

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.

The SiOxD Wound Matrix 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. The matrix applied to the wound bed naturally sloughs off during wound healing and does not require manual removal.

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.
- SiOxD Wound Matrix is supplied sterile. 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.

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:

- Always use aseptic techniques when handling the SiOxD Wound Matrix.
- Remove the dressing from its packaging and place it on a sterile surface.
- 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.
- Trim the SiOxD Wound Matrix to size such that the edges match the edges of the wound bed.

Application:

- Place the SiOxD Wound Matrix in the wound bed.
- Gently smooth the matrix to ensure it is fully adhered to the wound bed. If necessary, trim excess matrix material to ensure the matrix edges match the edges of the wound.

- If placed on bleeding wounds, additional matrices may be applied until bleeding is stopped.
- Rinse the wound with sterile saline, if needed.
- A non-adherent secondary wound dressing (e.g., multi-layer compression bandage system, or other appropriate dressing) can be placed over SiOxD Wound Matrix but is not required. Only light, brief compression is required.

Dressing Changes:

- If secondary dressings are used, it is recommended that clinicians manage dressing changes as appropriate. To prevent damage to the SiOxD Wound Matrix, only change the non-adherent dressing as needed.
- Take care not to dislodge the SiOxD Wound Matrix when the non-adherent and secondary dressings are changed.
- Change the secondary dressing as needed, depending on the amount of exudate produced, type of secondary dressing used, and the clinicians need to inspect the wound for signs of infection or healing.













Wound Assessment:

- SiOxD Wound Matrix persists in the wound bed acting as a protective covering to promote natural wound healing until it naturally and completely sloughs off during the wound healing process within 30 days of application. Do not use the product for a total of more than 30 days.
- As healing occurs, sections of SiOxD Wound Matrix may gradually peel. Carefully trim any remaining loose edges that are not in contact with the wound. Take care not to disturb the area of SiOxD Wound Matrix that is in contact with the wound bed.
- In the event the material does need to be manually removed from the wound bed, use warm (37°C) sterile saline to continuously rinse the wound site to help detach the material, so as not to cause further damage to the wound bed. Forced removal may result in wound reinjury. If used, change the secondary dressings as needed, and when SiOxD Wound Matrix is re-applied.

Reapplication of SiOxD Wound Matrix:

- If the wound is free of infection and necrosis but not fully epithelialized, reapply newly prepared SiOxD Wound Matrix over the previous application.
- Reapply SiOxD Wound Matrix as needed, based on physician or provider discretion, repeating application steps.

Symbols Glossary:

	Catalog number
	Lot number
	Expiration Date
	Sterilization Using Gamma Irradiation
	Single Use
	Dual-Sterile Barrier
	No Latex in Product
	Do not use if packaging is damaged
	Manufacturer
	Refer to Instructions for Use
	Recommended storage temperature
	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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