

TRANS-Fold
Manifold
Instructions for use

Manufacturing Facility



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PRODUCT DESCRIPTION

The 'Trans-Fold' is a Manifold device.

DEVICE COMPONENT DESCRIPTION

Trans-fold is used to control the flow of the solution and allocate the fluid as a disposable device in PCI procedure. Well designed, excellent process and rigorous selection of the raw material assure the quality of the product.

TRANS FOLD – Product matrix with Product Reference No.

Reference no.	Pressure (PSI)	Port	On/Off Condition
TRLD02RN	250	2 Port	Right On
TRLD02RF			Right Off
TRLD52RN	500		Right On
TRLD52RF			Right Off
TRLD03RN	250	3 Port	Right On
TRLD03RF			Right Off
TRLD53RN	500		Right On
TRLD53RF			Right Off

INDICATIONS

Trans-Fold is intended for connection between the devices, such like injection syringe, angiographic catheter, drip set to the bottle delivering contrast agent or saline flush, or pressure monitoring system, etc. Each fluid channels can be independently controlled by switch.

CONTRAINDICATIONS

None Known

WARNINGS

- Read the instructions before use.
- The device is designed for single use only. Do not re-sterilize and /or reuse.
- Do not use it after expiry date.
- Do not use if sterile barrier is damaged.
- Suggested working pressure is under 500PSI & 250PSI.
- Please dispose the device after use, according to the local legislation.

PRECAUTIONS

- Luer connector must be well connected, incorrect connection or lose connection may cause leaking or air getting into blood vessel.
- All connections should be finger tightened. Over tightening can cause cracks and leaks to occur that could result in embolism and or exposure to biohazards.
- 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.
- Do not inject air into the blood vessel.
- For qualified physicians use only.

INSTRUCTION FOR USE

- Check that the package is well sealed without any damage.
- Check the manifold and flush with normal saline before use.
- Connect luer connectors of manifold with other devices.
- Stopcock handles point to the open direction.
- Screw stopcocks of the manifold into control flow.

ADVERSE EFFECTS:

Procedures requiring introduction should not be attempted by physicians unfamiliar with possible complications.

Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to the following:




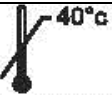
- Air embolism
- Allergic Reaction
- Arterial/Venous Thrombosis
- Cardiac or respiratory arrest
- Death
- Hematoma at the puncture site










- Infection

PACKAGING

- **Sterile:** This device is sterilized with ETO gas and is non-pyrogenic.
- **Contents:** One Trans-fold, Manifold device.
- **Storage:** Store blow 40 °C & keep away from direct light & humidity.

SYMBOL

Description	Symbol
Manifold size	X Port
Manifold Type	Right XXX
Reference No.	REF
Batch No.	LOT
Use By	 YYYY MM
Expiry Date	 YYYY MM
Sterile and Method of sterilization	STERILE EO
Single use only & do not re-sterile	
Storage Condition	
Medical Device	MD

Description	Symbol
Pyrogen free	
Read the documents /Instruction for use	
Name of Manufacturer	
Content : Trans-Fold	
Do not use if package open or damaged	
Keep away from direct sun light	
Keep dry	
Warning / Attention: See Instructions for Use	
Single Sterile barrier system	

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