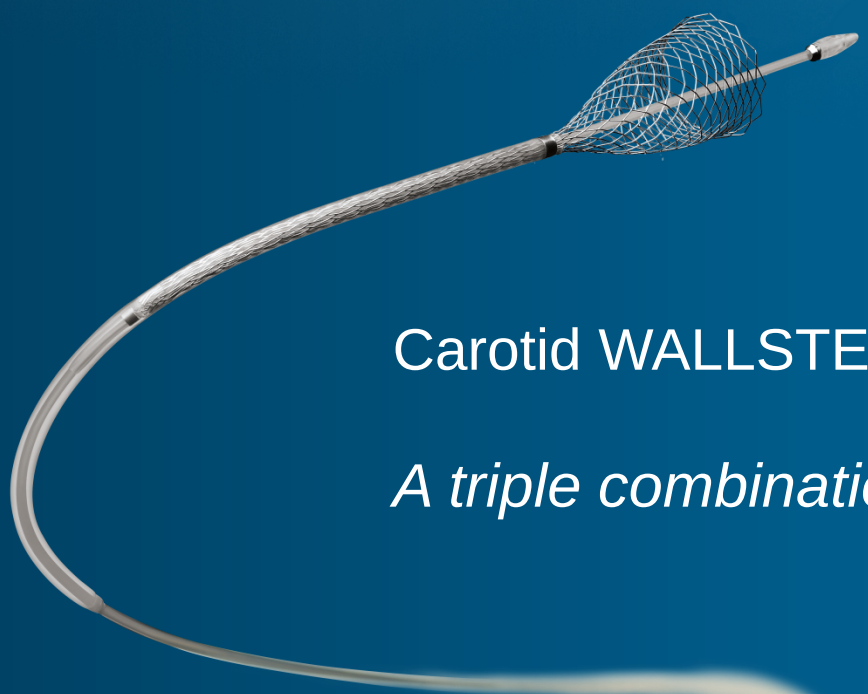

Carotid WALLSTENT® Endoprosthesis

A triple combination for stroke risk reduction

In-Service Presentation

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 labelling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Indications, operating specifications and availability may vary by country. Check with local product representation and country specific Information For Use for your country.
This material is not approved for use or distribution in France

IMPORTANT INFORMATION

These materials are intended to describe common clinical considerations and procedural steps for the on-label use of referenced technologies as well as current standards of care for certain conditions.

Of course, patients and their medical circumstances vary, so the clinical considerations and procedural steps described may not be appropriate for every patient or case.

As always, decisions surrounding patient care depend on the physician's professional judgment in light of all available information for the case at hand.

BSC does not promote or encourage the use of its devices outside their approved labeling.

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

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Carotid WALLSTENT® Endoprosthesis

Boston Scientific's closed cell carotid stents have the triple combination engineered for safe and effective carotid stenting: Optimal Scaffolding, Cell Design and Radial Force

Presentation Contents:

- Stent Design
- Product Specs
- Sizing
- Deployment Technique

Carotid WALLSTENT® Endoprosthesis Indications and Contraindications

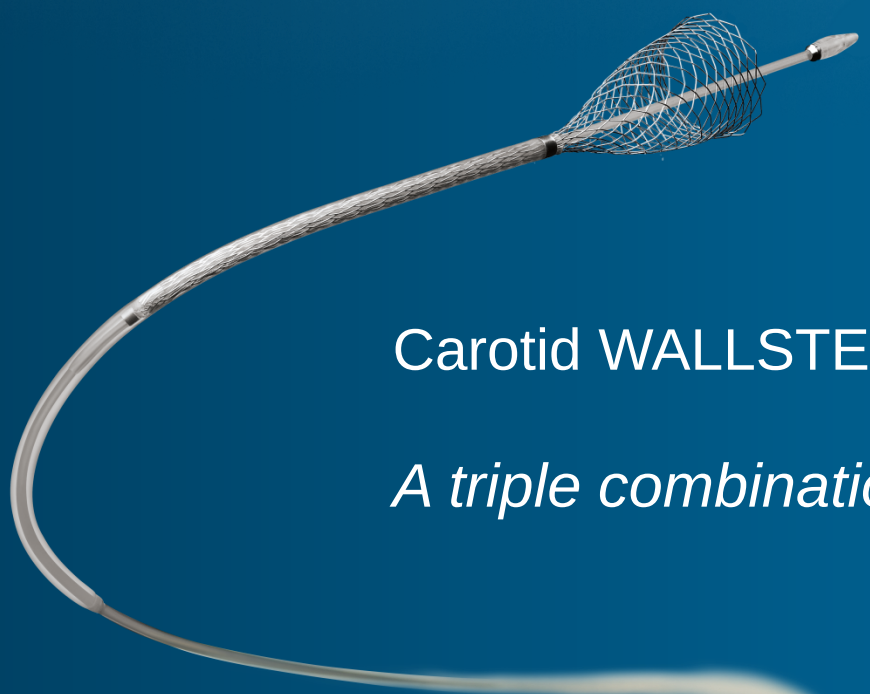
Indications

For the treatment of patients at high risk for adverse events from carotid endarterectomy due to either anatomic or comorbid conditions who require carotid revascularization in the treatment of ipsilateral or bilateral carotid artery disease and meet the criteria outlined below:

- Patients with neurological symptoms and ≥50% stenosis of the common, internal carotid artery and/or the bifurcation by ultrasound or angiogram OR
- Patients without neurological symptoms and ≥80% stenosis of the common, internal carotid artery and/or the bifurcation by ultrasound or angiogram, AND
- Patients with a reference vessel diameter within the range of 4.0mm and 9.0mm at the target lesion

Contraindications

- Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of a guide catheter, sheath, embolic protection system or stent system
- Patients with uncorrected bleeding disorders
- Lesions in the ostium of the common carotid artery
- Patient Selection: In addition to the contraindications described above, there are a number of patient characteristics with respect to which the safety and efficacy of this device have not been established. Please review the full product directions for use for more information on those particular patient characteristics



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Carotid WALLSTENT® Endoprosthesis

A triple combination for stroke risk reduction

Stent Design

Carotid WALLSTENT® Endoprosthesis Device Description

- **Stent**
  - A closed cell design self-expanding stent composed of wires braided in a tubular mesh configuration
  - The wire is composed of biomedical grade cobalt-chromium-iron-nickel-molybdenum alloy (commonly known as Elgiloy®) containing an enhanced radiopaque tantalum core

- **Stent Delivery System**
  - Monorail™ Catheter Design, 0.014” guide wire compatible Delivery System
  - 5F (6 & 8 mm) and 6F (10 mm) low profile, highly flexible

- **Highly Deliverable**
  - Highly flexible stent delivery system provides excellent tracking through tortuous anatomy

