FlowGate™
BALLOON GUIDE CATHETER

ReadyPack Accessories
Simplify prep and use when time is critical

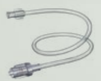
Guide Assist Catheter (Dilator)
Facilitates delivery of the balloon guide catheter

Outer Diameter	6F
Inner Diameter	0.041 - 0.050in
Effective Length	123cm

Luer Activated Flow Valve
Engineered to maintain balloon inflation and simplify balloon prep

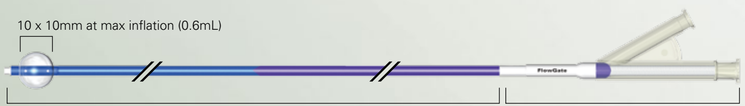
Peel Away Sheath
Designed to protect the balloon and the distal tip of the balloon guide catheter when inserting the catheter through the insertion sheath

RHV & Tuohy Borst With Sideport
Can be used interchangeably to accommodate desired catheter working length



Extension Tubing
Facilitates aspiration with a 60mL syringe

FlowGate Balloon Guide Catheter Specifications



FlowGate Balloon Guide Catheter

Reference Number	Description	Outer Diameter	Inner Diameter	Effective Length
90254	8F x 85cm FlowGate BGC	8F	0.084in	85cm
90253	8F x 95cm FlowGate BGC	8F	0.084in	95cm

FlowGate™ and Merci® Balloon Guide Catheters

See package insert for complete indications, complications, warnings, and instructions for use.

INDICATIONS FOR USE

FlowGate™ Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.

COMPLICATIONS

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Possible complications include, but are not limited to, the following: infection, hematoma, distal embolization, vessel thrombosis, dissection, false aneurysm formation, acute occlusion, clot formation, hemorrhage at the puncture site, intracranial hemorrhage, arterial rupture, stroke and death.

COMPATIBILITY

Introducer sheath French size must be greater than or equal to balloon guide catheter French size.

WARNINGS

- Contents supplied STERILE, using an ethylene oxide (EO) process. Nonpyrogenic.
- Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning.
- Never advance or torque catheter against resistance without careful assessment of cause of resistance using fluoroscopy. If cause cannot be determined, withdraw catheter. Movement against resistance may result in damage to vessel or catheter.
- To reduce risk of complications due to slow balloon deflation, adhere to the following recommendations:
  - Wet distal shaft with saline before advancing peel-away sheath over balloon.
  - Use peel-away sheath to advance catheter into introducer sheath.
  - Minimize pushing forces on shaft during advancement. These forces can cause wrinkles in shaft that can slow balloon deflation.
  - Do not use device if shaft is damaged during use.
  - Prepare balloon according to Recommended Procedure.
- To reduce risk of complications due to air emboli, remove air from balloon according to Recommended Procedure.
- Withdrawing balloon through introducer sheath may damage balloon. Do not use catheter again after withdrawing balloon through introducer sheath.
- To avoid balloon leakage, do not allow balloon to contact calcified or stented arteries and do not allow balloon to move during inflation.
- Do not use a device that has been damaged. Use of damaged devices may result in complications.
- Do not exceed maximum recommended balloon inflation volume. Excess inflation volume may rupture balloon.
- For through-lumen, do not exceed 2068 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may result in catheter rupture or tip detachment.
- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter to rupture, resulting in vessel trauma. Remove and replace catheter.
- Do not steam shape guide catheter.

PRECAUTIONS

- Prescription only – device restricted to use by or on order of a physician.
- Store in a cool, dry, dark place.
- Do not use open or damaged packages.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave.
- Upon removal from package, inspect device to ensure it is not damaged.
- Do not expose device to solvents.
- Use device in conjunction with fluoroscopic visualization and proper anti-coagulation agents.
- Torquing guide catheter while kinked may cause damage that could result in separation of catheter shaft.
- If a device becomes lodged in guide catheter, or if guide catheter becomes severely kinked, withdraw entire system (guide catheter, guidewire and catheter sheath introducer).
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through guide catheter lumen.

Trevo® Retriever

See package insert for complete indications, complications, warnings, and instructions for use.

