
XACT[®] *Carotid Stent System*

Information for Prescribers

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Limited to use by physicians experienced in carotid stenting and who have received appropriate training in the use of the *Xact* Carotid Stent System. The *Xact* Carotid Stent System is indicated for use with the Emboshield[®] Embolic Protection System.

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1.0 DEVICE DESCRIPTION

The *Xact* Carotid Stent System is comprised of a delivery system and a self-expanding stent. The delivery system is a rapid exchange (RX) system designed to deliver the self-expanding stent to the carotid vasculature.

The self-expanding stent is cut from Nitinol tube into a flexible tubular prosthesis. Upon deployment of the stent into the carotid vasculature via the delivery system, the stent should appose the vessel wall and apply an outward pressure to establish patency. The *Xact* stent is available in both tapered and straight configurations, with diameters ranging from 6 mm through 10 mm. Stent lengths range from 20 mm through 40 mm. For more details, see the stent size matrix in Table 1 of this document.

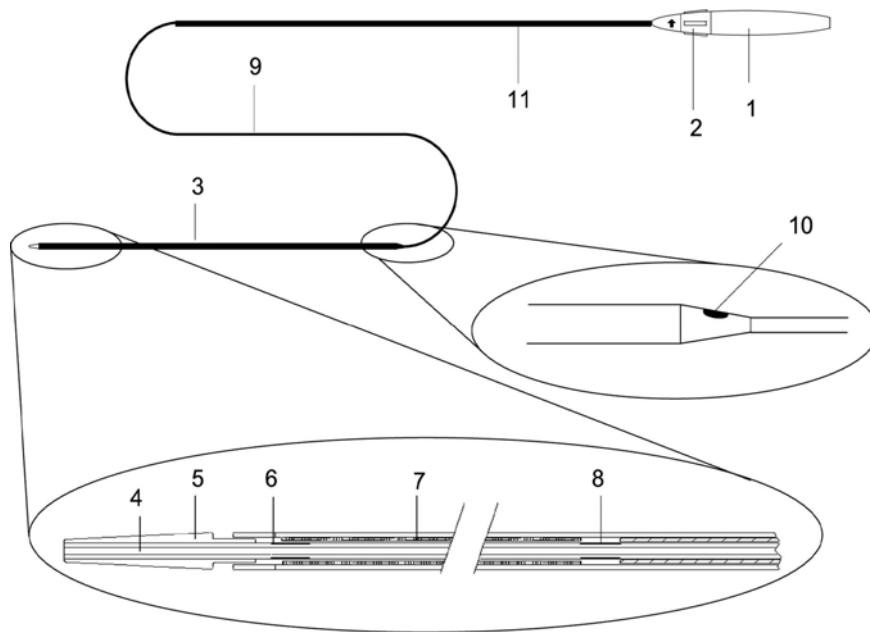


Figure 1: Xact RX Carotid Stent System

Delivery System

- | | | | |
|----|---------------------|-----|----------------------------|
| 1. | Handle | 6. | Radiopaque Distal Marker |
| 2. | Deployment Actuator | 7. | <i>Xact</i> Stent |
| 3. | Distal Outer Sheath | 8. | Radiopaque Proximal Marker |
| 4. | Guide wire Lumen | 9. | Catheter Shaft |
| 5. | Tip | 10. | Guide Wire Exit Port |
| | | 11. | Stabilizer |

The delivery system has an outer diameter (OD) of 5.7 Fr and is compatible with 8 Fr guiding catheter or a 6 Fr sheath - with a 0.088" inner diameter or greater. The delivery system has a working length of 136 cm. See Figure 1 for a graphical depiction of the *Xact* Stent System. The delivery system is comprised of a tip (5), distal outer sheath (3), catheter shaft (9), and stabilizer (11). The distal outer sheath houses the crimped *Xact* stent (7). At the proximal end of the distal outer sheath is the BareWire™ guide wire exit port (10). The proximal portion of the shaft and stabilizer connect the delivery system to the handle (1). The stabilizer (11) works with the hemostasis valve on the guiding catheter / sheath to help improve stent placement accuracy during deployment.

The inner system assembly consists of a tip (5) installed over a 0.014" BareWire guide wire compatible guide wire lumen (4). The guide wire lumen (4) is flushed via the tip (5) using the flushing tip. For more detailed instructions on device flushing, see the section entitled Delivery System Preparation in this document. The crimped *Xact* stent is constrained between the guide wire lumen (4) and the distal outer sheath (3). There are radiopaque marker bands on the delivery system located at the proximal (8) and distal (6) ends of the stent. Prior to deployment, these radiopaque markers are used as guides to position the stent.

Deployment of the *Xact* stent is achieved by grasping the handle (1) and rotating the deployment actuator (2) in a clockwise direction. See the section entitled Stent Deployment in this document for detailed instructions on deploying the stent.

Tapered Stent

This stent is designed to fit tapered carotid anatomy, especially lesions involving the carotid bifurcation (Figure 2).

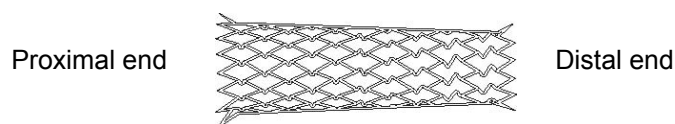


Figure 2: Tapered Stent

Straight Stent

This stent is designed to be used within non-tapered carotid anatomy and lesions not involving the bifurcation (Figure 3).

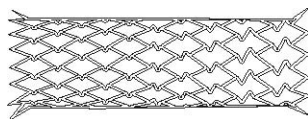


Figure 3: Straight Stent

Table 1: Device Range

Catalogue No.	Stent Length	Configuration	Unconstrained Stent Diameter
82095-01	20 mm	Straight	7 mm
82093-01	20 mm	Straight	8 mm
82089-01	20 mm	Straight	9 mm
82099-01	20 mm	Straight	10 mm
82094-01	30 mm	Straight	7 mm
82092-01	30 mm	Straight	8 mm
82088-01	30 mm	Straight	9 mm
82098-01	30 mm	Straight	10 mm
82091-01	30 mm	Tapered	8 - 6 mm
82087-01	30 mm	Tapered	9 - 7 mm
82097-01	30 mm	Tapered	10 - 8 mm
82090-01	40 mm	Tapered	8 - 6 mm
82086-01	40 mm	Tapered	9 - 7 mm
82096-01	40 mm	Tapered	10 - 8 mm

2.0 INDICATIONS

The *Xact* Carotid Stent System (*Xact*), used in conjunction with the Emboshield Embolic Protection System is indicated for the improvement of the lumen diameter of carotid arteries in patients considered at high risk for adverse events from carotid endarterectomy who require percutaneous carotid angioplasty and stenting for occlusive artery disease and meet the criteria outlined below:

Patients with carotid artery stenosis ($\geq 50\%$ for symptomatic patients by ultrasound or angiography or $\geq 80\%$ for asymptomatic patients by ultrasound or angiography), located between the origin of the common carotid artery and the intra-cranial segment of the internal carotid artery AND

Patients must have a reference vessel diameter ranging between 4.8 mm and 9.1 mm at the target lesion.

