Membracel –Porous Regenerative Membrane

Product Trade Name: Membracel

For pediatric and adult use
Sterile - sterilized using ethylene oxide

Description

Membracel – *Porous Regenerative Membrane is a single layer dressing 100% composed bacterial cellulose, formed of microfibrils obtained by processing cellulose synthesized in a laboratory by Acetobacter Xylinum bacterium. It has artificially developed pores, fine texture and uniform structure.*

Expected product action

Pain relief, injury protection, drainage of secretions, reduction of exposed regions to infectious agents and acceleration of the healing process and subsequent epithelization.

Indications

Membracel acts as a temporary replacement of the skin and is suitable for injury treatments resulting from the loss of epithelium that are characterized as superficial or deep wounds, such as second-degree burns, dermal abrasions, excoriation, recipient and donor areas for skin grafts, nail beds (post-nail excision), pressure sores, varicose ulcers of stasis, arterial ulcers, plantar perforating maladies, epidermolysis bullosa, and post-physical cauterization (cryotherapy, thermal cauterization, CO2 laser and Erbium).

Contraindications

- Membracel should not be used to tunnel lesions,ulcers in sacro-coccygeal area, life-threatening iinjuries, 1st and 3rd degree burns, infected wounds, malignant lesions or suspected malignancy.

Benefits

- Drainage of the exudate and gas exchange through created porosity;
- Stimulates formation of granulation tissue by direct contact of Membracel with the lesion bed;
- Monitoring of the cicatricial process without removal of Membracel, allowed by its natural translucency;
- Provides insulation which allows for the preservation of viable cells from the lesion bed during exchange of the secondary dressing;
- Immediate pain relief, as Membracel is thin and malleable, has high affinity with the body's liquid and is extremely fine in texture, thus allowing rapid hydration and perfect isolation of exposed nerve terminals;

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- Free passage of medications applied via Membracel to the injured area;
- Progressive and oriented epithelization promoted in the periphery-center direction of the lesion, with progressive adhesion of Membracel as a consequence of the cicatricial;
- Evolution and gradual reduction of exudate in its peripheral region;
- Exemption from allergic reactions with prolonged contact of Membracel with the skin;
- Ease of exchange of the secondary dressing and / or Membracel due to the absence of residues adhering to the lesion.

Dressing Sizes

Consider the size of the wound to choose the most suitable size, so that Membracel covers the entire exposed injury area exceeding by at least 1/3 in. beyond its edges.

Pore sizes

Consider the type of wound, volume and characteristics of existing exudate of the wound to choose the ideal pore size:

Medium - 1 to 2mm: Indicated for low and / or moderate exudation. Used in most cases.

Large - 2 to 3mm: Indicated in cases of excessive and / or thick exudation.

Membracel is capable to maintain the humidity control for the wound due to two combined actions: absorption of part of the exudate by Membracel's hydrophilic composition (crystalline cellulose) with the simultaneous elimination of excess exudate (when necessary) through the membrane pores. In cases that the drainage of exudate is required, use sterile gauze on the membrane to absorb the excess exudate.

Membracel- Instructions for Use:

1- Clean the lesion with saline solution (SSI 0.9%) in a jet or other specific solution. If necessary, perform the debridement for removal of non-viable tissues;
2- Remove Membracel from the envelope and place it over the lesion, in order to cover the lesion with an excess of 1/3 in. beyond its edges. The product can be applied using either side;
3- With the use of sterile tweezers, moisten the membrane with a sterile gauze and saline until settles on the wound;
4- Wait 3 to 4 minutes for the membrane's self-adherence to the lesion and peripheral region;
5- It is recommended to place a protection to avoid contamination and the membrane detachment (mainly during bath);

If necessary, apply an absorbent secondary dressing on Membracel, such as sterile gauze. For fixation use bands, compression bandages and microporous tape.

For greater treatment efficiency, it is recommended to change the secondary dressing whenever saturated with exudate or has lost absorption capacity, or in accordane with instructions as provided by your healthcare professional.

Membracel- Frequency of Change:

1- The change frequency will depend on the condition of the wound and the volume of exudate. Initially it is normal to change/ replace Membracel every 5 days. Over time, this interval will naturally increase, due to the reduction in the exudate volume secreted by the injury;
2- Membracel can be maintained for up to 12 days if it does not peel off, rupture, signs of infection, acute pain, foul odor or stench.

Procedures for changing the Secondary Dressing (when applicable):

1- Remove the secondary dressing applied over Membracel;
2- Clean the wound region without removing Membracel using saline solution (0.9% SSI) and sterile gauze to compress and remove excess exudate under Membracel through its pores. Avoid over moistening Membracel to prevent damage to the membrane and or detachment;
3- Place the gauze or other sterile absorbent secondary dressing. Attach the secondary dressing with microporous adhesive tape or band, so that it is lightly pressed over Membracel and the injury.

Procedures for changing Membracel:

If you need to change Membracel, follow the below instructions.

