Cordis®
A Cardinal Health company

10257072.6

Instructions for Use

ANGIOGUARD® XP Emboli Capture Guidewire System

Explanation of symbols on labels and packaging:	
	**Manufacturer**
	**Use-by Date**
	**Catalogue Number**
	**Lot Number**
	**Caution: Federal (USA) law restricts this device to sale by or on order of a physician**
	**Do not resterilize**
	**Do not re-use**
	**Caution**
	**Consult Instructions for Use**
	**n units per box**
	**Keep away from sunlight**
	**Keep dry**
	**Do not use if package is damaged**
	**Non-Pyrogenic**
	**Sterilized using ethylene oxide**

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

Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.

STERILE. The ANGIOGUARD® XP Emboli Capture Guidewire System is sterilized with ethylene oxide gas. Nonpyrogenic. Radiopaque. FOR ONE USE ONLY. DO NOT RESTERILIZE. Store in a cool, dark, dry place.

1. Device Name

The device brand name is the **ANGIOGUARD XP** Emboli Capture Guidewire.

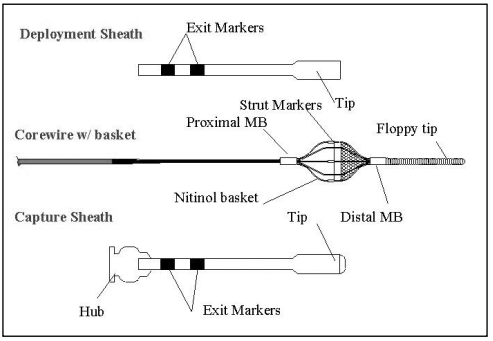
2. Description

The **ANGIOGUARD XP** Emboli Capture Guidewire system consists of the following components:

- A 300 cm long, .014" disposable guidewire with an integrated deployable filter basket near the distal end to trap and capture emboli and a torque/locking device on its proximal end;
- A filter introducer;
- A deployment sheath;
- A capture sheath; and
- A guidewire introducer.

The filter basket consists of a thin, porous membrane supported by a fine metal skeleton. The membrane contains numerous 100-micron pores to ensure adequate perfusion. Radiopaque markers are located proximal and distal to the filter basket to aid in placement of the device using fluoroscopy. Radiopaque markers are also located on every other strut of the wire filter basket just proximal to the filter material. The filter introducer component is used to flush the deployment sheath and to load the filter basket into the deployment sheath prior to use. The deployment sheath maintains the filter basket in the closed position. The torque component locks the sheath in place on the wire. The system is then inserted into the body. Upon reaching the anatomical site, the deployment sheath is removed and the filter deploys inside the arterial lumen. With the device in place, the carotid stenting procedure may then be performed.

The separate capture sheath, which has a radiopaque marker at its distal end, is used to capture and retrieve the proximal (uncovered) portion of the filter basket. The capture sheath is advanced over the guidewire inside the patient. When the capture sheath's distal radiopaque marker band and the basket's proximal marker band touch, the basket is captured. The filter membrane is not captured by the sheath. The torque device (same one used for delivery) is connected to the capture sheath and tightened on the guidewire to ensure the filter basket with the trapped emboli remain captured when removing the guidewire/capture sheath assembly from the patient. The following device schematic correlates to the preceding device description.

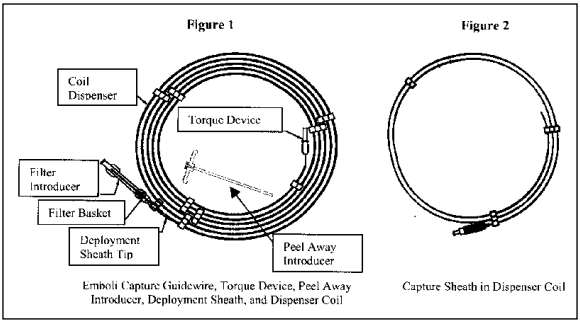


The **ANGIOGUARD XP** Emboli Capture Guidewire is provided as noted in **Table 1** below.

Table 1 - ANGIOGUARD XP Emboli Capture Guidewire System

CATALOG CODES Medium Support	CATALOG CODES Extra Support	GUIDEWIRE DIAMETER (in)	SYSTEM LENGTH (cm)	FILTER BASKET DIAMETER (mm)
403014MC	403014EC	.014	300	4
503014MC	503014EC	.014	300	5
603014MC	603014EC	.014	300	6
703014MC	703014EC	.014	300	7
	803014EC	.014	300	8

The **ANGIOGUARD® XP** Emboli Capture Guidewire is packaged as noted in **Figures 1 and 2**.



3. Indications for Use

The **ANGIOGUARD XP** Emboli Capture Guidewire is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing carotid artery angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be from 3 mm to 7.5 mm (see Section 9.3 of these instructions for basket/vessel sizing).

4. Contraindications

Use of the **ANGIOGUARD XP** Emboli Capture Guidewire is contraindicated in the following patients:

1. Patients in whom antiplatelet and or anticoagulation therapy is contraindicated.
2. Patients in whom the guide catheter is unable to be placed.
3. Patients with uncorrected bleeding disorders.
4. Patients with known allergies to Nitinol.
5. Lesions in the ostium of the common carotid artery.

5. Warnings

5.1 General Warnings

1. Only physicians who have received appropriate training for carotid stenting and who are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.
2. The safety and efficacy of **ANGIOGUARD** have not been demonstrated with carotid stent systems other than the Cordis **PRECISE** stent.
3. Overstretching of the artery may result in rupture and life-threatening bleeding.
4. Patient ACT of >300 seconds needs to be maintained during **ANGIOGUARD XP** Emboli Capture Guidewire deployment. (See Section 9.1 of these instructions.)
5. The safety and effectiveness of this device as an emboli protection system has not been established in the coronary, cerebral, or peripheral vasculature, other than carotid arteries.

5.2 Patient Selection Warnings

1. Safety and effectiveness of the angioplasty and carotid stenting procedure has **NOT** yet been established in patients with the characteristics noted below.

Lesion Characteristics:

- Patients with evidence of intraluminal thrombus thought to increase the risk of plaque fragmentation and distal embolization.
- Patients whose lesion(s) may require more than two stents.
- Patients with total occlusion of the target vessel.
- Patients with lesions of the ostium of the common carotid.
- Patients with highly calcified lesions resistant to PTA.
- Concurrent treatment of bilateral lesions.

