The smart canula ™

next generation design for superior performance

BEDIENUNGSANWEISUNG
DIRECTIONS FOR USE
MODE D'EMPLOI
INSTRUZIONE PER L'USO

Venous Smart Canula ™

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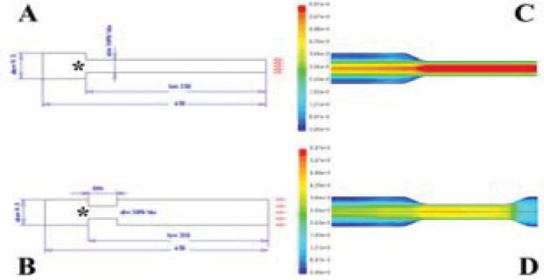
DESCRIPTION

The ***smart canula™*** is designed for less invasive vascular cannulation in conjunction with extra-corporeal circulation and intended for single use

PRODUCT TYPES

Various ***smart canula™*** sizes are available with either 3/8, or 1/4 inch connecting diameter. Due to the ***smart canula™*** principle "collapsed cannula insertion and expansion in situ" superior blood flows can be achieved. The following is intended to illustrate the potential of the ***smart canula™*** principle:



The simplified geometry of a percutaneous cannula (A), and a ***smart canula™*** (B) are compared by computational fluid dynamics (CFD). It can be shown, that higher velocities (red) occur in the long narrow segment (C) of a percutaneous cannula as compared to the zone of interest (*) in the shorter constriction of a ***smart canula™*** (D) for an identical blood flow.

(A) simplified geometry of a percutaneous cannula with an inner diameter of 9.3 mm at the outlet and 4.75 mm (50%) at the inlet. The total length is 450 mm and the norrow intravascular segment (diameter is determined by the acccess vessel) measures 350 mm in length. (B) simplified geometry of a ***smart canula™*** with an inner diameter of 9.3 mm at the outlet and a local constriction due to a narrow access vessel allowing for 50 % of residual inner diameter (similar to A). (C) plot of the velocity fields calculated for a percutaneous cannula with the simplified geometry shown in figure (A) and a blood flow of 4 l/min (the colour code corresponds to the contours of the velocity fields in m/s) : the calculated mean inlet speed for the percutaneous cannula accounts for 3.76 m/s. (D) plot of the velocity fields calculated for a ***smart canula™*** with local constriction as shown in figure B and a blood flow of 4 l/min (same color code for the velocity fields as shown in figure (C) : the calculated mean inlet speed for the smart canula accounts for 0.94 m/s which turns out to be one quarter of (C).

INTENDED USE

The ***smart canula™*** is designed for cannulation of the cardio-vascular system in conjunction with extracorporeal circulation.

INTENDED USERS

Intended users for the ***smart canula™*** are cardio-vascular surgeons, cardiologists, anaesthesists, intensivists, radiologists and other medical specialists.

CLASSIFICATION

The venous ***smart canula™*** is a CE marked device of product class III (Rule 7). The applicable conformity assessment module is Annex II (full quality system) directive 93/42 EEC

PERFORMANCE

The drainage capacity of the ***smart canula™*** at a drainage load (suction) of 40 mmHg with water as medium can be summarized as follows:

36F ***smart canula™*** **S** connecting to 3/8"
> 6.0 l/min for all lengths

24F ***smart canula™*** **ST** connecting to 3/8"
> 6.0 l/min for all lengths

20F ***smart canula™*** **ST** connecting to 1/4"
> 4.0 l/min for all lengths

DIRECTIONS FOR USE

Positioning of a self-expanding cannula in the vascular system requires in addition to the ***smart canula™*** with the appropriate size, the corresponding mandrel, a guide-wire (0.035"), and in case of percutaneous insertion, a hollow needle (18G) and a set of corresponding dilators (0.035" platform up to the nominal diameter of the ***smart canula™***).

*The **smart canula™** has to be selected in proper dimensions (cannula length, cannula diameters) in order to be able to position the entire uncovered part of the cannula within the vascular system.*

Check for completeness of the components prior to the intervention, make sure that the sterile barrier system is undamaged, and keep back-up components available.

Open the sterile blister with the selected ***smart canula™*** with its mandrel, respecting strictly the rules for sterile procedures.

Identify the target vessel and evaluate the approximate length of cannula introduction as a function of the type of procedure planned. If deemed necessary, use a sterile marker and mark the planned length of cannula insertion on the covered part of the self-expanding ***smart canula™*** .

Heparinize the patient systemically for extra-corporeal circulation in standard fashion (target ACT is 480 s). Puncture the access vessel with a hollow needle and aspirate blood in order to assess the correct position of the needle tip (for percutaneous cannula insertion).

