Kodiak™ Dual Port Coaxial Introducer Kit

ARGON MEDICAL DEVICES, INC.
1445 Flat Creek Road
Athens, Texas 75751 USA
Tel: +1 (903) 675 9321
Tel: +1 (800) 927 4669
www.argonmedical.com

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https://www.argonmedical.com/resources/product-information

The symbols glossary is located electronically at www.argonmedical.com/symbols

Intended Use/Purpose
The Kodiak™ Dual Port Coaxial Introducer Kit is intended to introduce devices into the vasculature.

Device Description
The kit consists of the following components:
- 16F ID (5.6mm) (20.2F OD, 6.8mm) x 45cm outer sheath
- 14F ID (4.7mm) (16.4F OD, 5.5mm) x 53cm inner sheath
- 14F OD (4.7mm OD, 1.0mm ID) x 61cm dilator
- 7F ID (2.3mm) / 7F ID (2.3mm) Y-connector
- 16ga blunt flushing needle
- High pressure Luer adapter

Each sheath contains a hemostasis valve, side-port, and radiopaque marker band. The Y-connector contains a hemostasis valve on each 7F port.

This system is not made with natural rubber latex.

Indication for Use
The Kodiak™ Dual Port Coaxial Introducer Kit is indicated to introduce therapeutic or diagnostic devices into the vasculature.

Contraindications for Use
The device is not intended for coronary and neurovascular use.

Side Effects
There are no known side effects for this system.

Warnings
- Contents are supplied sterile and are intended for single use only. Do not reuse or re-sterilize. Reuse or reprocessing has not been evaluated and may lead to device failure and subsequent patient illness, infection, or other injury.
- Inspect package integrity prior to use. Do not use if package is open or damaged or if the expiry date has been exceeded.
- Inspect component integrity prior to use. Do not use if any component is damaged.
- Do not continue to use if any component is damaged during the procedure.
- Ensure vessel access is large enough for successful introduction and withdrawal of system components. Do not force any components through an access site that is too small.
- Ensure the outer diameter of the device to be introduced is small enough to fit through the applicable system components. If more than one device is to be introduced, ensure the combined outer diameter is small enough to fit through the applicable system components.
- Both ports of the Y-Connector allow for introduction of a 7F device (2.36mm OD device); however, using two 7F devices simultaneously may be difficult to manipulate in the 14F ID (4.7mm) of the inner sheath.
- Angled 7F devices may be more difficult to introduce and retrieve.
- Do not advance or withdraw devices through the system if resistance is felt.
- Use fluoroscopic guidance when advancing, retracting, or manipulating system components in the vasculature.
- Do not use excessive force when advancing, retracting, or manipulating system components.
- Before withdrawing the system through tortuous anatomy, insert the dilator to avoid possible damage to the system.

Precautions
- This device is intended for use only by medical personnel trained in vascular diagnostic and interventional techniques. Standard techniques for placement of vascular access sheaths should be employed.
- Maintain sheath positioning when inserting, manipulating, or withdrawing a device through it.
- Follow all contraindications, warnings, cautions, precautions, and instructions for all infusates, including contrast medium, as specified by their manufacturer.
- Before inserting or removing devices through the inner sheath, aspirate through the side-port to clear the sheath, then flush with heparinized saline.
- Do not advance sharp objects through the hemostasis valve.
- Minor air ingress through hemostasis valve during aspiration is possible, do not reintroduce air into the sheath.
- Do not puncture the hemostasis valve.
- Grasp the dilator as close to the distal tip as possible when advancing through the hemostasis valve to prevent kinking.

Potential Complications
Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the potential complications. These events may be serious in nature and may require hospitalization or intervention to address the condition. Possible complications of system usage include, but are not limited to the following:

- Access site injury or infection
- Air embolism
- Bleeding
- Distal embolization
- Extravasation
- Hematoma
- Local inflammation or pain
- Vessel injury, including laceration or perforation

Pre-Procedure Preparation
1. Remove all components from packaging using sterile technique.
2. Ensure the maximum outer diameter of the device to be introduced can pass through the applicable system components.
3. Ensure the length of the device to be introduced is long enough to pass through the applicable system components.
4. Flush the system with heparinized saline. To flush the Y-connector, connect a syringe of heparinized saline to the 16ga blunt flushing needle, and pass the blunt end of the needle through each hemostasis valve.
5. Insert the 14F dilator through the hemostasis valve on the inner sheath, grasping the dilator close to the hemostasis valve while advancing.
6. Insert the inner sheath through the hemostasis valve of the outer sheath.
7. Follow accepted clinical practice for vessel access and guidewire insertion. The system can accept up to an 0.038” guidewire. If needed, pre-dilate the access site using a series of dilators up to 20F.

Directions for Use
Sheath Insertion:
1. Insert the 14F dilator and coaxial sheath assembly over the guidewire.
2. Remove the dilator. If applicable, the guidewire may remain to support advancement of devices through the vasculature.
3. If using the Y-connector, connect it to the hub of the inner sheath.
4. Aspirate through the side-port of the inner sheath, then flush with heparinized saline.

5. Insert appropriately sized devices through the Y-connector or inner sheath. Use the devices as recommended in the manufacturer's directions for use.

Sheath Removal:

1. Aspirate through the side-port of the inner sheath, then flush with heparinized saline.
2. Remove all devices from the system.
3. Remove the coaxial sheath assembly. Upon removal of the sheath assembly, precautions should be taken to prevent bleeding, vessel damage, or other serious injury. Advancement of the dilator into the sheath assembly prior to sheath assembly withdrawal may aid in withdrawal of the sheath assembly from the vasculature.
4. Re-establish hemostasis following hospital protocol.

Note: A follow up venogram/angiogram may be performed through the inner sheath or outer sheath. First, aspirate and flush the sheath to clear any residual thrombus, then connect the high pressure Luer adapter to the hub of the sheath. The sheaths are rated for power injection of undiluted contrast, at 37°C, at a maximum rate of 15mL/s.

Disposal

After use, handle and dispose in accordance with facility policies and procedures concerning biohazardous materials and waste. Handle in a manner that will prevent accidental puncture.

Storage

Store at controlled room temperature.

Note: In the event a serious incident related to this device occurs, the event should be reported to Argon Medical at quality.regulatory@argonmedical.com as well as to the competent health authority where the user/patient resides.