

SURGICAL MATERIALS

SURGICAL DRESSINGS

WOUND DRESSINGS AND MEDICATED BANDAGES

Semipermeable Hydrocolloid Dressing

Definition Semipermeable Hydrocolloid Dressing is a sterile, self-adhesive, waterproof, multi-component structure. The skin contact layer is made from an adhesive matrix containing a homogenous dispersion of hydrophilic substances such as Carmellose Sodium, Gelatin, Hydroxyethylcellulose, the calcium salt of Alginic Acid, chitosan and pectin. The hydrocolloid matrix is applied in a uniform manner to a carrier which may consist of a semipermeable film or a polymeric foam layer or a combination of both. A protective release liner is present on the wound contact surface and this is removed before application of the dressing. The hydrophilic components of the dressing take up wound exudate to form a gel, the nature of which is determined by the formulation of the dressing. The dressings are supplied in sheets, individually wrapped and sterile.

Remove the dressing from the packaging immediately before carrying out the following tests.

Uniformity of weight Remove the release liners from 10 dressings. Weigh each dressing and determine the average weight. None of the individual weights deviates from the average weight by more than 10%.

Waterproofness Complies with the test, Appendix XX K, with the following modification. Maintain the hydrostatic head for 18 hours.

Adhesiveness Complies with Test 1 for Adhesiveness, Appendix XX H, beginning at the words 'If the material being examined is not more than 25 mm wide, ...'.

Extensibility Carry out the test using a suitable tensiometer with a jaw separation of 50 mm.

Cut 10 samples, each 25 mm × 75 mm, of the dressing being examined. Cut samples from one or more dressings in equal numbers from two directions at right angles to each other and parallel to the edges or axes of the dressing. Remove the release liner and determine the load required to produce a 20% extension in each sample at a rate of extension of 100 mm per minute.

The load shall not exceed 10 N per 25 mm width in any of the samples examined.

pH Allow a sample, 15 mm × 15 mm, of the dressing being examined to stand in 20 ml of distilled water at 36.5°

to 37.5° for 24 hours. The pH of the resulting solution is 4.0 to 7.0, Appendix V L.

Fluid handling Cut a circular sample of dressing, remove the release liner and affix to the upper flange of a Paddington cup (see Fig. 47) with the wound contact surface facing inwards. Place the retaining ring on the outer surface of the dressing and fasten in place. Weigh the cup together with the base and clamps (W_1). Invert the cup and, using a suitable pipette, add 20 ml of sodium chloride and calcium chloride solution. Fix the base in position and reweigh (W_2). Repeat the procedure on a further four samples. Place the assembled cups in an incubator at 36.5° to 37.5° containing 1 kg of freshly regenerated silica gel. After 24 hours, remove the cups from the incubator, allow them to equilibrate at room temperature for 30 minutes and reweigh (W_3). Remove the base from each cup, gently pour out any excess fluid and leave the cup to drain in the inverted position for 13 to 17 minutes. Reweigh the cup and all its associated components, including the dressing (W_4).

Calculate the weight of moisture vapour lost through the dressing ($W_2 - W_3$) and the weight of fluid absorbed

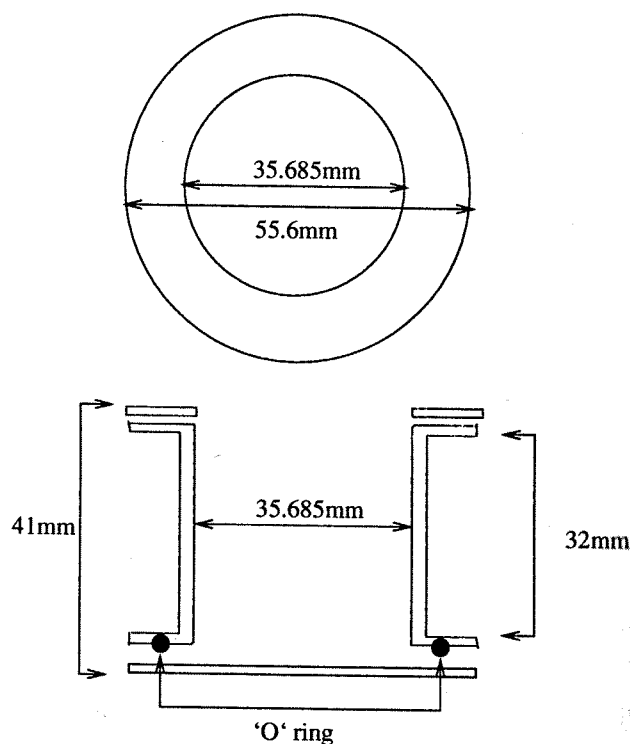


Fig. 47
Paddington cup

by the hydrocolloid mass ($W_4 - W_1$). The sum of these two values represents the fluid handling capacity of the dressing.

The average of the results of the fluid handling capacity of the five samples shall be not less than 1.5g/10 cm² per 24 hours.

Repeat the test using fresh samples and a contact time of 48 hours and determine the fluid handling capacity as before. The average shall be not less than 2.0 g/10 cm² per 48 hours.

Sterility Complies with the *test for sterility*, Appendix XVI A, Method II (Direct inoculation), using about 10 cm² as the minimum quantity for each culture.

NON-ABSORBABLE SUTURES

Sterile Non-absorbable Sutures ☆

Definition Add the following statement at the end of the second paragraph.

They may be stored dry or in a preserving liquid to which an antimicrobial agent but not an antibiotic may be added.

Production First sentence. After 'non-capillary' add 'and to improve handling'.

TABLE I Diameters and breaking loads
Gauge number 0.15, Diameter B min. For '0.005' read '0.012'.

Labelling Amend the fourth statement to read '(4) the colour of the suture or that it is undyed;'.
Add the following statement.

(8) the material, polymer, polymers or copolymers from which the suture is made.

1/95

Add a five-pointed star (☆) to the title of the amendment in the *British Pharmacopoeia* 1993, *Addendum* 1995.