

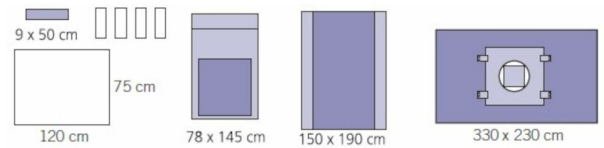
evercare[®] C-section set, incision film

REF: 1261-02

evercare[®] C-section set, sterile is an all-in-one C-section solution for fast draping. Integrated fluid collection pouch with tube holders and integrated incision film.

Key Features

- ▶ Incision film
- ▶ Fluid collection pouch
- ▶ Tube holders
- ▶ Adhesive OP Tape
- ▶ Main drape complies to EN 13795-1 High performance critical product area requirement



REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
1261-02	C-section set, sterile	See Material table	5 / 10

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 10993-01
EN ISO 10993-5
EN ISO 10993-7
EN ISO 10993-10

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

Compliance with product standards: EN13795-1

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
1 Mayo stand cover	78 x 145 cm, reinforced, PP nonwoven, plastic laminate/polyethylene film laminate, blue, absorbent patch 65 x 85 cm
4 Hand towels	30 x 34 cm, Pulp, natural white, thread reinforced
1 Op-tape	9 x 50 cm, Nonwoven polyester, blue, adhesive coated
1 baby sheet	75 x 120 cm, PP nonwoven, white
1 C-section drape	330x 230 cm: PP nonwoven/polyethylene film laminate, blue integrated fluid collection pouch and tube holders: PE/EVA film, transparent edging foam PU, blue integrated incision film aperture 36 x 36 cm: adhesive coated polyethylene film
1 Instrument table cover	150 x 190 cm, PP nonwoven/polyethylene film laminate, blue

Warnings & Recommendations

Warnings	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.
Storage Recommendation	Recommended storage in clean, dry space in ambient temperature. 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, PE/PET film	420 x 603
Dispenser Pack	TCF or ECF quality	485 x 285 x 287
Transport Carton	TCF or ECF quality	500 x 310 x 590
Packing Tape	Transparent	N/A

Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
1261-02	06438129116847	06438129316841	06438129516845

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.