

SISplus Resorbable Tissue Patching

Avalon Medical's **SIS**^{plus} offers you all the benefits you've come to expect from an SIS product, along with the increased rapid healing response that comes with our unique ion therapy. **SIS**^{plus} is a porcine-derived surgical patch intended for tissue repair and reinforcement. The graft is supplied sterile in peel-open packages and is intended for one-time use.

This product is intended for use by trained veterinary professionals.

CONTRAINDICATIONS

This graft is derived from a porcine source and patients demonstrating sensitivity to porcine derived products should not receive this product.

PRECAUTIONS

- **SIS**^{plus} material is NOT intended for ocular use. For ocular applications, please purchase our **SIS**^{plus} ocular discs.
- Do not resterilize. Discard all open and unused portions.
- Graft is sterile if package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Single-layer graft should not be used in applications requiring high strength.
- The graft may not have enough strength to support stresses encountered in some ventral hernias or large-area, body-wall repairs.
- Ensure that the graft is is rehydrated prior to suturing and stapling.
- Ensure that all layers of the graft are secured when suturing or stapling.

POTENTIAL COMPLICATIONS

The following complications are possible with the use of surgical graft materials. If any of these conditions occur, the graft should be removed:

- Infection
- Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation).

STORAGE

This graft should be stored in a clean, dry location at room temperature.

SHELF LIFE

The shelf life of this product is 18 months.

STERILIZATION

This graft has been radiation sterilized.

USE OF ANTIMICROBIALS

Because the graft is at times used in surgical fields where sterility cannot be assured, the use of antimicrobials is common practice and may prevent infectious complications.

INSTRUCTIONS FOR USE

These recommendations are designed to serve as a general guideline. They are not intended to supersede typical institutional protocols or professional clinical judgment concerning patient care.

Note: Handle the graft using aseptic technique. Minimize contact with latex gloves.

Required Materials:

- A sterile dish for hydration of graft
- Sterile forceps
- Rehydration fluid: at least 50mL of room temperature sterile, isotonic saline
- 1. Add to the dish at least 50 mL of the rehydration fluid for each graft sheet.
- 2. Using aseptic technique, remove the graft inner pouch from its outer bag.
- 3. Open the inner pouch carefully, and aseptically remove the graft sheet with the sterile forceps.
- 4. Place the graft into the sterile dish in the sterile field, carefully introducing the material to the surface of the rehydration fluid and allowing it to slowly rehydrate. (Multiple graft sheets may be rehydrated simultaneously in the same dish.)
- 5. Allow a 1-layer graft sheet to rehydrate for three minutes. Allow a multiple layer graft sheet to rehydrate for ten minutes. <u>Do not agitate the graft material.</u>
- 6. Prepare the graft site using standard surgical techniques.
- 7. Using aseptic technique, trim the graft sheet to fit the site, providing a small (approximately 1/8th inch) allowance for overlap. **Note:** An alternative method is to trim the graft sheet to size prior to rehydration. If this method is selected, be sure to rehydrate the graft sheet prior to suturing or stapling into place.
- 8. Using an aseptic technique, transfer the graft sheet to the graft site and suture or staple into place, avoiding excess tension. **Note:** Surgical experience indicates that suturing or stapling graft sheets with close tissue approximation produces better outcomes. Do not suture closer than 2mm from the graft margin.
- 9. Complete the standard surgical procedure.
- 10. Discard any unused portions of the graft sheet.

BANDAGING

It is recommended that SIS^{plus} have an aqueous dermal gel applied (for example, sterile aloe gel) so the matrix remains moist during the healing process.

The aqueous dermal gel covering should be followed by nonstick surface bandaging material, which will protect the tissue bed and prevent leakage of serum into the contact layer and thereby prevent adhesion of the bandage to the wound.

Nonadhesive bandage material should cover the SISplus material prior to applying an appropriate outer dressing.

The outer dressing should be changed daily when reapplying the aqueous dermal gel to maintain the **SIS**^{plus} hydration status. The **SIS**^{plus} patch should not be removed.

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