

# MIRACLE DRESSING<sup>™</sup>

WOUND CARE SYSTEM

# Overview and Case Studies

#### MDS Case Studies and Before/After Photos

#### Case Study: Second and Superficial Third Degree Burns

A nine year old patient sustained 2nd and superficial 3rd degree burns on his buttocks and a 2nd degree burn on his back. The superficial 3rd degree burn covered 10% of his buttocks.

He was treated at a major burn center using standard burn care. The boy was sent home to have his parents change his dressing on a daily basis. Four days of these daily wound changes severely traumatized the patient and the wound. The boy refused to allow another wound change and was referred for MDS placement.



Total disruption of 2nd and superficial 3rd degree burn wounds by standard wound care.



Miracle Dressing Wound Care System in place on April 12th. The boy no longer experienced pain.



Miracle Dressing Wound Care System was removed after 21days, at which time the wound was healed, no scars.

### Case Study: Pressure Injury Wound Care

A retired 87 year old man's health had declined and he became more wheel chair dependent and bed bound, eventually developing Stage 1 and Stage 2 sacral and buttocks pressure wounds, secondary to atrophic skin. Standard wound dressing changes disrupted the surrounding skin and enlarged the wound.



Miracle Dressing Wound Care System was applied across the entire affected area on October 3.



Miracle Dressing Wound Care System was removed after 21 days. With typical wound care treatments, these wounds may never have healed to this extent.

# Case Study: Bruise (Ecchymoses) and Skin Tear

#### Leona S. Lower Leg Bruise Case Study



95 + year old patient fell 4 days prior to coming into the office with a skin tear and heavy bruising.



The 21-day breathable, stay-in-place Miracle Dressing System was then applied.



The Miracle Dressing was intact and still in place after 20 days.



The Miracle Dressing was carefully removed with isopropyl alcohol.



The Miracle Dressing in the process of being removed with isopropyl alcohol.



The vastly improved speed and quality of healing was evident the skin's condition, mimicking the skin quality of a 50-year-old.

#### Case Study: Skin Tear on Elderly Patient's Elbow

An 87 year old patient sustained a skin tear on her elbow three days before arriving for treatment.

Wounds near joints have extreme difficulty healing and marked increased propensity to get infected. If this wound had been treated with standard procedures, this wound would have resulted in a horrible scar.



Miracle Dressing Wound Care System was applied on February 1.



Miracle Dressing Wound Care System was removed after 20 days. This wound typically would have taken at least two and a half months to heal.

#### Case Study: Scalp Radiation and Skin Cancer Surgery Wound Care

Three and a half months before this 72 year old man came into the office, the patient had had a significant skin cancer removed from his scalp. As a result of this surgery, and a history of radiation therapy, he was left with a large wound and no healing had taken place because of the lack of collateral circulation around the wound. Typically, such a wound would require approximately 150 stitches to bring the sides together to close the wound.



Miracle Dressing Wound Care System was applied on March 24.



Miracle Dressing Wound Care System was removed after 21 days. This wound typically would have taken many months to heal to this extent.

# Case Study: Wound Closure Without Using External Stitches

An 80+ year old woman with an 1.5 x 3.5 cm elliptical lesion. MDS was used to replace external stitches and eliminate any scarring.



Elliptical excision of a basal cell carcinoma on her left cheek.



Undermining and deep Dexon absorbable sutures placed to close the wound.



Placed: Natural Marine Extract™ Time Release Crystals in agglutinant followed by Miracle Dressing™



18 days later the Miracle Dressing fell off on its own....



...leaving a completely healed wound without external stitch wounds.



Only 28 days after removal of Miracle Dressing, the wound is virtually invisible.

## Case Study: Wound Closure Without Using Stitches

A 3 ½ year old male child fell on the edge of a coffee table. The injury penetrated through the dermis and subcutaneous tissue down to the muscle. The patient experienced tremendous bleeding.



The MDS was placed without stitches, and using no anesthesia.



At 2 ½ weeks after the injury and the MDS placement. The MDS fell off 3 days later.



The patient five weeks after the injury.

