

<b>Foliodrape® PROTECT PLUS, Hand-Foot-Set I reinforced (Art. No. 938 929/1)</b>		Spec.-No.:	D 6.1001u
		Department:	CMO-DOE
		Date:	2014-06-01

## 1. General Product Description

*Foliodrape® PROTECT PLUS Hand-Foot Set I reinforced* for interventions like carpal tunnel syndrome (CTS), wrist fracture, ankle fracture, hallux valgus surgery.

The *Foliodrape® PROTECT PLUS Hand-Foot-Set I reinforced* 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 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 Hand-Foot-Set I reinforced*, therefore, is ensured if the product is used in line with the intended purpose.

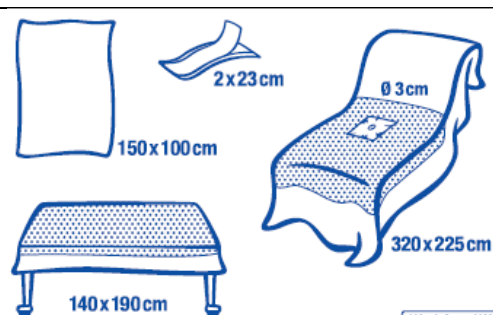
## 2. Application / Indication


*Foliodrape® PROTECT PLUS Hand-Foot-Set I reinforced* is a single-use product for sterile draping of the patient and the theatre equipment.

## 3. Presentations

<b>Art. No. 938 929/1</b>	<b><i>Foliodrape® PROTECT PLUS Hand-Foot-Set I reinforced</i></b>
	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

<b>Content:</b> 	1 reinforced table cover 140 x 190 cm 1 Hand-Foot drape reinforced with elastic cuff 320 x 225 cm (reinforcement 150 x 105 cm, fenestration Ø 3 cm) 1 approach drape 150 x 100 cm 1 hook-and-loop fastener 2 x 23 cm In crepe paper 100 x 100 cm
<b>Sterilization:</b>	With ethylene oxide gas according EN 556-1 and EN 11135-1
<b>Self adhesives:</b>	Skin-friendly, synthetic rubber based, latex- and colophony-free

<b>Foliodrape® PROTECT PLUS, Hand-Foot-Set I reinforced (Art. No. 938 929/1)</b>		Spec.-No.:	D 6.1001u
		Department:	CMO-DOE
		Date:	2014-06-01

## 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 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 Hand-Foot-Set 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: 2014-06-01

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

i. A.



Dr. Thomas Hoffmann