Carotid WALLSTENT® Endoprosthesis

Closed Cell Design

- Increased scaffolding promotes excellent **lesion coverage**, smooth inner lumen, plaque containment, angiographic results and easy embolic protection device retrieval*

Ease of Use

- Low-profile, 5F or 6F
- Flexibility
- Pin-and-pull delivery system

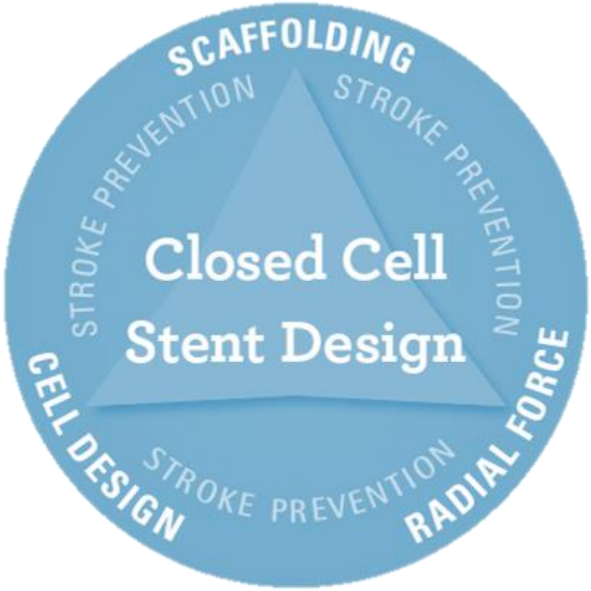
Designed to Facilitate Accurate Stent Placement

- Excellent **radiopacity**
- Unique ability to be reconstrained* when as much as 50% deployed allows repositioning for accurate stent placement*

**Please note that reconstrainment and repositioning are subject to specific limitations. Please refer to DFU cautions and warnings for additional information*

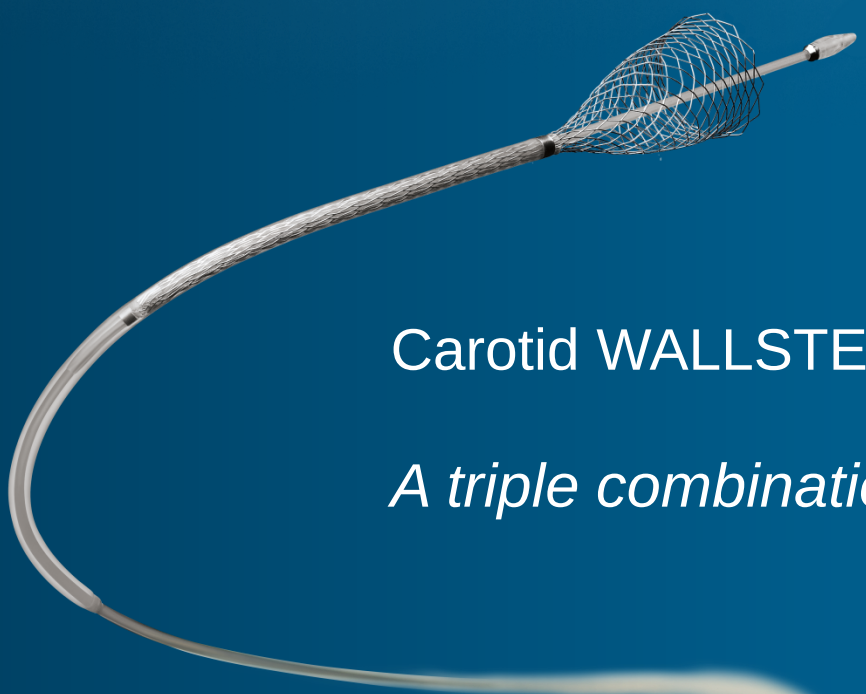
Carotid WALLSTENT® Endoprosthesis
A triple combination for stroke prevention

Maximum lesion coverage through reduced free cell area.



Fully connected or overlapped stent struts creating a smooth inner surface.

Optimal outward force to maintain lumen integrity and reduce adverse clinical events, such as hypotension.



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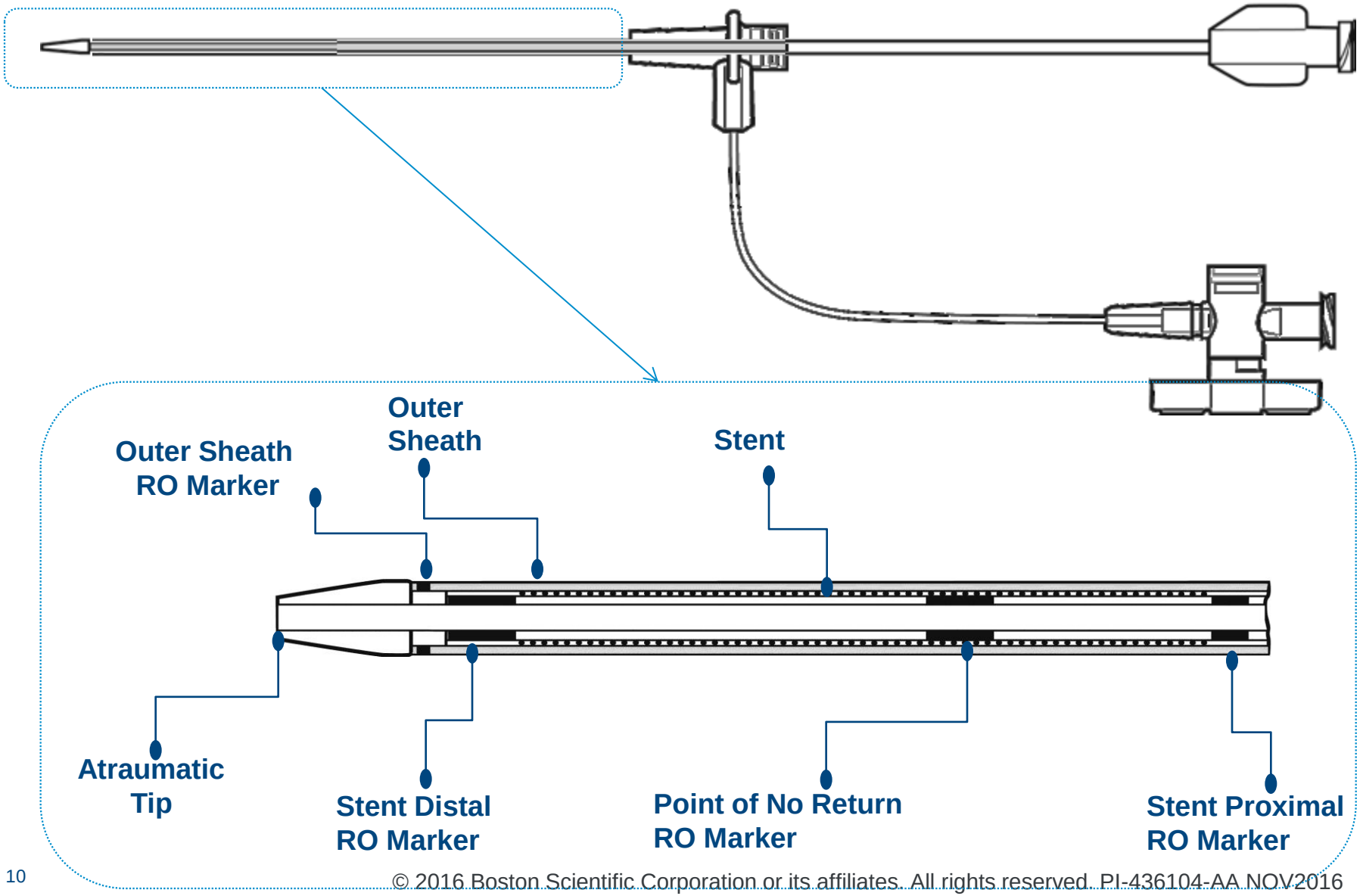
Carotid WALLSTENT® Endoprosthesis