# **MDS Wound Monitoring Feature**

Because Miracle Dressing is an extremely thin, relatively transparent, non-woven regenerated cellulose fiber bandage, it hugs the wound and surrounding skin. This allows the length, width, and depth of the wound to be easily measured.



# **Miracle Dressing Wound Care System (MDS)**

MDS is the combination of the Miracle Dressing and Natural Marine Extract Time Release Crystals in agglutinant (AME). The Miracle Dressing Wound Care System ("MDS") has a dressing component made of a non-woven, regenerated cellulose fiber bandage with a pressure-sensitive adhesive. It has high moisture vapor permeability and 1 mm perforations spaced on 3 mm centers. There are non-perforated lanes along the longitudinal edge (and along the center of wider dressings). It is available in widths up to 4 inches and various lengths up to 15 feet. There are diagrams and photos below that show the different configurations of the dressing and micrographs showing the 1 mm perforations and the various sizes of micropores formed by the cellulose fibers.

MDS also contains Natural Marine Extract™ Time Release Crystals in agglutinant (AME). AME is applied to the skin before attaching the dressing. The NME is in the form of lyophilized crystals composed of extracts from various marine animals and botanicals, including sea abalone and sea cucumber. These ingredients have been shown to rejuvenate old, atrophic skin and help heal even some of the most recalcitrant wounds.

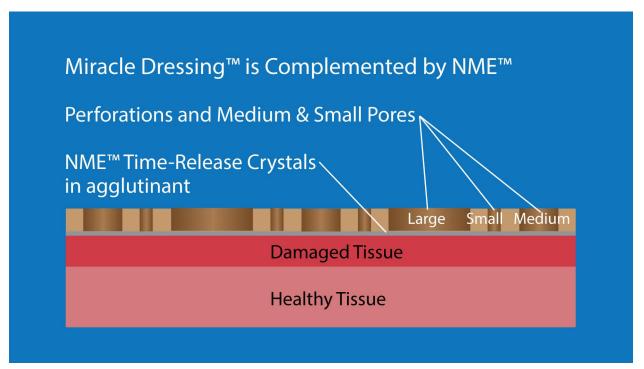
Miracle Dressings are Class I medical devices manufactured in our FDA registered facility. Our dressings are listed in the *FDA Establishment Registration & Device Listing* as 510(K) Exempt (under regulation #880.5240) and comply with all general regulatory safeguards required by the FDA (FD&C Act § 501, 502, 510, 516, 518, 519, and 520).

#### **MDS Product Kits**

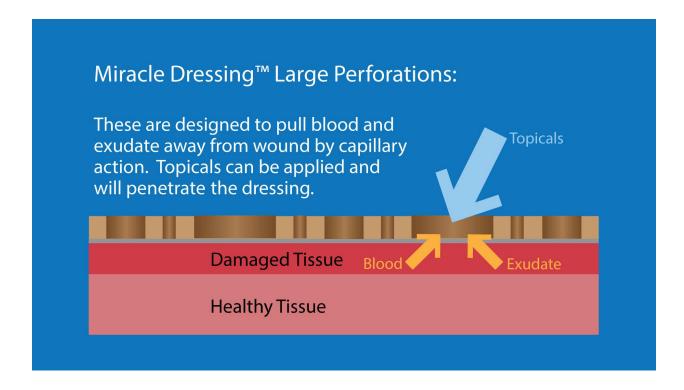
These are two of the MDS product kits. Kits for use with pressure injuries have "DO NOT REMOVE" stamped on them. This exemplifies the MDS paradigm shift in wound care. Weekend staff in SNFs were removing the dressing early because they were unaccustomed to a 21-day dressing. Adding the stamp has alleviated that problem.

