INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The 87 NeuGlide™ Catheter is a single lumen, braid and coil reinforced, variable stiffness guide catheter with a radiopaque marker at the distal tip. The catheter has an outer diameter of 0.100" (2.54 mm) and is offered in working lengths of 110 and 100 cm. The entire inner surface, and outer surfaces of the distal 61 cm of the 110 cm device, and 21 cm of the 100 cm device are coated with a lubricious hydrophilic coating. Additional dimensions are included on the device labels. The catheter has a luer hub on the proximal end. The catheter is compatible with 7F or greater introducer sheaths and 0.035" or smaller guidewires. A support catheter may also be used to assist in accessing the target vasculature. The catheter is packaged with an accessory Loading Tool. The Loading Tool is intended to be used to aid in the insertion process of the 87 NeuGlide™ Catheter into an introducer sheath.

INDICATIONS FOR USE

The 87 NeuGlide™ Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- Rx – Prescription only. Federal Law (USA) restricts this device to sale by or on the order of a physician.
- The 87 NeuGlide™ Catheter should only be used by physicians who have received appropriate training in interventional techniques and are proficient in using guide sheaths and catheters.
- Extreme caution should be used if it is required that the 87 NeuGlide™ Catheter be advanced near or through any aneurysms or other vascular malformations.
- The distal and interior surface of the catheter has a lubricious hydrophilic coating and should be hydrated per the preparation steps with heparinized saline before inserting the catheter into the patient. Failure to abide by this warning may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

PRECAUTIONS

- Use prior to the "Use By" date specified on the product package.
- This device is intended for single use only. Do not resterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Do not use if the labeling is incomplete or illegible.
- Prior to use, ensure that the dimensions (e.g. diameter and length) of the 87 NeuGlide™ Catheter and accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheter. The catheter should be hydrated through short immersion in a bath of heparinized saline and flushing with 20 cc of heparinized saline through the luer.
- Use the 87 NeuGlide™ Catheter in conjunction with fluoroscopic visualization. *Note: Sufficient shielding, reduced fluoroscopy times, and modified X-ray technical factors should be used when possible, to limit patient and physician exposure to X-ray radiation doses.*
- Exercise care when manipulating the device through tortuous anatomy. Do not advance or withdraw the 87 NeuGlide™ Catheter or accessory/adjunctive devices against resistance without careful assessment of the cause under fluoroscopy. If the cause cannot be determined, withdraw all devices as a single unit. Excessive manipulation or torquing the device against resistance may result in damage to the vasculature or the device.
- Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. The use of systematic heparinization and heparinized sterile solution should be considered.
- Maintain a constant infusion of an appropriate flush solution. If using a heparinized flush solution, care should be taken to account for the additional heparin being administered via the flush solution. Failure to do so can result in coagulopathy and excessive bleeding at the access site.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
- Use of an introducer sheath is necessary to introduce the 87 NeuGlide™ Catheter into the patient's vasculature. Attempting to introduce the catheter without this introducer can result in kinking or other damage to the device.
- Use the loading tool to cross introducer sheath valve to avoid damage to the catheter tip.
- Hemostasis valves should be appropriately used throughout the procedure to minimize blood loss. Monitoring of intra-procedural blood loss throughout the procedure should also be performed to ensure that appropriate management may be instituted as necessary.
- Do not use automated high-pressure contrast injection equipment with the 87 NeuGlide™ Catheter as it may damage the device.
- Use caution when manipulating, advancing and/or withdrawing the device through needles, metal cannulas, stents, or other devices with sharp edges, or through tortuous or calcified blood vessels. Manipulation, advancement, and/or withdrawal past sharp or beveled edges may result in destruction and/or separation of the outer coating, which may lead to clinical adverse events, resulting in coating material remaining in the vasculature or device damage. This may result in adverse events requiring additional intervention.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.

NOTE: Additional warnings and precautions are contained in the device preparation and use section.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to, the following:

- Acute occlusion, Ischemia
- Unstable angina
- Arrhythmia, including ventricular fibrillation
- Death
- Distal embolization
- Emboli
- False aneurysm formation
- Fever
- Access Site Complications (Hematoma or hemorrhage, sterile inflammation, granulomas)
- Infection, Sepsis
- Intracranial hemorrhage
- Hypotension/Hypertension
- Acute myocardial infarction
- Infarction/Necrosis
- Neurological defects including stroke
- Vessel spasm, thrombosis, dissection, perforation, rupture
- Drug reactions (e.g. coagulopathy, renal insufficiency/failure, allergic reaction)

This device is required to be used with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