A triple combination for stroke risk reduction

Product Specs

Carotid WALLSTENT® Endoprosthesis Schematic

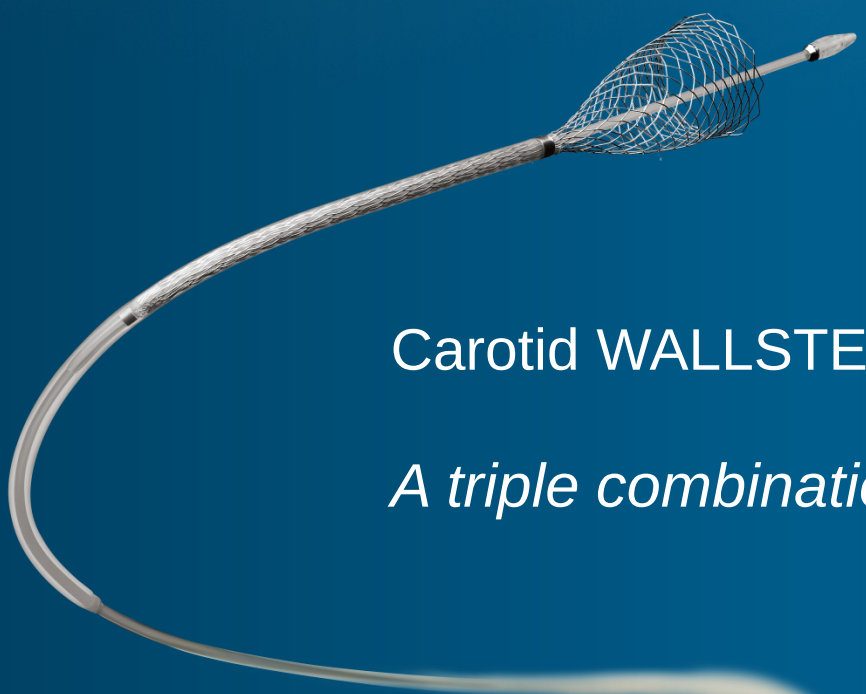


Carotid WALLSTENT® Endoprosthesis
Stent Sizes

Three Diameters (unconstrained): 6, 8 and 10 mm

Fully Open		Stent Size Implanted in vessel				Delivery System	
Stent Diam (mm)	Stent Length (mm)	Vessel Diam. (mm)	Stent Length (mm)	Vessel Diam. (mm)	Stent Length (mm)	Recom. Intro Sheath (F)	Cath. Size (F)
6	22	5	30	4	36	5	7
8	21	7	30	6	36	5	7
8	29		40		48		
8	36		50		62		
10	24	9	30	8	36	6	8
10	31		40		49		
10	37		50		59		

0.014'' guide wire compatible
135 cm working length



Carotid WALLSTENT® Endoprosthesis

A triple combination for stroke risk reduction

Stent Sizing

Carotid WALLSTENT® Endoprosthesis Stent Sizing

Select the Size Based On

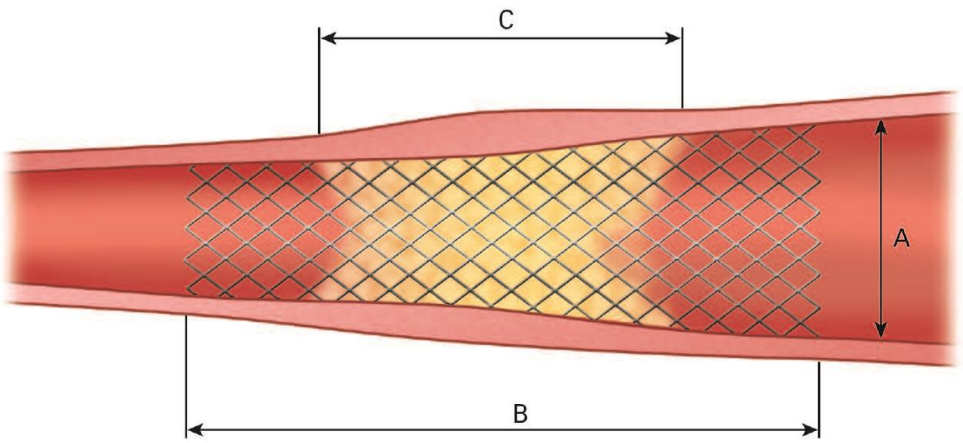
- Diameter of the largest artery adjacent to the stenosis
- Length of the segment to be stented

Sizing Considerations

- The unconstrained diameter of the Carotid WALLSTENT Endoprosthesis should be at least 1 to 2 mm larger than the diameter of the largest artery to be stented
- Stent should overlap healthy tissue by at least 5mm on each side of the lesion

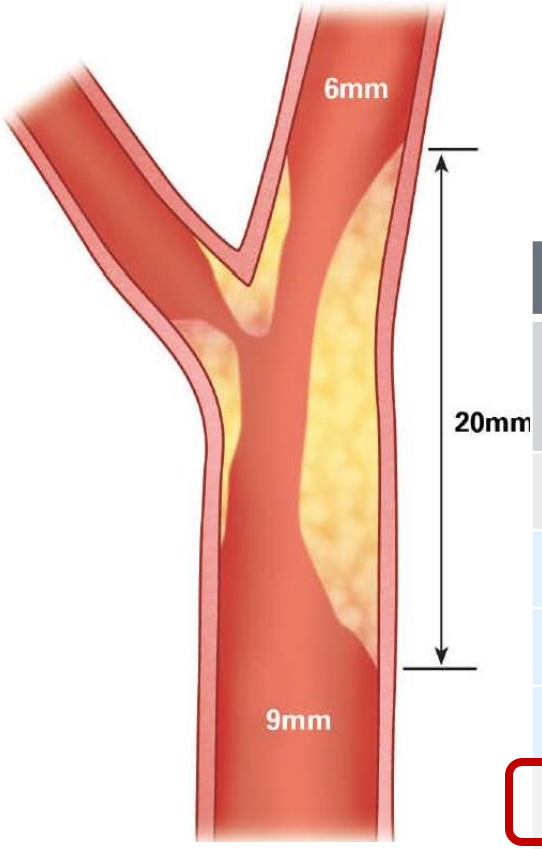
Unconstrained stent diameter mm = Vessel diameter (a) + 1 or 2mm

