

INSTRUCTIONS FOR USE - English SSPC1, SSPC2, SSPC3, SSPC4 Delivery Catheter

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Device Description

The Delivery Catheter is a single-use percutaneous catheter intended to introduce various types of catheters and pacing or defibrillator leads.

The Delivery Catheter is packaged with a dilator for introduction into the vasculature. Proximally, the Delivery Catheter is equipped with a hemostatic valve, and the distal tip is radiopaque to facilitate imaging under fluoroscopy. The Delivery Catheter is designed to be slittable, thereby allowing its removal after device placement. A variety of curves are available to accommodate various anatomies and different lead locations. The Delivery Catheter has an inner diameter of 6.5F, an outer diameter of 8F, and the dilator is compatible with a 0.035" guidewire.

Indications for Use

The Delivery Catheter is indicated for the introduction of various types of catheters and pacing or defibrillator leads.

Contraindications

- Obstructed or inadequate vasculature for venous access

Warnings

- Do not advance Delivery Catheter against resistance without careful assessment of the cause of resistance under fluoroscopy.
- Do not advance a lead or catheter through the Delivery Catheter against resistance without careful assessment of the cause of resistance under fluoroscopy.
- Do not remove the Delivery Catheter or a lead or catheter placed through the Delivery Catheter against resistance without careful assessment of the cause of resistance under fluoroscopy.
- Do not resterilize or reuse. Structural integrity and/or function may be impaired by cleaning, resterilization, or reuse.
- Do not expose the device to the MR Environment

Precautions

- The Delivery Catheter should be used by interventionalists experienced in performing cardiovascular procedures.
- Do not use if package is open or damaged.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories.
- Upon removal from package, inspect device to ensure no damage has occurred during shipping.
- Do not expose to solvents.
- Use in conjunction with fluoroscopic guidance and proper anti-coagulation agents.
- Ensure the catheter is thoroughly flushed and free of air prior to use.
- Care should be taken during the procedure to ensure that the hemostatic valve is not damaged and that the side port remains closed to reduce potential for air ingress or blood loss.

Complications

Possible complications include, but are not limited to, the following: exposure to x-ray radiation, adverse or allergic reactions to contrast agents, infection, hematoma, pneumothorax, embolization, vessel thrombosis, dissection, acute occlusion, clot formation, hemorrhage, vessel rupture, arrhythmia or heart block, hemodynamic changes, myocardial infarction, perforation of the heart, cardiac tamponade, stroke, and death.

Device Preparation

- Flush the Delivery Catheter with saline.
- Place the dilator in the Delivery Catheter.
- Flush the dilator with saline.

Recommended Procedure

- Obtain and verify venous access.
- Advance the Delivery Catheter and dilator together over a guidewire and to the desired location using fluoroscopy.
- Remove the dilator and guidewire.
- Advance a lead or catheter through the Delivery Catheter to the desired location using fluoroscopy. Ensure that the outer diameter of the lead or catheter is less than the inner diameter of the Delivery Catheter before attempting to introduce the lead or catheter.
Note: For leads with a mannitol capsule, it may be necessary initiate the capsule dissolution process by placing the lead tip in the catheter hub and waiting for approximately 30 seconds until the lead is able to advance freely through the Delivery Catheter.
- When a lead or catheter has been positioned in the desired location, the Delivery Catheter may be removed by slitting if it is desired to leave the lead or catheter in place. Alternatively, the Delivery Catheter may be removed without slitting following standard vascular technique.
- To slit, stabilize the lead and slitter in one hand in a fixed position. With the other hand, retract the hub of the Delivery Catheter toward the slitter and cut through hub. Continue slowly retracting the Delivery Catheter from the vessel and in line with the slitter until the entire device has been slit and removed.

Device Disposal

- After use, dispose of the catheter and packaging in accordance with hospital, administrative and/or local government policy.

Symbols Glossary

	Contents
	Maximum Usable length
	Outer diameter
	Inner diameter
	Maximum compatible guidewire outside diameter
	Model number
	Lot number
	Use by
	Non-pyrogenic
	Upper limit of temperature
	Do not expose to MR Environment
	Consult Instructions for Use
	CAUTION: Federal (USA) law restricts this device for sale by or on the order of a physician.
	Sterilized using radiation
	Do not store in direct sunlight
	Keep dry
	Do not use if package is damaged
	Do not reuse
	Do not resterilize
	Manufacturer
	Distributed by
	Sterile barrier system
	Date of manufacture

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