

Procedure Guide for Surgeons

A Revolutionary Approach to Soft Tissue Support and Repair in Abdominal Wall Surgery

The First and Only Silk-Derived Biological Scaffold

SÔFREGEN

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Abdominoplasty by Max R. Lehfeldt (Pasadena, CA) Ventral Hernia Repair by Mark W. Clemens (Houston, TX) TRAM Reinforcement by Mark W. Clemens (Houston, TX)

33 REFERENCES

SERI[®] Surgical Scaffold: Indications and Important Safety Information¹

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

Precautions

- SERI[®] Surgical Scaffold should be stored in a dry area in its original sealed package away from direct sources of heat at room temperature.
- Handle the implant using aseptic technique and sterile talc-free gloves.
- Dispose of non-contaminated, non-used devices in the trash.
- Dispose of contaminated devices in accordance with regulations for disposal of medical waste.
- Use of multiple layers of SERI® Surgical Scaffold has not been tested.

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.
- Do not cute SERI[®] Surgical Scaffold *in situ* without rinsing and aspiration of the surgical site to remove any device particulate debris that may have been generated.
- Do not use SERI® Surgical Scaffold past the expiration date indicated on the label.
- Do not use SERI[®] Surgical Scaffold if the sealed pouch is punctured, torn, or otherwise compromised.
- Do not use SERI® Surgical Scaffold if the device is visibly torn, frayed, or damaged.
- Do not re-sterilize. SERI[®] Surgical Scaffold is supplied sterile, and is for single patient use only.

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.seri.com or call Sofregen Medical Affairs at (617) 651-8871.

Caution: Rx only.

SECTION 1: Introduction and Overview

SERI[®] Surgical Scaffold is a knitted, multifilament long-term bioresorbable scaffold made entirely of silk protein. It is derived from silk that is highly purified to yield ultrapure fibroin. The device is a mechanically strong and biocompatible protein mesh. SERI[®] Surgical Scaffold is a sterile, single-use product and is supplied in a variety of sizes ready for use in open or laparoscopic procedures. The scaffold is flexible and well-suited for delivery through a laparoscopic trocar. It is tear resistant, with excellent suture retention, and can be cut in any direction. SERI[®] Surgical Scaffold provides immediate physical and mechanical stabilization of a tissue defect through its strength and porous (scaffold-like) construction.

SERI[®] Surgical Scaffold is designed to slowly bioresorb in parallel to neovascularization and native tissue ingrowth which results in eventual replacement of SERI[®] Surgical Scaffold with native tissue. As bioresorption occurs, load bearing responsibility is transferred to the new tissue ingrowth such that mechanical integrity is maintained at the site.



SERI[®] Surgical Scaffold: Features and Potential Clinical Benefits

SERI [®] Surgical Scaffold Features	Potential Clinical Benefits		
SERI [®] Surgical Scaffold Composition			
Highly purified, silk-derived biological scaffold ²	No use of human cadaver or animal tissue ²		
Proprietary water-based processing is designed to purify silk by removing sericin	Tissue response to SERI® Surgical Scaffold exhibits minimal inflammation. Silk scaffold helps promote favorable integration and neovascularization as the scaffold is bioreplaced over time with collagen ¹		
Predictability and Consistency of SERI® Surgical Scaffold Materials and Performance			
Bioengineering process produces a consistent, predictable product ²	Consistency of the product allows the surgeon to focus on surgical planning without worrying about product variability		
Neovascularization and Tissue Integration			
Properties of new tissue are distinct from those seen with scar tissue ²	The neovascularization and fiber ingrowth patterns seen with SERI® Surgical Scaffold are similar to those seen with native tissue in rat histology; with scar tissue, the fibers are dense and compacted and neovascularization is none or minimal ^{*, 2}		
Allows the patient's own tissue to provide ongoing continuous support through replacement of the scaffold with new tissue ²	Newly generated tissue demonstrates nearly twice the average strength of ovine fascia at 24 months in a sheep model ^{1,2,}		
	Newly generated tissue provided the majority of load-bearing strength by 6 months in a sheep model ^{(,2}		

