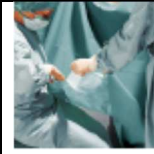


Foliodrape® Protect Plus, Gynaecology Set II reinforced (Art. No. 938 719/2)



Spec.-No.:	D 6.1002a
Department:	CMO-DOE
Date:	2014-06-01

1. General Product Description

Foliodrape® Protect Plus Gynaecology Set II reinforced for all trans- and intravaginal surgeries, e.g. vaginal and pelvis floor plastic surgeries, vaginal hysterectomy.

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

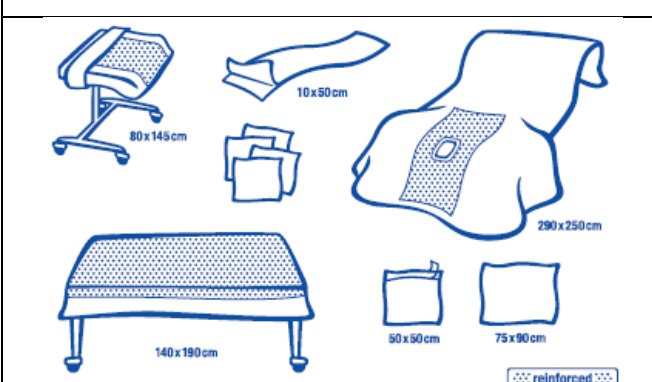
2. Application / Indication


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

3. Presentations

Art. No. 938 719/2	Foliodrape® Protect Plus Gynaecology 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 80 x 145 cm (telescopic folding)
	1 gynaecology drape 250 x 290 with oval fenestration (9 x 12 cm) and integrated leggings, reinforced (reinforced zone: 50 x 140 cm)
	1 drape 75 x 90 cm
	1 transparent drape self adhesive 50 x 50 cm
	1 adhesive tape 10 x 50 cm
4 cellulose towels 30 x 33 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.: 8023XXXXX

LOT	8	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 Plus Gynaecology 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: 2014-06-01

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i. A.



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