3.0 CONTRAINDICATIONS

Contraindications associated with angioplasty must be considered when using the *Xact* Carotid Stent System. These include, but are not limited to:

- 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, Emboshield 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.

4.0 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.

4.1 General

Refer to instructions supplied with all interventional devices to be used with the *Xact* Carotid Stent System for their intended uses, contraindications, and potential complications.

The safety and efficacy of the *Xact* Carotid Stent System has not been demonstrated with embolic protection systems other than the Emboshield Embolic Protection System.

The long-term performance (> 1 year) of the *Xact* Carotid Stent System has not been established.

As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm, or rupture.

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

In patients requiring the use of antacids and / or H₂-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents (e.g. aspirin) may be adversely affected.

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.

When multiple stents are required, stent materials should be of similar composition.

The safety and effectiveness of the *Xact* Carotid Stent System has NOT yet been established in patients with the characteristics noted below.

- Low to moderate risk for adverse events from carotid endarterectomy.
- Previously placed stent in target artery.
- Total occlusion of target lesion.
- Angiographically visible thrombus.
- Carotid string sign (a tiny, long segment of contrast in the true lumen of the artery).
- Vessel anatomy precluding the use of the stent system or appropriate positioning of the embolic protection system.

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- Presence of carotid artery dissection prior to initiation of the procedure.
 - Evidence of a stroke within the previous 30 days.
 - History of ipsilateral stroke with fluctuating neurologic symptoms within 1 year.
 - History of intracranial hemorrhage within the past 3 months.
 - Any condition that precluded proper angiographic assessment or made percutaneous arterial access unsafe, (e.g. morbid obesity, sustained systolic blood pressure > 180 mmHg).
 - Contraindication to aspirin, or to clopidogrel AND ticlopidine, or stent material.
 - History or current indication of bleeding diathesis or coagulopathy including thrombocytopenia or an inability to receive heparin in amounts sufficient to maintain an activated clot time at > 250 seconds.
 - Hemoglobin (Hgb) < 8 gm / dl (unless on dialysis), platelet count < 50,000, INR > 1.5 (irreversible), or heparin-associated thrombocytopenia.
 - Known cardiac sources of emboli.
 - Atherosclerotic disease involving adjoining vessels precluding safe placement of the guiding catheter or sheath.
 - Other abnormal angiographic findings that indicated the patient was at risk of a stroke due to a problem other than that of the target lesion, such as: ipsilateral arterial stenosis greater in severity than the target lesion, cerebral aneurysm, or arteriovenous malformation of the cerebral vasculature.
 - Severe dementia.
 - Life threatening allergy to contrast media that could not be treated.
 - Pregnant patients or patients under the age of 18.
 - Patients in whom femoral access is not possible.
 - Patients with aneurysmal dilation immediately proximal or distal to the lesion.

The safety and effectiveness of concurrent treatment of lesions in patients with bilateral carotid artery disease have not been established.

4.2 Specific

The device is intended for single use only. DO NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and risk of cross contamination. Do not use if packaging is damaged.

Do not use the product after the Use by Date specified on the label.

Store in a cool, dry area. Do not expose to organic solvents or ionizing radiation.

The clinician should be familiar with and experienced in standard techniques of Rapid Exchange percutaneous transluminal angioplasty and stenting and be knowledgeable of the current medical literature concerning the complications of such procedures.

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

Appropriate anti-platelet, anticoagulant and, if necessary, vasodilator therapy must be used during the procedure. Anticoagulant therapy sufficient to maintain an Activated Clotting Time of at least 250 seconds for the duration of the procedure is recommended.

Maintain a snug seal between the device and the hemostasis Tuohy / Borst valve during insertion. Failure to observe this may result in air being drawn into the access device through the hemostasis / Tuohy Borst valve. Device insertion should be performed slowly to minimize the risk of air entrainment.

During the insertion of Rapid Exchange catheters through guide catheters or sheaths careful handling is required to ensure that air is not drawn into the access device. It is therefore recommended that flushing of contrast media (or other fluids) is performed before or after insertion of the catheter, but not while the catheter is within the access device.

Do not advance any component of the *Xact* Stent Delivery System against significant resistance. The cause of any resistance should be determined via fluoroscopy and remedial action taken.

Perform all exchanges slowly to prevent air embolism or trauma to the artery.

Implanting a stent may lead to dissection of the vessel distal and / or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (carotid endarterectomy, further dilatation, or placement of additional stents).

The stent may cause 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 and PTA should be attempted.

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

If a filter element 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.

Ensure optimal positioning of the stent prior to deployment. Once deployment is initiated, the stent cannot be repositioned or recaptured. Stent retrieval methods (use of additional wire, snares, and/or forceps) may result in additional trauma to the carotid vasculature and

or the vascular access site. Complications may include death, stroke, bleeding, hematoma or pseudoaneurysm.

5.0 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. If pouch is damaged do not use.

Confirm the compatibility of the *Xact* Stent Delivery 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 prior to use.

Do not remove the stent from its delivery system as removal may damage the stent. The stent and delivery system are intended to be used in tandem. If removed, the stent cannot be put back on the delivery system.

The delivery system should not be used in conjunction with other stents.

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

During stent placement, 1.5 cm of vessel should be left between the distal margin of the stent and the Filtration Element. 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 placement of a temporary pacemaker, if needed.

The device must only be flushed using the 3-ml syringe and flushing tip provided.

The outside diameter of the Outer Sheath is 5.7 Fr. An appropriate sized sheath/guiding catheter should be selected based on this diameter.

Do not use a prepared *Xact* Carotid Stent System if the stent is not fully constrained within the Delivery System.

Do not use if the stent is partially deployed.

If, after preparation, a gap between the catheter tip and the outer sheath exists, rotate the Deployment Actuator in an anti-clockwise direction until the gap is closed.

Advancement and deployment of the *Xact* Carotid Stent System should only be performed under fluoroscopic observation.

Do not advance any component, or section thereof, of the *Xact* Carotid Stent System against significant resistance. The cause of any resistance should be determined via fluoroscopy and remedial action taken.

Do not attempt to reposition the Delivery System once the stent has made contact with the vessel wall.

Do not torque the *Xact* Carotid Stent System.

If 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.

If overlap of sequential stents is necessary, the amount of overlap should be kept to a minimum.

5.1 MRI Information

Through non-clinical testing, the *Xact* Carotid Stent has been shown to be MRI safe at field strengths of 3.0 Tesla or less, a maximum spatial gradient of 7.2 Tesla/meter and a maximum whole body averaged specific absorption rate (SAR) of 3.0 W / kg for 15 min of MRI. The *Xact* Carotid Stent should not migrate in this MRI environment. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3.0 Tesla or a maximum spatial gradient higher than 7.2 Tesla/meter.

In this testing, the stent produced a temperature rise of less than or equal to 0.6°C at a maximum whole body averaged specific absorption rate (SAR) of 3.0 W / kg for 15 min of MRI. The effect of heating in the MRI environment for overlapping stents or stents with fractured struts is not known.

MRI quality may be comprised if the area of interest is in the exact same area as or relatively close to the position of the stent.

