

SURFASOFT® INSTRUCTIONS FOR USE

Description:

SurfaSoft is an inert, neutral wound contact dressing material. SurfaSoft is manufactured from a monofilament woven polyamide thread, which allows drainage over 45% of its surface. Its design is strong, flexible and causes minimum adherence and friction to the skin-graft(s). This allows manipulation of anatomically difficult areas. The smooth surface of the material also means that bacteria do not easily adhere to it. Transparency of the SurfaSoft, allows wound inspection throughout the treatment.

SurfaSoft is well accepted by the wound tissue. The use of SurfaSoft has been proven as a problem free procedure over a number of years. SurfaSoft has been developed and tested by the surgical team of the Red Cross Hospital at Beverwijk in the Netherlands.

Instructions for Use:

- In order to improve the pliability of SurfaSoft, the sheet should be immersed in saline solution for a few seconds.
- After placement of skin-grafts on the wound bed, SurfaSoft may be applied in whole sheets, or in strips. Large pleats and folds should be carefully cut with scissors to ensure a good contact. Small folds and creases, however, do not influence the effectiveness of SurfaSoft.
- Anchor the SurfaSoft and the underlying graft by means of staples or suture distributed evenly over the wound surfaces and along the edges.
- Excessive blood and fluid can be removed from under the SurfaSoft by wiping the surface firmly with a damp gauze.
- A layer of damp gauze or non-woven material is then applied over the SurfaSoft. A further layer of dry gauze can be applied to discourage bacterial colonization.
- The gauze layer should be fixed using an elastic bandage with open structure which should be applied with a light pressure.
- The absorbent gauze layer may be impregnated with various antibacterial agents (such as 0.5 % chloramine, 1% chlorhexidine, furacine oil, etc.), as indicated by bacteriological testing.
- Dependent upon the degree of bacterial contamination, the dressings down to and including the absorbent gauze should be changed AT LEAST once a day. SurfaSoft however should remain on the wound.
- The staples or sutures may be removed after 5 days. The SurfaSoft can be removed after 7-14 days. Before removal, the SurfaSoft should be well soaked in physiological saline. SurfaSoft may well be rejected once the graft has taken.

Indications:

SurfaSoft may be used when:

- fixation of skin graft(s) with conventional wound dressing can be painful, unsatisfactory and time consuming,
- conventional wound dressings tend to disturb the healing process,
- conventional wound dressings can lead to inadequate drainage,
- change of conventional wound dressings can be painful and traumatic.

SurfaSoft may only be applied by a medical specialist.

Side Effects:

SurfaSoft is tested clinically over a number of years and no side effects have been experienced or reported. As a neutral polyamide material in design, no side effects are known in general.

Toxic effects of polyamide have not been reported, macroscopically nor microscopically. Skin implantations, subcutaneous and intracutaneous injections of dispersed TREVIRE fibres in mice have not shown any adverse reactions.

Contra-indications:

No contra-indications known.

If there are any indications which show adverse effect to the treatment area in relation to the treatment with SurfaSoft, please inform your local distributor and the supplier.

Sterilisation:

SurfaSoft is supplied sterilised by gamma-irradiation. Do not use if packaging is damaged or opened before usage.










Storage Directions:

Note: SurfaSoft should be stored at room temperature in a dust-free area designed for storage of STERILE medical devices. Upon receipt of shipment, ensure that the packaging materials are intact. Any shipment problems must be reported immediately to the supplier.

References:

- Robert W. Kreis, Adrianus F.P.M. Vloemans: Fixation of skin transplants in burns with SurfaSoft® and staples, 17-878223 Scand Plast Reconstr Surg 21.
- K.W. Cullen, A.J. Timperly, J.A. Clarke, A. Eldad: SurfaSoft, a new graft dressing, Burns (1988) Vol. 14/No. 1.
- W.R. Otto, J. Nanchanal, Q.L. Lu, N. Boddy, R. Dover: Survival of Allogeneic Cells in Cultured Organotypic Skin Grafts, Plastic and Reconstructive Surgery - July 1995- Vol. 96/No. 1.
- R.W. Kreis, A.F.P.M. Vloemans, M.J. Hoekstra, D.P. Mackie, R.P. Hermans: The Use of Non-viable Glycerol -preserved Cadaver Skin Combined with Widely Expanded Autografts in the Treatment of Extensive Third-degree Burns, The Journal of Trauma, Vol. 30 (3): 269-275; 1990.
- R.G.C. Teepe, R.W. Kreis: The Use of Cultured autologous Epidermis in the Treatment of Extensive Burn Wounds, The Journal of Trauma Vol. 30 (3): 269-275: 1990.
- R.G.C. Teepe, E.J. Koebrugge, M. Ponec, B.J. Vermeer: Fresh versus cryopreserved cultured allografts for treatment of chronic skin ulcers, British Journal of Dermatology (1990) 122, 81-89.
- R. Mahajan, J.G. Mosley: Use of a semipermeable polyamide dressing over skin grafts to venous leg ulcers, British Journal of Surgery (1995), 82, 000-000.

Key to pictograms on label:

	Store at 5 –25 °C
	Store in a dry environment
	Do not store in direct sunlight
	Do not reuse
	Attention, see instructions for use
	Sterilisation using irradiation
	Use by
	Batch code
	CE-certified

Requests for further information and complaints may be addressed to:

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