POSTMARKET SURVEILLANCE REGISTRIES (POPULATION: HIGH SURGICAL RISK; SYMPTOM STATUS: MIXED)

Endovascular TODAY

Name (Source)	Sponsor	Sample Size	Symptom Status	Age		Stent	EPD	Outcome Data[a] Safety (30 day)	Status
CAPTURE (Catheter Cardiovasc Interv. 2007;69:341-348; Ann Surg. 2007;246:551-558)	Abbott Vascular	3,500	482 symptomatic patients; 3,018 asymptomatic patients	24% ≥ 80 years		RX Acculink	RX Accunet	The 30-day primary endpoint event rate of death, stroke, and MI was 6.3%; the rate of major stroke and death was 2.9%; 4.8% of patients experienced a stroke; 41% of all strokes were major. The incidence of major strokes was statistically significantly greater among symptomatic compared with asymptomatic patients, 4.6% and 1.6%, respectively.	Completed
CAPTURE 2 (Stroke. 2010;4:757-764)	Abbott Vascular	5,297 evaluated (6,521 total)	Nonoctogenarians, 14% symptomatic patients; octogenarians, 15% symptomatic patients	22.2% were octogenarians, 1,166 were ≥ 80 years		RX Acculink	RX Accunet	For the overall cohort, the death/stroke rate was 3.3%; the stroke rate was 2.7% (0.8% major, 1.9% minor).	Completed
CASES (Catheter Cardiovasc Interv. 2007;70:316-323; J Am Coll Cardiol. 2010;56:49-57)	Cordis Corporation	A total of 1,492 patients were enrolled at 73 sites	21.8% symptomatic patients (78.2% asymptomatic patients)	Age eligible for study: 18 to 80 years		Precise Nitinol Stent System (5, 5.5, 6 F)	Angioguard XP Emboli Capture Guidewire	The primary endpoint of 30-day MAE was 5%.	Completed
CHOICE (http://www.strokecenter.org/trials/TrialDetail.aspx?tid=1033)	Abbott Vascular	10,000 planned; 7,122 actual	Not available	Not available		Rx Acculink, Xact	RX Accunet, Emboshield, and Emboshield Nav6	The primary outcome will be a composite of death, stroke, and MI.	Currently enrolling

[a]*Nonhierarchical.*

POSTMARKET SURVEILLANCE REGISTRIES (POPULATION: HIGH SURGICAL RISK; SYMPTOM STATUS: MIXED) (CONTINUED)

Endovascular TODAY

Name (Source)	Sponsor	Sample Size	Symptom Status	Age		Stent	EPD	Outcome Data[a]	Status
								Safety (30 day)	
CREATE PAS (ev3 Inc.)	ev3 Inc.	1,500 planned	Not yet available	Not yet available		Protege GPS and Protege RX	SpiderFX Embolic Protection Device	Not yet available	Currently recruiting participants
CRISTALLO (J Endovasc Ther. 2008;15:186-192)	Invatec	124	24.19% symptomatic	Mean age, 71.8±7.3 years		Cristallo Ideale	Different cerebral protection devices were utilized (proximal protection and distal filters)	Thirty-day follow-up was available for 119 (96%) patients [2 (1.6%) were lost to follow-up and 3 (2.4%) died from nonneurological causes unrelated to the device or procedure]. There were no major adverse neurological events within 30 days, but 2 (1.6%) device-/procedure-related transient ischemic attacks were reported (both resolved completely in < 24 hours). Four (3.2%) other non-neurological events (anemia requiring transfusion, worsening of pre-existing chronic renal failure, acute access site thrombosis, and monocular vision disturbance) were reported in the study period.	Completed
EXACT (http://www.strokecenter.org/trials/TrialDetail.aspx?tid=774; Presented at the i2 Summit 2007: Emboshield and Xact Post Approval Carotid Stent Trial)	Abbott Vascular	2,124; 1,500 planned	9.9% symptomatic	Data not available at time of publication		Xact Rapid Exchange Carotid Stent System	Emboshield BareWire Rapid Exchange Embolic Protection System	Death, stroke, MI: 4.6%; all stroke and death, 4.5%; major stroke and death, 1.8%; death, 1%; all stroke, 3.9%; major stroke, 1.3%, minor stroke, 2.7%; MI, 0.2%.	Completed
SAPPHIRE WW (Catheter Cardiovasc Interv. 2009;73:129-136)	Cordis Corporation	15,000 planned; 4,007 current (data available for first 2,001 out to 30 days)	27.7% symptomatic	72.2 ± 9.75 years		Precise Nitinol Stent System	Angioguard XP Emboli Capture Guidewire	At 30-day follow-up, the MAE rate was 4.4% (death, 1.1%; stroke, 3.2%; MI, 0.7%) for the overall population.	Currently recruiting participants
SONOMA (http://clinicaltrials.gov/ct2/show/NCT00478673)	Boston Scientific Corporation	298	Not available	Not available		NexStent Carotid Stent System (Monorail Delivery System)	FilterWire EZ Embolic Protection System	Not available	Completed; results not yet published

[a]*Nonhierarchical.*