SERI [®] Surgical Scaffold Features	Potential Clinical Benefits		
Ease of Surgical Use			
Multi-directional design ²	 Ease of handling in the surgical field² Scaffold can be cut in any direction² Ease of suturing² Permits egress of fluid from the wound² 		
Imaging & Safety			
No interference with imaging or radiation treatment	Ultrasound study found predominantly negligible occurrences of seroma or hematoma 6 months post-surgery in a sheep model ^{1,2}		
No "sidedness" or distinct orientation requirements	Concern about correct-side placement or orientation is eliminated		
Available in a 5 cm x 15 cm, 10 cm x 25 cm, 15 cm x 25 cm and 20 cm x 30 cm sheet	Can be cut to size while retaining the tensile strength ²		
Ease of Preparation and Storage			
No rehydration required ¹	Use directly from the package ¹		
No refrigeration required ¹	Store at room temperature in a dry room ¹		
Ready to use – with a 3-year shelf life ²	Minimize waste		

*Methodology: In a study using SERI® Surgical Scaffold in a rat model abdominal wall defect, SERI® tissue sample was taken after 4 weeks in vivo. In a separate rat model study, scar tissue sample was taken after 7 weeks in vivo and identified from the incision site.

^f 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.





SECTION 2 Guiding Principles

This Guide was developed based on information from published literature and input from leading plastic surgeons with extensive experience using SERI® Surgical Scaffold and soft tissue support and repair products generally.

This Guide is provided for your information only and is intended to serve as a component of a comprehensive educational training program; it is not intended to be a stand-alone instruction. As with other surgical and medical decisions, it is the responsibility of surgeons to use sound medical judgement in utilizing the procedures best suited to the needs of each patient and the skills and experiences of the surgeon.

Please refer to the SERI® Surgical Scaffold Instructions for Use for current information.





Device Properties and Orientation

- SERI[®] Surgical Scaffold is for single-layer use only.¹
- SERI[®] Surgical Scaffold must be placed in maximum possible contact with healthy, well-vascularized tissue to encourage tissue in-growth and remodeling.
- A unique mechanical characteristic of SERI® Surgical Scaffold is its limited stretch, which varies with the specific orientation of the material.
- While the material has no significant stretch when pulled along the shorter vertical axis, it does stretch minimally when pulled along the longer horizontal axis.



Vertical



Horizontal

• When pulled diagonally, collapse of the interstices creates additional stretch.



Diagonal

• Because of its diagonal stretch, place SERI® Surgical Scaffold along the long axis of the repair, to maximize the structural integrity of the abdominal wall reconstruction [Figure 1.]



Figure 1. Orientation

Product Preparation

Rinse

- SERI® Surgical Scaffold is recommended to be briefly dipped in either sterile saline or sterile antibiotic solution for 2 to 3 seconds prior to implantation [Figure 2.]
- SERI[®] Surgical Scaffold does not require rehydration or refrigeration and is readily available off the shelf and out of the package for immediate implantation.¹



Figure 2. Rinsing **SERI®** Surgical Scaffold

Size and Cut

- SERI® Surgical Scaffold does not unravel or fray when cut.²
- SERI[®] Surgical Scaffold can be fit to the contours of the patient's anatomy or intended placement. Ideally, cutting should be performed prior to implantation and followed by extensive rinsing in sterile saline or sterile antibiotic solution. [Figure 3.]
- If preferred, place SERI® Surgical Scaffold within the operative field and mark it to the appropriate size prior to cutting.¹

Horizontal and vertical orientation lines may

Drawing an ellipse for the intended

• If trimming in situ is required, irrigate to

ensure that any material fragments have

device placement [Figure 4.]

been removed.¹

Sizing and Cutting SERI® Surgical Scaffold help maintain orientation during implantation. location of sutures may also facilitate proper



Figure 3.

Figure 4. SERI® Surgical Scaffold With Orientation Marks







Product Preparation

Suturing

- SERI[®] Surgical Scaffold should be sutured securely in place, including all edges and corners, to eliminate any movement of SERI[®] Surgical Scaffold relative to adjacent tissue.
- It is imperative to suture the SERI® Surgical Scaffold under maximum tension with adequate sutures. When properly sutured under tension, it should be taut.
 - Tension on the scaffold may alleviate pressure on the abdominal defect and provide soft tissue support during tissue ingrowth.^{3,4}
- Place sutures at least 3 mm, or 1 full row, away from the cut edge.¹ [Figure 5.]



