Debrisoft® Duo

REF 159990, 159991, 159993

February 2025

1. Composition of the product

Debrisoft® Duo consists of:

- Polyester
- Polyacrylate
- Styrene-butadiene copolymer
- Ethylene vinyl acetate
- Carboxymethyl cellulose
- polyamide

This Product Data Sheet applies to the following item:

REF	L&R Nr.	Product	Feature
159990		Debrisoft® Duo	10 x 10 cm, sterile
159991			13 x 20 cm, sterile
159993*	31222		10 x 10 cm, sterile

*for US market only

2. Packaging, structure and composition

2.1 Unit container

- 1 piece = 1 deep draw package
  consisting of cellulose, polyamide und polyethylene

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 = 1 corrugated cardboard box (cellulose)

3. Manufacturing

Debrisoft® Duo 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 EN ISO 11135.

4. Description

Debrisoft® Duo is a two-sided pad for debridement. The soft white side consists of monofilament polyester fibres and a polyacrylate backing. The textured beige side consists of polyester-polyamide loops and serves as a grip pocket as well as for debridement.

5. Properties

- Efficient 2-in1 debridement pad
- Developed to allow more effective debridement of firmly adhering, fibrinous slough than standard mechanical debridement
- The additional textured beige side makes it easy to loosen firmly adherent, fibrinous slough.*
- The soft white side removes debris, exudate and biofilm from the wound

**based on in vitro data*

6. Intended purpose (see valid instructions for use)

The monofilament fibre pad is used to absorb exudate, debris and skin keratoses during the debridement of superficial wounds.

7. Medical device classification

Debrisoft® Duo is a medical device of Class IIb in terms of Rule 4 (according to the regulation (EU) 2017/745 on medical devices (MDR)).

8. Biological evaluation and biocompatibility

The biological risk evaluation performed according to ISO 10993-1 confirms the safety and acceptable biocompatibility of the device Debrisoft® Duo within its intended purpose.

9. Stability

Stored appropriately (keep dry, protected from dust and sunlight), Debrisoft® Duo have a shelf life of 5 years from the date of manufacture.

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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