



## Foliodrape® COMFORT Universal Slit Sheet Set (Art. No. 257 135)



Spec.-No.:	D 6.5306f
Department:	CMO-DOE
Date:	2013-01-23

### 1. General Product Description

*Foliodrape® COMFORT Universal Slit Sheet Set* is used mainly in ENT, in maxillofacial surgery and in strumectomies.

The *Foliodrape® COMFORT Universal Slit Sheet Set* carries the CE-mark according to EU directive 93/42/EWG for medical devices and is classified as class I medical devices. 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 Universal Slit Sheet Set*, therefore, is ensured if the product is used in line with the intended purpose.

### 2. Application / Indication


*Foliodrape® COMFORT Universal Slit Sheet Set* is a disposable product for sterile draping of the patient and the theatre equipment.

### 3. Presentations

<b>Art. No. 257 135</b>	<b>Foliodrape® COMFORT Universal Slit Sheet Set</b>
	sterile, 5 Sets per dispenser, 1 dispenser per transport carton
	Dimensions of dispenser: 565 x 370 x 295 mm (L x W x H)
	Dimensions of transport carton: 585 x 385 x 315 mm (L x W x H)

### 4. Product Characteristics

<b>Content:</b>	1 table cover 140 x 190 cm
	1 self adhesive drape sheet 200 x <u>240</u> cm
	1 self adhesive Slit Sheet drape 150 x 240 cm (Slit: 6.5 x 60 cm)
	4 cellulose towels 33 x 33 cm
	1 mayo stand cover 80 x 145 cm
	<u>underlined</u> is the side with the adhesive zone on
<b>Sterilization:</b>	With ethylene oxide gas

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5. Product Requirements

*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), table cover (D 6.5410a), and the mayo stand cover (D 6.5403).*

6. Labelling

Lot-No. with 9-digit code:

e.g.: 9XXX38YYY

LOT	9	XXX	38	YYY
	year of production	for internal purposes only	week of production	for internal purposes only

Expiry date:

e.g. ⌚ 2014 – 01  
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 Universal Slit Sheet Set* 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: 2013-01-23

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i. A.



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