PREMARKET APPROVAL REGISTRIES (POPULATION: HIGH SURGICAL RISK; SYMPTOM STATUS: MIXED)

Endovascular TODAY

Name (Source)	Sponsor	Sample Size	Symptom Status	Age	Stent		EPD	Outcome Review	Outcome Data[a]	Status
									Safety (30 day)	
ARCHER (J Vasc Sug. 2006;44:258-268)	Abbott Vascular	581 (Archer 1 = 158, Archer 2 = 278, Archer 3 = 145)	24% symptomatic	16% ≥ 80 years (Archer 1, 13.3% [21 / 158]; Archer 2, 15.5% [43/ 278]; Archer 3, 17.9% [26/145])	Over-the-Wire and Rapid Exchange Acculink Carotid Stent		Accunet Embolic Protection System	A Clinical Events Adjudication Committee adjudicated suspected primary endpoint events.	The 30-day primary endpoint of death, stroke, and MI was 8.3%.	Completed
ARMOUR (Invatec)	Invatec	262 (37 roll-in and 225 pivotal subjects)	15.1% symptomatic	28.9% ≥ 80 years	Various FDA approved		Mo.Ma Proximal Flow Suspension Cerebral Protection Device	A Clinical Events panel adjudicated suspected primary endpoint events.	The ITT 30-day major adverse cardiac and cerebrovascular events rate was 2.7% [95% confidence interval, 1%–5.8%], with a 30-day major stroke rate of 0.9%. Full analysis: 30-day major adverse cardiac and cerebrovascular events rate was 2.3% [95% confidence interval, 1%–5.8%], with a 30-day major stroke rate of 0.8%. No symptomatic patient had a stroke during the trial.	Completed
BEACH (J Am Coll Cardiol. 2008;51:427-434; Boston Scientific Corporation)	Boston Scientific Corporation	747 (189 roll-in; 480 pivotal and 78 bilateral subjects)	76.7% of pivotal (360/480) were asymptomatic with flow-limiting carotid stenosis > 80%	Not available	Carotid Wallstent Monorail Endoprosthesis		FilterWire EX and EZ Embolic Protection Systems	Adverse events were adjudicated by an independent clinical events committee.	The major stroke rate was 1% at 30 days; the ipsilateral stroke rate was 3.1% at 30 days.	Completed
CABERNET (Boston Scientific Corporation)	Boston Scientific Corporation	488 (34 roll-in and 454 pivotal subjects)	24.2% of pivotal (110/454) were symptomatic	Not available	EndoTex NexStent Carotid Stent and Monorail Delivery System		Filter Wire EX and EX Embolic Protection Systems	Not available	The major stroke rate was 1.3% at 30 days; the ipsilateral stroke rate was 2.7% at 30 days.	Completed
CREATE (ev3 Inc.; J Am Coll Cardiol. 2006;47:2384-2389)	ev3 Inc.	419	17.4% symptomatic	50% > 75 years	Protégé GPS and Protégé RX Carotid Stent Systems		Spider Embolic Protection Device	All clinical events were reviewed and adjudicated by an independent clinical events committee.	The 30-day primary endpoint was observed in 26 patients (6.2%), including death in 8 (1.9%), nonfatal stroke in 14 (3.3%), and nonfatal MI in 4 (1%).	Completed
CREATE SpideRX Arm (Published online in J Interv Cardiol. July 8, 2010)	ev3 Inc.	160	15% symptomatic	49% > 75 years	RX Acculink Carotid Stent		SpideRX Embolic Protection System	All clinical events were reviewed and adjudicated by an independent clinical events committee.	The 30-day primary endpoint of major adverse cardiac and cerebrovascular events after CAS was observed in 9 patients (5.6%), including death in 4 patients (2.5%), nonfatal stroke in 5 patients (3.1%), and nonfatal MI in 1 patient (0.6%).	Completed
EMPIRE (Published online in Catheter Cardiovasc Interv. September 7, 2010)	W. L. Gore & Associates	245	32% symptomatic	16% ≥ 80 years	Various FDA approved		Gore Flow Reversal System	Not available	The MAE rate was 4.5% (11 patients; *P* = .002 compared with the OPC). The stroke and death rate was 2.9%. No patient had a major ischemic stroke. Six patients (2.4%) had intolerance to flow reversal. The death and stroke rates in the symptomatic, asymptomatic, and octogenarian subgroups were 2.6%, 3%, and 2.6%, respectively, meeting AHA guidelines for CEA.	Completed
EPIC Pivotal Trial (Lumen Biomedical)	Lumen Biomedical	237 patients from 26 centers	20% symptomatic	21% ≥ 80 years	Any FDA approved carotid stent		FiberNet Embolic Protection System	All events were adjudicated by a clinical events committee.	The combined MAE rate at 30 days for all death, stroke, and MI was 3%. There were 3 major strokes (2 ischemic and 1 hemorrhagic) and 2 minor strokes (both ischemic) for a 2.1% 30-day stroke rate.	Completed

