

Telasorb® sterile (EO)



Spec.-No.: **D 9.3302**

Department: CMO-DGM

Date: 2015-04-22

1. General Product Description

Telasorb® X-ray detectable, prewashed disposable laparotomy sponges 20 threads, with Telatrast® X-ray detectable chip and loop securely sewn into the sponge.

Telasorb® carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class IIa medical device.

A conformity assessment has been performed for Telasorb® and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Telasorb® therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Telasorb® for staunching bleeding and for wound treatment, for gripping or retaining body tissue during laparotomy.

3. Presentations

Sterile, in 4-layer packaging with lot coded double check card for theatre counts

	4-ply, green	6-ply, green
Dimensions*	50 x 60 cm	50 x 60 cm
	45 x 45 cm	45 x 45 cm
	20 x 30 cm	
	90 x 8 cm	

*Original size before washing

4. Product Characteristics

Material composition:

lap sponge:	100 % absorbent cotton gauze acc. to EN 14079, chlorine free bleached, dyed green
pull loop:	100 % cotton, bleached, dyed green
x-ray detectable chip:	PVC with min. content of 60 % BaSO ₄
dye stuffs:	VAT dyes

5. Product Requirements lap sponge

Material: fulfills the requirements EN 14079 (after bleaching)

Sinking time: < 10 sec.

Water absorption capacity: 6 – 8 g water per g gauze

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Number of thread*: warp: 120/10 cm \pm 6
 weft: 80/10 cm \pm 5

*bleached fabric before washing

Area weight*: ≥ 27 g/m²

*bleached fabric before washing

Tensile strength dry: warp: ≥ 60 N/50 mm
 weft: ≥ 35 N/50 mm

Sterilization Ethylene oxide sterilization acc. to EN 11135 with validated process

6. Labelling

Lot-No. with 9-digit code:

Lot. - No.	4	999	01	00	1
Explanation	[4 = 2014]	[999 - 000]	Internal Code		
Definition	Year	Serial production order			

Expiry date:  Year Month
 Example: 2019 06
 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

Telasorb® sterile laparotomy sponges are tied in bundles and sealed in packs of 2 or 5 pieces. The sterile packaging is in accordance with DIN EN ISO 11607. The sterile packaging is packed in dispensers and in transport cartons. The transport carton sealed with adhesive tapes and packed onto europallet.

Date: 02nd June 2015

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i.A.



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