FlowGate2™ Balloon Guide Catheter

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

INDICATIONS FOR USE
FlowGate2™ 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
- 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
- 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.

AXS Catalyst® Distal Access Catheter

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

INTENDED USE/INDICATIONS FOR USE
The AXS Catalyst Distal Access Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices.

CONTRAINDICATIONS
None known.

ADVERSE EVENTS
Potential adverse events associated with the use of catheters or with the endovascular procedures include, but are not limited to: access site complications, allergic reaction, aneurysm perforation, aneurysm rupture, death, embolism (air, foreign body, plaque, thrombus), hematoma, hemorrhage, infection, ischemia, neurological deficits, pseudoaneurysm, stroke, transient ischemic attack, vasospasm, vessel dissection, vessel occlusion, vessel perforation, vessel rupture, and vessel thrombosis.

WARNING
Contents supplied sterile using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.

Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

- Limited testing has been performed with solutions such as contrast media, and saline. The use of these catheters for delivery of solutions other than the types that have been tested for compatibility is not recommended.
- Not intended for use with power injectors.
- 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.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the device against resistance could dislodge a clot, perforate a vessel wall, or damage the device.

PRECAUTIONS
- Carefully inspect all devices prior to use. Verify size, length, and condition are suitable for the specific procedure. Do not use a device that has been damaged in any way. Damaged device may cause complications.
- To control the proper introduction, movement, positioning and removal of the catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.
- Use the product prior to the "Use By" date printed on the label.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through catheter lumen.
- Torquing the catheter may cause damage which could result in kinking or separation of the catheter shaft.

Trevo® Retrievers

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; pain/headache; vessel spasm, thrombosis, dissection, or perforation; emboli; acute occlusion; ischemia; intracranial hemorrhage; false aneurysm formation; neurological deficits including stroke; and death.

COMPATIBILITY
The Trevo XP ProVue Retriever 3x20 mm is compatible with Trevo® Pro 14 Microcatheters (REF 90231) and Trevo® Pro 18 Microcatheters (REF 90238). The Trevo ProVue Retriever 4x20mm and Trevo XP ProVue Retriever 4x20 mm are compatible with Trevo® Pro 18 Microcatheters (REF 90238).
6x25mm Retrievers are compatible with Excelsior® XT-27® Microcatheters (150cm x 6cm straight REF 275081). 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.

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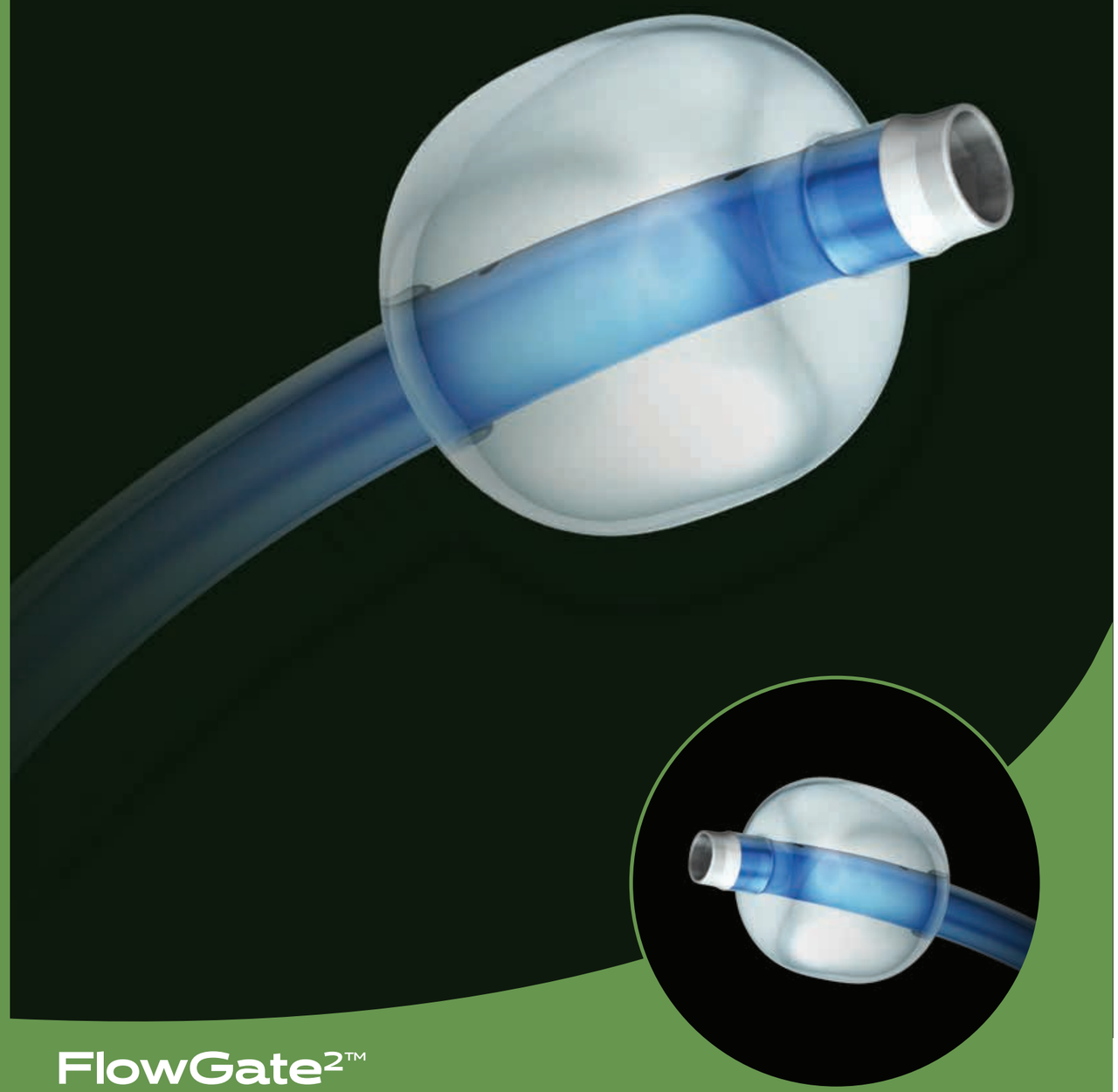
Preparation and procedure guide