DEVICE PREPARATION AND USE

1. Select an appropriate 87 NeuGlide™ Catheter based on the distance from the access site to the target anatomy. Ensure that the diameter of the 87 NeuGlide™ Catheter is appropriate for the vasculature.
2. Select an appropriate support catheter based on the dimensions of the 87 NeuGlide™ Catheter being used, the target vessel, and the surrounding anatomy to help aid in accessing the target vessel.
3. Open the product pouch and place the pouch card into the sterile field. Exercise care when removing the pouch card from the product pouch to prevent damage to the device and accessories.
4. Remove the 87 NeuGlide™ Catheter with Loading Tool from the pouch card by gently lifting the luer from the pouch card tab and removing the catheter shaft with Loading Tool from the protective tubing.
5. Connect a 20cc syringe and flush the 87 NeuGlide™ Catheter with heparinized saline.
6. Hydrate the outer surface of the 87 NeuGlide™ Catheter through short immersion in a bath of heparinized saline.
7. Inspect the 87 NeuGlide™ Catheter and accessories for kinks or other damage. **CAUTION:** *If damage is noted, do not use the device. Replace with an undamaged device.*

Use Steps for the 87 NeuGlide™ Catheter

8. Attach an RHV to the luer of the 87 NeuGlide™ Catheter.
9. Hydrate the outer surface of the 87 NeuGlide™ Catheter with heparinized saline.
10. Open the RHV and advance support catheter + guidewire (≤0.035" diameter) into the 87 NeuGlide™ Catheter until the distal tip of the support catheter is well past the distal tip of the 87 NeuGlide™ Catheter and then tighten the RHV to secure the support catheter in place. **CAUTION:** *Do not overtighten the RHV as it could deform the support catheter lumen and prevent passage of a guidewire.*
11. Insert the loading tool into the

introducer.

12. Gently insert the 87 NeuGlide™ Catheter / support catheter/guidewire assembly (device assembly) into the 7F or larger introductory sheath through the loading tool.
    Note: Follow the introducer sheath manufacturer's instructions for use when performing this step.
13. Under fluoroscopy, advance the device assembly through the introducer sheath and into the patient's vasculature using conventional catheterization techniques.
    Note: If injection through the 87 NeuGlide™ Catheter is necessary, remove the support catheter and guidewire and aspirate the 87 NeuGlide™ Catheter lumen prior to injection.
14. After gaining access to the desired vessel with the support catheter and guidewire, advance the 87 NeuGlide™ Catheter over the support catheter to the desired position.
15. Once the desired position is achieved, remove the support catheter and, if necessary, the guidewire.
16. The 87 NeuGlide™ Catheter can be used as a conduit for other interventional and diagnostic agents to access the target vascular site and distal vessels.
17. After the procedure has been completed, remove the 87 NeuGlide™ Catheter through the introducer sheath per standard procedure.
18. Discard the 87 NeuGlide™ Catheter appropriately per facility procedure.

PACKAGING

The 87 NeuGlide™ Catheter is packaged inside a protective HDPE tube and secured to an HDPE backer card. Accessories included in the catheter packaging include a Loading Tool preassembled on the catheter proximal shaft. The catheter/tube/backer card assembly is sealed in a Nylon/Tyvek pouch to maintain sterility post sterilization. The 87 NeuGlide™ Catheter is sterilized using Ethylene Oxide (EtO). The 87 NeuGlide™ Catheter will remain sterile unless the pouch is opened, damaged, or the "Use By" date has passed.

STORAGE AND HANDLING

Keep dry. Keep away from sunlight. Store at room temperature.

WARRANTY

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SYMBOLS GLOSSARY

Standard Reference: ISO 15223-1:2021(E) Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements. CFR is United States Code of Federal Regulations.

Symbol	Std Ref #	Title	Description of Symbol
	5.1.1	Manufacturer	Indicates the medical device manufacturer
	5.1.5	Batch Code	Indicates the manufacturer's batch code so that a batch or lot can be identified
	5.1.4	Use by date	Indicates the date after which the medical device is not to be used
	5.4.3	Consult instructions for use or electronic instructions for use	Indicates the need for the user to consult the instructions for use
	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	5.2.3	Sterilized by ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide
	5.6.3	Nonpyrogenic	Indicates a medical device that is non-pyrogenic
	5.2.8	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	5.4.6	Do not resterilize	Indicates a medical device that is not to be resterilized
	5.4.2	Do not reuse	Indicates a medical device that is intended for one single use only
	N/a	Contents	Indicate quantity of systems in package
	5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources
	5.3.3	Caution	Indicates the need for the user to consult the instructions for us for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture
	5.2.11	Single Sterile Barrier	Indicates a single sterile barrier system
R_x Only	21 CFR part 801.109(b)	Prescription only	Indicates "Warning: U.S. Federal Law (USA) restricts this device to use by or on the order of a physician"

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