

K963598



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Innovative Technologies Ltd

Safety & Effectiveness**Summary:****Classification Name:****Common / Usual Name:****Contact:****Prepared:**

Innovative Technologies Alginate/Pectin Wound Dressing

79 KMF Liquid Bandage, 880.5090

Alginate Wound Dressing

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Innovative Technologies' Alginate/Pectin Wound Dressings, are

highly conformable, sterile, primary wound dressings intended

to provide an environment ideally suited for the management of

moderate to heavily exuding partial to full thickness

wounds. The non-woven Alginate/Pectin fibre preparation, which

includes various sizes of flat dressings and wound packing, reacts

with wound exudate to form an integral, gelatinous, mass providing

for a moist healing environment. The gel may easily be lifted away

from the wound, reducing the potential for delicate peri-wound tissue

damage during dressing changes.

Dressings are supplied sterile in single use pouches or blister packs.

Product is gamma irradiated in accordance with the Sterilisation Of

Health Care Products - Requirements For Validation and Routine

Control - Radiation Sterilisation, 3rd Edition (ANSI/AAMI/

ISO11137-1994) and Microbiological Methods for Gamma

Sterilisation (AAMI TIR8-1991) for qualification of Method 1 for

dosimetric release with a sterility assurance level of 10^{-6} .

Biocompatibility testing including cytotoxicity, haemolysis, acute

systemic toxicity, skin irritation and sensitisation has been

successfully completed per ISO/Tripartite guidelines.

The Innovative Technologies' Alginate/Pectin Wound Dressings are

similar in design, composition and function to Kaltostat® Alginate

Wound Dressings manufactured by Convatec and Granuflex™

(Duoderm®) Hydrocolloid Dressings manufactured by Convatec.

COMPARATIVE FEATURES

<u>Characteristics</u>	<u>Innovative Tech</u>	<u>Kaltostat</u>	<u>Granuflex</u>
Material	Calcium Alginate / Citrus Pectin	Calcium Alginate	Gelatin, Pectin CMC
Surface Integrity	Needled / Nip rolled Integral	Needled Integral	Extruded/laminated Integral
Indications	Moderate to severe exuding wounds i.e. pressure, venous diabetic & arterial ulcers, donor sites, trauma wounds, dermal lesions and incisions, 1st & 2nd degree burns	Moderate to severe exuding wounds i.e. pressure, venous diabetic & arterial ulcers, donor sites, bleeding surface wounds, trauma injuries, incisions	Moderate to severe exuding wounds i.e. pressure, venous diabetic & arterial abrasions, donor sites, lacerations incisions, 1st and 2nd degree burns, trauma wounds
Packaging	Paper / Paper Pouch or Blister Pack	Paper / Poly Pouch	Blister Pack
Sterilisation Method	Gamma Radiation	Gamma Radiation	Gamma Radiation

Priscilla Whitehead 9/4/96
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