

COOK[®]

MEDICAL

Beacon[®] Tip Cava Vessel Sizing Catheter

Instructions for Use



T - B T C A V A - R E V O

BEACON® TIP CAVA VESSEL SIZING CATHETER

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

DEVICE DESCRIPTION

Beacon Tip Sizing catheters are single-use, sterile catheters with gold marker bands. These catheters are for use in angiographic procedures and available in a variety of lengths (70 and 90 cm) and tip configurations (PIG and VCF).

INTENDED USE

Beacon Tip Sizing Catheters are intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed. Beacon Tip Sizing Catheters have marker bands that can be used for anatomical measurements.

CONTRAINDICATIONS

None known

WARNINGS

- The outer surface of the inner catheter package is **NOT** sterile.
- This device has not been tested in the absence of anticoagulation.

PRECAUTIONS

- These products should be stored in their original sealed foil package with required labeling.
- Manipulation of the catheter requires fluoroscopic control.
- If resistance is encountered during manipulation, stop and determine the cause before proceeding any further.
- Do not attempt to heat or reshape the catheter curve; the catheter tip is made from a heat-sensitive material.

PRODUCT RECOMMENDATIONS

- The labeled pressure is the maximum power injector machine settings.
- Labeled flow rate achieved with 11.8cP contrast and contrast temperature of $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

INSTRUCTIONS FOR USE

1. Inspect the packaging and device to verify no damage. Do not use product if the catheter or packaging is damaged.
2. Open foil packaging and remove or expose inner package containing the sterile catheter. **NOTE:** The outer surface of the inner catheter package is not sterile.
3. Open inner packaging using standard operating room/catheterization lab aseptic techniques to present catheter to operator.
4. Flush the device prior to use.
5. Under fluoroscopic guidance, advance catheter over an appropriately sized wire guide or through an appropriately sized sheath introducer to the intended location. **NOTE:** If resistance is encountered during manipulation, stop and determine the cause before proceeding any further.
6. When using a contrast power injector, ensure all connections are secure. Please refer to the Product Recommendations section for pressure and flow rate information.

Peel-Away™ Straightener

Catheters with pigtail shaped or similar configurations are supplied with Peel-Away straighteners to be used as follows.



Fig. 1

- a) Slide the Peel-Away straightener forward to open the catheter tip. (Fig. 1)

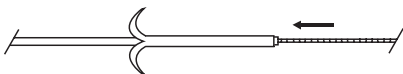


Fig. 2

- b) With catheter tip straight, advance the catheter over the wire guide. (Fig. 2)

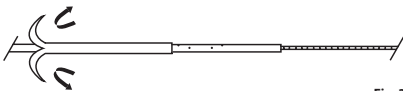


Fig. 3

- c) After the initial advancement of the catheter over the wire guide, pull back and peel away the straightener for catheter advancement. (**Fig. 3**)

NOTE: The Peel-Away straightener must not be used as a vascular introducer sheath.

HOW SUPPLIED

This product is sterilized by ethylene oxide gas. Catheters are supplied in a foil pouch and inner peel-open package. The outer surface of the inner package is non-sterile. Store in a dark, dry, cool place. Use immediately once foil pouch has been opened. Upon removal from package, inspect the product to ensure no damage has occurred. Intended for one-time use.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature.

A symbol glossary can be found at <https://cookmedical.com/symbol-glossary>



Quantity per box



MANUFACTURER

COOK INCORPORATED

750 Daniels Way

Bloomington, IN 47404 U.S.A.

www.cookmedical.com

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