[a]*Nonhierarchical.*

PREMARKET APPROVAL REGISTRIES (POPULATION: HIGH SURGICAL RISK; SYMPTOM STATUS: MIXED) (CONTINUED)

Endovascular TODAY

Name (Source)	Sponsor	Sample Size	Symptom Status	Age	Stent		EPD	Outcome Review	Outcome Data[a] Safety (30 day)	Status
MAVERIC I & II (Stroke. 2010;41:e102-e109; Epub December 24, 2009)	Medtronic	99 patients were enrolled in MAVERIC I (feasibility) and 399 patients were enrolled in MAVERIC II	Not available	MAVERIC I: 69.26 ± 10.20 (99); MAVERIC II 74.08 ± 9.39 (399); combined 73.12 ± 9.74 (498)	Medtronic AVE Self-Expanding Carotid Stent System		GuardWire Temporary Occlusion and Aspiration System	An independent Data Safety Monitoring Board, managed by the Harvard Clinical Research Institute (Boston, Mass), reviewed safety data during the study. Harvard Clinical Research Institute also performed the statistical analyses.	The 30-day MAE (any death, MI, or ipsilateral stroke) rate was 5.4% for the ITT population; stroke occurred in 4.2% and was the most common MAE at 30 days. Of these, 17 were ipsilateral to the stent placement site, and one patient experienced an ipsilateral and nonipsilateral stroke. The rate of death and MI in the first 30 days postprocedure was 1% and 1.4%, respectively.	Completed
MAVERIC III	Medtronic	413	Not available	Not available	Medtronic Exponent Self-Expanding Carotid Stent System		Medtronic Interceptor Plus Carotid Filter System	Not available	Not available	Ongoing, recruiting
PASCAL (http://www.strokecenter.org/trials/TrialDetail.aspx?tid=282)	Medtronic	115	Not available	Not available	Medtronic AVE Self-Expandable Stent		Any CE Mark-approved EPD	Not available	The 30-day MAE rate was reported to be 8%.	Unpublished
PRIAMUS (Invatec; J Cardiovasc Surg [Torino]. 2005;46:219-227)	Invatec	416	264 symptomatic (63.46%) with > 50% diameter stenosis and 152 (36.54%) asymptomatic patients with > 70% diameter stenosis were included	Mean age, 71.6 ± 9 years	Operator's choice of carotid stent		Mo.Ma Proximal Flow Suspension Embolic Protection System	Central data management and data analysis were performed at Bio-Statistic Department of University of Verona (Italy).	At 30-day follow-up, there were no deaths and no minor and major strokes, confirming the overall cumulative 4.56% incidence of all strokes and deaths rate, and of 0.72% rate of major strokes and deaths at follow up. In 245 cases (58.89%) there was macroscopic evidence of debris after filtration of the aspirated blood.	Completed
PROTECT (http://www.strokecenter.org/trials/trialDetail.aspx?tid=963&search_string=PROTECT)	Abbott Vascular	322	13% symptomatic	Mean age, 72.5 years, with 29.5% being 80 years	Xact Rapid Exchange Carotid Stent System		Emboshield Pro Rapid Exchange Embolic Protection System (Generation 5) and the Emboshield BareWire Rapid Exchange Embolic Protection System (Generation 3)	Not available	Within the 30-day postprocedure period, there were 3 strokes (all minor), 1 death, and 1 MI. The composite rate of stroke or death was 1.8% (95% CI 0.5–4.6) and the rate of stroke, death, and MI was 2.3% (CI 0.7–5.2). For secondary endpoints, the rate of TIA was 3.6%.	Ongoing, not recruiting participants
SECURITY (http://www.theheart.org/article/783475.do)	Abbott Vascular	305	Not available	28.2% were ≥ 80 years	Xact Carotid Stent		Emboshield BareWire	Adjudicated.	Death, stroke, MI, 7.5%; all stroke and death, 7.2%; major stroke and death, 3%; death, 1%; all stroke, 6.9%; major stroke, 2.6%; minor stroke, 4.3%; MI, 0.7%.	Completed
VIVA (Bard Peripheral Vascular)	Bard Peripheral Vascular	486 total at 34 sites; 79 roll-in and 407 pivotal	Not available	Not available	ViVexx Carotid Stent		Emboshield BareWire Rapid-Exchange Embolic Protection System	Not available	At 30 days, there were no deaths, and the composite MAE rate was 5.9%. The overall stroke rate was 4.3% combined and 4.4% for the pivotal group. The MI rate was 1.7%.	Completed

[a]*Nonhierarchical.*