



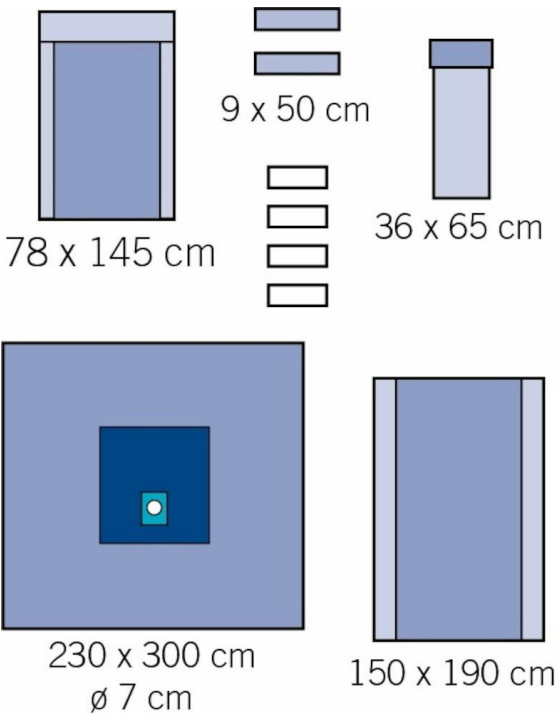
evercare<sup>®</sup> Extremity set

REF: 1231-100

evercare<sup>®</sup> Extremity set, sterile is a sterile draping set for extremity operations.

Key Features

- ▶ Elastic fenestration
- ▶ Absorbent patch
- ▶ Stockinette
- ▶ Tube holders
- ▶ Adhesive OP Tapes
- ▶ Main drape complies to EN 13795-1 High performance critical product area requirements

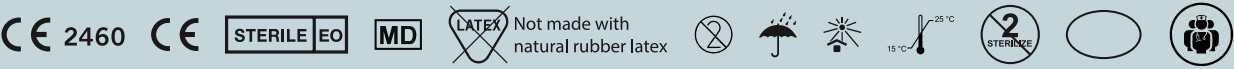


REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
1231-100	Extremity set, sterile	See Material table	6 / 12

Sales Unit: Transport Carton

## Regulations

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



<b>REACH regulation:</b>	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).
<b>Biological evaluation:</b>	EN ISO 10993-01 EN ISO 10993-5 EN ISO 10993-7 EN ISO 10993-10
<b>Compliance with legal requirements:</b>	Medical Device Regulation (EU) 2017/745, MDR class Is
<b>Compliance with product standards:</b>	EN13795-1
<b>Quality standards:</b>	EN ISO 13485
<b>Label information and packaging compliance:</b>	EN ISO 15223-1, EN ISO 20417, EN ISO 11607-1

## Material

Product Part	Raw Material & Characteristics
<b>1 Mayo cover</b>	78 x 145 cm, reinforced, Laminate: PP nonwoven/PE-film/PE-film, blue, absorbent patch 65 x 85 cm
<b>2 Adhesive Op-tape</b>	9 x 50 cm, Nonwoven polyester, blue, adhesive coated
<b>4 Hand towels</b>	30 x 34 cm, Pulp, natural white, thread reinforced
<b>1 Stockinette</b>	36 x 65 cm, Laminate: blue PP nonwoven/blue PE-film
<b>1 Extremity drape</b>	230 x 300 cm, Laminate: blue PP nonwoven /blue PE-film, blue absorbent patch50 x 100 cm, PP nonwoven, aperture 7 cm, elastic material styrene/butadiene/styrene, tube holders in blue nonwoven
<b>1 Instrument table cover</b>	150 x 190 cm, Laminate: PP nonwoven/polyethylene film laminate, blue

## Warnings & Recommendations

<b>Warnings</b>	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur. Do not use if package is damaged.
<b>Storage Recommendation</b>	Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone.
<b>Disposal Recommendation</b>	Dispose in accordance with local regulations.
<b>Shelf Life</b>	5 years

## Packing Information

Package	Material	Size ( L x W x H ) mm
<b>Single Pack</b>	Medical grade paper, PE/PET film	420 x 603
<b>Dispenser Pack</b>	TCF or ECF quality	485 x 285 x 287
<b>Transport Carton</b>	TCF or ECF quality	500 x 310 x 590
<b>Packing Tape</b>	Transparent	N/A

## Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
<b>1231-100</b>	06438129118254	06438129318258	06438129518252

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.