PACKAGE INSERT

ORTHONOVIS CONNECT

DESCRIPTION:

The OrthoNovis Connect is a sterile, conformable and porous wound dressing made of reconstituted collagen derived from equine tendon. It is chemically crosslinked to provide resistance to enzymatic degradation. The dressing is provided sterile for single use only.

For Single Patient Use and Single Occasion Use Only.

Product exposed to E-beam irradiation at a minimum of 25 kGy.

INDICATIONS FOR USE:

The OrthoNovis Connect is a collagen-based wound dressing for the local management of moderately to heavily exuding wounds, including:

- Partial and full thickness wounds
- Draining wounds
- Tunneling wounds
- Pressure sores/ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears)
- Surgical wounds (e.g., donor sites/grafts, post-laser surgery, post-Mohs' surgery, podiatric wounds, dehisced surgical incisions)

Caution: Federal law restricts this device for sale by or on the order of a physician.

CONTRAINDICATIONS

The OrthoNovis Connect is not designed, sold, or intended for use except as described in the Indications for Use section and is contraindicated in the following situations:

- Patients with a known history of hypersensitivity to equine collagen derived materials
- Active or latent infection
- Third degree burns

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 Wound Dressing immediately. Do not reseal the pouch or reuse the OrthoNovis Connect. Failure to observe these warnings could result in infection of the wound site.
- The product is for single use only.
- OrthoNovis Connect should not be applied until excessive exudates, bleeding, acute swelling, and infection is controlled.
- Do not use dressing on any patient who is unwilling or incapable of following postoperative care instructions.
- If using dressing on an area of the body that generally supports weight, ensure that appropriate support measures are used. (i.e. walking boot, cushioning dressing)

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.
- Use sterile, powder-free surgical gloves when handling the wound dressing. Otherwise, rinse powdered surgical gloves with sterile water or saline to remove any glove powder prior to handling the OrthoNovis Connect.
- Use only sterile water or sterile 0.9% saline solution to rehydrate.
- Single patient use only.
- Single occasion use only. ®

POTENTIAL COMPLICATIONS

Complications can occur with any surgical procedure and include but are not limited to:

- Infection
- Allergic reaction
- Chronic inflammatory response (initial application of wound dressings may be associated with transient, mild, localized inflammation)
- Excessive redness, pain, swelling, or blistering

INSTRUCTIONS FOR USE

Application

Note: Rehydrate the Wound Dressing according to the directions below to ensure optimal handling of the Dressing.

Materials Needed:

- Sterile forceps
- 1 x 500 mL (or larger) sterile bowl
- 1 x sterile lint-free towel or drape
- Minimum 100 mL of sterile water or sterile 0.9% saline solution

Procedure:

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 OrthoNovis Connect.
7. With a pair of sterile forceps, carefully transfer the Wound Dressing into the bowl, taking care not to touch the rim or outside of the container.
8. Leave the Wound Dressing in the bowl for a minimum of two minutes. Cover the bowl loosely with a sterile lint-free wrap or towel until ready for application.

NOTE: To ensure rapid rehydration, the dressing 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.

9. Prepare wound area 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.
10. To apply, cut the rehydrated OrthoNovis Connect 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.
11. 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 user preference.

Post-Application

- Change the secondary dressing as needed to maintain moist, clean wound area. Frequency of secondary dressing change will be dependent upon volume of exudates produced and type of dressing used and the clinician's need to inspect the wound bed for signs of infection or healing.

NOTE: If a hematoma or excess exudates collect under the dressing, small openings can be cut in the dressing to allow fluid to drain.

- As healing occurs, sections of the OrthoNovis Connect may gradually peel and or become incorporated with the developing granulation tissue. Do not forcibly remove sections of the OrthoNovis Connect that may adhere to the wound. On inspection, if OrthoNovis Connect is no longer covering the wound, place an additional piece of OrthoNovis Connect over that area of the wound.

NOTE: These recommendations for application are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care. The OrthoNovis Connect cannot be re-sterilized. Discard any unused pieces of OrthoNovis Connect

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 re-sterilized.

SAFETY

The OrthoNovis Connect is derived from equine Type I collagen. Products derived from equine sources are used in several marketed medical devices. The manufacturing process for the OrthoNovis Connect 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 product to sale by or on the order of a physician.

Exclusively Manufactured For:

ORTHONOVIS BIOLOGICS

OrthoNovis, Inc.
1 Hargrove Grade, 2F Palm Coast, Fl 32137
www.orthonovis.com cs@orthonovis.com

Manufactured by MLM Biologics, Inc. 606 SW 3rd Ave Gainesville, FL 32601
Tel: 844-4-MLM-BIO Fax: 844-465-6246 mlmbiologics.com

PN-20-100-C Rev. 06/2020