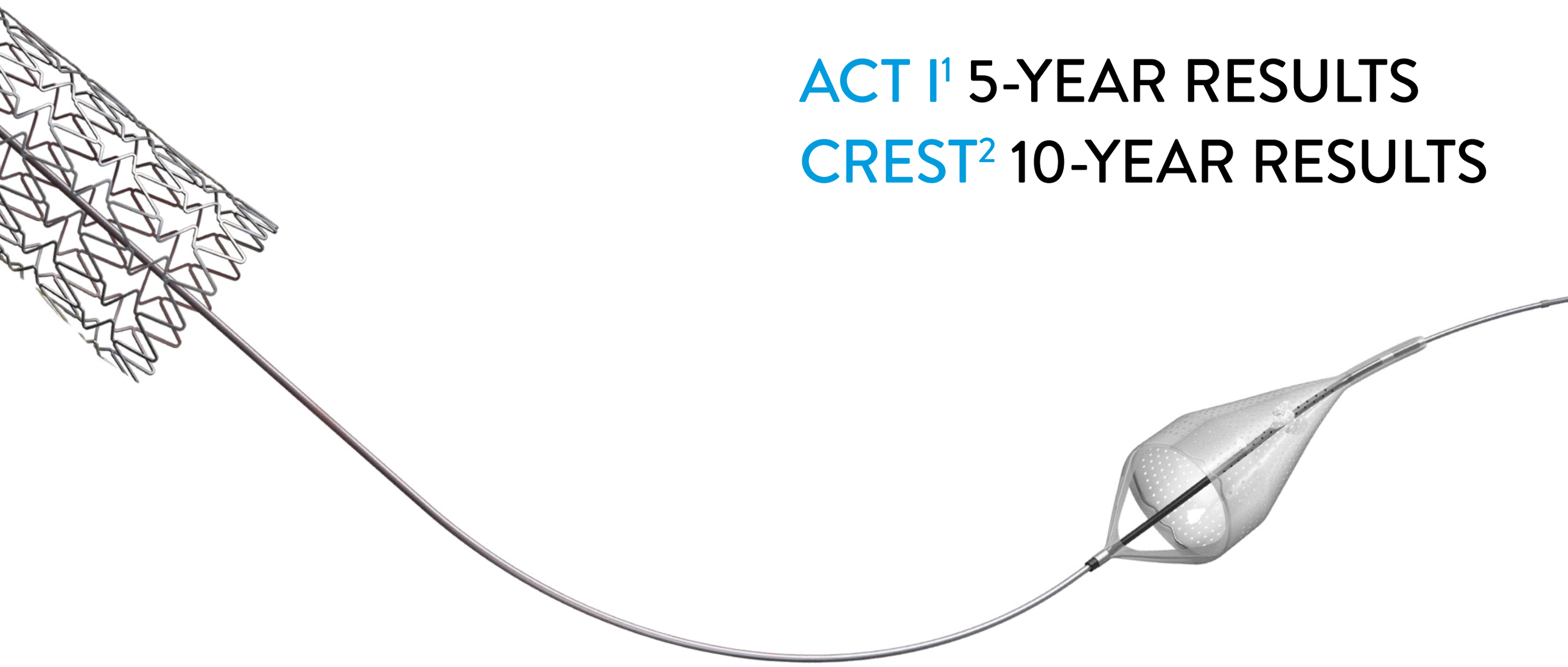
Abbott

ACT I[1] 5-YEAR RESULTS
CREST[2] 10-YEAR RESULTS



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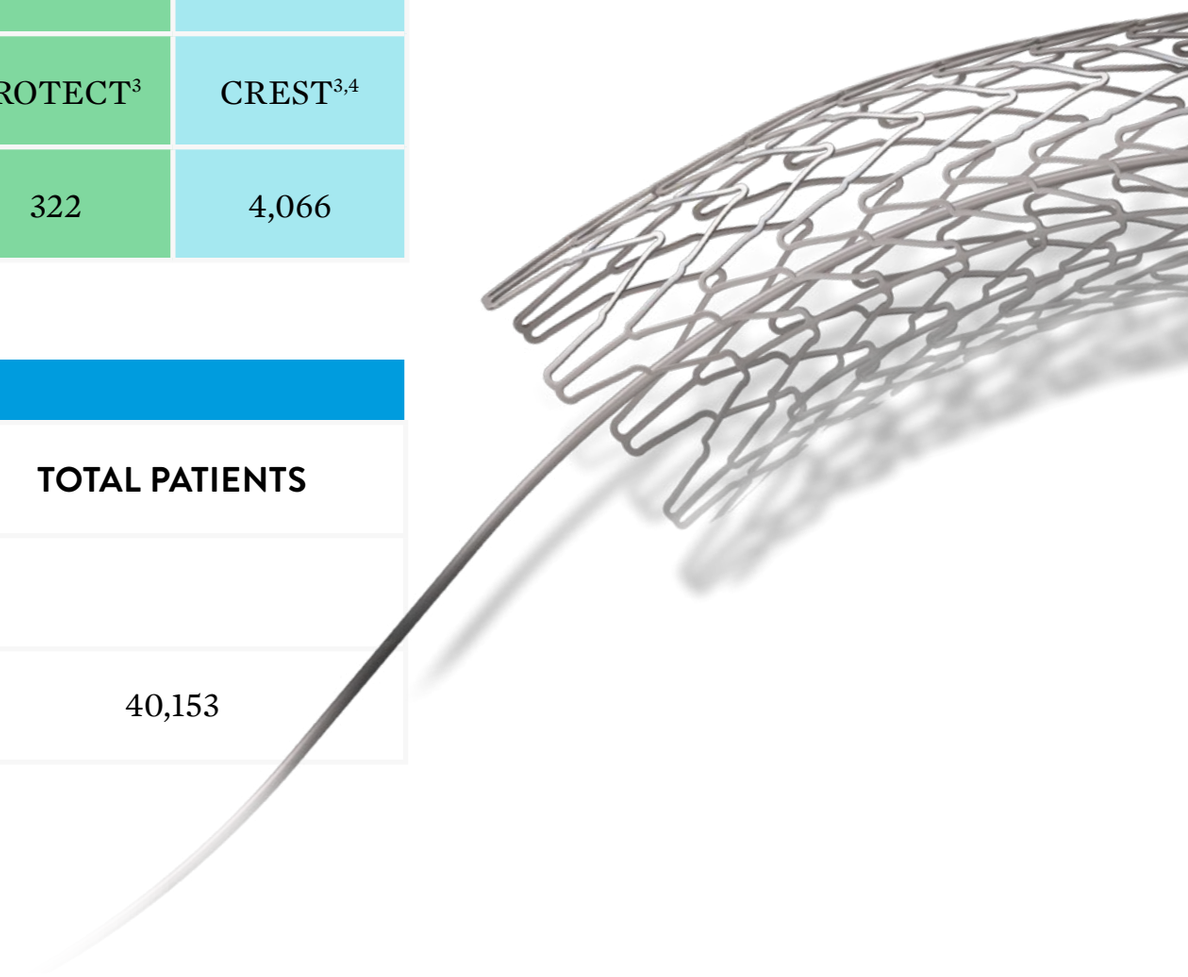
ABBOTT'S COMMITMENT TO CAROTID THERAPY

Since 1999 Abbott carotid stents have been studied in more than 40,000 patients in 10 clinical trials worldwide. Abbott is the sole industry sponsor in the landmark NIH-sponsored CREST clinical trial, a firm supporter of the CREST-2 randomized trial, and the first industry sponsor of the associated CREST-2 Registry. Abbott also sponsored ACT I, the first and only industry-sponsored multi-center randomized controlled trial to continue building clinical evidence in treating asymptomatic carotid stenosis in non-octogenarians with carotid stenting (CAS) versus carotid surgery (CEA).

