



## Zipline Access Catheter Instructions for Use

### Device Description

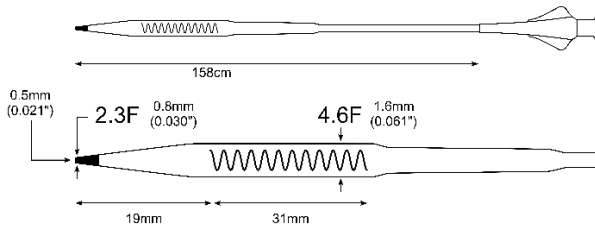
The Zipline Access Catheter is a single-use device. It is a single lumen variable stiffness catheter with a tapered flexible tip. It is designed to deliver large-bore catheters to the neurovasculature under fluoroscopy using standard endovascular techniques. Fluoroscopic visualization is achieved with a radiopaque tip at the distal end of the catheter, and a radiopaque coil proximal to the tapered tip. The Zipline Access Catheter has a hydrophilic coating on the outer surface at the distal end to enhance tracking through the vasculature. A luer fitting located on the catheter hub is used for the attachment of accessories.

### How the Device is Supplied

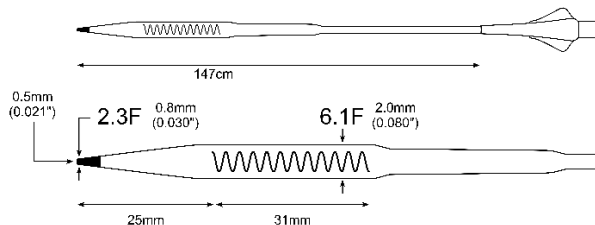
The Zipline Access Catheter is available in two sizes, as outlined in Table 1. It is supplied sterile and nonpyrogenic. An illustration of the catheter and some of its features can be seen in Figure 1.

**Table 1: Key Dimensions of Zipline Access Catheter**

Zipline Access Catheter	Inner Diameter	Outer Diameter at Distal Tip	Outer Diameter at Bulb	Proximal Outer Diameter	Maximum Outer Diameter	Tip to Coil Length	Distal Hydrophilic Coating Length	Working Length
Zipline70 <sup>®</sup>	0.021" (0.53 mm)	0.030" (0.76 mm)	0.061" (1.55 mm)	0.063" (1.60 mm)	0.064" (1.63 mm)	19 mm	44 cm	158 cm
Zipline88 <sup>®</sup>	0.021" (0.53 mm)	0.030" (0.76 mm)	0.080" (2.03 mm)	0.063" (1.60 mm)	0.080" (2.03 mm)	25 mm	39 cm	147 cm



**Figure 1: Overview of Zipline70 Access Catheter**



**Figure 2: Overview of Zipline88 Access Catheter**

The **Zipline70** and **Zipline88** Access Catheters are supplied individually. The Zipline Access Catheter is supplied in a coiled dispenser hoop attached to a backing card within a sealed pouch.

### **Indications for Use**

The Zipline Access Catheter is indicated to facilitate the insertion and guidance of catheters into a selected blood vessel in the neurovascular system.

### **Contraindications**

The Zipline Access Catheter is contraindicated for the delivery of liquids (such as contrast media) within the vasculature.

### **Warnings**

- The device has been sterilized by Ethylene Oxide (EO) and 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. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and cause patient infection or cross-infection. Contamination of the device may lead to injury, illness, or death of patient. Cleaning, disinfection, and resterilization may compromise the essential material and design characteristics of the device leading to device failure.
- The Zipline 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 device should be handled with care. If damage or kinks are noted in the device either prior to use or during the procedure, withdraw the device carefully and replace it 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 Zipline Access Catheter against resistance until the cause of resistance has been determined. If the cause cannot be determined, withdraw the catheter along with ancillary devices used. Movement against resistance may result in patient injury or catheter damage.
- After use, dispose in accordance with hospital, administrative, and/or local government policy. Used devices may pose a biohazard risk and must be disposed of properly. Disposal using a biohazardous container with biological hazard symbol is recommended.
- Do not expose the device to alcohol, antiseptic solution, or other solvents.
- The Zipline 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 injury.
- If the device becomes snagged or kinked, withdraw the catheter without torquing. Replace it with another device before continuing the procedure.
- Do not attempt to clear the inner lumen of the Zipline Access Catheter by infusion while the catheter is inside the patient body.
- Failure to abide by the warnings in this labelling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- The Zipline Access Catheter should not be used for the delivery of stents, stent-retrievers, occlusion coils, glue, or liquid embolic agents because the performance of such combination of devices has not been evaluated.

