		Technical Data Sheet
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Foliodrape® COMFORT Rectum Set I (Art. No. 257 159)		Spec.-no.:	D 6.5306j
		Department:	CMO-DOE
		Date:	2013-01-24

1. General Product Description

Foliodrape® COMFORT Rectum Set I for sterile draping for all abdominal – perineal simultaneous operations, e.g. in hernicolectomy, resection of the sigmoid colon, abdominal resection of the rectum and abdominal – perineal amputations of the rectum.

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

2. Application / Indication


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

3. Presentations:

Art. No. 257 159	Foliodrape® COMFORT Rectum Set I
	sterile, 4 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 reinforced 140 x 190 cm
	1 rectum drape 260 x 320 cm with abdominal and rectal apertures and integrated leggings
	1 drape sheet 75 x 90 cm
	1 mayo stand cover 80 x 145 cm
	2 velcro fasteners 2 x 23 cm
	4 cellulose towels 33 x 33 cm
	1 OR tape 10 x 50 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.: **9XXX38YYY**

LOT	9	XXX	38	YYY
	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 Rectum 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

PAUL HARTMANN AG
CMO- Development OTM & Exam. Gloves (CMO-DOE)

i. A.



Dr. Thomas Hoffmann