



Foliodrape® Protect, Universal Fenestrated Sheet Set (Art. No. 278 001)



Spec.-No.:	D 6.5350g
Department:	CMO-DOE
Date:	2013-01-28

1. General Product Description

Foliodrape® Protect Universal Fenestrated Sheet Set preferred for ENT surgeries.

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

2. Application / Indication

Foliodrape® Protect Universal Fenestrated Sheet Set is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations

Art. No. 278 001	<i>Foliodrape® Protect Universal Fenestrated Sheet Set</i>
	sterile, 6 Sets per dispenser, 2 dispenser per transport carton
	Dimensions of dispenser: 370 x 275 x 250 mm (L x W x H)
	Dimensions of transport carton: 585 x 390 x 270 mm (L x W x H)

4. Product Characteristics

Content:	1 table cover 150 x 160 cm
	1 Fenestrated drape sheet 170 x 250 cm (fenestration ø 10 cm, with adhesive zone around)
	1 cellulose towels 33 x 33 cm
Sterilization:	With ethylene oxide gas

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 6.1005a) and table cover (D6.1005d).

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6. Labelling

Lot-No. with 9-digit code:

e.g.: 5XXX38YYY

LOT	5	XXX	38	YYY
	year of production	for internal purposes only	week of production	for internal purposes only

Expiry date:

e.g.  2011 – 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.

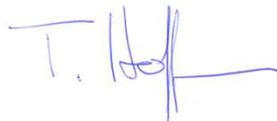
7. Packaging

Foliodrape® Protect *Universal Fenestrated Sheet Set* 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.

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