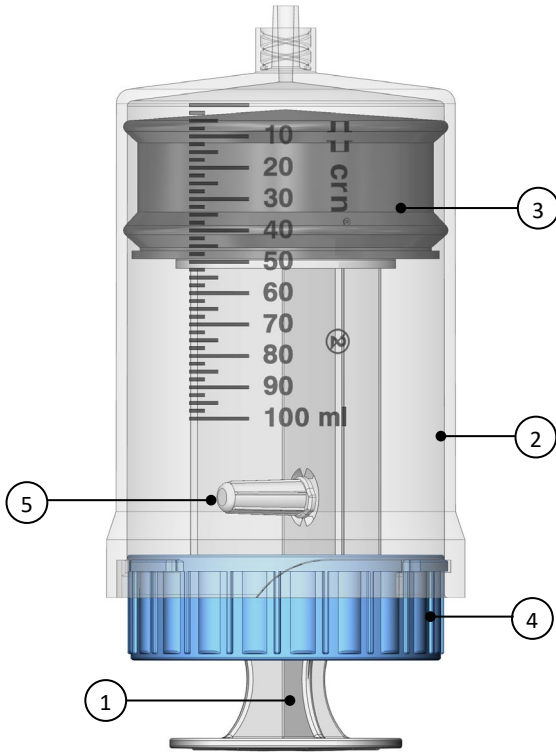


PRODUCT PARTS	DESCRIPTION	
	Dedicated reservoir, sterile, single-use for CANÈ S.p.A. CRONO® ambulatory infusion pumps.	
	CLASSIFICATION	
	Class IIa medical device, according to the rule 2 (Annex VIII of the MDR 745/2017).	
	EXCLUSIVE DISTRIBUTOR	
	CANÈ S.p.A. Via Cuornè 42/a 10098 Rivoli (TO) - Italy 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	2323555
	ITALIAN DEVICE CLASSIFICATION (CND)	A020102020102
REF CANÈ	CRN100ML	
REF MANUFACTURER	002612C20	

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 threaded adapter for plunger connection.	Polyisoprene POM Silicone oil (Polydimethylsiloxane)
4	P-STOP to impede piston extraction.	PP
5	CAP with female Luer Lock connector (ISO 80369-7).	PP

Notes:

Scale graduation space: 2.5 ml (ISO 7886-1).

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

Dead space: max. 0,20 ml (ISO 7886-1).

Tolerance on graduated capacity at 100 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	08015262035938	1	Blister 10x18 cm	Medical degree Paper PP/PE Plastic film
Secondary	18015262035935	30	Cardboard box 37,0x35,9x25,4 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.