

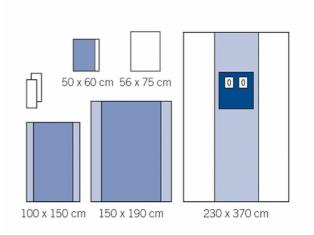
# evercare® Angiography set

REF: 1240-02

evercare <sup>®</sup> Angiography set, sterile is a set for draping patients and operating units in angiographic procedures.

# **Key Features**

- ▶ Transparent Side panels
- Absorbent patch
- Adhesive OP Tape
- ▶ Main drape complies to EN 13795-1 High performance critical product area requirements



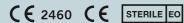
REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
1240-02	Angiography set, sterile	See Material table	5 / 10

Sales Unit: Transport Carton

Page 1 2023-12-05

### Regulations

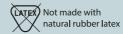
The product complies with legal requirements for medical devices. EO sterilized according to valid version of ISO 11135 standard.























**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).

EN ISO 10993-01 EN ISO 10993-5 **Biological evaluation:** 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 instrument table cover, folded	100 x 150 cm, Laminate: PP nonwoven/PE film, blue	
2 Hand towels	30 x 34 cm, Pulp, natural white, thread reinforced	
1 Absorbent sheet	56 x 75 cm, Spunlace nonwoven, of polyester/pulp viscose, white	
1 Adhesive drape sheet	50 x 60 cm, Laminate: PP nonwoven/polyethylene film, blue	
1 Angiography drape	230 x 370 cm, Laminate: PP nonwoven, blue/plastic film, transparent side panels absorbent patch 75 x 70 cm, PP nonwoven, dark blue, apertures 7 x 10 cm	
1 Instrument table cover	150 x 190 cm, Laminate: PP nonwoven/polyethylene film, blue	

Page 2 2023-12-05

## 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
1240-02	06438129117707	06438129317701	06438129517705

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.