Patient Characteristics:

- Patients at low-to-moderate risk for adverse events from carotid endarterectomy.
- Patients experiencing acute ischemic neurologic stroke or who experienced a stroke within 48 hours.
- Patients with an intracranial mass lesion (i.e., abscess, tumor, or infection) or aneurysm (> 9 mm).
- Patients with arterio-venous malformations in the territory of the target carotid artery.
- Patients with coagulopathies.
- Patients with poor renal function, who, in the physician's opinion, may be at high risk for a reaction to contrast medium.
- Patients with perforated vessels evidenced by extravasation of contrast media.
- Patients with aneurysmal dilation immediately proximal or distal to the lesion.
- Pregnant patients or patients under the age of 18.

Access Characteristics:

- Patients with known peripheral vascular, supra-aortic or internal carotid artery tortuosity that would preclude the use of catheter-based techniques.
- Patients in whom femoral or brachial access is not possible.

2. Risk of distal embolization may be higher if the **ANGIOGUARD XP** Emboli Capture Guidewire is not used during carotid stenting procedures.

5.3 Device Use Warnings

1. Do not use the device if there are abnormalities in the sterile barrier (e.g. broken seal, torn or breached barrier) or product.
2. This product is designed and intended for single use. It is not designed to undergo reprocessing and re-sterilization after initial use. Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
3. Use the **ANGIOGUARD XP** Emboli Capture Guidewire prior to the "Use By" date specified on the package.
4. Observe all guidewire movement in the vessels using fluoroscopic guidance.
5. DO NOT TORQUE THE GUIDEWIRE.
   - Do not torque a guidewire without observing corresponding movement of the tip; otherwise, vessel trauma could occur.
   - Torquing a guidewire against resistance may cause guidewire damage and/or guidewire tip separation. Always advance or withdraw the guidewire slowly. Never push, auger, withdraw or torque a guidewire that meets resistance. Resistance may be felt and/or observed using fluoroscopy by noting any buckling of the guidewire tip. Determine the cause of resistance under fluoroscopy and take the necessary remedial action.
6. Before the guidewire is moved, tip movement should be examined using fluoroscopy.
7. Perform all exchanges slowly to prevent air from entering the catheter system.
8. When introducing the guidewire, confirm that the guiding catheter or interventional sheath introducer tip is free within

the vessel lumen and not against the vessel wall. Failure to do so may result in vessel trauma upon guidewire exit from the tip. Use the radiopaque marker of the interventional device to confirm position.

6. Precautions

6.1 Pre-Procedure Precautions

1. The **ANGIOGUARD® XP** Emboli Capture Guidewire is supplied STERILE and is intended for single use only. Do not re-sterilize and/or reuse the device.
2. Use the **ANGIOGUARD XP** Emboli Capture Guidewire System prior to the "Use By" date printed on the package.
3. Guidewires are delicate instruments and should be handled carefully. Prior to use, and when possible during the procedure, inspect the guidewire carefully for coil separation, bends, kinks, or damage of the filter basket assembly.
4. Do not use if opened or damaged.
5. Confirm the compatibility of the **ANGIOGUARD XP** Emboli Capture Guidewire with the interventional device before actual use.

6.2 Device Use Precautions

1. If distal perfusion of dye is significantly reduced or no dye is perfusing past the distal marker band of the filter basket, the **ANGIOGUARD XP** Emboli Capture Guidewire may have reached its maximum capacity to contain emboli. Remove and replace with a new **ANGIOGUARD XP** system per Section 11.0 of these instructions.
2. Do not attempt to close the filter basket with the Deployment Sheath. The **ANGIOGUARD XP** Emboli Capture Guidewire should only be removed using the Capture Sheath.
3. Care during diagnostic or interventional device exchanges must be practiced to minimize movement of the guidewire/filter basket.
4. Use caution when withdrawing **ANGIOGUARD XP** Emboli Capture Guidewire through the deployed stent.

7. Adverse Events

7.1 Observed Adverse Events

Carotid stenting with distal protection was conducted on a total of 573 patients with carotid artery disease who were at high risk for adverse events from carotid endarterectomy (CEA) in the SAPPHIRE clinical study (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy). The study was conducted to evaluate the safety and effectiveness of the Cordis **PRECISE®** Nitinol Stent System and the **ANGIOGUARD® XP** Emboli Capture Guidewire.

The study included a randomized arm that compared stent patients to CEA patients (334 patients). The study also included a non-randomized stent arm for patients who met the same entry criteria as the randomized patients, but who were determined by the surgeon at the study site to be at too high a risk for adverse events from carotid endarterectomy (406 patients). Patients meeting the same inclusion criteria as the randomized patients, but determined by the interventionalist to be inappropriate for stent treatment, were entered into a non-randomized surgical arm (7 patients). The major adverse event (MAE) rate in all study arms was defined as death, stroke, or MI (Q-wave or non-Q-wave) to 30 days and death or ipsilateral stroke from 31 days to 360 days.

Only 7 patients were enrolled in the non-randomized surgical arm of the SAPPHIRE study. The 360-day MAE rate for these patients was 14.3%. Thirty-day complications in the SAPPHIRE Randomized Study arm (167 stent patients vs. 167 CEA patients) and the non-randomized stent arm (406 patients) are shown in **Table 2**. Differences in 30-day event rates in-hospital vs. out-of-hospital for major adverse events (MAE) and Transient Ischemic Attack (TIA) are also provided in **Table 2**, which follows. All acute bradycardia and hypotensive events occurred in-hospital. Differences in 30-day event rates observed in-hospital vs. out-of-hospital for MAE and TIA are also provided in **Table 2**, which follows.

Table 2 - Randomized & Non-Randomized Patient Events to 30 Days

30-Day Complications (In-Hospital vs. Out-of-Hospital)	Randomized Stent (N=167)		Randomized CEA (N=167)		Non-Randomized Stent (N=406)	
	In-Hosp	Out-of-Hosp	In-Hosp	Out-of-Hosp	In-Hosp	Out-of-Hosp
MAE	4.2% (7)	1.2% (2)	7.2% (12)	3.0% (5)	3.2% (13)	3.7% (15)
Death (All Cause)	0.0% (0)	1.2% (2)	1.2% (2)	1.2% (2)	1.2% (5)	1.0% (4)
Myocardial Infarction (Q or Non-Q)	2.4% (4)	0.0% (0)	4.8% (8)	1.2% (2)	1.0% (4)	0.7% (3)
Stroke	3.6% (6)	0.0% (0)	2.4% (4)	0.6% (1)	2.5% (10)	2.5% (10)
Transient Ischemic Attack (TIA)	3.6% (6)	0.0% (0)	2.4% (4)	0.0% (0)	3.2% (13)	2.2% (9)

