



## **Integra LifeSciences Statement on the U.S. FDA Safety Communication on Acellular Dermal Matrix (ADM) Products Used in Implant-Based Breast Reconstruction**

April 19, 2021

PRINCETON, N.J., April 19, 2021 (GLOBE NEWSWIRE) -- [Integra LifeSciences Holdings Corporation](#) (Nasdaq:IART), a leading global medical technology company and manufacturer of [SurgiMend Collagen Matrix](#), today issued the following statement regarding the U.S. FDA safety communication on the differences in complication rates between acellular dermal matrix (ADM) products used in implant-based breast reconstruction.

"Integra LifeSciences supports the efforts of the U.S. FDA to protect women's health, including its recent safety communication on ADM products used in implant-based breast reconstruction.

SurgiMend Collagen Matrix is currently cleared by the FDA for use in certain types of surgeries to reinforce tissue where weakness exists, such as plastic and reconstructive surgery, and hernia repair. Neither SurgiMend nor any other ADM (human or xenograft) is currently approved for use in breast reconstruction in the United States. It is important for patients to discuss the use of medical technologies, including SurgiMend, with their healthcare providers.

Integra is committed to delivering safe and effective medical technologies and products to our customers and their patients, including securing clearance or approval for a product indicated for breast reconstruction. We work to consistently meet or exceed industry and global regulatory standards to provide quality products and technologies designed to meet the needs of our customers and their patients.

We applaud the ongoing work of the various surgeon associations and patient advocacy groups in reinforcing the importance of quality patient care and promoting education, advocacy, and public awareness of various healthcare issues. Integra continues to collaborate with the clinical community to pursue solutions to advance women's health."

### **About the SurgiMend Collagen Matrix**

SurgiMend Collagen Matrix is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes. SurgiMend is specifically indicated for:

- Plastic and reconstructive surgery.
- Muscle flap reinforcement.
- Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernia.

### **About Integra LifeSciences**

Integra LifeSciences is a global leader in regenerative tissue technologies and neurosurgical solutions dedicated to limiting uncertainty for clinicians, so they can focus on providing the best patient care. Integra offers a comprehensive portfolio of high quality, leadership brands that include AmnioExcel®, Bactiseal®, CerebroFlo®, CereLink®, Certas® Plus, Codman®, CUSA®, Cytal®, DuraGen®, DuraSeal®, Gentrax®, ICP Express®, Integra®, MatriStem® UBM, MAYFIELD®, MediHoney®, MicroFrance®, MicroMatrix®, PriMatrix®, SurgiMend®, TCC-EZ®, and VersaTru®. For the latest news and information about Integra and its products, please visit [www.integralife.com](http://www.integralife.com).

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties and reflect the Company's judgment as of the date of this release. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ from predicted results. These risks and uncertainties include market conditions and other factors beyond the Company's control and the economic, competitive, governmental, technological and other factors identified under the heading "Risk Factors" included in item 1A of Integra's Annual Report on Form 10-K for the year ended December 31, 2020. These forward-looking statements are made only as the date thereof, and the Company undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise.

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