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LIMITLESS POSSIBILITIES

‘Trans-Hydro Wire’

Hydrophilic coated Guide wire

Instructions for use

Manufacturing Facility

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PRODUCT DESCRIPTION

The 'TRANS-HYDRO WIRE' is a Hydrophilic coated Guide wire.

DEVICE COMPONENT DESCRIPTION

'TRANS-HYDRO WIRE' is a Hydrophilic guidewire 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 hydrophilic coating over the distal region and is available in .014" and .018"diameters and 180cm and 300cm lengths. The straight distal end of the guide wire is shape able with a 3cm radiopaque distal tip. For specific guide wire model availability concerning diameters, lengths and tip configurations, refer to product labelling.

TRANS-HYDRO WIRE- Product Matrix with Product Reference No.

Length	Outer Diameter	Ref no. For Angle tip	Ref no. For straight type
150	0.018	HYRE-1815	HYRE-S1815
150	0.021	HYRE-2115	HYRE-S2115
150	0.025	HYRE-2515	HYRE-S2515
150	0.028	HYRE-2815	HYRE-S2815
150	0.032	HYRE-3215	HYRE-S3215
150	0.035	HYRE-3515	HYRE-S3515
150	0.038	HYRE-3815	HYRE-S3815
175	0.018	HYRE -1817	HYRE-S1817
175	0.021	HYRE -2117	HYRE-S2117
175	0.025	HYRE -2517	HYRE-S2517
175	0.028	HYRE-2817	HYRE-S2817
175	0.032	HYRE -3217	HYRE -S3217
175	0.035	HYRE-3517	HYRE-S3517
175	0.038	HYRE-3817	HYRE-S3817
260	0.018	HYRE-1826	HYRE-S1826
260	0.021	HYRE-2126	HYRE-S2126
260	0.025	HYRE-2526	HYRE-S2526
260	0.028	HYRE-2826	HYRE-S2826
260	0.032	HYRE -3226	HYRE -S3226
260	0.035	HYRE -3526	HYRE -S3526
260	0.038	HYRE -3826	HYRE -S3826

INDICATIONS

Trans-Hydro 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 guide wires are not intended for use in cerebral vasculature. Translumina Therapeutics LLP steerable exchange guide wires are used to facilitate the substitution of one diagnostic or interventional device for another.

CONTRAINDICATIONS

The following complication may occur:-

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

WARNINGS

- 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.

- 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.

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.

Precaution for Guide wire with Hydrophilic Coating

- Use of Hydrophilic coated guide wires may require longer compression time at the insertion site.
- Do not wipe hydrophilic coated guide wire, lest the heparin be wiped off.
- It has been reported that Hydrophilic induced thrombocytopenia has, in some case, been associated with the use of Hydrophilic coated catheters. Patients exhibiting symptoms of thrombocytopenia should be monitored for a marked reduction in platelet count and for the presence of heparin associated antiplatelet antibodies. If the condition is confirmed, the physician must remove the catheter if thrombocytopenia is to be reversed and further complications avoided. `the equipment manufacturer be contacted to determine if its analyser is affected. Flame photometry should be used to verify questionable electrolyte results.

INSTRUCTION FOR USE

PREPARATION FOR USE

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

HYDROPHILIC COATING -Avoid abrasion and peeling of the hydrophilic coating.

- Do not reinsert the guide wire into the dispenser once it has been removed.
- If the surface of a hydrophilic-coated guide wire becomes dry, wetting the surface with normal saline will renew the hydrophilic effect.
- Be sure to thoroughly wet the guide wire before introduction into an interventional device; if the guide wire is removed from the device and then used again, be sure to thoroughly rewet the guide wire before reinserting.
- After the guide wire is withdrawn from the body, it should be wiped with gauze soaked in heparinised saline and kept wet.

SUGGESTED DIRECTIONS FOR USE

Over-the-wire (OTW) systems

Refer to the instructions supplied with any interventional devices to be used in conjunction with the Translumina Therapeutics LLP for proper preparation.

- 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.
- Insert the guide wire through the guide wire port of the interventional device.
- 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.
- The interventional device may now be inserted through the haemostatic Y-adapter and into the guiding catheter.
- Advance the guide wire out of the interventional device and into the vasculature and beyond the lesion to be treated using accepted techniques. Do not move the guide wire without observing the response under fluoroscop

Adverse effects/Complications:

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

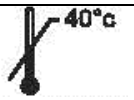
- Vessel damage, including perforation
- Artery dissection

- Tamponed due to artery perfusion
- Air embolism
- Infection
- Artery spasm
- Artery thrombus
- Hematoma at puncture site
- Cardiac perforation

PACKAGING

- **Sterile:** This device is sterilized with ETO gas and is non-pyrogenic.
- **Contents:** One Trans-Hydro Wire, Hydrophilic coated Guide wire.
- **Storage:** Store blow 40 ℃ & keep away from direct light & humidity.

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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