Motiva®
implants

Study of Safety and Effectiveness of the Motiva Implants®

Motiva USA

Motiva USA is an affiliated company of Establishment Labs, founded in 2004. We are a global, breast implant and medical technology company that designs, develops, manufactures and markets an innovative product portfolio consisting of advanced silicone-filled breast and body shaping implants.

Since approval in 2010, Motiva Implants® have been implanted in women in over 60 countries, including the UK, Sweden, Germany, Switzerland, Austria, Japan, Australia and South Korea.

Motiva Implants® are not approved for commercial distribution in the USA.

Clinical Study

You are being asked to volunteer to take part in a 10-year research study of breast implants. The purpose of this study is to determine the safety and effectiveness of the investigational Motiva Implants® SmoothSilk® Round and Ergonomix® in women who are undergoing primary breast augmentation, primary breast reconstruction and revision surgery.

PATIENT INCENTIVES

All patients participating in the study will receive investigational Motiva Implants® without a cost.

COMPENSATION

Consultations for all follow-up visits will be covered by Motiva USA. Additionally, patients will receive compensation for every annual follow-up exam and accompanying patient questionnaires are completed.

TRUST FUND

After the first year follow-up, a trust fund will be assigned to each patient enrolled in the study; patients will be fully compensated upon the completion of their 10-year study.

INCLUSION CRITERIA

- Genetic female.
- Patient age 22 and over and is seeking one of the following procedures: Primary Breast Augmentation, Primary Reconstruction, or Revision Surgery.
- Patient has adequate tissue available to cover implant(s).
- Willingness to follow all study requirements including agreeing to attend all required follow-up visits and signs the informed consent.
- Agrees to have device returned to Establishment Labs, if explanted.
- Willing to undergo Magnetic Resonance Imaging (MRI) evaluation if medically advised.

Motiva® implants

EXCLUSION CRITERIA

- Has any breast disease considered to be pre-malignant in one or both breasts or is reporting mutations in BRCA1 or BRCA2 without a previous bilateral mastectomy or an untreated cancer of any type.
- Has inadequate or unsuitable tissue (e.g., due to radiation damage, ulceration, compromised vascularity, history of compromised wound healing).
- Has an abscess or infection.
- Is pregnant or nursing or has had a full-term pregnancy or lactated within 6 months of enrollment.
- Is taking any drugs that would interfere with blood clotting, or that might result in elevated risk and/or significant postoperative complications.
- Has any medical condition such as obesity (BMI >40), diabetes, autoimmune disease, chronic lung or severe cardiovascular disease that might result in unduly high surgical risk and/or significant postoperative complications.
- Has any connective tissue/autoimmune disorder or rheumatoid disease, such as systemic lupus erythematosus, discoid lupus, scleroderma, or rheumatoid arthritis, among others.
- Has any condition that impedes use of Magnetic Resonance Imaging (MRI) including implanted metal device, claustrophobia or other conditions that would make MRI scan prohibited.
- Has a history of psychological characteristics that are unrealistic or unreasonable given the risks involved with the surgical procedure.
- Has been implanted with any non-FDA approved breast implant.
- Has been implanted with any silicone implant other than breast implants.
- HIV positive (based on medical history).
- Has been diagnosed with Anaplastic Large Cell Lymphoma (ALCL).
- Works for Establishment Labs, Motiva USA or any of their subsidiaries, the study surgeon, or ICON the Contract Research Organization (CRO) that is helping to conduct the study or are directly-related to anyone that works for Establishment Labs, Motiva USA or any of their subsidiaries, the study surgeon, or the CRO.

You should ask your surgeon to clarify any terms you do not understand or ask any questions that you have.

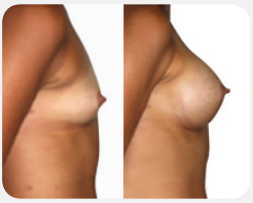
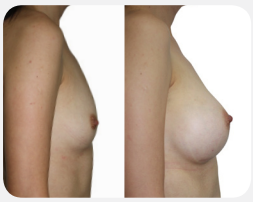
Motiva Implants®

Investigational Motiva Implants® Round and investigational Motiva Implants Ergonomix® are filled to 100% of the smooth shell volume.

Several technologies offered:

- SmoothSilk®/SilkSurface®
- TrueMonobloc®
- BluSeal®
- ProgressiveGel Plus™ or ProgressiveGel Ultima™
- Q Inside™ Safety Technology

In consultation with each patient, the investigator will determine the appropriate implant style and size.

ProgressiveGel PLUS™ Creating shape with a natural feel	ProgressiveGel Ultima™ The look and feel of a natural breast
Balanced gel elasticity and firmness	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
	

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