vet-ConneKt Tissue Matrix

PACKAGE INSERT

DEVICE DESCRIPTION

The vet-ConneKt Tissue Matrix is a sterile, conformable and porous material made of reconstituted collagen derived from equine tendon. The device undergoes proprietary processing to provide resistance to rapid enzymatic degradation, yet capable of fully integrating with the host tissue upon clinical application. It is provided sterile for single use only.

INDICATIONS

The vet-ConneKt Tissue Matrix is indicated for use in the management/reinforcement of surgical or traumatic wounds/repairs to hard or soft tissue, including but not limited to: partial and full thickness wounds, pressure ulcers, diabetic ulcers, surgical wounds, trauma wounds (abrasions, lacerations, second degree burns, and skin tears), de-gloving injuries, urinary augmentation, periodontal, general soft tissue/organ repair and tissue reinforcement. It should be used in non-load bearing applications only for hard tissue repairs.

WARNINGS

- Do not re-sterilize. Once the inner pouch has been opened, any unused product must be discarded.
- Do not use product if the pouch is not properly sealed prior to opening, as sterility may be compromised. Once the inner pouch is opened, use the device immediately. Do not reseal the pouch or reuse the vet-ConneKt Tissue Matrix. Failure to observe these warnings could result in infection of the wound/surgery site.
- vet-ConneKt Tissue Matrix should not be applied until excessive exudates, bleeding, acute swelling, and infection is controlled.

PRECAUTIONS

- Do not use this product without reading and understanding the complete instructions enclosed herein.
- The product is sterile if the package is unopened and undamaged. Do not use if the tamper-evident seal is broken.
- Sterile technique must be practiced throughout the procedure.

DEVICE PREPARATION

Materials Needed:

- Sterile forceps
- 1 x 500 mL (or larger) sterile bowl
- Minimum 100 mL of sterile water or sterile 0.9% saline solution or other rehydration fluid

Note: Rehydrate the product according to the directions below to ensure optimal handling.

1. Examine the expiration date. Do not use if the product is past the expiration date.
2. Remove the product pouch from the outer packaging. Do not place the double-pouched product or outer box on the sterile field.
3. Inspect the product pouch. Do not use if there is evidence that package compromise has occurred.
4. Set up the bowl with 100 mL minimum of sterile water or sterile 0.9% saline on the sterile field.
5. Aseptically break the seal and open the outer pouch away from the sterile field. Drop the sterile inner pouch with product on the sterile field.
6. Using sterile technique, open the inner pouch to expose the vet-ConneKt Tissue Matrix.
7. With a pair of sterile forceps, carefully transfer the vet-ConneKt Tissue Matrix into the rehydration fluid
8. Leave the device in the bowl for a minimum of two minutes.

NOTE: To ensure rapid rehydration, the device may be squeezed and put back in hydration fluid after initial hydration to open the porous matrix. The dressing should remain in the hydration fluid until use.

After initial water/saline hydration, the device may be loaded with any veterinarian preferred secondary fluid, including blood, bone marrow aspirate, platelet rich plasma, antibiotics, etc., prior to clinical use.

vet-ConneKt Tissue Matrix

PACKAGE INSERT

External Use:

1. Prepare wound/surgery site using standard methods to ensure wound is free of debris and necrotic tissue. An initial surgical debridement of the wound may be necessary to ensure the wound edges contain viable, bleeding tissue.
2. To apply, cut the rehydrated vet-ConneKt Tissue Matrix to a size slightly larger than the outline of the wound area. If the wound is larger than a single dressing, then multiple dressings may be used. Overlap adjoining dressings to provide coverage of the entire wound.
3. After application, use an appropriate, non-adherent secondary dressing to maintain a moist environment. The optimum secondary dressing is determined by wound location, size, depth, and veterinarian discretion.
4. The wound site should be periodically inspected (3-4 days) after device application. Do not forcibly remove the device from the wound surface. Dried device over wound margins can be trimmed. Gently clean the wound to remove any exudates, and reapply secondary dressing.
5. Repeat the steps from above (#4) during subsequent follow-up visits until wound is re-epithelialized. A second application of vet-ConneKt Tissue Matrix can be considered if wound is not completely closed after 3-4 weeks of initial treatment, or if a desired outcome is not achieved.
6. Always inspect the wound for signs of infection, and treat accordingly if infection is present; including removal of product, cleaning the wound site with irrigation and antibiotics, and reapplication of new product.

Internal Use:

1. Apply an appropriately sized and hydrated vet-ConneKt Tissue Matrix to the repair site.
2. Secure the vet-ConneKt Tissue Matrix using sutures avoiding excessive tension or gently pack the device into cavitating defects under non-load bearing conditions. For load bearing defects, use vet-ConneKt Tissue Matrix as a tissue augmentation/filler device in conjunction with an appropriate primary load bearing repair (internal/external fixators of user choice).
3. Proceed to close repair site using veterinarian preferred standard techniques and materials.

STORAGE

The device should be stored in a clean, dry location between 5°C and 37°C (41°F and 98°F). Do not expose the product to extreme temperatures. Do not refrigerate or freeze.

STERILIZATION

This device has been terminally sterilized by irradiation and cannot be resterilized.

SAFETY

The vet-ConneKt Tissue Matrix is derived from equine Type I collagen. The manufacturing process for the device meets USA and European Standards for animal tissue sourcing, handling, and inactivation of viruses and transmittable agents. The manufacturing and sterilization processes reduce all infectious agents and provides a sterility assurance level (SAL) of 10^{-6}.

PRODUCT DISCLOSURE

As a result of biological differences in individuals, no product is effective under all circumstances. We will replace any device which is defective at the time of shipment from MLM Biologics, Inc.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed veterinarian. 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 package insert before use.

Manufactured by: MLM Biologics, Inc.
12085 Research Drive
Alachua, FL 32615
Phone/Fax – 1-844-4-MLM-BIO (844-465-6246)
www.mlmbiologics.com
customerservice@mlmbiologics.com