English

Monitoring Life™

Meritrans DTXPlus™ Disposable Pressure Transducer Sets Safedraw™ Blood Sampling System

INSTRUCTIONS FOR USE

DESCRIPTION
This set contains Meritrans DTXPlus™ pressure transducer(s) and may contain Safedraw™ blood sampling system. As customer designated set configurations vary from institution to institution, it is the responsibility of institutions to establish their specific policies and procedures governing the use of the set including safety measures to supplement those described in this instruction sheet. **Section A** describes Meritrans DTXPlus™ transducers with or without Safedraw™. **Section B** describes EasyVent™ deadender cap usage. **Section C** describes standardise Safedraw™ sets. **Section D** describes blood sampling using Safedraw™.

INTENDED USE
The Merit Disposable Blood Pressure Transducer (DTX) is intended for invasive blood pressure monitoring. The Disposable Blood Pressure Monitoring Kit (DTX Kit) packaged with the Safedraw blood sampling model is intended to allow blood to be drawn from the patient without the patient being exposed to the outside environment (closed loop blood sampling).

SECTION A
The Meritrans DTXPlus™ family of transducers consists of five flush models (DT-XX, DT-XXV, DT-NN, DT-NNV and DT-XO) and one no-flush model (TNF-R).

The DT-XXV and DT-NNV models contains air vented hole on the transducer housing and is similar to DT-XX and DT-NN models.

The DT-XX and DT-XXV models have a blue clip fast-flush actuator and a zeroing stopcock as shown in Figure 1. To maintain catheter patency, the integral flush device delivers a continuous (nominal) flow rate of 3 mL/hr with a differential pressure of 200 mmHg (infusion bag pressure minus mean physiological pressure monitored). The flush device also incorporates an overpressure safety valve to prevent the pressure on the transducer from exceeding approximately 7000 mmHg. The valve will vent excess fluid safely back into the infusion bag while maintaining a sealed, sterile pathway. Merit fast-flush actuators (clip or pull tab) offer convenience in fluid filling, debubbling and fast-flushing.

The DT-XO model is similar to the DT-XX and DT-XXV models with a nominal flow-rate of 3 mL/hr but does not have a zeroing stopcock.

The DT-NN and DT-NNV models (up to 30 mL/hr nominal flow rate) for neonatal applications. It has an integral zeroing stopcock like the DT-XX and DT-XXV model but its clip actuator is yellow in colour. **USE ONLY IN CONJUNCTION WITH A MECHANICAL FLUID INFUSION PUMP**. The actual continuous infusion rate for neonatal monitoring is determined by the clinician and controlled by a mechanical infusion pump. Fast flushing with the flush-device in neonatal applications should only be done as part of initial fluid filling and debubbling procedure. Flushing after drawing blood or administering medications should be done manually with a syringe to control fluid infusion precisely. Fast flush rate varies with the type of administration set, the length and lumen diameter of pressure tubing which couples the transducer to the patient.

CAUTION: The DT-XXV and DT-NNV models with an air vented hole on the transducer housing for zeroing and calibration purposes must not be blocked.

The TNF-R model does not have a flush device, clip/pull tab actuator or a zeroing stopcock and may be supplied in a set along with a separate in-line flow/flush device.

CAUTION: D-cap (transparent deadender) may be supplied with TNF-R. Do not overtighten the D-cap as this may deform the male luer fitting of TNF-R and prevent connection of other components.

SET UP PROCEDURES
Use aseptic technique. Verify that all connections are secure and stopcock handles in the desired directions.

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.

All side ports of stopcocks are protected by vented caps which should remain in place until system is primed. Vented caps should always be replaced with non-vented caps unless it has EasyVent™ deadender caps. See Section B for more instructions.

CAUTION: Disposable transducers offer a single mode of electrical isolation through a diaphragm, air gap, insulation gel or some combination of the above and are not recommended for use with non-isolated patient monitors. If in doubt about the isolation characteristics of your monitor, refer to monitor service manual or call the monitor manufacturer.

