

Foliodrape® Protect, Varicose Vein Set (Art. No. 938 730/2)		Spec.-No.:	D 6.1000n
	Department:	CMO-DOE	
	Date:	2014-06-01	

1. General Product Description

Foliodrape® Protect Varicose Vein Set preferred for the varicose vein procedures.

The *Foliodrape® Protect Varicose Vein Set* carries the CE-mark according to EU directive 93/42/EWG for medical devices and is classified as class I 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 Varicose Vein Set*, therefore, is ensured if the product is used in line with the intended purpose.

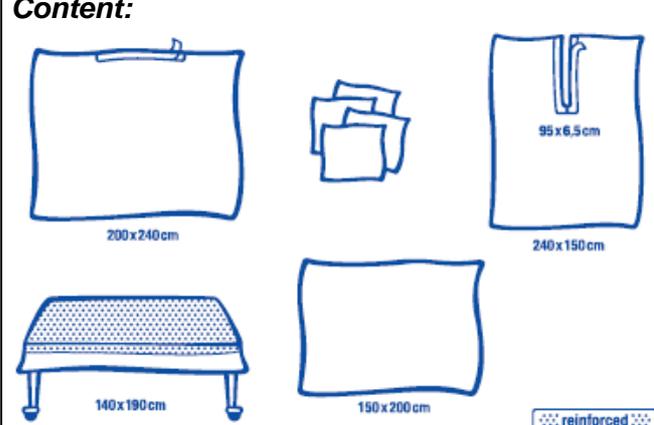
2. Application / Indication

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

3. Presentations

Art. No. 938 730/2	Foliodrape® Protect Varicose Vein Set
	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> 	<p>1 table cover 140 x 190 cm</p> <p>1 self-adhesive slit sheet drape 150 x 240 cm</p> <p>1 self-adhesive drape sheet 200 x <u>240</u> cm</p> <p>1 drape sheet 150 x 200 cm</p> <p>4 cellulose towels 30 x 33 cm</p> <p><u>underlined</u> is the side with the adhesive zone on</p>
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

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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 6.1005), and table cover (D 6.1005d).

6. Labelling

Lot-No. with 9-digit code:

e.g.: 5023XXXXX

LOT	5	023	XXXXX
	year of production	Serial production order	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 Varicose Vein Set 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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