Discover the innovation of lasting support and strength from native tissue[1,*]

The first and only Silk-derived Biological Scaffold is here

*At 24 months, native tissue was stronger than ovine fascia sampled and evaluated from 2 locations (rectus abdominis/internal oblique) in a full-scale animal (ovine subcutaneous thoracic wall implant) model study designed to measure the strength and thickness of newly generated native tissue at 1, 3, 6, 12, 18, and 24 months after implantation of SERI® Surgical Scaffold.[1]

Learn about SERI® Surgical Scaffold.

See actual results from soft tissue support and repair case studies.

Please see Indication and Important Safety Information inside.

SERI® Surgical Scaffold

Only from ALLERGAN

Featuring contributions from RESTORE Program training faculty and key investigators for SERI® Surgical Scaffold studies:

Bradley P. Bengtson, MD

Dr. Bengtson is a board-certified plastic surgeon specializing in several aspects of cosmetic surgery including breast revision surgery, breast reduction and lifts, and abdominoplasty. Based in downtown Grand Rapids, Michigan, Dr. Bengtson serves patients from all over the state of Michigan, the United States, Canada, and Europe.

Mark L. Jewell, MD

Based in Eugene, Oregon, Dr. Jewell is a board-certified plastic surgeon who currently serves as the US National Secretary of the International Society for Aesthetic Plastic Surgery (ISAPS). Dr. Jewell is an associate clinical professor of plastic surgery at Oregon Health Science University.

Max R. Lehfeldt, MD

Dr. Lehfeldt is a board-certified plastic surgeon based in Pasadena, California, who specializes in procedures of the face, breast, and body. Dr. Lehfeldt also actively teaches residents at the Huntington Memorial Hospital and the Dermatology Residency of Western University Health Sciences.

In the United States, Dr. Bengtson, Dr. Jewell, and Dr. Lehfeldt are leading experts on SERI® Surgical Scaffold.

Meet SERI® Surgical Scaffold

The field of plastic surgery is witnessing an exciting development with the recent availability of the first and only Silk-derived Biological Scaffold. Not derived from human cadaver or animal tissue, ultra pure SERI® Surgical Scaffold facilitates the generation of native, well-vascularized tissue through bioreplacement (see Figure 1).[1,2,*] This means native tissue ultimately provides support and strength where the patient needs it most.[1,2,*]

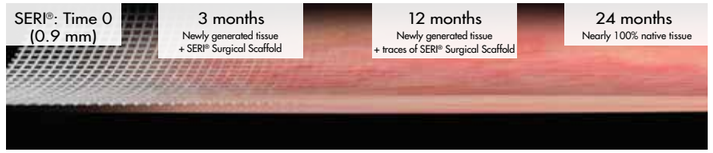


Figure 1. Thickness is a byproduct of ingrowth and SERI® Surgical Scaffold. Computer-generated images; for illustrative purposes only.

Unique product characteristics

SERI® Surgical Scaffold has been specifically designed to deliver lasting support and strength from native tissue.[1,2,*] Studies have shown that ultra pure, silk-derived SERI® Surgical Scaffold facilitates neovascularization (as early as 2 days)† and native tissue generation over time through bioreplacement (see Figure 2).[1,2,*] As demonstrated in a full-scale animal model study, this newly ingrown, well-vascularized tissue is ≈ twice the starting thickness of the scaffold alone—and was shown to exhibit nearly twice the average strength of ovine fascia—at 24 months.[1,*] The predictable bioresorption of SERI® Surgical Scaffold means that native tissue provides the majority of load-bearing strength over time.[1,2,*]

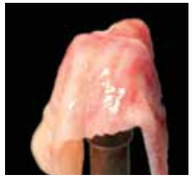


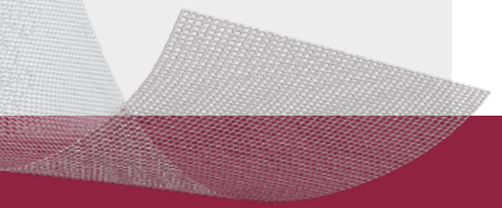
Figure 2. SERI® Surgical Scaffold and well-vascularized tissue ingrowth at 12 months in a full-scale animal (ovine) model study.[1,*]

What makes SERI® Surgical Scaffold different?