Figure 5. - Suturing Requirement: Sutures Placed at Least 1 Full Row From Edge

- The suture material selected should be durable enough to last a minimum of 3 months, or, alternatively, a permanent suture should be used, in order to avoid SERI displacement during tissue ingrowth and bioreplacement.¹
- The use of quilting or vertical mattress sutures may also help obliterate subcutaneous dead space, potentially reducing fluid accumulation.^{5,6}
 [Figure 6.]
- In some cases within this guide, specific suturing techniques are recommended by surgeons experienced with using SERI® Surgical Scaffold, or you may use your preferred suturing technique.



Figure 6. Mattress Sutures

Product Preparation

Drains

- Place closed-suction drains prior to closure to reduce fluid accumulation in the early postoperative phase.⁷
 - A drain should be placed near SERI[®] Surgical Scaffold as well as under subcutaneous flaps.
 - Use of drains in abdominal surgery with SERI[®] Surgical Scaffold is no different from use of drains with other prosthetic mesh products.

Postoperative Management

• Postoperative instructions for patients who undergo abdominal surgery with SERI® Surgical Scaffold are no different from postoperative instructions with other prosthetic mesh products.



Step-By-Step Guide: Overlay Placement of SERI[®] Surgical Scaffold

Overlay Placement – With or Without Concurrent Hernia Repair

Open abdominal procedures allow for easy visualization of the abdominal midline when performing an abdominoplasty, with or without a concurrent hernia repair. Placement of SERI® Surgical Scaffold as an overlay affords an opportunity for the desired surgical outcome by providing soft tissue support that helps contour the abdominal wall. While performing an abdominoplasty, it is common to find a hernia defect that requires repair. Support and reinforcement of incisional, ventral, and periumbilical hernias with surgical soft tissue support products has been shown to significantly reduce recurrence as compared with suture only repairs.⁸⁻¹¹ Using SERI® Surgical Scaffold as an overlay to support a hernia repair may reduce the need for reoperation and is less complicated than the retrorectus approach, which may be used in conjunction with an external oblique component separation, if necessary.

Cross-section of the abdominal wall above the arcuate line

SECTION 4 Step-by-Step Guides for 3 Surgical Procedures

Overlay Placement of SERI® Surgical Scaffold

STEP 1. Preparation, Sizing, and Cutting of the SERI® Surgical Scaffold

- Determine the size and shape of the SERI® Surgical Scaffold piece(s) you will be using, based on the dimensions of the defect and the placement of the scaffold.
 - Typically, a full 10 cm x 25 cm sheet of SERI[®] Surgical Scaffold will be needed and then trimmed accordingly.

STEP 2. Surgical Repair of the Abdominal Wall

• Dissect and expose to the level of the abdominal wall using your standard surgical technique

Photo courtesy of Bradley Bengtson, MD

Overlay Placement of SERI® Surgical Scaffold

STEP 3. Midline Plication

• Close the midline diastasis fascia using figure-of-8 suturing or your preferred suturing technique

STEP 4. Orientation and overlay Placement of the SERI[®] Surgical Scaffold

• Orient the SERI® Surgical Scaffold vertically and place as an overlay, centered over the midline of the abdominal wall, and tack in place.

SERI® Surgical Scaffold must be placed in maximum possible contact with healthy, well-vascularized tissue to encourage ingrowth and tissue remodeling.¹

Overlay Placement of SERI® Surgical Scaffold

STEP 5. Expose the Umbilicus

• Create a small slit in the scaffold to expose the umbilicus. A suture is placed into the umbilical dermis for easier location later in the process.

Creating a small slit in the scaffold allows for the umbilicus to be pulled through cleanly and eliminates overexposure of the abdominal wall, a potential contributor to hernia recurrence.

STEP 6. Tack and Suture the SERI® Surgical Scaffold Circumferentially

- Tack the SERI[®] Surgical Scaffold at 12:00, 6:00, 3:00, and 9:00 with a heavy absorbable suture, using interrupted sutures, always maintaining tension.
- Secure the scaffold with circumferential running sutures at least 3 mm, or 1 full row, from the edge.¹

Suture SERI® Surgical Scaffold under maximum tension and keep it taut, to alleviate pressure on the abdominal wall defect and to provide soft tissue support during tissue ingrowth.^{3,4}

Overlay Placement of SERI® Surgical Scaffold

STEP 7. Suture the SERI® Surgical Scaffold Over the Midline Plication

- Secure the scaffold over the midline repair, using running sutures, then to the underlying abdominal fascia. This helps provide additional soft tissue support and abdominal contouring.
- If a component separation was used to complete a hernia repair, additional sutures may be placed at the external oblique release point, suturing the lateral edge of the SERI® Surgical Scaffold at the linea semilunaris.