30-Day Complications	Randomized Stent (N=167)	Randomized CEA (N=167)	P-value*	Non-Randomized Stent (N=406)
Death (All Cause), Any Stroke or MI	4.8% (8)	9.6% (16)	0.14	6.9% (28)
Death (All Cause)	1.2% (2)	2.4% (4)	0.68	2.2% (9)
Myocardial Infarction (Q or Non-Q)	2.4% (4)	6.0% (10)	0.17	1.7% (7)
Q Wave MI	0.0% (0)	1.2% (2)	0.50	0.2% (1)
Non-Q Wave MI	2.4% (4)	4.8% (8)	0.38	1.5% (6)
Stroke	3.6% (6)	3.0% (5)	>0.99	4.9% (20)
Major Ipsilateral Stroke	0.6% (1)	1.2% (2)	>0.99	2.5% (10)
Major Non-Ipsilateral Stroke	0.6% (1)	0.6% (1)	>0.99	0.5% (2)
Minor Ipsilateral Stroke	2.4% (4)	0.6% (1)	0.37	1.7% (7)
Minor Non-Ipsilateral Stroke	0.6% (1)	0.6% (1)	>0.99	0.5% (2)
Transient Ischemic Attack (TIA)	3.6% (6)	2.4% (4)	0.75	5.4% (22)
Target Lesion Revascularization	0.0% (0)	0.0% (0)	-	0.5% (2)
Surgery	0.0% (0)	0.0% (0)	-	0.0% (0)
PTA	0.0% (0)	0.0% (0)	-	0.5% (2)
Target Vessel Revascularization (not involving the Target Lesion)	0.0% (0)	0.0% (0)	-	0.0% (0)
Surgery	0.0% (0)	0.0% (0)	-	0.0% (0)
PTA	0.0% (0)	0.0% (0)	-	0.0% (0)
Major Bleeding[1]	9.0% (15)	10.2% (17)	0.85	12.8% (52)
Cranial Nerve Injury	0.0% (0)	4.2% (7)	0.01	0.0% (0)
Severe Hypotension	17.4% (29)	3.0% (5)	<0.01	15.0% (61)
Bradycardia	8.4% (14)	3.0% (5)	0.06	3.2% (13)
Vascular Complications[2]	5.4% (9)	N/A	-	2.5% (10)
Device/Procedure Related Adverse Events[3]	0.0% (0)	-	-	0.0% (0)

* P-value displayed refers to comparison of randomized arms.

(1) Major Bleeding: Any non-access site-related bleeding resulting in a 25% or more decline in HCT or requiring transfusion.

(2) Vascular Complications: Events related to bleeding or vascular injury at the percutaneous access site.

(3) There were no device or procedure related events. In 17 of 19 initial stent delivery failures, a subsequent attempt was successful. In one case, the patient was treated with CEA. In the other case, the patient was treated with balloon angioplasty alone. One stent fracture was noted from one-year ultrasound films, with no adverse effect to the patient.

7.2 Potential Adverse Events

Adverse events that may be associated with the use of the **ANGIOGUARD® XP** Emboli Capture Guidewire, in conjunction with the Cordis **PRECISE®** Nitinol Stent System include, but may not be limited to:

- air embolism
- allergic/anaphylactoid reaction
- aneurysm
- angina/coronary ischemia
- arrhythmia (including bradycardia, possibly requiring need for a temporary or permanent pacemaker)
- arterial occlusion/restenosis of the treated vessel
- arterial occlusion/thrombus, at puncture site
- arterial occlusion/thrombus, remote from puncture site
- arteriovenous fistula
- bacteremia or septicemia
- cerebral edema
- damage to implanted stent(s)
- death
- embolization, arterial
- emergent repeat hospital intervention
- fever
- GI bleeding from anticoagulation/antiplatelet medication
- hematoma bleed, puncture site
- hematoma bleed, remote site
- hemorrhage
- hyperperfusion syndrome
- hypotension/hypertension
- infection
- intimal injury/dissection
- ischemia/infarction of tissue/organ
- local infection and pain at insertion site
- malposition (failure to deploy filter basket at intended site)
- myocardial infarction
- pain
- pseudoaneurysm
- renal failure
- seizure
- severe unilateral headache
- stroke
- transient ischemic attack
- vasospasm
- venous occlusion/thrombosis, at puncture site
- venous occlusion/thrombosis, remote from puncture site
- vessel rupture, dissection, perforation

7.3 Device Related Adverse Event Reporting

Any adverse event (clinical incident) involving the **ANGIOGUARD XP** Emboli Capture Guidewire should be reported to Cordis Corporation immediately. To report an incident, call the Product Quality Services Department at 1-800-327-7714.

8. Clinical Study Information

8.1 Objectives

The primary objective of the pivotal clinical study (SAPPHIRE) was to compare the safety and effectiveness of the Cordis **PRECISE** Nitinol Stent Systems, used in conjunction with the **ANGIOGUARD XP** Emboli Capture Guidewire, to carotid endarterectomy (CEA) in the treatment of carotid artery disease in patients at increased risk for adverse events from CEA. Study hypotheses examined whether the major adverse events (MAE) rate of randomized stent patients was not inferior to randomized CEA patients. Safety evaluations included assessments of major clinical events occurring during the procedure, prior to discharge, within 30 days, six months, one year and every 12 months thereafter for a total of three years; access site vascular complications; independent neurological assessments at 24 hours, 30 days, six months and one year post procedure. Effectiveness evaluations included assessments of successful stent deployment at the target lesion; less than 30% residual diameter stenosis at the completion of the procedure as measured by carotid angiography; and restenosis ($\geq$ 50%) as determined by carotid ultrasound at 30 days, six months and one year post procedure and every 12 months thereafter for a total of three years.

8.2 Study Design

The pivotal SAPPHIRE study was a multi-center, prospective, randomized, triangular sequential trial comparing patients at increased risk for adverse events from CEA who received a stent to a surgical (CEA) control. The safety and effectiveness of the Cordis **PRECISE** Nitinol Stent System, used in conjunction with the **ANGIOGUARD XP** Emboli Capture Guidewire in the treatment of de novo or restenotic obstructive carotid artery disease in these patients, was evaluated.

The study also included a non-randomized stent arm, which included those patients who met entry criteria but who were determined by the surgeon at the study site to be at too high a risk for adverse outcomes from surgery and therefore inappropriate for randomization. Likewise, patients meeting the entry criteria, but determined by the interventionalist to be unacceptable candidates for stenting and therefore not randomizable, had the option of entering a non-randomized surgical arm.

