Instructions for Use

Hyalomatrix®

Hyaluronic Acid Wound Device

This Instructions for Use is intended exclusively for distribution within the United States.
In an effort to best meet the needs of our customers and minimize waste, these Instructions for Use are being provided in electronic format. This document is subject to change; the most current version of this IFU is available online. If unsure if using the latest revision, please reprint the IFU at www.anikaifu.com. If a paper copy is preferred it may be requested, free of charge, by contacting Anika Therapeutics, Inc. at www.anikaifu.com. The onus resides with the user to ensure that the most up to date IFU is used.

Products may not be available in all markets. Product availability is subject to the regulatory clearance in individual markets. Please contact your local representative if you have questions *about product availability in your area.*

℞ ONLY

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician or properly licensed healthcare professional.

Read these instructions completely prior to use.

PRODUCT DESCRIPTION
Hyalomatrix® is a 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, which provides a flexible covering for the wound surface. The biodegradable matrix acts as a scaffold for cellular invasion and capillary growth.

INDICATIONS FOR USE
Hyalomatrix is indicated for the management of wounds including:

- Partial and full-thickness wounds
- Partial thickness 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

INTENDED PATIENT POPULATON
Hyalomatrix is intended for use in adult patients (18 years of age and older).

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

WARNINGS AND PRECAUTIONS

- Safety and effectiveness of Hyalomatrix have not been established for the indications described in this labeling in patients younger than 18 years old.
- Discontinue the use of the device if signs of fever are observed.
- 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. Do not expose to excessive heat and humidity.

INSTRUCTIONS FOR USE

APPLICATION INSTRUCTIONS:

1. Open the outer pouch and let the inner tray fall onto the sterile field.
2. Open the tray, gently remove the product.
3. 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.
4. Following wound bed preparation, immediately apply the device, keeping it 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. Overlap edges up to 1cm to create a fixation edge.
5. Reapplication of Hyalomatrix and all secondary dressings should be conducted according to standard wound care practices every 3 to 7 days. Heavy exudating wounds may require more frequent dressing changes.

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STERILE R	Sterilized using irradiation	REF	Catalog number
	Single Sterile barrier system with protective packaging inside	LOT	Lot number
	Do not resterilize		Use by date
	Do not re-use		Date of manufacture
	Do not use if package is damaged and consult instructions for use		Manufacturer
	Keep Dry	UDI	Unique Device Identifier
 www.anikaifu.com	Consult electronic instructions for use		

FOR FURTHER INFORMATION

If further information on this product is needed, please contact Anika Customer Service at 1-888-721-1600 in the U.S., or an authorized representative.

Manufacturer:

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