Prior to closing the abdominal fascia, sit the patient upright to ensure that appropriate tension has been placed on SERI[®] Surgical Scaffold for the desired abdominal contouring.

STEP 8. Reestablish the Umbilicus Through the Skin Flap

• Temporarily tack the inferior incision and pull the umbilicus through the skin flap. Suture the umbilicus in place.

Step-by-Step Guide for Overlay Placement

Step-by-Step Guide for Overlay Placement

Overlay Placement of SERI® Surgical Scaffold

STEP 9. Closure

- Place closed-suction drains in contact with SERI® Surgical Scaffold beneath the skin prior to closure to remove excess fluid in the early postoperative phase.^{7, 12-14}
 - Additional drains may be required if component separation was performed.
- Close the subcutaneous tissues and skin using your preferred method.

Step-By-Step Guide: Retrorectus Placement – Ventral Hernia Repair

Over the past few decades, fascial closure with internal reinforcement for hernia repair has become the "standard of care" in ventral hernia surgery. The retrorectus technique is relatively easy to learn, can be performed in a broad range of patients, and is associated with lower ventral hernia recurrence rates compared with either onlay or inlay prosthetic synthetic mesh and acellular dermal matrix (ADM) hernia repairs.^{4, 12-16} Additionally, the retrorectus approach:

- Prevents the device from having direct contact with the abdominal viscera. Contact with abdominal viscera could possibly lead to adverse events such as adhesions between the device and viscera, bowel obstruction, and fistula formation.¹²
- Maintains the functionality and integrity of the abdominal wall by leveraging the intraabdominal pressures to stabilize the prosthetic device against the rectus muscle and fascial closure.^{12,13}
- Minimizes the need for skin flap undermining, thus allowing for preservation of skin-flap perforating vessels. This technique also enables additional surface contact between the rectus muscle and rectus sheath, increasing exposure to vascularization and aiding tissue ingrowth.^{12,13,15}
 - Never use SERI[®] Surgical Scaffold in cases in which the scaffold would be in direct contact with the bowel or viscera.¹

Retrorectus Placement of SERI® Surgical Scaffold

STEP 1. Dissect the Posterior Rectus Sheath Away From the Rectus Abdominis Muscle

 Incise the peritoneum at the midline. Separate the posterior rectus sheath from the rectus abdominis muscle on both sides of the hernia defect. Continue to dissect laterally, being careful to preserve the blood supply to the rectus abdominis muscle.

STEP 2. Close the Posterior Rectus Sheath

• Create the retrorectus plane by approximating the tissue with running sutures to close the posterior rectus sheath along the midline. Reinforce with additional sutures as needed.

Always fully close the posterior rectus sheath prior to placement of SERI[®] Surgical Scaffold to prevent direct contact with the bowel and other viscera.³

Step-by-Step Guide for Retrorectus Placement

Retrorectus Placement of SERI® Surgical Scaffold

STEP 3. Cut the SERI[®] Surgical Scaffold to the Appropriate Size

• If the measurement of the defect requires, cut the SERI® Surgical Scaffold to fit the contours of the hernia defect and the anatomy of the newly created retrorectus plane.

STEP 4. Orient and Place the SERI[®] Surgical Scaffold into the Retrorectus Plane

• Insert the SERI® Surgical Scaffold in the newly created retrorectus plane anterior to the closed posterior rectus sheath and posterior to the rectus abdominis muscle.

Cross-section of the abdominal wall above the arcuate line

Retrorectus Placement of SERI® Surgical Scaffold

Retrorectus Placement of SERI® Surgical Scaffold

STEP 5. Suture the SERI® Surgical Scaffold

- Secure the scaffold with nonabsorbable, interrupted sutures placed approximately 1 cm to 2 cm apart through the anterior rectus sheath fascia.
 - > Place sutures on hemostats and tie them down separately.
- Quilting or vertical mattress sutures may also help obliterate subcutaneous dead space, potentially reducing fluid accumulation.⁵

Suture the SERI® Surgical Scaffold under maximum tension to alleviate pressure on the abdominal wall defect and to provide soft tissue support during tissue ingrowth.^{3,4}

 Photo courtesy of Mark Clemens, MD

STEP 6. Close the Rectus Abdominis Muscle Over the SERI[®] Surgical Scaffold

• Close the rectus abdominis muscle and anterior rectus sheath fascia over the scaffold using figure-of-8 sutures followed by running sutures.

