PAGINA 0

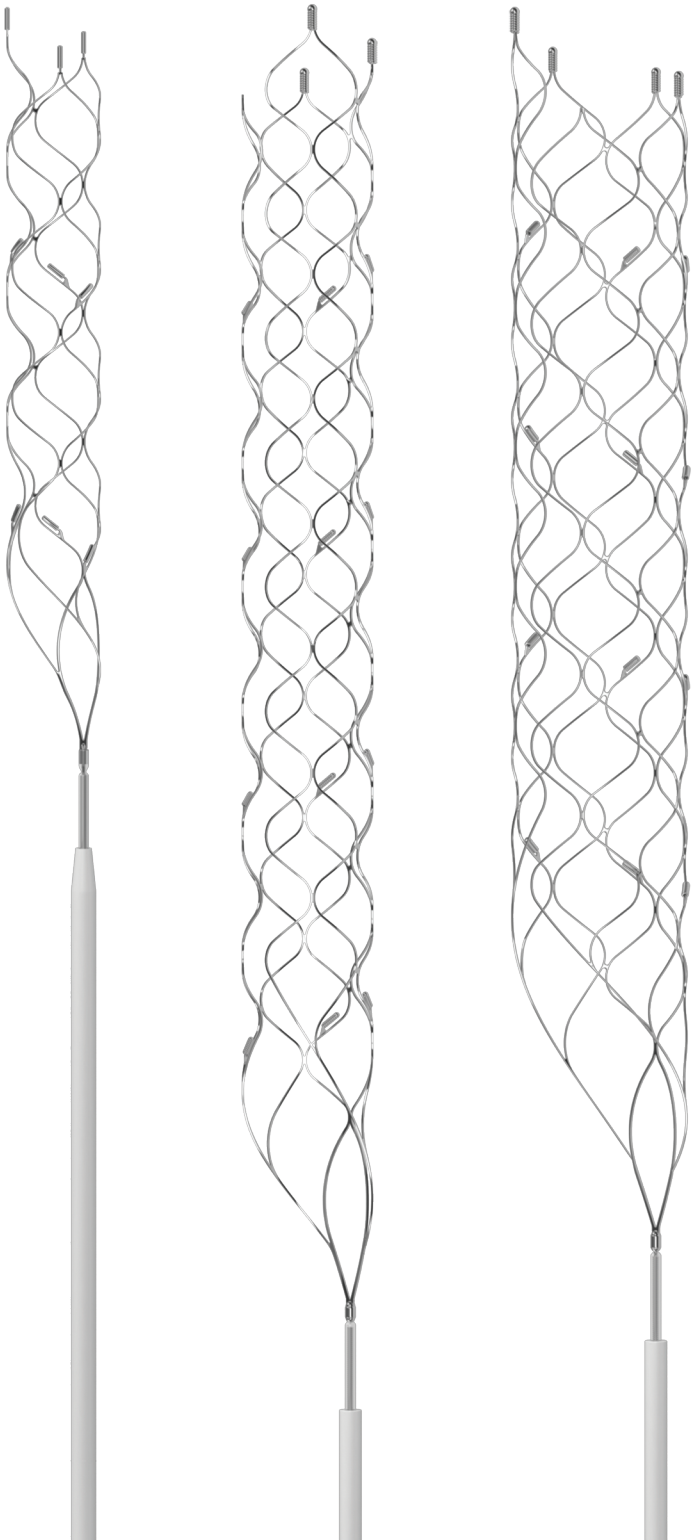
CREATA PENTRU A PUTEA SEMNA ELECTRONIC DOCUMENTUL

Digitally signed by Kojevnikov Dmitrii
Date: 2023.10.13 18:52:45 EEST
Reason: MoldSign Signature
Location: Moldova

Medtronic

The power package

Your talent. Our tools.



Powering the future of stroke treatment.

