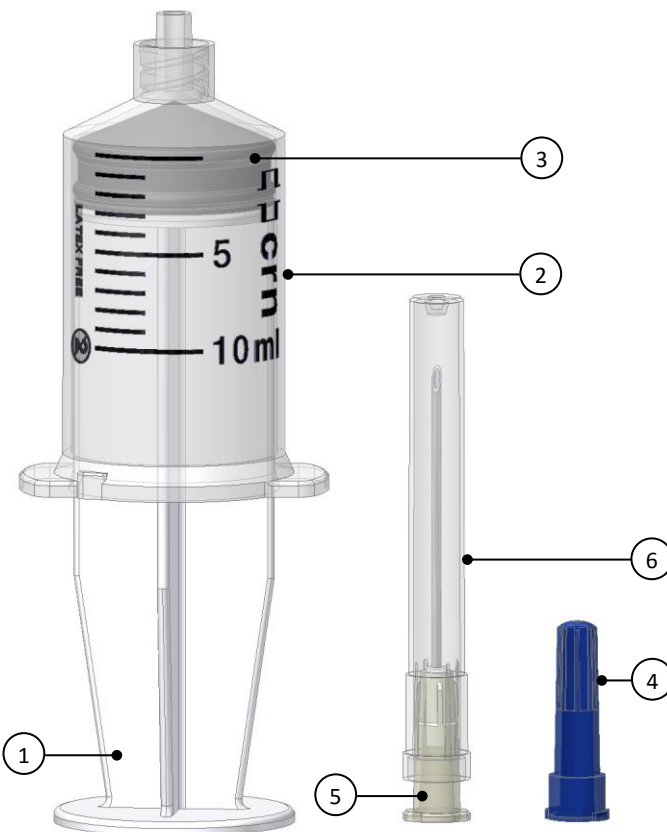


PRODUCT PARTS		DESCRIPTION	
		Dedicated reservoir, sterile, single-use for CANÈ S.p.A. CRONO ambulatory infusion pumps.	
		CLASSIFICATION	
		Class IIa medical device, according to Rule 2 of Annex IX of 93/42/EEC European directive and subsequent changes introduced by the 2007/47/EC European directive.	
		PRODUCT OWNER	
		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 0123
		ITALIAN DEVICE REPERTORY REGISTRATION	8490
		ITALIAN DEVICE CLASSIFICATION (CND)	A020102020101
REF CANÈ	CRN/10		
REF MANUFACTURER	00261262B12		
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	

PART N.	DESCRIPTION	MATERIAL
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: 1 ml (ISO 7886-1).

Scale numeration: every 5 ml (ISO 7886-1).

Dead space: max. 0,10 ml (ISO 7886-1).

Tolerance on graduated capacity at 10 ml: +/-4% (ISO 7886-1).

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

LATEX FREE product.

PACKAGING	PCS	FEATURES	MATERIAL
Primary	1	Blister 18x6 cm	Medical degree Paper PP/PE Plastic film
Secondary	80	Cardboard box 38,5x23,5x19 cm	Corrugated cardboard
Tertiary	320	Cardboard box 39,5x39,5x49 cm	Corrugated cardboard

STERILIZATION

Mixture: Ethylene Oxide 10% + CO₂ 90%.

Cycle validated according to ISO 11135-1 "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® reservoirs have been designed to be used exclusively with CRONO® model pumps.

The use of CRN® CRONO® reservoirs 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® reservoirs are used with other devices;

- CRONO® model pumps are used with reservoirs other than original CRN® CRONO® reservoirs.