translumina
LIMITLESS POSSIBILITIES

'Trans-Angio'

Angiographic Catheter

Instructions for use

Manufacturing Facility

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Doc. No:- TTL/IFU/ANIO/013.04.23 Rev.04

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1.0 PRODUCT DESCRIPTION

The 'TRANS-ANGIO' is an Angiographic Catheter.

1.1 DEVICE COMPONENT DESCRIPTION

The Angiographic Catheter is a braided intravascular catheter designed to deliver contrast medium into selected blood vessels during an angiographic procedure to facilitate the visualization of the vascular system of a target area. Angiographic catheters are available in various diameters and lengths, and with various tip-shape configurations. For details regarding catheter dimensions, tip-shape, guide-wire compatibility and maximum injection pressure refer to the product labels.

Table 1.1: Device Component Description

Components/parts of 'TRANS-ANGIO' Angiographic Catheter	Materials
*Hub	Polyamide
*Hub text	*French size in colour "4" = 4F: Red "5" = 5F: Grey "6" = 6F: Green
*Strain Relief (SR)	*Polyamide
	*Colorant white
**Base Coat Body	**Polyamide Polyether block-amide Radiopaque filler Zinc Stearate - Additive (≤ 0.5%)
***Braiding Wire	***Stainless Steel.
**Top Coat Body	**Polyamide Polyether block-amide Radiopaque filler Colorant Zinc Stearate - Additive (≤ 0.5%)
**Tip	**Polyether block-amide Radiopaque filler colorant
**Soft tip	**Polyether block-amide - Radiopaque filler
*Tip Straightened	*Polyamide Colorant Blue

Direct Body Contacting material = **
Indirect Body Contacting material = *
No body contact = ***

2.0 INDICATIONS

The TRANS-ANGIO is an Angiographic catheter is designed to deliver radiopaque contrast medium to selected sites in the vascular system.

3.0 CONTRAINDICATIONS

None known.

4.0 WARNINGS

- Refer to the symbol section of the Instructions for Use.
- Do not use the product when the "use by" date specified on the label has expired.
- Catheters are supplied non-pyrogenic and sterile using an ethylene oxide (EO) sterilization method. Do not use the catheter if its sterile barrier and/or packaging is compromised.
- Catheters are for single-procedure-use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the catheter and/or lead to product failure which, in turn, may result in patient injury, illness or death. Catheters are extremely difficult to clean after exposure to biological materials. Reuse, reprocessing or re-sterilization may create a risk of contamination of the catheter 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 catheter may lead to injury, illness or death of the patient.
- Inspect the catheter before use to verify that its size, shape and condition are suitable for the specific procedure. Do not use damaged catheters.
- Before and during use, flush the catheter with sterile heparinized saline solution to prevent or reduce blood clotting and air embolism. Use of systemic heparinization should be considered. In case of multiple use within the same procedure make sure the catheter is flushed and cleaned on the outside.
- Do not expose to organic solvents.
- Do not exceed the maximum injection pressure indicated on the label.

- Following use, a catheter may pose a biological hazard. Handling, disposal and destruction of used catheter and its packaging should be performed in accordance with applicable laws and regulations and following adequate processes.