Solitaire™ X

Revascularization Device

Your power package for consistent and confident performance.[1]

Navigate tortuous vessel anatomy with the stent retriever that built the stroke community's confidence in mechanical thrombectomy.[2]

Solitaire™ X device and you: together, with your expertise and our tools, we bring the power package that patients need consistently.[1]

Delivering the performance you expect:

- first-line treatment
- rescue therapy
- combined technique

Partner with us for first-pass performance

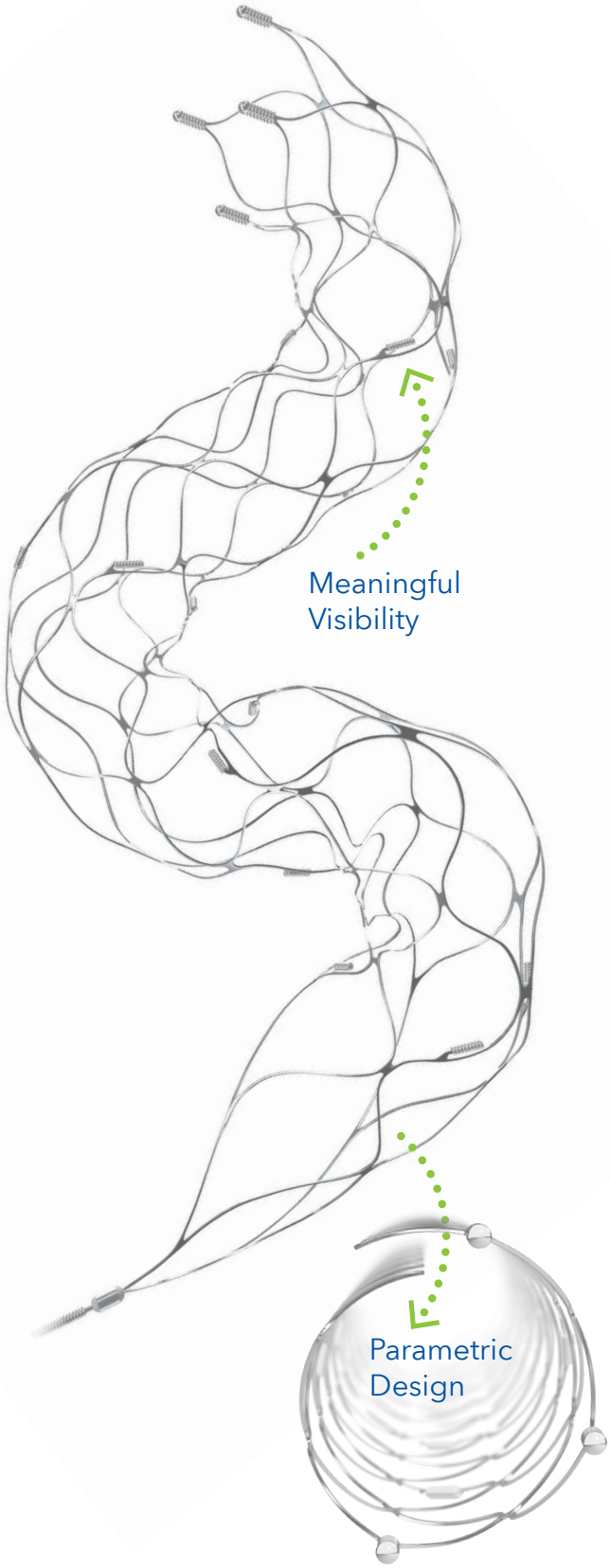
The parametric design of the Solitaire™ X device can empower you with reliable retrieval and optimal reperfusion rates[3-4]

Experience immediate flow restoration[5*]

