

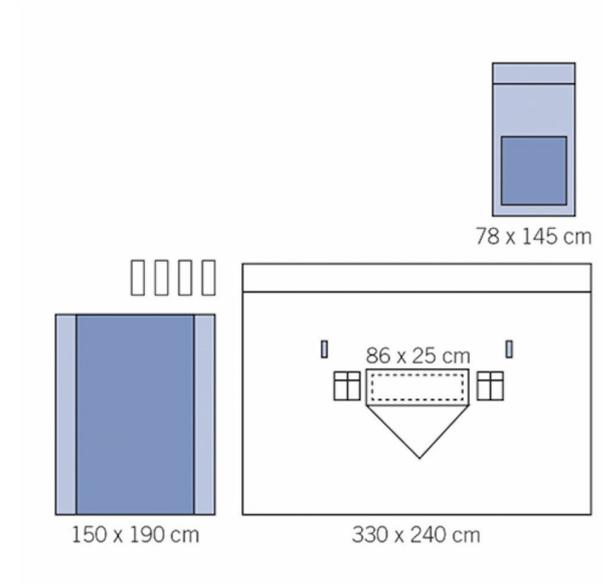
evercare[®] Vertical drape set Large

REF: 1226-02

evercare[®] Vertical drape set Large, sterile is a surgical draping set that provides a vertical barrier to keep the C-arm isolated from the sterile surgical field during hip/femur fracture or trauma procedures.

Key Features

- ▶ Incision film
- ▶ Transparent drape
- ▶ Fluid collection pouch
- ▶ Absorbent patch
- ▶ Tube holders
- ▶ Suction/diathermy pouches
- ▶ Main drape complies to EN 13795-1 High performance critical product area requirements



| REF | DESCRIPTION | SIZE | Pack Count dispenser/carton |
|---------|-----------------------------------|--------------------|-----------------------------|
| 1226-02 | Vertical drape set Large, sterile | See Material table | 7 / 14 |

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 |
|-------------------------|---|
| 4 Hand towels | 30 x 34 cm, Pulp, natural white, thread reinforced |
| 1 Mayo cover | 78 x 145 cm, reinforced, Laminate: blue PP nonwoven/blue-white PE film/blue PE film |
| 1 Vertical drape large | 240 x 330 cm, transparent polyethylene film, incision film 86 x 25 cm, adhesive coated polyethylene film, fluid collection and suction/diathermy pouches 24 x 24 cm, transparent polyethylene vinyl acetate, fluid collection pouch wire metal with blue polyethylene coating, bottom outlet white polypropylene, tube holders blue polyethylene film |
| 1 Universal cover drape | 150 x 190 cm, Laminate: PP nonwoven/PE 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 |
|----------------|----------------|----------------|------------------|
| 1226-02 | 06438129116755 | 06438129316759 | 06438129516753 |

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.