

## Telaprep® sterile



Spec.-No.: **D 2.2121a**  
 Department: **CMO-DGM**  
 Date: **2015-04-22**

### 1. General Product Description

Telaprep® gauze balls made of absorbent gauze (100 % Cotton; 24 thread) according to EN 14079, one-piece, with interwoven Telatrast® x-ray detectable thread.

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

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

### 2. Application / Indication

Telaprep® gauze balls are used for exposure of organs and body tissue during surgery.

### 3. Presentations

Sterile, in 4 layer packaging with lot coded double check card for theatre counts. Available in 3 sizes.

Dimensions of the manufactured gauze balls:

	Length Requirement mm	Length Tolerance		Width Requirement mm	Width Tolerance	
		mm	mm		mm	mm
Size1 Small	15,0	- 2,00	+ 2,00	8,0	- 1,0	+ 2,0
Size 2 Medium	20,0	- 2,00	+ 2,00	10,0	- 1.0	+ 2,0
Size 3 Large	26,0	- 2,00	+ 2,00	14,0	- 2,0	+ 2,0

### 4. Product Characteristics

Material composition:

Gauze: 100 % cotton according EN 14079, chlorine free bleached

X-ray detectable thread: Polypropylene with min. content of 60 % BaSO<sub>4</sub>

### 5. Product requirements

Material: fulfills the requirements EN 14079 (after bleaching)

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Sinking time: < 10 sec.

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

Number of thread: warp 120/10 cm ± 6

weft 120/10 cm ± 6

or

warp 140/10 cm ± 6

weft 100/10 cm ± 5

Area weight: ≥ 32 g/m<sup>2</sup>

Tensile Strength dry: warp ≥ 70 N / 50 mm

weft ≥ 40 N / 50 mm

or

warp ≥ 60 N / 50 mm

weft ≥ 50 N / 50 mm,

Optical brighteners: none

Sterilization: Steamed water according to DIN EN ISO 17665 with validated process

### 6. Labelling

Lot-No. with 9-digit code:

<b>Lot. - No.</b>	<b>3</b>	<b>999</b>	<b>01</b>	<b>00</b>	<b>1</b>
<b>Explanation</b>	[3 = 2013]	[999 - 000]	Internal Code		
<b>Definition</b>	Year	Serial production order			

Expiry Date:  Year Month

Example: 2019 6

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.

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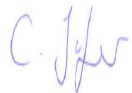
### 7. Packaging

10 respectively 20 pieces Telaprep® sterile, Telatrast® Modul System, gauze balls packed in slide boxes and peel pouches. The sterile packaging is in accordance with DIN EN ISO 11607. The peel pouches are packed in dispenser and transport cartons, sealed with adhesive tape and packed onto europallets.

Date: 29<sup>th</sup> May 2015

PAUL HARTMANN AG  
Product Development CMO-DGM

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A handwritten signature in blue ink, appearing to read "C. Jäger".

Cathrin Jäger