

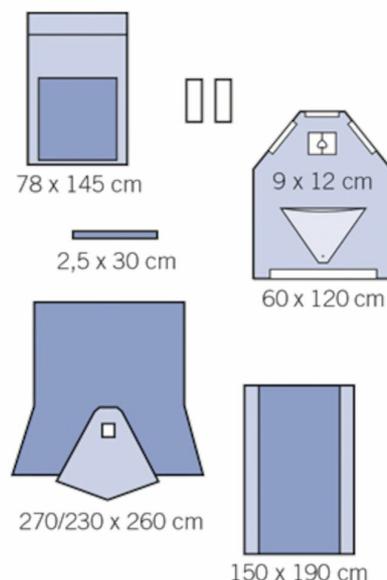
evercare[®] Gynaecology set

REF: 1251-02

evercare[®] Gynaecology set, sterile is a draping set for intravaginal and transvaginal procedures, e.g. in vaginoplasty and colpoperineoplasty, in vaginal uterus extirpation or in colposuspension to eliminate incontinence.

Key Features

- ▶ Fluid collection pouch
- ▶ Absorbent patch
- ▶ Integrated Leggings
- ▶ Adhesive OP Tape
- ▶ Main drape complies to EN 13795-1 High performance critical product area requirements



REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
1251-02	Gynaecology set, sterile	See Material table	6 / 12

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 cover	78 x 145 cm, reinforced, Laminate: PP nonwoven/PE-film/PE-film, blue, absorbent patch 65 x 85 cm
2 Hand towels	30 x 34 cm, pulp, natural white, thread reinforced
1 Tube holder	2,5 x 30 cm, Loop white nylon knit loop on a polyethylene film base, hook white polyethylene
1 Gynaecology drape	60 x 120 cm, aperture 9 x 12 cm, adhesives for fixation, laminate: PP nonwoven/PE film, blue fluid collection pouch transparent polyethylene vinyl acetate,
1 Gynaecology drape	270/230 x 260 cm, aperture 24 x 21 cm, integrated leggings, laminate: PP nonwoven/PE film, blue,
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	420 x 603
Dispenser Pack	TCF or ECF quality	285 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
1251-02	06438129116823	06438129316827	06438129516821

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.