TRAM®

INSTRUCTIONS FOR USE

English

PRODUCT DESCRIPTION
A manifold with integral transducer is a pre-calibrated, single use device for physiological pressure measurement and fluid delivery. A separate reusable interface cable is used with this system to connect the transducer to a pressure monitor.

INTENDED USE
The Merit manifold with integrated transducer is used in cardiovascular diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices. Also used for measurement of blood pressure.

WARNINGS
- Ensure that you are making secure connections when using this device to prevent the introduction of air into the system. All connections should be finger tightened. Over tightening can cause cracks and leaks to occur.
- Check for fluid leakage before and during the procedure. Leaks can result in the loss of sterility, fluid or blood loss, and/or air embolism. If a product leaks before or during use, retighten the leaking connection or replace the product.
- Prior to pressure injecting through the manifold, open the zeroing port. This product does not incorporate protection from accidental over pressurization. Over pressurizing may permanently impair the accuracy of the device.

PRECAUTIONS
- Contents supplied sterile. Do not use if sterile barrier is damaged. If damage is found, contact a Merit Medical representative.
- Carefully read instructions before using product. If product is being used in conjunction with other manufacturers' components, also read instructions for use.
- Use proper aseptic techniques while handling product.
- The presence of air in the system will damp the transmission of the patient's pressure to the transducer. Be sure to eliminate all air bubbles within the system.
- During fluid injection through the main lumen of the manifold, ensure proper orientation of the port handles so that fluid does not enter the side ports.
- Do not use yellow side port as an injection site for fluids.
- Inspect device prior to use to verify that no damage has occurred during shipping.

CONTRAINDICATIONS
None known.

Merit's DeVos manifolds are a standard manifold with a check relief valve as the end port. The DeVos manifolds are available with:
- 2 or 3 port standard port spacing and 4 port wide
- Half body style
- Right port orientation
- 180º/360º
- 200 PSI (14 BAR) pressure rating
- OFF handles (ON handles)

INSTRUCTIONS FOR USE
1. Using aseptic technique, open the package containing the sterile product.
2. Check all connections before use and finger tighten, if necessary. To prevent stripping, do not over tighten. Inspect for damage or improper assembly.
3. Begin set-up according to hospital protocol for catheterization/pressure monitoring procedures. Purge the system of air bubbles.
4. Ensure that all electrical connectors are dry. Connect the Meritrans disposable transducer cable to the reusable monitor cable. Align the connector pins, firmly join the connectors together.
5. To complete the set-up, open the stopcock to atmosphere and flush the transducer port free of air. Once the entire system has been fluid filled and the air is removed, the system is ready to be zero balanced. Ensure the yellow stopcock is open to air and the manifold transducer handle is closed to the patient.
6. Balance and calibrate the system according to the monitor manufacturer's instructions.
7. To monitor pressure, orient the port handles so that the transducer lumen is open towards the catheter or patient. (Inspect carefully for air bubbles and reflush, if necessary.)
   Note: Ensure all connections are securely tightened. Inspect carefully for air bubbles and flush the manifold lumen, if necessary.
8. The manifold should be returned to the original position used to zero balance the system. The reference point assures consistency as pressures can be affected by elevating the transducer.

REUSE PRECAUTION STATEMENT
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.

MERITRANS SPECIFICATIONS

Excitation Voltage	1.0 to 10 Vdc-5kHz
Excitation Impedance	240-350 Ω
Signal Impedance	300 Ω ±30Ω
Phase Shift	<5º
Sensitivity	5 µV/V/mmHg
Operating Temperature	15ºC to 40ºC
Storage Temperature	-25ºC to 70ºC
Maximum Half-Sine Shock Acceleration	4500 G
Zero Drift	1 mmHg/8 hours
Thermal Coefficient Offset	±0.3 mmHg/ºC
Thermal Coefficient Span	±0.1%/ºC
Light Sensitivity	<1 mmHg-

CAUTIONS

℞ Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Consult accompanying documents. Read instructions prior to use.
Single Use	Single use.
	Non-pyrogenic.
	Do not use if package is damaged.

MERITMEDICAL®

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