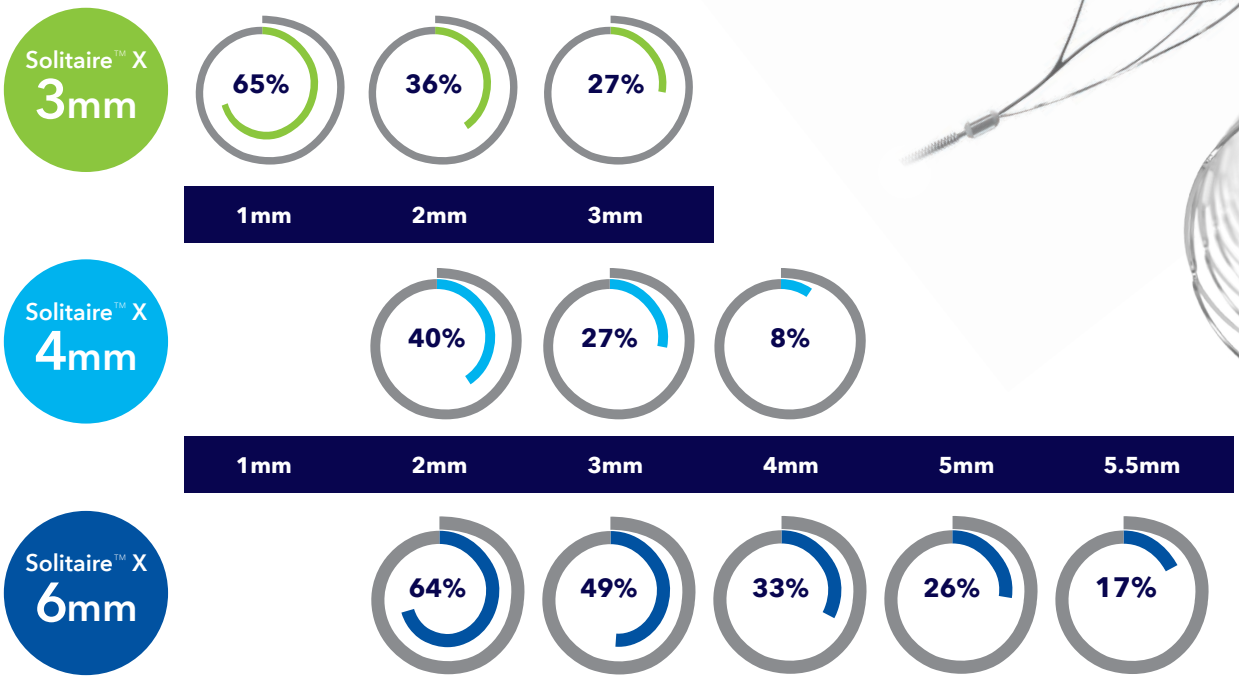
- Recanalization starts at first clot engagement with maximized initial radial force[5*]

Conform to anatomy with wall apposition and dynamic clot integration[6,7*]

- Simple, self-expanding design allows device to expand and compress in the vessel during deployment and retrieval
- Maintains consistent cell size and structure over varying vessel diameters[8*]
- Provides multiple planes of contact to integrate with the clot, even double layering in smaller vessels[9*]



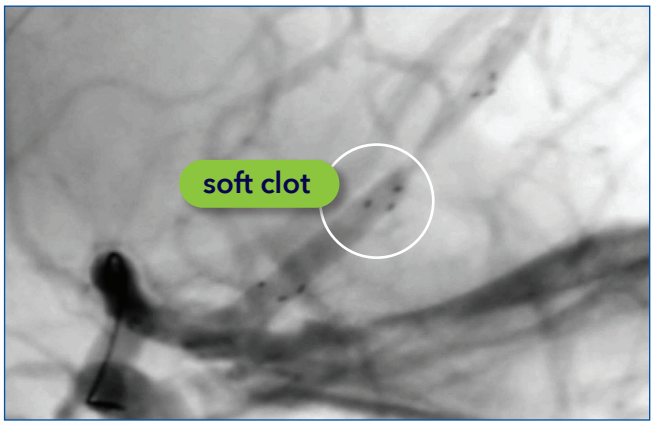
Percent Overlap by Vessel Diameter[7*]



* Based on bench testing results. Bench testing may not be representative of actual clinical performance.

Visualize accuracy with real-time imagery

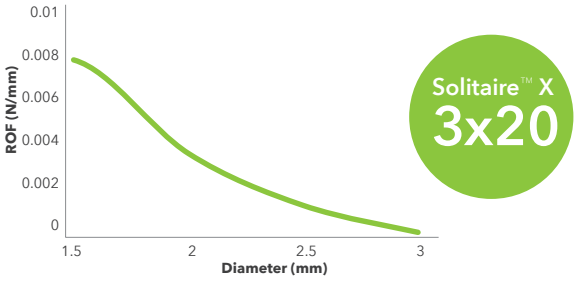
- Real-time visualization of the distinctive, evenly spaced platinum markers enables accurate alignment and feedback during the procedure with a 3D perspective[10*]
- Evaluate clot composition through body marker integration into the clot
  - Visualize the expansion and compression of the stent to help **identify clot characteristics**[11]