SAPPHIRE entry criteria were identical for all patients. All patients were evaluated to determine whether they met the entry criteria by a multi-disciplinary team consisting of a neurologist, interventionalist, and vascular surgeon. Patients meeting the criteria were either randomized to treatment by stent or CEA, or placed into the non-randomized stent or CEA arms, based on the medical judgment of the interventionalist and surgeon as noted above. Patients who were entered into this study were either asymptomatic with a $\geq$ 80% diameter stenosis or symptomatic with a $\geq$ 50% diameter stenosis. Symptomatic patients were defined as those patients who have one or more TIAs, characterized by distinct focal neurological dysfunction or monocular blindness with clearing of signs and symptoms within 24 hours or one or more completed strokes with persistence of symptoms or signs for more than 24 hours. In addition, ALL patients must also have had at least one anatomic or co-morbid risk factor placing them at high-risk for adverse events from CEA. These risk factors are as follows:

- Congestive Heart Failure (Class III/IV), and/or known severe left ventricular dysfunction <30%
- Open-heart surgery within 6 weeks
- Recent myocardial infarction (>24 hours and <4 weeks)
- Unstable angina (CCS class III/IV)
- Synchronous severe cardiac and carotid disease requiring open heart surgery and carotid revascularization
- Severe pulmonary disease to include any of the following:
  - Chronic oxygen therapy
  - Resting P02 of $\leq$ 60 mmHg
  - Baseline hematocrit $\geq$ 50%
  - FEV1 or DLCO $\leq$ 50% of normal
- Contralateral carotid occlusion
- Contralateral laryngeal palsy
- Post-radiation treatment
- Previous CEA recurrent stenosis
- High cervical ICA lesions
- CCA lesions below the clavicle
- Severe tandem lesions
- Abnormal stress test

The primary endpoint was a composite of MAE including death, any stroke, or myocardial infarction (MI), in the first 30 days following treatment and death or ipsilateral stroke between 31 days and 12 months. An independent Clinical Events Committee adjudicated all MAE's and other events. Endpoints were analyzed on an intent-to-treat basis.

A total of 747 patients were enrolled in the SAPPHIRE study at 29 centers in the United States. The randomized population included 334 patients (167 stent/167 CEA), 310 of who were treated per protocol. The primary reasons why the remaining 24 patients were not treated were: 1) Eleven patients withdrew consent; 2) Six patients were found not to meet inclusion criteria subsequent to randomization; 3) Five patients' conditions deteriorated and they became too high a risk for any treatment; and 4) Two patients were randomized to surgery that was never performed. The non-randomized stent arm included 406 patients and the non-randomized CEA arm included seven patients.

Follow-up evaluations were scheduled at 30 days, six months and one year post-procedure, and annually thereafter for three years.

Imaging data provided in this summary are based on findings from two independent centralized Core Laboratories, which reviewed ultrasound and angiographic films. A third independent laboratory analyzed trapped material contained in a percentage of all **ANGIOGUARD® XP** filter baskets. A Clinical Events Committee (CEC) adjudicated all clinical events and an independent Data Safety Monitoring Board (DSMB) monitored safety.

8.3 Patient Demographics

Table 3 provides the subject characteristics of randomized patients and non-randomized stent patients enrolled in the SAPPHIRE trial.

Table 3 - SAPPHIRE Patient Demographics*

Patient Characteristics	Randomized Stent	Randomized CEA	P-value**	Non-Randomized Stent
Age (Years)	72.5 ± 8.3	72.3 ± 9.1	0.86	71.4 ± 9.8
% Male	66.9% (111/166)	67.1% (108/161)	1.00	64.3% (261/406)
Diabetes	25.3% (42/166)	27.5% (44/160)	0.71	30.8% (125/406)
Coronary Artery Disease	85.8% (133/155)	75.5% (111/147)	0.03	68.9% (259/376)
Previous PTCA (Coronary)	34.8% (56/161)	23.4% (37/158)	0.03	21.2% (83/392)
Previous CABG	43.4% (72/166)	30.8% (49/159)	0.02	31.5% (128/406)
Previous Q-Wave or Non-Q-Wave MI	29.7% (46/155)	35.3% (54/153)	0.33	33.4% (122/365)
Angina at a Low Workload or Unstable Angina	24.1% (20/83)	14.7% (11/75)	0.16	31.5% (41/130)
Congestive Heart Failure	17.5% (29/166)	17.4% (28/161)	1.00	18.2% (74/406)
Coexistent Severe Coronary Artery Disease Requiring Carotid and Coronary Revascularization	15.9% (26/164)	16.5% (26/158)	1.00	12.8% (51/400)
Systolic Blood Pressure	151.7 ± 26.0	153.5 ± 26.9	0.54	148.2 ± 27.2
History of Dyslipidemia	78.5% (128/163)	76.9% (123/160)	0.79	73.9% (289/391)
Previous CEA/Recurrent Stenosis	22.6% (37/164)	22.2% (35/158)	1.00	37.7% (151/401)
Post-Radiation Treatment	4.3% (7/164)	5.7% (9/158)	0.61	16.2% (64/401)
Prior CEA	28.3% (47/166)	26.7% (43/161)	0.80	45.2% (183/405)
Contralateral Carotid Occlusion	23.6% (39/165)	25.3% (40/158)	0.80	16.3% (65/400)
History of Stroke	27.1% (45/166)	23.8% (38/160)	0.53	32.3% (129/399)
History of TIA	31.1% (50/161)	34.0% (53/156)	0.63	34.5% (138/400)
High Cervical ICA Lesions	4.3% (7/164)	4.4% (7/158)	1.00	12.7% (51/401)
CCA Lesions Below the Clavicle	0.0% (0/164)	0.0% (0/158)	-	3.0% (12/401)
Other Co-morbid Risk Factors Precluding CEA	0.0% (0/164)	0.0% (0/160)	-	7.9% (32/404)
Renal Insufficiency	6.0% (10/166)	7.5% (12/160)	0.66	7.4% (30/405)
Current Cigarette Use	16.9% (27/160)	16.4% (26/159)	1.00	13.5% (54/399)
Patients >80 years	19.3% (32/166)	20.5% (33/161)	0.78	19.2% (78/406)

* The denominator represents the total number of responses to a question in the case report form.
**P-value displayed refers to comparison of randomized arms.

8.4 Study Results

The 360-day major adverse events (MAE) rate, defined as death, stroke, or MI (Q-wave or non-Q-wave) to 30 days and death or ipsilateral stroke from 31 days to 360 days was 12.0% for the randomized stent patients compared with 19.2% for the control group. These results demonstrate non-inferiority (p=0.004) of carotid stenting to carotid endarterectomy (CEA) with the pre-specified non-inferiority delta of 3%.

The MAE rate at 360 days for the non-randomized stent patients was 15.8%. In a test of the primary endpoint against the Objective Performance Criteria (OPC), despite the fact that the rate was numerically less than the OPC plus the delta, the p- value was found to be 0.2899. In a test of the MAE rate when post 30-day non-neurological deaths are not included, the p-value was found to be <0.0001. The causes of these non-neurological deaths are well documented, and consist of cardiac deaths, cancer deaths, renal failure, and respiratory failure.