TRANSDUCER, INTERFACE CABLE CONNECTION
Connect transducer to reusable interface cable by aligning connector arrows and pushing them together (see Figure 2).

CAUTION: Failure to use a Merit interface cable may result in signal disruption. Always test reusable cable before use.

FILLING IV SET (See Figure 3, 4 & 5)
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.

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   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. There are two methods of filling the transducer set - Manual Filling and Automatic Filling. Proceed to the selected method for further instructions.

FOR DT-NN AND DT-NNV MODEL APPLY THE FOLLOWING STEPS.
6. Connect the IV set to the appropriate mechanical infusion pump. If the pump utilizes a cassette, connect the tubing to the cassette system. An in-line burette may be used between the IV and infusion pump, in accordance with your hospital standards, policies or procedures. If other components such as particulate or air eliminating filters are used, complete the necessary connections. This IV tubing system should remain disconnected from the transducer/flush-device tubing at this point.
7. Connect the transducer (see Figure 4) to the IV tubing system. Release the roller clamp. Set the pump on "purge" or at an infusion rate setting to allow the fluid to completely fill the IV set, burrette tubing and cassette system. After filling is completed, close the roller clamp.

   NOTE: Fluid filling and debubbling the IV tubing system before attachment to the transducer/flush-device will allow for faster, more bubble-free filling of the transducer, stopcocks, and pressure tubing.

MANUAL TRANSDUCER SET FILLING METHOD
CAUTION: Transducer should not be tapped with metal objects, such as hemostats, to purge air bubbles. Doing so may damage the transducer.
1. With pressure cuff still deflated, hold transducer vertical with zeroing stopcock facing up. Open roller clamp on IV set and squeeze clip actuator to allow solution to completely fill the monitoring system. For Safedraw™ sets, make sure that the barrel of the volume restricted syringe is completely depressed when filling the system. The side port of the stopcock should be filled and debubbled.

   NOTE: Since transducer is gravity-filled, ensure bag is higher than transducer and monitoring system.
2. Tap transducer on open palm of hand and at the same time squeeze clip actuator to purge air from transducer chamber (see Figure 6).

   NOTE: Transducer should not be tapped with metal objects such as hemostats to purge air bubbles as this may damage the transducer.
3. (**For Safedraw™ sets only**) After pressure tubing is filled with solution, the volume-restricted syringe and side port of attached stopcock is debubbled by turning the handle of attached stopcock "OFF" to the transducer. Slowly pull back and fill the volume restricted syringe with solution from pressure tubing until contact is made with the built-in syringe stop. Rotate the set so that syringe tip points up. Tap the syringe so that trapped air rises toward the Luer tip, then press the plunger fully back into syringe thereby forcing trapped air and solution into patient line. Turn the handle of attached stopcock "OFF" to the volume-restricted syringe.

   CAUTION: **DO NOT** perform purging with the patient line connected to the catheter or cannula. Doing so may infuse air into the patient. For either the Manual or Auto Transducer Filling Methods.
4. Activate the fast flush device to purge any air from the patient line.
5. Inspect all fluid-filled portions of the monitoring system to verify that bubbles have been eliminated. Pressurize the infusion bag to 300 mmHg. If bubbles remain in transducer chamber, flush again using technique shown in Figure 6.

AUTOMATIC TRANSDUCER SET FILLING METHOD
The Meritrans DTXPlus™ Transducer allows transducer filling (usually bubble-free) in about five minutes.
1. Place transducer in a transducer holder (TBG) or other holders which will hold the transducer in a vertical position (see Figure 7b).
2. Pressurize cuff to 300 mmHg and verify that drip chamber of IV set is not filled completely during pressurization as this prevents reading of flow-rate. Open roller clamp. Transducer will fill automatically.
3. Return in five minutes to inspect transducer for bubbles and flush to fill rest of monitoring set. Tap gently while squeezing clip actuator to remove any remaining air bubbles (see Figure 6).

SECURING THE TRANSDUCER SET (See Figure 7)
1. Replace all vented caps on side ports of stopcocks with non-vented caps (deadenders). If the side port has an EasyVent™ deadender cap, do not replace but tighten cap to achieve non-vented position. (See Section B.)
2. Mount transducer on a holder (see Figure 7b) or directly on patient's arm (see Figure 7a) with transducer zeroing port at mid-heart level.

