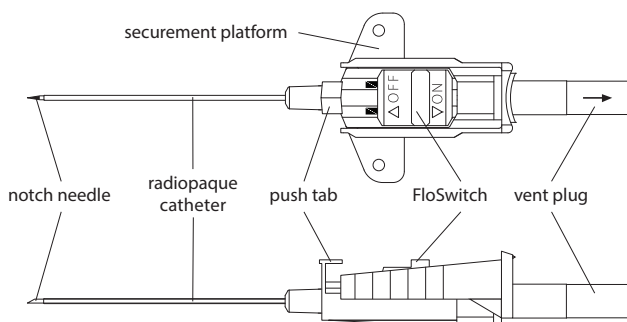


Arterial Catheter

INSTRUCTIONS FOR USE

**DESCRIPTION**

The Merit RadialFlo™ arterial catheter is designed to access the vasculature to sample blood and monitor blood pressure. The device is equipped with a FloSwitch to limit blood spill or control flow as needed. The needle includes a unique notch to provide instant blood return upon vessel entry. The radiopaque catheter provides visibility under X-ray and fluoroscopy.

INTENDED USE / INDICATION FOR USE

The Merit RadialFlo™ arterial catheter is a device that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood and monitor blood pressure. The Merit RadialFlo™ arterial catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

REUSE PRECAUTION

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

CONTRAINDICATION

RadialFlo™ is for arterial blood pressure monitoring and arterial blood sampling only. Do not use for arterial administration of intravenous infusions.

CLINICAL BENEFITS

- Allow blood pressure monitoring
- Allow blood sampling

WARNINGS

- Non-pyrogenic. Sterile, do not use if unit package is opened or damaged. Check integrity of the individual package before use.
- For single use only. Dispose of product after use. Do not resterilize. Reuse may lead to infection or other illness/ injury.
- Do not bend the needle when using the product.
- Do not use scissors / or sharp tools at or near the insertion site to avoid accidental catheter shear.
- Do not attempt to re-insert a partially or completely withdrawn needle into the catheter. If arterial puncture is unsuccessful discard the entire device.
- Exposure to blood, either through percutaneous puncture with a contaminated needle or via mucous membranes, may lead to serious illness such as hepatitis, HIV, AIDS, or other infectious disease.
- Physicians must be familiar with arterial access using over the needle technique.
- Physicians must be familiar with the complications associated with arterial catheterisation, i.e. arterial ischemia, air embolism, catheter fragmentation which required additional procedure.

Rx Only Federal Law (USA) restricts this device to sale by or on the order of a physician.

PRECAUTIONS

- RadialFlo™ inserted in emergency situations where sterile technique could be compromised should be replaced within 48 hours. Follow hospital/

institutional protocols or procedures on recommended indwelling time for RadialFlo™.

- Device lifetime specified as 96 hours based on CDC & Joint Commission Intl (JCI) recommendation for replacement frequency
- Ensure the placement location of RadialFlo™ does not prevent collateral flow to the extremity.
- Immediately dispose of the needle post insertion in appropriate sharps container.
- Report needlestick injuries immediately following established facility protocol.

MRI SAFETY INFORMATION

Non-clinical testing demonstrated that the RadialFlo™ is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 2,000-Gauss/cm (20-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

STORAGE CONDITIONS

Store in cool dry place away from direct sunlight.

GENERAL GUIDELINES

- The RadialFlo™ Arterial Catheter is available in one size as below specification:
 - Gauge Size: 20G
 - Standard outer diameter: 1.10mm
 - Standard length: 45mm
 - Flowrate: 49ml/min
- For proper use, clinicians must be familiar with and trained in the use of the RadialFlo™.
- Observe infection control precautions on ALL patients.
- Aseptic technique, proper skin preparation, and continued protection of the insertion site are essential.
- Examine the catheter insertion site frequently.
- If sutures are used to secure RadialFlo™, suture through the fenestrations in the securement platform.
- This product does not contain DEHP, DIBP, DBP & BBP.
- After use, dispose the device in a manner consistent with standard protocols for waste disposal.
- In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

INSTRUCTIONS FOR USE

1. Prepare the patient aseptically according to hospital policy and protocol.
2. Inspect the package to ensure there is no damage and sterility is maintained. Refer to the arrows on the device label to open the package (see Figure 1).

