translumina
LIMITLESS POSSIBILITIES

AGILE PRO

Instructions for use

Manufacturing Facility

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1.0 PRODUCT DESCRIPTION

The 'AGILE PRO' is an Intravascular Guiding Catheter.

1.1 DEVICE COMPONENT DESCRIPTION

The Guiding Catheter is a single use device that facilitates the passage of intravascular devices.

Table 1.1: Device Component Description

Components/parts of 'Agile Pro - Coronary Guiding Catheter'	Materials
Hub	Polyamide, Colorant Hub (foil) printing
Hub text	French Size in Colour "5" =5F: Grey "6" = 6F: Green "7" = 7F: Orange "8" = 8F: Blue
Strain relief	Polyamide, Colorant
inner body (Inner liner)	Polyamide High Density Polyethylene
Braiding Wire	Stainless Steel
outer body (Jacket)	Polyamide Radiopaque material Colorant
Intermediate tip	Poly Ether Block Amide Radiopaque Material Colorant
Tip	Poly Ether Block Amide Radiopaque filler
Filler ring	Poly Ether Block Amide Radiopaque filler & Colorant

2.0 INDICATION

The AGILE PRO Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The AGILE PRO Guiding Catheter is intended to be used in the coronary or peripheral vascular system.

2.0 CONTRAINDICATIONS

None known.

4.0 WARNINGS

- For the definitions of the warning symbols, refer to the symbol section of the Instructions for Use.
- Use prior to the "use by" date as indicated on the label.
- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if the product's sterile barrier or packaging is compromised. If damage is found, contact your company representative.
- For single patient use only. Do not reuse, reprocess, or re-sterilize. Re-use, re-processing or re-sterilization 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. Catheters are extremely difficult to clean after exposure to biological materials. Reuse, reprocessing or re-sterilization may 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.
- Inspect the catheter before use to verify that labelled dimensions, shape, and condition are suitable for the specific procedure, and to ensure compatibility with other devices.
- Do not use damaged products.
- Do not expose to organic solvents.
- Following use, devices may pose a biological hazard. Handling, disposal and destruction of used devices and its packaging should be performed in accordance with applicable laws and regulations and following adequate processes.
- When there is limited clearance between devices and the guide catheter lumen, devices must be advanced and withdrawn slowly with the valve open to reduce the risk of embolism.

5.0 PRECAUTIONS

- Indications, contra-indications 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.
- An appropriate anticoagulation therapy should be applied.
- To avoid catheter tip damage at unpacking, take the catheter at the hub and lift out gently. Careless handling during unpacking, preparation or during the procedure can affect product performance.
- In order to avoid catheter and blood vessel damage, insert the catheter through an introducer and carefully advance, manipulate and withdraw the catheter over a pre-positioned guide wire.
- Catheter manipulation should be performed under fluoroscopic guidance.
- In case of catheter kink, withdraw the entire system. Torque of a kinked catheter can result in vessel damage and catheter separation.
- Use slow hand injection of contrast agent whenever attempting to opacify the vessels using this catheter.
- While manipulating a therapeutic/diagnostic device, always control the position of the guiding catheter tip.
- If strong resistance is encountered during manipulation of the guiding or the therapeutic/diagnostic catheter, do not force passage. Determine the cause of the resistance before proceeding. If the cause cannot be removed, withdraw all devices simultaneously.
- The guiding catheter may occlude small target vessels. Avoid obstruction of the blood flow. Consider using a guiding catheter featuring side holes.

6.0 INSTRUCTION FOR USE

- Remove the catheter from its packaging and verify that the catheter is undamaged.
- Attach a haemostatic device to the catheter hub.
- Flush the catheter with saline.
- Introduce the guiding catheter into the vasculature over a guide wire through an introducer, or over an appropriately sized indwelling guide wire using a percutaneous entry technique of choice.
- Set up a continuous saline flush through the sidearm of the haemostatic device.
- Advance the catheter over the guide wire until the desired position is attained.
- Remove the guide wire while allowing back bleeding. Aspirate and flush the guiding catheter prior to hand injection of a contrast agent.
- It is important to determine that the arterial pressure measurements are appropriate as a confirmation that the catheter is properly positioned.
- Introduce the therapeutic/diagnostic device and perform the intended procedure according to the provided directions.

Note: it is recommended that a continuous saline flush be maintained during manipulation of the therapeutic/diagnostic device.

7.0 ADVERSE EFFECT

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.

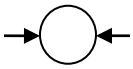
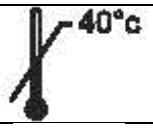
Possible complications include, but are not limited to the following:

- 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:** Agile Pro – Guiding 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-sterile	
Storage condition	
Medical Device	

Description	Symbol
French sizes diameter	5f= 0.058” 6f=0.071” 7f=0.082” 8f=0.091”
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	
Do not use if package open or damaged	
Single Sterile barrier system	

10.0 DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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