A comparison of the non-randomized stent arm and the randomized CEA arm was conducted utilizing a propensity score analysis that accounted for baseline imbalances due to the non-randomized (i.e., more observational) nature of group membership. The analysis found the treatment difference (non-randomized stent minus CEA) in 360-day MAE was –5.3%, with an adjusted 95% confidence interval of –13.4% to 3.0%. Thus, after adjusting for the higher risk of patients in the non-randomized stent arm, 360-day MAE outcomes were non-inferior to the CEA arm of the randomized study within a 3% delta. Principal safety and effectiveness results to 360 days are presented in **Table 4**, which follows. The cumulative percentage of MAE through 360-days for the randomized and non-randomized stent patients is presented in **Figure 3**, which follows. Non-randomized CEA patient event rates are not provided in **Table 4** since only seven patients were enrolled in that study arm and the data are insufficient for statistical analysis. For informational purposes, the MAE rate for non-randomized CEA patients to 360 days was 14.3% (1/7). **Figures 4 and 5** present the cumulative percentage of MAE through 360 days for randomized asymptomatic and symptomatic patients.

Table 4 - Principal Safety & Effectiveness Results To 360 Days (Intent to Treat)

Safety Measures & Other Clinical Events to 360 Days	Randomized Stent (N=167)	Randomized CEA (N=167)	P-value*	Non-Randomized Stent (N=406)
MAE[1]	12.0% (20/167)	19.2%(32/167)	0.10	15.8% (64/406)
Death (All Cause)	7.2% (12/167)	12.6% (21/167)	0.14	10.1% (41/406)
Stroke	6.0% (10/167)	7.2% (12/167)	0.83	9.1% (37/406)
Major Ipsilateral Stroke	0.6% (1/167)	3.0%(5/167)	0.21	3.2% (13/406)
Minor Ipsilateral Stroke	3.6% (6/167)	1.8% (3/167)	0.50	3.9% (16/406)
Myocardial Infarction (Q or Non-Q)	3.0% (5/167)	7.2% (12/167)	0.13	2.7% (11/406)
TIA	6.6% (11/167)	3.0% (5/167)	0.20	6.9% (28/406)
Major Bleeding[2]	9.0% (15/167)	10.2% (17/167)	0.85	13.3% (54/406)
Cranial Nerve Injury	0.0% (0/167)	4.8% (8/167)	0.01	0.0% (0/406)
Severe Hypotension	17.4% (29/167)	3.0% (5/167)	<0.01	15.5% (63/406)
Bradycardia	8.4% (14/167)	3.0% (5/167)	0.06	3.4% (14/406)
Vascular Complications[3]	5.4% (9/167)	N/A	-	2.5% (10/406)
Device/Procedure Related Adverse Events[4]	0.0% (0)	0.0% (0)	-	0.0% (0)
Efficacy Measures	**Randomized Stent (N=167)**	**Randomized CEA (N=167)**	**P-Value***	**Non-Randomized Stent (N=406)**
Lesion Success [5]	91.8% (145/158)	N/A	N/A	90.4% (368/407)
Procedure Success [6]	88.1% (140/159)	N/A	N/A	87.9% (355/404)
Device Success[7]	91.2% (145/159)	N/A	N/A	89.6% (363/405)
ANGIOGUARD® Success[8]	95.6% (152/159)	N/A	N/A	91.6% (372/406)
Post-Procedure In-Lesion Minimal Lumen Diameter (MLD in mm) Mean±SD (N) Range (min, max)	 3.9±0.8 (147) (2.1,7.3)	 N/A	 N/A	 3.8±0.8 (385) (2.0, 8.1)
Post-Procedure In-Lesion Percent Diameter Stenosis (%DS)[9] Mean±SD (N) Range (min, max)	 17.2±11.3 (147) (1.5, 49.3)	 N/A	 N/A	 18.5±12.6 (385) (-12.1, 64.7)
Post-Procedure In-Stent Minimal Lumen Diameter (MLD in mm) Mean±SD (N) Range (min, max)	 4.3±0.9 (147) (2.1, 7.9)	 N/A	 N/A	 4.1±0.8 (381) (2.2, 8.1)
Post-Procedure In-Stent Percent Diameter Stenosis (%DS)[10] Mean±SD (N) Range (min, max)	 8.3±16.7 (147) (-42.0, 46.6)	 N/A	 N/A	 10.9±14.2 (381) (-34.9, 43.8)
Binary Ultrasound In-Vessel Restenosis at 360 days[11]	19.7% (24/122)	31.3% (30/96)	0.06	27.7% (78/282)
Binary Ultrasound In-Stent Restenosis at 360 days[11]	15.6% (19/122)	13.5% (13/96)	0.70	18.4% (52/282)
Cumulative % of TLR at 360 days**[12]	0.6%	4.3%	0.04	0.8%
Cumulative % of MAE1 at 360 days**	12.2%	20.1%	0.05	16.0%

Numbers are % (counts/sample size).

*P-value displayed refers to comparison of randomized arms.

**Cumulative percentage estimates are by Kaplan-Meier methods with standard error estimates by Peto formula.

(1) Major Adverse Events (MAE) = Death, MI or stroke to 30 days and death or ipsilateral stroke from 31-360 days.

(2) Major Bleeding = Any non-access site related bleeding resulting in a 25% or more decline in HCT or requiring transfusion.

(3) Vascular Complications = Events related to bleeding or vascular injury at the percutaneous access site.

(4) There were no device or procedure related events. In 17 of 19 initial stent delivery failures, a subsequent attempt was successful. In one case, the patient was treated with CEA. In the other case, the patient was treated with balloon angioplasty alone. One stent fracture was noted from one-year ultrasound films, with no adverse effect to the patient.

(5) Lesion Success = The attainment of a final residual stenosis of <30% using any percutaneous method. If no in-stent measurements were available, in-lesion measurements were used, and if no QCA was available, visual estimates were used.

(6) Procedure Success = The attainment of a final residual stenosis of <30% and no in-hospital MAE. If no in-stent measurements were available, in-lesion measurements were used, and if no QCA was available, visual estimates were used.

(7) Device Success = The attainment of a final residual stenosis of <30% using only the assigned device. If no in-stent measurements were available, in-lesion measurements were used, and if no QCA was available, visual estimates were used.

(8) **ANGIOGUARD** Success = Successful deployment and retrieval of the **ANGIOGUARD** device.

