Millipede 088 Access Catheter Instructions for Use

Caution
Rx Only: Federal (USA) law restricts this device to sale by or on the order of a physician.

Device Description
The Millipede 088 Access Catheter is a sterile, single-use device. It consists of a Millipede 088 Access Catheter, a rotating hemostasis valve (RHV), and a valve crossing tool (Figure 1).

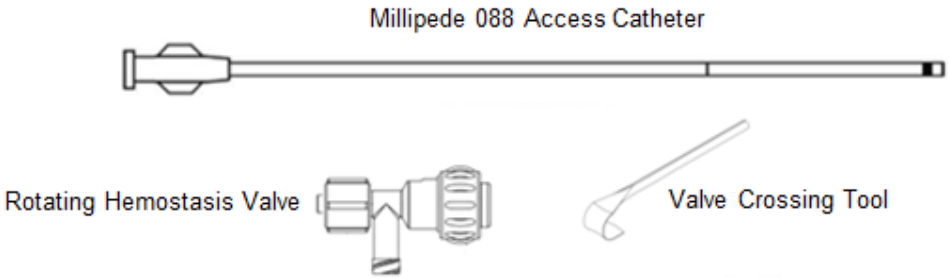

Figure 1: Schematic of Millipede 088 Access Catheter and Accessory Components

The Millipede 088 Access Catheter is a single lumen, reinforced, variable stiffness catheter. The distal section (distal 350mm) of the catheter has a hydrophilic coating on its outer surface to enhance tracking through the vasculature. A radiopaque marker provides the user with visual confirmation of the distal tip location under fluoroscopy.

The Millipede 088 Access Catheter is packaged with an accessory RHV. The RHV is designed to be attached to the proximal luer of the catheter and helps the user maintain hemostasis.

A valve crossing tool is included to facilitate insertion of the catheter through an access sheath with a cross-cut valve. The valve crossing tool is not required if the access sheath has a Touhy-Borst Valve.

How the Device is Supplied
The Millipede 088 Access Catheter is available in one outer diameter (8Fr) and one length, as outlined in Table 1. The Millipede 088 Access Catheter is supplied in a plastic carrier tube attached to a die-cut backing card within a sealed pouch. Also attached to the backing card are the RHV and valve crossing tool. The catheter and accessory components are supplied sterile and nonpyrogenic.

Table 1: Dimensions of Millipede 088 Access Catheter

Catheter	Profile Fr	Inner Diameter Proximal inch (mm)	Outer Diameter Proximal inch (mm)	Inner Diameter Distal inch (mm)	Outer Diameter Distal inch (mm)	Working Length cm
Millipede 088 Access Catheter	8	0.088 (2.24)	0.108 (2.74)	0.088 (2.24)	0.104 (2.64)	120

Indications for Use
The Millipede 088 Access Catheter is indicated for use in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovasculature.

Contraindications

- Do not use automate d high-pressure/powered contrast injection equipment with the Millipede 088 Access Catheter. Use may damage the device or cause injury to the patient.
- The Millipede 088 Access Catheter is contraindicated for delivery of liquid embolic agents, including those containing dimethyl sulfoxide (DMSO) or n-butyl cyanoacrylate (n-BCA).

Warnings

- The device is intended for single use only. DO NOT re-sterilize and/or reuse the device as this may cause impairment of structural integrity or function.
- The Millipede 088 Access Catheter should only be used by physicians trained in interventional neuro-endovascular techniques.
- Inspect the device packaging prior to use. Do not use opened or damaged packages as the sterile barrier may have been compromised.
- Inspect the device prior to use. Do not use the device if any damage or irregularities are observed.
- The Millipede 088 Access Catheter should be handled with care. If damage or kinks are noted in the device either prior to or during the procedure, withdraw the device carefully and replace with another before continuing the procedure.
- Take care not to use excessive force during insertion or withdrawal of the device.
- Do not advance or retract the Millipede 088 Access Catheter against resistance until the cause of resistance has been determined. If the cause cannot be determined, withdraw the catheter. Movement against resistance may result in patient injury or catheter damage.
- After use, dispose in accordance with hospital, administrative, and/or local government policy.
- Do not use the Millipede 088 Access Catheter with Ethiodol or Lipiodol contrast media or other such contrast media which includes the components of those agents.
- Do not expose the device to alcohol, antiseptic solution or other solvents.
- The Millipede 088 Access Catheter is not a steerable catheter with directional tip and is not intended to be navigated by torquing. Torquing the catheter may result in damage to the device or patient.
- If the device becomes snagged or kinked, withdraw the entire assembly (device, internal support catheter(s), and guidewire) without torquing. Replace with another before continuing the procedure.
- Do not attempt to clear the inner lumen of the Millipede 088 Access Catheter by infusion while the catheter is inside the patient body.
- Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- If injecting liquid through the catheter manually with a syringe, ensure that the pressure within the catheter does not exceed 300 kPa (43.5 psi). Higher pressures may damage the device or cause injury to the patient.
- The Millipede 088 Access Catheter should not be used for delivery of stent-retrievers because the performance of this combination of devices has not been evaluated.