   CAUTION: Safedraw™ blood sampling system is not intended to be patient-mounted.

   Several models of transducer sets are designed to accommodate both IV pole- and patient-mounting. These sets may have model numbers ending with "M" or "SM". When mounted on patients, precautions should be taken to ensure that a change in body position of the patient does not accidentally actuate the flush device. Merit fast-flush clip actuator is uniquely designed to minimize this risk as it can only be activated by squeezing the clip actuator with two fingers. However, precautions are still recommended.
3. Connect monitoring system to patient's cannula or catheter. Flush system to clear blood from cannula or catheter.

   CAUTION: Avoid flushing air bubbles or blood clots in catheter or cannula into the patient by making sure that monitoring system is filled completely with solution and by allowing a small amount of blood to flow back through the cannula before making the pressure line connection. For left atrial pressure monitoring, an air eliminator filter must be installed between the cannula and the transducer prior to flushing.
4. In multiple transducer installations, a colour coding system is used to identify the appropriate monitor inputs. Color coded labels are available. Affix appropriate labels to TBG or the monitoring line closest to each transducer.

   Red ('ARTERIAL') = Arterial Pressure

   Blue ('CVP') = Central Venous Pressure

   Yellow ('PA') = Pulmonary Artery Pressure

   White ('LAP') = Left Atrial Pressure

   White (Blank) = Miscellaneous Pressure

ZEROING AND CALIBRATION
1. Zero-balance the monitoring system to atmospheric pressure and calibrate transducer according to monitor manufacturer's instructions.

   NOTE: It is recommended that the three-way stopcock closest to the transducer be located at mid-heart level and used exclusively for zeroing purposes. The transducer can be quickly and easily vented to atmospheric pressure by turning the stopcock handle counter clockwise (i.e. "OFF" to patient line) and removing the non-vented cap from the zeroing port . If an EasyVent™ deadender cap is present, do not remove but loosen cap to achieve vented position (Section B).
2. Turn zeroing stopcock handle clockwise (i.e. "OFF" to zeroing side port) and admit patient's pressure to transducer. Check quality of waveform.
3. Allow approximately one minute for the system to equilibrate to ensure that flush device is operating properly. Then make a drop count to verify that the flow-rate is about 3mL/hr. A visual inspection for leaks should also be made. Thirty minutes after installation and periodically afterwards, check the system for correct bag pressure, flow rate, zero level and ensure no leaks. Leaks, however small, may lead to inaccurate flow-rate readings. If zero-drift is suspected e.g. abnormal reading, re-position transducer and re-zero. If problem persists, change the transducer. After each fast-flush, it is recommended to reconfirm flow rate.
4. Replace the deadender cap and turn stopcock closed to the side port. If the side port has an EasyVent™ deadender cap, do not replace but tighten cap to achieve non-vented position (Section B).
5. (**For DT-NN and DT-NNV only**) Set mechanical infusion pump to desired flow rate as prescribed by the physician.

   CAUTION: If a damped waveform is observed, it may be the result of several factors including but not exclusive to:
   - Mis-positioned stopcocks
   - Air in monitoring line, catheter or cannula
   - Loose connections
   - Improperly calibrated monitor
   - Blood clots in catheter, cannula or monitoring line
   - Catheter or Cannula positioned against a blood vessel wall

   WARNING: Abnormal pressure readings should correlate with patient's clinical manifestations If not, verify that the transducer is working by using a known or calibrated pressure source.

   Stopcock levers must be positioned at 90° for "OFF" position. Do not position them at 45° to achieve an "OFF" position as this is imprecise and may result in contamination, bleed back, or air embolism.

   The flush device and drip chamber are not intended as precise fluid-delivery systems. If the patient's condition stipulates precise fluid delivery, a mechanical pump should be used to prevent possible overinfusion of fluid.

SECTION B
Instruction for use of the EasyVent™ deadender cap which simplifies transducer zeroing.

