



## **INNOVAMATRIX™ AC INSTRUCTIONS FOR USE AND INFORMATION**

### **Description**

*InnovaMatrix™ AC* consists of extracellular matrix derived from porcine placental material. The device is supplied in a variety of sterile sheet configurations. It is packaged in double peel-open packages and is intended for single use only. The device is terminally sterilized using E-Beam sterilization and is for licensed healthcare practitioner use only.

### **Indications**

*InnovaMatrix™ AC* is indicated for the management of wounds including:

- Partial and full-thickness wounds
  - Pressure ulcers
  - Venous ulcers
  - Diabetic ulcers
  - Chronic vascular ulcers
  - Tunneled/undermined wounds
  - Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
  - Trauma wounds (abrasions, lacerations, second-degree burns and skin tears)
  - Draining wounds
- The device is intended for one-time use.

### **Contraindications**

This device is derived from porcine collagen and should not be used on patients with: sensitivity or allergy to porcine materials; sensitivity or allergy to collagen; or active or latent infection in or around the application site.

This device is not indicated for use in third degree burns.

### **Warnings**

Do not use if packaging is compromised or damaged.

### **Precautions**

- **Single patient, single use only.** Discard all open and unused portions of *InnovaMatrix™ AC*.
- Always use aseptic technique when handling the device.
- Do not re-sterilize.
- Do not use if expiration date has been exceeded.
- Do not apply until excessive exudate, bleeding, acute swelling and infection is controlled.
- Maximum exposure is four devices per treatment.

### **Storage**

This device should be stored in a clean, dry environment at room temperature in its unopened and undamaged original packaging.

### **Sterilization**

The device is terminally sterilized using E-Beam sterilization.

### **Potential Complications**

The following complications are possible. If any of these conditions occur, the device should be removed.

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

### **Human Clinical Data**

Human Repeat Insult Patch Testing and Skin Prick Testing was performed. 58 subjects completed the Human Repeat Insult Patch Testing with no reactions. 23 subjects completed the Skin Prick Testing with 22 subjects exhibiting no reactions. One of the 23 subjects had a low-grade positive reaction at the 15 minute timepoint which resolved to no reaction at the 6 hour and 24-48 hour timepoints.

### **Suggested Instructions for Use**

**NOTE: Always handle *InnovaMatrix™ AC* using aseptic technique.**

#### **I. Wound Bed Preparation**

- A. Prepare the wound bed using standard methods to ensure it is free of exudate and devitalized tissue. An initial excision or debridement of the wound may be necessary to ensure the wound edges contain viable tissue.
- B. Wait for any bleeding to stop before applying *InnovaMatrix™ AC*.
- C. Cleanse the wound thoroughly with sterile saline.

#### **II. Selection and Preparation of *InnovaMatrix™ AC***

- A. Measure the wound and select the appropriate size sheet of dry *InnovaMatrix™ AC*. If necessary, the product may be additionally fenestrated or meshed with a scalpel.
- B. Cut the sheet to a size and shape that will cover the entire wound surface and will extend slightly beyond the wound margins.

### III. Application of *InnovaMatrix™ AC*

- A. For ease of handling, apply *InnovaMatrix™ AC* by placing it in a dry state over the wound.
- B. Position the dry *InnovaMatrix™ AC* to completely contact the entire surface of the wound bed and extend slightly beyond all wound margins. If multiple sheets are necessary to cover the wound, slightly overlap the edges of the sheets.
- C. As required, securely anchor *InnovaMatrix™ AC* with physician's preferred fixation method (e.g., STERI-STRIP™, tissue sealant, bolsters, dissolvable clips, sutures, staples, or other appropriate fixation method) based on the type of wound, location of wound, patient's mobility, and patient compliance.
- D. Thoroughly rehydrate *InnovaMatrix™ AC* by applying sterile saline.
- E. To protect *InnovaMatrix™ AC* from adhering to the secondary dressing, apply an appropriate non-adherent primary wound dressing over the *InnovaMatrix™ AC*.
- F. Apply an appropriate secondary dressing (multi-layer compression bandage system, total contact cast, or other appropriate dressing) that will manage the wound exudate, keep the *InnovaMatrix™ AC* moist, and keep all layers securely in place.

### IV. Dressing Changes

- A. To prevent damage to the newly incorporating *InnovaMatrix™ AC*, only change the primary dressing as necessary, typically every seven (7) days.
- B. Change the secondary dressing as appropriate. Take care to avoid dislodging the *InnovaMatrix™ AC* when the secondary dressing is changed.

### V. Wound Assessment and Wound Bed Preparation for Reapplication of *InnovaMatrix™ AC*

- A. Change all dressings every seven (7) days, or as necessary.

NOTE: If a gel forms on the wound surface, do not attempt to forcibly remove it. Successful absorption of *InnovaMatrix™ AC* may form a caramel-colored or off-white gel. Do not remove this gel by debridement. This caramelization contains extracellular matrix (ECM), which continues to replace deficient and missing ECM in the wound.

- B. As healing occurs, sections of *InnovaMatrix™ AC* may gradually peel. Carefully remove any remaining loose products around the edge as needed.
- C. Gently cleanse the wound surface with sterile saline; leave the ECM gel intact.
- D. Carefully reassess the wound and record healing progression such as wound dimensions, wound depth, wound type, and other relevant information.

### VI. Reapplication of *InnovaMatrix™ AC* and Dressing Changes

- A. Change secondary dressings as needed (see step IV).
- B. If the wound is free of infection and necrosis but not fully epithelialized, reapply newly prepared *InnovaMatrix™ AC* over previously absorbed application (see steps II and III).
- C. Reapply *InnovaMatrix™ AC* every seven (7) days or as needed by repeating previous application steps.

**NOTE: If excess exudate collects under the sheet, small openings can be cut in the sheet to allow the exudate to drain.**

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**CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.**

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| LOT       | Batch Number                                   |
| REF       | Manufacturer's Catalogue Code                  |
|           | Date of Expiry                                 |
|           | Manufacturer's Trade Name and Shipping Address |
| STERILE R | Sterilized by Radiation                        |
|           | Do Not Re-Sterilize                            |
| R ONLY    | For Prescription Use Only                      |