INDICATIONS FOR USE

The Trevo® Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

COMPLICATIONS

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with possible complications which may occur during or after the procedure. Possible complications include, but are not limited to, the following: air embolism; hematoma or hemorrhage at puncture site; infection; distal embolization; vessel spasm, thrombosis, dissection, or perforation; emboli; acute occlusion; ischemia; intracranial hemorrhage; false aneurysm formation; neurological deficits including stroke; and death.

COMPATIBILITY

Retrievers are compatible with Trevo® Microcatheters (REF 90238). Compatibility of the Retriever with other microcatheters has not been established. Performance of the Retriever device may be impacted if a different microcatheter is used.

The Merci® Balloon Guide Catheters are recommended for use during thrombus removal procedures.

Retrievers are compatible with the Abbott Vascular DOC® Guide Wire Extension (REF 22260).

WARNINGS

- Contents supplied STERILE, using an ethylene oxide (EO) process. Nonpyrogenic.
- To reduce risk of vessel damage, adhere to the following recommendations:
  - Take care to appropriately size Retriever to vessel diameter at intended site of deployment.
  - Do not perform more than six (6) retrieval attempts in same vessel using Retriever devices.
  - Maintain Retriever position in vessel when removing or exchanging Microcatheter.
- To reduce risk of kinking/fracture, adhere to the following recommendations:
  - Immediately after unsheathing Retriever, position Microcatheter tip marker just proximal to shaped section. Maintain Microcatheter tip marker just proximal to shaped section of Retriever during manipulation and withdrawal.
  - Do not rotate or torque Retriever.
  - Use caution when passing Retriever through stented arteries.
- Do not resterilize and reuse. Structural integrity and/or function may be impaired by reuse or cleaning.
- The Retriever is a delicate instrument and should be handled carefully. Before use and when possible during procedure, inspect device carefully for damage. Do not use a device that shows signs of damage. Damage may prevent device from functioning and may cause complications.
- Do not advance or withdraw Retriever against resistance or significant vasospasm. Moving or torquing device against resistance or significant vasospasm may result in damage to vessel or device. Assess cause of resistance using fluoroscopy and if needed resheath the device to withdraw.
- If Retriever is difficult to withdraw from the vessel, do not torque Retriever. Advance Microcatheter distally, gently pull Retriever back into Microcatheter, and remove Retriever and Microcatheter as a unit. If undue resistance is met when withdrawing the Retriever into the Microcatheter, consider extending the Retriever using the Abbott Vascular DOC guidewire extension (REF 22260) so that the Microcatheter can be exchanged for a larger diameter catheter such as a DAC® catheter. Gently withdraw the Retriever into the larger diameter catheter.
- Administer anti-coagulation and anti-platelet medications per standard institutional guidelines.

PRECAUTIONS

- Prescription only – device restricted to use by or on order of a physician.
- Store in cool, dry, dark place.
- Do not use open or damaged packages.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave.
- Do not expose Retriever to solvents.
- Use Retriever in conjunction with fluoroscopic visualization and proper anti-coagulation agents.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution between guide catheter and Microcatheter and between Microcatheter and Retriever or guidewire.
- Do not attach a torque device to the shaped proximal end of DOC® Compatible Retriever. Damage may occur, preventing ability to attach DOC® Guide Wire Extension.

Microcatheter

See package insert for complete indications, contraindications, warnings and instructions for use.

INDICATIONS FOR USE

The Microcatheter is indicated for use in the selective placement of fluids and/or other devices or agents into the peripheral, coronary, and neuro vasculature during diagnostic and/or therapeutic procedures.

COMPLICATIONS

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Possible complications include, but are not limited to the following: hematoma at the puncture site; vessel perforation; emboli; hemorrhage; ischemia; vasospasm; neurological deficits including stroke; death.

COMPATIBILITY

Refer to product label for device dimensions. Refer to labeling provided with other medical technologies to determine compatibility.

WARNINGS

- Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning.
- Never advance catheter against resistance without careful assessment of cause using fluoroscopy. If cause cannot be determined, withdraw catheter. Movement against resistance may result in damage to vessel or catheter.
- Do not use device that has been damaged in any way. Damaged device may cause complications.
- Do not exceed maximum recommended infusion pressure. Excess pressure may result in catheter rupture or tip severance.