FLUID FILLING ZEROING STOPCOCK (See Figure 8)
1. The EasyVent™ deadender cap is usually attached to the zeroing stopcock in the vented position. If this is not so, loosen cap until it spins freely (DO NOT REMOVE CAP).
2. Actuate flush device to fill side port and allow fluid to exit through the EasyVent™ deadender cap.
3. After fluid filling, turn stopcock "OFF" to side port and tighten cap.

ZEROING TRANSDUCER
1. Turn stopcock "OFF" to patient line and loosen EasyVent™ deadender cap.
2. Zero monitor and tighten cap.
3. Turn stopcock "OFF" to zeroing side port and re-admit patient's pressure.

REMOVAL/REPLACEMENT OF CAP
1. To access side port of stopcock, loosen cap and pull cap off.
2. To replace cap on side port of stopcock, simply snap cap back and tighten.

SECTION C (See Figure 9)
Standardise Safedraw™ sets can be connected to other manufacturer's disposable transducer or dome sets.

CAUTION: Safedraw™ set models are intended for use with short arterial catheters (up to 6 cm). Use with larger volume catheters may cause insufficient line clearance of heparin-diluted blood and inaccurate lab values may result.

CONNECTION
1. Connect the in-line female Luer fitting of three-way stopcock to the distal end of monitoring set being used. If the monitoring set being used already has pressure tubing attached then this should be removed before attaching the Safedraw™ system.
2. Fill the dome or transducer portion following the manufacturer's instructions first.
3. Fill the Safedraw™ stand alone set by first filling pressure tubing and blood sampling septum. Next turn the volume restricted syringe stopcock "OFF" to the transducer. Slowly pull back and fill the volume restricted syringe with solution from the pressure tubing until contact is made with the built-in syringe stop. Rotate the set so that syringe tip points up. Tap the syringe so that trapped air rises toward the Luer tip. With syringe tip still pointing up, press the plunger fully back into the syringe thereby forcing any trapped air and solution into the patient line. Turn the handle of attached stopcock "OFF" to the volume-restricted syringe.

   CAUTION: DO NOT carry out Step 3, 4, or 5 with the patient line connected to the catheter or cannula. Doing so may infuse air into the patient.
4. Activate the fast flush device to purge any air from the patient line.
5. Inspect all fluid-filled portions of the monitoring system to verify that bubbles have been eliminated.
6. Pressurize the infusion bag to 300 mmHg. If bubbles remain in the transducer chamber, flush again, using technique shown in Figure 6.
7. Connect to patient's cannula or catheter. Flush system to clear blood from catheter or cannula.
8. Zero and calibrate the transducer according to the manufacturer's instructions.

   CAUTION: Allow approximately one minute for the system to equilibrate. Visual inspection for leaks should also be made. Thirty minutes after installation and periodically afterwards, the system should be checked for proper infusion bag pressure, flow rate and leaks. Any small leaks can cause misrepresentation of actual flow rate through the catheter.

SECTION D – SAFEDRAW BLOOD SAMPLING
Instructions for withdrawing blood using Safedraw™ systems with disposable transducers or reusable transducers with domes (see Figure 9 and 10).

CAUTION: Do not use a hypodermic needle to penetrate the septum.

1. Open the hinged protective cap from sampling septum. Wipe the septum surface with alcohol or Betadine.
2. Turn handle of stopcock with volume-restricted syringe attached "OFF" to the transducer.
3. Pull back on the syringe until it contacts built-in stops. Turn the stopcock "OFF" to the patient.
4. The septum can now be penetrated with Safe Needle, TA-BPN or direct transfer device, TA-STV to withdraw the blood sample. (Go to appropriate section then step 5.)

CAUTION: Luer slip syringes may be used, care should be taken to ensure the syringe does not dislodge from the Safe Needle during removal. To remove the Safe Needle and syringe from septum, grip the Safe Needle Shroud with one hand and carefully remove the Needle/Syringe Assembly.

