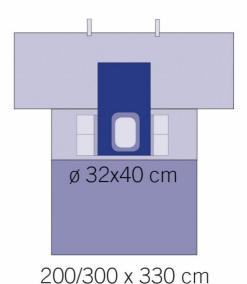


evercare[®] Thoracic drape 200/300 x 330 cm, aperture 32 x 40 cm REF: 1375-01

evercare[®] Thoracic drape, sterile is a tear-resistant and fluid-proof thoracic drape with incision film for cardiovascular procedures. Absorbent patch reinforcement for fluid management. Secure attachment for tubing with tube holders.

Key Features

- Incision film
- Fluid collection pouch
- Absorbent patch
- Tube holders
- Main drape complies to EN 13795-1 High performance critical product area requirements



REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
1375-01	Thoracic drape, aperture with incision film, fluid collection pouches, absorbent patch and tube holders, sterile, Blue	200/300 x 330 cm, aperture 32 x 40 cm, absorbent patch 50 x 150 cm	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.				
	MD Not made with atural rubber latex (2) + (1) +			
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 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
Laminate	PP nonwoven, blue / PE film, blue
Absorbent patch	PP nonwoven, blue / PE film, blue
Fluid collection pouch	PEVA transparent
Fluid collection pouch wire	Coated metallic
Incision film	Adhesive coated polyethylene

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
1375-01	06438129110524	06438129310528	06438129510522

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.