

WoundGelHA Matrix™ (Medical Device)

A Sodium Hyaluronate (2.5%) Based Wound Dressing
For External Use Only

Description:

WoundGelHA Matrix™ is formulated to provide wound care dressing and management.

WoundGelHA Matrix™ is a combination of emollients and sodium hyaluronate which function to maintain tissue hydration and support the healing process.

WoundGelHA Matrix™ has been demonstrated to be of value in the management of certain skin ulcers. Sodium hyaluronate is a salt of hyaluronic acid, a naturally occurring molecule found in various body tissues. The sodium hyaluronate present in **WoundGelHA Matrix™** is derived from synthetic sources.

Ingredients:

Sodium Hyaluronate (2.5%), hydroxyethylcellulose, Methylparaben, Polyethylene Glycol, Water.

Indications and Usage:

Under the supervision of a Healthcare Professional: **WoundGelHA Matrix™** [(based on FDA 510(k) K143527)] is indicated for management of wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative incisions and donor sites), mechanically or surgically debrided wounds, and for second degree burns.

OTC indications covered based on 510(k) K143527:

WoundGelHA Matrix™ is indicated for management of minor burns (1st degree burns), minor abrasions, minor cuts and helps to relieve dry waxy skin irritations associated with dry skin conditions.

WoundGelHA Matrix™ is a patented, highest available concentration of pharmacopoeial grade (molecular weight > 540,000 daltons) sodium hyaluronate (2.5%; bio-fermented, not animal-sourced) which is formulated in a non-ionic, stable, polymer matrix to improve stability, and moisture wound healing properties. The 2.5% pharmacopoeial grade sodium hyaluronate (99% purity; average molecular weight of 540,000 to 800,000 daltons) mimics the potency and healing benefits of natural hyaluronic acid in the human body.

WoundGelHA Matrix™ is a licensed 510(k) medical device.

Contraindications:

WoundGelHA Matrix™ is contraindicated in persons with a known hypersensitivity to any of the ingredients in the formulation.

Warnings:

Prolonged use of the product may give rise to sensitization phenomena. Should this occur, the patient should discontinue use of the product immediately and consult a physician.

Precautions and Observations:

- **WoundGelHA Matrix™** is for external use only.
- If signs of infection become present, consult a physician.
- Keep this and all medications out of the reach of children.

Supportive Care:

Appropriate supportive measures should be taken where indicated (e.g., the use of graduated compression bandaging in the management of venous leg ulcers) or pressure relief measures in the management of pressure ulcers. The control of blood glucose as well as appropriate advice regarding pressure relief measures should be provided to patients with diabetic foot ulcers. Colonization of chronic wounds is common and the use of **WoundGelHA Matrix™** is not contraindicated. **WoundGelHA Matrix™** may be used on infected wounds under medical supervision and in conjunction with other appropriate therapy and frequent monitoring of the wound by the healthcare professional.

Instructions for Use:

WoundGelHA Matrix™ should be applied after the ulcer or wound is cleaned with normal saline solution. Other cleaning agents are not recommended. Debridement (surgical cleaning) of the ulcer or wound may be performed at the discretion of the healthcare professional. Excess moisture should be removed using dry gauze. **WoundGelHA Matrix™** is applied liberally into the cavity of the ulcer or wound and to the surrounding area. After applying **WoundGelHA Matrix™**, a non-stick gauze dressing should be placed on the wound site then covered by an occlusive dressing. A gauze dressing should always be placed on the wound after applying **WoundGelHA Matrix™**. A self-adhesive bandage or suitable tape adhesive should be wrapped over the non-stick gauze dressing. The entire process of wound cleaning, applying **WoundGelHA Matrix™**, the application of a suitable covering and the bandaging of the area should be repeated weekly or as prescribed.

How Supplied:

WoundGelHA Matrix™ in a single 1/3oz. tube or three pack of 1/3oz. tubes (1oz. total) with tamper evident seal. Do not use if tamper evident foil seal is broken or missing. Expiry date is located on the crimped end of the tube.

Storage:

Store at room temperature, 15°-30°C (59°-86°F) in a dry place. Do not freeze or expose to temperatures above 30°C (95°F).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN **WoundGelHA Matrix™** covered by Patent Nos. 9,821,005 • 10,322,142.

MAGNA
Pharmaceuticals, Inc.