6.0 ADVERSE EVENTS

6.1 Observed Adverse Events

The SECURITY Registry Study was a prospective, multicenter, non-randomized study performed to demonstrate the safety and effectiveness of the Emboshield Embolic Protection System and *Xact* Carotid Stent System in treating carotid stenosis in patients at high risk ($\geq 50\%$ for symptomatic patients by ultrasound or angiography or $\geq 80\%$ for asymptomatic patients by ultrasound or angiography) for carotid endarterectomy. High-risk patients were defined as having an anatomical risk factor(s) and / or a co-morbidity risk factor(s). A total of three hundred and five (305) patients were enrolled at 30 sites in the United States and Australia.

Non-stroke neurological includes events such as visual / speech disturbances, confusion, seizure, weakness, and TIA.

TLR is defined as any repeat invasive procedure, including angioplasty, stenting, endarterectomy, or thrombolysis, performed to open or increase the luminal diameter inside or within 10 mm of the previously treated lesion. To be considered clinically indicated, the patient must be symptomatic with > 50% stenosis or asymptomatic with > 80% stenosis.

Adverse events are categorized by body system and are defined as follows:

- Access site complications include events such as bruising, hematoma, and bleeding.
- Vascular includes events such as peripheral vascular disease and deep vein thrombosis.
- Hemodynamic includes events such as hypo- and hypertension, syncope, and dizziness.
- Bleeding includes events such as non-access site bleeding, anemia up to 30 days, and Gastrointestinal (GI) bleeds up to 30 days.
- Blood dyscrasia includes events such as anemia later than 30 days, and thrombocytopenia.
- Respiratory includes events such as pneumonia, embolism, chronic obstructive pulmonary disease (COPD), and respiratory arrest.
- GI includes events such as nausea, ulcers and GI bleeds later than 30 days.
- Genitourinary includes events such as urinary tract infection, and prostatic hyperplasia.
- Infection includes events such as abscess, sepsis, and groin infection.
- Metabolic includes events such as electrolyte imbalance, diabetes Mellitus, and renal failure.
- Musculoskeletal includes events such as pain, fractures, and joint replacements.

The numbers and types of adverse events observed were anticipated given the high co-morbid state of these patients.

Table 2 presents the adverse events that were reported within the first 30 days following the procedure for registry patients enrolled in the SECuRITY Registry Trial. Table 3 presents the adverse events that were reported within the first year following the procedure for registry patients enrolled in the SECuRITY Registry Trial. Table 4 presents the cause of any patient deaths throughout the study.

Table 2: Serious Adverse Events Summary, Up to 30 Days

Event	≤ 30 days SECURITY (N=305)	
	n	%
Death	3	0.98 %
Stroke-Related (neurological)	3	0.98 %
Not Stroke-Related	0	0 %
All Strokes	21	6.89 %
Major	8	2.62 %
Ipsilateral Stroke	7	2.30 %
Non-ipsilateral Stroke	1 ¹	0.33 %
Minor	13	4.26 %
Ipsilateral Stroke	12	3.93 %
Non-ipsilateral Stroke	1 ²	0.33 %
Non-Stroke Neurological	25	8.20 %
Restenosis (≥ 50% stenosis as measured by ultrasound)	7	2.29 %
Target Lesion Revascularization (TLR), Clinically Indicated	0	0%
Cardiac	15	4.92 %
MI	2	0.66 %
Arrhythmia	4	1.31 %
Angina	4	1.31 %
Congestive Heart Failure (CHF)	3	0.98 %
Coronary Artery Disease (CAD)	2	0.66 %
Procedural Complication	109	35.74 %
Hypotension	86	28.20 %
Arrhythmia	7	2.30 %
Vasospasm	3	0.98 %
Dissection	10	3.28 %
In-stent Thrombosis	1	0.33 %
Emergent CEA	1	0.33 %
Emergent Intervention -other	1	0.33 %
Access Site Complication		
Requiring Repair / Transfusion	8	2.62 %
Vascular	3	0.98 %
Hemodynamic	11 ³	3.61 %
Bleeding	6	1.97 %
Requiring transfusion	1	0.33 %
GI Bleeding	5	1.64 %
Blood Dyscrasia	2	0.66 %
Respiratory	5	1.64 %
Gastrointestinal	18	5.90 %
Genitourinary	3	0.98 %
Infection	2	0.66 %
Metabolic	11	3.61 %
Musculoskeletal	32	10.49 %
Miscellaneous ⁴	1	0.33 %

¹ Stroke adjudicated as contralateral

² Stroke adjudicated as bilateral

³ Includes hypotension and hypertension not associated with the procedure.

⁴ Aortic Aneurysm Repair

Table 3: Serious Adverse Events Summary Up to 365 Days

Event	31-365 days SECURITY (N=302)		0-365 days SECURITY (N=305)	
	n	%	n	%
Death	26	8.6	29	9.5
Stroke-Related (neurological)	3	1.0	6	2.0
Not Stroke-Related	23	7.6	23	7.5
Unknown	0	0.0	0	0
Ipsilateral Stroke	5	1.7	24	7.9
Major	4	1.3	11	3.6
Minor	1	0.3	13	4.3
Non-ipsilateral Stroke	1	0.3	2	0.7
Non-Stroke Neurological	18	6.0	43	14.1
Restenosis (≥ 50% stenosis as measured by ultrasound)	14	4.6	20	6.6
Target Lesion Revascularization (TLR), Clinically Indicated	2	0.7	2	0.7
Cardiac	57	18.9	74	24.3
MI	5	1.7	7	2.3
Arrhythmia	6	2.0	10	3.3
Angina	6	2.0	10	3.3
Congestive Heart Failure (CHF)	10	3.3	15	4.9
Coronary Artery Disease (CAD)	30	9.9	32	10.5
Procedural Complication	0	0.0	109	35.74
Hypotension	0	0.0	86	28.20
Arrhythmia	0	0.0	7	2.30
Vasospasm	0	0.0	3	0.98
Dissection	0	0.0	10	3.28
In-stent Thrombosis	0	0.0	1	0.33
Emergent CEA	0	0.0	1	0.33
Emergent Intervention -other	0	0.0	1	0.33
Access Site Complication Requiring Repair / Transfusion	0	0	8	2.62
Vascular	42	13.9	45	14.7
Hemodynamic	25	8.3	36	11.8
Bleeding	4	1.3	10	3.3
Requiring transfusion	1	0.3	2	0.7
GI Bleeding	3	1.0	8	2.6
Blood Dyscrasia	9	3.0	11	3.6
Respiratory	15	5.0	20	6.6
Gastrointestinal	8	2.6	26	8.5
Genitourinary	8	2.6	11	3.6
Infection	6	2.0	8	2.6
Metabolic	14	4.6	25	8.2
Musculoskeletal	19	6.3	51	16.7
Miscellaneous ⁵	4	1.3	5	1.6

⁵ Adenocarcinoma, aortic aneurysm repair, aortic valve replacement and malignant hepatic neoplasm

Table 4: Cause of Death (< 30 days, 31-365 days)

Cause of Death	0 - 30 days		31 - 365 days	
	n	%	n	%
Stroke (neurological)	3	0.98	3	0.99
Cardiac	0	0.00	10	3.31
Cancer	0	0.00	4	1.32
Renal Failure	0	0.00	3	0.99
Respiratory	0	0.00	1	0.33
Diabetes	0	0.00	1	0.33
Device related deaths	0	0.00	0	0.00
Accidental	0	0.00	1	0.33

6.2 Potential Adverse Effects

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

- Abrupt closure
- Allergic reactions
- Aneurysm
- Angina/Coronary ischemia
- Ateriovenous 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

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- 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

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- 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 this device should be reported immediately to Abbott Vascular, Customer Service: 1 (800) 227-9902.

