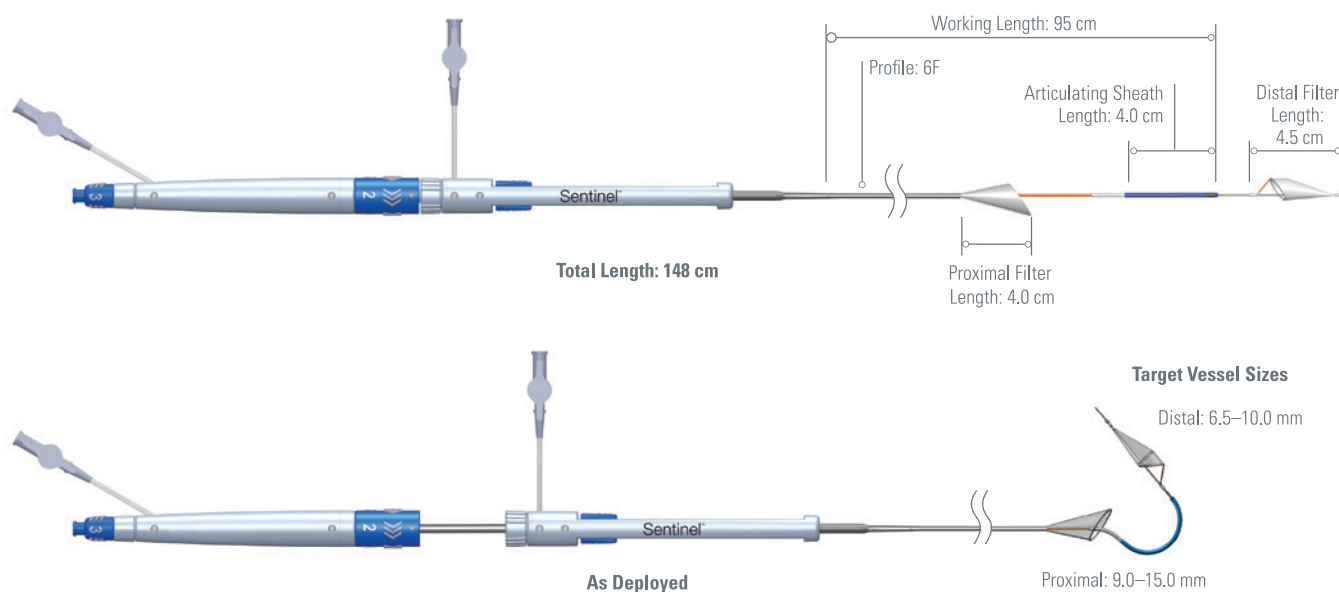


SENTINEL™
 Cerebral Protection System

Product Overview

Product Description

A percutaneously delivered dual-filter protection device, designed to capture and remove debris dislodged during TAVI procedures. SENTINEL delivers a Proximal Filter to the brachiocephalic artery, and a Distal Filter to the left common carotid artery. At procedure completion, the filters and debris are recaptured into the catheter and removed from the patient.

SENTINEL CPS Specifications

| | |
|--------------------------------|--|
| Indications for Use | The SENTINEL System is indicated for use as an embolic protection device to capture and remove embolic material (thrombus/debris) that may enter the cerebral vascular system during endovascular procedures.* |
| Access Route | Right Radial Access Only (6F Radial Access Introducer Sheath) |
| Deployment Procedure | Sequential Filter Deployment and Retrieval |
| Guidewire Compatibility | 0.35 mm (0.014") Diameter Floppy Tip Coronary Guidewire, 175 cm Minimum Length |
| Use | Single Use |
| Sterilization | E-beam Radiation |
| Carton Size | 61.55 in x 1.05 in x 3.55 in |
| Shelf Life | 2 Years |
| Storage Information | Store at room temperature |

Ordering Information

| SENTINEL™ CPS System | | | |
|----------------------|--------------------|-------------------------------------|-------|
| Order Number (GTIN) | Ref/Catalog Number | Description | Units |
| 00863229000028 | CMS15-10C | SENTINEL Cerebral Protection System | 1 |

Accessory and Preparation Overview

Recommended Guidewires (0.014" in diameter and 180 / 300 cm in length)

- Boston Scientific Choice™ PT Extra Support
- Abbott Asahi Grand Slam™
- Abbott Asahi Prowater™
- Abbott Hi-Torque Balance: Middleweight™ or Heavyweight™
- Abbott Extra S'Port™
- Abbott Whisper Extra Support™

DO NOT USE a guidewire with excessive stiffness that may alter shape of the Articulating Sheath curve and make cannulation of the left common carotid difficult.

DO NOT USE a guidewire with an intermediate coil as this may result in compromised guidewire movement.

Recommended Sheath

- Radial Sheath 6F Terumo Glidesheath™: Regular or Slender

Additional Accessories

- Berenstein / JR-4 Catheter (hockey stick) (90 cm – 130 cm)
- 0.035" J-wire (exchange length)
- 0.035" Terumo Glidewire™ Guidewire (exchange length; stiff-angled or straight)
- Wire Torquer Device
- Vasodilating / anti-vasospasm medication per institutional / physician preference
- Syringe, 10 cc Locking
- Basin large enough to hold ~1.5-2" saline depth
- Debris Strainer / Debris Filter

The image displays the product labeling for the SENTINEL™ CPS System. The main label includes the following information:

- Model Number for Ordering:** CMS15-10C
- Product Expiration Date:** YYYY-MM-DD
- GTIN:** 00863229000028
- LOT:** 12345678
- REF:** CMS15-10C
- Use By:** 2010-12-31

Below the main label are three UDI labels, each containing the following information:

- UDI Product Code:** 00863229000028
- Expiration:** YYMMDD
- Lot Number:** 12345678

At the bottom of the labeling is a CE mark label with the following information:

- CE 2797**
- Made in USA**
- 1745 Copperhill Parkway, Suite 1**
- Santa Rosa, CA 95403 USA**

To view full product information, visit bostonscientific.eu/SENTINEL

* See Instructions for Use (IFU) for details.

All trademarks are property of their respective owner. CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device. Information for use only in countries with applicable health authority product registrations. Information not for use or distribution in France.

SH-1767102-AA Printed in Germany by medicalvision

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DINSH0181EF