Before the introduction of SERI® Surgical Scaffold, surgeons primarily relied on acellular dermal matrices (ADMs)—products sourced from human cadaver or animal tissue—and synthetic meshes.[3] Today, SERI® Surgical Scaffold represents a new class of biological products to deliver soft tissue support and repair. One reason it stands apart in this category is because it's the first and only Silk-derived Biological Scaffold that provides support and strength from native tissue.[1,2,*] After experiencing its many benefits, more of your colleagues are adopting this newly available medical device for breast revision and abdominal wall procedures.

*__Methodology:__ In a full-scale animal (ovine subcutaneous thoracic wall implant) model study designed to measure the strength and thickness of newly generated native tissue at 1, 3, 6, 12, 18, and 24 months after implantation of SERI® Surgical Scaffold.[1]

†__Methodology:__ In a study using SERI® Surgical Scaffold in a rat model abdominal wall defect.[1] Note: Similar results in humans have not been confirmed.



Learn more and see well-vascularized tissue results with SERI® Surgical Scaffold at SERI.com

NOT YOUR ORDINARY SILK

Commercial silk sutures contain sericin, which is associated with an exaggerated inflammatory response.[1,4] In addition, surgical silk suture is composed of fibrous proteins that are first processed into strands, then braided, and may be dyed and coated with wax or silicone.[4] Because of this, silk sutures typically can become encapsulated and do not integrate into the native tissue.[1] However, SERI® Surgical Scaffold is different from ordinary silk. It undergoes the proprietary *BIOSILK*™ purification process designed to remove sericin and other impurities for an ultra pure, sterile product.[2] As a result, natural silk is transformed into an ultra pure, biological scaffold that exhibits favorable biocompatibility with minimal inflammation.[1,2]

Case review: Augmentation-mastopexy using SERI® Surgical Scaffold for soft tissue support and repair

Case courtesy of Bradley P. Bengtson, MD

"SERI® Surgical Scaffold is a great way to offer soft tissue support for mastopexy patients who have undergone significant weight loss. I also use it to help repair soft tissue in breast revision surgery such as fold malposition, lateral displacement, symmastia, stretch deformity in the lower pole of the breast, and wrinkling and rippling. Based on my experience, there is nothing quite like SERI® Surgical Scaffold for soft tissue support and repair because of its unique properties as a biological silk scaffold. It offers a nice strength with pliability, and it is bioresorbed over time to deliver lasting support and strength from the patient's own supportive collagen framework. Because of this, SERI® Surgical Scaffold has changed my practice by expanding what I can offer my patients."

– Bradley P. Bengtson, MD
Grand Rapids, Michigan

Patient assessment

- A 55-year-old woman presented with Grade III ptosis and loose skin stretch
- She was a healthy nonsmoker with a body mass index within normal range
- She had had 3 pregnancies and had given birth to 3 children
- She had no history of prior breast surgeries

Surgical plan

- The surgical plan was to perform a primary mastopexy with augmentation via an IMF approach
- A 240-cc, round, silicone-filled implant was selected for placement submuscularly in each breast
- The goal of surgery was to reduce the N:IMF from 12 cm to 9.5 cm
- SERI® Surgical Scaffold was used to provide soft tissue support at the lower pole and additional soft tissue support of the breast from the upper pectoralis fascia to the apex of the inferior pedicle
- This support may help reduce the chance of future lower-pole stretch deformity that commonly occurs following these procedures

Postoperative results: 8 months

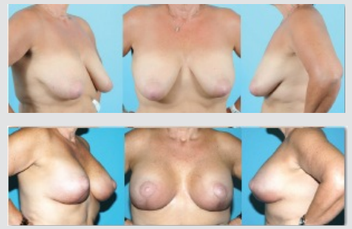


Figure 3. Before use of SERI® Surgical Scaffold.

Figure 4. After use of SERI® Surgical Scaffold at 4 months.

Figure 5. After use of SERI® Surgical Scaffold at 8 months.

Actual patient photos. Individual results may vary.

