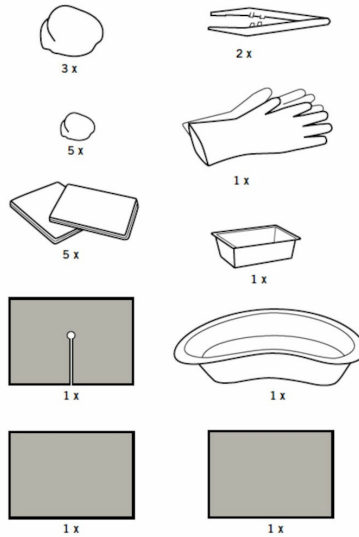




evercare[®] Catheterization set, nonwoven, large, sterile

REF: 1942-01

evercare[®] Catheterization set, nonwoven, large, sterile is a compact sterile catheterization set containing items needed for regular catheterization.



REF	DESCRIPTION	SIZE	PACK COUNT dispenser/carton
1942-01	Catheterization set, nonwoven, large, sterile	See Material table	8 / 32

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
Compliance with legal requirements:	Medical Device Regulation (EU) 2017/745, MDR class Is
Compliance with product standards:	EN ISO 11135
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
1 X-long nitrile gloves (30 cm), size M	Nitrile, powder-free, blue
1 Utility drape 60x75 cm	Laminate: tissue/PE
1 Split sheet 60x75 cm	Laminate: tissue/PE
5 Round sponges, Ø 30	Nonwoven pes/viscose, elastic ring SEBS/PP
1 Small bowl 108 x 84 x 43 mm	Polystyrene, white
2 Forceps, green, 127 mm	Polystyrene, green
3 Round, Ø 50 mm	Nonwoven pes/viscose, elastic ring SEBS/PP
5 Nonwoven swabs, 7,5x7,5 cm, 4-ply	Nonwoven pes/viscose
1 Kidney bowl 255 x 155 x 44 mm	Polystyrene, blue
1 Utility drape (Tray wrap) 60 x 60 cm	Laminate: tissue/PE

Warnings & Recommendations

Warnings	The product is single use. If reused, the performance of product may deteriorate and 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
Single Pack	Medical grade paper, Plastic film	327 x 200
Dispenser Pack	Carton, TCF or ECF quality	378 x 283 x 205
Transport Carton	Carton, TCF or ECF quality	590 x 390 x 430
Packing Tape	PVC-free, Transparent	N/A

Barcodes

REF	Single Pack	Dispenser	Transport Carton
1942-01	6438129120387	6438129320381	6438129520385

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.