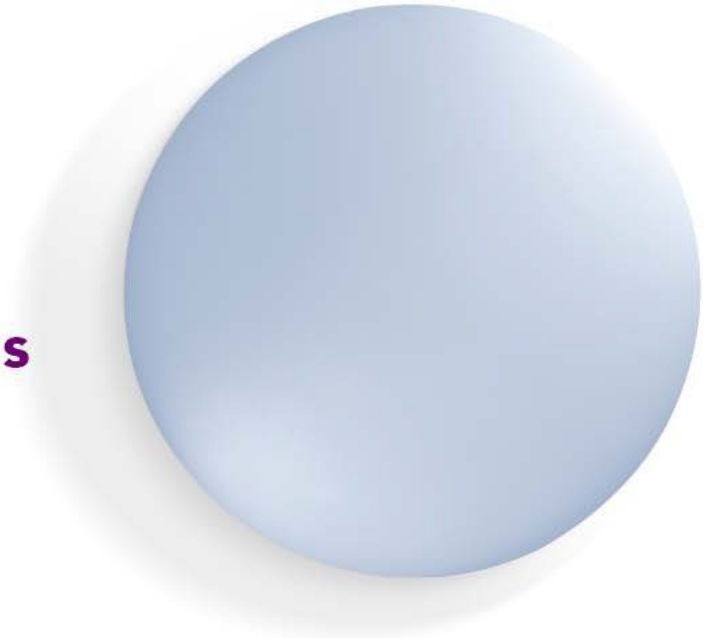


Study of Safety and Effectiveness of Motiva® Breast Implants



About the Study

Consider volunteering to participate in a breast implant research study. The study sponsor is seeking participants for breast reconstruction for:



Immediate reconstruction: implant placement immediately after a mastectomy (i.e. during the same procedure)	Delayed reconstruction: implant placement at a later date after a mastectomy (i.e. during a separate procedure)	Other indications: Congenital breast deformities, tuberous breasts, Poland's Syndrome, pectus excavatum, pectus carinatum, severe ptosis and severe asymmetry
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The purpose of this study is to determine the safety and effectiveness of Motiva Implants®. Motiva® USA, the study's sponsor, is a subsidiary of Establishment Labs – a global medical device manufacturer whose smooth silicone gel breast implants are commercially available in more than 70 countries.

We invite women aged 18 or older who meet the study's eligibility criteria to participate (detailed in the Eligibility section below). If you agree, your progress will be closely followed by an experienced plastic surgeon through 10 years to review the status and health of your breast implants.

The participating surgeons and study locations are listed below. You will be compensated for your time and effort to participate in this study. For more information, visit <https://motivaimplants.com/ustrial/> and <https://clinicaltrials.gov/ct2/show/NCT03579901>.

How to Participate

Participation in the Motiva Implants® study involves:



Enrollment

- Call your preferred study surgeon (contact information below)
- Provide information (including relevant personal and family history) to confirm your eligibility to participate
- Clarify any questions you may have with the study surgeon
- Give consent: read and sign the informed consent form to enroll
- Complete questionnaires about the current status of your breast(s)

Breast Implant Surgery

With routine care procedures in place, undergo primary breast reconstruction surgery with an experienced, board-certified plastic surgeon.

Follow-Up Visits

Return for follow-up visits through 10 years following implant surgery with your plastic surgeon to evaluate how you feel with your breast implants, how satisfied you are, and whether or not you've experienced any complications. This information is captured to continuously support the safety and performance of breast implants through research. You will fill some questionnaires about the current status of your breast after the surgery.

Participating Surgeons & Study Locations



Rest assured that each surgeon/investigator in the study is board certified and experienced in breast surgical procedures. The following are participating institutions:

Investigational Site	Investigator Name	Location	Contact Information
Glicksman Plastic Surgery	Caroline Glicksman	Sea Girt, New Jersey	732-974-2424
Northwestern Specialist in Plastic Surgery	Dr. Neil Fine	Chicago, Illinois	(312) 266-6240
CaloAesthetics® Plastic Surgery Center	Dr. Brad Calobrace	Louisville, Kentucky	(502) 899-9979
Cleveland Clinic	Dr. Graham Schwarz Dr. Risal Djohan Dr. Isakov Raymond Dr. Steven Bernard	Cleveland, Ohio	(216) 444-4659*
NYU Plastic Surgery Associates	Dr. Nolan Karp Dr. Mihye Choi	New York, New York	(212) 335-5779
Mount Sinai New York	Dr. Marco Harmaty Dr. Peter Henderson Dr. Philip Torina Dr. Jordan Jacobs	New York, New York	(212) 241-8250
Northwestern Plastic Surgery	Dr. John Kim	Chicago, Illinois	(312) 695-6022
Emory University Hospital	Dr. Albert Losken	Atlanta, Georgia	(404) 686-8143
Kiya Movassaghi, MD, FACS	Dr. Kiya Movassaghi	Eugene, Oregon	(541) 686-8700
Houston Methodist	Dr. Warren Ellsworth	Houston, Texas	(832) 522-8400
MD Anderson	Dr. Mark Clemens	Houston, Texas	(877) 651-4559
Fifth Avenue Millennium Aesthetic Surgery, PLLC	Dr. Leo Keegan	New York, New York	(212) 288-9800

*Please leave a voicemail with your contact information.

Victoriakliniken	Dr. Charles Randquist	Saltsjöbaden, Sweden	+46(0)853021000
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Eligibility



Basic eligibility criteria include the following (participant must meet ALL criteria below):

1. You are a genetic female.
2. You are aged 18 years or older.
3. You require a breast implant reconstruction surgery.
4. You have adequate tissue conditions to cover breast implants.
5. You are willing to follow all study requirements and visits.
6. You agree to return your breast implants to the Sponsor if they need to be removed to conduct additional testing on them.
7. You agree to participate in magnetic resonance imaging (MRI) at the designated post-op timepoints and/or if requested by your study doctor.

Your study surgeon will discuss and confirm with you any additional eligibility criteria.

Contact Information

For questions about the study, please contact your preferred study doctor, or request additional information by email to USClinicaltrial@establishmentlabs.com.