
		Technical Data Sheet		
Foliodrape® COMFORT Slit Sheets			Spec.-No.:	D 6.5905e
			Department:	CMO-DOE
			Date:	2013-01-25

1. General Product Description

Foliodrape® COMFORT Slit Sheets made of soft, three-layer material; with adhesive area around the U-shaped slit for rapid positioning around the operation site, impermeable to moisture and bacteria; abrasion-resistant and low linting. *Foliodrape® COMFORT Slit Sheets* can be use for surgery on the extremities.

Foliodrape® COMFORT Slit Sheets carries the CE-mark according to EU directive 93/42/EWG for medical devices. The product is classified as a class I medical device.
A conformity assessment has been performed for *Foliodrape® COMFORT* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.
The safe use of *Foliodrape® COMFORT Slit Sheets*, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication


Foliodrape® COMFORT Slit Sheets is a disposable product for sterile draping of the patient.

3. Presentations

- Art. No. 256 002** *Foliodrape® COMFORT Slit Sheet 75 x 90 cm* (Slit 6,5 x 40 cm)
sterile, in crepe paper, 20 pieces per dispenser, 4 dispenser per transport carton
- Art. No. 256 224** *Foliodrape® COMFORT Slit Sheet 150 x 200 cm* (Slit 6.5 x 65 cm)
sterile, in crepe paper, 8 pieces per dispenser, 2 dispenser per transport carton
- Art. No. 256 235** *Foliodrape® COMFORT Slit Sheet 200 x 260 cm* (Slit 6.5 x 95 cm)
sterile, in crepe paper, 5 pieces per dispenser, 2 dispenser per transport carton

4. Product Characteristics

Composition:	Three-layer Nonwoven-Film-Nonwoven laminate
Nonwoven (outside):	Absorbent viscose, colour: aqua
film:	PE-film; colour: aqua
Nonwoven (inside):	PP-SMS, colour: white
Adhesive (laminate):	Dispersion adhesive / Hotmelt
Self adhesive area:	Adhesive based on synthetic rubber, latex-free; covered with silicon paper
Sterilization	with ethylene oxide

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5. Product Requirements (typical values)

Foliodrape® COMFORT corresponds to all requirements of European standard for surgical drapes EN 13795, for the highest performance level "High performance, critical area".

For details see Technical Data sheet of the base material (D 6.5030).

6. Labelling

Lot-No. with 9-digit code:
e.g.:

LOT	9	XXX	38	YYY
	year	internal code	week of production	internal code

Expiry date:

e.g. ⌚ 2014 12
 year month

Shelf life: 5 years

The product will be sterile during this period as long as the packaging is not damaged and the storage conditions are kept.

7. Packaging

Foliodrape® COMFORT Slit Sheets is sealed into sterile packaging (peeling pouch) according to EN ISO 11607 and EN 868. The peel pouch is packed into folding box and transport carton, sealed with adhesive tapes and stored on euro-pallet.

Date: 2013-01-25

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i. A.



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