FlowGate2™
BALLOON GUIDE CATHETER

Preparation and procedure guide

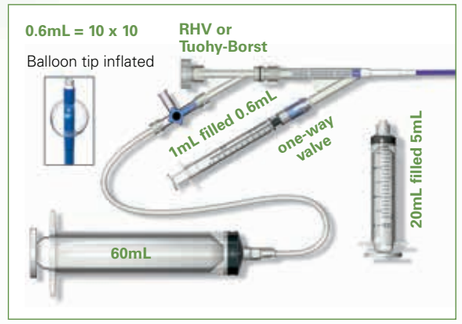
Set-up

Included

BGC
Dilator (Guide-assist)
RHV/Tuohy-Borst
Flow valve
Extension tubing

Not included (but recommended)

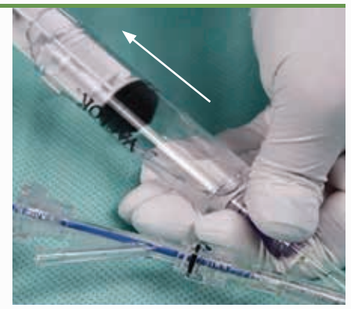
1mL syringe
20mL syringe
60mL syringe
3-way stopcock



Prep steps

STEP 1 | Remove air

1. **Fill a 20mL** syringe with **5mL of 50/50 contrast/saline**.
2. **Attach the flow valve** to the balloon hub; **attach the 20mL syringe** to the flow valve.
3. **Pull negative** on the syringe plunger to aspirate the balloon lumen. **Maintain negative** pressure until air bubbles stop forming in the syringe.
4. **Release** syringe plunger to allow media to be drawn into the balloon lumen. Do not infuse media.
5. **Repeat** once more.
6. **Remove** the 20mL syringe.



STEP 2 | Inflate

1. **Fill a 1mL** syringe with 0.6mL of balloon inflation media.
2. **Attach the 1mL** syringe to the flow valve.
3. **Inflate** the balloon by transferring the balloon inflation media from the syringe to the balloon.

STEP 3 | Diffuse air

1. **Remove** the 1mL syringe to maintain balloon inflation.
2. **Allow air bubbles to diffuse** from the balloon.

STEP 4 | Deflate

1. **Reattach the 20mL** syringe.
2. **Pull negative** on the syringe plunger until the balloon is completely deflated.

FlowGate²™

BALLOON GUIDE CATHETER

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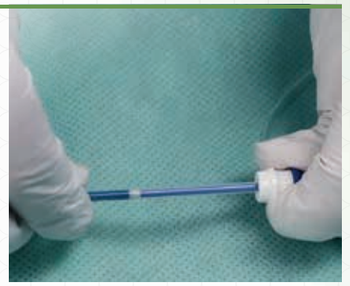
Procedure summary

Insert

- **Wet** the distal shaft of the balloon guide catheter with saline.
- Advance the peel-away sheath over the balloon.
- Using the **peel-away sheath**, insert the guidewire/dilator/guide catheter assembly into the introducer sheath.
- **Retract the peel-away** sheath from introducer hub and peel off of guide catheter shaft.
- Remove dilator (if applicable) and guidewire.



If using a clot retrieval device such as Trevo® Retriever

- Inflate the balloon prior to retraction.
- Gently infuse 50/50 contrast saline with a 1mL syringe until the desired balloon diameter is attained.
- Apply vigorous aspiration using 60mL syringe or pump and withdraw clot retrieval device inside of balloon guide catheter.
- Continue to aspirate until device is nearly withdrawn from guide.
- Deflate the balloon with 20mL syringe.
- Ensure balloon is completely deflated before withdrawing guide catheter.

If using a distal access catheter such as AXS Catalyst® 6 Distal Access Catheter

- Apply vigorous aspiration through the access catheter using 60mL syringe or pump during withdrawal of retrieval device.
- Continue to aspirate until device is withdrawn from the body.

All photographs taken by Stryker Neurovascular.