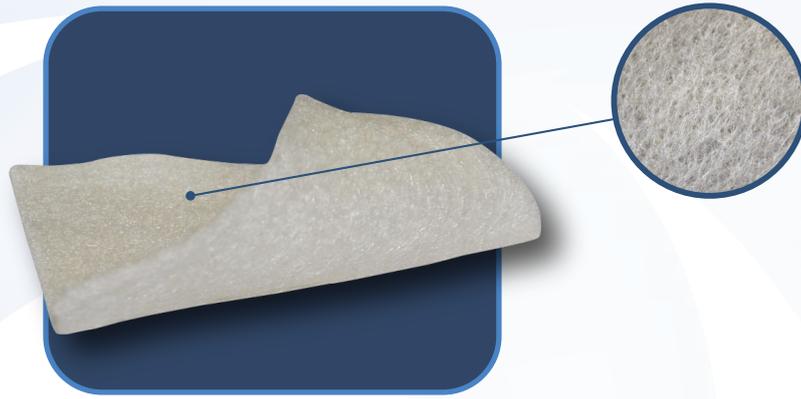


Calcium Alginate Dressings

Pharma-Algi® F and Pharma-Algi® F Extra



Device description:

Calcium Alginate Dressings are absorbent and haemostatic wound dressings, made of alginate nonwoven fibers that form an absorbent pad. In the presence of exudate, the fibers absorb liquid and swell and calcium ions present in the fiber are partially replaced by sodium, causing the dressing to take on a gel-like appearance. This provides a micro-environment that is believed to facilitate wound healing.

A) Pharma-Algi® F is 100% calcium alginate wound dressing consisting of haemostatic and highly absorbent pad of non-woven alginate fibers. The alginate fibers are bonded together using a needle punching process which minimizes fiber shed and enhances the physical strength of the dressing in the wound. The wound dressing is designed to be fast gelling and to allow removal intact.

100% Calcium alginate
non-woven absorbent pad



100% Calcium alginate
non-woven absorbent pad



B) Pharma-Algi® F Extra is a sterile, non-woven pad consisting of alginate and carboxymethylcellulose (CMC) fiber. The wound dressing is designed to be fast gelling and to allow removal intact.

Non-woven absorbent pad consisting of calcium
alginate plus sodium carboxymethyl cellulose



Non-woven absorbent pad consisting of calcium
alginate plus sodium carboxymethyl cellulose



Intended Purpose:

Calcium Alginate Dressings are indicated for the management of moderate to heavily exuding chronic wounds and to control minor bleeding in superficial acute wounds.

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Indications:

Calcium Alginate Dressings may be used in the management of minor conditions such as superficial acute wounds; Lacerations, Skin tears, Abrasions, Minor burns, Donor sites and Post-operative wounds.

Under the care of a healthcare professional, Calcium Alginate Dressings may be used as a primary wound dressing in the management of full thickness wounds with moderate to heavy exudate that have breached dermis and may also be prone to minor bleeding such as Chronic wounds; Leg ulcers, Diabetic foot ulcers, Venous stasis ulcers, Pressure ulcers, Arterial ulcers, Surgical wounds, Cavity wounds, Chronic wounds, Traumatic wounds and Donor sites.

Intended patient population:

Calcium Alginate Dressings are designed to be used on patients with one of the wound types listed in the Indications for use.

Calcium Alginate Dressings are suitable for all patient population regardless of their gender or age except those in the contraindications section.

Intended users:

Calcium Alginate Dressings are intended to be used by healthcare professionals and carers or patients under the direction and instructions for use provided by their physician, nurse or healthcare professional.

Performance Characteristics:

Calcium Alginate Dressings forms a gelled sheet upon contact with wound exudate, the excess of which is absorbed in this process. Utilizes the proven benefits of moist wound healing, accelerating the healing process of even hard-to-heal wounds.

When **Calcium Alginate Dressings** absorbs the exudate from the lesion, the sodium ions in the exudate replace the calcium ions in the alginate, when a significant proportion of the calcium ions in the fibers have been replaced by sodium, causing the fibers to swell and to absorb the exudate forming a gel. The gelation of the fibers also permits easy removal of the dressing. In case of **Pharma-Algi® F Extra**, the dressing formulation contain a carboxymethylcellulose (CMC) fibers to improve the gelling properties of the dressing.

Calcium Alginate Dressings have been shown to absorb and retain bacteria during formation of the gel matrix, which can be removed during dressing changes minimizing bacterial infections, thereby promoting rapid re-epithelialization and granulation tissue formation.

A description of other devices, which are intended to be used in combination with it:

Calcium Alginate Dressings designed to be used as a primary dressing.

Calcium Alginate Dressings shall be covered with an appropriate secondary dressing to be held in place. The alginate will absorb exudate and form a gel over the wound surface. Wound exudate will evaporate from this gel surface. The secondary dressing shall not limit this evaporative process especially when exudate is heavy as this might trap the exudate (drainage) over the wound and macerate (overhydrate) the skin around the wound. Cover with a nonocclusive, semi-occlusive secondary dressing or any appropriate retention bandage or tape to secure the wound dressing in place if required or if the dressing has been cut.

