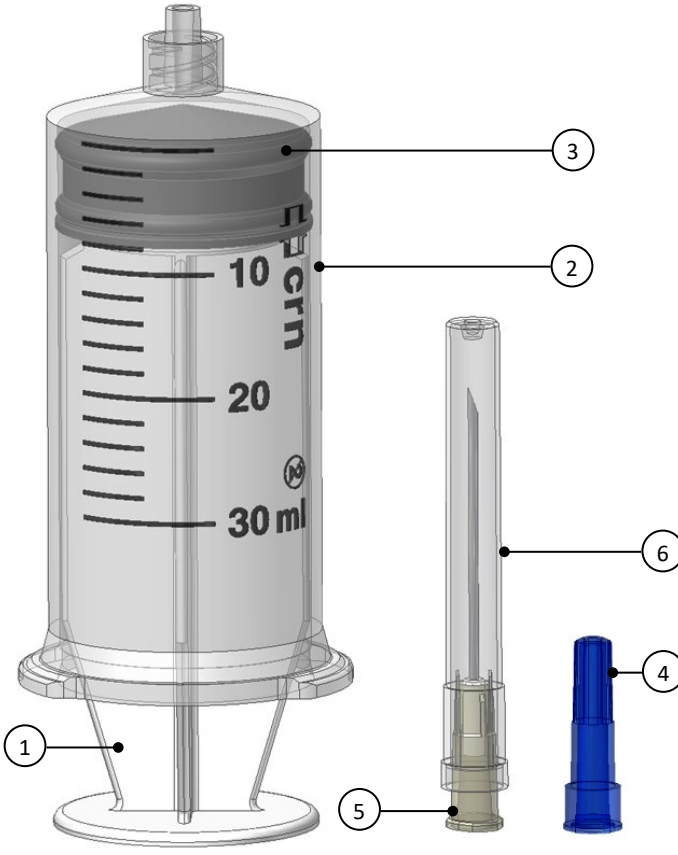


| PRODUCT PARTS | DESCRIPTION | |
|--|--|---------------|
|  | Dedicated reservoir, sterile, single-use for CANÈ S.p.A. CRONO [®] ambulatory infusion pumps. | |
| | CLASSIFICATION | |
| | Class IIa medical device, according to the rule 2 (Annex VIII of the MDR 745/2017). | |
| | EXCLUSIVE DISTRIBUTOR | |
| | CANÈ S.p.A. Via Cuorgnè 42/a 10098 Rivoli (TO) - Italy Tel.: +39-011-9574872 | |
| | MANUFACTURER | |
| | Pentaferte Italia s.r.l. Viale Piane Nocella n.23 64012 Campli (TE) - Italy Tel.: +39-0861-560201 | |
| | CE MARKING | CE 0051 |
| | ITALIAN DEVICE REPERTORY REGISTRATION | 2323602 |
| | ITALIAN DEVICE CLASSIFICATION (CND) | A020102020101 |
| REF CANÈ | CRN/30 | |
| REF MANUFACTURER | 00261282B12 | |

| PART N. | DESCRIPTION | MATERIAL |
|---------|--|--|
| 1 | PLUNGER with threaded head for piston connection. | PP |
| 2 | BARREL with male Luer Lock connector (ISO 80369-7). | PP Silicone oil (Polydimethylsiloxane) Black ink |
| 3 | PISTON with two sealing rings and internal screw for plunger. | Polyisoprene Silicone oil (Polydimethylsiloxane) |
| 4 | CAP with female Luer Lock connector (ISO 80369-7). | PP |
| 5 | NEEDLE 19 G x 11/2" - 1,10 mm x 40 mm - (ISO 7864) Barrel with Luer Lock connector (ISO 80369-7). | Stainless steel AISI 304 Epoxy resin Silicone oil (Polydimethylsiloxane) |
| 6 | NEEDLE COVER | PP |

Notes:

Scale graduation space: 2 ml (ISO 7886-1).

Scale numeration: every 10 ml (ISO 7886-1).

Dead space: max. 0,17 ml (ISO 7886-1).

Tolerance on graduated capacity at 30 ml: +/-4% (ISO 7886-1).

 Lubrication maximum quantity: 0,25 mg/cm² of barrel internal surface (ISO 7886-1).

| PACKAGING | GTIN CODE | PCS | FEATURES | MATERIAL |
|-----------|----------------|-----|---------------------------------|--|
| Primary | 08015262021535 | 1 | Blister 18x6 cm | Medical degree Paper PP/PE Plastic film |
| Secondary | 18015262021532 | 70 | Cardboard box 38,1x23,3x18,5 cm | Corrugated cardboard |
| Tertiary | 28015262021539 | 280 | Cardboard box 39,5x39,5x48,4 cm | Corrugated cardboard |

STERILIZATION

Cycle validated according to ISO 11135 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices".

| EXPIRY DATE (SHELF LIFE) | STORAGE CONDITIONS |
|---------------------------------|--|
| 5 years from manufacturing date | -10°C to 40°C Keep the product away from direct sunlight, in dry rooms and protected from extreme temperatures and excessive moisture |


WARNING

The crn[®] CRONO[®] Réservoir have been designed to be used exclusively with CRONO[®] model pumps.

The use of crn[®] CRONO[®] Réservoir with other pumps, not of the CRONO[®] series, can cause damage to the pump and injury to the patient.

CANÈ S.p.A. declines all responsibility if:

- crn[®] CRONO[®] Réservoir are used with other devices;

- CRONO[®] model pumps are used with reservoirs other than original crn[®] CRONO[®] Réservoir.