Catheter	Maximum Infusion Pressure
MC 14 (REF 90043) MC 18 (REF 90044) Trevo 18 MC (REF 90047)	2070 kPa (300 psi)
Trevo Pro 18 MC (REF 90238)	1034 kPa (150 psi)

- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter to rupture, resulting in vessel trauma. Remove and replace catheter.

PRECAUTIONS

- Store in cool, dry, dark place.
- Do not use open or damaged packages.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave.
- Upon removal from package, inspect device to ensure it is not damaged.
- Do not expose device to solvents.
- Use device with fluoroscopic visualization and proper anti-coagulation agents.
- Hydrate microcatheter with saline for 2 minutes minimum before use. Once hydrated, do not allow it to dry.
- To maintain hydrophilic coating lubricity, provide continuous flow of appropriate solution between microcatheter and guide catheter.
- Hemostatic side-arm adapters may be used to provide seal around guidewire and microcatheter.

90814275.AA

Concentric Medical
301 East Evelyn
Mountain View, CA 94041

EC REP
EMERGO Europe
Molenstraat 15
2513 BH , The Hague
The Netherlands

CE 0459

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538-6515

stryker.com/neurovascular
stryker.com/emea/neurovascular

Date of Release: MAR/2014

EX_EN_GL

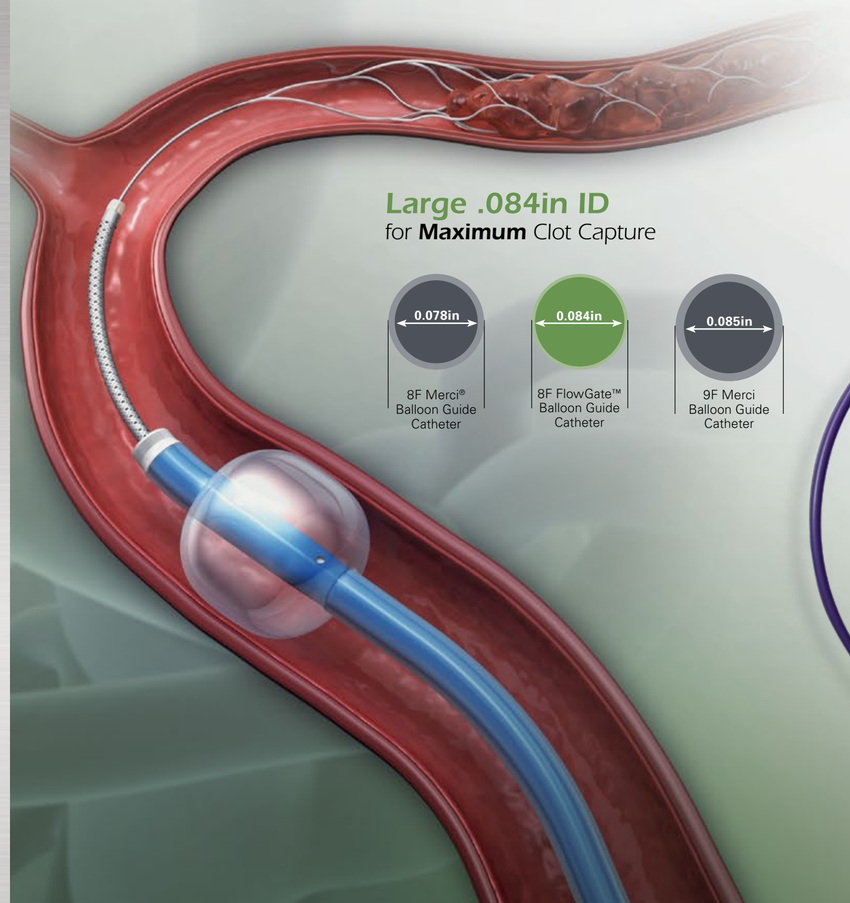
stryker® Neurovascular

FlowGate™
BALLOON GUIDE CATHETER

Take Control. Capture More.

