

Foliodrape PROTECT PLUS, Head/Neck Set (Art. No. 938 928/1)

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

1. General Product Description

Foliodrape® PROTECT PLUS Head/Neck Set reinforced for all kind of Head/Neck surgeries.

The *Foliodrape® PROTECT PLUS Head/Neck Set reinforced* carries the CE-mark according to EU directive 93/42/EEG for medical devices and is classified as class I sterile medical device. A conformity assessment has been performed for *Foliodrape® PROTECT PLUS* 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 Head/Neck Set reinforced*, therefore, is ensured if the product is used in line with the intended purpose.

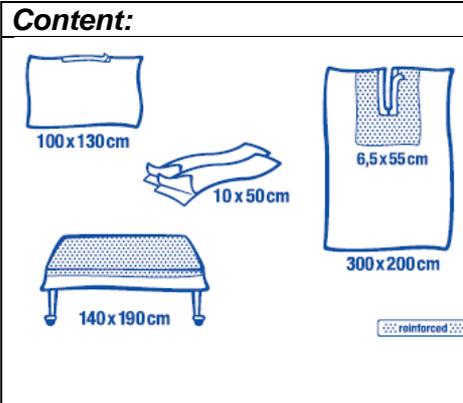
2. Application / Indication

Foliodrape® PROTECT PLUS Head/Neck Set reinforced is a single-use product for sterile draping of the patient and the theatre equipment.

3. Presentations

Art. No. 938 928/1	<i>Foliodrape® PROTECT PLUS Head/Neck Set reinforced</i>
	sterile, 6 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 Slit sheet drape reinforced 300 x 200 cm (reinforcement 50 x 110 cm, slit 6,5 x 55 cm)
	1 Drape 100 x 130 cm (adhesive (80 cm))
	2 OR-Tapes 10 x 50 cm
	1 back table cover reinforced 140 x 190 cm
	Underlined 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 und 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 purpose 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 PLUS Head/Neck Set 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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