7.0 SYNOPSIS OF CLINICAL STUDY

The SECuRITY Registry Trial was a prospective, multicenter, non-randomized safety and efficacy study of an embolic protection device and a carotid artery stent in 305 pivotal patients and 93 lead-in patients with carotid artery disease conducted at 30 sites. The primary endpoint was the incidence of Major Adverse Events (MAEs), defined as death, stroke or myocardial infarction (Q-wave and non Q-wave) at 30-days post-procedure for the Emboshield and MAE (death, stroke or MI) at 30 days post-procedure and the incidence of ipsilateral stroke at one year for the *Xact* Stent. Secondary endpoints were the incidence of vascular complications other than MAEs at 30 days, and restenosis and / or target lesion revascularization (TLR) at 6 months and one year post-procedure.

Study Objective

The primary objective of the study was to evaluate the safety and efficacy of the *Xact* Carotid Stent System and the Emboshield Embolic Protection System in treating carotid stenosis in patients at high risk for carotid endarterectomy ($\geq 50\%$ stenosis for symptomatic patients by ultrasound or angiography or $\geq 80\%$ for asymptomatic patients by ultrasound or angiography).

Investigational Devices

The investigational devices used over the duration of the SECuRITY Registry Trial consisted of the Rapid Exchange (RX) and Over the Wire (OTW) versions of the *Xact* Carotid Stent System and the RX and OTW Emboshield Embolic Protection System.

The *Xact* Carotid Stent System is comprised of a self expanding, nitinol stent that is specifically designed for use in carotid interventional procedures and a delivery system. Table 5 below provides an outline of the SECuRITY Registry endpoints.

The Emboshield system is comprised of a Filtration Element, a BareWire (guide wire), a Delivery Catheter and a Retrieval Catheter. The Emboshield system is a temporary

percutaneous, transluminal intra-arterial filtration system, which is placed distal to the target lesion. The Filtration Element is designed to appose the vessel wall distal to the target lesion in order to capture potential emboli thereby reducing the chance of distal embolization while maintaining blood flow during carotid angioplasty and stent procedures. The filtration element and retrieval catheter are removed from the patient upon completion of the procedure.

Table 5: Study Endpoints

Endpoint	Definition
Primary Endpoint	Incidence of Major Adverse Events (MAEs), defined as death, stroke or myocardial infarction (Q-wave and non Q-wave) at 30-days post-procedure for the Emboshield and MAE (death, stroke or MI) at 30 days post-procedure and the incidence of ipsilateral stroke at one year for the <i>Xact</i> Stent.
Secondary Endpoints	Definition
Safety	Incidence of vascular complications other than MAE at one month.
Acute Success	Lesion success: defined as < 50% residual stenosis of the target lesion using the <i>Xact</i> stent and Emboshield filter. Device success: <i>Xact</i> Stent: < 50% residual stenosis in the target lesion. Emboshield: Deployment and retrieval of the device during the procedure, in the absence of angiographic distal embolization.
Procedure success	Defined as < 50% residual stenosis of the target lesion using any method, and the absence of major adverse events at 30 days.
Long Term Success	Restenosis: defined as a narrowing > 50% at 6 and 12 months post-procedure, as determined by ultrasound. Revascularization: target lesion revascularization associated with a narrowing of > 80% within 12 months post procedure.

7.1 Statistical Methods

The proportion of patients experiencing a primary endpoint adverse event in the SECURITY Registry was compared to a weighted historical control (WHC) rate based on a review of outcome assessments for endarterectomy published in peer reviewed literature. It was established that the one-year control rate for patients having high-risk co-morbidities was 14% and the one-year control rate for patient with anatomic risk factors was 11%. The WHC rate for this trial was then computed by weighting these rates by the actual proportion of patients in the study with co-morbidities versus anatomic risk factors.

Patients with at least one high-risk co-morbidity: $266 / 303 = 87.8\%$

Patients with anatomic risk factors only: $37 / 303 = 12.2\%$

WHC = $(87.8\% \times 14\%) + (12.2\% \times 11\%) = 13.6\%$

All patients who met eligibility requirements, and who were available for clinical follow-up, were included in the denominator. Two (2) patients had neither high-risk co-morbidities nor anatomic risk factors and were excluded from the calculation of the weighted historic control.

The analysis and subsequent interpretation of the results from this study are based on inferential statistics. The test statistic used for this analysis was the Clopper-Pearson

method for calculating 95% binomial confidence intervals, based on the observed primary composite endpoint failure rate. If the upper bound of the 95% binomial confidence interval was found to be less than the WHC plus the margin of clinical equivalence, the null hypothesis would be rejected and non-inferiority of the *Xact* stent to CEA would be demonstrated.

The SECuRITY protocol required regular patient follow-up by the treating physician and follow-up neurological assessments by a neurologist. Core laboratories provided independent assessments for the angiographic, ultrasound, ECG, and pathologic evaluation of captured debris (Emboshield only). Medical monitors reviewed all safety data to ensure appropriate reporting of adverse events. A Clinical Adjudication Committee adjudicated suspected primary endpoint events. A Data Safety Monitoring Board monitored adverse events to ensure patient safety.

Eligibility Criteria Summary

Eligible patients were male and female adults with a lesion in the internal carotid artery or internal carotid artery extending into the common carotid artery who were at high risk for CEA.

All patients had to meet the following inclusion criteria to be considered for the study:

The patient had a carotid artery stenosis ($\geq 50\%$ for symptomatic patients or $\geq 80\%$ for asymptomatic patients by ultrasound or angiography), located between the origin of the common carotid artery and the intra-cranial segment of the internal carotid artery.

Patient was ≥ 18 years of age.

Patient had a lesion located in the internal carotid artery.

Target Internal Carotid Artery (ICA) vessel diameter was visually estimated to be ≥ 4.0 mm and ≤ 9.0 mm for *Xact* stent treatment segment and to be ≥ 3.5 mm and ≤ 6.0 mm for the Emboshield.

Anticipated life expectancy of the patient was at least one year.

The patient (or their legal guardian) understood the nature of the procedure and provided written informed consent.

Patient was willing to comply with the protocol requirements and to return to the treatment center for all required clinical evaluations.

Patient had no childbearing potential or a negative pregnancy test within 5 days of the study procedure.

