

# Chaperon™ Guiding Catheter System

## Chaperon™ Guiding Catheter

### Instructions for Use

#### DEVICE DESCRIPTION

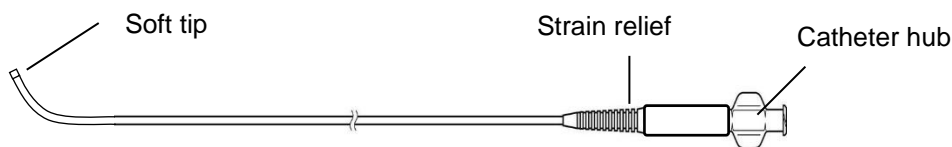
The Chaperon Guiding Catheter System consists of a Guiding Catheter and Inner Catheter. The Guiding Catheter, also available individually, can be used with a guidewire or combined with the Inner Catheter to access the neuro and peripheral vasculature.

The Guiding Catheter is designed to facilitate passage of intravascular devices through the vasculature. The Guiding Catheter is a non-tapered, braid-reinforced, variable stiffness catheter with a pre-shaped distal segment and incorporates a radiopaque marker located approximately 2 mm proximal to the distal tip.

The Inner Catheter, if supplied, is designed to facilitate advancement of the Guiding Catheter through the vasculature. The Inner Catheter is a braid-reinforced, variable stiffness catheter with a pre-shaped distal segment. The distal end of the catheter is coated with a hydrophilic polymer and the proximal end contains a Luer lock adapter for connection to the Guiding Catheter hub.

Both Guiding Catheter and Inner Catheter are fabricated with various pre-shaped tips. An example is illustrated below.

Guiding Catheter



Inner Catheter



The maximum injection pressures are listed in the following table.

Product Size		Maximum Pressure of Inner Catheter
Outer Catheter	Inner Catheter	
5 F	4 F	750 psi
6 F	5 F	1000 psi

## **CONTENTS**

The Guiding Catheter is packaged individually or combined with the Inner Catheter.

## **INDICATIONS FOR USE / INTENDED PURPOSE**

The Chaperon Guiding Catheter System and Chaperon Guiding Catheter are intended for general intravascular use, including the neuro and peripheral vasculature. The Chaperon Guiding Catheter System and Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. The Chaperon Guiding Catheter System and Chaperon Guiding Catheter are not intended for use in coronary arteries.

## **CONTRAINDICATIONS**

There are no known contraindications.

## **CAUTION**

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

## **WARNINGS**

The device should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.

The device is provided sterile and non-pyrogenic unless the unit package is opened or damaged. Do not use if the packaging is breached or damaged.

The device is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose in accordance with hospital and/or local government policy.

Inspect the device prior to use for any irregularities or damage and discard if observed.

The device should be manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined. Do not use with Ethiodol or Lipiodol contrast media, or other such contrast media which includes the components of those agents.

## **PRECAUTIONS**

Verify the device compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular technique and possible complications associated with these procedures.

Exercise care in handling the device to reduce the chance of accidental damage. Do not expose the device to organic solvents such as alcohol or medications, which might damage the device.

Extreme care must be taken to avoid damage to the vasculature through which the device passes. The device may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.

Torquing a kinked device excessively may result in separation of components from the device. Do not continue to use the device if it is severely kinked from any cause and withdraw the entire system (the device and guidewire, and sheath introducer if necessary).

Exercise care when manipulating the device in tortuous vasculature to avoid damage to the device.

## **POTENTIAL COMPLICATIONS**

Potential complications include, but are not limited to: vessel or aneurysm perforation, vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudoaneurysm, seizure, stroke, infection, thrombus formation, additional procedure/treatment required, inability to treat or diagnose patient, toxic reaction, and death.

This device requires the use 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.

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State or Local Health Authority in which the user and/or patient is established.

## **PREPARATION FOR USE**

Gently remove the Guiding Catheter and the Inner Catheter (if applicable) from its packaging. Inspect the devices to ensure they are not damaged. If damage is detected, do not use and replace with another device.

Hydrate the hydrophilic coating on the Inner Catheter (if applicable) by soaking it in heparinized saline prior to introduction into the Guiding Catheter.

Purge the catheter lumens by flushing with heparinized saline prior to use.

Introduce the Inner Catheter (if utilized) into the Guiding Catheter completely and secure the devices together by rotating the Luer lock adapter of the Inner Catheter onto the Guiding Catheter hub. Do not use the device if extreme friction is detected.

Note: To maintain a continuous flush through the Guiding Catheter lumen, a rotating hemostatic valve (RHV) may be attached to the Guiding Catheter hub. If an Inner Catheter is used, it should be placed through the RHV and Guiding Catheter.

## **DIRECTIONS FOR USE**

Carefully insert the Guiding Catheter System or Guiding Catheter through the introducer sheath and advance into the vasculature over a 0.035" or 0.038" guidewire.

If an Inner Catheter is not used, set up a continuous heparinized saline flush through the sidearm of a rotating hemostatic valve attached to the Guiding Catheter hub. It is recommended that continuous heparinized saline flush be maintained between the Guiding Catheter and any intraluminal device passed coaxially through it.

Under fluoroscopic guidance, advance or withdraw the Guiding Catheter System or Guiding Catheter over the guidewire until the desired position is attained. If injecting through the Inner Catheter at this point, remove the guidewire and aspirate the Inner Catheter lumen with a syringe prior to injection. If injecting through the Guiding Catheter, remove the Inner Catheter and guidewire and aspirate the Guiding Catheter lumen with a syringe prior to injection.

Slowly remove the Inner Catheter (if utilized) and guidewire prior to introduction of other intravascular devices.

## **STORAGE**

Keep dry and away from sunlight. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.























## **MATERIALS**

The device does not contain latex or PVC materials.

## SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The Summary of Safety and Clinical Performance (SSCP) for the device will be accessible in the European database on medical devices (EUDAMED: <https://ec.europa.eu/tools/eudamed>), when available. The SSCP will be linked to the Basic UDI-DI in the EUDAMED public website.

## SYMBOLS

	Lot Number		Do Not Reuse
	Catalog Number		Use by Date
	Contents		Manufacturer
	Sterilized Using Ethylene Oxide		Authorized Representative in the European Union
	Importer		Caution
	CE Mark		Non-pyrogenic
	Single Sterile barrier system		Medical Device
	Do not use if package is damaged		Country and Date of manufacture
	Keep Dry		Keep Away from Sunlight
	Do Not Resterilize		Consult Instructions for Use
	For Prescription Use Only		Unique Device Identifier

## WARRANTY

MicroVention, Inc. 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 MicroVention's control directly affect the device and the results obtained from its use. MicroVention's obligation under this warranty is limited to the repair or replacement of this device through its expiration date, and MicroVention shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. MicroVention neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. MicroVention 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.

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**MicroVention, Inc.**

35 Enterprise  
Aliso Viejo, CA 92656, USA  
PH: +1.714.247.8000  
www.terumoneuro.com



**MicroVention Europe SARL**

30 bis, rue du Vieil Abrevoir  
78100 Saint-Germain-en-Laye  
France  
PH: +33 (0)1 39 21 77 46



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