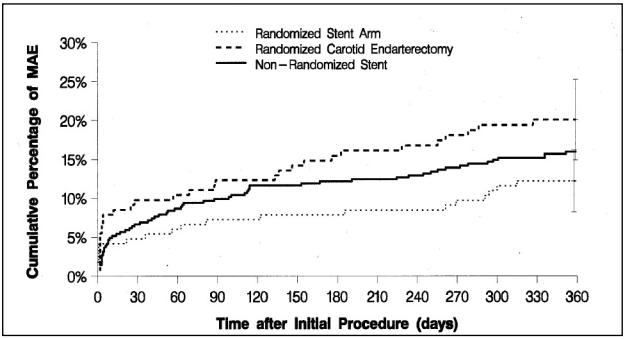
(9) In-lesion % DS Measurement = Defined as the % diameter stenosis either within the stented segment or within 5 mm proximal or distal to the stent edges.

(10) In-stent % DS Measurement = Defined as the % diameter stenosis within the stented segment.

(11) Binary Restenosis is defined by Ultrasound as % diameter stenosis >50%.

(12) TLR = Target Lesion Revascularization

Figure 3
Cumulative Percentage of MAE* at 360 days

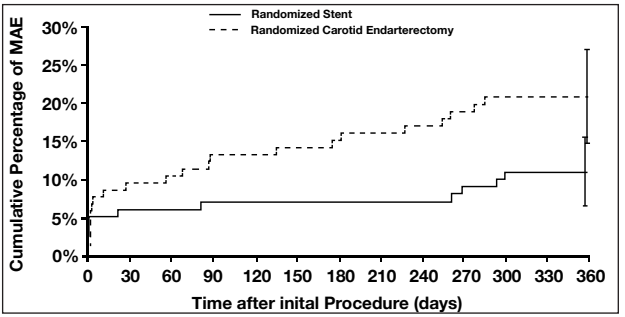


Time After Procedure (Days) – Randomized Patients				
	0	30	180	360
Stent				
N at risk	167	158	152	143
% with events	1.8	4.2	7.9	12.2
CEA				
N at risk	167	146	136	118
% with events	0.6	9.8	15.5	20.1
Test Between Groups				
Log-Rank P-Values	0.053			

Time After Procedure (Days) – Non-Randomized Patients				
	0	30	180	360
Stent				
N at risk	406	382	352	329
% with events	1.5	6.9	12.2	16.0

* Major Adverse Events (MAE) = Death, MI or stroke to 30 days and death or ipsilateral stroke from 31-360 days.

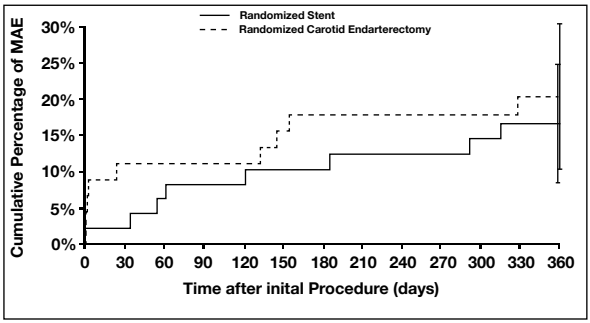
Figure 4
Cumulative Percentage of MAE* at 360 days – Asymptomatic Randomized Stent and CEA Patients



Time After Procedure (Days)			
	0	30	360
Stent			
N at risk	117	109	100
% with events	2.6	6.0	10.5
CEA			
N at risk	119	103	84
% with events	0.8	9.4	20.3
Test Between Groups			
Log-Rank P-Value	0.044		

* Major Adverse Events (MAE) = Death, MI or stroke to 30 days and death or ipsilateral stroke from 31-360 days.

Figure 5
Cumulative Percentage of MAE* at 360 Days – Symptomatic Randomized Stent & CEA Patients



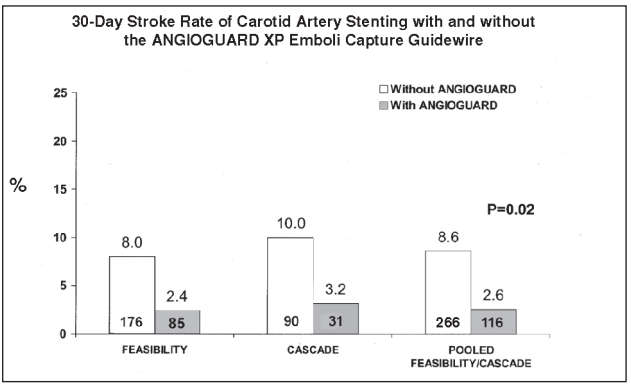
	Time After Procedure (Days)		
	0	30	360
Stent			
N at risk	50	49	42
% with events	0.0	2.0	16.3
CEA			
N at risk	46	42	32
% with events	0.0	10.9	20.0
Test Between Groups			
Log-Rank P-Values	0.582		

* Major Adverse Events (MAE) = Death, MI or stroke to 30 days and death or ipsilateral stroke from 31-360 days.

Basket Content Analysis - A pathology core lab analyzed the contents of 294 **ANGIOGUARD® XP** filter baskets from the non-randomized stent arm of the SAPPHIRE trial and determined that 59.5% (175/294) of the baskets contained material that had been captured during the carotid stenting procedure. Physicians reported that there was visible material present in 56% of the 393 baskets inspected in the non-randomized stent arm and in 72.2% of the 158 baskets inspected in the randomized stent arm.

30-Day Stroke Rate of Carotid Artery Stenting with and without ANGIOGUARD XP Emboli Capture Guidewire - Two non-randomized studies utilizing the **PRECISE®** stent (and its predecessor, the **S.M.A.R.T.®** stent) were conducted in Europe (CASCADE) and in the United States (U.S. Feasibility Study).

Thirty-one (31) of 131 patients in CASCADE and 85 of 261 patients in the U.S. Feasibility study were treated with stenting in conjunction with the **ANGIOGUARD** embolic protection device while the remaining patients were treated with stenting alone. Because the number of patients in each trial is small, an exploratory analysis was performed in which the data for 30-day stroke from these two trials were combined. 30-day stroke rates for patients treated by stenting alone and for patients treated by stenting with distal embolic protection were analyzed in a post-hoc analysis; combined rates of 30-day stroke were 8.6% for the 266 patients treated with stenting alone and 2.6% for the 116 patients treated by stenting with distal embolic protection. In this analysis, the difference between these two rates (an absolute reduction of 6% and a relative reduction of 70%) is significant with a p-value of 0.02.



9. Directions for Use

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

9.1 Peri-Procedural Care

It is recommended that heparin (intravenous) be given during the procedure immediately after guiding catheter cannulation. The initial bolus dose of heparin should be approximately 3,000 to 5,000 units (with necessary weight adjustments). Additional bolus doses of heparin should be given to maintain an ACT near 300 seconds during the entire procedure. No heparin should be given after the procedure until hemostasis at the puncture site is achieved.