In case of inadequate blood aspiration, partially pull back the hollow needle and reposition the latter within the access vessel. For cannula insertion with open technique, the access vessel should be prepared with a vessel loop, and clamped, prior to performing a small incision.

Insert the flexible tip of the J-wire through the hollow-needle or the vascular lumen respectively while blood flows back.

Check integrity of guide wire before use. The guide wire should be advanced in the direction of the target vessel without resistance. The guide-wire should not be pulled back into the hollow-needle, as the cutting edge of the hollow-needle could damage the guide wire. Do not use damaged guide wire. Additional guide wire for back-up is required.

Advance the guide wire into the target vessel, until the tip of the J-wire is positioned beyond the target area for the cannula tip (e.g. superior vena cava).

It is recommended to check the position of the guide wire tip by echocardiography, image amplifier, digital control, or another suitable technique.

Keep the guide wire in this position, and remove the hollow needle by pulling the latter away from the patient over the guide wire. Increase the size of the access orifice at the level of the vessel (or the skin for a percutaneous technique) with a blade. For percutaneous cannulation, progressive dilatation of the access channel with a series of dilators adapted to the guide wire is required. It is recommended to control back-bleeding during dilator exchange by gentle finger pressure.

Dilators must be rinsed prior to use by connection of a seringe with NaCl 0.9% to the port of the dilator

Collapse the ***smart canula™*** by stretching it over the corresponding mandrel (each ***smart canula™*** comes with its specific mandrel of adequate length). The ***smart canula™*** should be stretched so far, that it collapses over its entire uncovered length and also the first 10 mm of its covered length.

Insert the stiff end of the guide wire into the conical tip of the collapsed ***smart canula™*** . Advance the guide wire until it finds its way through the mandrel and the stopper. Grab the guide wire when it appears in the center of the stopper and insert the ***smart canula™*** a few centimetres into the access vessel. Hold the guide wire section which is outside of the body straightened out and advance the ***smart canula™*** with its tip into the target zone in such a fashion, that at least 10 mm of its covered part are positioned in the access vessel. Make sure that the ***smart canula™*** tip is in the right position (ultrasound, image amplifier, digital control, etc).

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*Deeper insertion of the **smart canula™** should only be performed over a guide wire. If the mandrel has already been removed, the latter has to be reinserted, and the **smart canula™** has to be stretched, in order to reinsert the guide wire through its tip.*

Remove the guide wire **before** the mandrel. Rotate the stopper in order to avoid cannula tip dislocation. Backflow of blood has to be controlled digitally prior to clamping the silastic sleeve of the ***smart canula™***. The ***smart canula™*** expands automatically and adapts to vessel lumen.

*Only the silastic sleeve of the **smart canula™** should to be clampea (never the metal supported part where the cannula can be damaged).*

Fix the ***smart canula™*** gently in standard fashion (close to the cannulation orifice) to prevent unplanned decannulation. Avoid flow limitations due to kinked ***smart canula™*** positions or narrowing suture or fixation.

Connect the self-expanding ***smart canula™*** to the primed extracorporeal circuit in standard fashion using a barbed connector corresponding to the size of the ***smart canula™*** and secure proper debubbling.

After completion of cardio-pulmonary bypass, the ***smart canula™*** should not be left longer within the vascular system than necessary

For longer perfusion periods it is necessary to secure adequate perfusion for the body parts which are dependent on the cannulated vessels.

Use standard techniques for disconnecting extra-corporeal circulation tubings.

Simple traction is sufficient for ***smart canula™*** removal (axial extension of the ***smart canula™*** automatically reduces its diameter). Gentle digital compression of the cannulation orifice during ***smart canula™*** removal allows for control of bleeding. Standard compression techniques are required for hemostasis after percutaneous cannulation, whereas adequate vascular reconstruction is necessary following an open cannulation procedure or issues during cannula removal.

Typical application of the ***smart canula™*** within the body is 2 hours, whereas the maximum is 6 hours.

As with all medical devices, this device is to be used by trained medical practitioners only.

*The **smart canula™*** is designed for single use only. Do not re-use ! Risks of re-processing include device destruction and malfunction, inadequate cleaning, and inadequate re-sterilization.

LEGENDS

	Read first the directions for use
	Single use / do not resterilize
STERILE EO	Sterilized with ethyleneoxide
	Do not use if package is damaged
	Date of manufacturing
	Use before
LOT	Lot number
REF	Product number
SN	Serial number
CE 0344	Certified in conformity with the Directive 93/42/EEC Annex II (full quality system) by the notified body Nr. 0344
	Important!

Smartcanula 6 hours,
Version : 2021 01 23

Smartcanula Patents: US 6626859, WO 015273, AU770989, JP5059305, EP1248571, US8679053, EP1651121, HK1091109, US7967776, CN02149340, US8992455, US8679053