Case conclusions

- Dr. Bengtson believed the use of SERI® Surgical Scaffold was beneficial in achieving the desired result for the patient
- The target N:IMF distance of 9.5 cm achieved intraoperatively was retained through 4 months
- At 8 months postoperatively, N:IMF on maximal stretch had increased 1 cm to 10.5 cm, and there was good retention of volume in the upper pole

Indications for Use

SERI® Surgical Scaffold is indicated for use as a transitory scaffold for soft tissue support and repair to reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction.

Important Safety Information

Contraindications

- Patients with a known allergy to silk
- Contraindicated for direct contact with bowel or viscera where formation of adhesions may occur

Please see additional Important Safety Information on the following pages.

SERI® Surgical Scaffold

Neovascularization: a defining characteristic of SERI® Surgical Scaffold

"Revascularization" is defined as the reestablishment of blood supply to the tissue.[5] This effect has been demonstrated in ADMs.[6-9]

Neovascularization, defined as the proliferation (ingrowth) of new blood vessels,[5] has been demonstrated with SERI® Surgical Scaffold.[1,*,†] Although it does not contain cells or blood vessels, this Silk-derived Biological Scaffold facilitates the rapid ingrowth of new blood vessels (in as early as 2 days)† and native tissue generation over time.[1,2,*]

Now, surgeons don't need to rely solely on donated cadaver or animal tissue. Through bioreplacment, SERI® Surgical Scaffold facilitates neovascularization and the generation of native tissue over time.[1,2,*,†]

As SERI® Surgical Scaffold bioresorbs, new blood vessels grow through its macroporous design.[1,2] The presence of collagen aids this process by providing a surface for endothelial attachment.[10,11] These endothelial cells form the walls of blood vessels and help facilitate the ingrowth of the surrounding tissue.[12] Ultimately, **SERI® Surgical Scaffold is gradually bioreplaced with native, well-vascularized tissue through this process.**[1,2,*,†] This newly generated tissue demonstrated nearly twice the average strength of ovine fascia through 24 months in a full-scale animal model study.[1,*]

*__Methodology:__ In a full-scale animal (ovine subcutaneous thoracic wall implant) model study designed to measure the strength and thickness of newly generated native tissue at 1, 3, 6, 12, 18, and 24 months after implantation of SERI® Surgical Scaffold.[1]

†__Methodology:__ In a study using SERI® Surgical Scaffold in a rat model abdominal wall defect.[1]
Note: Similar results in humans have not been confirmed.

Case review: Revision abdominoplasty using SERI® Surgical Scaffold for soft tissue support and repair

Case courtesy of Max R. Lehfeldt, MD

"SERI® Surgical Scaffold offers a new way for surgeons to support the soft tissue in the abdomen, especially for cases that have always presented challenges in the past. For abdominal wall procedures where there is no bowel contact, I use it exclusively. One reason I use SERI® Surgical Scaffold is because it is ultimately replaced by the patient's native collagen. SERI® Surgical Scaffold is an incredibly elegant solution for long-term soft tissue support where the patient needs it most. Also, its generous 25 cm x 10 cm size gives surgeons the flexibility to tailor the scaffold to each patient's specific challenges in the breast or abdomen. Plus, you get consistency with predictable material properties. You can expect each sheet to be identical out of the box versus the variability you may get with tissue-based products."

– Max R. Lehfeldt, MD
Pasadena, California

Patient assessment

- A 48-year-old female presented for an elective revision abdominoplasty; she had undergone 6 unsuccessful abdominoplasties
- The patient had a history of recurrent umbilical herniation, but she was otherwise in good health
- She had poor abdominal contour; a wide, high abdominal scar; and no waist definition
- On physical examination, Dr. Lehfeldt found thin abdominal wall soft tissue and palpable underlying plication sutures

Surgical plan

- The surgical plan included repair of the recurrent umbilical hernia and midline fascial plication
- Dr. Lehfeldt planned to lower the high and wide abdominal scar
- SERI® Surgical Scaffold would be placed as an overlay for soft tissue reinforcement of the abdominal wall to support the repeat plication and umbilical hernia repair

Postoperative results:

6 months

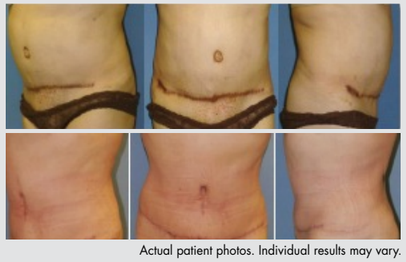


Figure 6. Before use of SERI® Surgical Scaffold.

