Ver.4
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CELLO™
Balloon Guide Catheter

Instructions for Use

Device Description
The CELLO™ Balloon Guide Catheter is a coaxial-lumen, braid-reinforced, variable stiffness catheter with two radiopaque markers on both the distal and proximal ends of the balloon and a bifurcated luer hub on the proximal end. A compliant silicone balloon is mounted on the distal end. Balloon Guide Catheter dimensions and recommended balloon inflation volumes are indicated on the product label.

Indications for Use
The CELLO Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.

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. Maximum guidewire diameter is indicated on the product label.

Warnings
- The CELLO Balloon Guide Catheter should only be used by physicians who have received appropriate training in interventional techniques.
- Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning.
- Never advance or torque the catheter against resistance without careful assessment of cause of resistance using fluoroscopy. If the cause cannot be determined, withdraw the catheter. Movement against resistance may result in damage to the vessel or the catheter.
- To reduce risk of complications due to slow balloon deflation, adhere to the following recommendations:
  - Wet the distal shaft with saline before passing it into the introducer sheath.
  - Minimize pushing forces on the shaft during advancement. These forces can cause wrinkles in the shaft that can slow balloon deflation.
  - Do not use the device if the shaft is damaged during use.
  - Prepare the balloon according to the recommended procedure.
- To reduce the risk of complications due to air emboli, remove air from the balloon according to the recommended procedure.
- Withdrawing the balloon through introducer sheath may damage the balloon. Do not use the catheter again after withdrawing the balloon through the introducer sheath.
- To avoid balloon leakage, do not allow the balloon to contact calcified or stented arteries and do not allow the 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 indicated on the label. Excess inflation volume may rupture the balloon.
- Excess pressure may result in catheter rupture or tip detachment.
- If flow through the catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause the catheter to rupture, resulting in vessel trauma. Remove and replace the catheter.
- Do not steam shape the guide catheter.
- Balloon should be inflated by one of the followings;
  1. Inflating the balloon with the dilator inserted (recommended).
  2. Inflating the balloon 3 seconds or more with 1 mL syringe.

Precaution
- Single use only.(If the product is to be re-used, it may cause infection to patients or damage to the product)
- 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 the device and accessories. Do not autoclave.
- Upon removal from package, inspect the device to ensure it is not damaged.
- Do not expose the device to solvents.Do not use oily contrast media, consisting of ethyl ester of iodinated poppy-seed oil fatty acids, such as Lipiodol.
- The guidewire used with this system should incorporate a hydrophilic coating.
- Use the device in conjunction with fluoroscopic visualization and proper anti-coagulation agents.Do not conduct MRI inspection while the product is in place.
- Torquing the guide catheter while kinked may cause damage that could result in separation of the catheter shaft.
- If a device becomes lodged in the guide catheter, or if the guide catheter becomes severely kinked, withdraw the 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 the guide catheter lumen.

Recommended Procedure
1. Gently remove the catheter from the pouch by grasping the hub and slowly pulling the catheter straight out of the protective tubing without bending the shaft. Inspect the catheter before use to verify that its size, shape and condition are suitable for the specific procedure.
2. Dilator Instructions (if applicable):
   - Remove dilator from protective tube.
   - Gently insert dilator into the guide catheter lumen.
   - Flush dilator with heparinized saline.
3. Prepare balloon inflation media by mixing contrast with saline (50% by volume or equivalent to 150mg/mL iodine).
4. Fill a 20 mL syringe with about 5 mL of balloon inflation media. Attach a 3-way stopcock to the balloon hub. Attach a 20 mL syringe to the stopcock.
5. Attach a 1 mL syringe to the balloon 3-way stopcock. Turn the stopcock towards the 1 mL syringe.
6. With the 20 mL syringe pointing downward:
   - Pull back on the syringe plunger to aspirate the balloon lumen. Maintain negative pressure until the air bubbles stop forming in the syringe.
   - Release the syringe plunger to allow media to be drawn into the balloon lumen. Do not infuse media.
   - Again pull back on the syringe plunger to aspirate the balloon lumen. Maintain negative pressure until air bubbles stop forming in the syringe.
   - Release the syringe plunger to allow media to be drawn into the balloon lumen. Do not infuse media.
7. Turn stopcock off towards the balloon hub. Transfer maximum recommended balloon inflation volume from the 20 mL syringe to the 1 mL syringe.
8. Inflate the balloon with the maximum recommended inflation volume. Turn stopcock off towards the balloon hub.
9. Inspect the balloon for leakage. Keep the balloon inflated until the air bubbles diffuse from the balloon. If air remains in the balloon, it should dissipate if left in a sterile field for several minutes.
10. Deflate the balloon by turning stopcock off towards the 1 mL syringe and aspirating with the 20 mL syringe.
11. After ensuring that the balloon is fully deflated, wet the distal shaft with saline and insert the balloon portion of the catheter into the inserter.
12. Gently insert the tip of the guidewire and the inserter/guide catheter assembly through the proximal valve of the introducer sheath.
13. During insertion of the catheter, when the balloon passes the sheath inducer, pull back the inserter only and peel it away from the catheter.
14. Place the guide catheter in the selected vessel using fluoroscopy.
15. Remove dilator (if applicable) and guidewire.
16. Attach a rotating hemostatic valve (RHV) to the guide catheter through-lumen hub. Flush the through-lumen with heparinized saline. Attach a 3-way stopcock to the RHV and to appropriate flush solution.
17. To inflate the balloon, transfer the maximum recommended balloon inflation volume from the 20 mL syringe to the 1 mL syringe and gently infuse the balloon inflation media with the 1 mL syringe until desired balloon diameter is attained.
18. Ensure the balloon is completely deflated before withdrawing the guide catheter.

Symbols Glossary

	Attention, See Instructions for use
	This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilization increase the risks of patient infection and compromised device performance.
LOT	Lot number
REF	Catalogue number
STERILE EO	Sterile (ethylene oxide)
	Nonpyrogenic
	Use by
CONT	Contents
Rx. Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

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