

MIRRAGEN[®]

ADVANCED WOUND MATRIX



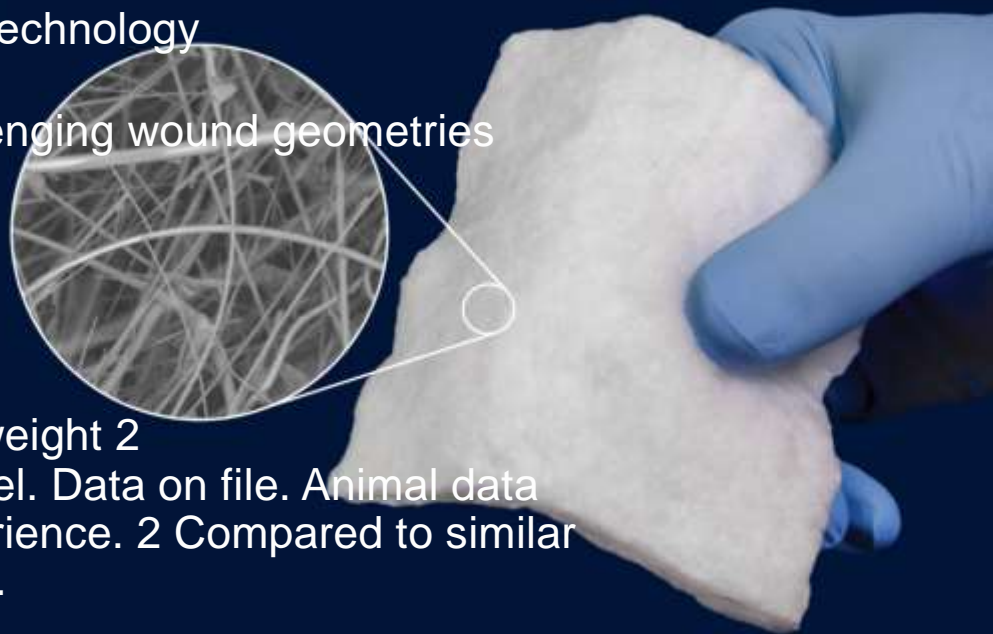
MIRRAGEN[®]

ADVANCED WOUND MATRIX

- Innovative bioactive resorbable glass fiber technology
- Flexible, moldable – easy solution for challenging wound geometries
- Resembles fibrin clot microstructure
- Up to 40% faster healing^{1, 2}

• Absorbs up to 400% moisture exudates by weight²

¹ Full-thickness, porcine wound healing model. Data on file. Animal data may not be reflective of human clinical experience. ² Compared to similar devices in head-to-head testing. Data on file.



Indicated for professional use for partial and full-thickness wounds, such as:



1.Diabetic ulcers;

8.Operational wounds ;

2.Venous ulcers;

9.Partial and complete wounds;Oozing wounds;

3.Cronic vascular uncers;

10.Penetrating wounds; Torn wounds ;Dry wounds;

4.Pressure ulcers;

11.War injuries ;

5.Pediatrics;

12. Trauma wounds (abrasions,lacerations, skin tears)

6.Ginecology and Obstetrics;