Stroke: *Our Only Focus. Our Ongoing Promise.*

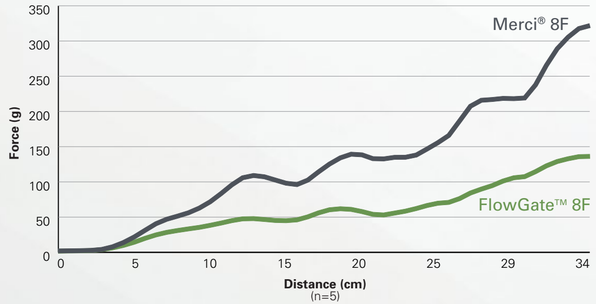
Take Control. Capture More.

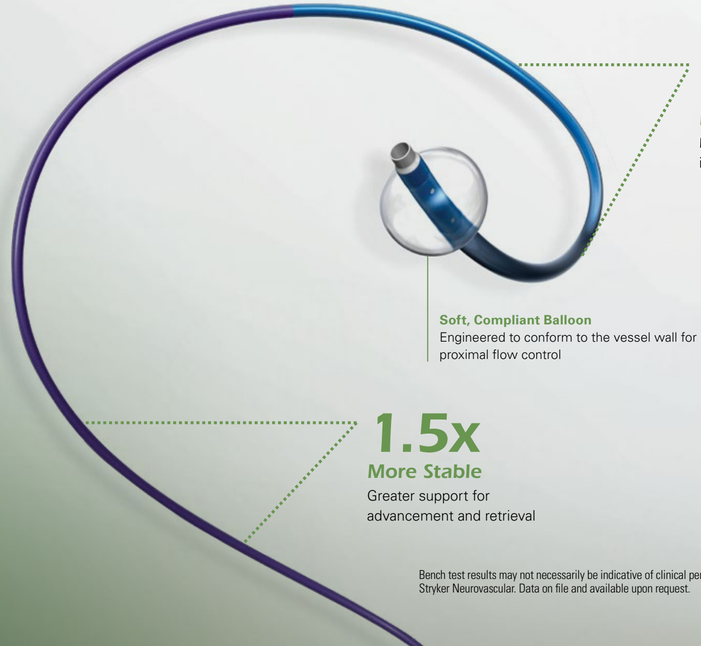


Large .084in ID
for **Maximum** Clot Capture

Easy Access

Trackability





2x
More Flexible
Improves distal access in tortuous anatomy

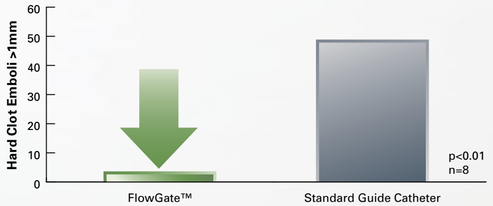
Soft, Compliant Balloon
Engineered to conform to the vessel wall for proximal flow control

1.5x
More Stable
Greater support for advancement and retrieval

Bench test results may not necessarily be indicative of clinical performance. Testing completed by Stryker Neurovascular. Data on file and available upon request.

Control Flow for Better Outcomes.

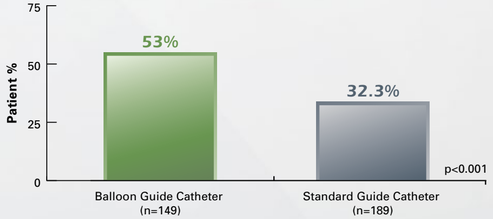
Distal Emboli[1]



18x
Fewer Hard Clot Distal Emboli

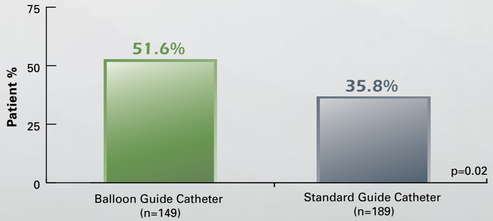
1. Chueh et al., "Reduction in Distal Emboli With Proximal Flow Control During Mechanical Thrombectomy: A Quantitative In Vitro Study," *Stroke*, 2013 (44), 1396-1401.

Better TICI 3 Revascularization[2]



21%
Improvement
in procedural success

Independent Predictor of Good Clinical Outcomes[2]



16%
Improvement
in 90-day good outcomes (mRS 0-2)

2. Balloon guide catheter improves recanalization, procedure time, and clinical outcomes with Solitaire in acute stroke: analysis of the NASA Registry. T Nguyen et al. *J Neurointervent Surg* 2013(5) A2-A3 2013.