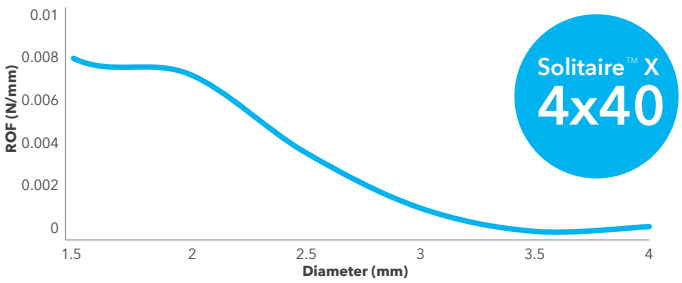
Images courtesy of Dr. Alejandro Tomasello Weitz

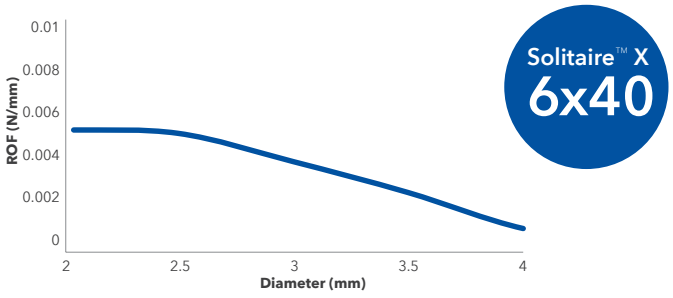
Encapsulate the clot without damaging the wall[12†]

- Differentiated radial outward force promotes clot and vessel wall contact during retrieval with the optimal amount of radial force[13*]



Radial Outward Force Across the Solitaire™ X Device Portfolio[13*]





† Based on bench and animal testing results. Bench and animal testing may not be representative of actual clinical performance.

Optimize outcomes by minimizing the number of passes[14-16]

A large real-world patient cohort demonstrated a **First Pass Effect (FPE) rate of 40.5%** and a **modified FPE (mFPE) rate of 58.9%** across patients treated with the Solitaire™ device[17‡]

‡ FPE defined as mTICI2c/3; modified FPE defined as mTICI 2b-3

Did you know?