Stent length (b) = Lesion length (c) + 10mm (5mm per side)



Warning: Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration

Carotid WALLSTENT® Endoprosthesis Learning Exercise

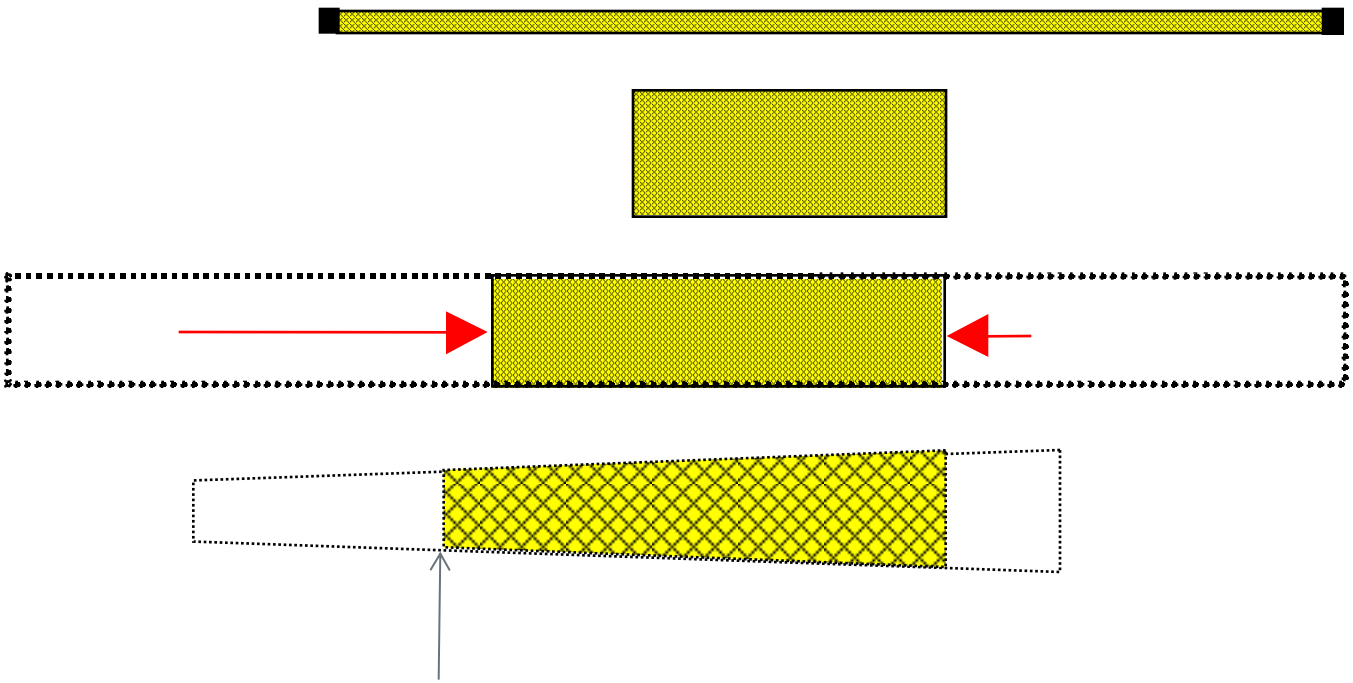


- What stent diameter do you want? 1
  10mm unconstrainted diameter
- What stent length do you want? 2
  30mm implanted length
- Which stent do you chose?
  10x24mm

Fully Open		Stent Size Implanted in vessel				Delivery System	
Stent Diam (mm)	Stent Length (mm)	Vessel Diam. (mm)	Stent Length (mm)	Vessel Diam. (mm)	Stent Length (mm)	Intro Sheath (F)	Cath. Size (F)
6	22	5	30	4	36	5	7
8	21	7	30	6	36	5	7
8	29		40		48		
8	36		50		62		
10	24	9	30	8	36	6	8
10	31		40		49		
10	37		50		59		

Carotid WALLSTENT® Monorail® Endoprosthesis Stent Sizing

Fully Open		Stent Size Implanted in vessel				Delivery System	
Stent Diam (mm)	Stent Length (mm)	Vessel Diam. (mm)	Stent Length (mm)	Vessel Diam. (mm)	Stent Length (mm)	Intro Sheath (F)	Cath. Size (F)
10	24	9	30	8	36	6	8



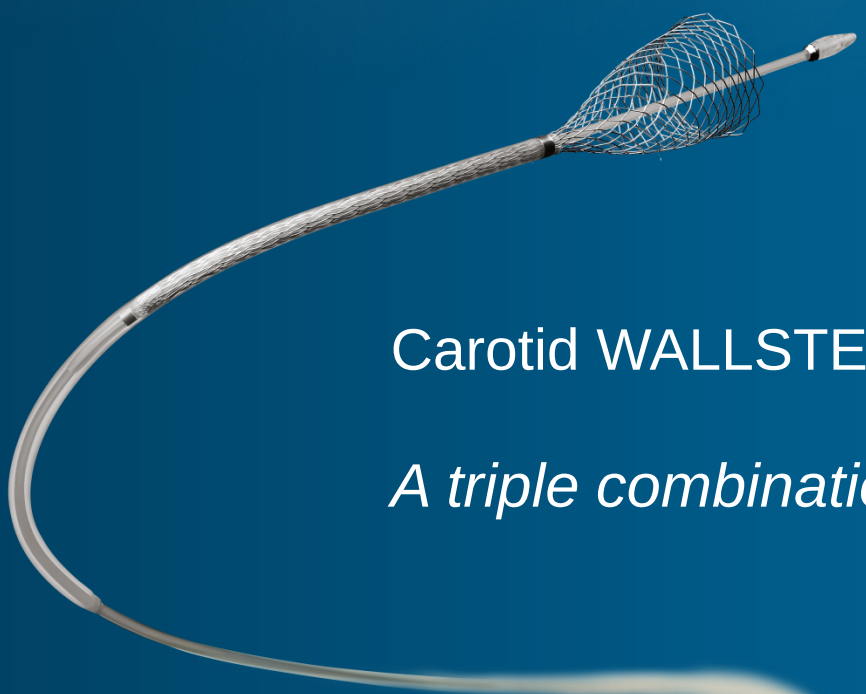
Stent mounted on delivery catheter

Fully open stent: 10mmx24 mm

Stent implanted in 9 mm vessel: 30 mm

Stent implanted in vessel of varying diameter

If the vessel is tapering to smaller diameter the stent can adapt to a longer length



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Carotid WALLSTENT® Endoprosthesis

A triple combination for stroke risk reduction

Deployment Technique

IMPORTANT INFORMATION

- Please note that this in-service presentation is intended to supplement to and not a substitute to the detailed information provided in the full product instructions for use.

