

evercare[®] Gynae/cyst set

REF: 1250-01

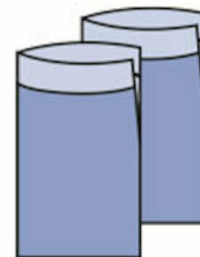
evercare[®] Gynae/cyst set, sterile is a flexible set for cystoscopies and gynaecological procedures.

Key Features

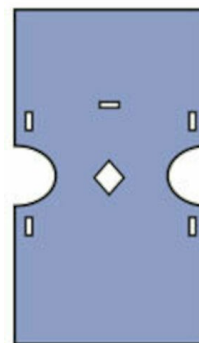
- ▶ 2 Leggings
- ▶ Main drape complies to EN 13795-1 High performance critical product area requirements



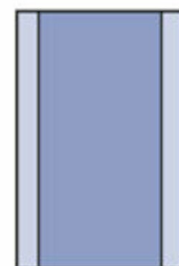
75 x 80 cm



75 x 120 cm



75 x 175 cm



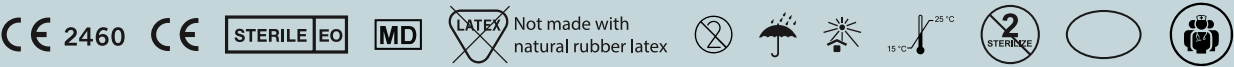
150 x 190 cm

REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
1250-01	Gynae/cyst set, sterile	See Material table	5 / 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
1 Utility drape	75 x 80 cm, Laminate: PP nonwoven/PE –film, blue
2 Leggings	75 x 120 cm, Laminate: PP nonwoven/PE –film, blue
1 Gyn/cyst drape	75 x 175 cm, Laminate: PP nonwoven/PE –film, blue, aperture 9 x 15 cm
1 Instrument table cover	150 x 190 cm, Laminate: PP nonwoven/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	350 x 415
Dispenser Pack	TCF or ECF quality	485 x 242 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
1250-01	06438129110241	06438129310245	06438129510249

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.