TRIALS UTILIZING ABBOTT DEVICES						
END DATE	2003	2003	2006	2006	2008	2009
CLINICAL TRIAL	ARCHeR[3]	SECuRITY[3]	CAPTURE[3]	EXACT[3]	PROTECT[3]	CREST[3,4]
PATIENTS	657	398	4,331	2,232	322	4,066

TRIALS UTILIZING ABBOTT DEVICES					
END DATE	2010	2012	2013	2016	**TOTAL PATIENTS**
CLINICAL TRIAL	CAPTURE 2[5]	CHOICE[6]	ACT I[1,7]	CANOPY[3]	
PATIENTS	6,426	18,855	1,663	1,203	40,153

Acculink X.ACT Acculink and X.ACT



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ACT I[1] 5-YEAR RESULTS

ACT I[1] results demonstrated (for asymptomatic, non-octogenarian, standard anatomic risk patients with significant carotid stenosis):

- CAS is non-inferior to CEA for 30-day DSMI and 1-year ipsilateral stroke
- CAS and CEA have similar 5-year rates of stroke and survival

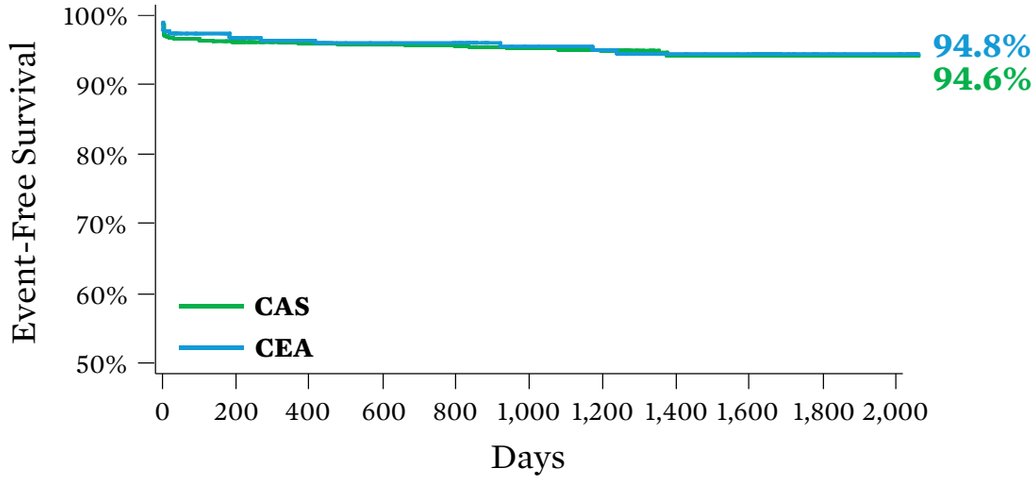
	CAS	CEA
PRIMARY COMPOSITE ENDPOINT	3.8%	3.4%
30-DAY STROKE OR DEATH	2.9%	1.7%
30-DAY MINOR STROKE	2.4%	1.1%
30-DAY COMPOSITE MEASURE OF COMPLICATIONS*	2.8%	4.7%
CRANIAL NERVE INJURY	0.1%	1.1%

The difference between CAS and CEA is statistically significant for only the Primary Composite Endpoint (p=0.01) and Cranial Nerve Injury (p=0.02)

		CAS	CEA	p[1]
Similar Results for CAS and CEA	**31 DAYS – 5 YEARS FREEDOM FROM IPSILATERAL STROKE**	97.8%	97.3%	0.51
	5 YEARS FREEDOM FROM STROKE	93.1%	94.7%	0.44
	5 YEARS SURVIVAL	87.1%	89.4%	0.21
Close to Significance Favoring CAS	**5 YEARS FREEDOM FROM CLINICALLY DRIVEN REVASCULARIZATION**	98.4%	96.7%	0.05

[1] Log-rank.

FREEDOM FROM DEATH, STROKE, AND MI WITHIN 30 DAYS AND IPSILATERAL STROKE 31 DAYS TO 5 YEARS



DAYS	0	(0, 30]	(30, 365]	(365, 730]	(730, 1,095]	(1,095, 1,460]	(1,460, 1,825]
CAS # at risk	1,089	1,067	1,016	862	729	544	364
CEA # at risk	364	354	325	285	246	182	112

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CREST² 10-YEAR RESULTS

CREST² 10-year results demonstrated stenting is as **safe and durable as surgery at 10 years.**

