English

Monitoring Life™

Careflow™ Central Venous Catheter
Careflow™ Arterial Catheter

INSTRUCTIONS FOR USE

The Merit Careflow™ Catheter is a radio-opaque polyurethane catheter. (Central Venous and Radial, Femoral Arterial Catheter).

INTENDED USE

The Merit Careflow Central Venous Catheter is an intravenous catheter that is intended for short term use (no longer than 30 days) to access the human circulatory system via insertion through either the internal Jugular or Sub-Clavian Vein using Seldinger technique, where the catheter tip resides in the superior vena cava. The Central Venous Catheter is intended for infusion of drugs, Total Parenteral Nutrition (TPN) fluids, large volume infusions, repeated blood sampling and to monitor the central venous pressure.

The Merit Careflow Arterial Catheter is intended for short term use (no longer than 30 days) to access the radial and femoral arteries for repeated blood sampling and to allow invasive blood pressure measurement.

A full list of components is shown on the package lid.

USER / PATIENT / CLINICAL

User: Qualified nurses, clinicians and physicians

Patient: Adult and Pediatric applications

Clinical: Hospitals or appropriate clinical environments

GENERAL WARNINGS

1. Use only as directed by a physician.
2. Physicians must be familiar with the complications associated with central venous catheterisation, i.e. vessel perforation, air embolism, catheter embolism, pleural and mediastinal damage, septicaemia, thrombosis and cardiac tamponade secondary to vessel wall or atrial perforation.
3. Complications are associated with right atrial and inadvertent right ventricular catheterisation. Physicians must be aware of these complications before advancing the catheter beyond the depth required for normal vena cava placement. Do not advance the catheter past this depth unless procedure requires right atrial placement. If catheter is advanced beyond normal vena cava placement depth, monitor electrocardiogram during insertion and confirm final position by chest X-Ray.
4. It is recommended that patients be placed in a slight Trendelenburg position during insertion procedure to reduce the risk of air embolism.
5. We recommend that the lumens of Careflow™ Catheter (Central Venous and Radial, Femoral Arterial Catheter) are flushed with sterile saline solution prior to catheter insertion.
6. All catheter placements must be inspected for flow rates, security of dressing and security of luer connections.
7. To reduce or eliminate the potential for catheter migrations, we advise that every catheter placement be secured by suturing at the eyelets of the junction boot housing/hub and that, where the use of the secondary fixation device is necessary, it should be used as additional support and not the only means of fixation. Additionally, the security of catheter fixation and position of the catheter tip should be checked throughout use.
8. When removing dressings at or close to catheter sites, care must be taken to avoid severing the catheter.
9. Acetone must not come into contact with the catheter as the material may weaken and this may result in leakage or aspiration.
10. Exposure of product componentry to topicals containing alcohol is not recommended.
11. Do not attempt to re-insert a partially or completely withdrawn introducer cannula.
12. Use of a syringe smaller than 5 mL to irrigate or de-clot an occluded catheter may cause intraluminal or catheter rupture.
13. Syringes are supplied for blood aspiration only.
14. Luer connections: as standard practice the security of luer connections must be checked routinely.
15. Physicians should be aware that central venous and arterial catheters are intended for use no longer than 30 days.
16. Patients with suspected hypersensitivity to nickel should undergo skin test to assess hypersensitivity prior to use of Merit Guidewires in the placement of central venous and arterial catheters.

WARNINGS - SELDINGER TECHNIQUE

1. Do not withdraw the guidewire against needle bevel, as this increases the risk of severing the guidewire.
2. During insertion do not reinsert a partially or completely withdrawn needle into the cannula.
3. Ensure the flexible end of the guidewire is advanced into the vein.
4. Ensure the guidewire moves freely in the needle introducer.
5. A firm grip must be maintained on the guidewire at all times.
6. When using the 'J' wire straightener maintain a firm grip on the plastic sleeve.
7. Ensure the dilator is removed prior to catheter advancement.
8. The moveable suture devices are designed as additional support and must not be used as the only means of fixation.
9. Potential for guidewire breakage. Although the incidence of guidewire breakage is extremely uncommon, physicians must be aware of the potential of guidewire breakage if undue force is applied to the wire. If resistance is met when attempting to remove the guidewire after central venous placement, the wire may be kinked within the area of the catheter tip and the vessel. Undue force may cause the wire to break. If resistance is encountered, withdraw the catheter relative to the guidewire (2-3 cm) and attempt to remove the wire. If resistance is still apparent remove the wire and the catheter simultaneously.
10. Physicians should be aware that the guidewire can pick up material from the vein. This may prevent the guidewire from being withdrawn through the catheter.
11. Do not force the guidewire. If resistance is met, carefully withdraw the guidewire and re-attempt insertion.
12. If femoral approach is used, place patient in supine position for insertion procedure.

