

STERILE
KALTOSTAT®

Calcium-Sodium
Alginate Wound Dressing



III Convatec

INSTRUCTIONS FOR USE



- For Single Use

STERILE - Gamma Sterilized

PRODUCT DESCRIPTION

Kaltostat® Wound Dressing is a soft, white-to-off-white, sterile non-woven pad or ribbon dressing of calcium-sodium alginate fiber. The alginate fibers absorb wound fluid and convert to a firm gel/fiber mat. This gel forms a moist, environment at the wound interface. The gel allows trauma-free removal with little or no damage to newly formed tissue. Depending upon the wound, the dressing may be left in place for up to seven days. Upon contact with a bleeding wound, Kaltostat promotes hemostasis. This primary dressing should be used with a secondary cover dressing.

INDICATIONS

For Over-the-Counter use, Kaltostat Wound Dressing may be used for:

- minor abrasions
- minor lacerations
- minor scalds and burns

Under the supervision of a healthcare professional, Kaltostat Wound Dressing may be used for the management of external wounds such as:

- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology), diabetic ulcers and pressure ulcers (partial and full thickness);
- donor sites, surgical wounds left to heal by secondary intent, traumatic wounds.

Kaltostat may also be used in:

- the local management of bleeding wounds: lacerations, abrasions, nose bleeds, dental extractions, and after surgical wound debridement;
- exudate absorption in oncology wounds such as: fungating cutaneous tumors, cutaneous metastasis and Kaposi's sarcoma.

CONTRAINDICATIONS

Kaltostat Wound Dressing should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components. Kaltostat is not indicated for use as a surgical sponge.

Kaltostat Wound Dressing is not indicated for heavily bleeding wounds.

PRECAUTIONS AND OBSERVATIONS

- Caution: Sterility is guaranteed unless pouch is damaged or opened prior to use. Single use.
 - This wound dressing should not be used with other wound care products without first consulting a healthcare professional.
 - Should you observe irritation (reddening, inflammation), maceration (whitening of skin), hypergranulation (excess tissue formation) or sensitivity (allergic reaction), consult a healthcare professional.
 - Kaltostat Wound Dressing is designed to create a moist environment that assists in wound healing. If a Kaltostat Wound Dressing has initially formed a gel that is allowed to dry out, removal from the wound can be difficult. Drying out is generally not a problem with exuding wounds. Kaltostat Wound Dressing should be removed only with sterile normal saline. Reapplying saline may be necessary to maintain the gel. If the gel dries out, saturate the dried gel with saline to re-hydrate it; this process can take several hours to soften the dried gel.
 - The dressing may be used on infected wounds only under the care of a healthcare professional.
- In addition, for pressure ulcers, venous stasis ulcers, arterial ulcers, diabetic ulcers, donor sites, surgical wounds left to heal by secondary intent, traumatic wounds, oncology wounds and the local management of bleeding wounds:*
- Treatment of the wound types listed above should be under the supervision of a healthcare professional.
 - Appropriate supportive measures should be taken where indicated (e.g. use of graduated compression bandaging in the management of venous leg ulcers or pressure relief measures in the management of pressure ulcers).
 - Colonization of chronic wounds is common and is not a contraindication to the use of the dressing. The dressing may be used on infected wounds under medical supervision together with appropriate therapy and frequent moni-

toring of the wound.

- The control of blood glucose, as well as appropriate supportive measures, should be provided with diabetic foot ulcers.
- For oncology wounds, a secondary dressing of high absorbency is recommended.
- In cavity wounds, the ribbon dressing may be used to pack the wound. For wounds such as fistulae and sinus tracts, employ appropriate techniques during the insertion and removal of the dressing.
- Kaltostat Wound Dressing is not intended for use as a surgical sponge. Kaltostat is not intended to control heavy bleeding. Alternative measures must be considered in those emergency situations where large quantities of blood may be lost.

DIRECTIONS FOR USE

1. Wound Site Preparation and Cleansing

Before applying Kaltostat Wound Dressing, cleanse the areas with an appropriate wound cleanser.

Under the care of a healthcare professional, if necessary, before applying Kaltostat Wound Dressing, the wound should be debrided of excessive necrotic tissue and eschar and irrigated with an appropriate non-toxic cleansing solution.

2. Dressing Preparation and Application

- a. Kaltostat Wound Dressing should be trimmed to the exact size of the wound.
- b. For heavily exuding wounds, Kaltostat Wound Dressing should be applied dry onto the wound. An appropriate secondary dressing should be used to secure Kaltostat Wound Dressing in place.
- c. For lightly exuding wounds, Kaltostat Wound Dressing should be placed on the wound and moistened with sterile normal saline. An appropriate secondary dressing should be used to secure Kaltostat Wound Dressing in place.
- d. When using Kaltostat ribbon in deep cavity wounds, leave at least 2.5 cm or 1 inch outside the wound for easy retrieval.

3. Dressing Change and Removal

- a. On heavily exuding wounds, change the Kaltostat Wound Dressing when strike-through of the secondary dressing occurs or whenever Good Clinical Practice so dictates.
- b. Removal should be trouble free on heavily exuding wounds. Kaltostat Wound Dressing will gel at the wound/dressing interface and lift away.
- c. Removal from lightly exuding wounds may be assisted by saturating the dressing with sterile normal saline.
- d. Cleanse the wound site with an appropriate wound cleanser before applying a new dressing.
- e. As with any dressing, Kaltostat Wound Dressing should be removed from the wound and the wound cleansed at appropriate intervals. Alginate fibers and gels inadvertently left in the wound will simply be absorbed by the body.

4. Bleeding Wounds

Apply Kaltostat Wound Dressing to the bleeding area to promote hemostasis. Remove when the bleeding has stopped. Apply additional Kaltostat Wound Dressing as outlined above.

Discard any unused portion of the product after dressing the wound.

If the immediate product packaging is damaged, do not use.

Protect from light.

Store in a cool, dry place. (<25°C/77°F).

If further information or guidance is needed, please contact Convatec Professional Services.

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