

Foliodrape® Protect Plus, Extremity Set II reinforced (Art. No. 938 774/1)		Spec.-No.:	D 6.1001-05
		Department:	CMO-DOE
		Date:	2015-11-02

1. General Product Description

Foliodrape® Protect Plus Extremity Set II reinforced for interventions like knee-TEP, knee joint arthroscopy patella surgeries, lower leg surgeries etc.

The *Foliodrape® Protect Plus Extremity Set II reinforced* carries the CE-mark according to EU directive 93/42/EEG for medical devices and is classified as class I sterile medical device. A conformity assessment has been performed for *Foliodrape® Protect Plus* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of *Foliodrape® Protect Plus Extremity Set II reinforced*, therefore, is ensured if the product is used in line with the intended purpose.

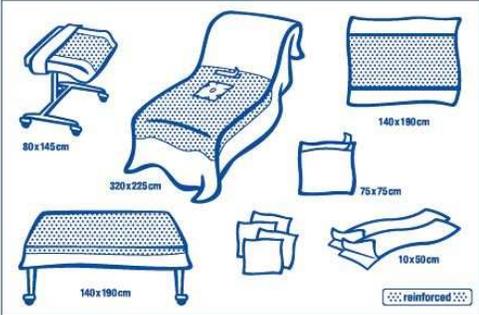
2. Application / Indication

Foliodrape® Protect Plus Extremity Set II reinforced is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations

Art. No. 938 774/1	Foliodrape® Protect Plus Extremity Set II reinforced
	sterile, 5 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 mayo stand cover (telescopic folded) 80 x 145 cm
	1 reinforced extremity drape sheet with elastic cuff and velcro fastener 320 x 225 cm (ø fenestration 5 x 7 cm, reinforced zone 150 x 105 cm)
	1 approach drape 140 x 190 cm
	1 self-adhesive drape 75 x 75 cm
	4 cellulose towels 30 x 33 cm
2 or-tapes 10 x 50 cm	
Sterilization:	With ethylene oxide gas according to EN 556-1 and EN 11135-1
Self adhesives:	Skin-friendly synthetic rubber, latex free and colophony free

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5. Product Requirements

Foliodrape® Protect Plus 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, D 6.1005b), mayo stand cover (D 6.1005c) and back table cover (D 6.1005d).

6. Labelling

Lot-No. with 9-digit code:

e.g.: 5023XXXXX

LOT	5	023	XXXXX
	year of production	serial production order	for internal use

Expiry date:

e.g. ⌚ 2020 – 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 Plus Extremity Set II reinforced 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: 2015-11-02

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i. A.



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