9.2 Pre-Procedure

The percutaneous placement of the **ANGIOGUARD® XP** Emboli Capture Guidewire 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. 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.

a) **Inject contrast media** – Perform a percutaneous angiogram using standard technique.
b) **Identify and mark the lesion** – Fluoroscopically identify and mark the lesion, observing the most distal level of the stenosis.

9.3 Device Selection and Preparation

CAUTION: The **ANGIOGUARD XP** Emboli Capture Guidewire is supplied STERILE and is intended for single use only. DO NOT resterilize and/or reuse the device. Do not use if opened or damaged.

CAUTION: Use the **ANGIOGUARD XP** Emboli Capture Guidewire system prior to the "Use By" date printed on the package.

CAUTION: Guidewires are delicate instruments and should be handled carefully. Prior to use, and when possible during the procedure, inspect the guidewire carefully for coil separation, bends, kinks, or damage of the filter basket assembly. Do not use defective equipment.

CAUTION: Confirm the compatibility of the **ANGIOGUARD XP** Emboli Capture Guidewire with the interventional device before actual use.

Select the appropriate diameter filter basket in accordance with **Table 5**, which follows.

Table 5
Filter Basket Sizing Recommendation

Nominal Filter Basket Size	Recommended Vessel Size
4.0 mm	3.0 mm < Vessel ≤ 3.5 mm
5.0 mm	3.5 mm < Vessel ≤ 4.5 mm
6.0 mm	4.5 mm < Vessel ≤ 5.5 mm
7.0 mm	5.5 mm < Vessel ≤ 6.5 mm
8.0 mm	6.5 mm < Vessel ≤ 7.5 mm

1. The packaging contains two plastic coil-tubing dispensers (see **Figures 1 and 2**). One contains the Guidewire with Filter Basket, Filter Basket Introducer, Peel-away Guidewire Introducer, Torque Device, and yellow Deployment Sheath. The second contains the blue Capture Sheath, which will not be needed until the filter basket is ready to be removed from the vessel. Place the Capture Sheath aside until needed.
2. During shipping, the deployment sheath tip may become disengaged from the filter basket introducer. Verify that the deployment sheath tip is engaged. If not, engage manually by inserting the deployment sheath tip into the filter basket introducer.
3. Fill a 5 ml Luer lock syringe with sterile saline and purge all air.
4. Attach syringe to Luer lock hub on the end of the filter introducer.
5. Inject 5 ml of saline to purge all air from the deployment sheath and filter basket (ensure distal tip of the deployment sheath is inside the filter basket introducer tip prior to purging the system). You should see saline dripping from the proximal end of the deployment sheath (inside the coil dispenser).
6. Disconnect syringe.
7. Remove the two proximal (closest to the torque device) anti-migration clips holding the guidewire in the dispenser coil.
8. Ensure the torque device is locked onto the guidewire.
9. Gripping the torque device in one hand and the coil dispenser in the other, pull on the wire until the basket is completely docked into the tip of the deployment sheath. When completely docked, approximately half the filter basket will still be visible out of the end of the deployment sheath.
10. After the deployment sheath is completely docked, remove the remaining distal anti-migration clip (closest to the filter introducer) and continue to pull back on the torque device to disengage the docked deployment sheath/guidewire assembly from the filter introducer.
11. Loosen the torque device.
12. While holding the torque device in one hand, gradually pull back on the guidewire with the other hand. Continue to pull the guidewire through the torque device until the proximal end of the deployment sheath is visible at the proximal end of the torque device.
13. Tighten the torque device onto the deployment sheath to secure the deployment sheath to the guidewire.
    NOTE: If desired, the torque device can be carefully moved to another position on the sheath and retightened.
14. The filter basket, now loaded inside the deployment sheath tip and secured to the guidewire with the torque device, can be completely removed from the coil dispenser.
15. The device is now prepped and ready for use.
16. Capture Sheath – After the interventional or diagnostic procedure is complete, attach a 5 ml Luer lock syringe, prepared as described in step 3 of this section, to the capture sheath hub and flush with 5 ml of sterile saline. You should see saline dripping out of the other end of the capture sheath (inside the coil dispenser). Remove the syringe and then remove the capture sheath from the coil dispenser. The capture sheath is now ready for use.

9.4 Filter Deployment and Capture Procedure

WARNING: Patient ACT of >300 seconds needs to be maintained during **ANGIOGUARD XP** Emboli Capture Guidewire deployment. (See Section 9.1 of these instructions.)

WARNING: Observe all guidewire movement in the vessels using fluoroscopic guidance.

WARNING: Before the guidewire is moved, the tip movement should be examined using fluoroscopy.

WARNING: DO NOT TORQUE THE GUIDEWIRE.

- Do not torque a guidewire without observing corresponding movement of the tip; otherwise, vessel trauma could occur.
- Torquing a guidewire against resistance may cause guidewire damage and/or guidewire tip separation. Always advance or withdraw the guidewire slowly. Never push, auger, withdraw or torque a guidewire that meets resistance. Resistance may be felt and/or observed using fluoroscopy by noting any buckling of the guidewire tip. Determine the cause of resistance under fluoroscopy and take the necessary remedial action.

1. Insert the peel-away guidewire introducer into the interventional sheath introducer or the hemostatic valve of the Y connector attached to the guiding catheter. Ensure the hemostatic valve is fully opened before inserting the guidewire introducer.
2. Carefully insert the deployment sheath/guidewire assembly through the peel-away guidewire introducer and into the guiding catheter or the interventional sheath introducer. An 8F (2.7 mm) with a .088" minimum ID guiding catheter or a 6F (2.0 mm) interventional sheath introducer is recommended for ease of removal.

   WARNING: When introducing the guidewire, confirm that the guiding catheter or interventional sheath introducer tip is free within the vessel lumen and not against the vessel wall. Failure to do so may result in vessel trauma upon guidewire exit from the tip. Use the radiopaque marker of the interventional device to confirm position.