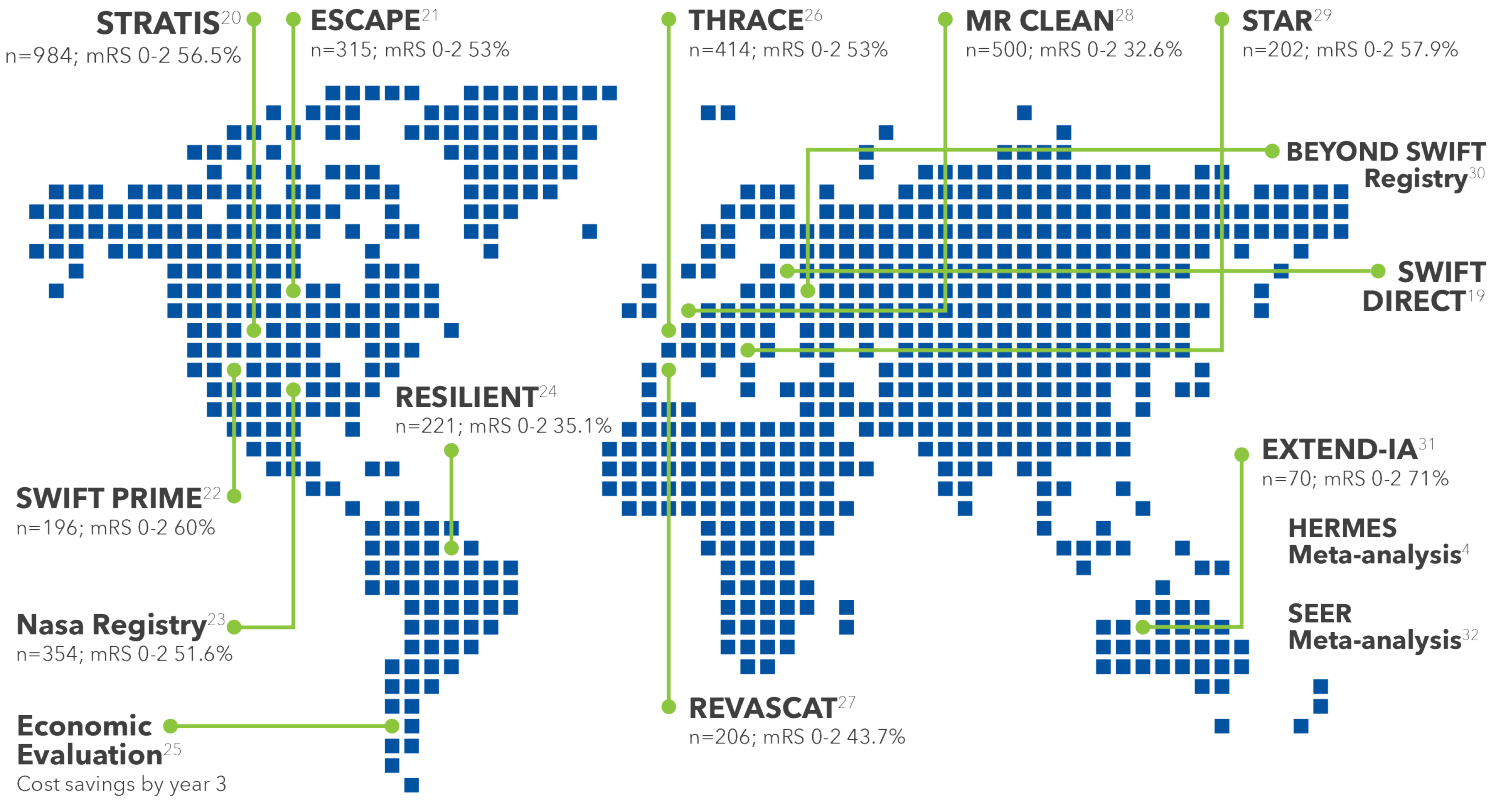
A systematic review and meta-analysis of 67 studies including 16,870 patients demonstrated an overall **FPE rate of 28%** and an overall **mFPE rate of 45%** for mechanical thrombectomy.[18‡]

Achieve the clinical outcomes you expect

A large real-world patient cohort demonstrated the following results with the Solitaire™ device[20]:

- 87.9% successful reperfusion (mTICI 2b-3, per image core lab)
- 56.5% modified Rankin Scale (mRS) 0-2 at 90 days
- 1.4% symptomatic intracranial hemorrhage

The Solitaire™ device is the most-published stent retriever with over 200 studies demonstrating clinically proven, tried-and-true performance.[3,4]