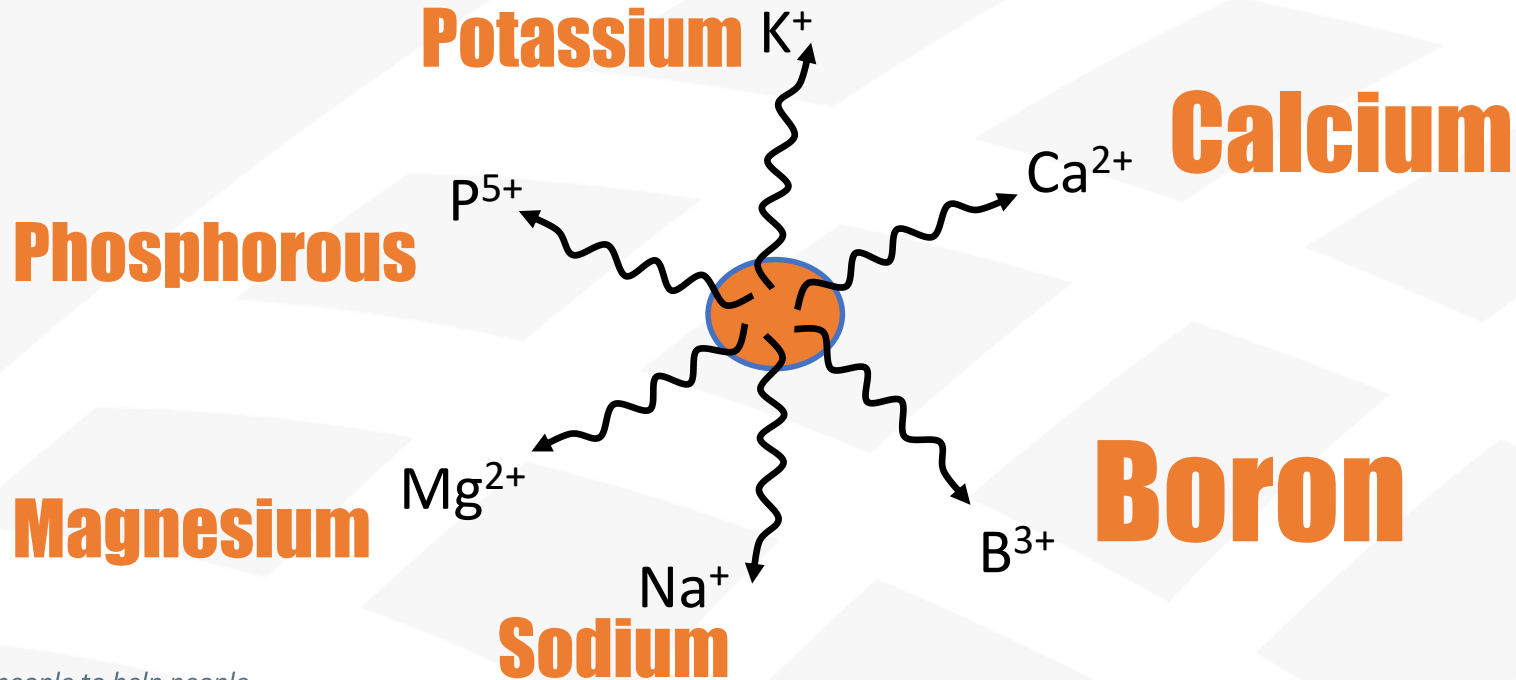
13.Surgical wounds ,donor sites ,grafts ,post-Moh's surgery ,post laser surgery.

He 7.Cosmetology;

14.Burns 1 and 2 degrees.

MIRRAGEN – WAHT CONSISTS OF?

New and innovative wound care solution, made of soft , molded, biocompatible resorbable biologically active borate glass.








Borate glass.

- Innovative inorganic synthetic biologically active material, which causes a specific biological reaction at the interface of the material which leads to the formation of a bond between the patient's tissues and the material.
- Silicate part is used to restore bone.
- The borate portion is used to repair soft tissue.

How does it work MIRRAGEN?

- Physically absorbs wound exudate.
- Fiber is completely soluble in wound fluid / layer, releasing its powerful ionic constituents which:
 - initiate hemostasis phases (Ca²⁺)
 - promote recovery ECM, collagen, cytokines (BMP, FGF), MMPs (B3+, Ca²⁺)
 - provide cellular energy to the building block, ATP (P5+)
 - acid-base balance control (Na+, P5+, K+)
 - promotes angiogenesis (B3+)
 - inhibition of inflammation (B3+)
 - minimizing infectious organisms, bacteria and fungi (B2+)

Restores the healing environment in chronic wounds and wounds with impaired trophic.

	 <p>Acell MicroMatrix</p>	 <p>Organogenesis Dermagraft</p>	 <p>Medline Hyalomatrix</p>	 <p>MiMedix EpiFix</p>	 <p>MIRRAGEN Advanced Wound Matrix</p>
Material	bllder collagen xenograft	Bioabsorbable fibroplasts	Hyaluronic acid + silicone layerr	amnion allograft	Synthetic inorganic borate glass
Intended for chronic wounds					
synthetic					
Translucent					
Storage without special requirements					
No effect on the immune system					
Easily tolerated by the patient					
absorbs liquid					
Antibacterial					
Average price per cm \$ per square cm	~\$150/cm ²	~\$187/cm ²	~\$40/cm ²	~\$237/cm ²	~\$15/cm ²

Summary

Intended for the treatment of difficult and long-lasting chronic wounds.

