



Establishment Labs Announces Motiva® Implants IDE Clinical Trial Underway with First Patient Enrolled and Surgery Completed

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NEW YORK, April 27, 2018 (GLOBE NEWSWIRE)

Establishment Labs Holdings Inc., a global medical device company focused on breast aesthetics and reconstruction technologies, today announced the enrollment and successful completion of implant surgery on the first patient in its U.S. investigational device exemption (IDE) clinical trial of its Motiva® in female patients who are undergoing primary breast augmentation, primary breast reconstruction, or revision surgery. With a population size of approximately 750 patients over 22 years of age, at up to 40 study sites in the United States, Canada, Sweden, and Germany, all subjects will be selected according to a strict protocol established by FDA regulations.

Patients meeting the inclusion and exclusion criteria may be enrolled in the study. The primary safety endpoint is based on the incidence, severity, method of resolution, and duration of all complications on a “per-implant” and “per-subject” basis. The use of 3D imaging systems, such as Divina[®], performed pre-operatively and at 1-10 year visits, will supplement the data and corroborate the manual measurements performed. An MRI sub-study will be done in parallel to determine the percentage of ruptures, with a subset of the treated population selected to obtain MRIs at 1,2,4,6,8 and 10 years.

Additional information regarding the trial will be available on clinicaltrials.gov and www.motivaimplants.com/UStrial

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 strict quality assurance testing throughout the manufacturing process. Motiva Implants are sold in more than 60 countries worldwide. All of Establishment Labs' manufacturing facilities are fully compliant with both FDA and ISO applicable standards.

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