Each patient had to fulfill at least one (1) of the anatomical risk factors or co-morbid risk factors listed below to be inclusion in the study:

Anatomic Risk Factors

Previous radiation treatment to the neck or radical neck dissection

Target lesion was at or above the second vertebral body C2 (level of jaw)
Inability to extend the head due to cervical arthritis or other cervical disorders

Tracheostomy or tracheal stoma

Laryngectomy

Contralateral laryngeal nerve palsy

Severe tandem lesions

Co-morbid Risk Factors

Previous carotid endarterectomy with significant restenosis (as defined above for symptomatic or asymptomatic patients)

Total occlusion of the contralateral carotid artery

Left ventricular ejection fraction < 35%

Congestive Heart Failure New York Heart Association (NYHA) Functional Class III or higher

Dialysis dependent renal failure

Canadian Cardiovascular Society Angina Classification III or higher or unstable angina

Requires simultaneous or staged coronary artery bypass surgery, cardiac valve surgery, peripheral vascular surgery, or abdominal aortic aneurysm repair within 60 days

> 80 years of age

Myocardial infarction within previous 6 weeks

Abnormal stress test. Treadmill, thallium or dobutamine echo were acceptable. The stress tests had to be sufficiently abnormal to place the patient at an increased risk for CEA

Severe pulmonary disease, including at least one of the following: requirement chronic O2 therapy, resting PO2 \leq 60 mm Hg, Hematocrit \geq 50%, FEV1 or DLCO \leq 50% of normal

Description of Patients Evaluated

Table 6 summarizes the patient follow-up and includes one patient that died three hundred seventy four (374) days post index procedure.

Table 6: SECuRITY Patient Follow-up

	30-days	6-months	12-months
Patients Enrolled	305		
Cumulative Death	3	13	26
Cumulative Withdrawal or Loss-to-Follow-up	10	26	36
Patients Evaluable	302	292	279
Patients Evaluated	292	266	243
Follow-up Rate (%)	96.7	91.1	87.1

Baseline demographics and lesion characteristics for the SECuRITY Registry Trial are presented in Table 7.

Table 7: Baseline Demographics

Demographic	SECuRITY Trial
Age	
Mean ± SD	74.5 ± 9.1
Range (min, max)	48.0, 92.2
Age > 80 years	33.8% (103 / 305)
Gender	
Male	63.6% (194 / 305)
Females	36.4% (111 / 305)
Medical History	
Diabetes	30.8% (94 / 305)
Hypertension requiring treatment	86.6% (264 / 305)
Hyperlipidemia	73.8% (225 / 305)
Current Smoker	72.5% (221 / 305)
Number of Symptomatic Patients (TIA,/stroke within 180 days)	21% (64 / 305)
Baseline Lesion & Vessel Characteristics	
Eccentric	29.0% (87 / 300)
Concentric	71.0% (213 / 300)
Calcified	21.0% (63 / 300)
Ulcerated	23.0% (69 / 300)
Lesion Length	
Mean ± SD	15.0 ± 6.5
Range (min, max)	2.0, 46.8
Minimum Lumen Diameter (MLD, mm)	
Mean ± SD	4.8 ± 0.9 (n = 299)
Range (min, max)	0.8, 9.5
Percent Diameter Stenosis (%DS)	
Mean ± SD	73.2 ± 17.3 (n = 299)
Range (min, max)	-160, 93.2
High-Risk Inclusion Criteria	
Anatomic Risk Factors	
Previous Radiation Treatment to Neck or Radical Neck Dissection	5.9% (18 / 305)
Target Lesion At or Above Second Vertebral Body C2	9.2% (28 / 305)
Inability to Extend the Head Due to Cervical Arthritis or Other Cervical Disorders	3.0% (9 / 305)
Tracheostomy or Tracheal Stoma	0.0% (0 / 305)

Laryngectomy	0.3% (1 / 305)
Contralateral Laryngeal Nerve Palsy	0.0% (0 / 305)
Severe Tandem Lesions	1.3% (4 / 305)
Co-Morbid Risk Factors	
Previous Carotid Endarterectomy with Significant Restenosis	21.0% (64 / 305)
Total occlusion of the Contralateral Carotid Artery	8.9% (27 / 305)
Left Ventricular Ejection Fraction <35%	79.% (24 / 305)
Congestive Heart Failure NYHA III or Higher	6.2% (19 / 305)
Dialysis Dependent Renal Failure	1.6% (5 / 305)
CCSAC III or Higher or Unstable Angina	7.5% (23 / 305)
Requires Simultaneous or Staged CABG, Cardiac Valve Surgery, Peripheral Vascular Surgery, or Abdominal Aortic Aneurysm Repair Within 60 Days	7.2% (22 / 305)
>80 Years of Age	33.8% (103 / 305)
MI Within Previous 6 Weeks	0.7% (2 / 305)
Abnormal Stress Test	12.1% (37 / 305)
Severe Pulmonary Disease	2.0% (6 / 305)

7.2 Results

At 30 days following the study procedure, 92.5% of the treated patients were free of major adverse events (MAEs), defined as death, stroke or myocardial infarction. The primary endpoint of the study was a composite rate of the 30-day MAEs and ipsilateral strokes at one year. The composite rate of occurrence for the primary endpoint measure at 12 months was 8.5%.

Acute success in effectively treating the target lesion was demonstrated in 96.7% (295 / 305) of the patients undergoing the study procedure. Device success was also achieved in a majority of the study procedures for both study devices: 94.1% (287 / 305) for the *Xact* stent and 96.7% (295 / 305) for the Emboshield Embolic Protection System.

Overall procedural success was demonstrated in 269 patients (88.2%), as measured by a residual stenosis of < 50% at the completion of the procedure and the absence of major adverse events (MAE; Stroke, Death, or MI) at 30 days. Five (5) patients (1.6%, 5 / 305), experienced a vascular complication that required treatment with additional therapeutic measures, including aspiration of a stagnate column of blood prior to filter retrieval, placement of a second stent, application of a pressure dressing to the access site and surgical drainage for a groin abscess.

Change to minimum lumen diameter (MLD) was calculated for 299 patients where the MLD measured was the section (segment) of the carotid considered for stenting. The average change was 2.3 mm and the average percent change in lumen diameter was -55.5%.

At 12 months, long-term durability of the procedure was also demonstrated by 99.3% (0.7%, 2 / 305) of the treated patients being free from repeat revascularization. Additionally, at 6 months and 12 months post-procedure, restenosis was demonstrated in a small percentage of the patient population, 4.9% and 4.1%, respectively.

In the SECuRITY trial the median number of days-to-discharge was 1.7. The longest hospital stay post-stenting in each study was 16 days. Approximately, 70% of patients in the SECuRITY Trial remained in the hospital for 1 day following the carotid stenting procedure. Additionally, 6% of patients stayed 5 or more days, generally for the treatment of a co-morbid condition.

The primary objective of the SECuRITY trial was met. The upper bound of the 95% one-sided binomial confidence interval was found to be less than the WHC plus the margin of clinical equivalence, demonstrating that the carotid stenting with the *Xact* stent is non-inferior to carotid endarterectomy.

The clinical results of this study indicate that the *Xact* Carotid Stent System, when used in conjunction with the Emboshield Embolic Protection System, provides a safe, effective and durable method for the treatment of carotid stenosis in patients at high-risk for carotid endarterectomy.