Using Safe Needle-Model TA-BPN

a. Firmly tighten any blood sampling syringe to the Safe Needle (see Figure 10).

b. Align the Safe Needle with the septum and push the Safe Needle completely into the septum.

NOTE: Ensure that the arches on both sides of the needle shield are aligned with the Luer extensions of the septum. This allows the Safe Needle to be completely inserted into the septum.

c. Aspirate the blood sample into sample syringe. If withdrawal of blood is difficult, pull back on the syringe plunger slowly. If difficulties are still experienced, check the catheter or cannula for occlusion.

d. To remove the Safe Needle and sampling syringe from septum, slowly pull the Needle/Syringe assembly away from septum while holding the Safe Needle shroud. When the needle is approximately half way out, a slight resistance will be felt. At this point, pull back very slightly on the syringe plunger, then remove the Needle/Syringe assembly from septum by slightly rotating the assembly clockwise and pull back.The above process will allow residual pressure in the syringe to equilibrate and prevent blood forming on either the tip of needle or the top of septum.

e. Wipe the surface of septum with alcohol or Betadine and cap the septum.

f. For transferring blood to an evacuated tube, press the syringe needle assembly containing blood into the evacuated tube stopper. The Safe Needle will penetrate the evacuated tube stopper.

CAUTION: When removing the Safe Needle, slowly extract to ensure the evacuated stopper is not pulled out along with the Safe Needle.

Using Direct Transfer Device Model TA-STV

Model TA-STV allows direct blood transfer from septum to evacuated tube.

CAUTION: DO NOT leave the direct transfer device model TA-STV in the septum after completing sampling. Doing so may contaminate the patient line or allow blood to leak out of the system.

a. Insert TA-STV, into the septum. Ensure that the arches of the Safe Needle are aligned with the Luer extensions of the septum.

NOTE: TA-STV must be inserted into the septum before an evacuated tube is placed into the tube receptacle or else the vacuum will be lost.

b. Insert evacuated tube into the receptacle end of TA-STV. Correct amount of blood will be drawn into the evacuated tube by the vacuum. Remove the evacuated tube.

c. If additional samples are required, press evacuated tubes one at a time into TA-STV receptacle end.

d. After the last evacuated tube has been removed, remove TA-STV from the sampling septum by pulling up until you feel a slight stop, then twist to remove and discard.

CAUTION: DO NOT pull back on the volume-restricted syringe plunger with the zeroing stopcock "OFF" to the transducer. Doing so may draw air into the syringe. **DO NOT** fill the volume-restricted syringe by turning the stopcock to which the syringe is connected "OFF" to the patient and aspirating unless the fast flush device is opened to allow fluid flow from the saline bag. Not activating the flush device may damage the transducer.

5. Re-infuse remaining blood to the patient and flush with saline by:

a. Turn stopcock handle with the volume restricted syringe attached "OFF" to the transducer.

b. Push syringe plunger of the volume restricted syringe all the way down.

c. Turn stopcock handle "OFF" to the volume restricted syringe.

d. Fast flush as needed to purge any remaining blood in the tubing and septum.

CAUTION: For neonatal and pediatric applications, do not fast flush, to prevent fluid overload but use a separate syringe to flush and record amount infused per hospital protocol.

6. Wipe septum surface with alcohol or Betadine and cap septum.

7. Check to monitor pressure waveform.

CAUTION: Avoid flushing air bubbles or clots contained within the catheter or cannula back into the patient by ensuring that monitoring line is completely filled with liquid and by allowing a small amount of blood to flow back through the cannula before making the pressure line connection.

COMPLICATIONS
Risks associated with the use of this product include:

SEPSIS/INFECTION
Positive cultures can result from contamination of the pressure system. Increased risks of septicemia and bacteremia have been associated with blood sampling, infusion fluids and catheter-related thrombosis.

AIR EMBOLI
Air can enter the system and ultimately the patient through stopcocks inadvertently left open from accidental. disconnection of monitoring system or from flushing residual air bubbles into the patient.

CLOTTED CATHETER AND BLEED-BACK
If a flushed system is not adequately pressurized relative to the patient's own blood pressure, bleed-back as well as catheter clotting may occur.

