MERIT MEDICAL®

Monitoring Life™

Stopcocks, Manifolds, Monitoring Extension Sets, IV Sets, Contrast Media Sets, Pressure Tubing, High Pressure Tubing, Deadender, Easy Vent Cap, Control Syringe, Adapter / Luer Fittings & Connector

INSTRUCTIONS FOR USE

INTENDED USE

The stopcocks, manifolds, monitoring extension sets, administrative IV sets, contrast media sets, pressure tubings, deadender, easy vent cap, control syringe, adapter/luer fittings and connector are intended for fluid management system.

The Stopcocks are intended for use in cardiovascular, radiologic, surgical and therapeutic applications to control or direct fluid flow between tubing, catheters or other devices.

The Angiographic Manifolds are intended for use in diagnostic and interventional applications to control or direct fluid flow between tubing, catheters, or other devices.

The Administrative IV Set and Contrast Management Set connect the IV solution / contrast media containers to the pressure monitoring components / angiographic system e.g., catheters, disposable transducers, manifold, etc.

The Pressure Tubing is intended to be used during an angiographic procedure as a conduit to supply a bolus of contrast media.

The High Pressure Tubing is intended as a high-pressure fluid path in the pressure monitoring system.

The Vent Caps are used for preventing contamination of the fluid path.

The Control Syringe is intended to be used for the intra-arterial or intravenous administration of radiographic contrast media. The syringe can also be used to inject fluids into, or withdraw fluids from, the body.

The Adapters / Luer fittings and Connectors are intended for use in interventional, diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices.

INDICATIONS FOR USE

The stopcocks, manifolds, monitoring extension sets, administrative IV sets, contrast media sets, pressure tubings, high pressure tubing, deadender, easy vent cap, control syringe, adapter / luer fittings and connector are indicated for use in patients during diagnostic and interventional applications.

USER / PATIENT / CLINICAL

User: Qualified nurses, clinicians and physicians

Patient: Pediatric and adult applications

Clinical: Hospitals or appropriate clinical environments

DESCRIPTION

CAUTION: Tighten all connections before use. Do not overtighten connections as this may crack the connection leading to leaks, air embolism, bleed backs or loss of pressure waveforms.

Use aseptic technique and proper setup when handling the device. This set may contain one or more of the components listed below:

FOR STOPCOCKS & MANIFOLDS

WARNING: Stopcocks and manifolds must be positioned 90° for "OFF" position. Do not position stopcocks at 45° to achieve an "OFF" position. 45° positioning of stopcocks isimprecise and may result in contamination, bleed-back or air embolism.

FOR MONITORING EXTENSION SETS

The set consists of a short length of pressure tubing bonded to a three-way stopcock on one end and a male Luer fitting on the other. It reduces disturbances of the cannula hub by placing the stopcock a short distance from the puncture site. It is intended for use with radial artery cannula.

1. Connect stopcock to distal end of monitoring set.
2. After priming, replace vented cap on the stopcock side port with yellow non-vented cap (deadender).

FOR IV SETS (PRESSURE MONITORING APPLICATION)

The following instructions apply to IV sets with either micro or macro-drip chambers in single line configurations.

1. Prepare sterile flush solution in a non-vented solution bag per physician's prescription.
2. Evacuate air from solution bag by pushing IV spike into solution bag and rotate bag down to facilitate trapped air to escape through spike. Open roller clamp and gently squeeze IV bag until air is forced into drip chamber.

   NOTE: Eliminating air from solution bag will prevent air from entering monitoring system when solution is exhausted or when bag is inverted.
3. Close roller clamp and squeeze bag slightly to force solution into drip chamber (about 1/3 filled since level will increase when bag is pressurized). Place bag in pressure cuff and hang on IV pole.

   CAUTION: If drip chamber is filled completely, drip cannula would be submerged in solution and drop-count (flow-rate determination) would not be possible. With a differential pressure of 200 mmHg (bag pressure minus mean physiological pressure monitored), 2-4 drops per minute from a micro-drip IV Administration Set or 2-4 drops per three minutes from a macro-drip IV set equates to 2-4mL/hr flow-rate.

   NOTE: To minimize air bubble-formation, fill monitoring system by gravity without pressurizing bag.
4. Open roller clamp and fill IV Set by gravity. Tap IV Set to free trapped bubbles. Close roller clamp.
5. Connect filled IV set to monitoring system.

FOR CONTRAST MEDIA SETS

1. Open package using aseptic technique and close roller clamp.
2. Remove protective cap from spike and insert spike into contrast media container.
3. Open clamp and fill tubing with fluid. Ensure air is purged from administration line. Fluid should flow freely. If flow is slow or no flow occurs, tap vent filter on side of spike.
4. After air has been purged and proper flow is established, close roller clamp.
5. Remove protective cap from male Luer-Lok™ fitting and connect set to manifold system.
6. Open clamp to allow flow.

Non-compliant or pressure tubings should be used for all pressure monitoring set ups (between transducer and catheter) to ensure accurate pressure readings.

CAUTION: Compliant tubings may dampen the pressure waveform and cause inaccurate readings.

CONTRAST MANAGEMENT SET

WARNING

1. Do not use tubing assembly on more than one patient
2. Do not leave the spike assembly in a contrast bag/bottle for more than 6 hours or for more than 2 cases.

INSTRUCTION FOR USE

1. Spike the contrast bag/bottle and allow free flow of contrast solution into the reservoir
2. Tilt the reservoir to avoid bubble formation during filling
3. Fill to about 10mL, then aspirate solution into the tubing assembly
4. Debubble the system
5. At the end of procedure, turn stopcock on the spike assembly to an "OFF" position, then disconnect the tubing assembly
6. Retain spike assembly in contrast bag/bottle with a male deadender attaching to the distal end of the stopcock

COMPLICATIONS

Risks associated with the use of this product include: sepsis/infection, other illness and injury, air emboli, bleed-back, and loss of pressure waveform. For further information regarding complications, contact your Merit representative.

CLINICAL BENEFITS

- Facilitate blood pressure monitoring

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 waste disposal. Do not resterilize.

Device lifetime is 72 - 96 hours base on CDC & Joint Commission Intl (JCI) recommendation.

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

The administration IV set in this device contains Cobalt (CAS number: 7440-48-4) defined as CMR 1B in a concentration above 0.1% weight by weight. The risk associated with any potential CMR activity is mitigated substantially by the exceptionally low rate of Cobalt elution from the stainless steel components during patient contact. Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

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.

	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
 or 	Single Sterile Barrier System or Single sterile barrier system with protective packaging inside
UDI	Unique Device Identifier
	Does not Contain DEHP, DIBP, DBP, BBP
	Consult Instructions for Use For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within 7 calendar days, call U.S.A. or EU Customer Service.
EC REP	Authorized Representative in European Community
	Manufacturer
REF	Catalog number
LOT	Batch code
	Contains Cobalt

CE 2797

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EC REP

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