



Establishment Labs Announces Positive Clinical Study Results for its Motiva Implants® Published in the Aesthetics Surgery Journal

September 14, 2017

NEW YORK, September 14, 2017 (GLOBE NEWSWIRE)

Establishment Labs, a global medical device company focused on aesthetic technologies with a strong emphasis on product development and innovation, announced today that the results of a three-year, retrospective clinical study using the Company's Motiva Implants® were published in the peer-reviewed Aesthetic Surgery Journal.

The study evaluated the experience of 5,813 consecutive female patients receiving Motiva Implants for breast augmentation, from 2013 to 2016 at Dolan Park Hospital in Bromsgrove, England. The study, based on the experience of 16 board-certified plastic surgeons, evaluated rates of complications and reoperation following the procedure, with postoperative follow-up care over the three-year period. Two surface technologies of Motiva Implants were investigated: SilkSurface® and VelvetSurface®.

Clinical highlights of the clinical study included:

- Total reoperation occurred at a rate of 0.76% (95% confidence interval)
- No serious adverse events or cases of implant rupture for device failure were observed
- No incidences of capsular contracture in primary cases, late seroma, asymmetry, persistent swelling, breast pain or rippling
- Low rates of early complications with no late complications reported
- Motiva SilkSurface® resulted in lower complication rates compared to Motiva VelvetSurface® implants

"These findings help validate the differentiated safety profile of Motiva Implants," said Juan José Chacón Quirós, CEO and founder of Establishment Labs. "We expect this to be the start of many peer reviewed articles that suggest a truly differentiated product and competitive advantage. Establishment Labs does not believe that industry, doctors, or patients need to accept the complication rates associated with the majority of implants today, and that high complication rates do not have to be endemic to breast augmentation. This paper is a credit to the commitment that Establishment Labs has made to innovation in breast augmentation and reconstruction, and reaffirms our belief that our commitment to technological development can vastly improve many of the problems that have plagued this industry."

"Motiva Implants demonstrated low reoperation rates that are encouraging considering there remains a clear unmet need for improved safety and durability of silicone breast implants," stated Dr. Marcos Sforza, Scientific Medical Director of the Hospital Group and Medical Advisory Board member of Establishment Labs.

"After 10 years as the scientific Medical Director of the largest hospital for cosmetic surgery in Europe, and having used all the available brands of implants, I had become increasingly disappointed with industry and the lack of new solutions and technologies for breast augmentation and reconstruction. We commenced using Motiva in 2013 because of their commitment to innovation and patient-centric approach, and our belief that we could do better has been validated by our results. Using Motiva Implants has revolutionized our practice across the board, and we can proudly confirm with this publication that we have not seen one double capsule or late seroma in over 12 thousand implants used in breast augmentation. Compared to our previous experience in breast augmentation, revision rates have been reduced more than 10 times with higher patient satisfaction rates. These results are good for the breast augmentation and reconstruction markets, they are good for patients, plastic surgeons, and industry alike, and I look forward to future innovations and a revitalized aesthetic industry," stated Dr. Sforza.

[Read the full Aesthetic Surgery Journal Publication](#)

About Establishment Labs:

Establishment Labs is a global, privately held, medical technology company with a strong emphasis on innovation that designs, develops, manufactures and markets an innovative product portfolio. Its CE-marked Motiva Implants® line of silicone breast implants (<http://www.motivaimplants.com>) utilizes ultra-high purity medical-grade silicone and is subject to the strictest quality assurance testing throughout the manufacturing process. Motiva Implants® are sold in more than 60 countries worldwide. Puregraft®'s FDA cleared and CE-Marked technology provides plastic surgeons with purified fat for reinjection on the sterile field and is used in hospitals and clinics around the world. Divina® is a proprietary 3D imaging technology for full integration in consultation and surgical planning of unique solutions for breast aesthetic and reconstruction. All manufacturing facilities are fully compliant with both FDA and ISO applicable standards.

Contact

Lynn Pieper Lewis or Leigh Salvo
Gilmartin Group
(415) 937-5404

