COOK MEDICAL

Check-Flo Performer® Introducer

Instructions for Use

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CHECK-FLO PERFORMER® INTRODUCER

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

Performer introducers are designed to perform as a guiding sheath and/or introducer sheath and come with a Check-Flo® valve. Some Performer introducers are available with a radiopaque tip incorporated in the sheath material to identify the location of the sheath's distal tip.

INTENDED USE

Performer introducers and guiding sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature.

CONTRAINDICATIONS

This device is not intended for coronary and neurovascular use.

WARNINGS

Before withdrawing the sheath through tortuous anatomy, insert the introducer dilator to avoid possible breakage.

PRECAUTIONS

- This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular access sheaths should be employed.
- The maximum diameter of the instrument or catheter to be introduced should be determined to ensure that it will pass through the introducer.
- All instruments or catheters used with this product should move freely through the valve and sheath. Damage to the valve/introducer may result when the fit is tight.
- When inserting, manipulating or withdrawing a device through an introducer always maintain introducer position.
- Before removing or inserting devices through the introducer, aspirate through the side-arm of the valve to clear the introducer, then flush with heparinized saline.
- When inflating a balloon at, or close to, the introducer tip, ensure the balloon is not inside the distal tip of the introducer.
- When puncturing, suturing or incising the tissue near the introducer, use caution to avoid damaging the introducer.
- Do not attempt to insert or withdraw the wire guide and/or introducer if resistance is felt.
- Withdrawal or manipulation of the distal spring coil portion of the mandril wire guide through a needle tip may result in breakage.
- The potential effects of phthalates on pregnant/nursing women or children have not been fully characterized and there may be concern for reproductive and developmental effects.

POTENTIAL ADVERSE EVENTS

Adverse events that may be associated with the use of an introducer set include, but are not limited to:

- Bleeding
- Extravasation
- Hematoma
- Vessel laceration
- Vessel perforation
- Local inflammation
- Local pain
- Access site infection
- Distal embolization

INSTRUCTIONS FOR USE

Sheath Introduction

1. Upon removal from package, ensure the inner diameter (ID) of the introducer is appropriate for the maximum diameter of the instrument or catheter to be introduced.
2. Using the side-arm of the valve, flush the introducer by filling the introducer assembly completely with heparinized saline.
3. Flush the dilator with heparinized solution.
4. Insert the dilator completely into the introducer.
5. Using standard Seldinger technique, access the target vessel with the appropriate needle.
6. Insert an appropriate wire guide into the vessel through the needle, then remove the needle, leaving the wire guide in place.
7. Insert the dilator/sheath combination over the wire guide.
8. Remove the wire guide and dilator; aspirate and flush the introducer side-arm.
9. Insert an appropriately sized device as needed.

Sheath Removal

1. Insert a wire guide at least 10 cm past the tip of the sheath.
2. Insert the introducer dilator over the wire guide into the sheath.
3. Withdraw the sheath and dilator as a unit.
4. Remove the wire guide.

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

This symbol on the label indicates that this device contains phthalates. Specific phthalates contained in the device are identified beside or below the symbol by the following acronyms:

- **BBP: Benzyl butyl phthalate**
- **DBP: Di-n-butyl phthalate**
- **DEHP: Di(2-ethylhexyl) phthalate**
- **DIDP: Diisodecyl phthalate**
- **DINP: Diisononyl phthalate**
- **DIPP: Diisopentyl phthalate**
- **DMEP: Di(methoxyethyl) phthalate**
- **DNOP: Di-n-Octyl phthalate**
- **DNPP: Di-n-pentyl phthalate**

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