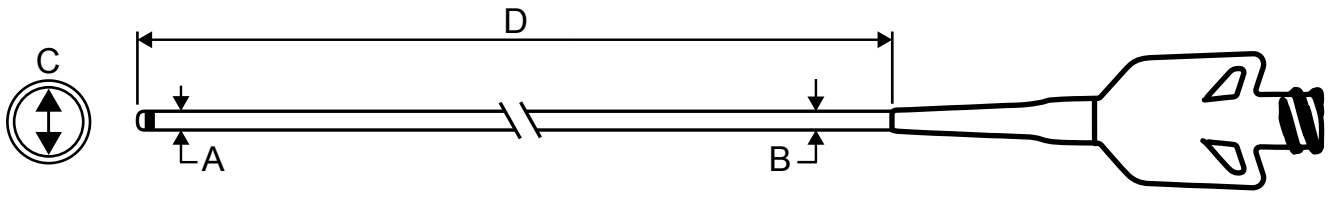
NeuroVasc TECHNOLOGIES

Technical Brochure

eNVoke™ Microcatheter



Product Information

eNVoke™ Diameter Group	REF Catalogue Number	Description	"C" Inner Diameter	"D" Usable Length	Stiffness
eNVoke™ 17	FG-005-1714	eNVoke™ Microcatheter, 017, 167 cm, Soft	0.017 inch (0.43 mm)	167 cm	Soft
	FG-005-1715	eNVoke™ Microcatheter, 017, 167 cm, Regular			Regular
	FG-005-1724	eNVoke™ Microcatheter, 017, 167 cm, 2 MB, Soft			Soft
	FG-005-1725	eNVoke™ Microcatheter, 017, 167 cm, 2 MB, Regular			Regular
	FG-005-1726	eNVoke™ Microcatheter, 017, 167 cm, 2 MB, Support			Support
eNVoke™ 21	FG-005-2614	eNVoke™ Microcatheter, 021, 160 cm, Soft	0.021 inch (0.53 mm)	160 cm	Soft
	FG-005-2615	eNVoke™ Microcatheter, 021, 160 cm, Regular			Regular
eNVoke™ 27	FG-005-3614	eNVoke™ Microcatheter, 027, 160 cm, Soft	0.027 inch (0.69 mm)	160 cm	Soft
	FG-005-3615	eNVoke™ Microcatheter, 027, 160 cm, Regular			Regular

Dimensions

eNVoke™ Diameter Group	"C" Inner Diameter	"A" Distal Outer Diameter	"B" Proximal Outer Diameter
eNVoke™ 17	0.017 inch (0.43 mm)	0.027 inch (0.69 mm)	0.029 inch (0.74 mm)
eNVoke™ 21	0.021 inch (0.53 mm)	0.033 inch (0.84 mm)	0.036 inch (0.91 mm)
eNVoke™ 27	0.027 inch (0.69 mm)	0.037 inch (0.94 mm)	0.039 inch (0.99 mm)

eNVoke™

INTENDED USE / INDICATIONS FOR USE

The eNVoke™ catheters are intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral, and coronary vasculatures.

DEVICE DESCRIPTION

The eNVoke™ catheters are variable stiffness, single lumen catheters designed to access small, tortuous vasculature. They are available in a variety of lengths, stiffnesses, and inner and outer diameters. The outer surface of the catheter has a hydrophilic coating on the distal end to reduce friction in the vessel. The catheter also incorporates a liner to facilitate introduction of interventional devices through its lumen. The proximal end has a luer hub for attachment to other devices and the distal tip has radiopaque marker(s) to aid visualization and positioning under fluoroscopy.

