CAS CLINICAL TRIAL UPDATE 2007

Study	Sponsor	Sample Size	Stent	Embolic Protection Device	Study Design
HIGH RISK					
ARCHeR	Abbott Vascular	N=581	ARCHeR 1: Acculink OTW ARCHeR 2: Acculink OTW ARCHeR 3: RX Acculink	ARCHeR 1: none ARCHeR 2: Accunet OTW ARCHeR 3: RX Accunet	High-risk registry
BEACH	Boston Scientific Corporation	N=747	Carotid Wallstent Monorail Endoprosthesis	FilterWire EX and EZ	High-risk registry
CABERNET	EndoTex	N=488	NexStent Carotid Stent	FilterWire EX and EZ	High-risk registry
CREATE	ev3	N=419	Protégé GPS Straight and Tapered	Spider OTW	High-risk registry
CREATE SpideRX Arm	ev3	N=160	Acculink; RX Acculink	SpideRX	High-risk registry
EMPiRE	Gore & Associates	N=320	Any approved carotid stent	Gore Neuro Protection System	High-risk registry
EPIC US Feasibility	Lumen Biomedical	N=30	Guidant Acculink	FiberNet EPD	Multicenter, US-based, prospective, feasibility study in high-risk patients
Epic EU	Lumen Biomedical	N=50	Any approved carotid stent	Fibernet EPD	Multicenter, prospective European feasibility study in high-risk patients
EPIC Pivotal Trial	Lumen Biomedical	Approx. N=250	Any approved carotid stent	Fibernet EPD	Multicenter, US-based, prospective, pivotal study in high-risk patients
MAVErIC I & II	Medtronic	N=99 (phase I) N=399 (phase II)	Exponent	GuardWire	High-risk registry
MAVErIC III	Medtronic	N=413	Exponent	Interceptor Plus	High-risk registry
MO.MA	Invatec	N=157	Any	MO.MA	Multicenter EU registry (75% of the final population was high-risk)
PASCAL	Medtronic	N=113	Exponent	Any CE Mark-approved device	Outside US high-risk registry
PRIAMUS	Invatec	N=416	Any	MO.MA	Multicenter Italian registry (63.5% symptomatic patients)
PROGUARD	Kensey Nash Corporation	N=300	Any approved carotid stent	TriActiv ProGuard System	High-risk registry

Prepared by the editors of *Endovascular Today* in conjunction with the device manufacturers.

	Target Vessel Size (mm)	30-Day Results	Final Results	Status
	Stent: 4 to 9; EPD segment: 3.25 to 7	All death, stroke, MI=8.3%	Final 1-y data, all death, stroke, MI within 30 d and all ipsilateral stroke from 31 d to 1 y=9.6%; weighted historical control=14.5%	FDA approval received August 2004
	Stent: 4 to 9; EPD segment: 3.5 to 5.5	n/a	1-y results (non–Q-wave MI: 0 to 24 hrs; stroke, death, Q-wave MI: 0 to 30 d; ipsilateral stroke, neurological death: 31 to 360 d)=9.1%	FDA approval letter received January 2006
	Stent: 4 to 9; EPD segment: 3.5 to 5.5	n/a	Primary endpoint 1: 1-y results, all death, stroke, MI 0 to 30 d, and ipsilateral stroke and any death related to ipsilateral stroke 31 to 365 d=4.7%. Primary endpoint 2: 1-y results, all death, stroke, MI 0 to 365 d=11.9%	FDA approval received December 2006
	Stent: 4.5 to 9; EPD segment: 4 to 7	MACE: 6.3%	Primary endpoint: 30-d composite MI, ipsilateral stroke, procedure-related contralateral stroke, and death, and ipsilateral stroke from 31 to 365 d=7.8%	FDA approval received January 2007
	Stent: 3.6 to 9.1; EPD segment: 4 to 7	MACE: 5.6%	n/a	510(k) clearance
	Stent: 4 to 9	n/a	n/a	Enrolling
	EPD segment: 2.5 to 7	n/a	n/a	Completed enrollment
	EPD segment: 2.5 to 7	n/a	n/a	Enrolling
	EPD segment: 2.5 to 7	n/a	n/a	FDA IDE approval pending
	Stent: 5.5 to 9.5	30-d phase I and II pooled results: MAE=5.4%	Phase I and II pooled results: 30-d MAE=5.4%; 1-y MAE=11.8%	Completed
	Stent: 5.5 to 9.5	n/a	n/a	Active
	Mean ICA reference diameter: 6.28	30-d all MACE=5.7%	n/a	Completed
	Stent: 5.5 to 9.5	30-d results: MAE=8%	n/a	Enrollment completed
	Mean diameter stenosis: 80%±9.8	30-d all stroke and deaths=4.5%; 30-d MI=0%	n/a	Completed
	Stent: 4 to 9; EPD segment: 3 to 6	n/a	n/a	Enrolling

