


Foliodrape® Protect, Urology Set I (Art. No. 938 700/2)		Spec.-No.:	D 6.1004
		Department:	CMO-DOE
		Date:	2016-01-25

1. General Product Description

Foliodrape® Protect Urology Set I containing a Urology drape sheet with suprapubic fenestration, genital fenestration, latex-free fingerstall and fluid collection pouch. Preferred for interventions like prostata resection, utereorenoscopy, laser-lithotripsy and urethrotomy.

The *Foliodrape® Protect Urology Set I* 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* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of *Foliodrape® Protect Urology Set I*, therefore, is ensured if the product is used in line with the intended purpose.

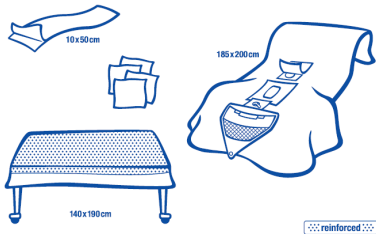
2. Application / Indication


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

3. Presentations

Art. No. 938 700/2	Foliodrape® Protect Urology Set I
	sterile, 8 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 Urology drape sheet 185 x 200 cm with suprapubic fenestration (ø 7 cm, self-adhesive), genital fenestration (7 x 10 cm, self-adhesive), latex-free fingerstall, integrated leggings and fluid collection pouch (with integrated sieve)
	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

Foliodrape® Protect, Urology Set I (Art. No. 938 700/2)		Spec.-No.:	D 6.1004
		Department:	CMO-DOE
		Date:	2016-01-25

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.: 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.

		<h1>Technical Data Sheet</h1>
--	--	-------------------------------

Foliodrape® Protect, Urology Set I (Art. No. 938 700/2)		Spec.-No.:	D 6.1004
		Department:	CMO-DOE
		Date:	2016-01-25

7. Packaging

Foliodrape® Protect Urology Set I 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