

Calcium Alginate Family - IFU – EU MDR

Technical Document			
Title	Calcium Alginate Family - IFU – EU MDR	Project Number	629
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Related Documents	Calcium Alginate Labels – EU – EU MDR		
Reference Documents/ Standards	N/A		
Abstract	<p>This document contains the Instructions for Use of the product family Calcium Alginate, considering the location:</p> <ul style="list-style-type: none"> Galaxy House, 31 Herald Way, Binley Industrial Estate, Coventry, CV3 2RQ, United Kingdom. <p>This document should be signed and approved by Regulatory Affairs before being printed.</p>		

Calcium Alginate

Calcium Alginate Wound Dressing / Packing Rope

Instructions for use

Product Description:

Calcium Alginate Wound Dressings and Packing Rope are soft, conformable wound coverings with a high mannuronic acid content. The calcium alginate fibres react with wound exudate or blood to form a gel which creates a moist wound environment. The high exudate absorption capacity promotes wound healing.

Calcium Alginate Wound Dressings / Packing Rope are individually sterile packed and sterilised by irradiation. The products are sterile as long as the packaging is unopened and undamaged.

Product composition:

Calcium Alginate Wound Dressings / Packing Rope consist of a homogeneous 100% calcium alginate fibres. The alginate fibres are composed of around 60% mannuronic acid and around 40% guluronic acid.

Intended use:

Calcium Alginate Wound Dressings / Packing Rope can be used for the treatment of acute and chronic wounds.

Indications:

Calcium Alginate wound dressings / packing rope can be used for the treatment of wounds which are moderate to heavily exuding, superficial or deep, for:

- pressure ulcers
- arterial ulcers
- venous lower leg ulcers
- diabetic ulcers
- post-operative wounds
- skin graft and donor sites

If required, the dressings can be used in conjunction with a suitable moisture-retaining secondary dressing to keep the product in place and/or under compression.

Patient population:

Adult and pediatrics patients.

Contraindications:

Known allergy and / or hypersensitivity to any of the product components. Dry wounds.

Side effects:

In very rare cases skin irritations or allergies may occur. Maceration or pain on removing the dressing has been described in isolated cases with this product group.

Application:

1. Preparing the wound:

Clean the wound carefully in accordance with current clinical standards. The skin surrounding the wound should be clean and dry.

2. Applying the wound dressing:

- a. The size of the dressing depends on the wound size.
- b. If required, the wound dressing and packing rope may be cut to size with sterile scissors.
- c. Place the Calcium Alginate Wound Dressing on the moist wound bed. In the case of slightly exuding wounds, moisten the dressing with physiological saline solution (0.9%).
- d. Loosely pack deep wounds with the Calcium Alginate Packing Rope.
- e. Secure the Calcium Alginate Wound Dressings / Packing Rope with a suitable secondary dressing.

3. Dressing change:

The intervals at which the Calcium Alginate wound dressings / packing rope must be changed are determined by the treating physician. Depending on the level of exudate, Calcium Alginate wound dressings / packing rope can

remain on/in the wound for up to 7 days before being replaced. The dressing is intended to be used for a maximum total treatment period of 30 days.

- a. Remove the secondary dressing in accordance with current clinical standards.
- b. Remove the non-gelled part of the wound dressings / packing rope and rinse out any gel left behind in the wound with physiological saline solution (0.9%) before assessing the wound and applying a new dressing.

Precautions:

- Wounds must be assessed and managed appropriately, as indicated, under the supervision of a medical professional. The use of a suitable primary or secondary dressing is at the discretion of the treating physician and depends on the patient's general situation. In the case of infected wounds, the treating physician will decide on the basis of the patient's general condition whether an occlusive secondary dressing can be applied.
- Application in the case of heavily bleeding wounds, during pregnancy or lactation is decided on by the treating physician. At present, no documented clinical experience with the product in such cases is available.
- Calcium Alginate Wound Dressings / Packing Rope are for single use only and must not be resterilised.
- Increased infection risk: after the first use, the dressing may harbor bacteria and debris from the wound, which can transfer back into the wound on reuse. This contamination increases the risk of infection or reinfection, as reused dressings cannot maintain a sterile environment.
- Reduced absorbency: the dressing is engineered to absorb and lock in wound exudate efficiently during a single use. Reusing it compromises this ability, as the dressing may already be partially or fully saturated, leading to inadequate absorption of exudate. This can cause fluid to pool on the wound bed, which can lead to maceration (softening) of the surrounding skin.
- Loss of structural integrity: the dressing is composed of fibres designed to maintain a certain structure for optimal wound coverage and exudate management. Reusing the dressing can cause the fibres to break down, reducing its structural integrity, which may result in incomplete wound coverage or dressing fibres being left in the wound.
- Delayed healing: due to the compromised absorbency and increased infection risk, reuse of the dressing can delay the healing process. A clean, effective dressing promotes optimal wound conditions, while a reused dressing may hinder progress, potentially leading to chronic or poorly healing wounds.
- Potential for skin irritation: if the dressing is damaged, residual fibres, or degraded materials may irritate the wound or surrounding skin, causing discomfort and potentially worsening the wound.

Storage Instructions:

Do not freeze or refrigerate. Store below 25°C.

Disposal:

Recyclable packaging should be recycled according to the relevant national recycling systems. Dispose of the dressing in line with current clinical practices for clinical waste.

Note:

Any serious incident that occurs in relation to the Calcium Alginate wound dressings / packing rope should be reported to the manufacturer and competent authority of the relevant established Member State.



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