Precautions

- The safety and effectiveness of the coated device has not been established, or is unknown, in vascular regions other than those specifically indicated.
- Exercise care in handling the device to reduce the chance of accidental damage.
- Use device in vessels that are larger than the outer diameter of the device (>0.108 inches or >2.74 mm).
- Use device prior to the “Use By” date.
- The Millipede 088 Access Catheter is intended to be used with a guidewire (0.038in or smaller). Consult the guidewire instructions for use and verify compatibility prior to use.
- This device requires the use of an internal support catheter(s) of ≤6F (0.083in or smaller). Consult the internal support catheter(s) instructions for use and verify compatibility prior to use.
- Prior to use, verify that the Millipede 088 Access Catheter is compatible with ancillary devices that are to be used for the procedure.
- The Millipede 088 Access Catheter and accessories should be used in conjunction with fluoroscopic guidance and appropriate anticoagulation and anti-platelet therapy per standard medical practice.
- Avoid excessive wiping of the coated device.
- Avoid wiping the device with dry gauze as this may damage the device coating.
- Maintain a constant infusion of appropriate flush solution.

- Use caution when manipulating the Millipede 088 Access Catheter in tortuous vasculature to avoid damage.
- Presence of calcifications, irregularities, or other devices may damage the Millipede 088 Access Catheter and potentially affect its insertion or removal.
- The hydrophilic coating on the Millipede 088 Access Catheter should be hydrated using heparinized saline for 10 seconds prior to use. Do not allow the coating to dry.
- Avoid pre-soaking devices for longer than instructed, as this may impact the coating performance.
- Operators should take all necessary precautions to limit X-radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible.

Potential Complications
Potential complications associated with the Millipede 088 Access Catheter include, but are not limited to, the following:

- Acute occlusion or thrombosis
- Allergic reaction or anaphylaxis from contrast media
- Arteriovenous fistula
- Blood loss
- Death
- Device malfunction
- Embolism
- Fever
- Hematoma, hemorrhage, or inflammation at the site of entry
- Infarction or necrosis
- Infection or sepsis
- Intracerebral/intracranial hemorrhage
- Ischemia
- Kidney damage from contrast media
- Neurological defects, including stroke
- Pseudoaneurysm
- Seizure
- Vasospasm
- Vessel or aneurysm perforation or dissection

The device is required to be used with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to, alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

Compatibility
The Millipede 088 Access Catheter is to be used with the support devices recommended below.

- Internal Support Device(s):
  - Catheter ≤6F (0.083 in/2.11 mm or smaller) and/or microcatheter.
  - Guidewire (0.038in or smaller).
- External Support: Long access sheath with an internal diameter of 0.113 in/ 2.87mm or greater, and of a minimum of 80cm in length.

Note: Care should be taken to check device dimensions to ensure compatibility, and appropriate indication for use in the intended procedure.

Storage
Keep dry. See device label for shelf life. Do not use the device beyond the labelled shelf life.

Directions for Use

1. Prepare a long sheath, internal support catheter(s) and guidewire according to the manufacturers' Instructions for Use.

2. Carefully remove the Millipede 088 Access Catheter from the packaging and inspect for kinks or damage.
3. Flush the lumen of the Millipede device with heparinized saline.
4. Hydrate the hydrophilic coating on the external surface of the Millipede device using heparinized saline for 10 seconds prior to use. Ensure that the coating does not dry.
5. Securely attach the supplied RHV to the Millipede 088 Access Catheter. Connect a line through the side arm of the RHV for continuous infusion of heparinized saline.
6. After obtaining femoral access, use standard techniques and devices to position the long sheath in the relevant vessel proximal to the target vessel.
7. Insert the Millipede and internal support catheter(s) into the long sheath. If the sheath incorporates a hemostasis valve, the valve crossing tool should be used to protect the Millipede 088 Access Catheter tip during insertion. Once the flexible distal tip is within the sheath, the valve crossing tool may be retracted.
8. Using conventional catheterization techniques under fluoroscopic guidance, advance the Millipede 088 Access Catheter over the guidewire and internal support catheter(s) to the target location.

Warranty

Perfuze Ltd. warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure and other matters beyond Perfuze's control directly affect the device and the results obtained from its use. Perfuze's obligation under this warranty is limited to the repair or replacement of this device and Perfuze shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. Perfuze neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Perfuze assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.

Explanation of Symbols on Package Labelling

 Inner Diameter	 Outer Diameter
 Lot Number Here	 Use By
 Date and country of Manufacture	 Do not reuse
 Do not resterilize	 Non-Pyrogenic
 Keep Dry	 Do not use if sterile barrier system or its packaging has been damaged
 Catalogue number	 Sterilized using Ethylene Oxide
 Consult Instructions for Use	**Contents:** 1 Millipede 088 Catheter 1 Rotating Hemostasis Valve 1 Valve Crossing Tool
 Manufacturer Perfuze Ltd. Unit 6, Galway Business Park, Dangan, Galway, H91 W7CP, Ireland	 Indicates the item is a Medical Device