DESCRIPTION:

LacertaMatrix is a single use, non-pyrogenic, flexible, and conformable wound matrix made from alligator-derived hyaluronic acid (HA) and porcine gelatin. **LacertaMatrix** protects, covers, and maintains a moist wound environment to support the body's natural wound healing process. When a clean and moist environment is maintained, the natural wound healing process is characterized by cellular infiltration, capillary growth, and soft tissue formation within the wound bed.

INDICATIONS FOR USE:

LacertaMatrix is indicated for use in the management of the following wounds:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled / undermined wounds
- Surgical wounds (donor sites/grafts, post Moh's surgery, post laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears)
- Draining wounds

CONTRAINDICATIONS:

- Do not use the device in patients with a known sensitivity to materials of porcine (pig) or reptilian (alligator) origin.
- **LacertaMatrix** is not indicated for use on third degree burns.

PRECAUTIONS:

- **LacertaMatrix** is intended for use in a hospital or professional healthcare environment only.
- Do not apply to wounds with uncontrolled clinical infection, acute inflammation, excessive exudate or bleeding.
- Always handle **LacertaMatrix** using aseptic technique.
- **LacertaMatrix** is supplied sterile in a dual-pouch configuration. Both the inner and outer pouch provide a sterile barrier. Do not use if any of the packaging is compromised or if either of the seals are broken.
- Discard the device if mishandling has caused possible damage or contamination.
- Single use product. Do not reuse.
- Do not re-sterilize. Reuse, re-sterilization, reprocessing and/or repackaging may result in device failure and/or patient injury.
- Discard **LacertaMatrix** if past its expiration date.
- Minimize manipulation of the device during rehydration and application.

POTENTIAL COMPLICATIONS:

Allergic reaction, infection, and/or inflammation are possible with the use of this device. If any of the complications occur and cannot be resolved, the healthcare provider should consider removal of the device. Report any serious incident that has occurred in relation to this device to the manufacturer and the authority having jurisdiction in the user's locale.

STORAGE:

LacertaMatrix should be stored at less than 25°C/77°F in a clean and dry area.

INSTRUCTIONS FOR USE:

These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgement concerning patient care.

Wound Preparation:

- Prepare the wound bed by cleansing, irrigation and, if necessary, sharp debridement to ensure the wound is free of debris, necrotic tissue or infected tissue.

Application:

- Select a device size which is slightly larger than the wound. **LacertaMatrix** can be applied as a whole sheet or trimmed so that it contacts the wound margins.
- Multiple devices to a maximum of 200cm^2 may be applied in a single procedure as needed to support the patient's wound size.
- Inspect the packaging to ensure it is intact and undamaged.
- Using aseptic technique, carefully remove the **LacertaMatrix** device from the double pouch configuration.
- Ensure that **LacertaMatrix** conforms to the underlying wound bed. Place the device in maximum contact with healthy, well-vascularized tissue for best results.
- **LacertaMatrix** will resorb into the wound over time (typically over a period of approximately 2 weeks).
- Protect **LacertaMatrix** using an appropriate secondary dressing. Wound type, location, size, depth, amount of exudate, and user preference should be used to determine the optimal dressings.
- Change the secondary dressing as needed to maintain a 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.
- To protect **LacertaMatrix** from adhering to the secondary dressing, consider applying a non-adherent dressing over the device to help protect the tissue while facilitating an optimal moist wound healing environment.

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

Symbols Glossary:

℞ ONLY	Prescription Only
REF	Catalog number
STERILE R	Sterilization Using Irradiation
LOT	Lot Number
	Single Use
	Do not resterilize
	Double-Sterile Barrier with Protective Packaging
	Do not use if packaging is damaged
	Use-by-Date
	Refer to Instructions for Use
BIO	Contains Biological material of animal origin
	Manufacturer
	Distributor

Manufactured For:
Lacerta Life Sciences
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Woodstock, GA 30188
United States

Distributed By:
LMC OPCO, LLC
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