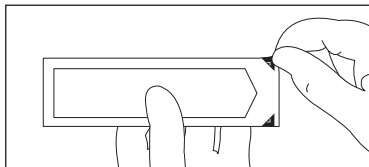


Figure 1

3. Remove the device from the package (see Figure 2).

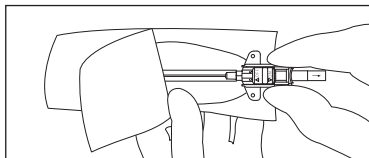


Figure 2

4. Remove the protective needle cover in a straight outward motion (see Figure 3).

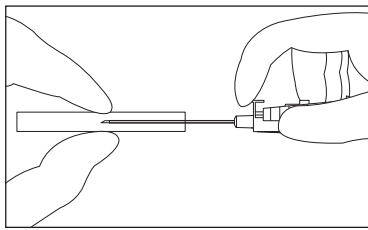


Figure 3

5. Ensure the FloSwitch is in the appropriate open position prior to needle insertion (see Figure 4).

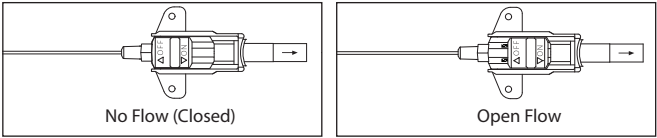


Figure 4

6. Position the device bevel-up prior to insertion (see Figure 5).

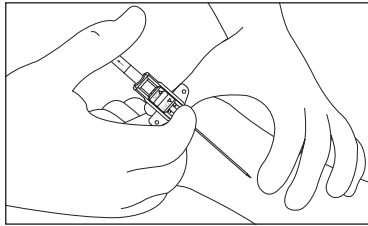


Figure 5

7. Insert the needle through the skin ultrasonically, via palpation, vessel transfixion, or according to hospital protocol.
 8. Confirm instant blood return up the catheter once the vessel is accessed. Blood return should continue into the blood return chamber. For continuous blood return, remove the vent plug (see Figure 6) and attach a syringe (see Figure 7).

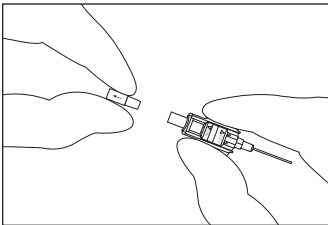


Figure 6

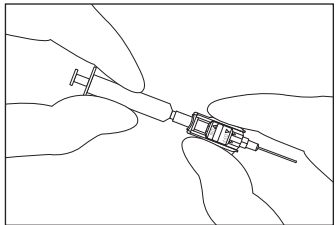


Figure 7

9. Use the push tab (see Figure 8) to advance the catheter. Remove the needle from the catheter and discard into a sharps container.

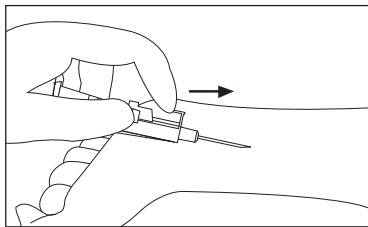


Figure 8

10. With the needle withdrawn, activate the FloSwitch (see Figure 9) to stop the flow of blood.

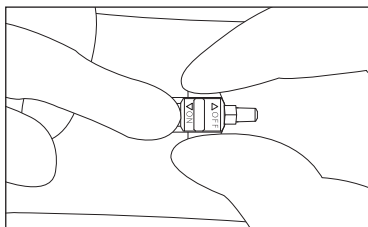


Figure 9

11. Connect the pressure line or monitoring kit as required (see Figure 10).

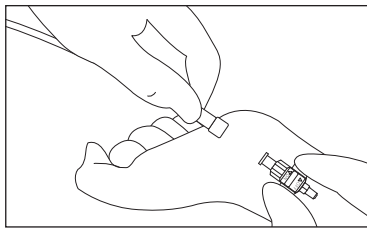


Figure 10

12. Open the Flow Control Switch and flush the system per facility protocol.
 13. Stabilize and secure RadialFlo™ with a sterile dressing (see Figure 11).

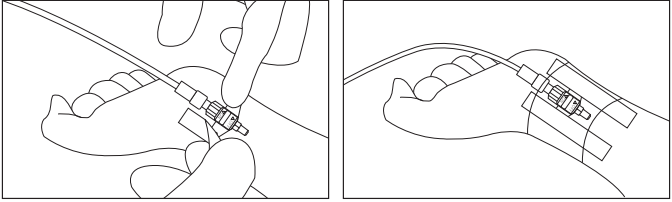


Figure 11

14. Upon removal of the device, examine the device to ensure that it is intact and discard in accordance with the facility protocol.

Symbol	Designation
	Catalog Number
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Consult instruction for use. For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U. Customer Service.
	Caution
	Sterilized using Ethylene Oxide
	Single use
	Do not resterilize
	Do not use if package is damaged and consult instruction for use.
	Lot Number
	Use by date
	Does not contain DEHP, DIBP, DBP & BBP
	Non-pyrogenic
	Manufacturer
	Authorized Representative in the European Community
	Keep dry
	Keep away from sunlight
	MR Conditional
	Medical Device
	Unique Device Identifier
	Date of Manufacture
	Single Sterile Barrier System



Manufacturer:

Merit Medical Singapore Pte. Ltd.,
198 Yishun Avenue 7,
Singapore 768926



Authorized Representative:

Merit Medical Ireland Ltd,
Parkmore Business Park West,
Galway, Ireland
EU Customer Service +31 43 358 82 22