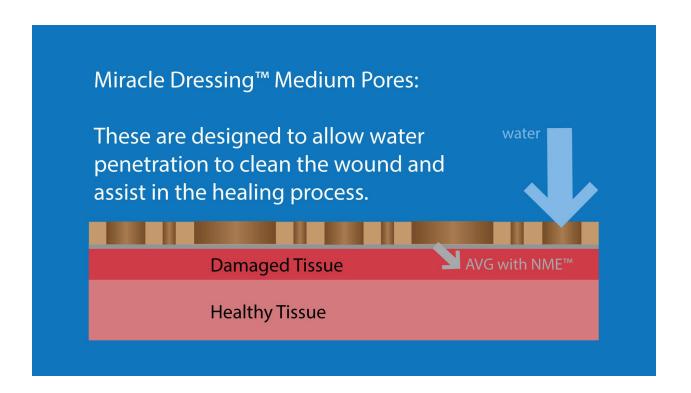


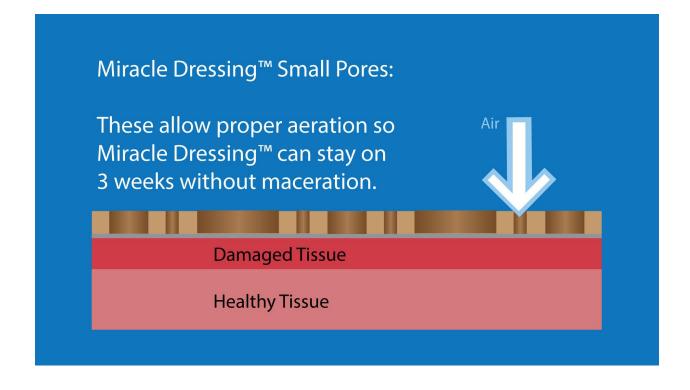
#### **MDS Illustrations**



After blood and exudate is cleaned away, topicals/medicinals including Miracle of the Sea® Natural Marine Extract in Aloe Vera Gel can be added.







#### Miracle of the Sea® Natural Marine Extract in Aloe Vera Gel

Natural Marine Extract is a therapeutic skin product developed and tested by dermatologists and plastic surgeons to successfully enhance thin, weak, atrophic skin. It is associated with greater functioning fibrocytes which allow more production of collagen, elastin and hyaluronic acid. This is the basis for the accentuation of healing of even the toughest wounds. These create greater strength, elasticity, and thickness, which are the basic characteristics of young skin. NME also helps heal micro-fissures, which create a significant inflammatory reaction. Inflammation of the skin, as in all parts of the body, is the single most damaging process, causing cleaving of telomeres of DNA that leads to cellular dysfunction, aging and the propensity to damage from trauma, pressure, shear force or pinching.

During MBET's 17-year investigation of over 3,400 plant and animal substances from the ocean, its Marine Biology, Pharmaceutical and Physician Teams identified 88 transformative compounds with benefits for human health. These 88 compounds are now being deployed in different combinations and concentrations for cutaneous and systemic health benefits. Ingredients of these compounds have been shown to 1) rejuvenate old atrophic skin and heal wounds; and 2) stimulate the immune system to kill cancer cells. The first patented result of this extraordinary collaboration has been the development of Natural Marine Extract (NME). Natural Marine Extract is a completely natural and edible product, composed of twelve compounds from marine species including: Holothuria cinerascens (ashy sea cucumber), Spirulina pacifica (Hawaiian spirulina), Chalmys rubida (Pacific pink scallop), Strongylocentrotus franciscanus (giant red urchin), Holothuria mexicana (donkey dung sea cucumber), Haliotis fulgens (green abalone), Arthrospira platensis (spirulina), Stichopus chloronotus (greenfish sea cucumber), Stronylocentrotus purpuratus (purple urchin), Haliotus rufescens (red abalone), Holothuria scabra (sandfish, a sea cucumber), Ascophyllium nodosum (knotted wrack kelp), Macrocystis integrifolia (giant kelp) and Microcystis aeruginosa (blue green algae).

A sample of Miracle of the Sea Natural Marine Extract in Aloe Vera Gel (NME in AVG) is included in the MDS kit. We recommend applying the NME in AVG to provide another source of NME to the wound, which enhances the performance of the MDS.

