

evercare[®] Surgical sponges X-ray detectable, nonwoven, 5-pack, sterile





REF: 3112-01, 3113-01, 3114-01, 3115-01

evercare[®] Surgical sponges X-ray detectable, nonwoven, 5-pack, sterile have color coding for easy product identification and numeric control system for counting assistance. The control system contains following information: color code, REF number, dry weight of the product, number of individual swabs, size of individual swabs, material, and control batch number. As part of the production process the products are counted and controlled by a metal detector and the material is vacuummed to minimize loose threads. These sponges are low linting and cost efficient. The pouch has cavities in the plastic film to reserve space for exact number of products inside. The number of units in a pouch is always stated.

Key Features

- X-ray detectable
- Sterilized with EO
- Numeric control system
- Colour coding system for easy product identification
- Wrapped into a sealed lint-free easy-to-open wrap
- High absorbency
- X-ray detectable thread woven to the material for safety
- PVC- and phthalate-free X-ray detectable thread



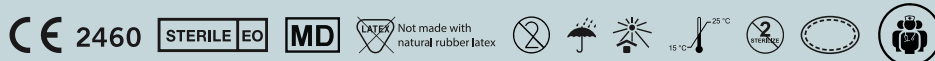
REF	DESCRIPTION	COLOR CODING	SIZE	PACK COUNT unit/dispenser/carton
3112-01	Surgical sponges X-ray detectable, nonwoven, 5-pack, sterile, Yellow		1, Ø 20	105 / 840
3113-01	Surgical sponges X-ray detectable, nonwoven, 5-pack, sterile, Blue		3, Ø 27	90 / 720
3114-01	Surgical sponges X-ray detectable, nonwoven, 5-pack, sterile, Grey		4, Ø 40	50 / 400
3115-01	Surgical sponges X-ray detectable, nonwoven, 5-pack, sterile, Black		5, Ø 47	50 / 400

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 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 10993-05 EN ISO 10993-07 EN ISO 10993-10 EN ISO 10993-11
Compliance with legal requirements:	Medical Device Regulation (EU) 2017/745, MDR class Is
Compliance with product standards:	EN ISO 11135, EN 1644-1, EN 1644-2
Quality standards:	EN ISO 13485
Label information and packaging compliance:	EN ISO 15223-1, EN 1041, EN ISO 11607-1

Material

Product Part	Raw Material & Characteristics
Nonwoven	Viscose 60 % Polyester 40 %, white
X-ray detectable thread	PP, DEHP-free, PVC-free, Phthalate free X-ray thread (with barium sulphate), blue
Elastic ring	Silicon, latex-free
Inner pouch	Medical grade paper and PA/PE film

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	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	PVC-free, Transparent	N/A

Barcodes

REF	Single Pack	Dispenser	Transport Carton
3112-01	6438129120943	6438129320947	6438129520941
3113-01	6438129120950	6438129320954	6438129520958
3114-01	6438129120967	6438129320961	6438129520965
3115-01	6438129120974	6438129320978	6438129520972

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.