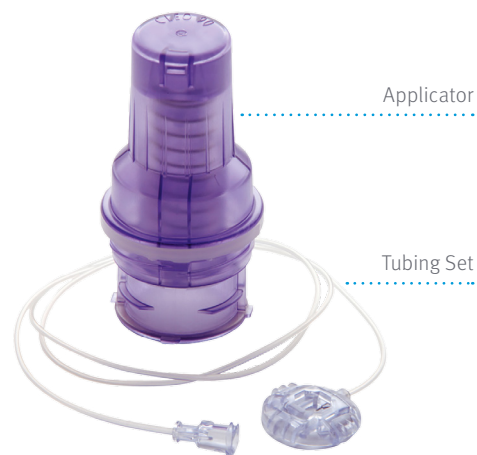


Cleo™ 90 Infusion Set



Device Classification

Classification: IIa
GMDN: 35833

Device Description

The Cleo 90 Infusion Set is a single use device. It consists of an applicator that contains an adhesive site with cannula and needle, and a separate extension tubing set with buckle for connection to the site. After insertion of the needle and cannula, the applicator automatically retracts the needle, providing needle protection. The infusion set can be used with standard luer lock connectors.

Indications

The Cleo 90 Infusion Set is designed for subcutaneous infusion of medication (including insulin) only. The set is not intended for intravenous (IV) infusion or to infuse blood or blood products.

Patient Population

This product is intended for adult and paediatric populations with the exception of neonates.

Clinical Features

The Cleo 90 Infusion Set features the Flex-Attach™ 360° site tubing connection. The unique design of the attachment (cannula and buckle) allows the tubing to rotate 360° around the access site so the patient is not restricted in their movement; so essentially the space in which they can move in is unrestricted compared to other systems which do not allow 360° movement. Another feature of the Cleo 90 Infusion Set is the automatic retraction of the needle after insertion, helping to reduce accidental needle sticks.

Components Composition

APPLICATOR

- › Retractor housing: Makrolon™ Rx2530
- › Needle hub: Makrolon Rx2530
- › Needle: Stainless steel, coated with fluorinated silicone (NuSil™ MED-420)
- › Compression spring: Stainless steel
- › Septum: Silicone
- › Needle Cannula: FEP
- › Cap: Polyethylene
- › Adhesive: Medical Grade Acrylate

TUBING SET

- › Connector “buckle”: Makrolon Rx2530
- › Luer (female): Makrolon Rx2530
- › Tubing: HDPE (inner layer), Polyurethane (outer layer)
- › Adhesive: Dymax 1180-M
- › Needle: Stainless steel
- › Not made with natural rubber latex

The materials used in the ICU Medical products listed do not contain DEHP.

Legal Manufacturer Name and Address

ICU Medical, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442
USA

Country of Origin

Mexico

Sterilisation Method

Ethylene Oxide

Shelf Life

5 years



STERILE EO

Labelling and Packaging

The Cleo 90 Infusion Set tubing is packaged individually in a pouch affixed with a pre-printed label. An additional label is also applied to the pouch, which provides the lot number, expiration date and length. The applicator cap has a round label on the end, which provides the lot number, expiration date and cannula length. Ten tubing pouches, ten applicators are packaged together with a single IFU in a labelled shelf carton.

The transit carton includes 18 shelf cartons.

Technical Specifications

Product Code	Cannula Length in mm	Cannula Priming Volume	Tubing Length in inch	Tubing Length in cm	Tubing Priming Volume	Mean nominal flow rate mL/minute	Nominal flow rate mL/hour
21-7220-24	6	0.002 ml	24	61	0.132 mL	0.53	31.8
21-7221-24	6	0.002 ml	31	79	0.176 mL	0.46	27.6
21-7222-24	6	0.002 ml	42	107	0.196 mL	0.32	19.2
21-7230-24	9	0.003 ml	24	61	0.132 mL	–	–
21-7231-24	9	0.003 ml	31	79	0.176 mL	–	–
21-7232-24	9	0.003 ml	42	107	0.196 mL	0.34	20.4

It is provided sterile and is for single use.

Cannula Gauge 25G — Introducer Needle Gauge 28G

For more information, visit www.icumed.com or call +44 (0)845 850 0445

Makrolon is a trademark of COVESTRO INTELLECTUAL PROPERTY GMBH & CO. KG.
NuSil is a trademark of Nusil Technology, LLC.

The product complies with current legislation and has the corresponding CE marking (2797).
For additional information, warnings and/ or safety precautions, refer to the manufacturer's Instructions for Use.

icumedical
human connections