- Please carefully read all product instructions prior to using this device and observe all warning and precautions noted in those materials as failure to do so may result in complications

Carotid WALLSTENT® Endoprosthesis Inspection Prior to Use

Carefully remove the Carotid WALLSTENT Monorail Endoprosthesis from its packaging and place it uncoiled on the steriled field.

Do not remove the packaging stylus from the inner lumen. Visually inspect the entire Carotid WALLSTENT Monorail Endoprosthesis for damage and check that the stent and the distal radiopaque marker are fully covered by the distal end of the outer sheath

Caution: The delivery system has an internal hypotube. Take care to avoid unnecessary handling, which may kink or damage the delivery system. Do not use if the device is kinked.

Caution: Special care must be taken not to handle or in any way disrupt the stent on the delivery system. This is most important during catheter removal from packaging, stylus removal, placement over the guidewire and advancement through a hemostatic valve and guiding catheter or guiding sheath hub.

Caution: Do not remove the stent from its delivery system as removal may damage the stent. The stent on the delivery system is intended to perform as a system. If removed, the stent cannot be put back on the delivery system.

Carotid WALLSTENT® Endoprosthesis
Preparation: 3 flushes

- Attach a 5-ml syringe filled with **sterile heparinized saline** to the T-connector and vigorously inject the saline into the annular space **between the coaxial inner shaft and outer sheath** until the fluid comes **out of the guidewire hole**

- Clamp the device between the fingers covering the guidewire hole and continue flushing until the saline solution comes **out of the catheter tip and the outer sheath at the distal marker**. If necessary, refill the syringe.

- Hold the distal tip of the delivery system and gently remove the packaging stylus. If the packaging stylus does not remove easily, do not use the device. **Flush again after removal of packaging stylus** and observe saline **exiting distal tip**.

Caution: Do not expose the delivery system to organic solvents (e.g., alcohol) as structural integrity and/or function of the device may be impaired.

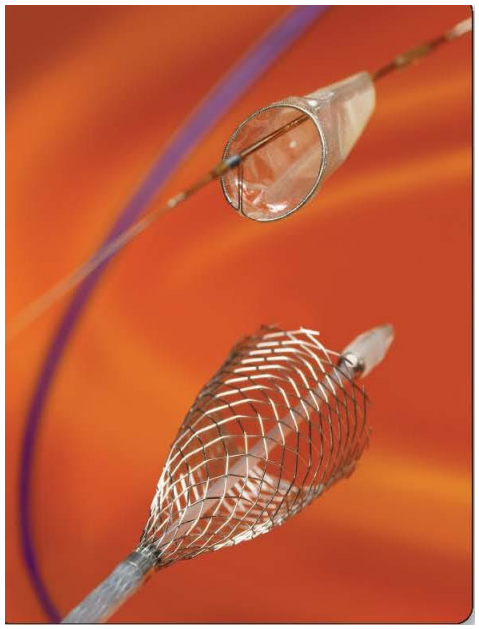
Caution: Ensure the stent delivery system is fully flushed with heparinized saline prior to use. Do not use if saline is not observed exiting the distal end of the outer sheath.

Caution: Do not hold the outer sheath where the stent is present during stylus removal.

Embolic Protection System Preparation and Delivery

The Carotid WALLSTENT Monorail Endoprosthesis should be used in conjunction with a Boston Scientific carotid embolic protection system.

Please refer to the Directions for Use included with the embolic protection system for information on device preparation and placement.



Warning: If a filter-based embolic protection system is used, allow for and maintain adequate distance between the filter and the stent delivery system or deployed stent to avoid potential entanglement. If filter basket entanglement or basket detachment occurs, surgical conversion may be needed.

Lesion Preparation

Warning: Maintain an Activated Clotting Time (ACT) of ≥ 275 seconds (≥ 200 seconds if using GP IIb/IIIa inhibitors) to prevent thrombus formation on the devices.

Caution: Venous access should be available during carotid stenting to manage bradycardia and/or hypotension by either pharmaceutical intervention or placement of a temporary pacemaker, if needed.

Warning: The use of a guiding sheath or guiding catheter with a fixed hemostasis valve may cause the embolic protection device filter membrane to tear at the hemostasis valve upon removal.

Caution: When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed.

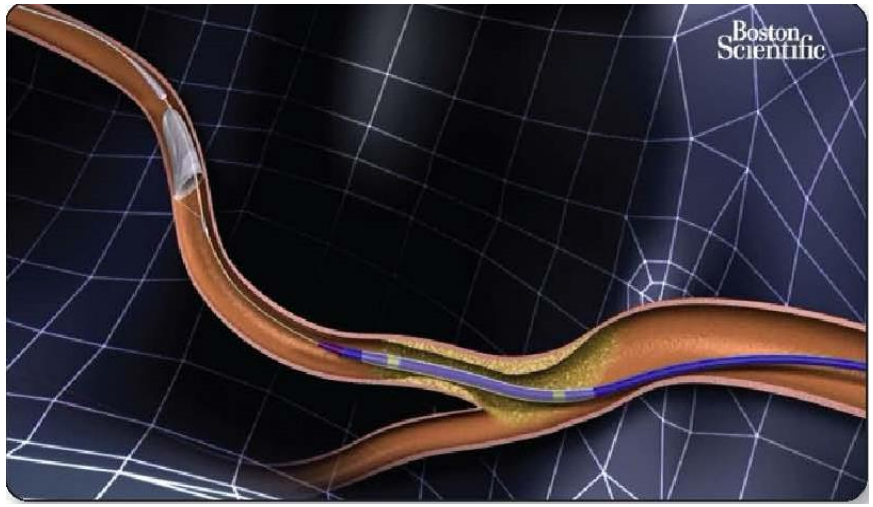
Warning: To minimize the possible introduction of air into the delivery system, it is important to maintain tight catheter connections and to thoroughly flush the delivery system.

Warning: Maintain continuous flush while removing and inserting devices on the guidewire. Perform all exchanges slowly to prevent air embolism or trauma to the artery.

Note: If no pre-dilatation is performed, there must be an adequate luminal opening to enable passage of the stent delivery system.