Photo courtesy of Mark Clemens, MD

STEP 7. Closure

- Place closed-suction drains in contact with SERI® Surgical Scaffold beneath the skin prior to closure to remove excess fluid in the early postoperative phase per normal protocol.⁷¹²⁻¹⁴
 - Additional drains may be required if component separation was performed.
- Close Scarpa's fascia, the subcutaneous tissues, and skin using your preferred method.

Photo courtesy of Mark Clemens, MD

Step-By-Step Guide: Inlay or Overlay* Placement – Transverse Rectus Abdominis Musculocutaneous (TRAM) and Deep Inferior Epigastric Perforator (DIEP) Donor Site Reinforcement

TRAM/DIEP procedures provide excellent donor flaps for the reconstruction of the breast, but these procedures are not without tradeoffs. They provide the soft tissue and vasculature necessary for breast reconstruction; however, the remaining abdominal site may be compromised and at risk for muscle weakness, bulge formation, and/or hernia.^{17,18} Harvesting a well-perfused abdominal flap requires selecting tissue that contains sufficient vasculature to prevent potential partial flap necrosis; this includes incorporation of medial and/or lateral abdominal perforators. Doing so may result in significant gaps in the anterior rectus fascia. Reinforcement of the donor site using SERI® Surgical Scaffold as an inlay or overlay helps promote native tissue ingrowth for the soft tissue support of the abdominal donor site.

*If using an overlay placement, refer to page 11 of this guide.

Inlay Placement of SERI® Surgical Scaffold

STEP 1. Preparation, Sizing, and Cutting of the SERI[®] Surgical Scaffold

 Determine the size and shape of the SERI[®] Surgical Scaffold you will be using, based on the dimensions of the donor site and the placement of the scaffold, to provide soft tissue support and repair where needed.

STEP 2. Create the Donor Site

• Harvest the tissue, muscle, and perforating vasculature for the TRAM flap based on your standard surgical procedure.

Photo courtesy of Mark Clemens, MD

STEP 3. Inlay Orientation and Placement of the SERI[®] Surgical Scaffold

- Insert the sized and cut pieces of SERI® Surgical Scaffold under the anterior rectus fascia in the inlay plane.
 - Use SERI® Surgical Scaffold to reinforce the abdominal tissue donor site, especially if removing the lateral row perforators.

Photo courtesy of Mark Clemens, MD

STEP 4. Tack the SERI® Surgical Scaffold

• Tack into place with nonabsorbable suture at 12:00, 6:00, 3:00, and 9:00, keeping the material under tension.

Photo courtesy of Mark Clemens, MD

STEP 5. Suture the SERI® Surgical Scaffold

- Complete the inlay using running sutures to close any remaining spaces between the tacked sutures, keeping the SERI® Surgical Scaffold taut under physiologic tension.
 - If the patient is thin, consider using buried knots to reduce the potential for palpability of the suture.
- The fascia should fall loosely over the inlay when SERI® Surgical Scaffold is sutured under proper tension.

Photo courtesy of Mark Clemens, MD

Inlay Placement of SERI® Surgical Scaffold

STEP 6. Suture the Fascia

- Complete the primary fascial coaptation using figure-of-8 followed by running sutures.
- A contralateral fascial plication may be performed to achieve symmetry or to restore the umbilicus to the midline, if needed.

Photo courtesy of Mark Clemens, MD

STEP 7. Closure

- Place drains in the abdomen through separate stab incisions above the pubis per normal protocol.
- Close the subcutaneous tissues and skin using your preferred method.

SECTION 5 Clinical Case Studies

SECTION 5 Clinical Case Studies

Clinical Case Studies

Case in Brief

Poor aesthetic outcomes and recurrent umbilical herniation after 6 attempts to correct. Revision abdominoplasty was performed, using SERI® Surgical Scaffold for soft tissue support and repair.