1- Moisten the adhered part of Membracel with sterile gauze soaked in saline (0.9% SSI) for approximately 4 or 5 minutes;
2- Detach Membracel's edges, gently rubbing the soaked gauze in the periphery-center direction of the lesion until Membracel is completely removed;
3- Clean the lesion bed using saline solution (SSI 0.9%) in a jet or other specific solution. Apply a new Membracel membrane, following procedures above titled "Membracel- Instructions for Use".

Special Care:

1- Never use oily products, ointments or creams with Membracel, since this practice prevents its attachment to the lesion. Should further topical treatment be necessary, products in the form of Solutions are most recommended. However, avoid use of hydrogen peroxide as this will cause chemical degradation of Membracel;
2- Avoid wetting Membracel during bathing (protect the dressing with waterproof material);

3- Caution: Sterilization is guaranteed as long as the packaging is not damaged or opened before use. Do not use Membracel if the packaging is broken and / or date has expired;
4- Systemic antimicrobial therapy may be prescribed by your physician when the wound presents infection. In this case, Membracel can be used in conjunction with systemic antibiotic;
5- If it is necessary to cut Membracel, it is recommended to use sterile scissors;
6- The use of Membracel should be supervised by a healthcare professional.

Products:

Membracel is available in packages of **1 or 10** Porous Regenerative Membranes.

Dimensions	Pore Size	Quantity per Package
1.9 x 2.9 in	Medium	10
	Large	10
3.7 x 4,7 in	Medium	10
	Large	10
6.3 x 8.2 in	Medium	10
	Large	10

PRODUCT FOR SINGLE USE ONLY.
DESTROY AND DISPOSE AFTER USE.
FOLLOW DOCTOR'S INSTRUCTIONS.

Batch number, manufacturing date and expiration date: refer to packaging envelope.

This product, when stored at room temperature (between 59° F and 86° F) away from light and moisture, is good for 60 months from date of manufacture.

Mechanism of action

The mechanism of action of the regenerating matrix corresponds to its physico-chemical characteristics and its interaction with the living tissue in the lesion, and is explained through the following properties:

1- Protects exposed tissue: Membracel adheres gently to exposed tissue of the lesion, and isolating or separating it from the external environment, thus avoiding direct contact with contaminants and macroscopic foreign bodies;
2- It favors autolytic debridement: due to crystalline cellulose composition, the product allows the formation of a layer of interstitial fluid / exudate between it and the wound bed. This facilitates mobilization of communication molecules (Cytokines and growth factors) between resident cells and transient cells (leukocytes), which arrive more easily at the lesion site in a humid environment, facilitating the inflammatory process of cleansing dead cells and tissue

remains, without which cicatrization would progress. This property prevents the formation of classic fibrin-leukocyte crust, which has shown to delay healing;

3- Allows humidity control: excess exudate generates maceration of healthy epidermis surrounding the lesion, weakening the edges of the wound, recognized as an important source of cells and extracellular matrix for the formation of new substitute tissue, which may favor chronification of the Inflammatory phase; By greater contact of the wound bed with cellular debris and protein fragments. The humidity control is recognized as a first- line intervention in the treatment of chronic wounds. Due to two combined actions: absorption of part of the exudate by Membracel's hydrophilic polymer composition (crystalline cellulose) with the simultaneous elimination of excess exudate (if necessary) through the membrane pores.
4- During cicatrization this cell can be stimulated to differentiate into myofibroblast, in which it can exert contraction forces that, on a larger scale, approximate the edges of the wound and make the scar a smaller area when compared to the initial area. The migration process mainly needs a 3D environment rich in extracellular matrix molecules to interact during the movement and reception of chemotactic signals. The humid environment favor these processes.

Keratinocytes are community cells connected by strong connections that form the epidermis and are responsible for covering the dermis and protecting it from the external environment, preventing the entry of microorganisms and substances. The migration of this cell is collective and proportional to the proliferation of new cells. This process requires a less humid but not totally dry environment. It is believed that the guide plane given by the regenerating matrix favors the migration of this cellular type under the dressing, this property benefits the aesthetics of the scar. Undoubtedly, the control of excess exudate greatly influences this part of the healing process.

Collagen production: In an experimental preclinical study in 2006, it was demonstrated that with the use of the regenerating membrane, type I collagen is produced and deposited more rapidly during cicatricial remodeling, which gives greater resistance to the new tissue.
It is hypoallergenic: the organic composition of the cellulose depending on the purity (99.9% in the case of Membracel) is safe and generates little or no cellular and tissue interaction without generating residual or allergic inflammatory reaction.

Decreases topical sensation of pain by sealing the area of the lesion: as previously mentioned, cellulose seals the surface of the lesion by adhering gently to it, thereby occluding the exposed nociceptive nerve endings that generate the sensation of pain. When pain is the consequence of an acute or chronic inflammatory process not caused by bacterial colonization, it may be resolved by use of the porous regenerative membrane- Membracel once the equilibrium of the wet medium is resolved.

For the correct functioning of the mechanism of action of the cellulose regenerating Membracel, it is important to note that a detailed evaluation of the needs of the wound,

the use of the previous antiseptic treatment and as required, of the instrumental or surgical debridement is necessary. The cellulose membrane Membracel has no activity.