

# SSPC Delivery Catheter

Models SSPC1, SSPC2, SSPC3 and SSPC4

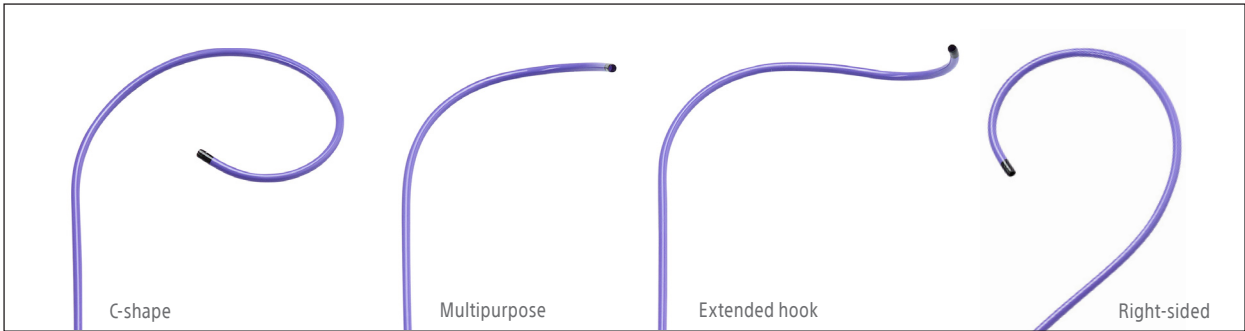
The SSPC or Site Selective Pacing Catheter family are single-use percutaneous catheters intended to introduce various types of catheters and pacing or defibrillator leads.

The SSPC 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.

## Delivery Catheter Specifications

Working Length	40 cm
Outer Diameter	8Fr Compatible with 8Fr introducer
Inner Diameter	6.5Fr Accommodates FINELINE™ II Sterox EZ Model 4471 58 cm active fix and INGEVITY™+ Model 7842 59 cm active fix pacing leads
Tip	Radiopaque Allows better visualization of tip of catheter and lead under fluoro
Hub	Hemostatic seal Side flush port
Cutter	Universal cutter is packaged separately
Dilator & Guide Wire	Dilator is packaged with SSPC Catheter Compatible with 0.035" guide wire – packaged separately

*Note: Ensure that the outer diameter of the lead delivered is less than the inner diameter of the SSP Catheter (< 6.5F) prior to attempting to introduce the lead or catheter into the vein.*

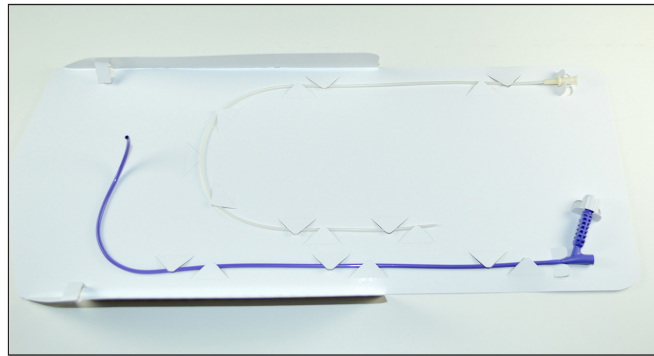


Name	Boston Scientific Model Number	Description
SSPC1	669181	“C-shape” designed for RA septal locations
SSPC2	669182	“Multipurpose” designed for RA and RV septal locations
SSPC3	669183	“Extended hook” designed for dilated RA and RV septal locations
SSPC4	669184	“Right sided” designed for right sided venous access to RA septal locations

# SSPC Delivery Catheter

## Models SSPC1, SSPC2, SSPC3 and SSPC4

- 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 packaging.*

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

### SSPC1, SSPC2, SSPC3, SSPC4 Delivery Catheter

#### 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 Deliver 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 Deliver Catheter or a lead or catheter placed through the Deliver 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, resterilisation, 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.

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The SSPC Delivery Catheters are manufactured by CenterPoint Systems.

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1. When Conditions of Use are met.

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CRM-650502-AB