

# CAROTID ARTERY STENTING UPDATE

Study	Sponsor	Sample Size	Stent	Embololic Protection Device	Lesion Location	Study Design	Target Vessel Size (mm)	Results	Status
ARCHeR	Guidant	n=437	OTW Acculink	OTW Accunet	ICA and carotid bifurcation	High-risk registry	Stent: 4 to 9.1 EPD segment: 3.25 to 7.0	30-day results; stent patients: MACE=7.8%; Acculink success rate=97.8%	30-day results announced at ACC/SIR 2003; currently in the 1-year follow-up period
ARCHeR RX	Guidant	n=145	RX Acculink	RX Accunet	ICA and carotid bifurcation	High-risk registry	Stent: 4 to 9.1 EPD segment: 3.25 to 7.0	N/A	Enrolling
BEACH	Boston Scientific	n=480 (400 evaluable)	Carotid Wallstent Monorail endoprosthesis	Filterwire EX and EZ	ICA/CCA	High-risk registry	Stent: 4 to 9 EPD segment: 3.5 to 5.5	N/A	Enrolling
CABERNET	EndoTex	n=380	NexStent	FilterWire EX	ICA/CCA	High-risk registry	Stent: 4 to 9 EPD segment: 3.5 to 5.5	N/A	Enrolling
CREATE	ev3	n=400	Protégé	SPIDER	ICA	High-risk registry	Information not provided	N/A	Information not provided
CREST	NIH and Guidant	n=2,500	OTW Acculink	OTW Accunet	ICA and carotid bifurcation	Randomized multicenter trial for symptomatic, CEA-eligible patients	Stent: 4 to 9.1 EPD segment: 3.25 to 7.0	N/A	Enrolling
MAVERIC Int'l	Medtronic	n=51	Exponent	Interceptor	ICA/CCA	Outside US high-risk registry	Stent: 5.5 to 9.5	30-day results: MACE=5.9%	CE Mark approved
MAVERIC II	Medtronic	n=99 (Phase I) n=399 (Phase II)	Exponent	GuardWire	ICA/CCA	US IDE high-risk registry	Stent: 5.5 to 9.5	30-day Phase I results: MACE=4%	Enrollment completed; currently in 1-year follow-up
PASCAL	Medtronic	n=115	Exponent	Any CE Mark-approved device	ICA/CCA	Symptomatic and asymptomatic patients	Stent: 5.5 to 9.5	30-day results: MACE=8%	Enrollment completed; currently in 1-year follow-up
SAPPHIRE	Cordis	n=724*	Precise	AngioGuard-XP	ICA/CCA	Randomized (CEA and CAS) multi-center trial of high-risk patients; evaluated by multidisciplinary team	EPD segment: 3.5 to 7.5	30-Day results; stent patients: MACE=5.8 surgical patients: MACE=12.6%, P=.04; AngioGuard XP success rate=98.6%	Trial completed. 30-day results presented at AHA 2002. One-year results to be presented at TCT 2003.
SECURITY	Abbott Vascular Devices	n=320	MedNova Xact	MedNova NeuroShield/EmboShield	ICA/CCA	High-risk registry	Stent: 4 to 9 EPD segment: 3.5 to 6	N/A	30-day results to be presented at TCT 2003

\*Randomized n=310; Stent Registry (Surgical Refusal)=407; Surgical Registry (Stent Refusal)=7

Company	Stent	Tapered Stents		Straight Stents		Markets Available†	Embololic Protection Devices			Markets Available†
		Diameter (prox/dist)(mm)	Lengths (mm)	Diameters (mm)	Lengths (mm)		Name	Type	Position	
Abbott Vascular	Mednova Xact	10/8, 9/7, 8/6	30, 40	7, 8, 9, 10	20, 30	Outside US	EmboShield	Filter	Distal	Outside US
ArteriA	N/A	N/A	N/A	N/A	N/A	N/A	PAES	Continuous flow reversal	Proximal	Outside US and US
Boston Scientific	Carotid Wallstent Monorail Endoprosthesis	N/A	N/A	6, 8, 10	20, 30, 40	Outside US	Filterwire EZ	Filter	Distal	Outside US
							Filterwire EX	Filter	Distal	N/A
Cordis	Precise	10/7, 9/7, 8/6	30	5, 6, 7, 8, 9, 10	20, 30, 40	EU (carotid/biliary) US (Biliary)	AngioGuard XP	Filter	Distal	EU
Cordis	Precise RX	10/7, 9/7, 8/6	30	5, 6, 7, 8, 9, 10	20, 30, 40	CE Mark approval pending for carotid	AngioGuard RX	Filter	Distal	EU
EndoTex	NexStent	Self-tapering; all diameters 4 to 9	30	4, 5, 6, 7, 8, 9	30	Outside US‡	FilterWire EX	Filter	Distal	N/A
ev3	Protégé	10/7, 8/6	30, 40	6, 8, 9, 10	20, 30, 40, 60, 80	US, Europe	Spider	Filter	Distal	Europe (SVG/carotid)
Guidant	RX Acculink	10/7, 8/6	30, 40	5, 6, 7, 8, 9, 10	20, 30, 40	Outside US	RX Accunet	Filter	Distal	Outside US
Medtronic	Exponent	N/A	N/A	6, 7, 8, 9, 10	20, 30, 40	US clinical trials	Interceptor	Filter	Distal	Outside US
							GuardWire	Occlusion	Distal	Outside US

†markets in which the product is commercially available; ‡CE Mark approval, not distributed