INFUSION OF HIGH MOLECULAR CONCENTRATION FLUIDS
If it is your hospital's practice to perform these infusions through the pressure line, we recommend that all system components be exchanged for new sterile components once the infusion has been completed.

OVER INFUSION
Excessive fluid may be infused into the patient if the bag pressure is greater than 300 mmHg. This may result in fluid overload and/or a potentially harmful increase in blood pressure.

ABNORMAL PRESSURE READINGS
Pressure readings can change quickly and dramatically because of loss of proper calibration, loose connections, air in the system and zero drift or shift.

For further information regarding complications, contact your local representative.

CONTRAINDICATIONS

- Do not use a flush device when monitoring intramuscular or intracranial pressures.
- Do not use the Meritrans DTXPlus™ transducers with non-isolated pressure monitors.
- Do not use for left atrial pressure monitoring without an air eliminator filter between the cannula and the transducer prior to flushing.
- Do not use without a mechanical fluid infusion pump (for DT-NN and DT-NNV).

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. Dispose of product after use. Do not resterilize.

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

For reordering information or assistance please contact local representative.

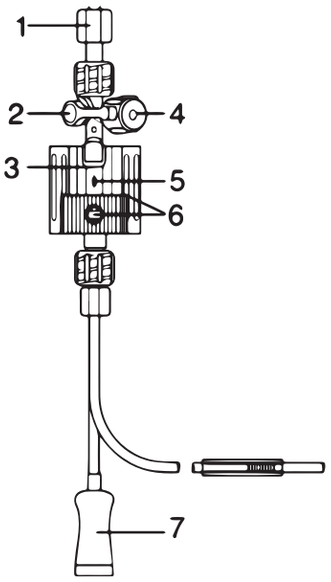

Fig. 1

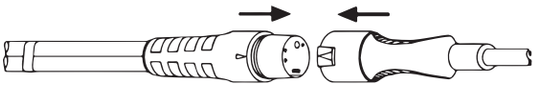

Fig. 2

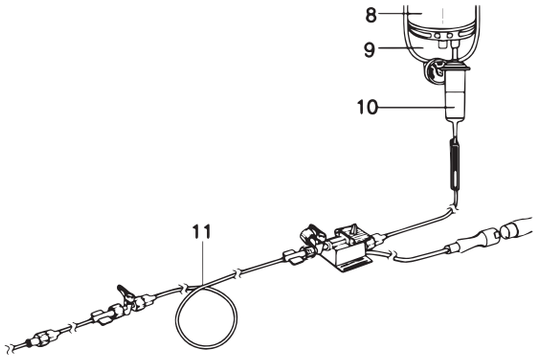

Fig. 3

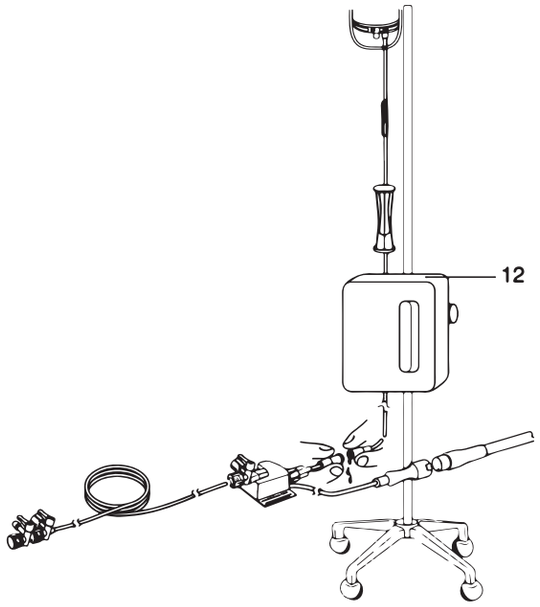

Fig. 4

1. Line to patient
2. Stopcock
3. Fluid channel
4. Transducer zeroing port
5. Pressure sensor
6. Fast-flush actuators (clip or pull tab)
7. Electrical connector
8. Flush solution
9. Pressure cuff
10. Drip chamber
11. Pressure tubing
12. Mechanical infusion pump
13. Volume-restricted syringe with or without Touchguard™(protective sheath to keep the plunger end free of dust and contaminant)
14. Blood sampling septum
15. Hinged protective cap
16. Small-bore pressure tubing

