

<b>Foliodrape® COMFORT Neurosurgery Set I (Art. No. 257 233)</b>		Spec.-no.:	D 6.5339b
		Department:	CMO-DOE
		Date:	2013-01-31

**1. General Product Description**

Foliodrape® COMFORT Neurosurgery Set I for a sterile draping during craniocerebral procedures in neurosurgery, e.g. in stereotactic brain operations, intracranial tumours as well as in closed or open craniocerebral injuries with intracranial haemorrhage, hydrocephalus and osteoplastic or osteoplastic trepanation.

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

**2. Application / Indication**

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

**3. Presentations:**

<b>Art. No. 257 233</b>	<b>Foliodrape® Comfort Neurosurgery Set I</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 neurosurgery drape sheet 245 x 320 cm with incision film and fluid collection bag
	2 self-adhesive drape sheets 50 x 50 cm
	2 velcro fastener 2 x 23 cm
	1 mayo stand cover 80 x 145 cm
	1 adhesive tape 10 x 50 cm
	4 cellulose towels 33 x 33 cm
<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**

<b>LOT</b>	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.

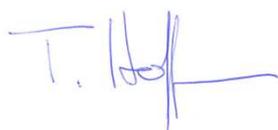
**7. Packaging**

Foliodrape® COMFORT Neurosurgery 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: 2013-01-31

PAUL HARTMANN AG  
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i. A.



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