

Foliodrape® Protect Plus, Sectio Set I reinforced (Art. No. 938 736/2)		Spec.-No.:	D 6.1002g
		Department:	CMO-DOE
		Date:	2016-01-25

1. General Product Description

Foliodrape® Protect Plus Sectio Set I reinforced for gynaecological surgeries with Pfannenstiel cut, e.g. hysterectomy, open prostatectomy.

The *Foliodrape® Protect Plus Sectio 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 Sectio Set I reinforced* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use and effectiveness of *Foliodrape® Protect Plus Sectio Set I reinforced*, therefore, is ensured if the product is used in line with the intended purpose.

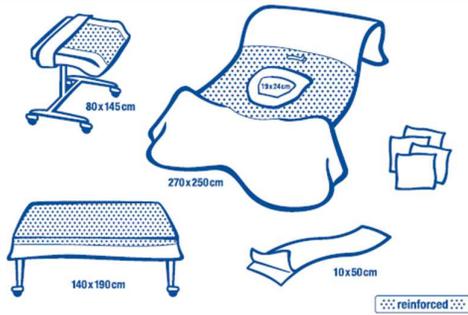
2. Application / Indication

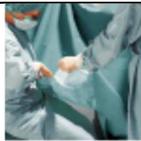
Foliodrape® Protect Plus Sectio Set I reinforced is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations

Art. No. 938 736/2	Foliodrape® Protect Plus Sectio 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 back table cover reinforced 140 x 190 cm</p>
	<p>1 mayo stand cover 80 x 145 cm</p> <p>1 sectio drape reinforced 270 x 250 cm with integrated leggings (reinforcement 70 x 190 cm, incision film 32 x 29 cm, "coffee filter" fenestration 24 x 19 cm)</p>
	<p>1 OR Tape 10 x 50 cm</p>
	<p>4 cellulose towels 30 x 33 cm</p>
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.: 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 Sectio 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

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

i. A.



Dr. Evelyn Hartmann