

Foliodrape® Protect, Universal Set I (without ITC) (Art. No. 938 721/2)		Spec.-No.:	D 6.1000d
		Department:	CMO-DOE
		Date:	2014-06-01

1. General Product Description

Foliodrape® Protect Universal Set I (without ITC) for a wide variety of ambulant surgeries with low liquid levels.

The *Foliodrape® Protect Universal Set I (without ITC)* carries the CE-mark according to EU directive 93/42/EWG for medical devices and is classified as class I sterile medical device.

A conformity assessment has been performed for *Foliodrape® Protect Universal Set I (without ITC)* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of *Foliodrape® Protect Universal Set I (without ITC)*, therefore, is ensured if the product is used in line with the intended purpose.



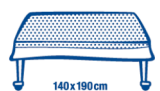

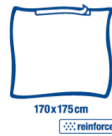
2. Application / Indication

Foliodrape® Protect Universal Set I (without ITC) is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations

Art. No. 938 721/2	Foliodrape® Protect Universal Set I (without ITC)
	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

Content:	1 reinforced table cover 140 x 190 cm
	1 self adhesive drape sheet 150 x <u>240</u> cm (adhesive 90 cm)
	1 self adhesive drape sheet 170 x <u>175</u> cm (adhesive 90 cm)
	2 self adhesive drape sheets 75 x <u>90</u> cm (adhesive 90 cm)
	1 adhesive tape 10 x 50 cm
	4 cellulose towels 30 x 33 cm
Sterilization:	With ethylene oxide gas according EN 556-1 and EN 11135-1
Self adhesives:	Skin-friendly, synthetic rubber based, latex- and colophony-free

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5. Product Requirements

The *Foliodrape® draping materials* correspond 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 6.5410).


6. Labelling

Lot-No. with 9-digit code:

e.g.: 4XXX38YYY

LOT	4	XXX	38	YYY
	year of production	for internal purposes only	week of production	for internal purposes only

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 Universal Set I (without ITC) 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.

8. storage conditions

Store in dry place and keep dry.

Date: 2014-06-01

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