CAS CLINICAL TRIAL AND REGISTRY UPDATE

Study	Sponsor	Sample Size	Stent	Embolic Protection Device	Study Design	Target Vessel Size (mm)
High Risk						
ARCHeR	Abbott Vascular	N=581	Archer1: Acculink OTW; Archer 2: Acculink OTW; Archer 3: RX Acculink	Archer 1: none; Archer 2: Accunet OTW; Archer 3: RX Accunet	High-risk registry	Stent: 4 to 9; EPD segment: 3.25 to 7
ARMOUR	Invatec	N=228	Any FDA-approved carotid stent	Mo.Ma	Multicenter prospective US and EU study in high surgical risk population	Any vessel size compatible with FDA-approved carotid stents
BEACH	Boston Scientific Corporation	N=747	Carotid Wallstent Monorail Endoprosthesis	FilterWire EX Embolic Protection System; FilterWire EZ Embolic Protection System	High-risk registry	Stent: 6, 8, 10; EPD segment: 3.5 to 5.5
CABERNET	EndoTex, now a Boston Scientific company	N=488	NexStent Carotid Stent	FilterWire EX Embolic Protection System; FilterWire EZ Embolic Protection System	High-risk registry	Stent: 4 to 9; EPD segment: 3.5 to 5.5
CREATE	ev3	N=419	Protégé GPS, straight and tapered	Spider OTW	High-risk registry	Stent: 4.5 to 9; EPD segment: 4 to 7
CREATE SpideRX Arm	ev3	N=160	Acculink; RX Acculink	SpideRX	High-risk registry	Stent: 3.6 to 9.1; EPD segment: 4 to 7
EMPiRE	Gore & Associates	N=320	Any FDA-approved carotid stent	Gore Neuro Protection System	High-risk registry	Stent: 4 to 9
EPIC US Feasibility	Lumen Biomedical	N=30	Guidant Acculink	FiberNet EPD	Multicenter, US-based, prospective, feasibility study in high-risk patients	EPD segment 2.5 to 7
EPIC EU	Lumen Biomedical	N=50	Any approved carotid stent	FiberNet EPD	Multicenter, prospective European feasibility study in high-risk patients	EPD segment 2.5 to 7
EPIC Pivotal Trial	Lumen Biomedical	N=254	Any approved carotid stent	FiberNet EPD	Multicenter, prospective, pivotal study in high-risk patients	EPD segment 2.5 to 7
MAVErIC I & II	Medtronic	N=99 (phase I); N=399 (phase II)	Exponent	GuardWire	High-risk registry	Stent: 5.5 to 9.5
MAVErIC III	Medtronic	N=413	Exponent	Interceptor Plus	High-risk registry	Stent: 5.5 to 9.5
MO.MA	Invatec	N=157	Any	Mo.Ma	Multicenter EU registry (75% of the final population was at high risk)	Mean ICA reference diameter: 6.28
PASCAL	Medtronic	N=113	Exponent	Any CE Mark-approved device	Outside US high-risk registry	Stent: 5.5 to 9.5
PRIAMUS	Invatec	N=416	Any	Mo.Ma	Multicenter Italian registry (63.5% symptomatic patients)	Mean diameter stenosis: 80%±9.8
PROTECT	Abbott Vascular	N=320	Xact Carotid Stent	EmboShield Pro Embolic Protection System	High-risk registry	Stent: 4.8 to 9.1; EPD segment 2.5 to 7
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	Stent: 4 to 9.5; EPD segment: 3.5 to 7.5

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

	30-Day Results	Final Results	Status
	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
	n/a	n/a	Enrollment begins September 2007
	MAE=5.6%	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%	Pending FDA approval
	MAE=3.9%	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 results, all death, stroke, MI: 0 to 365 d=11.9%	FDA approval received December 2006
	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
	MACE=5.6%	n/a	510(k) clearance
	n/a	n/a	Enrolling
	n/a	n/a	Completed enrollment
	n/a	n/a	Enrolling
	n/a	n/a	Enrolling
	30-d phase 1 and 2 pooled results: MAE=5.4%	Phase 1 and 2 pooled results: 30-d MAE=5.4%; 1-y MAE=11.8%	Completed
	n/a	n/a	Active
	30-d all MACE=5.7%	n/a	Completed, published
	30-d results MAE=8%	n/a	Enrollment completed
	30-d all stroke and deaths=4.5%; 30-d MI=0%	n/a	Completed, published
	n/a	n/a	Enrolling
	4.4% total MAE; 0% major stroke rate	Key Randomized Results: 1-y results; stent patients: death, stroke, MI rate=12%; surgical patients: death, stroke, MI rate=19.2% Precise lesion success <30%=99.4%; AngioGuard XP success rate=98.1% 2-y results: TLR=1.4%	Trial completed; 1-y results published in N Engl J Med, October 2004; 3-y results pending publication