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Study	Sponsor	Sample Size	Stent	Embolic Protection Device	Study Design
HIGH RISK (continued)					
SAPPHIRE	Cordis Endovascular	N=724*	Precise (5.5 F, 6 F)	AngioGuard-XP	Randomized (CEA and CAS) multicenter trial of high-risk patients; evaluated by multidisciplinary team
SECuRITY	Abbott Vascular	N=305	Xact Carotid Stent	EmboShield Embolic Protection System	High-risk registry
VIVA	Bard Peripheral Vascular	N=400	Vivexx	Industry partner	High-risk registry
NORMAL RISK					
ACT I	Abbott Vascular	N=1,658	Xact Carotid Stent	EmboShield Embolic Protection System	Randomized multicenter trial for asymptomatic, CEA-eligible patients
CARES	Cordis Endovascular	N=2,200	Precise RX	AngioGuard RX	Multicenter, non–high-risk, pivotal study
CREST	NIH†	N=2,500	RX Acculink	RX Accunet	Randomized multicenter trial for CEA-eligible patients
EVA-3S	Multiple devices used	N=527	Not specified	Not specified	Multicenter, randomized, noninferiority
SPACE	Multiple devices used	N=1,200	Not specified	Not specified	Randomized, noninferiority trial
TACIT	n/a	N=2,400	Not specified	Not specified	Randomized (CAS and medical therapy) multicenter trial
POSTMARKET SURVEILLANCE					
CAPTURE	Abbott Vascular	N=1,500	RX Acculink	RX Accunet	Multicenter, high-risk, postmarketing surveillance study
CAPTURE 2	Abbott Vascular	N=10,000	RX Acculink	RX Accunet	Multicenter, high-risk, postmarketing surveillance study
CASES	Cordis Endovascular	N=1,500	Precise	AngioGuard-XP	Multicenter, high-risk, postmarketing surveillance study
CHOICE	Abbott Vascular	N=5,000	RX Acculink	RX Accunet	Multicenter, high-risk, postmarketing surveillance study
CREATE PAS	ev3	N=1,500	Protégé RX	SpiderFX	Multicenter, high-risk, postmarketing surveillance study
EXACT	Abbott Vascular	N=1,500	Xact Carotid Stent	EmboShield Embolic Protection System	Multicenter, high-risk, postmarketing surveillance study
SAPPHIRE WW	Cordis Endovascular	N=10,000	Precise Precise RX	AngioGuard XP AngioGuard RX	Multicenter, high-risk, postmarketing surveillance study
SONOMA	Boston Scientific Corporation	N=1,500	NexStent	FilterWire EZ	Multicenter, high-risk, postmarketing surveillance study

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Target Vessel Size (mm)	30-Day Results	Final Results	Status
Stent: 4 to 9.5; EPD segment: 3.5 to 7.5	4.4% total MAE; 0% major stroke rate	Key Randomized Results: 1-y results: CAS: death, stroke, MI=12%; CEA: death, stroke, MI=19.2%; Precise lesion success <30%=99.4%; Angioguard XP success rate=98.1%; 2 y results: TLR=1.4%	Trial completed; 3-y results pending publication
Stent: 4.8 to 9.1; EPD segment 2.8 to 6.2	All death, stroke, MI=7.5%	Final 1-y data: all death, stroke, MI within 30 d plus all ipsilateral stroke from 31 d to 1 y=8.5%	FDA approval received September 2005
Stent: 3.5 to 11	n/a	n/a	Enrolling
Stent: 4.8 to 9.1; EPD segment 2.8 to 6.2	n/a	n/a	Enrolling
Stent: 4 to 9.5; EPD segment: 3.5 to 7.4	n/a	n/a pending publication	IDE approved
Stent: 4 to 9; EPD segment: 3.25 to 7	n/a	n/a	Enrolling
Symptomatic stenosis >60%	Stroke or death: post-CAS: 9.6, post-CEA: 3.9	6-mo incidence of any stroke or death: CEA=6.1, CAS=11.7	Stopped prematurely
Stenosis >70%	Ipsilateral ischemic stroke and death: CAS: 6.84, CEA: 6.34	See 30-d results	Completed
Stenosis <60%	n/a	n/a	Enrolling
Stent: 4 to 9; EPD segment: 3.25 to 7	n/a	n/a pending publication	Completed; results to be published
Stent: 4 to 9; EPD segment: 3.25 to 7	n/a	n/a	Enrolling
Stent: 4 to 9.5; EPD segment: 3 to 7.5	n/a	n/a pending publication	Completed; results to be published
Stent: 4 to 9; EPD segment: 3.25 to 7	n/a	n/a	Enrolling
Stent: 4.5 to 9; EPD segment: 3 to 7	n/a	n/a	Trial enrollment begins 2Q 2007
Stent: 4.8 to 9.1; EPD segment 2.8 to 6.2	n/a	n/a	Enrolling
Stent: 4 to 9.5; EPD segment: 3.0 to 7.5	MACE: CAS=5.8, CEA=12.6	n/a	Enrolling
Stent: 4 to 9; EPD segment: 3.5 to 5.5	n/a	n/a	Starting soon

*Randomized n=310; stent registry (surgical refusal)=407; surgical registry (stent refusal=7). †Abbott Vascular provides product support.