

Foliodrape® COMFORT Hand/Foot Drapes Art. No. 254 440		Spec.-No.:	D 6.5905d
		Department:	CMO-DOE
		Date:	2013-01-25

1. General Product Description

Foliodrape® COMFORT Hand/Foot Drapes made of soft, three-layer material; with elastic fenestration; aperture diameter 3 cm, impermeable to moisture and bacteria; abrasion-resistant and low linting. Foliodrape® COMFORT Hand/Foot Drapes can be use for surgery on the extremities, e.g.: at osteosynthesis of the hand or at hallux valgus operation.

Foliodrape® COMFORT Hand/Foot Drapes carries the CE-mark according to EU directive 93/42/EWG for medical devices. The product is classified as a class I medical device. A conformity assessment has been performed for Foliodrape® COMFORT and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of *Foliodrape® COMFORT Hand/Foot Drapes*, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication


Foliodrape® COMFORT Hand/ Foot Drapes is a disposable product for sterile draping of the patient.

3. Presentations

Art. No. 254 440 **Foliodrape® COMFORT Hand/Foot Drapes 245 x 320 cm**
sterile, 7 pieces per dispenser, 1 dispenser per transport carton

4. Product Characteristics

Material:	
• laminate:	nonwoven/film/nonwoven
- nonwoven: - adhesive: - film: - nonwoven:	viscose fibres chemically bonded, green adhesive based on vinyl acetate copolymer and hotmelt polyethylene film, matted thermobonded polypropylene SMS
mass per square meter:	approx. 77 g/m ²
• elastic fenestration: - film - adhesive tape - backing paper	polyethylene film, green, matted clear polyester film with adhesive based on synthetic rubber latex free silicone paper
sterilisation:	with Ethylenoxide

Foliodrape® COMFORT Hand/Foot Drapes Art. No. 254 440		Spec.-No.:	D 6.5905d
		Department:	CMO-DOE
		Date:	2013-01-25

5. Product Requirements

Foliodrape® COMFORT 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 6.5030).


6. Labelling

Lot-No. with 9-digit code:

e.g.: **9XXX38YYY**

LOT	9	XXX	38	YYY
	year of production	for internal purpose only	week of production	for internal purposes only

Expiry date:

e.g.  2014 – 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® COMFORT Hand/ Foot Drapes is wrapped into crepe paper, 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: 2013-01-25

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

i. A.



Dr. Thomas Hoffmann