5.0 PRECAUTIONS

- Indications, contraindications and use of this catheter should always consider actual medical insights and standards. The patient's suitability for use of the product should be considered.
- Administration of pre-, intra- and postoperative medication should be performed according to actual medical standards.
- To avoid catheter tip damage at unpacking, take the catheter at the hub and lift out gently. Always handle the catheter with utmost care. Careless handling at unpacking or during preparation can affect product performance
- In order to avoid catheter damage and blood vessel damage, introduce, advance, and withdraw the catheter through a catheter sheath introducer and over a pre-positioned guide-wire.
- When inserting a catheter with a pigtail tip-shape over a guide-wire that is positioned in the patient, the pigtail tip should be straightened carefully only with a tip-straightener to avoid tip damage. Do not straighten by hand.
- Take extreme care to avoid damage to the vasculature through which the catheter passes. The catheter may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.
- Advancement, manipulation and withdrawal of the catheter should always be performed under fluoroscopic guidance.
- Should the catheter shaft become severely kinked, withdraw the entire system (angiographic catheter, guide-wire and catheter sheath introducer). Excessive torqueing could damage the catheter, leading to possible catheter breakage.
- If strong resistance is encountered during manipulation, discontinue the procedure and determine the cause of the resistance before proceeding. If the cause of the resistance cannot be determined, withdraw the catheter. Simultaneous retraction of all used devices can be considered.
- Withdrawing the catheter from the vasculature and/or guide wire from catheter lumen should be carried out with utmost care.

6.0 INSTRUCTION FOR USE

- Carefully take the catheter from its packaging.
- Flush the catheter with sterile heparinized saline solution.
- Introduce the catheter into the vasculature over an indwelling guide wire using a percutaneous entry technique of choice and carefully advance the catheter to the desired location under fluoroscopic control.
- After removing the guide wire, angiography can be performed.
- For catheter removal, reinsertion of the guide wire is recommended. Carefully withdraw the catheter under fluoroscopic control.

7.0 ADVERSE EFFECTS/COMPLICATIONS:

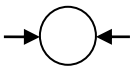
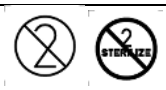
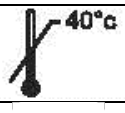
Use of this product in clinical procedures should be restricted to those physicians who have had relevant and adequate training and are familiar with the conceivable complications that may occur at any time during or after the procedure. Possible complications include, but are not limited to the following:

- Arrhythmia
- Bleeding complications
- Death
- (Air) Embolism
- Haematoma at the puncture site
- Haemorrhage
- Infection
- Myocardial ischemia and/or infarction
- Neurological Deficit including Transient Ischemic Attack / Stroke
- Plaque migration
- Pseudoaneurysm
- Thrombus formation
- Vessel trauma including dissection, perforation and / or rupture
- Vessel Occlusion
- Vessel Spasm

8.0 PACKAGING

- **Sterile: The device is sterilized with ETO gas.**
- **Contents: Angio – Angiographic Catheter**
- **Storage: Store in a cool, Dark, dry place below 40°c**

9.0 Symbols

Description	Symbol
Catheter Length	
Catheter Diameter	
Reference No.	
Batch No.	
Manufactured Date	 YYYY MM
Expiry Date	 YYYY MM
Sterile and Method of sterilization	
Single use only & do not re-sterilize	
Storage condition	
Do not use if package open or damaged	
Medical Device	

Description	Symbol
Max. Guide wire Diameter	0.97mm (0.038”)
Name of Manufacturer	
Content	
Read the documents/Instruction for use	
Keep away from direct sun light	
Keep dry	
Warning / Attention: See Instructions for Use	
Pyrogen free	
MR-Unsafe	
Single Sterile barrier system	

10.0 WARRANTY

Translumina Therapeutics LLP, warrants that reasonable care has been used in the design and manufacture of the device. This warranty is in lieu of and excluded all other warranties not expressly set forth herein, whether expressed or implied by operation of low or otherwise, including, but not limited to, any implied warranties or merchantability of fitness. Handling storage, cleaning and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond TRANSLUMINA THERAPEUTICS LLP, control directly affect the device and the results obtained from its use. TRANSLUMINA THERAPEUTICS LLP, obligation under this warranty is limited to the repair or replacement of this device and TRANSLUMINA THERAPEUTICS LLP, shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. TRANSLUMINA THERAPEUTICS LLP, assumes no liability with respect to device reused, reprocessed or re-sterilized and makes no warranties expressed or implied, included but not limited to merchantability or fitness for intended use, with respect to such device.