Table 8: Non-Hierarchical Summary of Safety Measures in the SECuRITY Trial

Events	≤ 30 days SECuRITY (N=305)	
	n	%
30 Day Primary Endpoint (Death, Stroke and MI)	23	7.5 %
Death	3	0.98 %
Stroke-Related (neurological)	3	0.98 %
Not Stroke-Related	0	0 %
All Strokes	21	6.89 %
Major	8	2.62 %
Ipsilateral Stroke	7	2.30 %
Non-ipsilateral Stroke	1 ⁶	0.33 %
Minor	13	4.26 %
Ipsilateral Stroke	12	3.93 %
Non-ipsilateral Stroke	1 ⁷	0.33 %
Non-Stroke Neurological	25	8.20 %
Cardiac	15	4.92 %
MI	2	0.66 %
Arrhythmia	4	1.31 %
Angina	4	1.31 %
Congestive Heart Failure (CHF)	3	0.98 %
Coronary Artery Disease (CAD)	2	0.66 %
Procedural Complication	109	35.74 %
Hypotension	86	28.20 %
Arrhythmia	7	2.30 %
Vasospasm	3	0.98 %
Dissection	10	3.28 %
In-stent Thrombosis	1	0.33 %
Emergent CEA	1	0.33 %
Emergent Intervention -other	1	0.33 %
Access Site Complication		
Requiring Repair / Transfusion	8	2.62 %
Vascular	3	0.98 %
Hemodynamic	11 ⁸	3.61 %
Bleeding	6	1.97 %
Requiring transfusion	1	0.33 %
GI Bleeding	5	1.64 %
Blood Dyscrasia	2	0.66 %
Respiratory	5	1.64 %
Gastrointestinal	18	5.90 %
Genitourinary	3	0.98 %
Infection	2	0.66 %
Metabolic	11	3.61 %
Musculoskeletal	32	10.49 %
Miscellaneous ⁹	1	0.33 %

⁶ Stroke adjudicated as contralateral

⁷ Stroke adjudicated as bilateral

⁸ Includes hypotension and hypertension not associated with the procedure

⁹ Aortic aneurysm repair

Table 9: Summary of Efficacy Measures in the SECURITY Trial

Efficacy Measures	%	95% CI	X/n
One Year Primary Endpoint (Stroke, Death, MI within 30 days plus ipsilateral stroke 31-365 days)	8.5	(-, 0.116)	(26 / 305)
Lesion Success (< 50% stenosis using the Xact stent and Emboshield filter)	96.7%	(0.941, 0.984)	(295 / 305)
Device Success – Xact Stent (< 50% residual stenosis, successful delivery of the stent)	94.1%	(0.908, 0.965)	(287 / 305)
Device Success - Embolic Protection Device (Successful deployment / retrieval of the filter, absence of angiographic distal embolization)	96.7%	(0.941, 0.984)	(295 / 305)
Procedural Success (< 50% stenosis using any method and freedom from MAE at 30 days)	88.2%	(0.840, 0.916)	(269 / 305)
Long Term Success (absence of Ipsilateral stroke at 365 days post-procedure [0-365 days])	92.2%	(0.889, 0.952)	(282 / 305)
Restenosis (\geq 50% stenosis as measured by ultrasound)*			
At 6 Months post-procedure	4.9%	(0.020, 0.067)	(12 / 246)*
At 12 Months post-procedure	4.1%	(0.014, 0.055)	(9 / 221)*
Restenosis (Cumulative)			
0 – 6 Months post-procedure	5.6%	Not Available	(17 / 305)
0 - 12 Months post-procedure	6.6%	Not Available	(20 / 305)
Target Lesion Revascularization (Surgical / percutaneous revascularization involving the target lesion within 365 days)	0.65%	(0.000, 0.018)	(2 / 305)
Total Vascular Complications	1.6%	(0.005, 0.038)	(5 / 305)

*At the end of the one year follow-up period only two subjects had a clinically indicated need for revascularization.

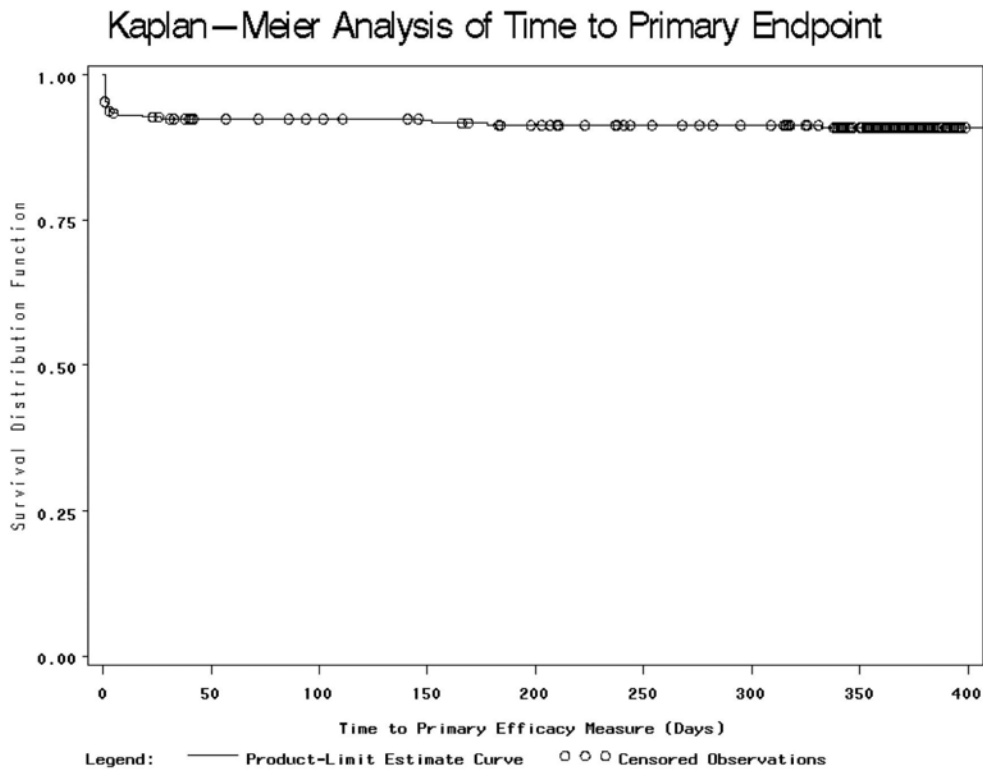
Table 10: Improvement in Target Lesion Lumen Diameter

	Pre-Procedure to Post-Procedure Change (n=295**)		
	Change Mean	S.D.	95% CI
In Lesion MLD* (mm)	2.3 mm	0.7 mm	(2.3, 2.4)
In Lesion Diameter Stenosis (%)	-55.5%	15.6%	(-57.3, -53.7)

*Minimum Lumen Diameter of the section (segment) of the carotid considered for stenting.

**Number of patients for which pre-and post-angiographic data was available.

Figure 4: Freedom from Composite Endpoint of Stroke, Death and MI (0-365 days)



Months after Index Procedure	0	1	3	6	12
Days after Index Procedure	0	30	90	180	365
Number at Risk	305	276	264	253	157
Number Censored	0	6	18	26	121
Number of Events	0	23	23	26	27
Percent Event Free	100%	92.4%	92.4%	91.4%	91.0%
One-Sided Lower 95% CI	100%	89.9%	89.9%	88.6%	87.4%

8.0 CLINICIAN USE INFORMATION

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.

