevated, avoiding lateral positions. Keep your arms close to your body and avoid lifting heavy objects until allowed by your surgeon.
- Do not drive during the first 2 days post surgery at the very minimum and abstain from exercise until approved by your surgeon.
- Do not expose your breasts directly to sunlight until approved by your surgeon.
- Gently massage your breasts with a circular motion, starting 48 hours after your surgery.
- Healing creams may be recommended by your surgeon.

Following the instructions and advice of your surgeon is key to the success of your surgery.

***For further information, go to:
www.motivaimplants.com***



FACTORS TO CONSIDER

Before you make the decision to go ahead with surgery, please take the time to consider some important factors about breast augmentation:

- Breast implants will not prevent your breasts from sagging. To correct sagging breasts, you may need a breast lift in addition to breast augmentation.
- Breast implants aren't guaranteed to last a lifetime and there is the possibility of implant rupture post surgery. Also, your breasts will continue to age after augmentation and factors such as weight gain or weight loss may further change the way your breasts look and feel. Any of these issues may require additional surgery, in order to be corrected.
- If you have breast implants at the time of undergoing a mammogram, you will require additional and specialized views, as breast implants can affect the visibility of this examination. Routine MRI scans for breast cancer screening may be recommended.
- Breast implants may affect breast-feeding depending on the surgical technique applied. Some women are able to successfully breast-feed following breast augmentation. However, for some others, breast-feeding can be a challenge.
- If you decide to have your breast implants removed and not replaced, you may need a breast lift or other corrective surgery to help your breasts maintain an aesthetically pleasing appearance.
- In case your insurance does not cover breast implants, be prepared to handle any expenses that accompany breast augmentation, including related surgeries or future imaging tests.

Potential Risks, Complications and Undesirable Effects of Breast Implants

For comprehensive information regarding risks, complications and undesirable effects of breast augmentation with implants, please refer to:
<http://motivaimplants.com/docs/potential-risks.pdf>

TRACEABILITY PROGRAM, REGISTRATION AND WARRANTY

Traceability Program

Through a series of strict policies, procedures and guidelines that enable the efficient global traceability of all pre-production breast implant components and post-surgical implantations, Establishment Labs guarantee patients and surgeons that no incident or adverse event related to **Motiva Implant Matrix®** Silicone Breast Implants is ever overlooked, assuring the highest level of patient protection.

To assist in this important process, every **Motiva Implant Matrix®** package contains traceability stickers that provide breast implant specific information that will be attached to your Motiva ID Card (My Motiva ID™) and on the medical files.

Additionally, we have created the first breast implant in the world that contains Q Inside Safety Technology™, which allows physicians to immediately ascertain the manufacturer name, serial number, lot number, batch number and other implant specific data, *in vivo*, from outside the body using a proprietary handheld reader.

We place the highest priority on patient privacy and confidentiality. Our RFID technologies are passive in nature and inaccessible without the appropriate equipment. The databases that store the device and patient data collected from the registration process, are maintained in secure data centers, which observe the strict privacy guidelines indicated by local legislation, following the same information security protocols that are currently in place in hospitals and surgical centers. All personal data provided is only disclosed with the patients' authorization.



How to Register Your Implants



When registering your Motiva implant(s), simply visit www.motivaimplants.com with your Motiva Card (Motiva ID™) to hand. You will receive an official response from our system, confirming the warranty activation and the inclusion of your implant(s) in our traceability program.

Registering your Motiva implants is very simple:

1. Go to www.motivaimplants.com and click "Implant Registration" "Your Implants".
2. Complete your contact information and then the medical information regarding your procedure.
3. Click "Register your implants" You will then receive an official response from our system, confirming the warranty and the inclusion of your breast implant(s), in our traceability program.
4. Ensure that you keep your warranty card in a safe place.

Always Confident Warranty® and Replacement Policy

Following FDA recommendations, Establishment Labs provides a limited warranty, covering its **Motiva Implant Matrix®** product range, providing a replacement product in the event of rupture for the lifetime of the implant. Although the FDA has indicated silicone breast implants should be expected to last 10 years on average, new developments in materials and process technology are focused on extending their lifespan. Establishment Labs provides assistance in cases of capsular contracture Baker grades III and IV through its product replacement policy program. Visit www.motivaimplants.com, regarding the Always Confident Warranty®.

In select markets, through Lloyd's of London, we offer an industry-first, third party insurance program to provide financial assistance for revision surgeries in case of implant rupture, implant rotation and capsular contracture Baker grades III or IV, however the warranty must be fully activated for this to be applicable.



Glossary of Terms

Breast augmentation: A surgical procedure to increase breast size. The very first time a breast implant is placed to increase breast size is called a primary augmentation. All subsequent surgeries where the implant is replaced is called revision augmentation.

Breast enhancement: Improvement of the breast appearance by lifting sagging breasts, placing breast implants and reducing excessively large breasts etc.

Breast implant: An internal artificial device or implant intended to replace and enhance the natural breast.

Breast reconstruction: A surgical procedure to replace breast tissue that has been removed due to cancer, trauma or abnormality.

Capsular contracture: A tightening of the scar tissue surrounding an implant. May require an additional surgery to correct.

Capsule: Scar tissue that forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture.

Glandular: Relating to a gland.

Rupture: A tear or hole in a silicone implant shell. Silicone implant ruptures may be silent or symptomatic. Ruptures can be intracapsular or extracapsular.

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Notes

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Establishment Labs:

Coyol Free Zone, Alajuela, COSTA RICA
info@motivaimplants.com

Motiva European Distribution Center:

Sint Jansveld 11A, 2160 Wommelgem, BELGIUM
info@edcmotiva.com

Motiva USA:

2121 S.W. 3rd Avenue, Suite 200, FL 33129, USA
motivausa@establishmentlabs.com



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