

Hyalomatrix® (Non-Silicone) Hyaluronic Acid Wound Device

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION:
Hyalomatrix (Non-Silicone) is a sterile, flexible, and conformable hyaluronic acid matrix for advanced wound care. It is composed of a non-woven pad made entirely of HYAFF®, a benzyl ester of hyaluronic acid. The biodegradable matrix acts as a scaffold for cellular invasion and capillary growth.

As Hyalomatrix (Non-Silicone) is applied on the wound bed, the HYAFF matrix provides a 3D scaffold able to be colonized by fibroblasts and onto which extracellular matrix components are regularly laid down, facilitating an ordered reconstruction of the dermal tissue.

INDICATIONS FOR USE:
Hyalomatrix (Non-Silicone) is indicated for the management of wounds including:
- Partial and full-thickness wounds
- Second-degree burns
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undetermined wounds
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, skin tears)
- Draining wounds

CONTRAINDICATIONS
Individuals with hypersensitivity to hyaluronan and/or its derivatives.

WARNINGS AND PRECAUTIONS:
- Hyalomatrix (Non-Silicone) does not possess intrinsic bacteriostatic or bactericidal properties and should not be used on wounds that are confirmed as infected.
- If wound infection is suspected but not confirmed, as a standard pre-surgical practice and prior to product application, the treating physician should consider:
  - a topical antiseptic or antibiotic treatment
  - a systemic antibiotic course
- During the time that wound infection is suspected, the wound should be inspected daily.
- If wound infection is confirmed, Hyalomatrix (Non-Silicone) must be removed.
- Hyalomatrix (Non-Silicone) must be used immediately after opening the pouch.
- Hyalomatrix (Non-Silicone) is for single use only. Portions of unutilized product must be discarded. Sterility is guaranteed as long as the package is closed and undamaged.
- In case of damaged primary packaging, do not use the product and report to local distributor.
STORAGE
Store at room temperature.

INSTRUCTIONS FOR USE

APPLICATION:
1. Always handle Hyalomatrix (Non-Silicone) using aseptic techniques.
2. Open the outer pouch and let the inner tray fall onto the sterile field.
3. Open the tray, gently remove the product.
4. Prepare wound bed using standard methods to ensure wound is free of debris and necrotic tissue. If necessary, surgically debride the wound to ensure the wound edges contain viable tissue.
5. Following wound bed preparation, immediately apply the device, keeping it in contact with the wound bed. Hyalomatrix (Non-Silicone) conforms well to wound edges and it can be cut to fit the shape of the wound.
6. Once in place, cover Hyalomatrix (Non-Silicone) with an appropriate, sterile non-adherent, secondary dressing held in place with surgical tape or a bandage as appropriate. The optimum secondary dressing is determined by wound location, size, depth, and user preference. If large quantities of exudate are anticipated, an appropriate absorbent secondary dressing may be required.

POST-APPLICATION (DAY 1-14):
- Inspection of the wound bed is recommended every 3-4 days. During this time frame, patients normally experience a significant reduction in local pain. Frequently, Hyalomatrix forms a yellow-green colored gel that is sometimes characterized by a bad odor. This is the result of the normal degradation process of HYAFF and is not necessarily indicative of a local infection.
- Change secondary dressing(s) as needed – the frequency of secondary dressing change will be dependent upon volume of exudate produced and type of dressing used.
- After the first week, weekly inspections of the wound bed may be sufficient to monitor the repair process.
- When the resorption/integration process of the HYAFF based material has progressed, a well-vascularized granulation tissue becomes clearly visible.

REMOVAL (DAY 14-21):
- It is not necessary to remove the remnants of HYAFF fibers which have not yet resorbed. Nevertheless, should one choose to remove such remnants, the wound should be rinsed with sterile saline prior to gentle removal of the remaining fibers using sterile forceps.
- In case of incomplete healing by day 21, a second application of Hyalomatrix (Non-Silicone) or a tissue graft may be required.

AVAILABLE SIZES
Hyalomatrix (Non-Silicone) is available in various presentations:

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<th>Size</th>
<th>Pouch Count</th>
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CAUTION:
Federal (USA) Law restricts this device to sale by or on the order of a physician or properly licensed healthcare professional.

REF MSS4011NS  REF MSS4022NS  REF MSS4044NS
REF MSS4048NS  REF MSS4088NS

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AML 3000015/A