

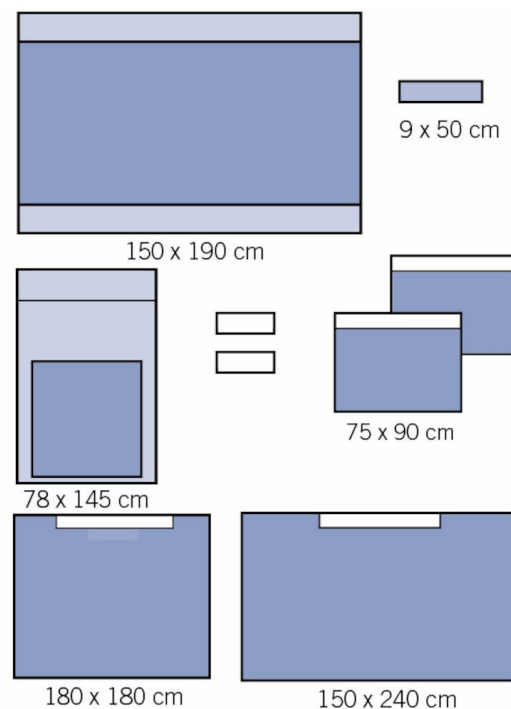
evercare® Essentia universal set

REF: 1003

evercare® Essentia universal set, sterile is a basic universal set for non-invasive surgery designed for cost efficiency. Material that ensures mini-mal particle release (low linting), soft and gentle adhesive edges, and absorbent top layer.

Key Features

- ▶ Absorbent top layer
- ▶ Adhesive OP Tape
- ▶ Softer adhesive allows for gentler removal and repositioning of the drape
- ▶ Main drape complies to EN 13795-1 High performance critical product area requirements



| REF | DESCRIPTION | SIZE | Pack Count dispenser/carton |
|------|---------------------------------|--------------------|-----------------------------|
| 1003 | Essentia universal 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.

2460

CE

STERILE

EO

MD

LATEX

Not made with natural rubber latex

15 °C

25 °C

2

STERILIZATION

| | |
|---|---|
| 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: blue PP nonwoven/blue-white PE film/blue PE film |
| 2 Hand towels | 30 x 34 cm, Pulp, natural white, thread reinforced |
| 1 Adhesive OP-tape | 9 x 50 cm, Nonwoven polyester, blue, adhesive coated |
| 2 Adhesive drape | 75 x 90 cm, Laminate blue PP nonwoven/blue PE-film |
| 1 Adhesive drape large | 150 x 240 cm, Laminate blue PP nonwoven/blue PE-film |
| 1 Adhesive drape, medium | 180 x 180 cm, Laminate blue PP nonwoven/blue PE-film |
| 1 Instrument table cover | 159 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 | 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 |
|-------------|----------------|----------------|------------------|
| 1003 | 06438129122817 | 06438129322811 | 06438129522815 |

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.