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WoundGelHA Matrix™

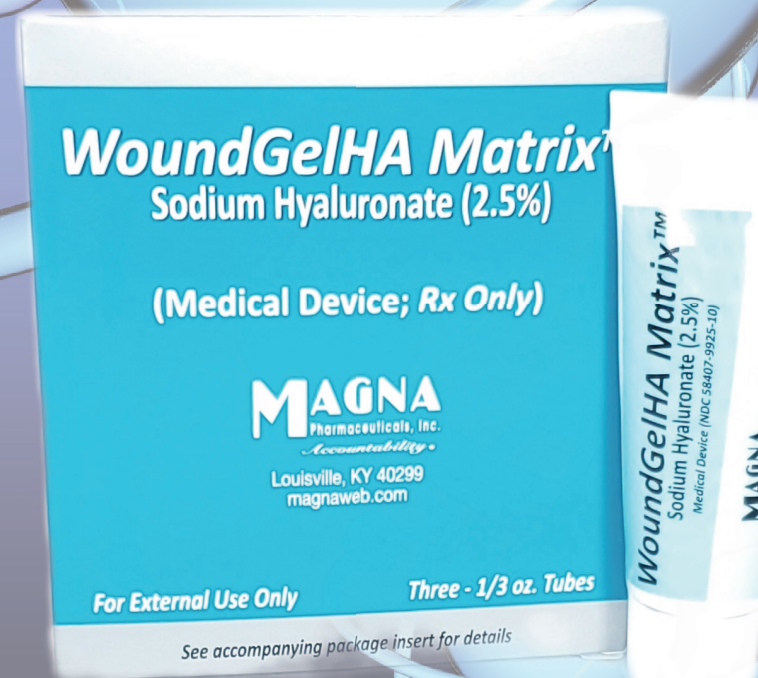
Rx Medical Device

For Use in the Management & Healing of Wounds

Benefits

- Less frequent dressing change, every 5 to 7 days. Saves staff time & supplies.
- Decreased potential for wound contamination.
- Facilitates refractory wound healing.

**2.5% Hyaluronic Acid
Polymer Matrix**



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WoundGelHA Matrix™

(Rx Medical Device for External Use Only)

1. **WoundGelHA Matrix™ (WGHA)** hyaluronic acid (HA) is an ideal low molecular weight (approximately 500,000 daltons).
 2. **Patented**, biosynthetic, nonionic, polymer matrix enables manufacture of HA potency & stability.
 3. Helps restore a natural environment within the skin to facilitate the healing of refractory wounds.
 4. Gel viscosity facilitates application/penetration down into the wound.
 5. The nonionic polymer successfully forms a polymer matrix with HA.
 6. WGHA increases local hyaluronic acid levels, which enhance wound healing.
 7. WGHA contains a combination of emollients that help restore and maintain hydration and balance within the tissue to promote healing.
 8. Weekly, easy, applications (every 5 to 7 days; just apply and cover with occlusive dressing).
 9. High quality, affordable price.
- See references to support #1-9 above.*

For Use in the Management & Healing of Wounds

- Decubitus (Pressure) Ulcers
- Diabetic Ulcers
- Surgical Wounds (Post-operative Incisions & Donor Sites)
- Leg Ulcers (including Venous Stasis ulcers)
- Second Degree Burns
- Mechanically or Surgically Debrided Wounds

Wound Treated July 26-November 14



July 26th

August 2nd

November 14th

“With the conclusion of the study, the PI was satisfied that more than 85% of the [refractory] subjects had their wounds closed or improved, particularly when 5 [of 20] patients had their wounds closed after an average of 15 weekly wound gel treatments.” - Chan, M.

Wound Treated August 25-November 7



October 17th

August 25th

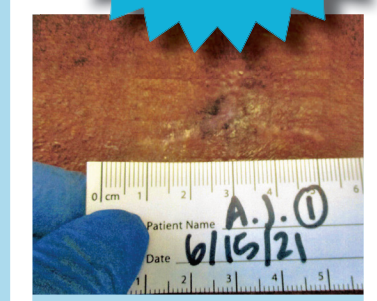
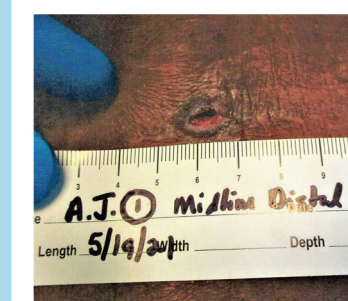
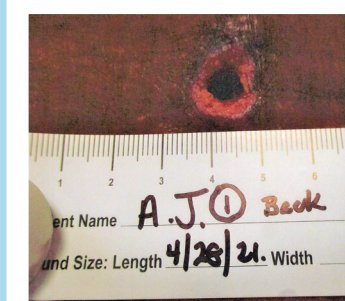
November 7th

Instructions for Use

- Clean wound area with normal saline solution (other cleaning agents are not recommended). Remove excess moisture. Debridement (surgical cleaning) of the ulcer or wound may be performed at the discretion of the healthcare professional.
- Excess moisture should be removed using dry gauze.
- Apply **WoundGelHA Matrix™** liberally into the cavity of the ulcer or wound and to the surrounding area.
- Cover area with non-stick gauze dressing then cover by an occlusive dressing.
- Repeat the above process every 5-7 days or as prescribed.

**Dressing Only
Needs To Be
Changed Every
5-7 Days!**

Wound Treated April 28-June 15, 2021



I am a board certified hyperbaric physician based out of Dallas, Texas. My staff and I love WoundGelHA Matrix. We have experienced positive outcomes for most patients with varying wound etiologies. In our office we fondly refer to WoundGelHA Matrix as “The Closer.” This product is a must resource for limb salvage - (Dr. S. Payseur, MD, email message to author, August 2, 2021).

Wound Treated April 1-April 30



April 1

April 16

April 30

April 30

“The results showed that the hyaluronic acid gel may improve the time to heal of the incision lines compared to those treated with standard of care and reduces complication rates...” - Mayer, P.V.

References:

Chan, M. (2016) *Evaluation of the Cost Effectiveness of the Use of Ionic Polymer Matrix (IPM) Wound Gel Bio.* Mayer, P.V. (2015) *Hyaluronic Acid Gel Improves Wound Healing in Diabetic Patients After Digit Amputations.* Drizen et al., “Polymer Matrix Compositions Composing a High Concentration of Bio-fermented Sodium Hyaluronate and Uses Thereof,” US Patent 10,322,142 B2, June 18, 2019.