COOK MEDICAL

Arterial Pressure Monitoring Set/Tray

Instructions for Use

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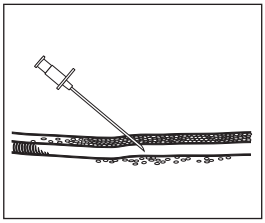

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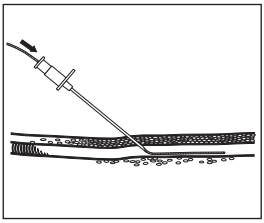

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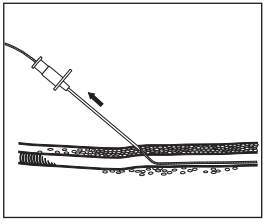

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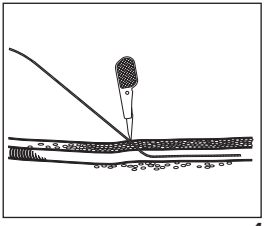

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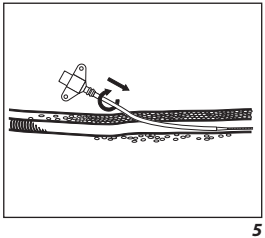

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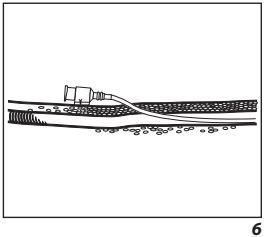

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ARTERIAL PRESSURE MONITORING SET/TRAY

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

The Arterial Pressure Monitoring Set/Tray consists of a single-lumen catheter, a wire guide, and a needle. Sets and trays may also contain a dilator and accessories for use in percutaneous vascular access procedures under sterile techniques. The catheter and its components do not contain natural rubber latex.

INTENDED USE

The Arterial Pressure Monitoring Set/Tray is intended for arterial blood pressure monitoring and blood sampling in adult and pediatric patients.

- 2.5 French catheters are intended for patients from birth and older.
- 3.0 and 4.0 French catheters are intended for patients aged 1 year and older.
- 5.0 French catheters are intended for patients aged 12 years and older.

CONTRAINDICATIONS

- Severe coagulopathy
- Infection
- Inflammation of site
- Presence of arterial graft at site
- Absent pulse
- Thromboangiitis obliterans (Buerger disease)
- Full-thickness burns over the cannulation site
- Inadequate circulation to the extremity
- Raynaud syndrome
- Coronary vasculature
- Neurovasculature

WARNINGS

- Only medical practitioners licensed by law, and trained and experienced in proper positioning of catheters in the vascular system using percutaneous entry (Seldinger) technique should place this catheter.
- Complications arising from the use of this device can result in serious injury or death; the catheter tip can erode or perforate vascular walls. Other risks include, but are not limited to, thrombosis and possible infection.
- To avoid vascular injury, do not use excessive force when advancing dilators. The wire guide must always lead the dilator by several centimeters. Do not advance the dilator more than a few centimeters.
- Pressure monitoring catheters should be placed under sterile conditions.
- Prepare and drape the patient using standard technique, according to hospital protocol.
- If lumen flow is impeded, do not force injection or withdrawal of fluids. Notify the attending physician immediately.
- This catheter should not be used for long-term (>30 days) indwelling applications.
- Do not cut, trim, or modify the catheter or components, prior to placement or intraoperatively.

PRECAUTIONS

- Select puncture site and length of catheter needed by assessing patient anatomy and condition.
- Verify that there is an adequate palpable pulse in the vessel prior to attempting the procedure.
- Use proper clinical judgment to determine the appropriate catheter size for the selected anatomy and to ensure vessel perfusion is not negatively impacted by catheter placement.

- Patient movement can cause catheter tip displacement. Use should be limited to controlled hospital situations.
- Non-clinical testing showed the potential for thrombus formation on the device in the absence of anticoagulation. Appropriate anticoagulation should be administered in order to reduce the potential for thromnus formation.

POTENTIAL ADVERSE EVENTS

- Thrombosis
- Embolism
- Air embolism
- Infection
- Iatrogenic blood loss
- Occlusion
- Hematoma
- Vasospasm

PRODUCT RECOMMENDATIONS

- Access sites for the Arterial Pressure Monitoring catheters include, but are not limited to, the following arteries:
  - Radial
  - Brachial
  - Dorsalis Pedis
  - Femoral
  - Posterior Tibial
  - Axillary
- Anticoagulation is recommended to be used during the use of this device.

INSTRUCTIONS FOR USE

1. Palpate the artery gently with the non-dominant hand proximal to the insertion site.
2. Introduce the thinwall percutaneous entry needle into the vessel, at a 30-45 degree angle to the skin, directly over the point at which the pulse is palpated. When you see a flash of blood return, advance the needle further into the vessel. (**Fig 1**)
3. Pass the straight or straightened wire guide (using j-tip straightener) slowly through the needle and advance the wire guide 5-10 cm into the vessel. If a straight wire guide is provided, always advance the flexible end through the hub and into the vessel. (**Fig 2**)

   NOTE: If you encounter resistance while inserting the wire guide, do not force the wire guide.

   CAUTION: Avoid withdrawing the wire guide through the needle; breakage of the wire guide may result.
4. While maintaining wire guide position, withdraw the needle and wire guide straightener (if necessary). (**Fig 3**)
5. If necessary, enlarge the puncture site with a scalpel. (**Fig 4**)
6. If a dilator is included and dilation is required, advance the dilator over the wire guide and into the puncture site in a controlled manner. Withdraw the dilator, leaving the wire guide in place.
7. Introduce the single-lumen catheter over the wire guide while maintaining the wire guide's position. Advance the catheter carefully into the vessel with a gentle twisting motion. Do not advance the catheter tip beyond the distal tip of the wire guide. Always be sure to have the wire guide leading during catheter placement. (**Fig 5**)
8. After the catheter is in position, remove the wire guide. Confirm catheter position via return of pulsatile blood from the hub of the catheter.

   NOTE: Placing a thumb over the catheter hub will help minimize blood onto the procedure site. (**Fig 6**)

   NOTE: If the catheter does not have to be introduced to its full length, additional suture should be carefully placed around the catheter and affixed to the skin at the entry site. This will help prevent movement or displacement of the catheter. The lumen should now be flushed with
   5-10 cc of normal saline prior to use and/or maintained according to standard hospital protocol.
9. Connect the catheter to a pressure transduction system.
10. Suture/secure the winged hub into place.

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

Manufacturer
COOK INCORPORATED
750 Daniels Way
Bloomington, IN 47404 U.S.A.

www.cookmedical.com

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