


		Technical Data Sheet
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Foliodrape® PROTECT, Extremity Set (Art. No. 938 915/2)		Spec.-no.:	D6.1001x
		Department:	CMO-DOE
		Date:	2014-06-01

1. General Product Description

Foliodrape® PROTECT Extremity Set is for interventions in the area of the leg (arthroscopy, knee, extremities).

The Foliodrape® PROTECT Extremity Set carries the CE-mark according to EU directive 93/42/EEG for medical devices and is classified as class I medical device.

A conformity assessment has been performed for Foliodrape® PROTECT and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Foliodrape® PROTECT Extremity Set, therefore, is ensured if the product is used in line with the intended purpose.

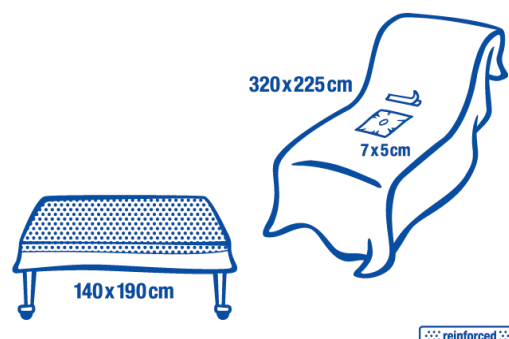
2. Application / Indication

Foliodrape® Extremity Set is a single-use product for sterile draping of the patient and the theatre equipment.


3. Presentations:

Art. Nr. 938 915/2	Foliodrape® PROTECT Extremity Set
	sterile, 9 Sets per dispenser, 1 dispenser per transport carton
	Abmessungen Dispenser: 545 x 374 x 234 mm (L x B x H)
	Abmessungen Transportkarton: 590 x 390 x 250 mm (L x B x H)

4. Product characteristics

Content: 	1 table cover reinforced 140 x 190 cm
	1 extremity drape sheet 225 x 320 cm, fenestration 5 x 7 cm, with elastic collar and hook-and-loop fastener
	In crepe paper 100 x 100 cm
Sterilization:	With ethylene oxide gas according EN 556-1 and EN 11135-1

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5. Product requirements:

The Foliodrape® draping materials 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 6.1005), and table cover (D 6.5410).

6. Labelling Lot no. with 9-digit code:

e.g.: 4XXX38YYY

LOT	4	XXX	38	YYY
	year of production	for internal purposes only	week of production	for internal purposes only

Expiry date:

e.g.  2019 – 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® PROTECT Extremity set wrapped into sterile crepe paper, 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: 2014-06-01

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

i. A.



Dr. Thomas Hoffmann