PHOENIX™ WOUND MATRIX FENESTRATED

PRODUCT DESCRIPTION

The Phoenix Wound Matrix Fenestrated (PWM Fenestrated) is a sterile, single use device intended for the management of wounds. The PWM Fenestrated is a conformable, non-woven, fibrous, three-dimensional matrix. The PWM Fenestrated is made from two types of polymer fibers: Poly(lactide-co-caprolactone) and Polyglycolic acid, which are bioabsorbed after degrading via hydrolysis. The following table represents the available sizes:

Reference #	Size
FG-0021	20cm x 10cm
FG-0022	10cm x 10cm
FG-0023	5cm x 5cm
FG-0024	4cm x 3cm
FG-0025	2.5cm x 2.5cm
FG-0026	1.6cm diameter disc

INDICATIONS

The PWM Fenestrated 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, second degree burns, skin tears) and draining wounds.

CONTRAINDICATIONS

None known.

PRECAUTIONS

- Do not use PWM Fenestrated if packaging is damaged or broken prior to use.
- PWM Fenestrated is supplied sterile. This packaging will serve as an effective barrier against contamination until the printed expiration date.
- PWM Fenestrated is single use only. It should not be re-packaged or re-sterilized. Re-packaging or re-sterilization may result in damage to the device, device failure, reduced biocompatibility, and complications such as infection. Unused portions of the PWM Fenestrated should be discarded.
- PWM Fenestrated may adhere to the wound bed after prolonged exposure. Removal of adhered material may result in re-injury of the wound bed.

ADVERSE REACTIONS

No adverse reactions attributable to this product have been observed.

INTRUCTIONS

Preparation:

- Always use aseptic techniques when handling the PWM Fenestrated.
- 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.
- Trim the PWM Fenestrated to size such that the edges match the edges of the wound bed.

Application:

- Place the PWM Fenestrated in the wound bed.
- Gently smooth the matrix to ensure it is free of air bubbles. If necessary, trim excess matrix material to ensure the matrix edges match the edges of the wound.
- Rinse the matrix and wound with sterile saline.
- Apply an appropriate non-adherent dressing over the PWM Fenestrated.
- Select an appropriate secondary dressing to maintain adherence, protect the wound, and manage the wound environment.
- Additional wrapping and bandaging may be applied as needed.

Dressing Changes:

- Take care not to dislodge the PWM Fenestrated when the non-adherent and secondary dressings are changed.
- To prevent damage to the PWM Fenestrated, only change the non-adherent dressing as needed.
- 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:

- During dressing changes, reassess the wound. Record relevant information such as wound dimensions and wound depth to evaluate the healing progression.
- The PWM Fenestrated persists in the wound bed until it completely degrades via hydrolysis, typically within 7-14 days. It is not meant to be removed.
- In the event that the material does need to be removed from the wound bed, use warm (37°C), sterile saline to continuously rinse the wound bed to help detach the material, so as not to cause further damage to the wound bed. Forceful removal of the PWM Fenestrated may result in reinjury.

Wound Assessment (cont.):

- As healing occurs, sections of the PWM Fenestrated may gradually peel. Loose edges that are not in contact with the wound bed may be gently trimmed. Do not disturb the PWM Fenestrated sections that are in contact with the wound bed.
- If the PWM Fenestrated has completely degraded, reapply a new, sterile PWM Fenestrated. See Reapplication of the PWM Fenestrated below.

Reapplication of the PWM Fenestrated:

- If the wound is free of infection and necrosis, but not fully epithelialized, reapply a newly prepared PWM Fenestrated over the previously absorbed application.
- Reapply PWM Fenestrated every 7-14 days, or as necessary, following the appropriate preparation and application steps.

ADDITIONAL INFORMATION

PWM Fenestrated must be stored in its original packaging, preferably in a cool and dry place (30°C max). Dispose of packaging and unused PWM Fenestrated materials following normal waste disposal procedures.

SYMBOLS

LOT	Lot Number
REF	Reference Number
	Manufacturer Information
	Date of Manufacture
	Maximum Storage Temperature
Rx Only	Caution: US Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.
	Do Not Re-sterilize
	Single Use Only
	Do Not Use if Package is Damaged or Crushed
	Use By Date
STERILE R	Sterilized via irradiation
	Refer to Instructions for Use Before Use

Nanofiber Solutions – 5164 Blazer Parkway – Dublin, OH 43017, USA
Nanofiber Solutions is the exclusive manufacturing partner for Renovoderm

For an electronic version of this IFU, visit:
https://www.renovoderm.tech/IFU

RM-0102 Rev. 02 8/2021