3. To remove the peel-away guidewire introducer, retract the peel-away guidewire introducer from the interventional sheath introducer or hemostatic valve of the Y connector attached to the guiding catheter. Snap open the peel-away guidewire introducer hub and peel apart the entire introducer shaft.
4. Advance the guidewire through the guide catheter or interventional sheath introducer until it is proximal to the tip of the guiding catheter or interventional sheath.
5. Tighten the hemostatic valve slightly to reduce the flow of blood from around the deployment sheath/guidewire assembly. Ensure that movement of the guidewire is still possible.
6. Using fluoroscopy, advance the deployment sheath/guidewire assembly out further from the guide catheter or interventional sheath introducer. Use the torque device to steer the guidewire across the lesion.
   NOTE: With reference to step 7 of this section, allow sufficient space between the lesion and filter basket to prevent interference with the distal tips of all other diagnostic and interventional devices to be used throughout the procedure.
7. Position the filter basket of the **ANGIOGUARD® XP** Emboli Capture Guidewire so both distal and proximal radiopaque markers are distal to the lesion to be treated.
8. After achieving the appropriate filter basket position in the vessel, remove the torque device from the deployment sheath/guidewire assembly.
   NOTE: With reference to step 9 of this section, always maintain filter basket position during deployment sheath removal.
   NOTE: With reference to step 9 of this section, never attempt to recapture the filter basket using the deployment sheath. If repositioning of the device is necessary, use the capture sheath and reposition as described in step 14 of this section.
   NOTE: With reference to step 9 of this section, the distal tip of the deployment sheath is larger in diameter than the sheath body. The hemovalve may need to be adjusted to allow clearance for the larger distal tip.
9. While maintaining the deployment sheath/guidewire assembly position, deploy the filter basket by sliding the deployment sheath proximally. Making sure to maintain the guidewire position, continue to remove the deployment sheath by sliding the sheath proximally until it is totally removed from the guidewire.
10. Close the hemovalve.
11. The filter basket of the **ANGIOGUARD XP** Emboli Capture Guidewire is now fully deployed within the vessel. Confirm full deployment by fluoroscopy. The marker bands on the filter basket struts should be fully apposed to the vessel wall.
12. Using fluoroscopy, inject dye to determine that there is adequate flow distal to the filter basket (or distal band of the guidewire) and that the guidewire remains in the proper position.
13. Once filter basket position is confirmed, .014 in. (0.36 mm) compatible interventional devices can be loaded through the open hemovalve on to the guidewire for treatment of the lesion. Use the standard technique of over the guidewire or single operator exchange while treating the lesion. Be careful not to move the filter basket during exchanges.

   CAUTION: With reference to step 14 of this section, never attempt to close the filter basket with the deployment sheath. The **ANGIOGUARD XP** Emboli Capture Guidewire should only be removed using the Capture Sheath.

14. Once the lesion is treated and all of the interventional or diagnostic devices have been removed, thread the prepped (per step 16 of section 9.3) capture sheath over the proximal end of the guidewire. Open the hemovalve and advance the capture sheath until the distal marker on the sheath lines up with the proximal marker on the filter basket. This will close the filter basket.

    CAUTION: Use caution when withdrawing the **ANGIOGUARD XP** Emboli Capture Guidewire through the deployed stent.

    NOTE: With reference to step 15 of this section, do not try removing the captured system by only pulling on the capture sheath.
    NOTE: With reference to step 15 of this section, never pull the captured system into the guiding catheter or interventional sheath introducer if there is resistance. If resistance is encountered, reposition the capture sheath to ensure that the filter basket is properly seated into the capture sheath. Using fluoroscopy, verify capture sheath position by checking marker band alignment between the capture sheath and guidewire and confirm filter basket closure by ensuring reduction of the filter basket diameter shown by the radiopaque strut markers.
15. Place the torque device over the guidewire and attach the Luer lock to the capture sheath hub. With the torque device locked to the capture sheath, tighten the torque device to the guidewire. Then remove the system by pulling the guidewire proximal to the Capture Sheath hub through the guide catheter or interventional sheath introducer and out of the hemostasis valve as a single unit. Care should be taken when pulling the captured basket through the open hemovalve to avoid potential release of captured emboli within the guiding catheter.

10. How to Detect if the ANGIOGUARD XP Emboli Capture Guidewire is Full

1. Once the **ANGIOGUARD XP** Emboli Capture Guidewire is deployed in the vessel, it may capture emboli during the entire time of the interventional procedure. Therefore, it is recommended to check the status of the **ANGIOGUARD XP** Emboli Capture Guidewire during regular intervals during the intervention.
2. Using fluoroscopy, perform a distal dye injection through the guide catheter or interventional sheath introducer and observe the flow of dye distal to the filter basket or distal marker on the guidewire.

   CAUTION: If the distal perfusion of dye is significantly reduced or no dye is perfusing past the filter basket or distal marker band, the **ANGIOGUARD XP** Emboli Capture Guidewire may have reached its capacity to contain emboli. If there is a severe reduction in distal dye perfusion, it is recommended to exchange the **ANGIOGUARD XP** Emboli Capture Guidewire for a new one.

11. How to Exchange a Full ANGIOGUARD XP Emboli Capture Guidewire

WARNING: Perform all exchanges slowly to prevent air from entering the catheter system.

CAUTION: The **ANGIOGUARD XP** Emboli Capture Guidewire should only be removed using the Capture Sheath and should be removed through the **guide catheter or interventional sheath introducer only**. See Section 9.4, steps 14 and 15 of these instructions for proper filter basket capture and system removal.

To exchange an **ANGIOGUARD XP®** Emboli Capture Guidewire that has captured its capacity of emboli:

1. Remove all interventional devices from the **ANGIOGUARD XP** Emboli Capture Guidewire.
2. Prep the Capture Sheath as outlined in Section 9.3, step 16 of these instructions.
3. Back-load the Capture Sheath over the proximal end of the **ANGIOGUARD XP** Emboli Capture Guidewire. Advance the Capture Sheath until the distal marker on the sheath lines up with the proximal marker on the guidewire as described in Section 9.4, step 14 of these instructions.
4. After the Capture Sheath is in position, using fluoroscopy, confirm filter basket closure by ensuring reduction of the filter basket diameter shown by the radiopaque strut markers, keeping in mind that the emboli that have been captured may not allow the **ANGIOGUARD XP** Emboli Capture Guidewire to reach its initial low profile.
5. Open the hemovalve to allow the **ANGIOGUARD XP** Emboli Capture Guidewire free movement and to assure that the **ANGIOGUARD XP** Emboli Capture Guidewire is not damaged as it is removed since it may contain emboli.
6. Remove the **ANGIOGUARD XP** Emboli Capture Guidewire and Capture Sheath as described in Section 9.4, steps 14 and 15.
7. Deploy a new **ANGIOGUARD XP** Emboli Capture Guidewire as described in Section 9.3, steps 1 through 16 and Section 9.4, steps 1 through 15.

12. Patient Information

A Patient Brochure, which includes information on carotid artery disease, the carotid stent implant procedure, and the **ANGIOGUARD XP** Emboli Capture Guidewire is available from Cordis and can be obtained by accessing www.mycardinalmsds.com or by contacting Cordis at 1-800-327-7714.

13. Label Designation/How Supplied

Interventional .014" (0.36 mm) compatible devices mean:

- Cordis **PRECISE**® Nitinol Stent System
- Angioplasty balloons

The **ANGIOGUARD XP** Emboli Capture Guidewire is supplied sterile (by ethylene oxide gas) and is intended for ONE USE ONLY.

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Cordis Corporation
14201 North West 60th Avenue
Miami Lakes, Florida 33014, USA

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