Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or properly licensed practitioner. This product is not for human use. These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.
Always read product IFU before use.

Precautions:
As a derivative of porcine SIS, Vetrix® BioSIS ECM® should not be used on animals with known allergic conditions to porcine material.

Vetrix® BioSIS ECM® is sterile if the package is dry, unopened, and undamaged. Do not use if material seal has been broken.

Do not reuse or resterilize. Discard all open and unused portions of material.

Discard Vetrix® BioSIS ECM® if mishandling has caused damage or contamination.

Do not use for intravascular injection (venous or aterial).

Vetrix® BioSIS ECM® should be used on clean wound bed. All purulent debris and scar tissue should be removed prior to use.

When using disinfectants or substances that can be irritating to normal tissues, always irrigate area with healthy amount of sterile physiologic saline to remove any residual residues.

Potential Complications:
Complications and/or reactions are possible with any soft tissue repair. Such examples include but are not limited to infection, inflammation, allergic reaction, unexplained fever or chills, redness, pain, or swelling. As with any medical procedure, no guarantees can be made regarding the outcome or long term results.

Storage:
Vetrix® BioSIS ECM® should be stored in its unopened and undamaged package in a clean, dry environment. Keep the product out of direct sunlight/heat. Store at room temperature or cooler. Do not freeze.

Vetrix® BioSIS ECM® has been sterilized using Ethylene Oxide sterilization process. Product dating is 18 months from manufacturing date.

VETRIX
Rethink Healing

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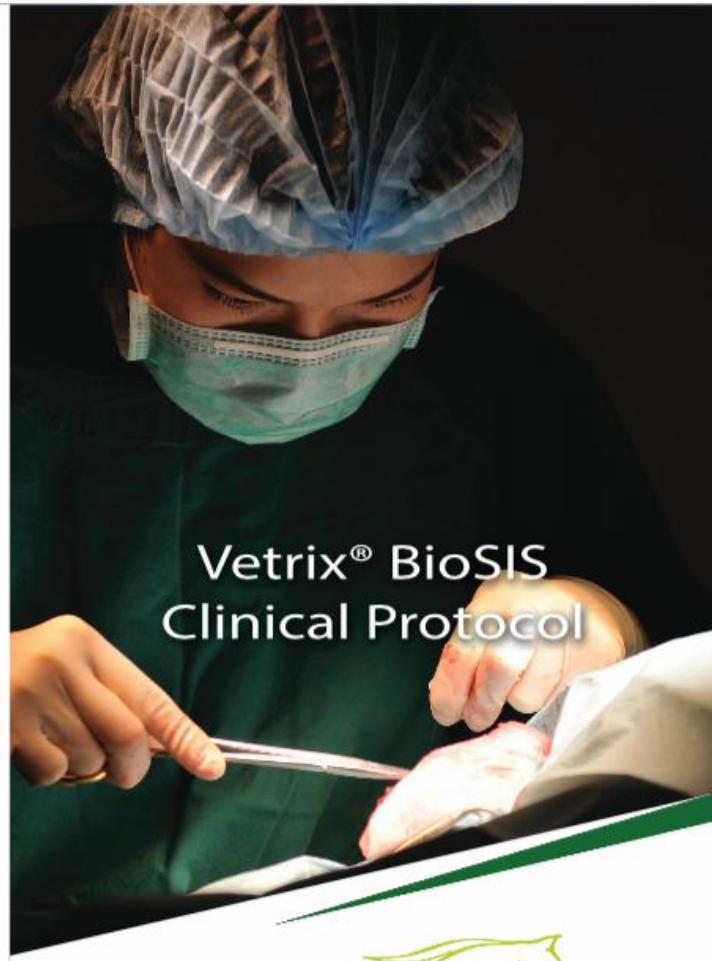

Vetrix® BioSIS Clinical Protocol

VETRIX
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VETRIX® BIOSIS BIOSCAFFOLD

DEVICE DESCRIPTION

VETRIX® BioSIS is derived from porcine small intestinal submucosa (SIS). It is a naturally occurring extracellular matrix (ECM) that maintains and supports a healing environment for wound management.

