

COOK

MEDICAL

Royal Flush® Plus High-Flow Catheters

Instructions for Use



T _ R F P H F _ R E V O

ROYAL FLUSH® PLUS HIGH-FLOW CATHETERS

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 Plus High-Flow Catheters are for use in angiographic procedures and available in a variety of lengths and tip configurations. For catheters with a labeled length 110 cm or longer, the length is measured from the proximal end of the strain relief to the distal end of the catheter (with pigtail curled if present). For other sizes, the length is measured from the distal end of the strain relief to the distal end of the catheter (with pigtail curled if present).

INTENDED USE

The Royal Flush Plus High-Flow Catheter is intended for the delivery of contrast media and therapeutic agents to the peripheral, carotid, 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.
- The possibility of catheter tip movement must be considered when using these catheters with a pressure injector.

PRODUCT RECOMMENDATIONS

- Maximum power injector machine settings should not exceed the labeled pressure.
- Labeled flow rate achieved with VISIPAQUE270 contrast media at $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

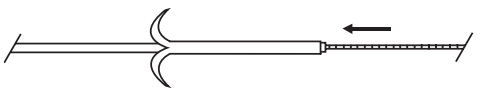
INSTRUCTIONS FOR USE

1. Inspect the packaging and device to verify no damage. Do not use 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 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.
5. To remove the catheter upon completion of use, reinsert the wire guide. Slowly withdraw the catheter over the wire guide or through the sheath, using fluoroscopic guidance as needed.
6. Upon completion of the procedure, dispose of the device per institutional guidelines for biohazardous medical waste.

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

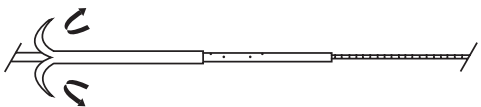


- a) Slide Peel-Away straightener forward to open catheter tip. (**Fig. 1**)



2

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



3

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

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

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