Patient History

A 48-year-old female presented for an elective revisional 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, I found thin abdominal-wall soft tissue, and palpable underlying plication sutures.

Surgical Planning

The surgical plan included repair of the recurrent umbilical hernia and midline fascial plication. I planned to lower the high and wide abdominal scar. The 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.

Operative Technique

STEP 1. Hernia Repair and Plication

The umbilical hernia repair was followed by an abdominal wall plication using figure-of-8 sutures and a running knotless tissue closure to reinforce the hernia repair and support lax tissues.

STEP 2. Overlay Placement and Orientation of the SERI® Surgical Scaffold

A 10 cm x 25 cm sheet of the scaffold was used. The corners were trimmed to fit the contours of the abdominal wall. The scaffold was oriented vertically, centered over the midline, and tacked in place.

STEP 3. Suture the SERI® Surgical Scaffold

The scaffold overlay was tacked with 2-0 synthetic absorbable PDS[™] sutures to anchor the material in place and stabilize the scaffold during tissue ingrowth. The scaffold was then inset with tension using O-VicryI[™] running sutures circumferentially. The SERI[®] Surgical Scaffold was plicated over the midline repair to the underlying abdominal fascia using running sutures to provide additional abdominal contouring.

STEP 5. Closure

A single drain was inserted in the lower abdomen through a stab incision. 2-0 synthetic absorbable PDSTM was used to close Scarpa's fascia, followed by 3-0 MONOCRYLTM for the deep dermis, and MonodermTM sutures to close the skin. Steri-StripsTM and supportive dressings were applied, with an abdominal binder for additional support.

Postoperative Care and Follow-up

The patient was treated as an outpatient and advised to avoid lifting more than 10 pounds for 4 weeks, and to refrain from excessive bending or twisting for 1 to 2 weeks. Six days after surgery, the drains were removed.

Results

There was no palpability of the 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.

Conclusion

Dr. Lehfeldt believed that using SERI® Surgical Scaffold helped maintain this patient's improved abdominal contour following repeat plication; it was especially critical during the early healing phase. Placing the scaffold as an onlay allowed tensile forces to be offloaded from the fascia to the scaffold, providing long-term support as SERI® Surgical Scaffold is bioreplaced over time.²

– Preoperative

 Postoperative Results at 6 Months

Dr. Lehfeldt found the large-pore design of SERI® Surgical Scaffold to facilitate fluid egress, thereby possibly reducing the risk of fluid collection and seroma formation.² He added that the design also allows for easy suturing and visualization of the underlying tissue during placement.²

Clinical Case Studies

Clinical Case Studies

Case in Brief

Ventral hernia repair with retrorectus placement of SERI[®] Surgical Scaffold for abdominal wall reinforcement and soft tissue support.

Patient History

A 67-year-old male presented with recurrent bladder cancer and a ventral hernia. He had a widened midline vertical scar in the upper abdomen, extending from the xiphoid process to the umbilicus. There was a palpable fascial defect in the upper abdomen but no evidence of entrapped bowel or other abdominal contents within the hernia at the time. No other bulges or hernias were present. The patient's history was significant for bladder cancer, diabetes, peripheral vascular disease, and hypertension.

Surgical Planning

A preoperative CT scan showed a 5-cm fascial defect with bowel herniation beneath the subcutaneous tissues. The surgical plan was to perform an ileal conduit construction with urostomy, as well as an abdominal wall reconstruction with bilateral component separation. SERI® Surgical Scaffold would provide abdominal reinforcement and soft tissue support. Creating a stoma would classify this case as a Grade 3 wound.²⁰

Preoperative CT Scan With Defect Identified

Operative Technique

STEP 1. Hernia Repair

Dr. Clemens used component separation to repair the ventral hernia. The defect was 10 cm wide and 22 cm long.

STEP 2. Creating the Retrorectus Plane

The posterior rectus sheath was separated from the rectus abdominis muscle and then closed on the midline to create a retrorectus plane. It was closed prior to placement of SERI[®] Surgical Scaffold.

STEP 3. Retrorectus Placement and Orientation of the SERI[®] Surgical Scaffold

A 10 cm x 25 cm sheet of the scaffold was inset in the retrorectus plane.

