



ONLY emboshield® Embolic Protection System

INDICATIONS

The **emboshield® Embolic Protection System** is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the Filtration Element placement should be between 2.8 and 6.2 mm.

CONTRAINDICATIONS

The **emboshield® Embolic Protection System** is contraindicated for use in:

- Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated.
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of the Guiding Catheter/ Introducer Sheath, BareWire™, Delivery Catheter, Filtration Element, and/or Retrieval Catheter.
- Patients with a known hypersensitivity to nickel-titanium.
- Patients with uncorrected bleeding disorders.
- Lesions in the ostium of the common carotid artery.

WARNINGS

Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.

General

Refer to instructions supplied with all interventional devices to be used with the emboshield® Embolic Protection System for their intended uses, contraindications, and potential complications.

Safety and effectiveness of this device as an embolic protection system have not been established in vasculatures outside of the carotid arteries (coronary, cerebral or peripheral).

The safety and efficacy of the emboshield® Embolic Protection System have not been demonstrated with carotid stent systems other than the Xact® Carotid Stent System.

The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure as suggested in these instructions. Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease.

Specific

The emboshield® device can only be used with the RX BareWire™. Use of the device with any guidewire other than the RX BareWire™ may lead to loss of the Filtration Element during the procedure.

PRECAUTIONS

Carefully inspect device components prior to use to verify that they have not been damaged and that the size, shape and condition are suitable for the procedure for which they are to be used. A device or access device which is kinked or damaged in any way should not be used.

Confirm the compatibility of the emboshield® Embolic Protection System with the interventional devices before actual use.

Precautions to prevent or reduce clotting should be taken when any interventional device is used. Flush or rinse all devices entering the vascular system with sterile isotonic heparinized saline or alternative anticoagulant, prior to use.

The emboshield® Embolic Protection System must be used with a guiding catheter or introducer sheath to maintain adequate support of the BareWire™ throughout the procedure.

To reduce the potential for the liberation of emboli during lesion crossing, the device should be carefully manipulated and not advanced against resistance.

If the Filtration Element moves into the stented segment prior to retrieval, **DO NOT RETRIEVE WITHIN THE STENT.**

Advance the Centering Catheter so that its tip opposes the proximal portion of the Filtration element and gently push the Filtration Element distally until it is situated in an unstented portion of vessel. Retrieval can then proceed.

During stent placement, 1.5 cm of vessel should be left between the distal margin of the stent and the Filtration Element. Please refer to Table 1 in the instructions for use. The stent delivery system should not contact the Filtration Element.

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

Removal of the RX BareWire™ guidewire with the emboshield® Filtration Element through any interventional devices other than the emboshield® Retrieval Catheter has not been tested.

ADVERSE EVENTS

Potential Adverse Effects

As reported in the literature, the following adverse events are potentially associated with carotid stents and embolic protection systems:

- Abrupt closure

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- Allergic reactions
 - Aneurysm
 - Angina/Coronary ischemia
 - Arteriovenous Fistula
 - Bacteremia or septicemia
 - Bleeding from anticoagulant or antiplatelet medications
 - Bradycardia/arrhythmia
 - Cerebral edema
 - Cerebral hemorrhage
 - Congestive Heart Failure
 - Death
 - Drug reactions
 - Embolism (including air and device)
 - Emergent or urgent Endarterectomy
 - Fever
 - Filter thrombosis/occlusion
 - Fluid overload
 - Groin hematoma, with or without surgical repair
 - Hemorrhage or hematoma
 - Hemorrhagic stroke
 - Headache
 - Hypotension
 - Hyperperfusion syndrome
 - Hypertension
 - Infection/sepsis
 - Ischemia/infarction of tissue/organ
 - Myocardial Infarction
 - Other conduction disturbances
 - Pain and tenderness
 - Pain, infection, or discomfort at the access site
 - Pseudoaneurysm
 - Renal failure/insufficiency
 - Restenosis of the stented artery
 - Seizure
 - Stent deformation, collapse, fracture, movement of stent, possibly requiring emergency surgery
 - Stent/filter entanglement/damage
 - Stroke or other neurological complications
 - Thromboembolic episodes
 - Thrombophlebitis
 - Total occlusion of the artery
 - Transient ischemic attacks (TIAs)
 - Vascular access complications (e.g. loss of pulse, femoral artery pseudoaneurysm and infection)
 - Ventricular fibrillation
 - Vessel dissection, rupture, or perforation
 - Vessel thrombosis (partial blockage)
 - Unstable angina pectoris

Any adverse event occurring involving the emboshield® Embolic Protection System should be reported immediately to Abbott Vascular, Customer Service: 1-800 222-6883.