

## Serica Technologies Receives FDA 510(k) Clearance for *SeriScaffold*<sup>TM</sup> Technology for Soft Tissue Repair

MEDFORD, MA February 25, 2009 - **Serica Technologies, Inc.**, a growth-stage medical device company developing silk-based biomaterial platforms for tissue regeneration, announced it has received 510(k) clearance from the U.S.

Food and Drug Administration (FDA) for its *SeriScaffold*(TM) silk-based, long term bioresorbable scaffold technology (see also Tissue Engineering).

"We are delighted to receive FDA clearance under the 510(k) process. This 510(k) clearance represents a major milestone for Serica as well as for our bioengineered silk-based biomaterial for soft tissue repair applications," said Gregory H. Altman, PhD, President and CEO, Serica Technologies.

The *SeriScaffold* platform technology has the potential to provide a new solution as an off-the-shelf, long-term bioresorbable scaffold for support and repair of weakened or damaged connective tissue. Most notably, *SeriScaffold* could be used as a sophisticated tissue repair scaffold for the approximately 60,000 women who, according to the American Society of Plastic Surgeons, annually undergo reconstructive procedures resulting from illnesses such as breast cancer.

"Major challenges still exist for both surgeons and patients faced with breast reconstruction and other forms of plastic and reconstructive surgery," said John E. Gross, MD, FACS, Associate Professor of Surgery at the University of Southern California (USC/Keck) School of Medicine and a prominent practicing plastic surgeon in Greater Los Angeles. "For example, in many types of breast surgeries, either following mastectomy, mastopexy (breast lift) or body contouring procedures, there is a significant need for scaffolding technology that can immediately support a geometrically complex implantation site at the time of surgery, and provide the body both the time and structure necessary for optimal healing. A silk-based scaffold that supports immediate tissue infiltration and maintains its integrity over a longer term, as it is being bioresorbed by the body, may be significant in addressing these clinical needs."

"First and foremost, it is our sincere hope that the properties of the *SeriScaffold* technology could represent a significant shift in soft tissue repair, in terms of the surgical outcome and healing process, for patients," added Altman.

"We plan to leverage the well known physical properties of silk in additional surgical applications, and will be initiating new clinical studies using our novel technology. Our goal is to develop a portfolio of tailored scaffold products, to be available in a multitude of contoured shapes and sizes, for those patients undergoing breast reconstruction and/or augmentation," said Altman. "It is our intent that our product portfolio serve the unique needs of this patient population where a significant loss of tissue occurs during surgery, with the hope of better restoring the repair site to a more natural state."

The *SeriScaffold*(TM) platform technology provides a unique natural protein-based alternative to synthetic materials and graft products harvested from human or animal cadaver tissue. "We believe our proprietary *SeriScaffold* technology has applications for a wide range of necessary procedures for patients requiring reconstructive plastic surgery, as well as for patients undergoing elective and other forms of soft tissue repair surgery," said Altman.

With additional research and development planned, SeriScaffold technology-based products have the potential to be lead products in the plastic surgery market, where 860,000 aesthetic augmentation and reconstructive surgical procedures are conducted annually. This silk-based scaffold technology is also showing promise in other procedures including rotator cuff and hernia repair surgeries.

"Serica is actively seeking a strategic partner to advance the SeriScaffold product array, particularly in the aesthetic and reconstructive surgery market, while the company continues to advance its ligament and tendon platform technology in the orthopaedic marketplace," said Altman.

#### About the Reconstructive and Aesthetic Plastic Surgery Market

According to the American Society of Plastic Surgeons, the reconstructive and aesthetic plastic surgery market represents a wide range of surgical procedures, including nearly 500,000 procedures related to breast reconstruction, reduction and non-cosmetic breast implant removal. Body contouring post massive weight loss represents over 65,000 procedures and cosmetic plastic surgeries total over 856,000 surgical procedures, including breast augmentation, facelifts, neck lifts and tummy tucks.

#### About Serica's Biomaterials

The body's structural tissue can be destroyed, removed or weakened due to trauma, disease or aging. Serica is developing natural, silk biomaterials designed to act as "scaffolds" to provide support and relief to damaged tissues, in order to promote restored function. The company's ligament grafts for ACL repair, surgical meshes, and gels are comprised of the fiber protein of the B. mori silkworm, which has centuries of human use. In pre-clinical studies, Serica's silk-based products are shown to be bioresorbed at slower rates than other common structural proteins, such as collagen, as well as other water soluble synthetic polymers, to enable optimal healing. Serica's silk-based biomaterials require no re-hydration or advance preparation for surgical implantation.

Serica is developing products for a wide variety of applications where current materials fail to meet the needs of clinicians and patients, including connective tissue repair of the knee, shoulder, abdomen, breast, neck and face.

#### About Serica Technologies Inc.

Serica Technologies, Inc., formerly Tissue Regeneration, Inc., is a growth-stage medical device company pioneering silk-based biomaterial platforms for tissue regeneration. Incorporated in 1998, Serica's proprietary products currently in preclinical and clinical development are being studied in the areas of orthopaedic and sports medicine, aesthetic and reconstructive plastic surgery and other structural tissue repair needs, and drug delivery applications. Serica's team of engineers and scientists are located in a state-of-the-art 26,000-square-foot office, R&D and manufacturing facility in Medford, MA. For more information about Serica Technologies, please visit <http://www.sericainc.com/>.

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