



Collagen Dermal Matrix

**INSTRUCTIONS FOR USE**

**DESCRIPTION:**

Cohealyx™ Collagen Dermal Matrix is an absorbent, porous, collagen matrix engineered from purified collagen derived from bovine dermal tissue. Cohealyx™ Collagen Dermal Matrix should be applied directly to the wound, covering the entire wound surface. The device may be secured with mechanical means, if necessary.

Cohealyx™ Collagen Dermal Matrix is supplied sterile, non-pyrogenic and for single use only.

**INDICATIONS AND USAGE:**

Cohealyx™ Collagen Dermal Matrix is indicated for the management of wounds, including:

- Full thickness and partial thickness wounds
- Chronic wounds (e.g. pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers)
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, and skin tears)
- Draining wounds
- Partial thickness burns

**CONTRAINDICATIONS:**

This product is not indicated for patients with a known allergy to bovine-derived collagen materials.

**PRODUCT APPLICATION:**

These suggested instructions are provided as general guidance and are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

Cohealyx™ Collagen Dermal Matrix should always be handled using aseptic technique.

Prepare the wound bed to ensure the wound is free of debris and necrotic tissue.

Open package and deliver product to sterile field.

Cut Cohealyx™ Collagen Dermal Matrix to desired size. Multiple pieces may be used to cover the entire wound bed in a single layer.

Hydrate Cohealyx™ Collagen Dermal Matrix in room temperature 0.9% sterile saline.

Apply directly to the wound, covering the entire wound bed. Cohealyx™ Collagen Dermal Matrix may be secured in the wound bed, if necessary.

Use an appropriate, non-adherent, dressing to cover the dermal matrix and secondary dressing(s) to maintain proper moisture level in the wound bed.

Change the dressings as needed based on clinical assessment.

Cohealyx™ Collagen Dermal Matrix is to remain in the wound bed until fully resorbed. Care should be taken when performing dressing changes to not disturb the dermal matrix.

**PRECAUTIONS:**

Cohealyx™ Collagen Dermal Matrix should not be used on infected or contaminated wounds.

Cohealyx™ Collagen Dermal Matrix should be removed if excessive redness, pain, swelling or blistering occurs.

Cohealyx™ Collagen Dermal Matrix may be replaced or reapplied at the clinician's discretion.

Cohealyx™ Collagen Dermal Matrix cannot be re-sterilized or re-used. Open, unused Cohealyx™ Collagen Dermal Matrix must be discarded. In vivo stability may be adversely affected if re-sterilized. Cross-contamination and infection may occur if re-used.

Do not use if the product sterilization barrier or its packaging is compromised.

**ADVERSE REACTIONS:**

Hypersensitivity reactions have been noted with the use of other products containing collagen.

**STORAGE:**

The product should be stored at room temperature (15°C/59°F to 30°C/86°F). Avoid excessive heat and humidity.

**CAUTION:**

Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner.

**HOW SUPPLIED:**

Cohealyx™ Collagen Dermal Matrix is supplied sterile and for single use only. The device is available in a variety of sizes.



Electronic IFU (eIFU): <https://eifu.collagenmatrix.com/>

**SIZES:**

| Product Codes           | Size          |
|-------------------------|---------------|
| BDCDM24 / BDCDM24-5     | 2 cm x 4 cm   |
| BDCDM55 / BDCDM55-5     | 5 cm x 5 cm   |
| BDCDM1010 / BDCDM1010-5 | 10 cm x 10 cm |
| BDCDM1020 / BDCDM1020-5 | 10 cm x 20 cm |
| BDCDM2035 / BDCDM2035-5 | 20 cm x 35 cm |

**LABELING SYMBOLS:**

Symbols may be used on some international package labeling for easy identification.

|  |  |
|--|--|
|  | Use-by date  |
|  | Do not re-use  |
|  | Do not use if the product sterile barrier system or its packaging is compromised             |
|  | Consult instructions for use or consult electronic instructions for use                      |
|  | Sterilized using irradiation   |
|  | Do not re-sterilize  |
|  | Lot number   |
|  | Federal (USA) law restricts this device to sale by or on the order of a physician or dentist |
|  | Catalogue number   |
|  | Temperature limit  |
|  | Non-pyrogenic  |
|  | Manufacturer   |



**Manufacturer:**

Collagen Matrix, Inc.  
15 Thornton Road, Oakland, NJ 07436 USA

**Distributed by:**



AVITA Medical  
28159 Avenue Stanford, Suite 220  
Valencia, CA 91355 USA  
[www.avitamedical.com](http://www.avitamedical.com)