Lesion Preparation

- Define the largest artery diameter and the proximal and distal limits of the stenosis.
- Use the selected guiding catheter or guiding sheath.
- If needed, pre-dilate the lesion with an appropriate size balloon dilatation catheter *(example: Sterling® Monorail® Balloon Catheter)*



- Maintain the embolic protection system wire position across the stenosis and withdraw the balloon dilatation catheter. Do not remove the guiding catheter or guiding sheath.

Delivery

- After the pre-dilatation catheter has been removed, backload the Carotid WALLSTENT™ Monorail™ Endoprosthesis over the 0.014 in (0.36 mm) embolic protection system wire.
- When advancing (or retracting in emergency situations) the Carotid WALLSTENT Monorail Endoprosthesis and during deployment, loosen the hemostatic valve of the introducer to allow easy movement.
- Maintain the stent delivery system as straight as possible outside the body removing all slack.

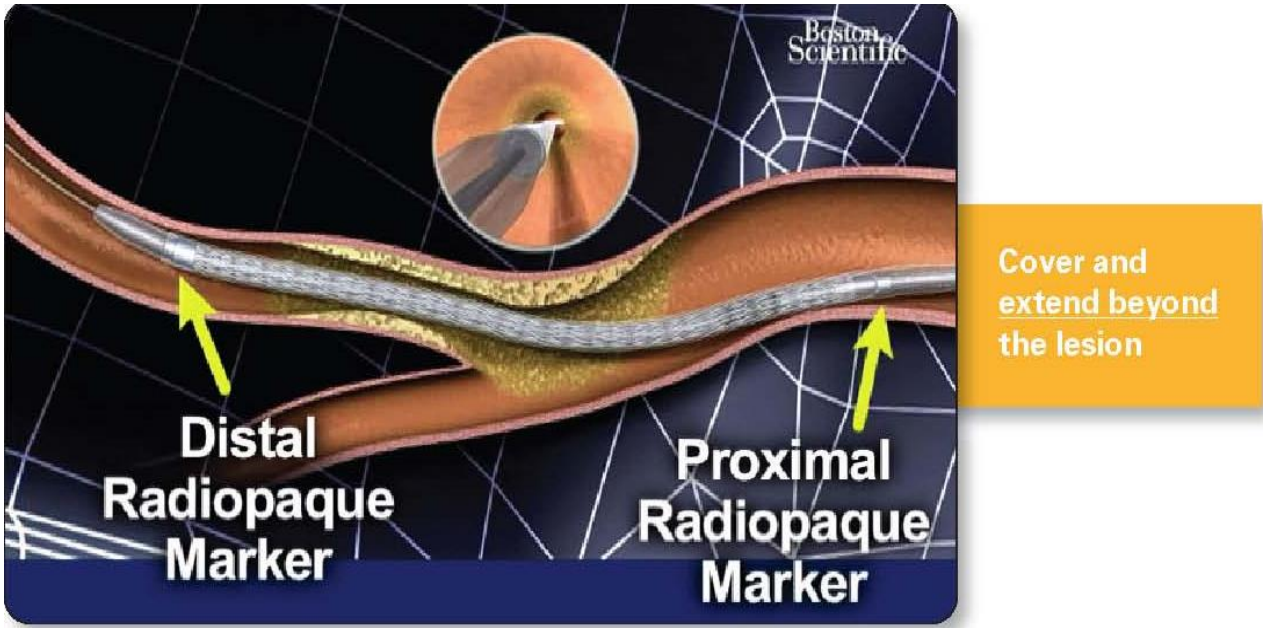
Caution: For best device performance, the inner and outer shaft guidewire holes (13, 14 in Figure 1) should remain within the guiding catheter or sheath.

Caution: The delivery system is not designed for use with power injection. Use of power injection may adversely affect device performance.

Caution: If the shaft kinks during preparation of the Carotid WALLSTENT Monorail Endoprosthesis or its insertion over the guidewire, remove the device and use another one.

Delivery

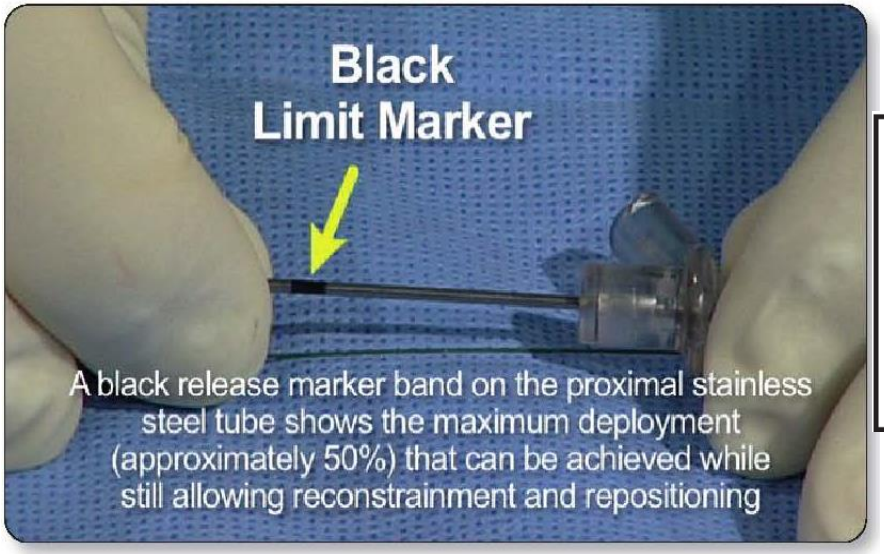
As the Carotid WALLSTENT Endoprosthesis deploys, it shortens from both ends towards the middle. Therefore, place the proximal and distal radiopaque markers of the inner shaft overlapping both edges of the stenosis.

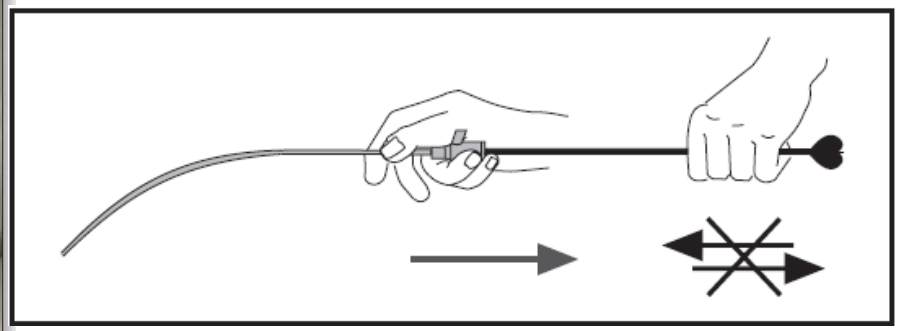


Immobilize the stainless steel tube and confirm stent position angiographically.

