		Technical Data Sheet	
Foliodrape® Protect Plus, LAP/Paediatrics/Spinal Drape reinforced (Art. No. 938 825)		Spec.-No.:	D 6.1009c
		Department:	CMO-DOE
		Date:	2016-01-25

#### 1. General Product Description

*Foliodrape® Protect Plus LAP/Paediatrics/Spinal Drape reinforced* for spine surgery, intervertebral disc herniation.

*Foliodrape® Protect Plus LAP/Paediatrics/Spinal Drape 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* 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 LAP/Paediatrics/Spinal Drape reinforced*, therefore, is ensured if the product is used in line with the intended purpose.

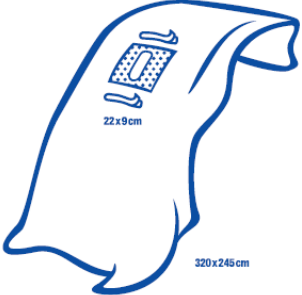
#### 2. Application / Indication

*Foliodrape® Protect Plus LAP/Paediatrics/Spinal Drape reinforced* is a disposable product for sterile draping of the patient and the theatre equipment.

#### 3. Presentations

Art. No. 938 825	<i>Foliodrape® Protect Plus LAP/Paediatrics/Spinal Drape reinforced</i>
	sterile, 9 drapes 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 Spinal drape reinforced 320 x 245 cm (reinforcement 50 x 40 cm, fenestration 22 x 9 cm) with self-adhesive area and two integrated Velcro fasteners for securing suction tubes and cautery cables
<b>Sterilization:</b>	With ethylene oxide gas according to EN 556-1 and EN 11135-1
<b>Self adhesives:</b>	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).*


#### 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.



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#### 7. Packaging

*Foliodrape® Protect Plus LAP/Paediatrics/Spinal Drape reinforced* 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: 2016-01-25

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i. A.



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