1. TR-NV15436C, D00272862C, D00344794B, TR-NV15519A, TR-NV15666 **2.** Powers WJ, Derdeyn CP, Biller J, et al. 2015 American Heart Association/American Stroke Association focused update of the 2013 guidelines for the early management of patients with acute ischemic stroke regarding endovascular treatment: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2015;46(10):3020-3035. **3.** Medtronic Data on File. Solitaire Literature Review Aug2022. **4.** HERMES: Goyal M, Menon BK, van Zwam WH, et al. Endovascular thrombectomy after large-vessel ischaemic stroke: A meta-analysis of individual patient data from five randomised trials. *Lancet*. 2016;387(10029):1723-1731. **5.** TR07-264A **6.** TR07-128B **7.** TR-NV13807A, TR-NV15666AA, D00419703A, D00324045A **8.** TR-NV12554A **9.** TR-NV13807A, D00419703A **10.** TR-NV12692A **11.** Tomasello A. The best of both worlds: Combination therapy for ischemic stroke. Oral presentation at: *International Stroke Conference*; February 9, 2022; New Orleans, LA. **12.** D00188173B **13.** D00419703A **14.** García-Tornel Á, Requena M, Rubiera M, et al. When to Stop [published correction appears in *Stroke*. 2020 Jun;51(6):e118]. Stroke. 2019;50(7):1781-1788. **15.** Zaidat OO, Castonguay AC, Linfante I, et al. First pass effect: A new measure for stroke thrombectomy devices. *Stroke*. 2018;49(3):660-666. **16.** Flottmann F, Leischner H, Broocks G, et al. Recanalization rate per retrieval attempt in mechanical thrombectomy for acute ischemic stroke. *Stroke*. 2018;49(10):2523-2525. **17.** Jadhav AP, Desai SM, Zaidat OO, et al. First pass effect with neurothrombectomy for acute ischemic stroke: Analysis of the systematic evaluation of patients treated with stroke devices for acute ischemic stroke registry. *Stroke*. 2022; 53(2):e30-e32. **18.** Abbasi M, Liu Y, Fitzgerald S, et al. Systematic review and meta-analysis of current rates of first pass effect by thrombectomy technique and associations with clinical outcomes. *J Neurointerv Surg*. 2021;13(3):212-216. **19.** SWIFT DIRECT: Fischer U, Kaesmacher J, Strbian D, et al. Thrombectomy alone versus intravenous alteplase plus thrombectomy in patients with stroke: An open-label, blinded-outcome, randomised non-inferiority trial. *Lancet*. 2022; 400(10346):104-115. **20.** STRATIS: Mueller-Kronast NH, Zaidat OO, Froehler MT, et al. Systematic evaluation of patients treated with neurothrombectomy devices for acute ischemic stroke: primary results of the STRATIS registry. *Stroke*. 2017;48(10):2760-2768. **21.** ESCAPE: Goyal M, Demchuk AM, Menon BK, et al. Randomized assessment of rapid endovascular treatment of ischemic stroke. *N Engl J Med*. 2015;372(11):1019-1030. **22.** SWIFT PRIME: Saver JL, Goyal M, Bonafe A, et al. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. *N Engl J Med*. 2015;372(24):2285-2295. **23.** Nasa Registry: Nguyen TN, Malisch T, Castonguay AC, et al. Balloon guide catheter improves revascularization and clinical outcomes with the Solitaire device: Analysis of the North American Solitaire Acute Stroke Registry. *Stroke*. 2014;45(1):141-145. **24.** RESILIENT: Martins SO, Mont'Alverne F, Rebello LC, et al. Thrombectomy for stroke in the public health care system of Brazil. *N Engl J Med*. 2020;382(24):2316-2326. **25.** Economic Evaluation: Lylyk P, Cirio J, Toranzo C, Aiello E, Valencia J, Paredes-Fernández D. Mechanical thrombectomy for acute ischemic stroke due to large vessel occlusion in Argentina: An economic analysis. *J Stroke Cerebrovasc Dis*. 2022;31(8):106595. **26.** THRACE: Bracard S, et al. Bracard S, Ducrocq X, Mas JL, et al. Mechanical thrombectomy after intravenous alteplase versus alteplase alone after stroke (THRACE): A randomised controlled trial [published correction appears in *Lancet Neurol*. 2016 Nov;15(12):1203]. *Lancet Neurol*. 2016;15(11):1138-1147. **27.** REVASCAT: Jovin TG, Chamorro A, Cobo E, et al. Thrombectomy within 8 hours after symptom onset in ischemic stroke. *N Engl J Med*. 2015;372(24):2296-2306. **28.** MR CLEAN: Berkhemer OA, Fransen PS, Beumer D, et al. A randomized trial of intraarterial treatment for acute ischemic stroke [published correction appears in *N Engl J Med*. 2015 Jan 22;372(4):394]. *N Engl J Med*. 2015;372(1):11-20. **29.** STAR: Pereira VM, et al. Pereira VM, Gralla J, Davalos A, et al. Prospective, multicenter, single-arm study of mechanical thrombectomy using Solitaire Flow Restoration in acute ischemic stroke [published correction appears in *Stroke*. 2013 Dec;44(12):e239. Moreno, Alfredo [corrected to Moreno, Antonio]] [published correction appears in *Stroke*. 2021 Jan; 52(1):e48]. *Stroke*. 2013;44(10):2802-2807. **30.** BEYOND SWIFT: Meinel TR, Kaesmacher J, Mordasini P, et al. Outcome, efficacy and safety of endovascular thrombectomy in ischaemic stroke according to time to reperfusion: Data from a multicentre registry. *Ther Adv Neurol Disord*. 2019;12:1756286419835708. **31.** EXTEND-IA: Campbell BC, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. *N Engl J Med*. 2015; 372(11):1009-1018. **32.** SEER: Campbell BC, Hill MD, Rubiera M, et al. Safety and efficacy of solitaire stent thrombectomy: Individual patient data meta-analysis of randomized trials. *Stroke*. 2016;47(3):798-806. **33.** M003592CDOC2

