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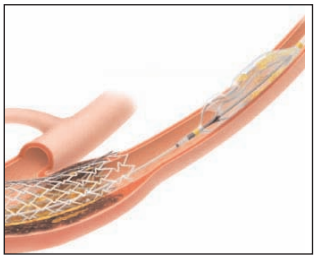
ABBOTT VASCULAR LAUNCHES XACT® CAROTID STENT AND EMBOSHIELD® EMBOLIC PROCTECTION SYSTEM IN THE U.S.(1)

In September, 2005, **Abbott Vascular** (Redwood City, CA), received U.S. Food and Drug Administration approval for the **Xact® Carotid Stent** and 510(k) clearance for the **Emboshield® Embolic Protection System**, to treat patients at risk of stroke.

The Xact Stent is designed specifically for the carotid vessel and consists of a rapid-exchange delivery system to deliver the self-expanding stent. The Xact Carotid Stent has a closed-cell design that creates a tightly knit, yet highly flexible mesh intended to help restore the diameter of the carotid artery lumen, promote a smooth inner vessel surface, and potentially reduce the release of emboli during treatment. The ends of the stent are flared slightly, which facilitates passage of balloons and the filter retrieval catheter. The stent is composed of Nitinol (nickel titanium), which is more flexible than stainless steel, allowing for easier de-livery through the body. Nitinol also performs better in tortuous anatomy by conforming to the shape of the vessel and lying flush against the vessel wall.

The Emboshield® filter is fully retractable, providing a temporary percutaneous transluminal filtration system to capture and remove embolic materials released while performing angioplasty and stenting procedures. It is the only filter to operate freely on Barewire™ technology, enabling more precise placement and snag-free removal of the embolic protection device. With Barewire" technology, the wire crosses the lesion first, independent of the filter and delivery catheter. All other actions—filter placement/retrieval, balloon dilatations, and stent placement—then occur over this wire.



"The unique feature of the Embo-shield filter is that you can negotiate the lesion with the wire as the filter floats freely over the wire. You can move the wire without moving the filter, so there is potentially less risk of damaging the carotid or causing vasospasm," said Don Schwarten, MD, of Abbott Vascular.

Accurate Deployment Ensures Lesion Coverage

The Xact® carotid stent has a low crossing profile (0.076"), which is important for accurate delivery. Indications in the United States for the Xact® Carotid Stent include carotid artery stenosis >50% for symptomatic patients or >80% for asymptomatic patients, as determined by ultrasound or angiography. The lesion must be located between the origin of the common carotid artery and the intracranial 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. The Xact Stent is available in both tapered and straight configurations, with diameters ranging from 6 to 10 mm and lengths from 20 to 40 mm. The Emboshield® Embolic Protection System is indicated for use as a guidewire and as an embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the filtration should be between 2.8 and 6.2 mm.

SECuRITY Registry Study Shows Safety, Durability, and Effectiveness

Abbott received FDA approval and clearance for the Xact Carotid Stent and Emboshield Protection System based on its submission of SECuRITY Registry Study data. The SECuRITY Registry Study involved 305 patients who were at too high risk to undergo carotid endarterectomy. The overall 30-day major adverse event (MAE) rate (stroke, myocardial infarction, death) was 7.5% and the ipsilateral stroke incidence at 1-year post-treatment was 7.9%. At 1 year, 99.3% of the treated patients were free from repeat revascularization; at 6 and 12 months post-procedure, restenosis occurred in 4.9% and 4.1%, respectively.

Abbott Sponsors First Investigational Study in Asymptomatic Patients

According to The American Heart Association, approximately 75% of stroke patients are asymptomatic (*2*). Abbott Vascular is currently conducting the ACT I (Asymptomatic Patients with Significant Extracranial Carotid Occlusive Disease Trial) that is the first multicenter, randomized trial to compare the safety and efficacy of carotid artery stenting and carotid endarterectomy in asymptomatic patients. Up to 50 centers will be involved and approximately 1,800 participants will be enrolled.

Abbott Vascular, a division of Abbott, is transforming the treatment of vascular disease by combining the latest medical device innovations with world-class pharmaceuticals to advance medicine and improve patient care. Abbott Vascular offers a comprehensive portfolio of vessel closure, endovascular, and coronary products that are recognized internationally for their safety, ease of use, and effectiveness in treating patients with vascular disease.

For more information concerning Abbott Vascular, call 1-800-256-7341; or visit the company's Web site at www.abbottvascular.com.

References:

1. The Xact Stent is not licensed in accordance with Canadian law.
2. *Heart Disease and Stroke Statistics - 2004* update, Dallas, Texas: American Heart Association. 2003:1-52.