

Foliodrape® PROTECT PLUS, Universal Set reinforced extra large (Art. No. 938 901/2)



Spec.-No.:	D 6.1000f
Department:	CMO-DOE
Date:	2014-06-01

1. General Product Description

Foliodrape® PROTECT PULS Universal Set reinforced extra large for big abdominal and thoracic surgeries with heart lung machine and big amount of fluids, e.g. tumor resection, partly liver resection, breast amputation etc.

The *Foliodrape® PROTECT PULS Universal Set reinforced extra large* 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 PULS Universal Set reinforced extra large* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of *Foliodrape® PROTECT PULS Universal Set reinforced extra large*, therefore, is ensured if the product is used in line with the intended purpose.

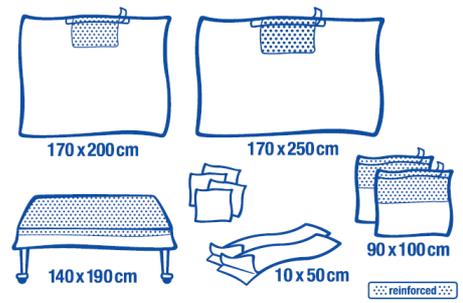
2. Application / Indication

Foliodrape® PROTECT PULS Universal Set reinforced extra large is a single-use product for sterile draping of the patient and the theatre equipment.

3. Presentations

Art. No. 938 901/2	Foliodrape® PROTECT PULS Universal Set reinforced extra large
	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 self adhesive, reinforced drape sheet 170 x <u>250</u> cm (adhesive 90 cm, reinforced zone 50 x 75 cm)
	1 self adhesive, reinforced drape sheet 170 x <u>200</u> cm (adhesive 90 cm, reinforced zone 50 x 75 cm)
	2 self adhesive, reinforced drape sheets 90 x <u>100</u> cm (adhesive 90 cm, reinforced zone 36 x 100 cm)
	2 adhesive tape 10 x 50 cm
	4 cellulose towels 30 x 33 cm <u>underlined</u> is the side with the adhesive zone on in crepe paper 100 x 100 cm
Self adhesives:	Skin-friendly, synthetic rubber based, latex- and colophony-free
Sterilization:	With ethylene oxide gas according EN 556-1 and EN 11135-1

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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, D 6.1005b) 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 PULS Universal Set reinforced extra large is wrapped in crepe paper and 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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