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Instructions For Use:

- Debride when necessary, cleanse the wound using sterile normal saline solution /suitable wound cleanser or in accordance with normal procedures. Remove excess solution from surrounding skin.
- Choose a size of **Calcium Alginate Dressings** /cut the dressing to size slightly larger than the wound and place it in intimate contact with the wound base, ensuring the entire surface is covered. The dressing is not intended to overlap the wound edges so any overlap shall be cut off (using clean scissors) or folded over the wound surface.
- For heavily exuding wounds, apply to wound bed directly. For wounds with minimal exudate, apply to moistened wound bed. If the wound is deep or extends wider /further than the visible break in the skin /deep or undermined, the alginate strip may be the best choice. Loosely pack deep wounds, ensuring the dressing does not overlap the wound margins.
- Cover with an appropriate secondary dressing to hold the **Calcium Alginate Dressings** in place. The alginate will absorb exudate and form a gel over the wound surface. Wound exudate will evaporate from this gel surface. The secondary dressing shall not limit this evaporative process especially when exudate is heavy as this might trap the exudate (drainage) over the wound and macerate (overhydrate) the skin around the wound. Cover with a nonocclusive, semi-occlusive secondary dressing or any appropriate retention bandage or tape to secure the wound dressing in place if required or if the dressing has been cut.
- Discard any unused portion of the product after dressing the wound.

Changing the Dressing:

1. Carefully remove the secondary dressing holding the **Calcium Alginate Dressings** in place.
2. If the wound appears dry, saturate the wound with saline before removing the dressing.
3. Using tweezers, forceps or a gloved hand, gently lift the dressing away from the wound base. The high wet strength generally allows it to remain in one piece.
4. If required, gently cleanse the wound of remaining dressing material using sterile normal saline solution prior to application of a new dressing.
5. Follow instructions for reapplying the dressing if required.

Frequency of Change:

Dressing change frequency will depend on the patient condition, level of exudate, type and condition of the wound. Change the dressing if the wound exudate begins to pool within the wound or if the secondary dressing has reached its absorbent capacity, becomes saturated with exudate (drainage) or whenever good wound care practice dictates that the dressing shall be changed.

Generally, dressings shall be changed daily in heavily exuding wounds, reducing to once to twice a week as the level of wound exude (drainage) decreases and healing proceeds.

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Pharma-Algi® F and Pharma-Algi® F Extra

Table of sizes and codes

Calcium Alginate Dressings:

Pharma-Algi® F	Pharma-Algi® F Extra	Size	Pieces/Box	Boxes/Case
PADALGIF5050	PADALGIFEX5050	5X5 cm	10	48
PADALGIF5075	PADALGIFEX5075	5X7.5 cm	10	48
PADALGIF75100	PADALGIFEX75100	7.5x10 cm	10	48
PADALGIF75150	PADALGIFEX75150	7.5X15 cm	10	48
PADALGIF75200	PADALGIFEX75200	7.5X20 cm	10	24
PADALGIF5070	PADALGIFEX5070	5x7 cm	10	48
PADALGIF6070	PADALGIFEX6070	6x7 cm	10	48
PADALGIF6080	PADALGIFEX6080	6x8 cm	10	48
PADALGIF5090	PADALGIFEX5090	5x9 cm	10	48
PADALGIF6083	PADALGIFEX6083	6x8.3 cm	10	48
PADALGIF50100	PADALGIFEX50100	5x10 cm	10	48
PADALGIF6082	PADALGIFEX6082	6x8.25 cm	10	48
PADALGIF6085	PADALGIFEX6085	6x8.5 cm	10	48
PADALGIF7080	PADALGIFEX7080	7x8 cm	10	48
PADALGIF6580	PADALGIFEX6580	6.5x8 cm	10	48
PADALGIF7575	PADALGIFEX7575	7.5x7.5 cm	10	48
PADALGIF6090	PADALGIFEX6090	6x9 cm	10	48
PADALGIF60100	PADALGIFEX60100	6x10 cm	10	48
PADALGIF5082	PADALGIFEX5082	5x8.25 cm	10	48
PADALGIF80100	PADALGIFEX80100	8x10 cm	10	48
PADALGIF82100	PADALGIFEX82100	8.25x10 cm	10	48
PADALGIF100100	PADALGIFEX100100	10x10 cm	10	48
PADALGIF70120	PADALGIFEX70120	7x12 cm	10	48
PADALGIF80120	PADALGIFEX80120	8x12 cm	10	48
PADALGIF100120	PADALGIFEX100120	10x12 cm	10	48
PADALGIF83120	PADALGIFEX83120	8.3x12 cm	10	48
PADALGIF90150	PADALGIFEX90150	9x15 cm	10	48
PADALGIF80150	PADALGIFEX80150	8x15 cm	10	48
PADALGIF82150	PADALGIFEX82150	8.25x15 cm	10	48
PADALGIF100140	PADALGIFEX100140	10x14 cm	10	48
PADALGIF100150	PADALGIFEX100150	10x15 cm	10	48
PADALGIF83180	PADALGIFEX83180	8.3x18 cm	10	24
PADALGIF82200	PADALGIFEX82200	8.25x20 cm	10	24
PADALGIF150150	PADALGIFEX150150	15x15 cm	10	24
PADALGIF90200	PADALGIFEX90200	9x20 cm	10	24
PADALGIF100200	PADALGIFEX100200	10x20 cm	10	24
PADALGIF83240	PADALGIFEX83240	8.3x24 cm	10	24

