

Telasorb® and Telasorb® E non-sterile



Spec.-No.: **D 9.3300**
 Department: CMO-DGM
 Date: 2015-04-22

1. General Product Description

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

Telasorb® and Telasorb® E carry 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 Telasorb® E and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Telasorb® and Telasorb® E, therefore, is ensured if the products are used in line with the intended purpose (see. 2. Application/Indication).

2. Application / Indication

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

3. Presentations

Non sterile, 17 or 20 threads, bundles in 5 pieces.

	2-ply, white [cm]	4-ply, white [cm]	4-ply, green [cm]	6-ply, white [cm]	6-ply, green [cm]
Dimensions*		20 x 30			
		30 x 30			
		45 x 45	45 x 45	45 x 45	45 x 45
		45 x 70			
					50 x 60
	75 x 75				
		90 x 8			

*Original size before washing

4. Product Characteristics

Material composition:

lap sponge: 100 % absorbent cotton gauze acc. to EN 14079, chlorine free bleach, white or dyed green
 pull loop: 100 % cotton, bleached, dyed blue or green
 x-ray detectable chip: PVC with min. content of 60 % BaSO₄
 dye stuffs: VAT dyes

5. Product Requirements

Material: fulfills the requirements EN 14079 (after bleaching)
 Sinking time: < 10 sec.

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

Number of threads: warp: 120/10 cm ± 6
 weft: 80/10 cm ± 5

Area weight: >=27 g/m²
 *bleached fabric before washing

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

Optical brighteners: none

Sterilizing capability: Steam sterilization according to EN 17665 with validated process
 Gas sterilization according to EN 11135 with validated process
 Radiation sterilization according to EN 11137 with validated process

6. Labelling

Lot-No. with 9-digit code:

Lot. - No.	5	999	01	00	1
Explanation	[5 = 2015]	[999 - 000]	Internal Code		
Definition	Year	Serial production order			

Expiry date:  Year Month
 Example: 2020 06
 Shelf life: 5 years

7. Packaging

5 pieces of Telasorb® and Telasorb® E non sterile laparotomy sponges in tied bundles in PE bag, packed in transport carton, sealed with adhesive tape and packed onto Euro pallets.

Date: 22th April 2015

PAUL HARTMANN AG
 Produktentwicklung CMO-DGM

i.A.



Cathrin Jäger