SSPC NXT Delivery Catheter

Models SSPC NXT 2.5, and SSPC NXT Y

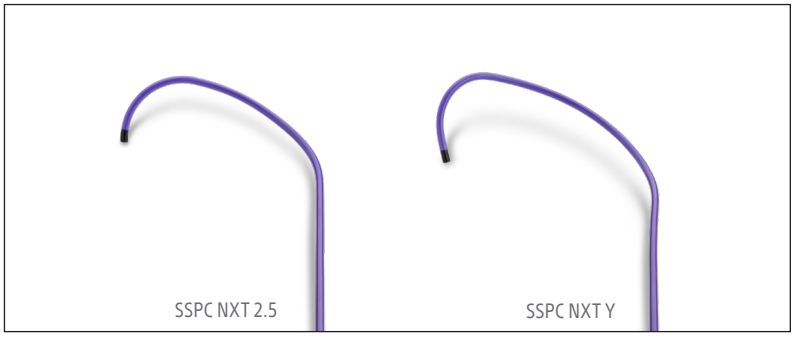
The SSPC NXT or Site Selective Pacing Catheter NXT family are next-gen lead delivery catheters built to complement the SSPC portfolio. SSPC NXT are single-use percutaneous catheters intended for the venous introduction of pacing or defibrillation leads.

SSPC NXT catheters are designed to feature increased catheter stability, a larger inner diameter of 7 Fr, a 42cm length, and additional shapes to target right ventricular locations, inclusive of the left bundle branch area.

The SSPC NXT 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. Two new shapes are available to accommodate various anatomies and different lead locations. The delivery catheter has an inner diameter of 7 Fr, an outer diameter of 9 Fr, and the dilator is compatible with a 0.035" guidewire.

Delivery Catheter Specifications

Working Length	42cm
Outer Diameter	9 Fr Compatible with 9 Fr Introducer
Inner Diameter	7 Fr
Tip	Radiopaque Allows visualization of tip of catheter and lead under fluoro
Hub	White hub with hemostatic seal and side flush port
Cutter	Universal cutter is packaged separately
Dilator & Guide Wire	Dilator is packaged with SSPC NXT Catheter Compatible with 0.035" guide wire – packaged separately



Name	Boston Scientific Model Number	Description
SSPC NXT 2.5	669286-100	Standard-Designed for standard RV septal locations
SSPC NXT Y	669287-100	Extended Reach-Designed for standard and dilated RV septal locations

SSPC NXT Delivery Catheter

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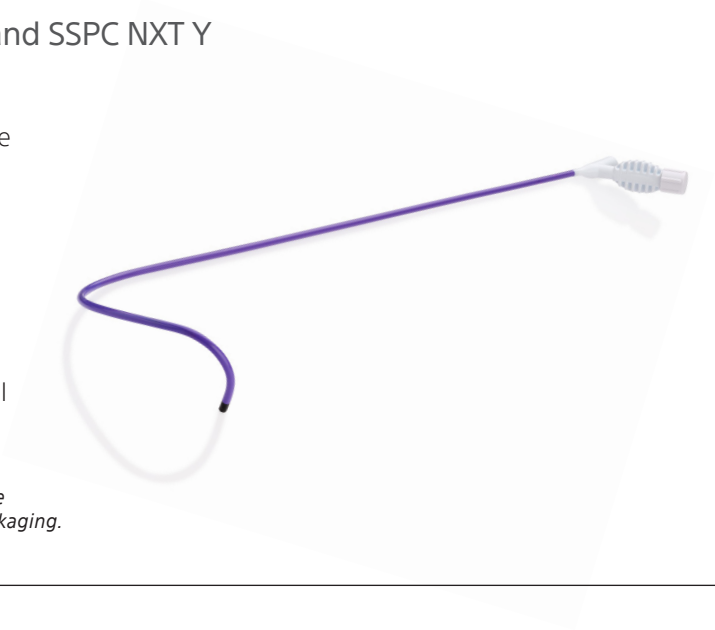
- Packaged with dilator for introduction into vasculature
- Equipped proximally with hemostatic valve
- Radiopaque distal tip to facilitate imaging under fluoroscopy
- Designed to be slit-able, thereby allowing its removal after device placement



Universal Cutter and .035'' guide wire are not included in the SSPC NXT packaging.

INTENDED PURPOSE / INDICATIONS FOR USE
The Delivery Catheter is intended for the venous introduction of pacing or defibrillation leads.

CONTRAINDICATIONS
Obstructed or inadequate vasculature for venous access

WARNINGS
Carefully read all instructions prior to use of this product. Observe all warnings and precautions, failure to do so may result in complications.
- Do not advance Delivery Catheter against resistance without careful assessment of the cause of resistance under fluoroscopy.
- Do not advance a lead 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 placed through the Delivery Catheter against resistance without careful assessment of the cause of resistance under fluoroscopy.
- Do not use if labeling is incomplete or illegible.
- Do not use if the package is open or there is any evidence of package or catheter damage.
- For single use/single procedure only. Do not reuse, reprocess, or resterilize. Such may cause failure of the tool and/or infection or cross-contamination.
- Do not expose the device to the MR environment. Testing has not been performed to establish safe use in this environment.

PRECAUTIONS
- Read these instructions and consult the literature provided by the lead manufacturer prior to use.
- Care should be taken to consider vessel size and other relevant aspects of patient anatomy relative to the specified size and shape of the selected Delivery Catheter.
- Inspect the device and its packaging prior to use. Do not use if damage is detected. Breaks or deformations could interfere with the proper function of the device.
- Use the device prior to the by "Use by date" noted on the product label.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories.
- Do not expose to solvents.
- Use in conjunction with fluoroscopic guidance and proper anticoagulation 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.

POTENTIAL ADVERSE EVENTS
Vessel trauma may result from the use of this device. Follow the enclosed directions carefully. Other potential adverse reaction that may result from the use of this device include but are not limited to: Possible complications associated with the Delivery Catheter include delay in procedure, vessel trauma, endocardial trauma, air ingress, blood loss, embolization (material, air), allergic reaction, lead dislodgement, infection, device incompatibility, incomplete therapy.

Possible complications associated with the use of ancillary devices with the Delivery Catheter include: • Air embolism • Bleeding • Bradycardia • Breakage/failure of the implant instrument • Cardiac perforation • Cardiac tamponade • Chronic nerve damage • Death • Extracardiac stimulation (muscle/nerve stimulation) • Hematoma • Heart block • Hemothorax • Incisional pain • Infection including endocarditis • Lead dislodgement • Myocardial infarction • Myocardial trauma • Pericardial effusion • Pericarditis • Pleural Effusion • Pneumothorax • Stroke • Tachyarrhythmias • Thrombosis/thromboemboli • Valve damage • Venous occlusion • Venous trauma (e.g., perforation, dissection, erosion)

Any serious incident that occurs in relation to this device should be reported to CenterPoint Systems LLC and the relevant local regulatory authority.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.
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The SSPC Delivery Catheters are manufactured by CenterPoint Systems.

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Made in US