Debrisoft® Pad, sterile

REF 34321, 34323

January 2018

1. Composition of the product

Debrisoft® Pad consists of monofilament polyester fibres and the reverse side is coated with polyacrylate. It also has a grip pocket made of polyester, polyamide and elastane and a label made out of polyester.

This Product Data Sheet applies to the following item:

REF	Product	Size
34321	Debrisoft® Pad, sterile	10 x 10 cm
34323	Debrisoft® Pad, sterile	13 x 20 cm

2. Packaging, structure and composition

2.1 Unit container

- 1 piece = 1 deep draw package
  consisting of cellulose, polyamid und polypropylen

2.2 Shelf Container

- 5 pieces = 1 folding box
  consisting of cellulose, instructions for use (cellulose)

2.3 Transit Container

- 50 pieces = 10 folding boxes
  consisting of corrugated cardboard box (cellulose)

3. Manufacturing

Debrisoft® Pad is produced according to specification in hygienic conditions and packed as described in its relevant packaging specification.
The product is sterilized by ethylene oxide with DIN EN ISO 11135.

4. Description

White, square device with stitched down border. Three of the four edges are rounded. On the reverse side it has a grip pocket and a label.

5. Properties

The product is individually packed and sterile (EO sterilisation).
Debrisoft® Pad is for single use only and must not be resterilized. The product is sterile as long as the packaging remains unopened and undamaged.

It is Suitable for dry, parchment-like, hyperkeratotic, seborrheic or oily healthy or damaged skin.

There are also very good results with Debrisoft® Pad in the treatment of wounds with major keratotic and necrotic coatings, provided these wounds have previously been treated with autolytic debridement.

6. Intended purpose (see valid instructions for use)

Debrisoft® Pad is intended as a rapid, highly effective, safe and virtually painless debridement method. Debrisoft® Pad is used for absorbing exudate, cellular debris and keratosis during debridement and it is gentle on intact tissue.

7. Medical device classification

Debrisoft® Pad is a medical device of Class Is in terms of Rule 4.
(Council Directive 93/42/EEC concerning medical devices, Annex IX)

8. Biological evaluation and biocompatibility (DIN EN ISO 10993)

The starting materials used in the manufacture of Debrisoft® Pad are safe if the product is used appropriately.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device Debrisoft® Pad and that it is designed, manufactured and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

9. Stability

Stored appropriately, Debrisoft® Pad have a shelf life of 5 years.

10. Disposal

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse.
Packaging materials must also be disposed of in compliance with applicable national requirements.

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signed by

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Director Global Portfolio Management