ANTHEM™ WOUND MATRIX FENESTRATED

PRODUCT DESCRIPTION

The Anthem Wound Matrix Fenestrated (AWM Fenestrated) is a sterile, single use device intended for the management of wounds. The AWM Fenestrated is a conformable, non-woven, fibrous, three-dimensional matrix. The AWM 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
AN-0031	20cm x 10cm
AN-0032	10cm x 10cm
AN-0033	5cm x 5cm
AN-0034	4cm x 3cm
AN-0035	2.5cm x 2.5cm
AN-0036	1.6cm diameter disc

INDICATIONS

The AWM 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 AWM Fenestrated if packaging is damaged or broken prior to use.
- AWM Fenestrated is supplied sterile. This packaging will serve as an effective barrier against contamination until the printed expiration date.
- AWM 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 AWM Fenestrated should be discarded.
- AWM 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.

INSTRUCTIONS

Preparation:

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

Application:

- Place the AWM 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 AWM 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 AWM Fenestrated when the non-adherent and secondary dressings are changed.
- To prevent damage to the AWM 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 AWM 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 AWM Fenestrated may result in reinjury.

Wound Assessment (cont.):

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

Reapplication of the AWM Fenestrated:

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

ADDITIONAL INFORMATION

AWM Fenestrated must be stored in its original packaging, preferably in a cool and dry place (30°C max). Dispose of packaging and unused AWM 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