INDICATIONS

VETRIX® BioSIS is indicated for use in the management of wounds, including but not limited to: partial and full thickness wounds, pressure ulcers, diabetic ulcers, surgical wounds (donor sites/grafts, post laser surgery wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, and skin tears), de-gloving injuries, urinary augmentation, periodontal, general soft tissue/organ repair and tissue reinforcement. This device is intended for one-time use only.

DEVICE APPLICATION

External Use

1. Discontinue the use of all topical medications at the wound site 48 hours prior to the application or use of the device.

2. Clean the wound bed. Remove all necrotic and/or scar tissue, and gently remove or irrigate any exudates. Obtain fresh tissue edges, and control bleeding.

3. Aseptically prepare the site, rinsing thoroughly with sterile saline to remove any residues left from cleaning agents before applying the VETRIX® BioSIS graft.

4. Remove VETRIX® BioSIS from the sterile packaging using standard aseptic/sterile technique. The device can be cut or sized at this time (it is recommended that the sheet be slightly larger than the area to be covered).

5. VETRIX® BioSIS can be rehydrated on the wound or soaked in sterile saline for 2 to 3 minutes before being placed.

VETRIX® BioSIS should be placed directly on the wound bed. If placed on the wound dry, moisten with sterile saline by gentle lavage.

6. In large wounds, more than one sheet of VETRIX® BioSIS may be necessary to obtain complete coverage. Overlap the edges slightly to ensure coverage of the entire wound.

7. Cover the VETRIX® BioSIS with sterile saline soaked non-adhering gauze followed by your standard bandaging procedure. The material and the wound bed should be kept moist.

8. If no adverse reactions occur, the wound should be inspected after 3 to 4 days and exudates removed. Do not remove material that is intact on the wound surface. Gently irrigate the wound to remove any colored exudates. Reapply the sterile saline soaked non-adhering gauze followed by your standard bandaging procedure.

9. Repeat this process every 4 to 5 days until the wound is re-epithelialized. A second application of VETRIX® BioSIS should be considered 2 to 3 weeks following the initial treatment, if not applied during a previous change of dressing. Attention should be given to the tissues surrounding the edges of the wound. As wound healing occurs, redness and swelling will decrease, and drainage will become less. These are signs of wound healing and are often seen before new epithelium is obvious.

10. Re-application of VETRIX® BioSIS can be applied until the desired effect is achieved.

Internal Use

1. Remove the VETRIX® BioSIS ECM Bioscaffold from the sterile packaging using standard aseptic/sterile technique. The device can be cut or sized at this time (it is recommended that the sheet be slightly larger than the area to be covered).

2. The VETRIX® BioSIS ECM Bioscaffold can be rehydrated by soaking in sterile saline for 2 to 3 minutes before being placed.

3. Using standard surgical technique, suture the device into place avoiding excessive tension along the suture line.

VETRIX® BIOSIS OCULAR DISCS

INDICATIONS

VETRIX® BioSIS Ocular Discs are intended, but not limited, to repair and promote healing for patients with corneal ulcers, corneal lacerations, smaller area wound management, organ punctures, and gastro-intestinal suture line reinforcement.

SITE PREPARATION

1. If possible, discontinue the use of all topical medications at the wound site 48 hours prior to the application of the VETRIX® BioSIS.

2. Clean the wound bed. Remove all necrotic and/or scar tissue, and gently remove or irrigate any exudates. Obtain fresh tissue edges by delicately swabbing the corneal surface with a swab.

DEVICE APPLICATION

1. Remove the VETRIX® BioSIS Ocular Disc from the sterile packaging using standard aseptic/sterile technique. The device can be cut or sized at this time (it is recommended that the graft be slightly larger than the area to be covered).

2. VETRIX® BioSIS should be rehydrated for use. This may be done using the wound site to "self-hydrate" the VETRIX® BioSIS graft, or by soaking in sterile saline for 60 to 90 seconds prior to placement.

3. Using standard surgical technique, suture VETRIX® BioSIS into place avoiding excessive tension along the suture line. VETRIX® BioSIS Ocular Discs are to be sutured intermittenly with non-absorbable suture while maintaining intimate contact with the wound bed.

FOLLOW UP

The wound should be re-examined one week after placement. If infection is displayed, culture for bacteria and fungus. Another disc application should be considered.