Figure 7. After use of SERI® Surgical Scaffold.

Actual patient photos. Individual results may vary.

Case conclusions

- There was no palpability of SERI® Surgical Scaffold at the initial postoperative visit or at 6 months postoperatively
- At 6 months postoperatively, the patient had no recurrence of abdominal hernia or any bulging or stretching of the abdominal wall
- SERI® Surgical Scaffold contributed to the support of the abdominal wall fascia to maintain an improved contour

RESTORE PROGRAM

A unique partnership connecting Allergan and the plastic surgery community

Allergan recognizes the importance of partnering with the plastic surgery community, and this led to the creation of the RESTORE Program, a full-scale training and product evaluation program. To date, it has provided over 250 surgeons with robust product training on SERI® Surgical Scaffold in a laboratory setting using actual cadavers. The training is followed by the opportunity to evaluate SERI® Surgical Scaffold with the surgeon's own patients. This allows participants to become familiar with the product as they formulate their own recommended surgical techniques. Most importantly, the RESTORE Program actively seeks surgeons' feedback on their experience with SERI® Surgical Scaffold. Allergan relies on these insights to drive a meaningful conversation with the plastic surgery community about the latest innovation for soft tissue support and repair.

Following the RESTORE Program experience last year, personal interviews with 23 surgeons indicated that participants were very satisfied with the training they received.[1] Perceived benefits were valuable hands-on experience with SERI® Surgical Scaffold and the opportunity to learn from product experts—which created excitement to use SERI® Surgical Scaffold in their own practice.[1]

During these interviews, one surgeon remarked, *"The training was amazing. Very good cadaver lab....It was hands-on, had a good staff, good conference. The enthusiasm of the staff, and being able to work with the tissue with the product was amazing....You were able to see and learn from the people who have been using [the product] during research and ask a lot of questions. It helps."*

A different surgeon shared another valued component of the RESTORE Program: *"Allergan had a great idea to generate interest in SERI® [Surgical Scaffold]. They gave [evaluation product] to surgeons and invited them to a cadaver lab where they got a chance to try it out and get feedback from people who have used SERI® [Surgical Scaffold]....It is a very good idea to have a teaching round, get them hands-on experience....There is an honest exchange of knowledge from peers."*

Want to participate in an upcoming RESTORE Program or educational webinar?

Register online at SERI.com.

Distinctive benefits that matter to surgeons and patients

Surgeons are already responding very positively to SERI® Surgical Scaffold. In fact, **98% (N = 256 total surgeons surveyed) of RESTORE Program participants reported a favorable impression of the product.**[1] This is based upon many characteristics of SERI® Surgical Scaffold including its flexibility, drapability, and ease of use.[1] Dr. Lehfeldt confirms this based on his personal experience with the product: *"SERI® Surgical Scaffold is easy to suture, shape, and drape. The porous material allows for easy visualization of critical underlying anatomical structures. You can always visualize where your needle is in relation to the material and the underlying structures."*

Surgeons also appreciate its predictable properties—from package to package—so they always know what to expect.[1]

Another important benefit is support and strength from native tissue.[1,2,*] As SERI® Surgical Scaffold is bioreplaced, it helps generate native, well-vascularized tissue to deliver soft tissue support over time.[1,2,*] Surgical experience has shown that not only do patients value the generation of their own strong and supportive tissue, they are also more open to silk-based SERI® Surgical Scaffold over products derived from cadaver or animal tissue. Certainly, a higher level of patient acceptance can be very influential in surgeons' decision to use it.

