

COOK

MEDICAL

White Sizing Catheter

Instructions for Use



T - W S C - R E V O

WHITE 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

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 (65, 70, 90, and 100 cm) and tip configurations (straight, PIG, VCF, and CFP).

INTENDED USE

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. Sizing Catheters have marker bands that can be used for anatomical measurements.

CONTRAINDICATIONS

None known

WARNINGS

Testing conducted does not support the use of this device in patients who cannot be systemically anticoagulated.

PRECAUTIONS

- Manipulation of the catheter requires fluoroscopic control.
- Due to thinwall construction, extreme care must be exercised during manipulation and withdrawal. Catheter insertion through a synthetic vascular graft should be avoided whenever possible.
- Do not attempt to heat or reshape the catheter curve; the catheter tip is made from a heat-sensitive material.
- The possible whiplash effect of the long, soft catheter tip must be considered during selective angiography.

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. Flush the device prior to use.
3. 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.
4. 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)

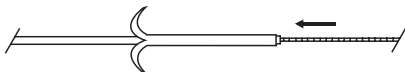


Fig. 2

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

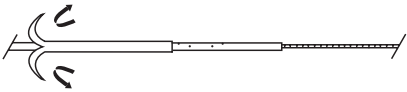


Fig. 3

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

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

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



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COOK INCORPORATED

750 Daniels Way

Bloomington, IN 47404 U.S.A.

www.cookmedical.com

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