Warning: The Xact Carotid Stent System is intended for one time use only. DO NOT resterilize and / or reuse it, as this can potentially result in compromised device performance and risk of cross contamination.

Warning: Do not use the product after the Use by Date specified on the label.

8.1 Materials Required

Confirm the compatibility of the Xact Carotid Stent System with the interventional devices before actual use.

6F introducer sheath or 8F guiding catheter compatible with the vascular anatomy. Minimum guiding catheter/sheath size inner diameter (I.D.) 0.088"/ 2.24 mm

0.096" (2.44 mm) Rotating Hemostatic Valve (RHV) (optional)

Emboshield Embolic Protection System and BareWire

Balloon dilation catheter (optional)

1,000 u / 500 cc heparinized normal saline (sterile)

3 ml luer-lock syringe

8.2 Periprocedural Care

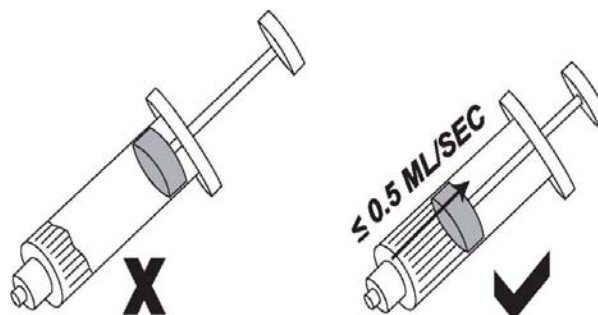
During the SECURITY trial, when possible, aspirin 325 mg once a day and clopidogrel 75 mg once a day were started at least 72 hours prior to the procedure. Administration of heparin was recommended immediately after sheath placement. At a minimum, prior to any intervention to the carotid artery, all patients received 5,000 units heparin IV / IA or an equivalent dose sufficient to achieve a target ACT of 200 to 250 seconds. After the procedure, aspirin 325 mg once a day was continued permanently and clopidogrel 75 mg daily for four weeks.

8.3 Pre-Procedure

Refer to Section 8.2 of these instructions for the suggested pre-procedure pharmacological treatment regimen. The placement of the stent in a stenotic or obstructed carotid artery should be done in an angiography procedure room. Angiography should be performed to map out the extent of the lesion(s) and the collateral flow. If thrombus is present, do not proceed with stent deployment. Access vessels must be sufficiently patent or sufficiently recanalized to proceed with further intervention. Patient preparation and sterile precautions should be the same as for any angioplasty procedure.

Using Contrast Media

During the insertion of rapid exchange catheters through guide catheters or sheaths careful handling is required to ensure that air is not drawn into the access device. It is therefore recommended that flushing of contrast media (or other fluids) is performed before or after insertion of the catheter, but not while the catheter is within the access device.



In the case where a contrast media injection must be performed with the catheter in place it is essential to ensure that no air is present within the access device prior to injection. This risk will be minimized by following the instructions of slow catheter insertion and good hemostasis valve control.

If aspiration is to be performed prior to contrast media injection it should be performed slowly and steadily at a rate of not more than 0.5 ml (0.5 cc) per second until it can be visually confirmed that no further air is entering the aspiration syringe.

8.4 Stent Sizing

See Table 11 and Table 12 for stent sizes and diameters and recommended reference vessel diameters for straight and tapered stents.

The *Xact* Carotid Stent System is provided in a range of lengths, diameters and configurations. Care should be taken to select the most appropriately sized Stent. The device range is specified in Table 1. The *Xact* Stent undergoes < 8% foreshortening during deployment.

WARNING: The *Xact* Carotid Stent System is contraindicated for use with lesions in the ostium of the common carotid artery.

Table 11: Stent Sizing (Straight Stent)

Reference Vessel Size	Unconstrained Stent Diameter
> 5.5 – 6.4 mm	7.0 mm
> 6.4 – 7.3 mm	8.0 mm
> 7.3 – 8.2mm	9.0 mm
> 8.2 – 9.1 mm	10.0 mm

Table 12: Stent Sizing (Tapered Stent)

Lumen Diameter Range for the Proximal End	Lumen Diameter Range for the Distal End	Tapered Unconstrained Stent Diameter
> 6.4 – 7.3 mm	4.8 – 5.5 mm	8.0 - 6.0 mm
> 7.3 – 8.2 mm	> 5.5 – 6.4 mm	9.0 - 7.0 mm
> 8.2 – 9.1 mm	> 6.4 – 7.3 mm	10.0 - 8.0 mm

8.5 Delivery System Preparation

- Remove the pouched device from the box.
- Examine the pouch for any signs of damage to the sterile barrier.

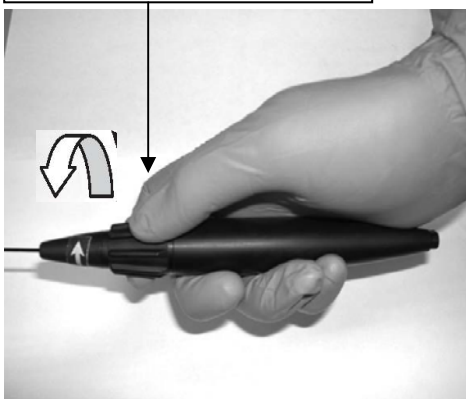
If it is suspected that the sterile barrier has been compromised, do not use the device and return it to the manufacturer.

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.

The device must only be flushed using the 3-ml syringe and flushing tip provided.

- Peel open the pouch and remove the device from the pouch, maintaining device sterility.
- Remove the device from its protection hoop by pulling the device out by the Handle. Examine the device for any damage. If any damage is observed, do not use the device and return it to manufacturer.
- Attach the 3-ml syringe, filled with sterile heparinized saline solution, to the Flushing Tip and flush via the device tip until saline exits both between the tip and the catheter shaft (Figure 1, No. 5 and 3) and also at the RX Guide Wire Exit Port (Figure 1, No. 10).
- Examine the distal end of the device to ensure that no part of the stent is exposed. Do not use the device if any portion of the stent is exposed, and return it to the manufacturer.
- If a gap between the tip and the Outer Sheath exists, rotate the Deployment Actuator in an anti-clockwise direction (opposite direction to arrow marking on handle) until the gap is closed (See Figure 5).

Deployment Actuator



- Hold the handle as shown in Figure 5
- Rotate the Deployment Actuator in the opposite direction to the arrow on the handle.

Note: Do not rotate the Deployment Actuator and the Handle together.

Figure 5: Retracting the Tip

8.6 Introduction Of The Stent Delivery System

Note: After percutaneous access is obtained, heparin should be used to maintain an ACT greater than 250 seconds.

- Access the treatment site using the appropriate accessory equipment compatible with the *Xact* 5.7 Fr Delivery System.

The outside diameter of the Outer Sheath is 5.7 Fr. The minimum guiding catheter / sheath size inner diameter (I.D.) required is 0.088”/ 2.24 mm.

The *Xact* Carotid Stent System is not to be deployed with an access device that uses an integrated leaflet type valve.

Do not use a prepared *Xact* Carotid Stent System if the stent is not fully constrained within the Delivery System.