According to Dr. Lehfeldt: *"My patients care that SERI® Surgical Scaffold is nontissue based. Patients can fundamentally relate to silk as a biological material that is pure. They are also receptive to the notion that SERI® Surgical Scaffold will be replaced with their own tissue."*

Dr. Bengtson agrees: *"The fact that SERI® Surgical Scaffold is a biological scaffold made from silk makes it much easier to convince patients to include it for their surgery."*

Dr. Jewell has observed the same patient acceptance in his practice: *"With SERI® Surgical Scaffold, there is no 'ick factor.' Patients have an easier time accepting a silk-based product over options sourced from human or animal tissue because they perceive it as more pure."*

*__Methodology:__ In a full-scale animal (ovine subcutaneous thoracic wall implant) model study designed to measure the strength and thickness of newly generated native tissue at 1, 3, 6, 12, 18, and 24 months after implantation of SERI® Surgical Scaffold.[1]
Note: Similar results in humans have not been confirmed.

Important Safety Information (continued)

Warnings

- SERI® Surgical Scaffold must be placed in maximum possible contact with healthy well-vascularized tissue to encourage ingrowth and tissue remodeling
- Caution should be used when implanting SERI® Surgical Scaffold in pregnant women. The use of a device that can impede tissue expansion may be hazardous during pregnancy

Please see additional Important Safety Information on the following pages.

SERI® Surgical Scaffold

Ease of use is valued by RESTORE Program surgeons

Personal interviews with 23 participating surgeons revealed the importance of the following product attributes[1]:

- **Predictable material properties[1]**
- **Nice hand feel and flexibility[2]**
- **Porous material for suture retention and enhanced visibility while suturing[2]**
- **No refrigeration or rehydration needed[2]**
- **Easy to cut and shape in the desired area[1,2]**
- **Large 10 cm x 25 cm size affords a variety of shapes and templates**

Versatile innovation with multiple applications

SERI® Surgical Scaffold has potential to offer soft tissue support and repair for several usage areas within breast revision and abdominal wall procedures. It is indicated for use as a transitory scaffold for soft tissue support and repair to reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction.[2]

Specific procedures that may benefit from the use of SERI® Surgical Scaffold for soft tissue support and repair include:

- Breast revision surgery
- Mastopexy with or without augmentation
- Breast reductions
- Abdominoplasty
- Abdominal wall repair including hernias
- Muscle flap reinforcement

Dr. Bengtson also envisions varied usage of SERI® Surgical Scaffold for soft tissue support and repair: *"For surgeons who have used other product technologies, it's an opportunity to utilize something different. As surgeons gain more experience with SERI® Surgical Scaffold, their comfort level will continue to rise and its usage will expand."*

In a brief survey completed prior to the start of last year's RESTORE Program, 181 participating surgeons expressed high interest in learning about SERI® Surgical Scaffold for breast revision procedures, including breast augmentation revision and breast lift.[1] This represents a widespread desire to learn more about an exceptional product that delivers support and strength from native tissue.[1,2,*]

Sign up to participate in an upcoming training opportunity.

Register online at SERI.com

New opportunities to learn in 2014

Allergan will conduct more educational programs throughout 2014 to support the plastic surgery community. Contact your Allergan sales representative for more details about upcoming programs.

Only from Allergan, your trusted partner in plastic surgery

SERI® Surgical Scaffold is available only from Allergan, a leader with many years of experience in plastic surgery. We stand behind each of our products because we believe in the potential value they can provide surgeons and their patients—and SERI® Surgical Scaffold is no exception.

Committed to providing robust support

Allergan remains committed to the plastic surgery community, as shown by the valuable educational programs we offer all year. Specifically, we proudly partner with surgeons through excellent training opportunities. Allergan recognizes the value of hands-on experience with SERI® Surgical Scaffold, which is why these programs are designed to offer a collaborative setting for product training.

To learn more about upcoming training opportunities in your area, contact your Allergan sales representative or visit SERI.com.

In addition, Allergan offers comprehensive reimbursement support. Our hotline team of specialists is ready to assist surgeons with all coding, billing, and reimbursement questions.

The Allergan Reimbursement Hotline
Call 1-855-888-7203
Monday through Friday
9 AM–9 PM, ET

*__Methodology:__ In a full-scale animal (ovine subcutaneous thoracic wall implant) model study designed to measure the strength and thickness of newly generated native tissue at 1, 3, 6, 12, 18, and 24 months after implantation of SERI® Surgical Scaffold.[1]
Note: Similar results in humans have not been confirmed.

