

COOK

MEDICAL

Royal Flush® Catheter

Instructions for Use



T - R F C - R E V O

ROYAL FLUSH® 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

Royal Flush Catheters are for use in angiographic procedures and available in a variety of lengths and tip configurations.

INTENDED USE

The Royal Flush Catheters are intended for the delivery of contrast media to the peripheral and coronary vasculature, not including the neurovasculature.

CONTRAINDICATIONS

None known

WARNINGS

None known

PRECAUTIONS

- This catheter is intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques. Standard techniques for placement of vascular sheaths, angiographic catheters and wire guides should be employed.
- 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

- Maximum power injector machine settings should not exceed the labeled pressure.
- Labeled flow rate achieved with 12.7cP contrast and contrast temperature of 22° C ± 2° C.

INSTRUCTIONS FOR USE

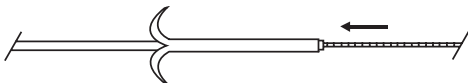
1. Inspect the packaging and device to verify no damage. Do not use the product if the catheter or the packaging is damaged.
2. Flush the catheter prior to use.
3. Under fluoroscopic guidance, advance the catheter over appropriately sized wire guide or through an appropriately sized sheath introducer 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.

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



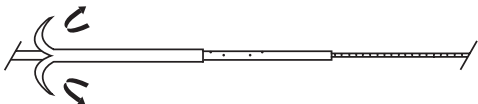
1

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



2

- b) With catheter tip straight, advance the catheter over the wire guide or into a sheath introducer. (Fig. 2)



3

- c) After initial advancement of catheter over the wire guide or into a sheath introducer, 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



MANUFACTURER

COOK INCORPORATED

750 Daniels Way

Bloomington, IN 47404 U.S.A.

www.cookmedical.com

© COOK 2017

2017-12

T_RFC_REVO