### **Precautions**

- The safety and effectiveness of the coated device has not been established, and is unknown, in vascular regions other than those specifically indicated.
- Exercise care in handling the device to reduce the chance of accidental damage.
- Use the Zipline Access Catheter in vessels that are larger than the outer diameter of the device.
- Use device prior to the "Use By" date.
- The Zipline Access Catheter is intended to be used with a guidewire (0.018 inches or smaller). Consult the guidewire instructions for use and verify compatibility prior to use.
- Prior to use, verify that the Zipline Access Catheter is compatible with ancillary devices that are to be used for the procedure.
- The Zipline 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 Zipline Access Catheter in tortuous vasculature to avoid damage.
- Use caution when manipulating, advancing, or withdrawing the Zipline Access Catheter through needles, metal cannulas, stents, or other devices with sharp edges or through tortuous or calcified blood vessels.

- The presence of calcifications, irregularities, or other devices may damage the Zipline Access Catheter and potentially affect its insertion or removal.
- Manipulation, advancement, and/or withdrawal past sharp or beveled edges may result in destruction and/or separation of the outer coating which may lead to clinical adverse events, resulting in coating material remaining in the vasculature or device damage.
- The hydrophilic coating on the Zipline Access Catheter should be hydrated using heparinized saline for 10 seconds prior to use. Do not allow the coating to dry.
- 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 Zipline Access Catheter include, but are not limited to, the following:

- Acute occlusion or thrombosis
- Allergic reaction or anaphylaxis
- 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.

### Serious Incidents

In the event a serious incident has occurred in relation to the use of this device, notify via a **Perfuze** representative or email [support@perfuze.com](mailto:support@perfuze.com).

### Compatibility

The Zipline Access Catheter may be used with the following ancillary devices:

- External catheters:
  - Inner diameter of 0.070 inches (1.8 mm) or larger for use with the **Zipline70** Access Catheter.
  - Inner diameter of 0.088 inches (2.2 mm) or larger for use with the **Zipline88** Access Catheter.
- Guidewire (0.018 inches or smaller).
- Rotating Hemostasis Valve (RHV).
- Standard syringe.

The **Zipline88** Access Catheter is compatible for use with **Millipede88**® Catheters based on nonclinical testing. The **Zipline70** Access Catheter is compatible for use with **Millipede70**® Catheters based on nonclinical testing.

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. Flush the packaging dispenser hoop containing the Zipline Access Catheter with heparinized saline and wait 10 seconds to activate the hydrophilic coating.
2. Flush the lumen of the Zipline Access Catheter with heparinized saline.
3. Carefully remove the Zipline Access Catheter from the packaging dispenser hoop and inspect for damage or kinks. If a kink or any damage is observed, replace with a new device. NOTE: Do not allow the Zipline Access Catheter to dry. The catheter should be maintained in heparinized saline solution to keep hydrated prior to use.
4. Attach an RHV to the hub of the Zipline Access Catheter. Connect a line through the side port of the RHV for continuous infusion of heparinized saline.
5. Insert a guidewire (0.018 inches or smaller) until the tip is just proximal to the tip of the Zipline Access Catheter.
6. Insert the Zipline Access Catheter and guidewire assembly through the RHV on the outer catheter.
7. Use standard catheterization techniques under fluoroscopy to advance the Zipline Access Catheter and guidewire to the desired location in the neurovasculature.
8. Advance the outer catheter over the Zipline Access Catheter to the desired location.
9. Once the outer catheter is in position, if desired, withdraw the guidewire and Zipline Access Catheter.

### Warranty

**Perfuzo 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, and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure and other matters beyond **Perfuzo's** control directly affect the device and the results obtained from its use. **Perfuzo's** obligation under this warranty is limited to the replacement of this device and **Perfuzo** shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. **Perfuzo** neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. **Perfuzo** assumes no liability with respect to devices reused, reprocessed or re-sterilized 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 Packaging

 LOT	Batch code		Use-by date
	Date and country of manufacture		Do not re-use
	Do not re-sterilize		Non-pyrogenic
	Keep dry		Do not use if package is damaged and consult instructions for use
 REF	Catalogue number	 STERILE EO	Sterilized using ethylene oxide
	Consult instructions for use		Manufacturer Perfuzo Ltd. Unit 6, Galway Business Park, Dangan, Galway, H91 W7CP, Ireland
 Rx Only	RX only - Federal (USA) law restricts this device to sale by or on the order of a physician	 MD	Indicates the item is a Medical Device

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