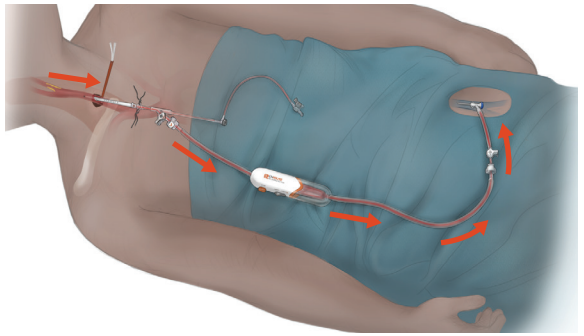
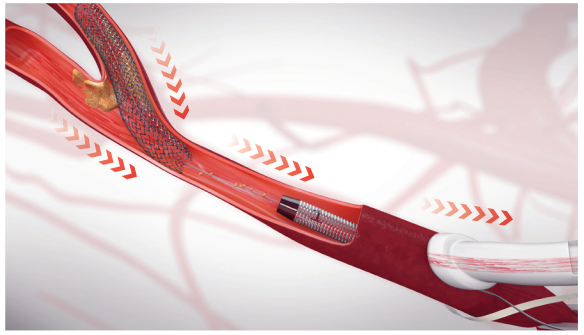
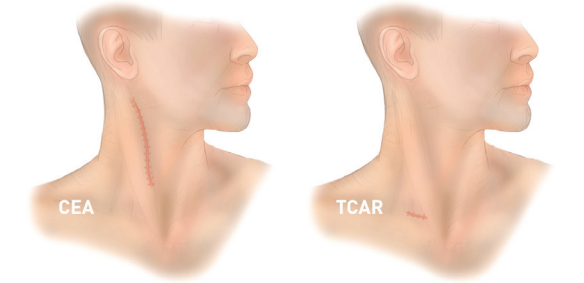
ROADSTER STUDY

Pivotal results of a prospective, single-arm, multi-center trial of Transcarotid Artery Revascularization in High Surgical Risk Patients with carotid stenosis.

	High Surgical Risk		Standard Risk
Patient Demographics & Technical Results	**ROADSTER Pivotal (n=141)**	**ROADSTER Total (n=219)**	**CREST CEA Total[1] (n=1,240)**
Age (mean)	72 ± 8.9	72.3 ± 8.6	69.2 ± 8.7
Age ≥75	50.4% (71)	41.6% (91)	28.5%[2]
Female	34.8% (49)	37.9% (83)	33.6%
Symptomatic	25.5% (36)	22.4% (49)	52.7%
Local Anesthesia	52.5% (74)	47.1% (103)	10.0%
Reverse Flow Time (median)	10 min	10 min	-
Clinical Results			
S/D/MI*	3.5% (5)	3.7% (8)	4.5% (56)
Major Stroke	**0.0% (0)**	**0.0% (0)**	**0.6% (8)**
Minor Stroke	**1.4% (2)**	**1.4% (3)**	**1.7% (21)**
Death	1.4% (2)	0.9% (2)	0.3% (4)
MI	0.7% (1)	1.4% (3)	2.3% (28)
All Stroke	**1.4% (2)**	**1.4% (3)**	**2.3% (29)**
Cranial Nerve Injury	0.7% (1)	0.5% (1)	5.3%[3]
CNI Unresolved 6M	**0.0% (0)**	**0.0% (0)**	**2.1%[3]**







CAUTION: Federal (US) law restricts this device for sale by or on the order of a physician. Please refer to package insert for indications, contraindications, warnings, precautions, and instructions for use.
Primary Endpoint: All stroke, MI & death at 30 days
*Hierarchical

1 NEJM 2010;363:11-23
2 Stroke 2011;42[12]:3484-90
3 Circulation 2012;125:2256-2264

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