STEP 4. Suture the SERI® Surgical Scaffold

The scaffold was tacked into position with nonabsorbable #1 PROLENE[™] U-stiches that were placed on hemostats and then tied sequentially. The fascia was approximated at the midline with nonabsorbable #1 PROLENE[™] figure-of-8 sutures followed by a running suture. 2-0 PDS[™] was used to place quilting sutures and to close Scarpa's fascia.

STEP 5. Closure

Three drains were placed within the fascial planes from the component separation. The skin was closed with 3-0 MONOCRYL[™] dermal sutures and 4-0 MONOCRYL[™] subcuticular sutures.

Postoperative Care and Follow-up

The patient was discharged from the hospital 7 days after surgery. Both at discharge and postoperatively, there was no palpability of the SERI® Surgical Scaffold. The patient was instructed not to lift anything weighing more than 10 pounds for 4 weeks and to avoid excessive bending or twisting for 1 to 2 weeks. His drains were removed 20 days postoperatively. At that time, he was doing well with no postoperative complications.

Results

At 6 months after surgery, the patient showed no evidence of hernia, bulge or stretch of the abdominal wall.

Conclusion

Dr. Clemens found the SERI® Surgical Scaffold easy to manipulate and suture.² The open knit of the material aided in suture placement and egress of flulid.² Additionally, the scaffold seemed strong enough to withstand the forces of an abdominal wall closure and help support and reinforce weakened tissues.^{2,9}

Clinical Case Studies

Muscle-sparing TRAM flap reconstruction with reinforcement of abdominal donor site using inlay placement of SERI® Surgical Scaffold for soft tissue support and repair.

Patient History

A 64-year-old woman presented for a planned mastectomy and immediate muscle-sparing TRAM flap reconstruction of the right chest wall. She also desired contralateral breast reduction for symmetry. The patient had a protuberant abdomen without hernia or bulges, confirmed by CT angiogram. She was morbidly obese, with a body mass index of 38. She had a history of right breast cancer, and had previously undergone a lumpectomy and radiation therapy.

Surgical Planning

A muscle-sparing TRAM flap reconstruction of the right chest wall and contralateral breast reduction for symmetry was planned with placement of SERI® Surgical Scaffold as an inlay reinforcement of the abdominal fascia, the donor site.

Operative Technique

STEP 1. Create the Donor Site

Dr. Clemens completed the muscle-sparing TRAM flap reconstruction of the right chest wall and contralateral breast reduction for symmetry.

STEP 2. Cut and Rinse the SERI® Surgical Scaffold

A sheet of SERI[®] Surgical Scaffold was cut into a 6 cm x 10 cm piece and rinsed with normal saline and triple antibiotic solution.

STEP 3. Inlay Placement and Orientation of the SERI[®] Surgical Scaffold

The piece of the scaffold was inserted under tension in the inlay plane of the donor site.

STEP 4. Suture the SERI® Surgical Scaffold

The SERI[®] Surgical Scaffold was tacked into place with nonabsorbable #1 PROLENE[™] interrupted figure-of-8 sutures around the circumference, approximately 1 cm to 2 cm apart. The anterior rectus fascia was then closed without tension using figure-of-8 sutures followed by a running #1 PROLENE[™] suture.

STEP 5. Closure

Three 15-French round hubless BLAKE[®] drains and a 3/16" trocar were placed in the abdomen through separate stab incisions above the pubis. The skin was closed with 3-0 MONOCRYLTM dermal sutures followed by 4-0 MONOCRYLTM subcuticular suture.

Postoperative Care and Follow-up

The patient was discharged from the hospital 4 days after the initial surgery. Both at discharge and postoperatively, threre was no palpability of the SERI® Surgical Scaffold. The patient was instructed to start walking as soon as possible and to avoid lifting for 6 weeks. The drains were removed 23 days after surgery. She had good pain control and no postoperative complications.

Results

At 8 months, the patient showed improved abdominal contour, with no evidence of hernia, bulge, or abdominal asymmetry.

Preoperative

Postoperative Results at 6 Months

Conclusion

Dr. Clemens indicated the SERI[®] Surgical Scaffold felt soft and pliable, yet strong enough to support the abdominal wall closure.

He found the knit of the scaffold easy to manipulate and that it enabled clear visualization throughout the procedure, without moving while being sutured to the abdominal wall.² It also allowed for transmission of fluids, which may have helped to prevent fluid buildup.²

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