Fig Figure

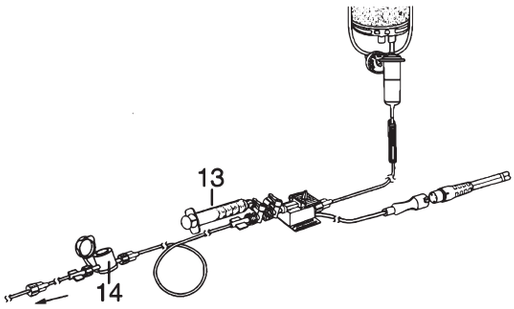

Fig. 5

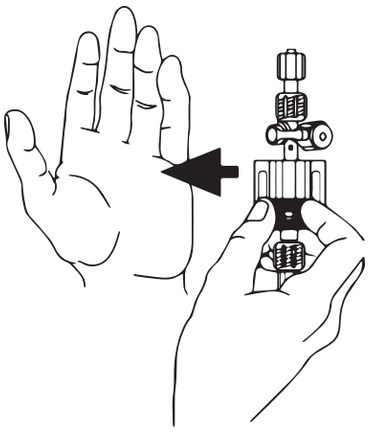

Fig. 6

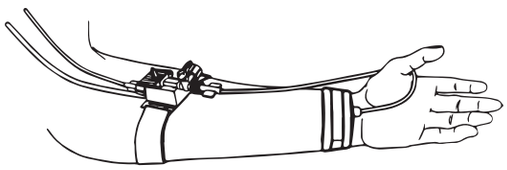

Fig. 7a

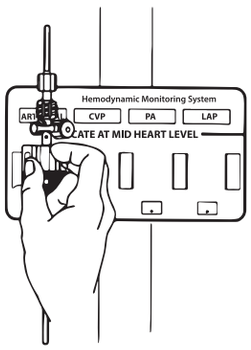

Fig. 7b

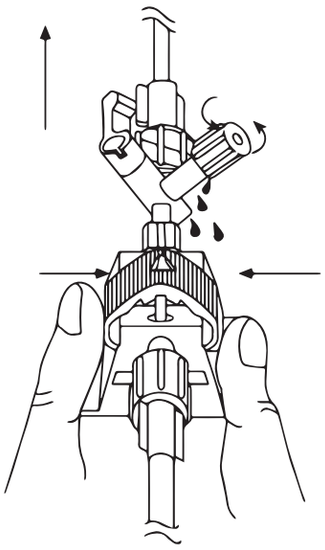

Fig. 8

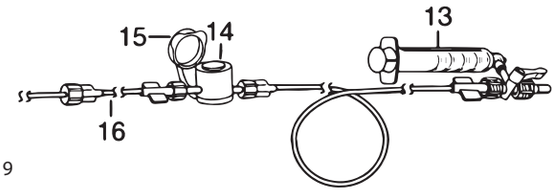

Fig. 9

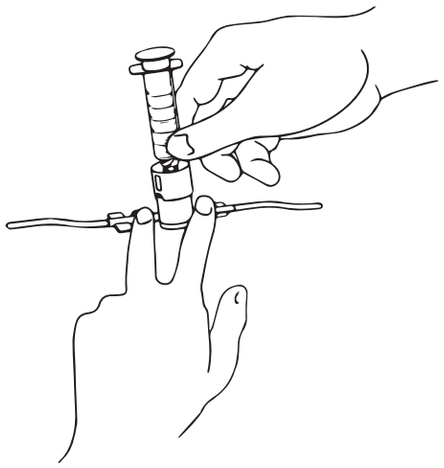

Fig. 10

	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
	Non-pyrogenic
STERILE EO	Sterilized using ethylene oxide
PHT DEHP DIBP DBP BBP	DEHP-DBP-BBP-DIBP free

www.merit.com

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

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