

HYALOMATRIX®

HYAI URONIC ACID WOUND DEVICE

PRODUCT DESCRIPTION

Hyalomatrix' is a bilayered, sterile, flexible and conformable hyaluronic acid wound device for advanced wound care. It is comprised of a non-woven pad made entirely of HYAFF', a benzyl ester of hyaluronic acid, and a semi-permeable silicone membrane, which controls water vapor loss, provides a flexible covering for the wound surface, and adds increased tear strength to the device. The biodegradable matrix acts as a scaffold for cellular invasion and capillary growth.

As Hyalomatrix is applied on the wound bed, the HYAFF wound contact layer 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 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

Individual hypersensitivity to hyaluronan and/or its derivatives and silicone.

WARNINGS AND PRECAUTIONS

- Hyalomatrix does not possess intrinsic bacteriostatic or bactericidal properties; therefore, it should not be normally used on infected wounds. When wound infection is suspected, the treating physician should consider, as a standard pre-surgical practice and prior to product application, a topical antiseptic or antibiotic treatment associated with a systemic antibiotic course.
- » When wound infection is suspected, daily inspection of the wound should be considered. Should the infection be confirmed. Hyalomatrix must be removed.
- » Hyalomatrix 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 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 from the protective folded sheet.
- 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.
- Following wound bed preparation, immediately apply the device, keeping the fibrous HYAFF-based layer in contact with the wound bed. Hyalomatrix conforms well to wound edges and it can be cut to suit to the shape of the wound.
- 6. Hyalomatrix should be firmly secured using surgical clips, or other mechanical means.
- 7. Do not overlap adjacent Hyalomatrix units.
- 8. Once in place, cover Hyalomatrix with an appropriate non-adherent, secondary dressing. The optimum secondary dressing is determined by wound location, size, depth, and user preference.

Post-Application (day 1-14):

- Inspection of the wound bed is recommended every 3-4 days. During this timeframe, 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 as needed the frequency of secondary dressing change will be dependent upon volume of exudates 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.

Note: if excess exudates collect under the sheet, small openings can be cut in the sheet to allow fluid to drain Removal (day 14-21):

- » Removal of the silicone layer of Hyalomatrix is recommended when the tissue underneath is healed, or ready for grafting. Typically, this process occurs between 14 to 21 days after application.
- » Remove by starting at one corner and pull gently. The silicone layer will easily peel off from the underlying healed tissue.
- » 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 or a tissue graft may be required.

AVAILABLE SIZES

Hyalomatrix is available in various presentations:

REF MSS4022	2.0 x 2.0 in (5 x5 cm)	1 per pouch	10 per box
REF MSS4044	3.9 x 3.9 in (10 x 10 cm)	1 per pouch	1 per box
REF MSS4048	3.9 x 7.9 in (10 x 20 cm)	1 per pouch	1 per box

Caution: Federal (USA) law restricts this device to sale by or on the order of a Physician or Practitioner.

www.medline.com

©2014 Medline Industries, Inc.

HYAFF° is a registered trademark of Anika Therapeutics S.r.l.

Hyalomatrix' is a registered trademark of Fidia Farmaceutici S.p.a.

Made in Italy for Medline Industries, Inc., Mundelein, IL 60060 USA.

1-800-MEDLINE RJ14ANK