

INSTRUCTIONS FOR USE – LEAFLET



Product Description

MEDICAL Chitosan is a soft, sterile, absorbent fibre wound dressing made from Chitosan. Chitosan is known for its bacteriostatic and haemostatic properties.

MEDICAL Chitosan is highly absorbent, conformable and transforms into a soft gel upon absorption of wound exudate. MEDICAL Chitosan helps maintain a moist environment for optimal wound healing, conforming closely to the wound bed for optimal interaction. The dressing can aid autolytic debridement and will remain intact during use (one-piece removal). MEDICAL Chitosan will not damage newly formed tissue.

Patient Target Group

The intended patient target group for MEDICAL Chitosan is any patient with acute or chronic wounds and who is not contra-indicated.

Indications

MEDICAL Chitosan is indicated for the management of moderate to heavily exuding chronic and acute wounds. MEDICAL Chitosan may be used to control minor bleeding in superficial wounds.

MEDICAL Chitosan can be used on infected wounds or wounds in which there is an increased risk of infection under the supervision of medical professionals.

Under medical supervision MEDICAL Chitosan may be used for the management of the following wounds:

- Pressure sores
- Diabetic ulcers
- Leg ulcers
- Cavity wounds
- Donor sites and Graft sites
- Surgical wounds (e.g. post-operative, wounds left to heal by secondary intent)
- Skin abrasions and lacerations
- Superficial and partial thickness burns
- Trauma Wounds

Contra-indications

The MEDICAL Chitosan is not indicated for use on the following:

- Surgical implantation
- To control heavy bleeding
- Individuals who are sensitive, or who have had an allergic reaction, to the dressing.
- 3rd degree burns

Precautions

- Should consult a medical professional if irritation (reddening, inflammation), maceration (whitening of skin), hyper-granulation (excess tissue formation) is observed.
- The dressing should be used under the supervisions of medical professionals.
- The dressing may adhere if used on very lightly exuding wounds. If the dressing is not easily removed, moisten it with saline solution prior to removal.
- The dressing is not intended for use as a surgical sponge.
- The product contains highly purified derivative of shell fish. Do not use on patients with a known sensitivity to chitosan.
- For external use only.
- Do not use if package is open or damaged.
- Do not re-use, as it may cause infection.
- The use of the dressing during pregnancy is not evaluated.
- Report to the manufacturer and local authority if any serious incident occurred.

DIRECTIONS FOR USE**Site Preparation**

Debride when necessary and irrigate/clean the wound site in accordance with standard protocols

Dressing Selection

For flat or shallow wounds select an appropriate size dressing that allows for a minimum of 0.5 cm overlap onto the skin surrounding the wound (to allow for the dressing to gel and to maximise conformability). Use a ribbon (rope) dressing for cavity wounds.

Dressing Application

1. Always use aseptic techniques when dressing a wound.
2. Cut, fold or layer, the dressing to fit the wound
3. Loosely fill deep wounds, to allow the MEDICAL Chitosan to absorb wound fluid and to expand filling the wound. Do not pack tightly.
4. When using MEDICAL Chitosan ribbon dressings in deep cavity wounds, insert the ribbon in one piece and leave at least 2.5cm outside the wound for ease of removal.
5. Cover and secure with an appropriate dressing such as self-adhesive dressing or bandages.
6. For dry wounds (to aid a moist wound environment) place a MEDICAL Chitosan on the wound and wet with sterile water or saline over the wound area only. Cover the dressing with an occlusive or semi-occlusive dressing to maintain moisture at the wound site and to avoid subsequent dressing adherence to the wound.
7. For minor bleeding wounds, apply the MEDICAL Chitosan to the wound with a light pressure, maintain the pressure for few minutes until the bleeding is stopped, secure the dressing with a suitable dressing.
8. Trim away the edges of the dressings when they become loose during healing.

Dressing Change and Removal

1. MEDICAL Chitosan shall be changed on the maximum 4 days or when the dressing has reached its absorption capacity, or when the conditions of the wound or the surrounding skin or the level of exudate requires.
2. If simple removal of the dressing is difficult due to adherence, it should be fully saturated with sterile saline or sterile water to fully gel the dressing, remove slowly.
3. Irrigate the wound site with a suitable wound cleanser (e.g. sterile saline) prior to application of a new dressing.

Disposable

The dressing should be disposed of in accordance with local waste guidelines.

Storage

Store in a cool, dry place.

Do not re-sterilise

The use by date of this product is printed on the packaging.

Summary of Safety and Clinical Performance (SSCP)

The link of SSCP is:



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SYMBOLS USED ON LABELLING



Single use



Do not Re-sterilise



Use by date



Sterile. Method of sterilisation: EO



Product Reference.



Batch number.



Attention, see instructions for use.



Does not contain Latex



Manufacturer



EC Representative



CE mark



Keep Away from Sunlight



Keep Dry



Do not use if package is open or damaged



Medical Device



Date of manufacture

GTIN

Global Trade Item Number



Unique device identifier



Single sterile barrier system



Contains material of animal origin