SUGGESTED PROCEDURE: SELDINGER TECHNIQUE (VENOUS ACCESS)

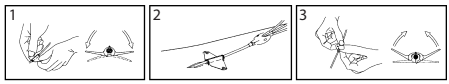
1. Prepare the insertion site using the full aseptic technique required for venous access. Use aseptic technique and proper setup when handling the device.
2. The guidewire may be introduced either by using a thin walled steel needle or introducer cannula.
3. Feed the desired flexible end of the guidewire through the introducer into the vein. If a 'J' wire is to be used, the 'J' can be straightened prior to insertion by using the plastic insertion sleeve.
4. Remove the introducer.
5. A vessel dilator may be used to enlarge the cutaneous puncture site. If further enlargement of puncture site is necessary, use a scalpel.
6. When using multi lumen catheters, lumens other than distal should be flushed and attached to desired fluid administration set or, alternatively, heparin locked as standard hospital practice.
7. Pass the distal tip of the catheter over the guidewire. (Sufficient guidewire length must remain exposed at the hub end of the catheter to maintain a firm grip on the guidewire.) Grasping the catheter near the skin, push the catheter into the vein with a slight twisting motion and advance into the final position.
8. Hold the catheter in position, withdraw the guidewire and aspirate with a syringe to ensure correct placement.
9. The distal hub should be connected to the appropriate fluid administration set. If a hub with Floswitch™ is being used this can now be switched off.
10. The catheter may now be secured by suturing eyelets of the junction boot housing/hub to the skin.
11. Apply sterile dressing as appropriate.

SUGGESTED PROCEDURE: SELDINGER TECHNIQUE (ARTERIAL ACCESS)

1. Prepare the insertion site using the full aseptic technique required for arterial access. Use aseptic technique and proper setup when handling the device.
2. Using the needle, puncture the artery, aspirate and advance the needle into the artery.
3. Feed the desired flexible end of the guidewire through the needle into the artery. If a 'J' guidewire is to be used, the 'J' can be straightened prior to insertion by using the plastic insertion sleeve.
4. Hold the guidewire in place and remove the needle.
5. Pass the tip of the catheter over the guidewire. (Sufficient guidewire length must remain exposed at the hub end of the catheter to maintain a firm grip on the guidewire.) Grasping the catheter near the skin, advance the catheter to the final indwelling position.
6. Hold the catheter in position, withdraw the guidewire and aspirate with a syringe to ensure correct placement. Attach monitoring kit or luer lock plug as appropriate.
7. The catheter can be secured by suturing the hub to the skin.
8. Apply sterile dressings as appropriate.

SECONDARY FIXATION DEVICE (5FR AND 8.5FR CATHETERS)

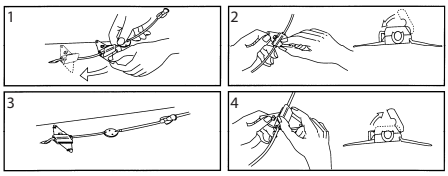
NOTE: This device is found in certain models only.



1. Position the secondary fixation device on catheter. To close the device, press down on each wing. A 'click' sound confirms that the device is secured and cannot be moved easily.
2. To ensure fixation, suture at each eyelet on the wings of the Secondary Fixation Device.
3. To open the device, press down on the 2nd hinge, pull up on each wing.

SECONDARY FIXATION DEVICE (7FR AND 9.5FR CATHETERS)

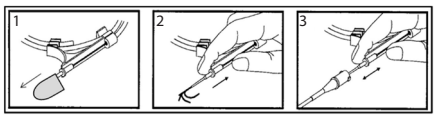
NOTE: This device is found in certain models only.



1. Ensure the Secondary Fixation Device is in place at the point of suture.
2. To close the device, snap the top plate in place.
3. To ensure fixation, suture at each eyelet on the wings of the Secondary Fixation Device.
4. To open the device, hold the lock device down and pull the plate up, using the lever.

VENAGUIDE™

NOTE: This device is found in certain models only.



1. Release guidewire by removing the guidewire cap.
2. Straighten guidewire 'J' by retracting into introducer system with thumb.
3. Insert into hub of introducer needle and advance guidewire into vein. Advance to required depth.

   WARNING: To prevent over-insertion stop when last depth mark reaches the venepuncture site.

GUIDING SYRINGE

NOTE: This accessory is found in certain models only.

This device is used for introducing guidewires for use with Merit Central Venous Catheters.

1. Insert introducer needle attached to Guiding Syringe into vessel and aspirate.
2. Feed the desired flexible end of the guidewire through the hole in rear of Guiding Syringe plunger into the vein. If a 'J' wire is to be used, straighten guidewire 'J' by retracting into introducer system with thumb.
3. Hold the guidewire in place and remove introducer needle and Guiding Syringe.

   WARNING: Do not aspirate with guidewire in place or air may enter the syringe

   CAUTION: Do not reinfuse blood to minimize the risk of blood leakage from rear of syringe.

FLOSWITCH™ INTRODUCER
This device is used for introducing guidewires for use with Merit Central Venous Catheters.

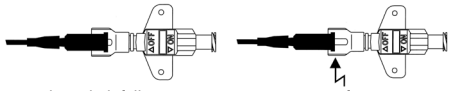
Using a Floswitch™ introducer cannula, puncture the vein, aspirate and advance the cannula into the vein and remove the needle. At this stage the Floswitch™ may be switched off. The switch must be opened again to facilitate guidewire or catheter passage.

