



# Fact Sheet

## About Abbott's Carotid Stent Clinical Trial Program

Abbott is the leader in clinical studies for carotid stenting, with five clinical studies underway, evaluating more than 10,000 patients with carotid artery disease. Of these five trials, two -- ACT I and CREST -- are randomized trials designed to understand the benefits of carotid artery stenting (CAS) in a broader patient population (patients at normal risk for undergoing surgery for their condition who may or may not exhibit symptoms of disease); Abbott is the only company studying this population in such detail. Four of the trials -- CAPTURE, CAPTURE 2, EXACT, and CHOICE -- are post-market studies designed to gather real-world clinical information about CAS patients. In addition, Abbott is enrolling in PROTECT, a long-term follow-up study of the Xact carotid stent that is also designed to gain investigational device exemption (IDE) approval for Abbott's next-generation embolic protection filter system, the Emboshield® Pro.

### **RANDOMIZED STUDIES**

- **ACT I**

ACT I is a prospective, multi-center trial that will enroll a maximum of 1,658 randomized patients, at up to 50 sites in North America. The study is designed to demonstrate the non-inferiority of CAS when compared to carotid endarterectomy (CEA) for the treatment of asymptomatic carotid artery disease (CAD) in people at normal risk for surgery. This study is using Abbott's Emboshield® BareWire™ Rapid Exchange Embolic Protection System with the Xact® Rapid Exchange Carotid Stent System.

- **CREST**

Sponsored by the National Institute of Neurological Disorders and Stroke (NINDS), and the National Institutes of Health (NIH), CREST is a randomized clinical trial designed to evaluate the efficacy of CAS as compared to CEA in preventing stroke, myocardial infarction (MI) and death in the 30-day period immediately following the procedure. Abbott is the industry sponsor of CREST. CREST is also evaluating the incidence of ipsilateral, or same side, stroke during a multi-year follow-up period in patients who were at normal risk for undergoing surgery at the time their CAS procedure was performed. CREST will randomize

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2,500 patients. This trial is forecasted to complete enrollment in 2008. CREST utilizes Abbott's ACCULINK™ carotid stent and ACCUNET™ embolic protection systems.

**POST-MARKET STUDIES**

• **CAPTURE**

CAPTURE is an FDA-required post-approval study utilizing Abbott's FDA-approved RX ACCULINK Carotid Stent System and RX ACCUNET Embolic Protection System. Key objectives of CAPTURE are to determine whether carotid artery stenting can be performed safely in real-world clinical settings by physicians from various disciplines.

Patients in CAPTURE are being treated by 353 physicians at 144 hospitals in the United States. CAPTURE has enrolled more than 4,200 patients to date and is closed to enrollment.

• **CAPTURE 2**

CAPTURE 2 is a non-randomized, descriptive post-market registry that may study up to 5,000 patients at approximately 200 clinical sites in the United States. CAPTURE 2 is designed to collect real-world performance data from the RX ACCULINK and RX ACCUNET Systems, when used by a broad group of physicians under commercial use conditions.

Positive 30-day results, presented at ACC 2007, indicate that carotid stenting is a safe treatment option for patients with CAD who may be at risk of adverse events from surgery. The primary endpoint of death, stroke, or heart attack at 30 days, was 5.2% for patients enrolled in CAPTURE 2. The 30-day results also demonstrated a low rate of major stroke and/or death, with 1.3% of CAPTURE 2 patients experiencing a major stroke or death.

• **EXACT**

EXACT is a 2,000-patient, multi-center, post-approval study designed to collect clinical outcome and performance data on the Emboshield Embolic Protection System and the Xact Stent when used in real world settings by a broad group of physicians. The primary endpoint is 30-day composite of death, stroke and MI. A 12-month follow-up will be conducted on 500 patients with the endpoint of ipsilateral stroke.

Early results from the EXACT trial indicate that the primary endpoint of death, stroke, or heart attack at 30 days, was 4.6% for patients enrolled in EXACT. The 30-day results also demonstrated a low rate of major stroke and/or death, with 1.8% of EXACT patients experiencing a major stroke or death.

- **CHOICE**

CHOICE is a worldwide post-market registry that will include both of Abbott's carotid artery stenting and embolic protection systems. CHOICE may include as many as 5,000 patients and will be conducted at several hundred clinical sites in the United States and Europe. Primary endpoints for CHOICE are stroke, death and MI at 30 days. The study will also help gather additional and more extensive clinical data to broaden patient access to carotid stenting procedures. Data from CHOICE will also provide a deeper and broader understanding of carotid stenting in international clinical settings.

**PMA/510(k) STUDY**

- **PROTECT**

PROTECT, a long-term follow-up study of the Xact stent, will also provide data that will be used to obtain 510(k) clearance for the Emboshield® PRO Embolic Protection System in subjects at high risk for CEA. The primary endpoint of this 320 patient study, to be conducted at 50 U. S. sites, is a composite of stroke, MI and death at 30-days and ipsilateral strokes between 31 and 365 days.

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