- Deploy the Emboshield System. Other percutaneous interventional devices should be passed over the BareWire.
- If required, pre-dilate the lesion using standard angioplasty techniques over the BareWire.
- Advance the *Xact* Carotid Stent System over the BareWire. The Deployment Actuator should not be rotated before the constrained stent (within the Stent Delivery System) has been positioned at its intended deployment location. If, after preparation, a gap between the catheter tip and the outer sheath exists, rotate the Deployment Actuator in an anti-clockwise direction until the gap is closed.

Maintain a snug seal between the device and the hemostasis Tuohy / Borst valve during insertion. Failure to observe this may result in air being drawn into the access device through the hemostasis / Tuohy Borst valve. Device insertion should be performed slowly to minimize the risk of air entrainment.

Do not advance any component of the *Xact* Carotid Stent System against significant resistance. The cause of any resistance should be determined via fluoroscopy and remedial action taken.

8.7 Stent Deployment

- Advance the Stent Delivery System until the radiopaque markers are appropriately positioned proximal and distal to the target lesion.

The Deployment Actuator should not be rotated during introduction of the Stent Delivery System.

- Ensure that the hemostasis valve is tightened on the Stabilizer (Figure 1, No. 11). Secure the Handle in one hand. Ensure that the portion of the catheter shaft that remains outside the sheath / guide catheter is straight (**Figure 6-a**). The direction of

rotation, which will initiate stent deployment, is shown by the arrow on the Handle. Slowly rotate the Deployment Actuator of the Handle in a clockwise direction (**Figure 6-b**). This rotation will initiate stent deployment.

If a filter element 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. During stent placement, 1.5 cm of vessel should be left between the distal margin of the stent and the Filtration Element. The stent delivery system should not contact the Filtration Element.

- The Delivery System may be repositioned prior to the stent making contact with the vessel wall. The hemostasis valve must be opened prior to repositioning the stent. The hemostasis valve should be re-tightened on the Stabilizer before stent deployment is continued.

Do not attempt to reposition the Delivery System after the stent has made contact with the vessel wall.

- Deployment is complete when the entire stent is released and in contact with the vessel wall.
- Once the stent has made contact with the vessel wall, do not move the Delivery System until the stent has been fully deployed (**Figure 6-c**).

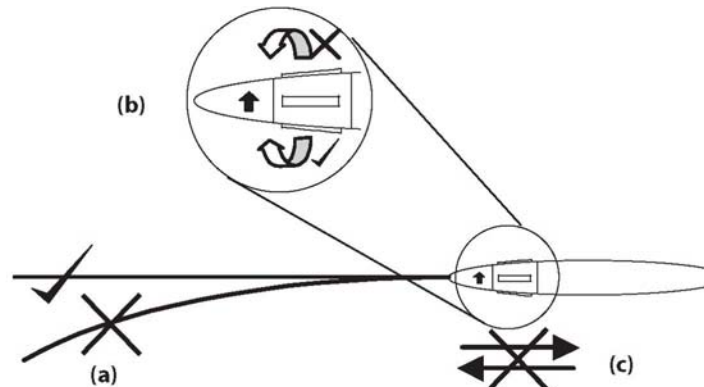


Figure 6: Stent Deployment

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. Stenting in this order obviates the need to cross the proximal stent for placement of the distal stent, and reduces the chance of dislodging stents that have already been placed.

CAUTION: If overlap of sequential stents is necessary, the amount of overlap should be kept to a minimum (approximately 5 mm). In no instance, should more than 2 stents ever overlap.

CAUTION: Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting the stent geometry and placement of the stent.

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

8.8 Post-deployment Stent Dilatation

- Open the hemostasis valve and withdraw the Delivery System under fluoroscopic observation.

If any significant resistance is met during Delivery System withdrawal, the cause of any resistance should be determined via fluoroscopy and remedial action taken.

- Using fluoroscopy, assess the stent deployment.
- The stent may be post dilated if required.

8.9 Post Stent Placement

Once final angiography confirms a satisfactory result, the Emboshield System should be retrieved as per the Instructions for Use. All other ancillary devices should be removed and, if required, the puncture site closed.

9.0 PATIENT INFORMATION

A Patient Guide which includes information on carotid artery disease and the carotid stent implant procedure using embolic protection is available from Abbott Vascular upon request. Please contact Customer Service at 1 (800) 227-9902 to obtain copies.

10.0 HOW SUPPLIED

Sterile: This device is sterilized by Ethylene Oxide. Non-pyrogenic.

Contents: Each *Xact* Carotid Stent System contains an *Xact* stent premounted on a delivery system, a 3 ml Syringe and a Flushing Tip

Storage: Store in a dry, cool place.

Disclaimer of Warranties

There is no express or implied warranty, including any implied warranty of satisfactory quality or fitness for a particular purpose, on the Emboshield Embolic Protection System described in this document. Under no circumstances shall Abbott Vascular be liable for any direct, incidental or consequential damages other than as expressly provided by specific law. Description or specifications in Abbott Vascular printed matter, including this document,

are meant solely to generally describe the product at any time of manufacture and do not constitute any express warranties.

As a result of biological differences in individuals, no product is 100% effective under all circumstances. Abbott Vascular has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after the device leaves Abbott Vascular's possession. No representative of Abbott Vascular may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

11.0 PATENTS AND TRADEMARKS

This product and/or its use are protected by one or more of the following United States patents:

5,421,955; 5,457,605; 5,458,615; 5,507,768; 5,514,154; 5,569,295; 5,603,721; 5,649,952; 5,725,572; 5,728,158; 5,759,192; 5,766,238; 5,780,807; 5,782,855; 5,916,234; 6,056,776; 6,066,167; 6,066,168; 6,131,266; 6,143,016; 6,241,758; 6,352,824; 6,369,355; 6,375,676; 6,375,826; 6,432,133; 6,468,302; 6,511,504; 6,521,865; 6,537,311; 6,568,235; 6,576,006; 6,582,460; 6,596,022; 6,599,296; 6,602,284; 6,626,937; 6,635,083; 6,641,608; 6,651,478; 6,676,693; 6,679,980; 6,689,159; 6,695,862; 6,709,454; 6,755,854; 6,764,506; 6,814,749; 6,840,081; 6,846,323; 6,855,161; 6,893,458; 6,896,697; 6,908,479; 6,927,359; 6,929,657; 6,929,660; 6,939,373; 6,964,750; 6,997,944; 7,018,403; 7,112,055; 7,128,757; 7,128,758; 7,152,452; 7,163,553; 7,175,650; 7,175,655; 7,258,697; 7,303,798; and 7,308,748.

Additional patents pending.

Xact and *Emboshield* are registered trademarks of the Abbott Group of Companies.
BareWire is a trademark of the Abbott Group of Companies.

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CUSTOMER SERVICE


















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Graphical Symbols for Medical Device Labeling

 Catalogue Number	 Nominal stent length
 Use By	 Nominal stent diameter
 Lot Number	 Minimum Guiding Catheter
 Sterilized by Ethylene Oxide	 Maximum Guide wire Diameter
 Reference Vessel Diameter	 Manufacturer
 Consult Instruction For Use	 Do not use open or damaged goods
 Single use only	 Temperature Limitation
 Do not re-sterilize	 Contents (Numeral represents quantity of units inside)
 Rapid Exchange	

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