COMPATIBILITY

Catheter	Minimum Guide Catheter Inner Diameter	Maximum Guidewire Diameter
eNVoke™ 17	.044 inch (1.12 mm)	.014 inch (0.35 mm)
eNVoke™ 21	.044 inch (1.12 mm)	.014 inch (0.35 mm)
eNVoke™ 27	.044 inch (1.12 mm)	.014 inch (0.35 mm)

- Use of the eNVoke™ in a lumen less than .003 inch (0.08 mm) larger than the outer diameter of the eNVoke™ is not recommended.
- Limited testing has been performed with solutions such as contrast media and saline. Delivery of solutions other than the types tested is not recommended.
  - Compatibility with glue or glue mixtures has not been established.
  - Compatibility with DMSO or agents suspended in DMSO has not been established.
  - Ensure embolic material compatibility with eNVoke™ prior to use.

CONTRAINDICATIONS

- None known.

PRECAUTIONS

- Carefully read these directions before using this product. Observe warning and safety precautions.
- The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice.
- The device should only be used by physicians experienced in angiographic and percutaneous interventional procedures, at medical facilities with the appropriate fluoroscopic equipment.
- Use device prior to "Use-by" date printed on label.
- Prevent exposure to temperatures in excess of 55°C. Exposure to temperatures above this temperature may damage device and accessories. Do not autoclave.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution between guide catheter and microcatheter and between the microcatheter and guidewire.
- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove and replace catheter.
- Torqueing the catheter may cause damage which could result in kinking to separation of the catheter shaft.
- If an intraluminal device becomes lodged in the catheter, or if the catheter becomes severely kinked, withdraw the entire system (intraluminal device, catheter, and guiding catheter).
- The Shaping Mandrel is not intended for use inside the body. Ensure Shaping Mandrel is removed from the catheter prior to introduction into the RHV or other accessories.
- Use only a steam source to shape the catheter tip. Do not use other heat sources or the catheter may be damaged.
- Verify that the diameter of any guidewire or accessory device that is used is compatible with the inner diameter of the catheter prior to use.
- The eNVoke™ catheter has a lubricious hydrophilic coating on the outside of the distal end.
  - The coating must be kept hydrated in order to be lubricious.
  - The coating is incompatible with solvents such as alcohols or cleaning agents. Avoid using alcohols, antiseptic solutions, or other solvents as these may damage the coating, which could affect device safety and performance.
  - Avoid wiping the device with dry gauze as this may damage the device coating. Avoid excessive wiping of the coating.
  - Avoid device insertion through a metal cannula or needle. Manipulation, advancement, and/or withdrawal through a metal device may result in coating material remaining in the metal device leading to adverse events such as embolization.
- Caution: Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician.

POTENTIAL COMPLICATIONS

Possible complications of the use of the eNVoke™ catheter include, but are not limited to:

- Adverse reaction to antiplatelet/anticoagulation agents or contrast media
- Additional surgical Intervention
- Allergic reaction
- Aneurysm or pseudoaneurysm
- Aneurysm perforation or rupture
- Anesthesia complications
- Arteriovenous fistula
- Cerebral infarct
- Change in mental status
- Death
- Device deformation, collapse, fracture, or malfunction
- Edema, including braid and pulmonary
- Embolization (air, tissue, or thrombotic emboli)
- Hematoma at the site of entry
- Hemorrhage
- Hypotension/hypertension
- Infection
- Inflammation, including sterile inflammation or granulomas at the access site
- Intracranial hemorrhage including subarachnoid hemorrhage and hemorrhagic transformation
- Ischemia
- Myocardial embolism
- Myocardial infarct
- Neurological deficits including stroke and death
- New stroke/ cerebrovascular accident/ transient ischemic attack (TIA)
- Pain at the site of entry
- Post procedural bleeding
- Pulmonary embolism
- Pulmonary infarct
- Pseudoaneurysm
- Renal failure
- Respiratory failure
- Shock
- Stroke
- Thrombosis (acute and subacute)
- Tissue necrosis, transient or long-lasting
- Vascular thrombosis
- Vascular occlusion
- Vascoconstriction (Vasospasm)
- Vessel trauma, dissection, perforation, rupture, or injury

NeuroVasc TECHNOLOGIES

EC REP

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Pending FDA Clearance, Not Available for Sale in the United States.

℞ Only

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