CANNULA

FOR ORGAN PERFUSION

INSTRUCTIONS FOR USE

EN

carnamedica

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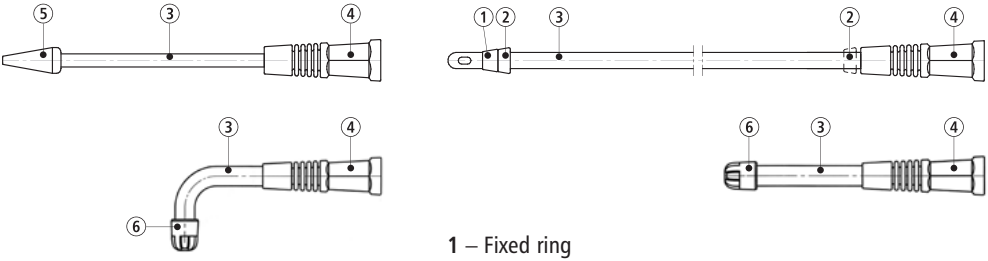
1. PRODUCT APPLICABILITY

Cannula for organ perfusion, regardless of their type – that is their length and size (diameter) – are intended for flushing and replacing residual blood in donor organs (with organ-protecting & preserving fluids, during the process of organs preparation for transplantations), using the force of gravity or using mechanical perfusion devices.
The perfusion adapter is intended for removal of perfusion fluid residues in organs
The manufacturer does not assume different applications of the product, other than those described above.
The cannulas are sterile, non-toxic and apyrogenic products. Prior to use, the physician shall individually determine the type of the cannula, its size, shape and length, as needed.

Available sizes of the cannulas:

Product Name	Catalog number (REF)	Drain length (mm)	Drain size (F)	Fixed ring / Perfusion basket (F)	Slidable ring (F)	Anti-bend connector colour
Cannula for organ perfusion 8F	KP8-14	305	8	14	—	Dark blue
	KP8-14-K	175				
Cannula for organ perfusion 10F	KP10-16	305	10	16	—	Black
	KP10-16-K	175				
Cannula for organ perfusion 12F	KP12-19	305	12	19	—	Clear
	KP12-19-K	175				
Cannula for organ perfusion 16F	KP16-22-26	305	16	22	26	Orange
	KP16-22-K	115			—	
Cannula for organ perfusion 20F	KP20-28-32	305	20	28	32	Yellow
	KP20-28-K	115			—	
Cannula for organ perfusion 25F	KP25-34-40	305	25	34	40	Blue
	KP25-34-K	115			—	Orange
	KP25-34-K-B	95.5			—	Blue
Cannula for organ perfusion – back table adapter	KP16-32A (adapter)	130	16	**Taper size (F)** 32		Orange

The following picture shows the basic components of the cannula.



1 – Fixed ring
2 – Slidable ring
3 – Cannula drain
4 – Anti-bend connector
5 – Taper
6 – Cannula basket

2. CONTRAINDICATIONS

None No information on contraindications.
The final decision regarding the product use in a procedure to be made by the surgeon.

3. RECOMMENDATIONS

Cannula basic packaging must be always opened immediately prior to its use. Also, before the product application check its expiration date and the condition of its packaging (only undamaged unit packaging guarantees sterility of the product). Avoid activities that may cause mechanical damage to the product. Do not use the product, if any damage of the cannula or of its packaging is found. The cannula is a disposable product. Product re-sterilization is unacceptable. Used cannulas should be destroyed and disposed of properly.
Only medical personnel with appropriate professional qualifications and necessary surgical experience may perform procedures using the cannula. During preparation as well as during the procedure, it is necessary to follow any applicable medical procedures and to ensure fully aseptic treatment.

4. INSTRUCTIONS FOR USE

Each time, prior to use, it is necessary to verify that the size of the cannula has been chosen appropriately matching the diameter of the vessel. In case of mechanical perfusion, additionally it is necessary to check that the length of the cannula is appropriate and that it ensures easy installation in the container of the mechanical perfusion device. Before use, the cannula shall be removed from its packaging while ensuring fully aseptic handling. Next, introduce the cannula into the vessel supplying blood to the organ, outside the ring(s). If resistance is felt during introduction, it is necessary to abort the process and to consider use of another cannula with a smaller diameter or another organ cannulation option. The cannula introduced into the organ container should be secured with a suture applied above the ring. Connect the cannula to the system that supplies protecting (preserving) liquids using the anti-bend linker. Before commending with liquids administration, check the entire system for correct connection and tightness.

5. POSSIBLE RISKS AND COMPLICATIONS

The cannula is a surgical, invasive product introduced to the arterial system of the donor, requiring precautions during its use.
In the course of the procedure the following complications may be experienced:
Leaks at the suture securing against slipping, damage to the inner wall of the organ vessel, organ's vessel perforation, organ vessel delamination, organ vessel's vasospasm or damage to the artery being cannulated.

6. STORAGE

Cannulas shall be stored in dry, ventilated rooms in ambient temperatures (permissible temperature range: from 5° C to 45° C). Protect against moisture, mechanical damage, organic solvents.

7. LIABILITY

Carnamedica Sp. z o.o. shall not be liable for any damages resulting from the product misuse or from its use that fails to comply with the operating instructions. Carnamedica Sp. z o.o. shall not be liable for any damages resulting from the product re-use or from use of products, that have been independently modified or re-sterilized by the user. Carnamedica Sp. z o.o. shall not liable for any damages resulting from use of a product with damaged unit packaging, e.g. with packaging damaged during transportation, storage or at the destination.

If any product defects are discovered in use, it is necessary to keep the defective product and to secure it along with its original packaging and to immediately notify Carnamedica Sp. z o.o. **The product may be used by qualified medical personnel only.**

Use immediately after removal from the unit packaging.

THE CANNULA IS A DISPOSABLE PRODUCT.

PRODUCT RE-STERILIZATION IS UNACCEPTABLE.

THE USED CANNULA SHALL BE DISPOSED/DESTROYED E.G. BY RECYCLING.

Meaning of symbols appearing in the instructions for use and on labels

	Manufacturing date		Caution! Read the instructions for use!	CE 2274	The product meets the requirements of the European Medical Devices Directive MDD. The manufacturer is certified by the Notifying Authority No. 2274
	Shelf life		Do not use if the packaging is damaged.		See the instructions for use.
LOT	Lot no.	STERILE EO	Sterilised with ethylene oxide. sterile flow path	5°C 45°C	Restriction of acceptable storage temperatures
REF	Catalog number		Single-use product		Keep away from sunlight.
		MD	Medical Device	Manufacturer	**Carnamedica Sp. z o.o.** ul. Olszynki Grochowskiej 21 lok. U6 04-281 Warsaw, Poland