CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

SERI® Surgical Scaffold

DESCRIPTION

SERI® Surgical Scaffold is a knitted, multifilament, bioengineered, long-term bioresorbable scaffold. It is derived from silk that has been BIOSILK™ purified to yield ultra pure fibroin. The device is a mechanically strong and biocompatible bioprotein. SERI® Surgical Scaffold is a sterile, single use only 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.

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.

CONTRAINDICATIONS

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

PRECAUTIONS

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

WARNINGS

1. SERI® Surgical Scaffold must be placed in maximum possible contact with healthy well-vascularized tissue to encourage ingrowth and tissue remodeling.
2. 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.
3. Do not cut SERI® Surgical Scaffold *in situ* without rinsing and aspiration of the surgical site to remove any device particulate debris that may have been generated.
4. Do not use SERI® Surgical Scaffold past the expiration date indicated on the label.
5. Do not use SERI® Surgical Scaffold if the sealed pouch is punctured, torn, or otherwise compromised.
6. Do not use SERI® Surgical Scaffold if the device is visibly torn, frayed, or damaged.
7. Do not re-sterilize. SERI® Surgical Scaffold is supplied sterile, and is for single patient use only.

ADVERSE REACTIONS

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

SCAFFOLD IMPLANTATION INSTRUCTIONS

Consult scientific literature for specific surgical techniques; the following are general instructions for scaffold use.

1. Remove the device from the package. Although SERI® Surgical Scaffold does not require rehydration for mechanical or physical performance, a brief dip (minimum 2-3 seconds) in standard sterile rinse solution is recommended prior to implantation.
2. If cutting of the device is necessary, it should ideally be performed prior to implantation and be followed by extensive rinsing in standard sterile rinse solution.
3. Use the type of suture that is appropriate for your application.
4. Sutures should be placed at least 3 mm, or one full row, from the cut edge.
5. If preferred, the uncut scaffold may be sutured over the defect and trimmed once secured in place followed by extensive rinsing and aspiration of the surgical site.
6. The scaffold should be sufficiently anchored to stabilize it during tissue ingrowth.
7. For laparoscopic procedures, the device should be rolled along its long axis for delivery through a trocar. The following table provides recommended trocar sizing to accommodate the various sizes of SERI® Surgical Scaffold.

Scaffold Dimensions (Width x Length)	Minimum Trocar Size
5 cm x 15 cm	7/8 mm
10 cm x 25 cm	7/8 mm
15 cm x 25 cm	11 mm
20 cm x 30 cm	15 mm

STORAGE

SERI® Surgical Scaffold should be stored in a dry area in its original sealed package away from direct sources of heat at room temperature.

DEVICE TRACKING

Affix one peel-off label onto the patient record for each package of SERI® Surgical Scaffold opened and used.

Patented. See: http://www.allergan.com/products/patent_notices

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