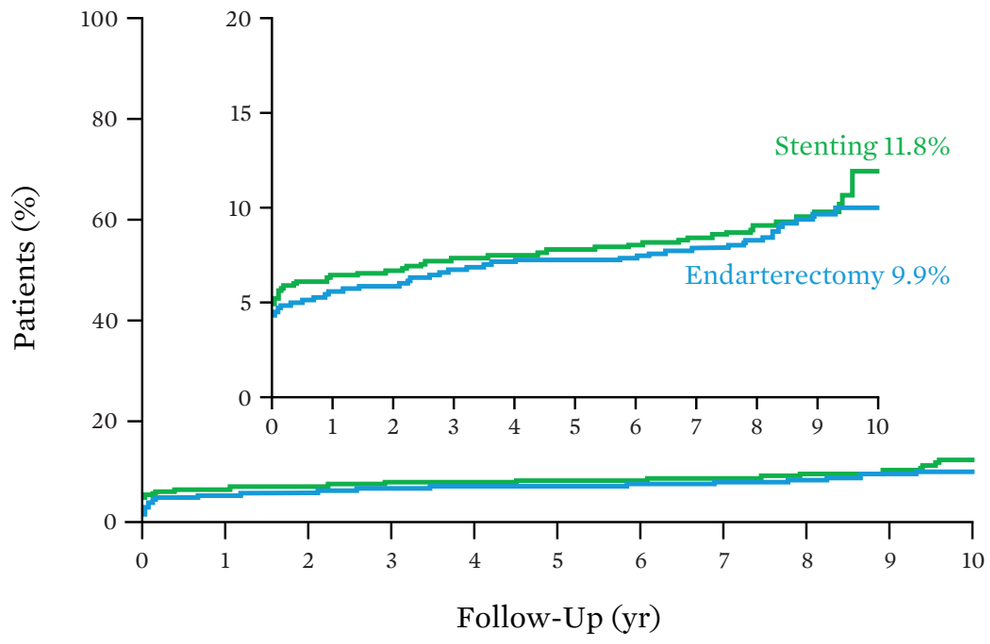
- No significant difference between the stenting group (CAS) and endarterectomy group (CEA) in the rate of the primary composite endpoint*
- No significant difference between symptomatic and asymptomatic patients between the CAS and CEA groups
- No significant difference in the rate of restenosis or revascularization between the CAS and CEA groups

	CAS	CEA
PRIMARY COMPOSITE ENDPOINT*	11.8%	9.9%
POST-PROCEDURAL IPSILATERAL STROKE OUT TO 10 YEARS	6.9%	5.6%
# OF EVENTS	42	41
RATE OF RESTENOSIS OR REVASCULARIZATION	12.2%	9.7%

POST-PROCEDURAL LONG-TERM STROKE

		# EVENTS	5-YEAR (%)	10-YEAR (%)
ASYMPTOMATIC	CAS	21	2.5	6.9
	CEA	20	2.7	5.6
SYMPTOMATIC	CAS	21	2.5	6.9
	CEA	21	2.7	5.6

PRIMARY COMPOSITE ENDPOINT



No. at Risk

Endarterectomy	1,240	1,104	1,036	949	833	736	695	620	438	243	66
Stenting	1,262	1,103	1,041	972	884	774	638	676	477	264	68

*Primary composite end point of stroke, myocardial infarction, or death (DSMI) during the periprocedural period or any subsequent ipsilateral stroke up to 10 years after randomization.