Deployment

Deploy the Carotid WALLSTENT Endoprosthesis stepwise a few millimeters at a time by sliding the T-connector gently towards, but not past, the black limit marker until the Carotid WALLSTENT Endoprosthesis is approximately 50% deployed.

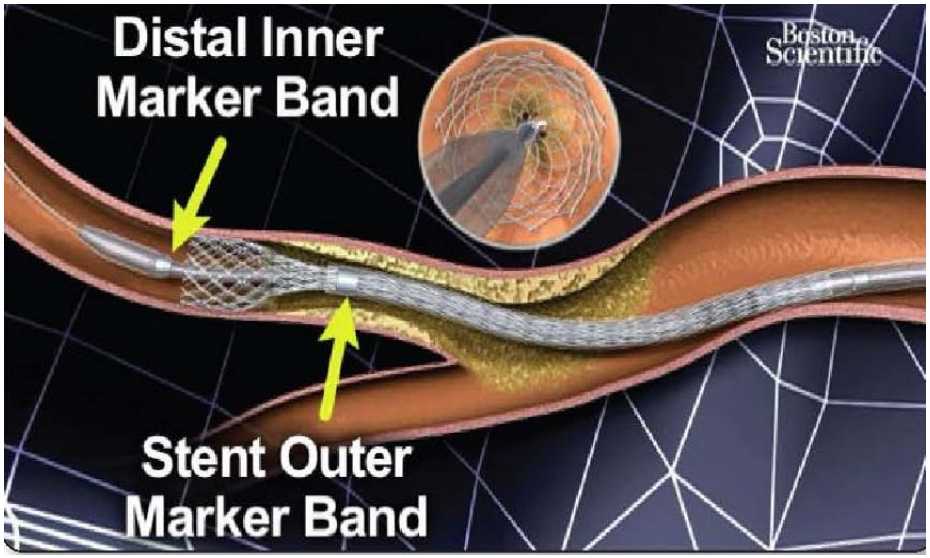




Caution: Do not push the stainless steel tube!

Deployment

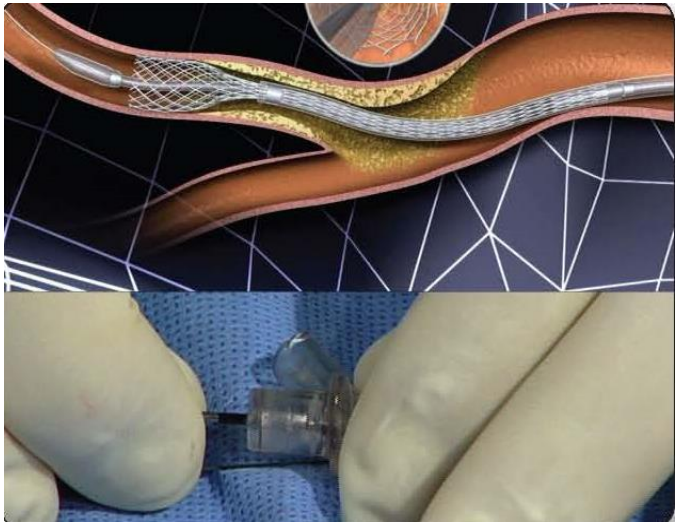
During deployment the radiopaque marker on the outer sheath is retracted from the distal marker, which allows fluoroscopic control of the Carotid WALLSTENT Endoprosthesis release.



Caution: Do not push the stainless steel tube!

Deployment

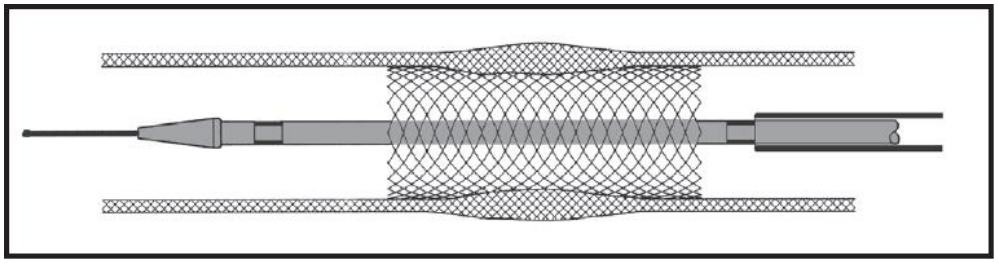
- Check position of the partially deployed Carotid WALLSTENT Endoprosthesis within the stenosis.
- Contrast medium can be injected through the guiding catheter or guiding sheath, if desired.
- If the Carotid WALLSTENT Endoprosthesis does not need to be repositioned, continue with final deployment.

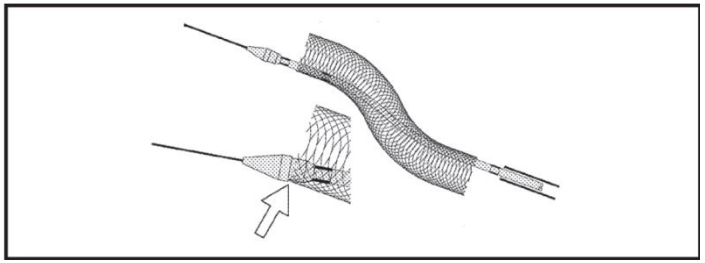


Caution: Do not push the stainless steel tube!

Deployment

- Immobilize the stainless steel tube once again.
- When the Carotid WALLSTENT Endoprosthesis is in its final position, gently slide the T-connector on the immobilized stainless steel tube towards the heart shaped hub, until complete deployment of the Carotid Endoprosthesis.
- After full Carotid WALLSTENT Endoprosthesis deployment, carefully remove the stent delivery system under fluoroscopic guidance, leaving the embolic protection system in place.





Caution: If the tip catches on the distal stent filaments upon removal of the stent delivery system, free the tip with gentle movements!

Note: Balloon dilatation with an undersized balloon inside the Carotid WALLSTENT™ Monorail™ Endoprosthesis is recommended.

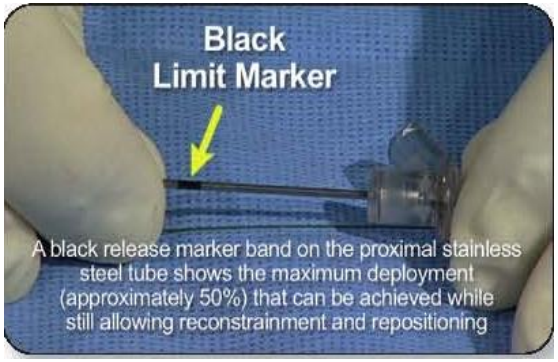
Caution: When more than one stent is required to cover the lesion or if there are multiple lesions, the distal lesion should be stented first, followed by stenting of the proximal lesion allowing a minimal overlap of at least 5 mm.

