



Integra LifeSciences Announces Complete Enrollment in DuraSorb® Monofilament Mesh U.S. IDE Study

June 28, 2023

Achieves Significant Milestone on Pathway to PMA Approval for Two-Stage Breast Reconstruction

PRINCETON, N.J., June 28, 2023 (GLOBE NEWSWIRE) -- Integra LifeSciences Holding Corporation (Nasdaq:IART), a leading global medical technology company, announced the completion of patient enrollment in the DuraSorb U.S. investigational device exemption (IDE) clinical study for two-stage breast reconstruction. [DuraSorb® Monofilament Mesh](#) is a bioabsorbable matrix currently 510(K) cleared for the reinforcement of soft tissue where weakness exists.

The DuraSorb IDE study, which is the first and only active, prospective, multi-center IDE study in the U.S. evaluating the use of a surgical matrix in two-stage breast reconstruction, has enrolled several hundred patients from seven major academic hospitals across the country sooner than anticipated. The purpose of this study is to evaluate the safety and effectiveness of DuraSorb to obtain pre-market approval (PMA) for use in patients undergoing two-stage breast reconstruction. The primary follow-up period is one year after device implantation.

"It is very exciting to see the completion of the DuraSorb arm enrollment for this important prospective multi-center study as well as the dedication of the medical professional teams across the study sites," said Dr. Yoon S. Chun, principal investigator and section chief, division of plastic and reconstructive surgery at Brigham and Women's Faulkner Hospital in Boston, Mass. "I look forward to completing this clinical research which will have a significant impact on our ongoing work to set new standards of care and achieve the highest quality outcomes for women undergoing reconstructive breast surgery."

"This is a significant milestone on our pathway to a PMA for DuraSorb. We look forward to continuing to work with the study investigators to maintain high patient follow-up," said Todd Cruikshank, vice president and general manager of Surgical Innovation Associates (SIA), a business of the Tissue Technologies division at Integra. "We are grateful to the investigators and patients enrolled in this study which is intended to help advance women's health and improve patient outcomes following breast cancer and mastectomy."

Today, there are no FDA-approved surgical matrices for implant-based breast reconstruction (IBBR). Integra remains the only company actively progressing toward PMAs for surgical matrices in breast reconstruction. In addition to the ongoing DuraSorb U.S. IDE study, Integra was the first manufacturer to submit a PMA application with [SurgiMend® PRS](#), a surgical matrix for use as soft tissue support in IBBR. Integra is on track to file a PMA update for SurgiMend PRS with the FDA this August.

"Integra's SurgiMend PRS, together with DuraSorb, will enable us to provide surgeons with two distinct soft tissue reinforcement solutions, which aim to address various clinical, contracting, and economic needs across more sites of care," added Robert T. Davis, Jr., executive vice president and president of Integra's Tissue Technologies division. "Achieving these important PMA milestones reinforces our commitment to our implant-based breast reconstruction strategy, innovating new treatment pathways, and restoring patient lives through technologies that transform surgical care."

About Integra LifeSciences

At Integra LifeSciences, we are driven by our purpose of restoring patients' lives. We innovate treatment pathways to advance patient outcomes and set new standards of surgical, neurologic and regenerative care. We offer a comprehensive portfolio of high quality, leadership brands that include AmnioExcel®, Aurora®, Bactiseal®, BioD™, CerebroFlo®, CereLink®, Certas® Plus, Codman®, CUSA®, Cytal®, DuraGen®, DuraSeal®, DuraSorb®, Gentrix®, ICP Express®, Integra®, Licox®, MAYFIELD®, MediHoney®, MicroFrance®, MicroMatrix®, NeuraGen®, NeuraWrap™, PriMatri®, SurgiMend®, TCC-EZ® and VersaTru®. For the latest news and information about Integra and its products, please visit www.integralife.com.

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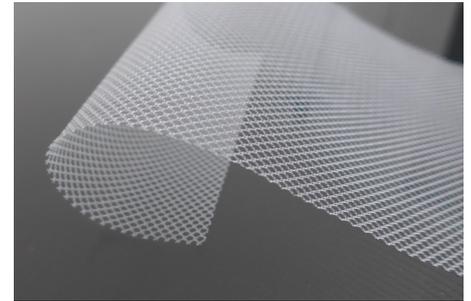
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DuraSorb



DuraSorb® Monofilament Mesh

