SiOxMed

SiOxD
Wound Matrix

Description:

The SiOxD Wound Matrix is a non-pyrogenic, sterile, single use device intended for use in local management of wounds. The SiOxD Wound Matrix is a soft, white, conformable, non-woven, absorbent, biocompatible fiber matrix made from synthetic biomaterials. The SiOxD Wound Matrix conforms in the defect space / wound bed and includes a fibrous, porous structure that allows for fluid absorption. The SiOxD Wound Matrix is structurally similar to collagen, a key component of the native extracellular matrix, and serves as a scaffold for cellular infiltration and vascularization. SiOxD Wound Matrix promotes a moist environment for the body's natural healing process.

Only light pressure without mechanical compression or secondary bandaging is required for proper device function. The matrix applied to the wound bed naturally sloughs off during wound healing and does not require manual removal. Reapplication may be performed every 6-24 hrs. To do so rinse with saline and reapply.

Indications for Use:

The SiOxD 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-Moh's surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, first degree and partial thickness burns, skin tears) and draining wounds.

Contraindications:
None known.

Warnings and Precautions:

- Do not use SiOxD Wound Matrix if packaging is damaged or broken prior to use.
- Do not use SiOxD Wound Matrix for a total of more than 30 days.
- Do not use SiOxD Wound Matrix in patients with demonstrated hypersensitivity to silicon dioxide (SiO_2) fibers.
- SiOxD Wound Matrix is supplied sterile. The internal protective plastic container, if used, is not a sterile barrier. This packaging will serve as an effective barrier against contamination until the printed expiration date.
- SiOxD Wound Matrix is single use only. It should not be re-packaged or resterilized. Re-packaging or resterilization may result in damage to the device, device failure, reduced biocompatibility, and complications such as infection. Unused portions of the SiOxD Wound Matrix should be discarded.
- SiOxD Wound Matrix may adhere to the wound bed after prolonged exposure. Removal of adhered material may result in re-injury of the wound bed.
- The device is not designed to be held in place with compression bandages or tapes. Only light pressure without mechanical compression or secondary bandaging is required for proper device function.
- If signs of infection occur, consult a healthcare provider immediately.

Storage:
Store at room temperature in a dry location. Avoid excessive heat or humidity. Refrigeration of SiOxD Wound Matrix is not necessary.

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.

Preparation :

1. Prepare the wound using standard methods to ensure it is free of debris and necrotic tissue. If necessary, surgically debride the wound to ensure it contains viable tissue. Controlled bleeding from the wound is acceptable.
2. The matrix may be peeled in layers and applied up to the maximum depolyable surface area if clinically appropriate.

Application:

3. Apply SiOxD Wound Matrix directly to the wound by gently pressing the matrix onto the wound surface.
4. Apply with light pressure and remove excess material. Excess material may be applied to other wound areas as needed.
5. Ensure full and even contact with the wound bed.

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6. Do not apply a secondary bandage on top of SIOxD Wound Matrix unless required. Leave the treated wound uncovered as much as possible to allow airflow.
7. If dressing is required, use only breathable materials that allow moisture vapor transmission. Avoid occlusive dressings.

Reapplication:

8. The matrix is safe to leave in place for up to 30 days and will slough off naturally during the healing process.
9. The matrix may be reapplied every 6-24 hours. To do so, rinse the wound with sterile saline or clean water to remove accumulated exudate.
10. Do not surgically debride the wound during reapplication of SiOxD. Allow the rinsing process to gently remove exudate and debris.
11. After rinsing, apply new SiOxD Wound Matrix using the method described above.
12. The reapplication process may be repeated at 6–24-hour intervals until the wound is dry, nonexudative or wound closure is achieved.
13. This process should be continued or modified based on clinical evaluation by a qualified healthcare professional.

MAXIMUM DEPLOYABLE SURFACE AREA:

Reference Number	Maximum Depolyable Surface Area
EDS-10014 – 2.5" Round, 0.1g	4.91 in² (31.68 cm²)
EDS-10021 – 2.5" Round, 0.3g	14.73 in² (95.03 cm²)
EDS-10022 – 2.5" Round, 0.7g	34.37 in² (221.74 cm²)
EDS-10053 – 2.5" Round, 1.0g	49.10 in² (316.76 cm²)
EDS-10015 – 4"x4" Square, 1.0g	49.10 in² (316.76 cm²)

How Supplied:
SiOxD Wound Matrix is supplied as follows:
REF: EDS-10062 – Single unit
REF: EDS-10058 – 10-unit carton

Symbols Glossary:

℞ ONLY	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.
REF	Catalog number
STERILE R	Sterilization Using Gamma Irradiation
2	Single Use
	Single-Sterile Barrier with Protective Packaging
LATEX	No Latex in Product
	Do not use if packaging is damaged
	Refer to Instructions for Use
	Non-Pyrogenic

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