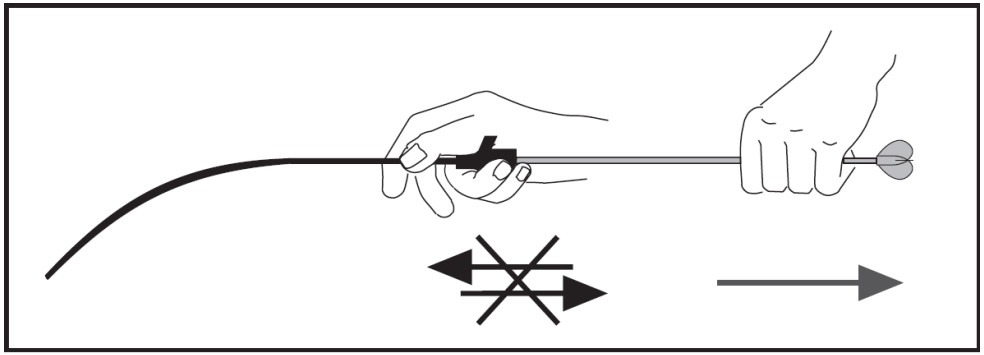
Caution: Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting stent placement.

Warning: Overstretching of the artery may result in rupture and life threatening bleeding.

Stent Repositioning
Only When Absolutely Necessary!

- Reconstrainment and repositioning of the Carotid WALLSTENT Endoprosthesis should be strictly avoided when the partially deployed Carotid WALLSTENT Endoprosthesis is already in contact with the plaque of the stenosis.
- Repositioning of a partially deployed Carotid WALLSTENT Endoprosthesis is possible if the stent has not been deployed past the limit marker.
- Immobilize the T-connector and carefully pull back the stainless steel tube, reconstraining the Carotid WALLSTENT Endoprosthesis into the outer sheath.
- Position the Carotid WALLSTENT Endoprosthesis appropriately across the lesion and commence deployment steps outlined earlier.

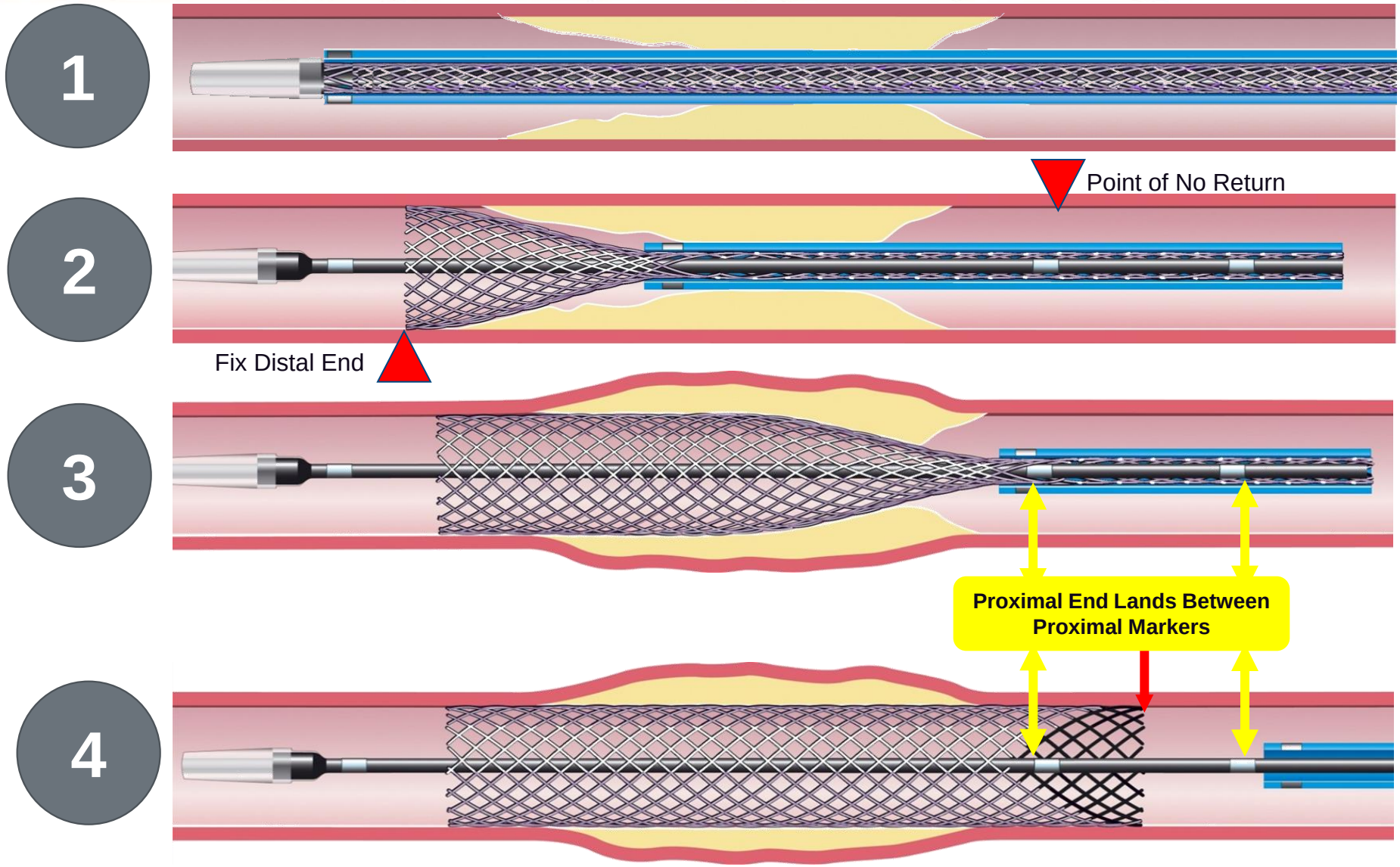




Caution: Do not reconstrain the Carotid WALLSTENT Endoprosthesis more than twice!

Caution: When reconstraining, do not pull the inner shaft with excessive force to avoid damage to the tip.

Stent Repositioning
Only When Absolutely Necessary!



Post Stent Placement

- Following stent placement, perform a final angiogram to confirm optimal angiographic appearance of the deployed stent and vessel patency.
- Upon completion of the angiogram, the embolic protection system should be removed according to the Directions for Use supplied with the device.
- Patients should be put on an appropriate regimen of anticoagulants and/or antiplatelets.

Warning: The stent may cause a thrombus, distal embolization, or may migrate from the site of implant down the arterial lumen. Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration. In the event of thrombosis of the expanded stent, thrombolysis should be attempted.

Warning: In the event of complications such as infection, pseudoaneurysm, or fistulization, surgical removal of the stent may be required.