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

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Study	Sponsor	Sample Size	Stent	Embolic Protection Device	Study Design	Target Vessel Size (mm)
High Risk (continued)						
SeCURITY	Abbott Vascular	N=305	Xact Carotid Stent	EmboShield Embolic Protection System	High-risk registry	Stent: 4.8 to 9.1; EPD segment 2.8 to 6.2
VIVA	Bard Peripheral Vascular	N=400	Vivexx	Industry partner	High-risk registry	Stent: 3.5 to 11
Normal Risk						
ACT I	Abbott Vascular	N=1,658	Xact Carotid Stent	EmboShield Pro; EmboShield Gen3 Embolic Protection System	Randomized, multicenter trial for asymptomatic, CEA-eligible patients	Stent: 4.8 to 9.1; EPD segment 2.5 to 7
ACST-2	NHS Health Technology Assessment Programme & BUPA Foundation	N=5,000	Any CE Mark-approved device	Optional, but any CE Mark-approved device	Randomized, multicenter trial for asymptomatic, CEA-eligible patients	Not specified; any asymptomatic carotid stenosis that is considered to warrant intervention
CARES	Cordis Endovascular	N=2,200	Precise RX	AngioGuard RX	Multicenter, non–high-risk, pivotal study	Stent: 4 to 9.5; EPD segment: 3.5 to 7.4
CREST	NIH/NINDS, UMDNJ†	N=2,500	RX Acculink	RX Accunet	Randomized (CEA and CAS) multicenter trial of low to moderate risk patients; evaluated by multidisciplinary team	Stent: 4 to 9; EPD segment: 3.25 to 7
EVA-3S	Multiple devices used	N=527	Not specified	Not specified	Multicenter, randomized, noninferiority	Symptomatic stenosis >60%
SPACE	Multiple devices used	N=1,200	Not specified	Not specified	Randomized, noninferiority trial	Stenosis >70%
TACIT	n/a	N= 3,700	Not specified	Not specified	Randomized (CEA, CAS, and medical therapy) multicenter trial	Stenosis ≥60%
Postmarket Surveillance						
CAPTURE	Abbott Vascular	N=1,500	RX Acculink	RX Accunet	Multicenter, high-risk, postmarketing surveillance study	Stent: 4 to 9; EPD segment: 3.25 to 7
CAPTURE 2	Abbott Vascular	N=10,000	RX Acculink	RX Accunet	Multicenter, high-risk, postmarketing surveillance study	Stent: 4 to 9; EPD segment: 3.25 to 7
CASES	Cordis Endovascular	N=1,500	Precise	AngioGuard XP	Multicenter, high-risk, postmarketing surveillance study	Stent: 4 to 9.5; EPD segment: 3.0 to 7.5
CHOICE	Abbott Vascular	N=5,000	RX Acculink/Xact Carotid Stent	RX Accunet/ Emboshield Embolic Protection System	Multicenter, high-risk, postmarketing surveillance study	Stent: 4 to 9.1; EPD segment: 2.8 to 7
CREATE PAS	ev3	N=1,500	Protégé RX	SpiderFX	Multicenter, high-risk, postmarketing surveillance study	Stent: 4.5 to 9.5; EPD segment: 3 to 7
CRISTALLO	Invatec	N=124	Cristallo Ideale	Any	Multicenter EU	Target vessel diameter: 5 to 9
EXACT	Abbott Vascular	N=1,500	Xact Carotid Stent	EmboShield Embolic Protection System	Multicenter, high-risk, postmarketing surveillance study	Stent: 4.8 to 9.1; EPD segment 2.8 to 6.2
SAPPHIRE WW	Cordis Endovascular	N=10,000	Precise; Precise RX; Precise Pro RX	AngioGuard XP; AngioGuard RX	Multicenter, high-risk, postmarketing surveillance study	Stent: 4 to 9.5; EPD segment: 3 to 7.5
SONOMA	Boston Scientific Corporation	N=1,500	NexStent	FilterWire EZ	Multicenter, high-risk, postmarketing surveillance study	Stent: 4 to 9; EPD segment: 3.5 to 5.5

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	30-Day Results	Final Results	Status
	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
	n/a	n/a	Enrolling
	n/a	n/a	Enrolling
	All death, stroke, and MI	30-d: all death, stroke, MI, plus all stroke and death to 5 years	Enrolling
	n/a	n/a; pending publication	IDE approved
	n/a	n/a	Enrolling
	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
	Ipsilateral ischemic stroke and death: CAS: 6.84, CEA: 6.34	See 30-d results	Completed
	n/a	n/a	Enrolling
	n/a	n/a; pending publication	Completed; results to be published
	n/a	n/a	Enrolling
	n/a	30-d MAE (death, stroke, MI) rate of 5%; 30-d results published in CCI, August, 2007	Completed; published in CCI, August 2007
	n/a	n/a	Enrolling
	n/a	n/a	Enrolling
	MANE=0%	MANE=0%	Completed; results to be published
	n/a	n/a	Enrollment closed; 1-y follow-up ongoing
	n/a	n/a	Enrolling
	n/a	n/a	Enrolling

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