

evercare[®] inLine Monoset, 1-way, PVC-free

REF: 10515-01

evercare[®] inLine Monoset is a safe sytem for mixing of drugs and preparation of medication. By using the system the users minimize the spillage and aerosols from hazardous drugs. Monosets are sterile, single use products that are used to conduct intravenous fluids into the vascular system of a patient by connecting to a source of infusion in one end and to an infusion device with vascular access in the other end. The fluid is transferred by the means of gravity and the flow rate is regulated by a blue roller clamp component.

Key Features

- ▶ Transparent Soft drip chamber for easy squeezing and filling
- ▶ 15-micron particle filter at bottom of the drip chamber
- ▶ Hydrophobic filter prevents leakage while priming
- ▶ Side Tubing
- ▶ 15 cm long tubing with side spike.
- ▶ C-Clamp to stop the flow of fluid within the tubing.
- ▶ Rotating luer lock

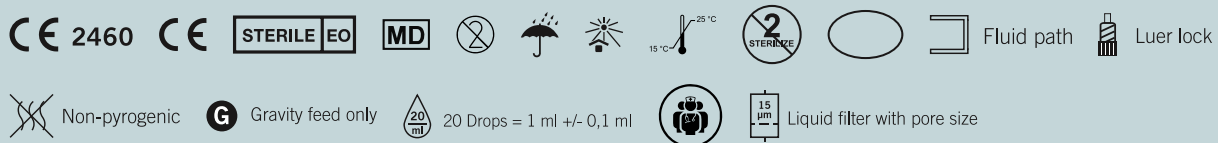


REF	DESCRIPTION	SIZE - Tube Inner/outer, L(length)	PRIMING VOLUME(ml) Approx	Pack Count dispenser/carton
10515-01	Monoset, 1-way, PVC-free	Ø 3/4.1 mm, L 180cm	0,065	15 / 60

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
Compliance with legal requirements:	Medical Device Regulation (EU) 2017/745, MDR class IIa
Compliance with product standards:	EN 8536-4, EN ISO 80369-7
Quality standards:	EN ISO 13485
Label information and packaging compliance:	EN ISO 15223-1, EN ISO 20417

Material

Product Part	Raw Material & Characteristics
Spike cover	PP, transparent
Spike	ABS, natural white
Side Tube	Polyolefin alloy, transparent, PVC-free, soft, kink resistant
C-clamp	PP, white
Vented side spike	ABS, natural white
Air vent cap	LDPE/HDPE, blue
Tube	Polyolefin alloy, transparent, PVC-free, soft, kink resistant
Drip chamber	Polyolefin alloy, transparent, PVC-free
Fluid filter	PP/nylon, pore size 15 µm
Roller clamp	ABS, roller body blue, roller wheel white
Rotating luer lock	ABS & PC, transparent
Purge filter cap	HDPE, light blue

Warnings & Recommendations

Warnings

The use of this product is restricted to a qualified doctor or nurse.
Read the instructions before use. The device should be used in accordance with the instructions.
Do not use for transfusion of blood or blood components.
The device is guaranteed sterile and pyrogen-free if the individual package has not been opened or damaged. Do not use if package is damaged or if protective caps are loose or missing.
Do not over-tighten a luer beyond the friction fit as this may damage both the luer and another connecting device.
Do not use any instruments for clamping the tubing or luer tightening.
Re-use may lead to infection or other illness/injury.

Storage Recommendation

Recommended storage in clean, dry space between 15 - 25 °C. 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, PP/PE film	235 x 100
Dispenser Pack	PP	305 x 460
Transport Carton	TCF quality, Carton	400 x 295 x 287
Packing Tape	PVC-free, Transparent	N/A

Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
10515-01	06438129123579	N/A	06438129523577

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.