INSTRUCTIONS FOR USE

DESCRIPTION
This set contains Meritans DTXPlus™ pressure transducer sets and may contain Safedraw™ blood sampling system. As customer designee, you are responsible for insuring that the unit is properly installed and that the set is properly configured, calibrated, and set up in accordance with the policies and procedures governing the use of the set including safety measures to supplement those described in this instruction sheet. The manufacturer is not responsible for the interpretation and/or correction of any information included in the administration of a patient. The installer must verify that a change in body position of the patient does not acutely devalue the fluid device. Meritans D-cap (transparent deadender) may be supplied with TNF-R. Do not overtighten the D-cap as this may deform the male luer 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 fluid device and drip chamber are not intended to be fluid delivery systems. If the patient’s condition stipulates precise fluid delivery, a mechanical pump should be used to prevent possible overinfusion of fluid.

INSTRUCTIONS FOR USE

FLUID FILLING ZERODING STOPCOCK (See Figure 8)
1. The D-cap (transparent deadender) cap does not contain the zeroing port. In a multiple transducer installation, a color coding system is used to identify the appropriate monitor inputs. It is recommended that the three-way stopcock closest to the transducer be located at mid-heart level and used exclusively for monitoring purposes. The transducer push to purge should be placed at heart level, putting the patient at a normal body position. (In a single transducer installation, the color coded labels may be omitted.)
2. Zero monitor and tighten cap.
3. Pressurize cuff to 300 mmHg and verify that drip chamber of IV set is not filled completely during pressurization as this prevents the fluid from passing through. In the event an EasyVent™ deadender cap, do not replace but tighten cap to achieve non-vented position. (See Section B.)

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

Safedraw™ Blood Sampling System

INSTRUCTIONS FOR USE

MANUAL TRANSDUCER SET FILLING METHOD

CAUTION: Do not attempt to inject fluid into the transducer housing. This system should only be filled with blood. The fluid device is not intended to be a precise fluid delivery device. If the patient’s condition stipulates precise fluid delivery, a mechanical pump should be used to prevent possible overinfusion of fluid.

SECTION C

Zeroing and Calibration
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 monitoring purposes. The transducer push to purge should be placed at heart level, putting the patient at a normal body position. (In a single transducer installation, the color coded labels may be omitted.)

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

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CAUTION: Liver clip syringes may be used, but 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 the septum, grasp the Safe Needle Shroud with one hand and carefully remove the Needle/Syringe Assembly.

Using Safe Needle-Model TA-BPN
- Firmly tighten any blood sampling syringe to the Safe Needle (see Figure 3).
- 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.
- Expose the blood sample into a sample syringe. Withdraw a sample of blood from the septum using the Safe Needle and syringe assembly. If the needle is appropriately 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 the 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.
- Wipe the surface of septum with alcohol or Betadine and cap the septum.
- 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 exchange for new sterile components once the infusion has been completed.

STORAGE CONDITIONS
- Store in cool dry place away from direct sunlight.
- Do not use without a mechanical fluid infusion pump (for DT-NN and DT-NNV).
- Do not use the Meritrans DTXPlus™ transducers with non-isolated pressure monitors.
- For further information regarding complications, contact your local representative.

CONTRAINDICATIONS
= Associations with the use of this product include.

SEPSIS/INFECTION
Positive cultures can result from contamination of the pressure system. Increased risks of sepsis 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 the monitoring line is completely filled with liquid and by allowing a small amount of blood to flow back through the cannula before activating the flush device may damage the transducer.

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 non 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 intracranial or intracardiac pressures.
- Do not use the Microtrans DT3Platinum transducers with non-isolated pressure monitors.
- Do not use for left atrial pressure monitoring without an an eliminator filter between the cannula and the transducer prior to flush.
- 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-sterile in an unopened, undamaged package. For single use only. Check integrity of the individual package before use. Dispose of product after use. Do not resterilize.

For additional information, call your local representative.
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

Non-pyrogenic

Sterilized using ethylene oxide

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.