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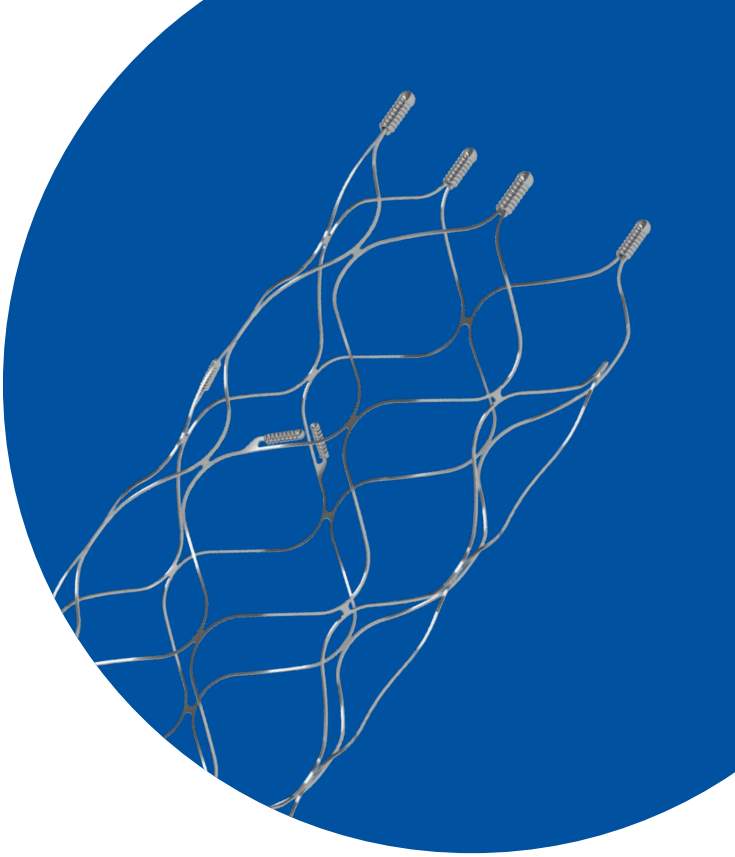
An investigator-initiated, multi-center, prospective, randomized, open-label, blinded-endpoint (PROBE) study in ischemic stroke patients receiving intravenous alteplase within 4.5h of stroke onset.



EXTEND-IA Key Findings

The EXTEND-IA trial was conducted to test the hypothesis that anterior circulation ischemic stroke patients, selected with a "dual target" of vessel occlusion and evidence of salvageable tissue on perfusion imaging within 4.5h of onset, would have improved reperfusion and early neurological improvement when treated with endovascular thrombectomy using the Solitaire™ FR Revascularization Device after intravenous (IV) alteplase, compared to alteplase alone.

IV t-PA Randomized ✓

Less than 5% loss to follow up ✓

Independent data review ✓

100%

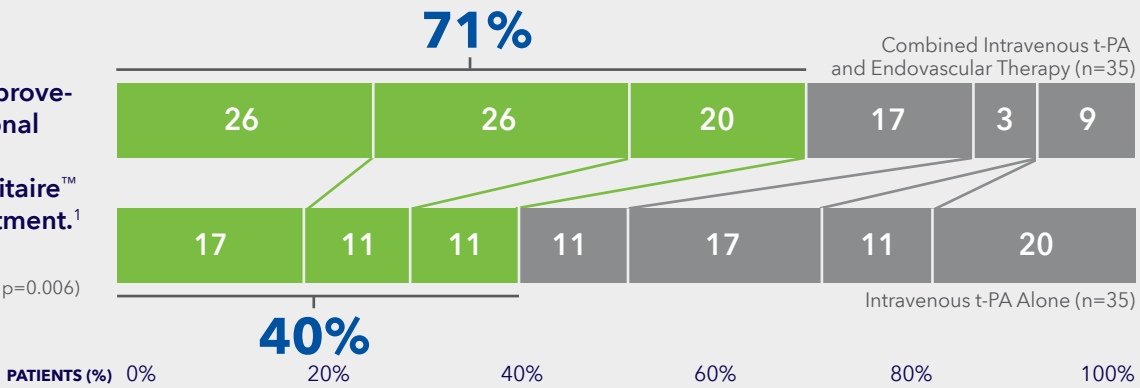
Solitaire™ FR Device*

0% 100%

Primary Endovascular Treatment

Statistically significant improvement in the rate of functional outcomes at 90 days with intervention using the Solitaire™ FR device as primary treatment.[1]

[1] Generalized OR 2.0 (95% CI 1.2-3.8; p=0.006)



No significant difference in study populations:

CHARACTERISTIC	INTRAVENOUS t-PA ALONE (n=35)	COMBINED INTRAVENOUS t-PA AND ENDOVASCULAR THERAPY (n=35)*
Number of randomized subjects	35	35
Age (year) - Mean (SD)	70.2 ± 11.8	68.6 ± 12.3
Male sex - no. (%)	17 (49)	17 (49)
BL NIHSS score, Median (IQR)	13 (9-19)	17 (13-20)
History of hypertension - no. (%)	23 (66)	21 (60)
History of diabetes - no. (%)	8 (23)	2 (6)
Time from stroke onset to initiation of alteplase (min) - Median (IQR)	145 (105-180)	127 (93-162)
Site of vessel occlusion - no. (%)		
· Internal carotid artery (ICA)	11 (31)	11 (31)
· First segment of middle cerebral artery (M1)	18 (51)	20 (57)
· Second segment of middle cerebral artery (M2)	6 (17)	4 (11)

Study results:

OUTCOME	Alteplase-Only Group (n=35)	Endovascular Therapy Group (n=35)*	UNADJUSTED EFFECT SIZE (95% CI)	P VALUE
Primary outcomes:				
Median Reperfusion at 24 hr – (IQR)	37 (-0.5 to 96)	100 (100 to 100)	4.9 (2.5 to 9.5)	<0.001
Early neurologic improvement: Reduction ≥ 8 points on NIHSS or a score of 0–1 at 3 days - no. (%)	13 (37)	28 (80)	6.8 (2.3 to 20)	<0.001
Secondary outcomes:				
Independent outcome (mRS 0-2) at 90 days - no. (%)	14 (40)	25 (71)	3.8 (1.4 to 10.0)	0.009
Final mTICI 2B-3 (in patients who had an initial occlusion angiography - no./total no.(%)	N/A	25/29 (86)	N/A	N/A
Death - no. (%)	7 (20)	3 (9)	0.38 (0.1 to 1.6)	0.18
Symptomatic intracranial hemorrhage at 27hr - no. (%)	2 (6)	0	−6 (−13 to 2)*	0.49
Home time (number of days spent at home during the first 90 days after the diagnosis of stroke) - median (IQR)	15 (0 to 69)	73 (47 to 86)	58 (17 to 90)	0.006

*The effect size in this category is a risk difference, as measured in percentage points for symptomatic intracerebral hemorrhage and parenchymal hematoma.

Study conclusion:

In ischemic stroke patients with a proximal cerebral arterial occlusion and salvageable tissue on CT perfusion imaging, early thrombectomy with the Solitaire™ FR stent thrombectomy device improves reperfusion, early neurologic recovery and functional outcome compared with alteplase alone.

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CAUTION: Federal (USA) law restricts these devices to sale distribution and use by or on order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

The Solitaire FR Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

* Solitaire™ FR Revascularization Device used in Endovascular therapy

SOURCE: Campbell BC, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. *N Engl J Med.* Mar 12 2015;372(11):1009-1018.