- A product of nano technology in the field of surgery. Bioactive inorganic synthetics,
- Organic free.
- By 40% speeds up the healing process.
- Reduces the frequency of dressings.
- Flexible compatible with complex wound geometries.
- Absorbs up to 400% wound exudates.
- Soluble -absorbed by the body.
- Translucent (x-ray).
- Shelf life, 5 years
- No storage requirements.

Healing people to help people



Storage and use

- No special requirements for product storage (enough room temperature conditions). Moisture balance is very important for quick healing.
- Direct dry processing or manipulation can separate fine particles from the matrix without any negative impact on the product.

PREPARATION FOR USE

- Remove necrotic or devitalized tissue from the wound before initial use MIRRAGEN.



APPLICATION

- To apply simply cut or tear off the part necessary to fill the wound surface ,(using sterile healthcare).
- Fill sinus wound tunnels with product.
- When treating a large wound,gause can be used as a filler, but MIRRAGEN should completely cover the surface of the wound.



During treatment

- MIRRAGEN may change color upon contact with wound fluid.
- MIRRAGEN, most likely will resemble the appearance of wet pescp and may be yellowish discolored in subsequent changes to the dressing.
- Do not be alarmed if the appearance of elements of old skin is present . This is part of the process, as it MIRRAGEN absorbs wound components.
- Soon the matrix material will differentiate and granulation tissue will form.
- After the first use ,cover with a sterile adhesive or bandage.
- Change the dressing once a week and add the product if necessary (usually double use for very deep wounds)



PRODUCT USE CASES

Pressure Injury

Patient: 60 y/o male. Dorsal foot – Contracture

Age of Wound: Unknown

at the beginning



after 2 weeks



after 3 weeks



Diabetic Foot Ulcer

Patient: 80 y/o male. Plantar foot – Metatarsal head
Age of Wound: 1 year

at the beginning



after 3 weeks



after 5 weeks



Pressure Injury

Patient: 80 y/o female. Left lateral malleolus. Acute (recurrent) Venous Stasis + PAD.
Previous Revascularization. Multi-layer Compression Therapy.
Age of Wound: Unknown

at the beginning



after 4 weeks



Pressure Injury

Patient: 80 y/o female. Right lateral malleolus. Acute (recurrent) Venous Stasis + PAD.
Previous Revascularization. Multi-layer Compression Therapy.
Age of Wound: Unknown

at the beginning



with MIRRAGEN®



after 11 weeks



Ischial Ulcer

Patient: 62 y/o male. Paraplegic.
Age of Wound: 8 months

at the beginning



with MIRRAGEN®



after 8 weeks



Pressure Injury

Patient: 82 y/o male. Right BKA. Prosthesis-related injury.

Age of Wound: Unknown

at the beginning



after 8 weeks



after 15 weeks

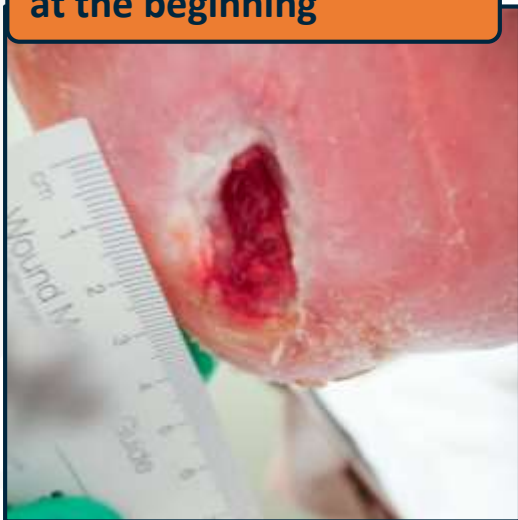


Diabetic Foot Ulcer

Patient: 52 y/o male. Insulin dependent diabetic, peripheral neuropathy, hypertension, renal failure on hemodialysis; history of chronic foot wounds.

Age of Wound: > 1 year

at the beginning



after 1 weeks



after 5 weeks



Venous Leg Ulcer

Patient: 62 y/o male. Non-insulin dependent diabetes, venous insufficiency, peripheral neuropathy, HTN, CHF, COPD, asthma.

Age of Wound: 3 months

at the beginning



after 6 weeks



after 15 weeks



Pressure Injury

Patient: 44 y/o male. Paraplegic. Frail with contractures and muscle wasting; tube fed, incontinent, dependent for all care.

Age of Wound: 4 months

at the beginning



after 4 weeks



after 23 weeks



Deep Tissue Injury (Traumatic)

Patient: 68 y/o female. Diabetes, peripheral neuropathy, and venous insufficiency.

