

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

Sorbcel™ Alginate/CMC Wound Dressing
 KMF Hydrophilic Wound Dressing
 Alginate Wound Dressing
 Priscilla Whitehead, Director QA/RA
 Thursday, June 20, 1996
 Innovative Technologies' Sorbcel™ Alginate/CMC 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/Carboxymethylcellulose 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' Sorbcel™ Alginate/CMC Wound Dressings are similar in design, composition and function to Kaltostat® Alginate Wound Dressings manufactured by Courtaulds and Aquacel™ Hydrofiber Wound Dressings manufactured by Convatec.

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COMPARATIVE FEATURES

| <u>Characteristics</u> | <u>Innovative Tech</u> | <u>Kaltostat</u> | <u>Aquacel</u> |
|------------------------|--|--|--|
| Material | Calcium Alginate / Sodium Carboxy-methylcellulose | Calcium Alginate | Sodium Carboxy-methylcellulose |
| Surface Integrity | Needled / Nip rolled | Needled | Needled |
| Absorbancy (BP) | Integral | Integral | Integral |
| Indications | 20 g/g | 17 g/g | 18 g/g |
| | 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 20/6/96
 Priscilla Whitehead, Director QA/RA