FLOSWITCH™ LUER LOCK ATTACHMENT

This device may be attached to a luer hub of a Central Venous Catheter.

1. As standard practice the catheter should be secured to the skin.
2. To attach the Floswitch™, insert the Floswitch™ luer into the catheter hub. Tighten the rotating collar ensuring that 'hand tight' connection has been made and that the catheter hub is fully advanced into the Floswitch™ collar (see figure 1.1).
3. The Floswitch™ should be fixed in position by either suturing or taping the wings. The recommended procedure for taping is shown in figure 2.
4. The black markings indicate flow status. When visible the catheter is open and there is free flow. When covered, the catheter is closed.

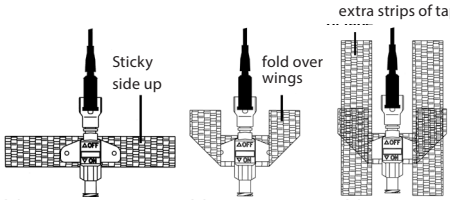
Figure 1. Floswitch™ Inspection Procedure



1.1 Catheter hub fully advanced into Floswitch collar

1.2 Inspection of connection necessary

Figure 2. Floswitch Taping Procedure



2.1 2.2 2.3

WARNINGS - FLOSWITCH™ PRODUCTS

1. The Floswitch™ should not be switched off (black marks covered) before the needle has been fully withdrawn. This applies to Floswitch™ introducers only.
2. The Floswitch™ must not be switched off (black marks covered) until the guidewire has been fully withdrawn.
3. When the catheter is not in use for infusion or aspiration, the Floswitch™ must be switched off and a suitable luer cap locked into the hub.
4. When using an intermittent injection bung attached to a Floswitch™, only use short needles. Ensure Floswitch™ is in 'ON' position prior to injecting or aspirating. Do not insert the needle more than 8 mm into the Floswitch™.
5. As standard practice, the security of the luer connection must be checked routinely. This is essential when lubricious substances such as Intralipids are being used. This applies to Floswitch™ luer lock attachment only.

COMPLICATIONS

Complications of Central Venous Catheters are associated with right atrial and inadvertent right ventricular catheterization. Physicians must be aware of these complications before advancing the catheter beyond the depth required for normal vena cava placement. Do not advance the catheter past this depth unless procedure requires right atrial placement. If catheter is advanced beyond normal vena cava placement depth, monitor electrocardiogram during insertion and confirm final position by chest X-Ray.

Other risks associated with the use of the Central Venous Catheter include:
Air Embolism, Catheter Embolism, (Pleural, Atrial, Mediastinal, or Vessel Dissection, Perforation, Hemorrhage) Septicaemia, Arrhythmia, Thrombosis, Delayed Tension Pneumothorax, Thrombophlebitis, Cardiac Tamponade, and Central Venous Catheter (CVC) Tip Misplacement, Misfunction, Occlusion and Impaired Central Venous Pressure (CVP) Measurement.

For further information regarding complications, contact your local representative.

CONTRAINDICATIONS

Percutaneous puncture of a central vein may be contraindicated in patients with pulmonary hypertension.

CLINICAL BENEFITS

Merit Careflow Central Venous Catheter:
- Allow blood pressure monitoring
- Allow repeated blood sampling
- Allow infusion of drugs, Total Parenteral Nutrition (TPN) fluids and large volume infusions

Merit Careflow Arterial Catheter:
- Allow blood pressure monitoring
- Allow repeated blood sampling

STORAGE CONDITIONS

Store in cool dry place away from direct sunlight.

STERILE and non-pyrogenic in unopened, undamaged package. For single use only. Check integrity of the individual package before use. After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal. Do not resterilize.

Re-use may lead to infection or other illness / injury.

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.

For reordering information or assistance, please contact local representative.

PERFORMANCE SPECIFICATIONS

Performance Specifications	Applicable to:
Radio-detectability	Catheter of Careflow Central Venous Catheter and Careflow Arterial Catheter

	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single use
	Do not resterilize
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution
	Keep Dry
	Keep away from sunlight
	Non-pyrogenic
	Use by date: YYYY-MM-DD
	Date of Manufacture: YYYY-MM-DD
STERILE EO	Sterilized using ethylene oxide
MD	Medical Device
	Single Sterile Barrier System
UDI	Unique Device Identifier
	Does not Contain DEHP, DIBP, DBP, BBP
	MR Conditional Non-clinical testing demonstrated that the device is MR Conditional. Per ASTM F2503-13, an MR Conditional item is one with demonstrated safety in the MR environment within defined conditions. A patient with this device can be safely 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 The information provided here should be used in conjunction with your institution's policies to evaluate the risks to patients and operators when using Floswitch™ in an MR environment.
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
EC REP	Authorized Representative in European Community
	Manufacturer
REF	Catalog number
LOT	Batch code

CE 2797

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