

MIRRAGEN[®]

ADVANCED WOUND MATRIX

Product Description

MIRRAGEN[®] Advanced Wound Matrix is solely composed of bioabsorbable fibers and particles. It is a flexible and moldable wound matrix that can be easily customized to fit the wound bed. The fiber structure of MIRRAGEN Advanced Wound Matrix allows it to absorb fluid from the wound and facilitate natural wound healing.

The bioabsorbable material used in MIRRAGEN Advanced Wound Matrix is a borate glass specially designed for medical applications. The material is biocompatible and will eventually be fully absorbed at the wound site. This resorption process is initiated by the exposure of the material to fluid at the wound site.

Indications for Use

MIRRAGEN Advanced Wound Matrix is intended for use in the management of wounds. Wound types include:

- 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, first and second degree burns, skin tears)
- Draining wounds

The product is designed for single patient/single treatment use only. DO NOT reuse.

Warnings

MIRRAGEN Advanced Wound Matrix is sterile only if the packaging is unopened and undamaged.

DO NOT re-sterilize.
DO NOT use expired product.

Precautions

MIRRAGEN Advanced Wound Matrix is intended to be used under the supervision of a healthcare professional.

Adverse Reactions

Possible adverse reactions may include local irritation, swelling, inflammation, excessive redness, or pain.

Contraindications

The use of MIRRAGEN Advanced Wound Matrix should be discontinued if any adverse reactions are observed.

How Supplied

MIRRAGEN Advanced Wound Matrix is supplied sterile. The material is packaged in a two-piece disposable tray that is sealed in a foil pouch.

Instructions for Use

MIRRAGEN Advanced Wound Matrix is sterile. Use aseptic techniques when applying the dressing.

1. Prepare the wound bed using standard wound cleaning and debridement procedures.
2. Dry the area surrounding the wound.
3. Cut or shape MIRRAGEN Advanced Wound Matrix to fit the size of the wound bed. Place the material directly in the wound, ensuring the entire wound bed is covered.
4. If applying MIRRAGEN Advanced Wound Matrix to a dry wound, moisten the wound bed and/or the material with sterile saline to aid in maintaining a moist wound environment.
5. Per user preference, use appropriate fixation as determined by wound location, size and depth. Add a non-adherent layer to secure MIRRAGEN Advanced Wound Matrix to the wound bed. Place a suitable secondary dressing over the MIRRAGEN Advanced Wound Matrix to manage the wound environment and protect the wound area. The secondary dressing should completely cover the MIRRAGEN material.

6. Reapplication of MIRRAGEN and all secondary dressings should be conducted according to standard wound care practices every 3 to 7 days. Heavily exudating wounds may require more frequent dressing changes.
7. As healing occurs, new tissue may grow into MIRRAGEN Advanced Wound Matrix. This is desirable, DO NOT forcibly remove or debride areas of MIRRAGEN that are embedded or adhered to the wound site. MIRRAGEN Advanced Wound Matrix is 100% bioabsorbable and will eventually be absorbed at the wound site.
8. Loose sections of MIRRAGEN Advanced Wound Matrix may be removed. Apply additional MIRRAGEN material to fill and cover the wound. Moisten the material with sterile saline, as needed.

Storage

Do not expose to excessive heat and humidity.

Shelf-life

Refer to pouch label.

Sterilization

This device has been sterilized with gamma irradiation.

Manufactured by:



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