

evercare® Surgical sponges, x-ray detectable, gauze, 5-pack, sterile

REF: 3101-01, 3102-01, 3103-01, 3104-01, 3105-01, 3106-01

evercare® Surgical sponges, x-ray detectable is a high quality surgical sponge of gauze, each sponge housed in its individual compartment. Double packed in 2 layers of peel open pouches. Color coding for easy product identification and numeric control system for counting assistance.

Key Features:

- ▶ Numeric control system
- ▶ X-ray detectable
- ▶ Color coding



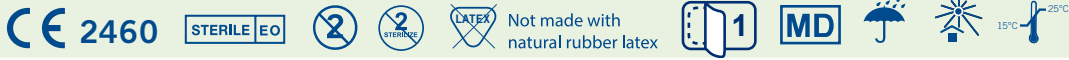
REF	DESCRIPTION	COLOR CODING	SIZE	PACK COUNT unit/dispenser/carton
3101-01	Surgical sponges, x-ray detectable, gauze, 5-pack, sterile		0, Ø 18 mm	5/140/1120
3102-01	Surgical sponges, x-ray detectable, gauze, 5-pack, sterile		1, Ø 26 mm	5/105/840
3103-01	Surgical sponges, x-ray detectable, gauze, 5-pack, sterile		3, Ø 30 mm	5/90/720
3104-01	Surgical sponges, x-ray detectable, gauze, 5-pack, sterile		4, Ø 35 mm	5/70/560
3105-01	Surgical sponges, x-ray detectable, gauze, 5-pack, sterile		5, Ø 55 mm	5/50/400
3106-01	Surgical sponges, x-ray detectable, gauze, 5-pack, sterile		2, Ø 28 mm	5/90/720

Sales Unit: Transport Carton

Technical Summary

Regulations

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



REACH regulation:	The product(s) covered by this data sheet does(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 10993-05, EN ISO 10993-07, EN ISO 10993-10, EN ISO 10993-11
Compliance with legal requirements:	Medical Devices Directive 93/42/EEC, Class IIa
Compliance with product standards:	EN ISO 11135, EN 14079
Quality standards:	ISO 13485
Label information and packaging compliance:	EN ISO 15223-1, EN 1041, EN ISO 11607-1

Material

Product Part	Raw Material & Characteristic
Gauze	100 % cotton, 20 threads/cm ² , white
X-ray detectable thread	PP, DEHP-free, PVC-free, Phthalate free X-ray thread (with barium sulphate), black
Elastic ring	Silicon, latex-free
Inner pouch	Medical grade paper & PA/PE film

Warnings and Recommendations

Warnings:	The product is single use. If reused performance of product may deteriorate, cross contamination may occur.
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
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Single Pack	Medical paper and Plastic film PP/PE	185 x 180
Dispenser Pack	Carton, TCF or ECF quality	185 x 185 x 195
Transport Carton	Carton, TCF or ECF quality	390 x 390 x 410
Packing Tape	Transparent, PVC-free	N/A

Barcodes

REF	Single Pack	Dispenser	Transport Carton
3101-01	 6 438129 120882	 6 438129 320886	 6 438129 520880
3102-01	 6 438129 120899	 6 438129 320893	 6 438129 520897
3103-01	 6 438129 120905	 6 438129 320909	 6 438129 520903
3104-01	 6 438129 120912	 6 438129 320916	 6 438129 520910
3105-01	 6 438129 120929	 6 438129 320923	 6 438129 520927
3106-01	 6 438129 120936	 6 438129 320930	 6 438129 520934



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