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ACT I[1] AND CEA COMPARISON

	ACT I[1]	CREST[2]	
DEVICES USED	X.ACT Stent System and Emboshield Family of Embolic Protection System	RX Acculink Carotid Stent System and RX Accunet Embolic Protection System	
STUDY DESIGN	Randomized, prospective, multi-center trial comparing CEA and CAS	Prospective, multi-center, randomized trial with blinded endpoint adjudication comparing CEA and CAS	
STUDY RESULTS			
LONG-TERM RESULTS	5-yr: CAS is non-inferior to CEA with regard to primary composite endpoint	10-yr: Stenting is as safe and durable as surgery at 10 years	
PATIENTS AND STUDY ENDPOINTS			
ENROLLMENT	1,453 patients (1,089 CAS; 364 CEA) enrolled between 2005-2013 328 randomized subjects having up to 5-year follow-up	2,502 patients enrolled between 2000-2008 in 117 centers in U.S. and Canada 1,607 consented to long-term (10-year) follow-up	
ASYMPTOMATIC/ SYMPTOMATIC	Asymptomatic only	Asymptomatic and Symptomatic	
RISK TYPE FOR CEA	Standard risk	Standard risk	
AGE	Non-octogenarians only 67.7 ± 7.0	All ages 69.0 ± 8.9	
CAROTID STENOSIS	≥ 70% stenosis	SYMPTOMATIC PATIENTS • ≥ 50% stenosis on angiography • ≥ 70% stenosis on ultrasonography • ≥ 70% stenosis on computed tomographic or magnetic resonance angiography if the stenosis on ultrasonography was 50-69%	ASYMPTOMATIC PATIENTS • ≥ 60% stenosis on angiography • ≥ 70% stenosis on ultrasonography • ≥ 80% stenosis on computed tomographic or magnetic resonance angiography if the stenosis on ultrasonography was 50-69%
PRIMARY ENDPOINT	Stroke, death, MI (DSMI) within 30 days and ipsilateral stroke 31 days to 1 year	DSMI during the periprocedural period or any ipsilateral stroke up to 10 years after randomization	
PRIMARY LONG-TERM ENDPOINT	--	Ipsilateral stroke after 36 days post-procedure up to 10 years+	
SECONDARY ENDPOINTS	Device success within 30 days, Procedural success within 30 days, Freedom from CD-TLR at 6 and 12 months, and ipsilateral stroke at years 2,3,4,5. Composite measure of complications*	--	

* Composite measure of complications includes cranial nerve injury, peripheral nerve injury, vascular injury, non-cerebral bleeding endartectomy, or puncture site bleeding.

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X.ACT AND ACCULINK DESIGN

X.ACT[3]

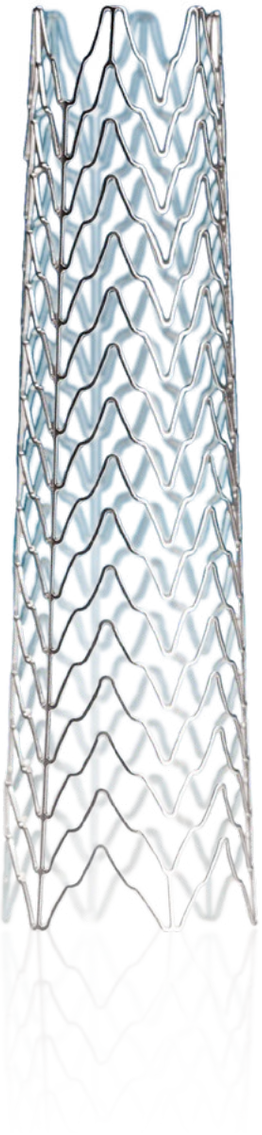
Straight

Tapered

ACCULINK[3]

Straight

Tapered



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Sources: 1. L. Wechsler, Asymptomatic Carotid Stenosis Stenting v. Endarterectomy Trial (ACT I), ISC 2016; K. Rosenfield, Randomized Trial of Stent versus Surgery for Asymptomatic Carotid Stenosis, published on February 17, 2016 at NEJM.org (DOI: 10.1056/NEJMoa1515706). 2. T. Brott, Long-term Results of Stenting vs Endarterectomy for Carotid-Artery Stenosis, ISC 2016; T. Brott, Long-term Results of Stenting versus Endarterectomy for Carotid-Artery Stenosis, published on February 18, 2016 at NEJM.org (DOI: 10.1056/NEJMoa1505215). 3. Data on file at Abbott. 4. Howard VJ et al. Does Sex Matter? 30-day Stroke and Death Rates after CAS (CREST Lead-In Phase). 5. ClinicalTrials.gov - CAPTURE 2 Trial, https://clinicaltrials.gov/ct2/show/NCT00302237 accessed Jan. 16, 2021. 6. ClinicalTrials.gov - CHOICE Trial, https://clinicaltrials.gov/ct2/show/NCT00406055, accessed Jan. 16, 2021. 7. ClinicalTrials.gov - ACT I Trial, https://clinicaltrials.gov/ct2/show/NCT00106938, accessed Jan. 16, 2021.

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