



Topical Wound Dressing

PRODUCT DESCRIPTION:

ECM³™ Collagen Sponge is a white to off-white, absorbent, porous, sponge-like collagen matrix intended for wound management. The dressing provides a physiologically favorable moist wound environment. When interacting with the wound fluid, the product immediately begins to absorb the exudates. The ECM³™ Collagen Sponge is applied directly to the secreting wound and protects the wound bed and delicate new tissue. In addition, the device, being comprised of hydrophilic collagen, has intrinsic hemostatic properties, which can be used to control minor bleeding.

The product is supplied sterile and for single use only.

INDICATIONS FOR USE:

ECM³™ Collagen Sponge is indicated for the management of moderately to heavily exuding wounds and to control minor bleeding. The ECM³™ Collagen Sponge may be used for the management of exuding wounds such as: pressure ulcers, venous stasis ulcers, diabetic ulcers, acute wounds, e.g., trauma and surgical wounds, and partial-thickness burns.

DIRECTIONS: *(For use under the guidance of a healthcare professional)*

TO APPLY:

1. Cleanse the wound, apply medication to the wound if indicated.
2. Ensure the intact skin surrounding the wound is dry.
3. Apply the dressing to the entire wound surface. The dressing can be hydrated using sterile saline or other isotonic solution.
4. Cover with an absorbent dressing.

CHANGING THE DRESSING:

1. The dressing should be changed as indicated by the amount of drainage (for example, if drainage seeps through the back of the dressing, or if the edge of the dressing becomes loose), and instructions provided with the absorbent cover dressing.
2. Remove the cover dressing.
3. Cleanse the wound.
4. Dry surrounding intact skin.

5. Repeat product application step three listed above as needed.
Do not reuse or reseal.
6. Discard open packaging and unused product.

NOTE: As healing occurs, sections of the Collagen Topical Wound Dressing may gradually peel and may be removed during dressing changes. Do not forcibly remove sections that may adhere to the wound. Alternatively, the product may form a gel, which can be rinsed away with gentle irrigation. On inspection if the product is no longer covering the wound, place an additional piece of the Collagen Topical Wound dressing over the wound.

PRECAUTIONS:

Some reactions such as transitory pain, bleeding, blistering, swelling and redness have been reported in isolated cases using a similar product. If these conditions continue for more than 3-5 days, discontinue use of the product and notify physician.

Do not reseal or re-sterilize. Discard open packaging and unused product per facility hazardous waste protocols.

For topical use only. Not for ophthalmic use. Avoid eye contact.

CONTRAINDICATIONS:

This product is not indicated for patients that have a known allergy or sensitivity to bovine-derived materials (e.g., milk, beef products, leather, etc.).

STORAGE:

Store dry at room temperature.



Advanced Wound Care

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