

SELEFA® Tamponing bandage, X-ray detectable, sterile

REF: 222063, 222064, 222065, 222066, 222067, 222068, 222069, 222070, 222071, 222072, 222073, 222074, 222075, 222076, 222077

SELEFA® Tamponing bandage, X-ray detectable, sterile is manufactured of gauze material fulfilling the requirements in standard EN 14079, increasing their absorbent properties and softness. Produced from environmental friendly bleached cotton fibres. Increased level of patient's safety is ensured by woven edges excluding the risk of a thread loose. They can be used for fluids or blood draining during outpatient procedures and surgical operations as well as to disinfect the operating field.

Key Features

- ▶ Woven edges prevent loose threads drawing
- ▶ 100% cotton gauze
- ▶ Sterilized with EO
- ▶ Peroxide bleached gauze
- ▶ X-ray detectable thread inter-woven into gauze
- ▶ Low linting
- ▶ Different sizes allow selection of absorbency level for individual needs
- ▶ Contains an X-ray detectable marker to help device detection and thus avoid gossypiboma
- ▶ Woven in density of 48 threads/cm²

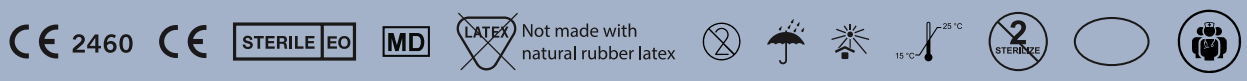


REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
222063	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	1 x 50 cm	10 / 120
222064	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	1 x 100 cm	10 / 120
222065	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	1 x 200 cm	10 / 120
222066	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	1 x 500 cm	10 / 120
222067	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	2 x 50 cm	10 / 120
222068	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	2 x 100 cm	10 / 120
222069	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	2 x 200 cm	10 / 120
222070	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	2 x 500 cm	10 / 120
222071	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	5 x 50 cm	10 / 120
222072	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	5 x 100 cm	10 / 120
222073	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	5 x 200 cm	10 / 120
222074	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	5 x 300 cm	10 / 120
222075	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	5 x 500 cm	10 / 120
222076	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	10 x 100 cm	10 / 120
222077	Tamponing bandage, X-ray detectable, 32-thread, cotton, single pack, sterile, White	10 x 300 cm	10 / 120

Sales Unit: Transport Carton

Regulations

The product complies with legal requirements for medical devices. EO sterilized according to valid version of ISO 11135 standard.



REACH regulation: The products covered by this data sheet do not contain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by European Chemicals Agency (ECHA).

Biological evaluation: EN ISO 10993-5
EN ISO 10993-7
EN ISO 10993-10
EN ISO 10993-11

Compliance with legal requirements: Medical Device Regulation (EU) 2017/745, MDR class IIa

Compliance with product standards: EN ISO 11135, EN 14079

Quality standards: EN ISO 13485

Label information and packaging compliance: EN ISO 15223-1, EN ISO 20417, EN ISO 11607-1

Material

Product Part	Raw Material & Characteristics
Gauze	100 % cotton, 48 threads / cm ² , white
X-ray detectable thread	PP, DEHP-free, PVC-free, Phthalate free X-ray thread (with barium sulphate), blue

Warnings & Recommendations

Warnings The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur.
Control the amount of items before use. If the amount is different than stated on the packaging, do not use the product.

Storage Recommendation Recommended storage in clean, dry space between 15 - 25 °C. Products should be protected from direct sunlight, other intensive light sources and ozone.

Disposal Recommendation Dispose in accordance with local regulations.

Shelf Life 5 years

Packing Information

Package	Material	Size (L x W x H) mm
Single Pack	Medical grade paper, PP/PE film	222063: 78 x 122
		222064: 78 x 122
		222065: 78 x 122
		222066: 78 x 122
		222067: 78 x 122
		222068: 78 x 122
		222069: 78 x 122
		222070: 78 x 122
		222071: 98 x 116
		222072: 98 x 116
		222073: 98 x 116
		222074: 98 x 116
		222075: 98 x 116
222076: 133 x 175		
222077: 133 x 175		
Dispenser Pack	Carton, TCF or ECF quality	222063: 80 x 124 x 52
		222064: 80 x 124 x 52
		222065: 80 x 124 x 102
		222066: 80 x 124 x 102
		222067: 80 x 124 x 52
		222068: 80 x 124 x 52
		222069: 80 x 124 x 152
		222070: 80 x 124 x 152
		222071: 102 x 128 x 52
		222072: 102 x 128 x 52
		222073: 102 x 128 x 152
		222074: 102 x 128 x 152
		222075: 102 x 128 x 202
222076: 135 x 177 x 52		
222077: 135 x 177 x 152		
Transport Carton	Carton, TCF or ECF quality	222063: 195 x 385 x 125
		222064: 195 x 385 x 125
		222065: 195 x 385 x 225
		222066: 195 x 385 x 225
		222067: 195 x 385 x 125
		222068: 195 x 385 x 125
		222069: 195 x 385 x 325
		222070: 195 x 385 x 325
		222071: 230 x 395 x 125
		222072: 230 x 395 x 125
		222073: 230 x 395 x 325
		222074: 230 x 395 x 325
		222075: 230 x 395 x 425
222076: 290 x 385 x 175		
222077: 290 x 385 x 415		

Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
222063	06438129154443	06438129354447	06438129554441
222064	06438129154450	06438129354454	06438129554458
222065	06438129154467	06438129354461	06438129554465
222066	06438129154474	06438129354478	06438129554472
222067	06438129154481	06438129354485	06438129554489
222068	06438129154498	06438129354492	06438129554496
222069	06438129154504	06438129354508	06438129554502
222070	06438129154511	06438129354515	06438129554519
222071	06438129154528	06438129354522	06438129554526
222072	06438129154535	06438129354539	06438129554533
222073	06438129154542	06438129354546	06438129554540
222074	06438129154559	06438129354553	06438129554557
222075	06438129154566	06438129354560	06438129554564
222076	06438129154573	06438129354577	06438129554571
222077	06438129154580	06438129354584	06438129554588

Evercare Medical AB is a partner that enables better lives for patients, facilitates everyday life for healthcare employees and contributes to lower care costs. We strive to reduce the environmental impact and, together with our suppliers, to improve working conditions throughout the value chain.