

Instructions for Use - Guiding Catheter

Contents

Intravascular guiding catheter.

Description

The hydrophilic coated guiding catheter is a single use device that facilitates the passage of intravascular devices.

Indications

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

Contraindications

None known.

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.
- Do not use the product if it is using an ethylene oxide (EO) process. Do not use if the product is sterile or packaged. It depends if it is compromised. If damage occurs, contact your company representative.
- The device/lead should not be reused, reprocessing or resterilization may compromise the structural integrity of the device and/or cause patient infection or cross-contamination. Removal of the device from the body, to the transition of infectious diseases 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 configuration are correct for the specific procedure, and to ensure compatibility with other devices.
- Do not use damaged products.
- Follows up use, devices may pose a biological hazard. Handling, disposal and destruction of used devices as its packaging should be performed in accordance with applicable laws and regulations and following adequate procedures.

When there is limited clearance between devices and the guide catheter, the device should be advanced and withdrawn slowly with the valve open to reduce the risk of embolism.

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.

An application-specific disclaimer

It is recommended that the catheter be applied.

To avoid catheter tip damage at unpacking, take care of the hub and lift out gently. Careless handling during unpacking, preparation or during the procedure may damage the catheter.

In order to avoid catheter and blood vessel damage, insert the catheter through an introducer and carefully advance, manipulate and withdraw the catheter to prevent damage to the catheter.

Catheter manipulation should be performed for fluoroscopic guidance.

In case of catheter kink, withdraw the entire system. Turn off a kinked catheter to prevent damage to the catheter.

Use of sharp instruments or cutting agent whenever attempting to opacity the vessels with this catheter.

When manipulating a therapeutic/diagnostic device, always control the position of the device tip.

If strong resistance is encountered during manipulation of the guiding or diagnostic device, do not force passage. Determine the cause of the resistance and take appropriate action to remove the catheter.

Use of the catheter for diagnostic purposes, if the cause cannot be removed, withdraw all devices simultaneously.

The catheter may become stuck in the hub or catheter tip.

Do not use with any incomplete equipment (e.g. MRI).

Complications

Of this product in clinical procedures should be restricted to those physician who have 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
• Embolism
• Fracture at the puncture site
• Haemorrhage
• Infection
• Myocardial ischemia and/or infarction
• Neurological deficit including Transient Ischemic Attack / Stroke
• Plaque migration
• Thrombus formation
• Vessel formation
• Vessel occlusion
• Vessel spasm

Directions for Use

Remove the catheter from its packaging and verify that the catheter is undamaged.

• Attach a haemostatic device to the catheter hub

• Remove the guidewire

• Introduce the hydrophilic coated guiding catheter into the vasculature over a guidewire through an introducer, or over an appropriate sized introducer.

• Set the continuous saline flush through the sleeve of the haemostatic device.

• Advance the catheter over the guidewire until the desired position is attained.

• Remove the guidewire while holding back bleeding. Aspirate and flush the catheter prior to hand injection of contrast agent.

• Inspect the catheter for any potential complications that may occur as a confirmation that the catheter is properly positioned.

• Introduce the therapeutic/diagnostic device and perform the intended procedure.

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

• After finalizing the procedure, reinsert a guidewire and remove the guiding catheter.

Disclaimer of Warranty and Limitation of Remedy

PendrCare International B.V. has no express warranty or remedy in the manufacture of this device.

This is an express or implied warranty, including written warranty, any implied warranty of merchantability or fitness for a particular purpose, on the PendrCare product described in this publication. Under no circumstances shall PendrCare be liable for any direct, incidental or consequential damages other than those expressed or implied in this warranty.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to make changes to any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

• PendrCare reserves the right to discontinue any product or service at any time without notice.

</div

