

Foliodrape® Protect Plus, Rectum Set I reinforced (Art. No. 938 714/2)	Spec.-No.:	D 6.1003b
	Department:	CMO-DOE
	Date:	2016-01-25

1. General Product Description

Foliodrape® Protect Plus Rectum Set I reinforced for all kinds of simultaneous abdominal-perineal surgeries, e.g. hemicolectomy, resection of colon sigmoideum, abdominal rectum resection, abdominal-perineal rectum amputation.

The *Foliodrape® Protect Plus Rectum Set I reinforced* carries the CE-mark according to EU directive 93/42/EWG for medical devices and is classified as class I sterile medical devices.

A conformity assessment has been performed for *Foliodrape® Protect Plus Rectum Set I reinforced* 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 Rectum Set I reinforced*, therefore, is ensured if the product is used in line with the intended purpose.

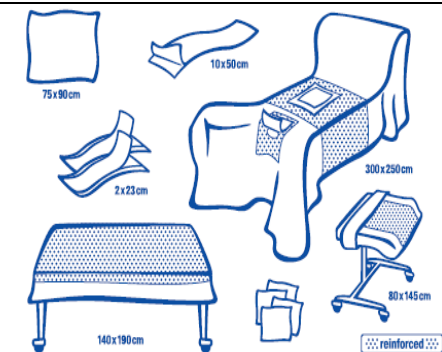
2. Application / Indication

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

3. Presentations

Art. No. 938 714/2	Foliodrape® Protect Plus Rectum Set I 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> 	<p>1 reinforced table cover 140 x 190 cm</p> <p>1 mayo stand cover 80 x 145 cm (telescopic folding)</p> <p>1 rectum drape reinforced 300 x 250 with abdominal (28 x 32 cm) and perineal fenestrations (12 x 15 cm) and integrated leg-gings, (reinforced zones: abdominal 75 x 190 cm, perineal 90 x 60 cm)</p> <p>1 drape 75 x 90 cm</p> <p>4 cellulose towels 30 x 33 cm</p> <p>1 adhesive tape 10 x 50 cm</p> <p>2 Velcro fastener (loose) 2 x 23 cm</p>
<p>Sterilization:</p>	With ethylene oxide gas according to EN 556-1 and EN11135-1
<p>Self adhesives:</p>	Skin-friendly synthetic rubber, latex free and colophony free

		<h1>Technical Data Sheet</h1>
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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.: 6023XXXXX

LOT	6	023	XXXXX
	year of production	serial production order	for internal use

Expiry date:

e.g. ⌚ 2021 – 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 Rectum Set I 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: 2016-01-25

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i. A.



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