

Raucodrape® Camera Drape

telescopic folded, sterile

REF 138965

July 2019

1. Composition of the product

Raucodrape® camera drape, telescopic folded consists of:

- film: polyethylene film (transparent, colourless)
LDPE (low density polyethylene)
EVA (ethylene vinyl acetate)
- natural latex-free elastic: synthetic rubber elastomer,
natural latex-free, white
- fixation tape:
 - carrier film: PE/EVA (polyethylene/ethylene vinyl acetate) film, white
 - adhesive: self-adhesive aqueous acrylate dispersion
 - carrier paper: kraft paper, polyethylene coated,
bleached, white
- pouch: polyethylene
- cardboard box: cellulose

This product data sheet covers the following items:

REF	Produktbezeichnung	Größe
138965	Raucodrape® camera drape, telescopic folded	13 x 250 cm, sterile

2. Packaging, structure and composition

2.1 Unit Container

1 piece = 1 deep-draw bag
made of cellulose, polyamide and polyethylene

2.2 Shelf Container

55 pieces = 1 cellulose folding box

2.3 Transit Container

220 pieces (4 folding bags) = 1 corrugated cardboard box

3. Manufacture

Raucodrape® camera drape is produced according to specification in hygienic conditions, packed as described in their relevant packaging specification. The product is sterilized by ethylene oxide in compliance with DIN EN ISO 11135-1.

4. Description

Raucodrape® camera drape is telescopically folded, individually packed and sterile.

5. Properties

Raucodrape® camera drape is tear-resistant, liquid-proof and bacteria-proof cover; it is low in particles, easy to drape and functionally folded.

Raucodrape® camera drape are free of DEHP-, PVC-, latex and colophonium. The material used meets the requirements of EN 13795.

Natural rubber latex is not an intentional ingredient in the production of the above mentioned products or its packaging. However, to the best of our knowledge we can't completely exclude any potential contaminations with latex traces from the production or the environment.

Raucodrape® camera drape is for single use only and must not be resterilized.

6. Intended purpose

Raucodrape® camera drape is intended to be used for covering the stock and the equipment during invasive operations.

7. Medical device classification

Raucodrape® camera drape is a medical device of Class Is products according to Rule 1. (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 Raucodrape® camera drape 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 Raucodrape® camera drape 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 – dry, clean and protected from sunlight – Raucodrape® camera drapes, have a shelf life of 5 years from manufacturing date.

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.

Lohmann & Rauscher International GmbH & Co. KG
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signed by
Dr. Klemens Schulz
Executive Board/ Chief Portfolio Officer