CMC Gelling Fiber Dressing Standard (Type I)

Instruction for Use

Product description

CMC Gelling Fiber Dressing Standard (Type I) is a soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethylcellulose fiber. This conformable and highly absorbent dressing absorbs wound fluid and transforms into a soft gel, which maintains a moist environment to support the body's healing process and minimize patient pain and discomfort during dressing changes or when dressing is in sit.

Intended Purpose

CMC Gelling Fiber Dressing is intended for moist wound healing and exudate management of moderately to heavily exuding wounds, including cavity wounds.

Indications

CMC Gelling Fiber Dressing is used for the management of moderately to heavily exuding chronic and acute wounds, such as leg ulcers, pressure ulcers (Stage II-IV), diabetic ulcers, surgical wounds (e.g., post-operative, wounds left to heal by secondary intent and donor sites), partial thickness burns, traumatic wounds (e.g., abrasions and lacerations), exudate absorption in oncology wounds.

Intended user

The product shall be used by or under the supervision of a healthcare professional.

Function principle

The fiber in the dressing rapidly swells after absorbing the wound exudate to form a soft clear gel. The unique gelling action of gelling fiber absorb and retain exudate and lock away harmful components contained within wound exudate, such as bacteria and proteinases. It's reducing the risk of wound infection and maceration, and maintaining the optimal moist healing environment.

Intended patient population

Patient who has the following: leg ulcers, pressure ulcers (Stage II-IV), diabetic ulcers, surgical wounds (e.g., post-operative, wounds left to heal by secondary intent and donor sites), partial thickness burns, traumatic wounds (e.g., abrasions and lacerations), exudate absorption in oncology wounds.

Clinical Benefit

Provide patient better comfort and can effectively minimise pain during dressing application or removal with no damage to the wound.

Contraindications

CMC Gelling Fiber Dressing should not be used on surgical implantation, heavy bleeding wounds or on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components.

Adverse reaction

Very occasionally, there will be some potential risks associated with the use of CMC Gelling Fiber Dressing with the following:
- Wound infections
- Risk of maceration (fluid leakage)
- Adverse reactions (blister, hypergranulation, eczema, intolerance etc.)

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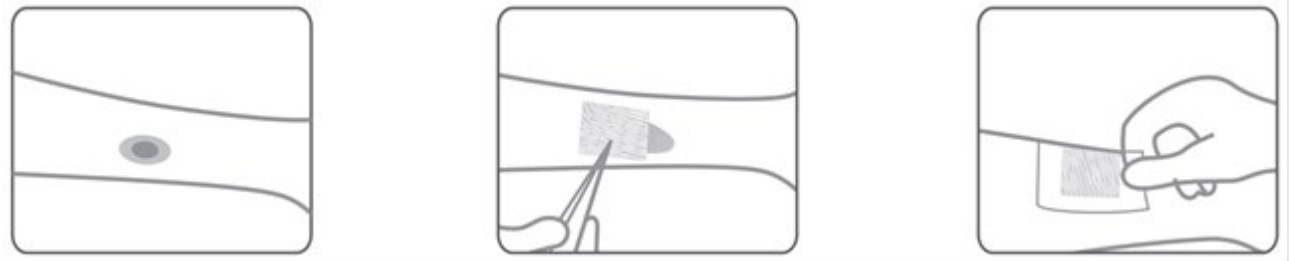

First step:
Cleanse the wound in accordance with normal procedures. Ensure the peri-wound skin is dry.

Second step:
Select appropriate dressing size for the wound. The dressing should overlap at least 1cm onto the skin surrounding the wound. The dressing may be cut or folded.

Third step:
When using the ribbon dressing, loosely pack the dressing to about 80% capacity leaving at least 2.5cm outside the wound for easy retrieval.

Fourth step:
Gently apply the dressing to the wound and cover with an appropriate moisture retentive secondary dressing such as, but not limited to, transparent film dressing, hydrocolloid dressing, foam dressing or bandage. The secondary dressing should be a moisture

retentive dressing, and the size of the dressing should be able to completely cover the wound area and overlap at least 2-3cm onto the skin surrounding the wound. See relevant package inserts for complete instructions for use of secondary dressing.

Fifth step:
For dressing remove, gently lift off secondary dressing and remove the dressing. If dressing appears dry, saturate with sterile saline or water to aid in removal. If necessary, gently irrigate the wound with sterile saline for removal of gel residue.

Note:
1. Change the dressing when fully saturated, at signs of leakage, or as indicated by clinical practice. The dressing may be left in place for several days (up to 7 days). Dressing change frequency will depend on wound characteristics and the amount of drainage.
2. If the dressing has dried and is adhered to the wound surface, fully saturate with sterile saline or water and removed gently.

Precautions/ Warnings

1. Sterile. Do not use if inner package is damaged or opened prior to use. Do not re-sterilise.
2. The dressing is for single-use only and should not be re-used. Re-use may lead to cross contamination or product deterioration.
3. The wound should be inspected for signs of infection according to clinical practice and gotten proper treatment.
4. The dressing can be used in combination with sterile water, saline solution or sodium hypochlorite wash solution.

Storage and transport conditions

Should be stored in a dry, ventilated, non-corrosive gas environment.
Keep away from fire and flammable materials.
Keep away from sunlight and rain.

Disposal

Disposal should be handled according to local environment procedures.

Other Information

1. The intended user does not need training for this product.
2. If any serious incident has occurred in relation to the use of this dressing, it should be reported to Winner Medical Co., Ltd.

Winner Medical Co., Ltd.
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Symbol					
Meaning	Batch code	Use-by Date	Do not reuse	Manufacturer	Date of manufacture
Symbol					
Meaning	Sterilized using irradiation	Keep dry	Medical device	Keep away from sunlight	Authorized representative
Symbol					
Meaning	Unique device identifier	Importer	This way up	Single sterile barrier system	Do not use if package is damaged
Symbol					
Meaning	CE marking		Do not resterilize	Consult instructions for use or consult electronic instructions for use	

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