

		<h1>Technical Data Sheet</h1>
--	--	-------------------------------

Foliodrape® Protect Plus, Angiography Set I reinforced (Art. No. 938 920)		Spec.-No.:	D 6.1011c
		Department:	CMO-DOE
		Date:	2016-06-15

1. General Product Description

Foliodrape® Protect Plus Angiography Set I reinforced is for femoral angiography diagnostical and therapeutical.

The *Foliodrape® Protect Plus Angiography Set I 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 Angiography Set I reinforced*, therefore, is ensured if the product is used in line with the intended purpose.

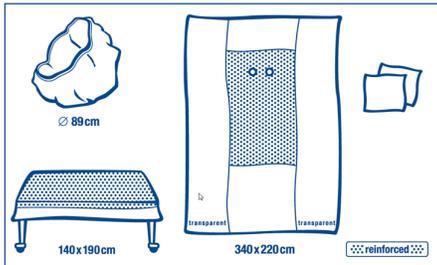
2. Application / Indication

Foliodrape® Protect Plus Angiography Set I reinforced is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations

Art. No. 938 920	<i>Foliodrape® Protect Plus Angiography Set I, reinforced</i>
	sterile, 5 Sets per dispenser, 1 dispenser per transport carton
	Dimensions of dispenser: 374 x 234 x 545 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 reinforced angiography drape, self-adhesive 220 x 340 cm (reinforced zone 175 x 90 cm, 2x incision films ø 16 cm with fenestration ø 8 cm)
	2 cellulose towels
	1 PE-Cover
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

Foliodrape® Protect Plus, Angiography Set I reinforced (Art. No. 938 920)		Spec.-No.:	D 6.1011c
		Department:	CMO-DOE
		Date:	2016-06-15

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) and the back table cover (D 6.1005d).

6. Labelling

Lot-No. with 9-digit code:

e.g.: 1023XXXXX

LOT	1	023	XXXXX
	year of production	serial production order	for internal use

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 Angiography Set I reinforced is folded 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: 2016-06-15

PAUL HARTMANN AG
Development OTM & Exam. Gloves (CMO-DOE)

i. A.



Dr. Leonie Lindner