Learn more and see well-vascularized tissue results with SERI® Surgical Scaffold at SERI.com

A lasting innovation: Support and strength from native tissue[1,2,*]

SERI® Surgical Scaffold offers an exciting product technology only from Allergan. Its usage will continue to grow as more surgeons realize its important benefits, such as lasting support and strength from newly generated, well-vascularized native tissue.[1,2,*] As the world's first and only Silk-derived Biological Scaffold, this unique product can arm surgeons with an innovative way to deliver soft tissue support and repair.

To learn more, contact your Allergan sales representative or visit SERI.com.

*At 24 months, native tissue was stronger than ovine fascia sampled and evaluated from 2 locations (rectus abdominis/internal oblique) in a full-scale animal (ovine subcutaneous thoracic wall implant) model study designed to measure the strength and thickness of newly generated native tissue at 1,3,6,12,18, and 24 months after implantation of SERI® Surgical Scaffold.[1]
Note: Similar results in humans have not been confirmed.

Case review: Breast revision surgery for recurrent lateral malposition using SERI® Surgical Scaffold for soft tissue support and repair

Case courtesy of Mark L. Jewell, MD

"From the first time I picked up a sheet of SERI® Surgical Scaffold, I knew it was something different. It's the only biologically based product of its kind made from pure silk. It feels unique, with a nice hand feel and nonslippery texture. Also, the material is easy to cut and shape into a variety of sizes and templates for specific areas in the breast. In this way, it lends itself to surgical innovation with opportunities for soft tissue support and repair. In addition to its predictable quality-controlled physical properties, it is engineered so native tissue provides support and strength over time, while the scaffold itself eventually goes away through bioresorption."

– Mark L. Jewell, MD
Eugene, Oregon

Patient assessment

- A 35-year-old woman who had breast augmentation in 2004 presented with lateral malposition
- The patient had hypermobile implants that fell off of the chest and into the lateral chest wall region when supine
- Her tissues were thin and visible/palpable; traction rippling/pleating were noted in the lateral breast mound region
- She had poor skin tone and an extremely loose skin envelope
- Her initial breast augmentation was completed by another surgeon, who utilized a "mega-pocket" technique with a saline implant filled to 285 cc in a biplanar location; she also had a circumareolar mastopexy

Surgical plan

- A lateral/inferior capsulorrhaphy was planned to diminish the size of the pocket with SERI® Surgical Scaffold inset as intracapsular soft tissue reinforcement and sutures placed to control her "mega-pocket"
- The goal was to achieve a tighter feel and appearance to her breasts
- The saline implants would be replaced with silicone implants, 350 cc

Postoperative results:

6 months

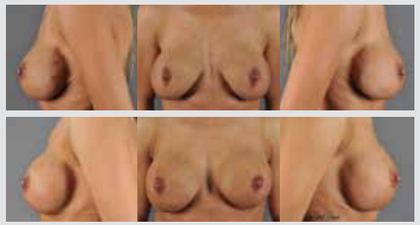


Figure 8. Before use of SERI® Surgical Scaffold.

Figure 9. After use of SERI® Surgical Scaffold.

Actual patient photos. Individual results may vary.

Case conclusions

- Utilizing SERI® Surgical Scaffold as an intracapsular overlay to reinforce the local soft tissues and the capsulorrhaphy suture line allowed Dr. Jewell to effectively correct the lateral fold at its natural position
- The patient's existing implants were kept in the capsule during the capsulorrhaphy procedure to provide fullness within the pocket and to help determine the appropriate resizing and dissection of the capsule

Important Safety Information (continued)

Adverse Reactions

Adverse reactions are those typically associated with surgically implantable materials, including infection, inflammation, adhesion formation, fistula formation, and extrusion.

Important: Before using SERI® Surgical Scaffold, read the Instructions for Use which accompany the product for full safety information. This can be found at www.allergan.com or call Allergan Product Support at 1-800-433-8871.

Caution: Rx only.

Please see additional Important Safety Information on back cover.

SERI® Surgical Scaffold

Discover more at SERI.com.

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