Wedge™ Microcatheter

Instructions for Use

DEVICE DESCRIPTION

The Wedge Microcatheter is a single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels. Radiopaque markers at the distal end facilitate fluoroscopic visualization. A larger diameter distal segment helps provide stability for navigation. The outer surface of the Wedge Microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the Wedge Microcatheter hub is used for the attachment of accessories.

CONTENTS

One Wedge Microcatheter with shaping mandrel and introducer sheath.

INDICATIONS FOR USE / INTENDED PURPOSE

The Wedge Microcatheter is intended for general intravascular use, including the peripheral and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents.

CONTRAINDICATIONS

There are no known contraindications.

CAUTION

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

WARNINGS

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

Inspect the Wedge Microcatheter prior to use for any irregularities or damage and discard if any inconsistencies are observed.

The Wedge Microcatheter should be advanced or manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.

Infusion pressure should not exceed 300 psi to avoid potential rupture of the Wedge Microcatheter.

The shaping mandrel is not intended for use inside the body. Ensure shaping mandrel is removed from Wedge Microcatheter prior to introduction into the RHV or other accessories.

PRECAUTIONS

Immediately prior to use visually inspect all the sterile barrier systems, that are labeled as sterile. Do not use if breaches in sterile barrier system integrity are evident such as a damaged pouch.

Verify Wedge Microcatheter compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.

The Wedge Microcatheter has a lubricious surface and should be hydrated prior to use.

Exercise care in handling the Wedge Microcatheter to reduce the chance of accidental damage.

Verify that the diameter of any guidewire or accessory device that is used is compatible with the inner diameter of the Wedge Microcatheter prior to use.

To reduce the risk of damage or separation of the device, avoid repeated bending at the same point of the Wedge Microcatheter.

Take precaution when manipulating the Wedge Microcatheter in tortuous vasculature to avoid damage to the Wedge Microcatheter. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.

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, vessel dissection, thrombus formation, and death.

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

Before removing the Wedge Microcatheter, fully hydrate the hydrophilic segment of the device by flushing heparinized saline through the dispenser tube using a syringe attached to the dispenser tube hub.

To remove the Wedge Microcatheter from the dispenser tube, gently pull the hub out from the dispenser tube. Remove the Wedge Microcatheter by pulling it from the dispenser tube. If resistance is met, repeat the flushing procedure until the Wedge Microcatheter is well hydrated and can be easily removed from the dispenser tube. Inspect the Wedge Microcatheter thoroughly to ensure it is not damaged. Do not allow Wedge Microcatheter to dry prior to introduction into the guiding catheter.

Wedge Microcatheter	Shaft Length	Guide / Aspiration Catheter Minimum ID	Guidewire Recommendation
Wedge Microcatheter 21	160 cm	0.070 in. / 1.78 mm	≤ 0.018 in. / ≤ 0.46 mm

Steam Shaping

- If tip shaping is desired, remove the shaping mandrel and the introducer sheath from the card. Bend the steam shaping mandrel to the desired shape. Note: the shaping mandrel should be over-bent by approximately one-third to achieve the desired shape in the Wedge Microcatheter (for example, for a 45º bend in the Wedge Microcatheter, shape the mandrel with a 60º bend). Carefully introduce the Wedge Microcatheter through the introducer sheath. Gently insert the shaped mandrel into the Wedge Microcatheter distal tip.
- Hold Wedge Microcatheter tip/shaping mandrel assembly approximately one inch from a steam source for approximately 30 seconds to form shape.

- Immediately place Wedge Microcatheter tip/shaping mandrel assembly into heparinized saline to set the shape.
- Carefully remove shaping mandrel from Wedge Microcatheter and discard.

Warning: Shaping mandrel is not intended for use inside the body.

DIRECTIONS FOR USE

Prior to use, flush the Wedge Microcatheter lumen thoroughly with heparinized saline to prime the Wedge Microcatheter and provide smooth movement of the guidewire within the Wedge Microcatheter. A rotating hemostatic valve (RHV) may be attached to the Wedge Microcatheter hub and used to facilitate the flushing process.

Carefully insert the distal section of the guidewire into the Wedge Microcatheter hub (refer to the guidewire instructions for use). A guidewire insertion tool may be used to facilitate insertion of the guidewire distal tip through an RHV and into the Wedge Microcatheter hub. Advance the guidewire until the distal tip is near the distal end of the Wedge Microcatheter. Gently tighten the RHV to maintain position.

Slip the torque device over the proximal end of the guidewire to the desired location (refer to guidewire or torque device instructions for use). Secure the torque device in place by tightening the rotating knob. The torque device may be repositioned by loosening and retightening the rotating knob.

A Wedge Microcatheter is placed into the appropriate vessel and the Wedge Microcatheter /guidewire assembly is then advanced through the guiding catheter to the target vessel or vascular lesion. Set up a continuous flush of heparinized saline by connecting RHVs with pressurized flush solution lines to the hub of the guiding catheter and Wedge Microcatheter.

Loosen the guiding catheter RHV and introduce the Wedge Microcatheter/guidewire into the guiding catheter using the introducer sheath. Carefully advance the Wedge Microcatheter/guidewire to the guiding catheter distal tip. After the Wedge Microcatheter /guidewire reaches the tip of the guiding catheter, remove the introducer from the Wedge Microcatheter shaft by retracting the introducer from the RHV and peeling off the introducer. During navigation in the vasculature, advance the guidewire a short distance, then advance the Wedge Microcatheter over the guidewire and repeat until the desired site is reached. The proximal portion of the Wedge Microcatheter does not have the hydrophilic surface and may encounter resistance when this section is advanced through the RHV.

Once the desired location has been reached, the guidewire is removed from the Wedge Microcatheter. The diagnostic or therapeutic agent(s) are then prepared for delivery through the Wedge Microcatheter. Warning: Do not exceed the maximum recommended infusion pressure of 300 psi.

Wedge Microcatheter	Wedge Microcatheter ID	Dead Space (Average)	Maximum Distal OD
Wedge Microcatheter 21	0.53 mm / 0.0210 in.	0.54cc	1.73 mm / 0.068 in.

Wedge Microcatheter	Approximate Nominal Flow Rates at 100 and 300 psi Infusion Pressure					
	Saline		60% Contrast		76% Contrast	
	100 psi	300 psi	100 psi	300 psi	100 psi	300 psi
Wedge Microcatheter 21	0.77 cc/sec	1.90 cc/sec	0.52 cc/sec	1.16 cc/sec	0.20 cc/sec	0.73 cc/sec

If removed from the patient, rinse the Wedge Microcatheter in a basin of heparinized saline and wipe it gently with sterile, wet gauze and place in a basin of heparinized saline or a flushed dispenser tube to keep the hydrophilic surface wet until use.

STORAGE

Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage. Store the Wedge Microcatheter under controlled room temperature. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

MATERIALS

The Wedge Microcatheter does not contain natural rubber latex or polyvinylchloride (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.

SYMBOLS

	Lot Number		Do Not Reuse
	Catalog Number		Authorized European Representative
	Contents		Use-by Date
	Sterilized Using Ethylene Oxide		Date of Manufacture
	CE Mark		Manufacturer
	Consult Instructions for use		Non-pyrogenic
	For Prescription Use Only		Do not use if package is damaged
	Medical Device		Single Sterile barrier system with protective packaging inside
	Keep Away from Sunlight		Country of manufacture
	Keep Dry		UDI

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 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,

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Prices, specifications and model availability are subject to change without notice.

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