# Natural Marine Extract (NME)™ Benefits

# The ingredients of Natural Marine Extract have been shown to stimulate fibrocytes to:

- Increase collagen production and strengthen the skin
- Increase elastin production and make the skin more elastic
- Increase hyaluronic acid and make the skin thicker
- Speeds the re-epithelialization process
- Create younger, thicker, healthier skin

# The ingredients of Natural Marine Extract also:

- · Act as an antioxidant, quelching free and hydroxyl radicals
- Have been shown to provide anti-microbial qualities
- Act as an anti-inflammatory

### The Healing Benefits of Natural Marine Extract:

- Promotes healing of pressure injuries, skin tears and ecchymoses
- Helps to heal burns, abrasions and superficial avulsions
- Seals micro-fissures of dry, atrophic skin
- Helps to improve the integrity, strength and resilience of injured skin

# **Mechanism of Action of Ingredients of NME**

NME stimulates stem cells, transforming them into new fibrocytes and new capillaries while it also lengthens telomeres to transform old, withered fibrocytes into young, productive fibrocytes. This rejuvenation process produces tremendous amounts of collagen, elastin, and hyaluronic acid. The effect is stronger, healthier skin.





# Natural Marine Extract 283-Subject Biopsy Comparison Study

# **Untreated Control**

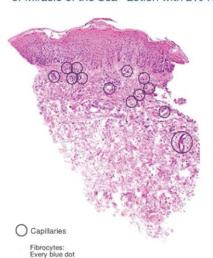
60 Year Old Skin Following 46 Applications of Lotion Without Natural Marine Extract™ (NME)



- The study used 46 applications over a four month period.
- The treatment created 10-15 times the number of blood vessels, 20-35 times the number of fibrocytes and two to six times the amount of collagen elastin and hyaluronic acid.
- The "skin age" of the treated 60 year old in this photo was now 30 years.

# Treated With NME™

60 Year Old Skin Following 46 Applications of Miracle of the Sea® Lotion with 2% NME



# Miracle of the Sea Natural Marine Extract (NME) Capsules

A healthcare professional or family caregiver may choose to recommend NME Capsules along with MDS. While NME Capsules are not required for MDS to be effective, they do provide synergistic, systemic support to the healing process.

NME Capsules contain the same marine species listed above, which are coarsely ground, with no fillers and no binders.



The Only 21-Day, Stay-In-Place Breathable Dressing That Promotes the Prevention and Healing of Stage 1 and 2 Pressure Injuries and Other Superficial Wounds.



Patient with 2nd and superficial 3rd degree burns on buttocks and back.

#### MIRACLE DRESSING WOUND CARE SYSTEM (MDS) PROVIDES THESE IMPORTANT BENEFITS:

- · Wounds can be cleaned and monitored with dressing in place
- Medicinals can be applied to the dressing and penetrate to the wound
- Reduces nursing time, effort and stress
- Decreases dressing and disposal costs
- Reduces pain and disruption of wound healing due to less frequent dressing changes

For more product information: MBETHealth.com • (800) 431-6238



# The Healing Power of Marine Science

#### NATURAL MARINE EXTRACT™ IN ALOE VERA GEL

#### **BIOPSY COMPARISON TYPICAL RESULT**

#### Untreated Control

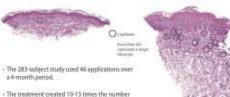
60 Year Old Skin Following 46 Applications of Lotion Without Natural Marine Extract\* [NME]

of blood vessels, 20-25 times the number of fibrocytes, and two to six times the amount of

collagen elastin and hyaluronic acid.

60 Year Old Skin Following 46 Applications of Mirade of the Sea Lotion\* with 2% NWE

Treated With NME™



For more product information: MiracleOfTheSea.com • (800) 711-6687

- Ingredients increase hyaluronic acid, collagen, elastin production, and speeds re-epithelialization
- · Generates younger, thicker, healthier skin
- Acts as an antioxidant, quelching free and hydroxyl radicals
- · Provides anti-microbial qualities
- Moisturizes and promotes healthy skin to reduce skin breakdown
- · Prevents and protects dry, chafed or cracked skin.
- Helps prevent transepidermal water loss (TEWL)
- · Strengthens fragile, easily bruised skin
- · Promotes healing of skin tears and ecchymoses.
- Helps to heal burns, abrasions and superficial avulsions
- · Seals the micro-fissures of dry, atrophic skin
- Helps to improve the integrity, strength and resilience of injured skin