

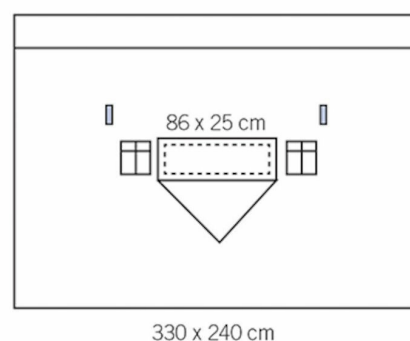
evercare® Vertical drape Large

REF: 1332-02

evercare® Vertical drape with small fluid collection pouch are a surgical drape that provides a vertical barrier to keep the C-arm isolated from the sterile surgical field during hip/femur fracture or trauma procedures. Sterile.

Key Features

- ▶ Fluid collection pouch
- ▶ Suction and diathermy pouch
- ▶ Incision film
- ▶ Complies to EN 13795-1 High performance critical product area requirements

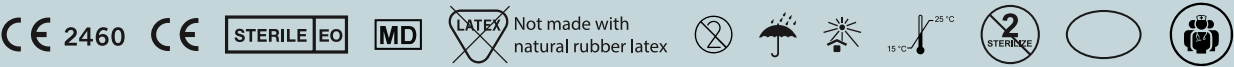


REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
1332-02	Vertical drape with integrated incision film, fluid collection and diathermy pouches, sterile, Transparent	330 x 240 cm, aperture 86 x 25 cm, pouches 24x 24 cm	10 / 20

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
Vertical drape	PE film, transparent
Incision film	Adhesive coated polyethylene
Fluid collection and suction/diathermy pouches	PEVA, transparent
Fluid collection pouch wire	Metal with blue polyethylene coating
Valve	PE, white
Tube holders	PE film, 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
1332-02	06438129119305	06438129319309	06438129519303

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.