



Foliodrape® Protect Extremity Set with Approach Drape (Art. No. 938 917)



Spec.-No.:	D 6.1001w
Department:	CMO-DOE
Date:	2014-11-17

1. General Product Description

Foliodrape® Protect Extremity Set with Approach Drape for interventions knee-TEP, knee joint arthroscopy, patella surgeries, lower leg surgeries etc.

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

2. Application / Indication

Foliodrape® Protect Extremity Set with Approach Drape is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations

Art. No. 938 917	<i>Foliodrape® Protect Extremity Set with Approach Drape</i>
	sterile, 7 Sets per dispenser, 1 dispenser per transport carton
	Dimensions of dispenser: 545 x 374 x 234 mm (L x W x H)
	Dimensions of transport carton: 590 x 390 x 250 mm (L x W x H)

4. Product Characteristics

<p>Content:</p>	1 reinforced table cover 140 x 190 cm
	1 reinforced extremity drape sheet with elastic cuff and velcro fastener 320 x 225 cm (ø fenestration 7 x 5 cm)
	1 approach drape 150 x 100 cm
Sterilization:	With ethylene oxide gas according to DIN EN ISO 11135-1



Technical Data Sheet

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5. Product Requirements

Foliodrape® Protect 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 6.1005a) and back table cover (D 6.1005d).

6. Labelling

Lot-No. with 9-digit code:

e.g.: 4023XXXXX

LOT	4	023	XXXXX
	year of production	serial production order	for internal use

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 with Approach Drape is wrapped in crepe paper and 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: 2014-11-17

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