


		Technical Data Sheet
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Foliodrape® COMFORT Laparoscopy Set I (Art. No. 257 162)		Spec.-no.:	D 6.5306h
		Department:	CMO-DOE
		Date:	2013-01-24

1. General Product Description

Foliodrape® COMFORT Laparoscopy Set I for sterile draping in laparoscopic procedures conducted with the patient in the lithomy position, e.g. in laparoscopic cholecystectomy, pelviscopy, herniotomy, appendectomy and vagotomy.

The Foliodrape® COMFORT Laparoscopy Set I 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 Laparoscopy Set I, therefore is ensured if the product is used in line with the intended purpose.

2. Application / Indication


Foliodrape® COMFORT Laparoscopy Set I is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations:

Art. No. 257 162	Foliodrape® COMFORT Laparoscopy Set I
	sterile, 6 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

Content:	1 table cover 140 x 190 cm
	1 laparoscopy sheet with integrated transparent MIS instrument bag 260 x 320 cm
	1 mayo stand cover 80 x 145 cm
	4 cellulose towels 33 x 33 cm
Sterilization:	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.:

LOT	9	xxx	34	xxx
	year of production	for internal purpose 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 Laparoscopy Set I 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: 2013-01-24

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i. A.



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