The total package for stroke treatment: Solitaire™ X device and you

Solitaire™ X Revascularization Device Portfolio Information[33]

Model	Recommended Vessel Diameter [A] (mm)		Microcatheter ID Range	Push Wire Length	Stent Diameter	Usable Length[B]	Stent Length	Length from Distal Tip to Flourosafe Marker	Radiopaque Markers		Radiopaque Stent Markers Spacing
	(min)	(max)	(min – max)	(cm)	(mm)	(mm)	(mm)	(cm)	Distal	Prox.	(mm)
SFR4-3-20-10	1.5	3.0	0.017" – 0.027" 0.43mm – 0.69mm	200	3.0	20.0	30.6	< 150	3	1	10
SFR4-3-40-10	1.5	3.0	0.017" – 0.027" 0.43mm – 0.69mm	200	3.0	40.0	51.6	<150	3	1	10
SFR4-4-20-05	1.5	4.0	0.021" – 0.027" 0.53mm – 0.69mm	200	4.0	20.0	31.0	<130	3	1	5
SFR4-4-20-10	1.5	4.0	0.021" – 0.027" 0.53mm – 0.69mm	200	4.0	20.0	31.0	<130	3	1	10
SFR4-4-40-10	1.5	4.0	0.021" – 0.027" 0.53mm – 0.69mm	200	4.0	40.0	50.0	<130	3	1	10
SFR4-6-20-10	2.0	5.5	0.021" – 0.027" 0.53mm – 0.69mm	200	6.0	20.0	31.0	<130	4	1	10
SFR4-6-24-06	2.0	5.5	0.021" – 0.027" 0.53mm – 0.69mm	200	6.0	24.0	37.0	<130	4	1	6
SFR4-6-40-10	2.0	5.5	0.021" – 0.027" 0.53mm – 0.69mm	200	6.0	40.0	47.0	<130	4	1	10

A. Based on the smallest vessel diameter at thrombus site.
B. Usable length that is at least as long as the length of the thrombus.

Up to 3 flow restoration recoveries[33]

For a compatible microcatheter to help you smoothly navigate through even the most complicated anatomy, choose from the Phenom™ 21 or 27 catheter to deliver the Solitaire™ X device.

Phenom™ Catheters

Product Name	Model	Outer Diameter	Inner Diameter	Working Length	Soft Distal Segment	Flexible SIngle Coil Segment	Tip Shape	Max. Guidewire
		(F)	(in)	(cm)	(cm)	(cm)		(in)
Phenom™ 21 Catheter	FG13160-0615-1S	2.6>2.3	0.021	160	6	15	Straight	0.018
Phenom™ 27 Catheter	FG15160-0615-1S	3.1>2.8	0.027	160	6	15	Straight	0.025

Medtronic

9775 Toledo Way
Irvine, CA 92618
USA
Tel 800-716-6700
Fax 763-526-7888

medtronic.com/NV

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 viewed at www.medtronic.com/manuals.

1. The Solitaire™ X Revascularization Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset. 2. The Solitaire™ X Revascularization Device is indicated 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 IV t-PA or who fail IV t-PA therapy are candidates for treatment. 3. The Solitaire™ X Revascularization Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion of the internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 segments with smaller core infarcts (<70 cc by CTA or MRA,<25 cc by MR-DWI). Endovascular therapy with the device should start within 6-16 hours of time last seen well in patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy.

Phenom™ Catheters are intended for the introduction of interventional devices or diagnostic agents into the neuro, peripheral, and coronary vasculatures.