Age of Wound: 4 months

at the beginning



after 11 weeks



after 14 weeks



Venous Stasis Ulcer

Patient: 43 y/o female. Presented with extreme wound odor that resolved after 3 visits. Morbid obesity, hypertension, hypothyroidism, lymphedema, and venous insufficiency; denies other health problems. Age of Wound: Approx. 3–4 months

after 1 weeks



after 7 weeks



after 19 weeks



Traumatic Injury

Patient: 70 y/o female. Obesity, diabetes, PVD, PAD, neuropathy, heart disease, and venous insufficiency.

History of smoking, chronic foot wounds and recurring infections.

Age of Wound: 2 months

at the beginning



after 5 weeks



after 30 weeks



Cerebrospinal ligament of the lumbar spine.Lower flaccid paraparesis.Double-sided rigid valgus.Trophic ulcer of the soft tissues of the right heel deep to the calcaneus

Patient: girl ,6 years old.

Time period for the presence of a wound:2,4 months.

Application of Mirragen 11.02.19

at the beginning



29 day



43 day



Calcaneus osteomyelitis with severe trophic ulcer of the heel and soft tissue defect.

Patient: boy ,12 years old.

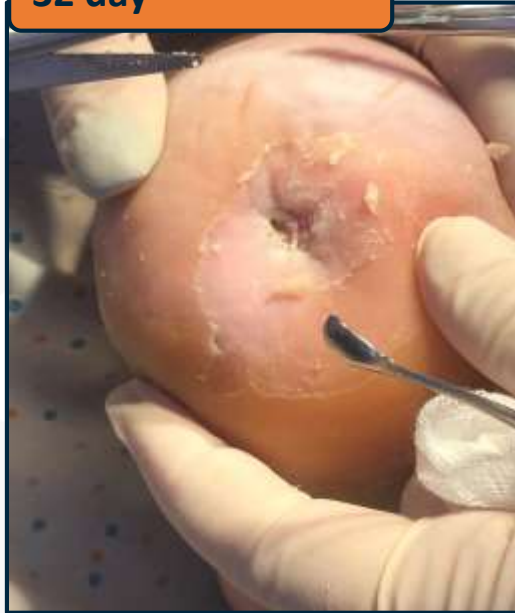
Time period for the presence of a wound:1,5 years.

Application of Mirragen 15.02.19

at the beginning



32 day



68 day



Pressure Injury

Patient: boy ,14years old.

Time period for the presence of a wound:6 months.

Application of Mirragen 26.03.19

at the beginning



21 day



30 day



VPR CNS POSTERIOR CEREBRAL HERNIA.INTERNAL HYDROCEPHALUS

Patient: girl ,6 months.

Time period for the presence of a wound:6 months.

Application of Mirragen 03.04.19

at the beginning



11 day



52 day



Decubitus soft tissue in the coccyx. Pressure sores

Patient: girl ,10 years old.

Time period for the presence of a wound:1,5 months.

Application of Mirragen 09.08.19

at the beginning



6 day



48 day



Extensive ankle wound.Laceration of the ankle due to an accident

Patient: boy ,12 years old.

Time period for the presence of a wound:1,5 months.

Application of Mirragen 25.09.19

at the beginning



8 day



65 day



VAST WOUND AFTER ROAD A TRANSPORT INCIDENT

Patient: boy ,12 years old.

Time period for the presence of a wound:1,5 months.

Application of Mirragen 25.09.19

at the beginning



1 day



7 day



Extensive wound of the leg. Scalped wound of the lower leg due to an accident

Patient: boy ,12 years old.

Time period for the presence of a wound:1,5 months.

Application of Mirragen 25.09.19

at the beginning



8 day



58 day



Burn, State after burn 3 degrees

Patient: women

Time period for the presence of a wound: 1,5 months.

Application of Mirragen 12.06.19

at the beginning



8 day



45 day



Condition after resection of the coccyx cyst

Patient: boy ,14 years old.

Time period for the presence of a wound:postoperative suture.

Application of Mirragen 05.04.19

at the beginning



1 day



5 day



Condition after resection of the coccyx cyst

Patient: boy ,15years old.

Time period for the presence of a wound:postoperative suture.

Application of Mirragen 08.04.19

at the beginning



1 day



5 day



Neurotrophic foot ulcer

Patient: men ,65 years old.

Time period for the presence of a wound:6 months.

