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LIMITLESS POSSIBILITIES

‘Trans-Wire’

PTFE Coated Guidewire

Instructions for use

Manufacturing Facility

Translumina Therapeutics LLP
Plot No.#12-Pharmacity, Selaqui,
Dehradun, 248011, Uttarakhand India.
Phone: + 91 135 2699944, 0135 2699795
Fax: + 91 135 2699944, 0135 2699795
Email: info@translumina.in
Web: www.translumina.in

Registered Office

Translumina Therapeutics LLP
Ground floor Metro Tower, LSC
MOR land, New Rajender Nagar.
New Delhi-110060, India,
Phone: +91 11 2874 2874
Fax: +91 11 2874 2873
Email: info@translumina.in
Web: www.translumina.in

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PRODUCT DESCRIPTION

The 'TRANS-WIRE' is a PTFE Coated Guide wire.

DEVICE COMPONENT DESCRIPTION

'TRANS-WIRE' a PTFE Coated guide wire, is a steerable guide wire constructed of a proprietary S.S. alloy core wire and a coiled Wire design at the distal end. The core wire is stainless steel with a c PTFE coating over the distal region. The straight distal end of the Guide wire is shape able with a radiopaque distal tip.

For specific guide wire model availability concerning diameters, lengths and tip configurations, refer to product labelling

TRANS-WIRE: Product Matrix (Reference No. as per various lengths vs. Diameter)

Ref No.	PTFE Coated Guide wire Length(cm)	PTFE Coated Guide wire Diameter (inch)	Ref No.	PTFE Coated Guide wire Length(cm)	PTFE Coated Guide wire Diameter (inch)
WIRE-1815	150	0.018	WIRE -3217	175	0.032
WIRE-2115	150	0.021	WIRE-3517	175	0.035
WIRE-2515	150	0.025	WIRE-3817	175	0.038
WIRE-2815	150	0.028	WIRE-1826	260	0.018
WIRE-3215	150	0.032	WIRE-2126	260	0.021
WIRE-3515	150	0.035	WIRE-2526	260	0.025
WIRE-3815	150	0.038	WIRE-2826	260	0.028
WIRE -1817	175	0.018	WIRE -3226	260	0.032
WIRE -2117	175	0.021	WIRE -3526	260	0.035
WIRE -2517	175	0.025	WIRE -3826	260	0.038
WIRE-2817	175	0.028			

INDICATIONS

Trans-Wire, Guide wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. Models with Floppy, Soft, and Medium tips (tip loads ≤9g) are intended for peripheral or coronary use. Translumina Therapeutics LLP steerable exchange guide wires are used to facilitate the substitution of one diagnostic or interventional device for another. **Translumina Therapeutics LLP guide wires are not intended for use in cerebral vasculature**.

CONTRAINDICATIONS

The following complication may occur: -

- Air embolism
- Hematoma at the puncture site
- Infection
- Perforation in the vessel wall.

WARNINGS

- This device is designed and intended for one time use only, do not re-sterilize or re-use.
- Discard after procedure. Structural integrity and/or function may be impaired through reuse or cleaning. Guide wire is extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Accordingly, Translumina Therapeutics LLP Devices will not responsible for any direct or consequential damages or expenses resulting from reuse of the guide wires.
- Torquing a guide wire against resistance may cause guide wire damage and/or guide wire tip separation. Always advance or withdraw the guide wire slowly. Never push, auger, withdraw or torque a guide wire that meets resistance. Resistance may be felt and/or observed under fluoroscopy by noting any buckling of guide wire tip. If guide wire tip prolapsed is observed or under for positioning, do not allow the tip in a prolapsed condition; otherwise, damage to guide wire may occur.
- If the guide wire tip becomes entrapped within the vasculature, do not torque the guide wire.
- This is an instruction for use which may be used for the all Translumina Therapeutics LLP Devices Guide wires. Specific precautions are included for guide wire coated with heparin. Refer to package label to determine if the guide wire you are using is coated with heparin, and then reference the additional precautions.

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PRECAUTIONS

- The provide dispenser is the best means of storage and handling of the guide wire.
- Guide wire should be routinely inspected prior to use and discarded should any deformities be present in the guide wires.
- Use prior to the "Use By" date.
- Do not withdraw the guide wire through a metal Cannula needle; Withdrawal may damage the guide wire or coating.
- If strong resistance is met during manipulation, discontinue the procedure and determine the cause for the resistance before proceeding. Avoid bending kinking or modifying the shape of the wire.
- Confirm the compatibility of guide wire diameter with the lead before actual use.

INSTRUCTION FOR USE

Preparation for use

1. Before removing the guide wire from the dispenser hoop, inject saline into the hub end of the hoop.

2. Release the guide wire from the retention clip and remove it from the hoop by pushing the exposed section of the guide wire into the hoop until the guide wire distal tip extends 5 – 6 cm (approximately 2 inches) past the end of the hoop.

3. Gently grasp the guide wire at the point closest to the hoop and remove it completely. Do not grasp the distal tip of the guide wire while removing it from the hoop; avoid damaging the guide wire distal tip. Inspect the guide wire prior to use to verify it is undamaged.

4. If indicated, the guide wire distal tip may be shaped using standard tip-shaping practices. Do not use a shaping instrument with a sharp edge. After shaping, verify that there is no damage to the guide wire before using it.

Directions for use

Over-the-wire (OTW) systems

1. Prior to inserting the guide wire into an interventional device, flush the lumen of the interventional device with heparinised saline. This will prime the interventional device and provide smooth movement of the guide wire within the lumen of the interventional device.

2. Insert the guide wire through the guide wire port of the interventional device.

3. Carefully insert the distal tip of the guide wire into the interventional device and advance the wire until the wire tip is just proximal to the distal tip of the interventional device.

4. The interventional device may now be inserted through the haemostatic Y-adapter and into the guiding catheter.

5. Advance the guide wire out of the interventional device and into the vasculature and beyond the lesion to be treated accepted techniques. Do not move the guide wire without observing the response under fluoroscopy

ADVERSE EFFECTS/COMPLICATIONS:

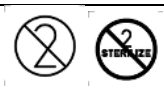
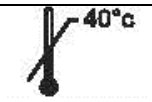
Possible complications and adverse events include, but are not limited to:

- Vessel damage, including perforation
- Artery dissection
- Tamponed due to artery perfusion
- Air embolism
- Infection
- Artery spasm
- Artery thrombus
- Hematoma at puncture site
- Cardiac perforation

PACKAGING

- **Sterile:** The device is sterilized with ETO gas.
- **Contents:** Trans Wire – PTFE coated Guide wire
- **Storage:** Store in a cool, Dark, dry place below 40°c

SYMBOL

Description	Symbol
Guide Wire Length	
Guide Wire Diameter	
Reference No.	
Batch No.	
Manufactured Date	 YYYY-MM
Use By	 YYYY-MM
Sterile and Method of sterilization	
Single use only & do not re-sterile	
Storage Condition	
Medical Device	

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

Disclaimer of Warranty and Limitation of Remedy

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