Application of Mirragen 20.11.19

at the beginning



1 day



7 day



INTERDIGITAL PHLEGMON (DIABETES MELLITUS)

Patient: women 79years old

Time period for the presence of a wound:3 months.

at the beginning



1 day



5 day



SOFT TISSUE INJURY (COMPLICATED BY AIDS)

Patient: men ,46 years old.

Time period for the presence of a wound:6 months.

at the beginning



1 day



8 day



Diabetes mellitus,diabetic foot

Patient:woman 60 years old

Time period for the presence of a wound:

Application of Mirragen 30\09\2019

at the beginning



8 day



21 day



POSTOPERATIVE FISTULA. Adenocarcinoma of the stomach. Gastrectomy.

Patient: Woman ,70 years old.

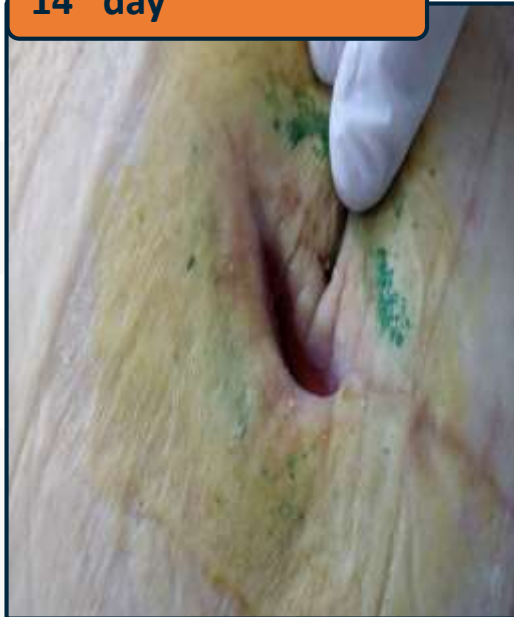
Time period for the presence of a wound:3,5 months,после after gastrectomy

Application of Mirragen 14.03.19

at the beginning



14 day



44 day



TROPHIC ULCER OF THE LEG

Patient: men ,75 years old.

Time period for the presence of a wound:2 years.

at the beginning



14 day



21 day



TROPHIC ULCER OF THE LEG

Patient: Woman ,48 years old.

Time period for the presence of a wound:3 months

Application of Mirragen 7.03.19

at the beginning



48 day



80 day



Childhood cerebral palsy (disabled childhood).Open fracture of the lower left femur.

Patient: boy ,7 years old.

Time period for the presence of a wound:6 months.

at the beginning



14 day



28 day





ISO 9001:2015

CERTIFICATE OF CONFORMITY
Full Quality Assurance System
(Technical regulations on medical devices, Annex 3, excluding items 8-11)

UA.TR.039.822

Manufacturer: ETS Wound Care,
13210, Dillon Outer Road Rolla, MO 65401, USA;

Products: Microfiber matrix for healing wounds MIRRAGEN™
1*6", (2,5*15,2 cm);
Microfiber matrix for healing wounds MIRRAGEN™
2*2", (5*5 cm);
Microfiber matrix for healing wounds MIRRAGEN™
4*4", (10,1*10,1 cm)
class IIb, according to Annex 2 of the Technical Regulations on
Medical Devices.

Notified Body SE "UMCC" declares that aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the products in accordance with Annex 3, excluding items 8-11, of the Technical Regulations of Medical Devices, approved by the Resolution of the Cabinet of Ministers of Ukraine dated 02.10.2013 № 753. The quality management system conforms to the relevant provisions of this Technical regulations and is subject to periodical surveillance.
For marketing products with risk class III, additionally a Design Examination Certificate is mandatory.

Report: № 822/0/0 date 03.12.2018.

Date of issue: 14.12.2018

Valid till: 13.12.2023

Acting director of The Notified Body



G. Martynenko



The validity of the Certificate can be verified in the database of the Notified Body (www.umcc.org.ua)

Notified Body State Enterprise "Ukrainian Medical Center of Certification" (SE "UMCC")
legal address: 02160, Ukraine, Kyiv, avenue of Vozzhdennyya, 7-a, actual address: 01042, Kyiv, Chyhyrnia Str., 18; tel. (044) 285 83 83
SE "UMCC" is notified for carrying out the conformity assessment for compliance with technical regulations
(Order of Ministry of Economic Development dated 29.08.2014 № 1044, the number of the notified body UA.TR.039)
Accredited by National Accreditation Agency of Ukraine for certification of quality management systems and conformity assessment
(Accreditation Certificates №80015 and №10101)

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