A DIFFERENCE
YOU CAN FEEL[1]

WITH PRECISION
YOU CAN SEE[2]

Solitaire™ X
Revascularization Device

Medtronic

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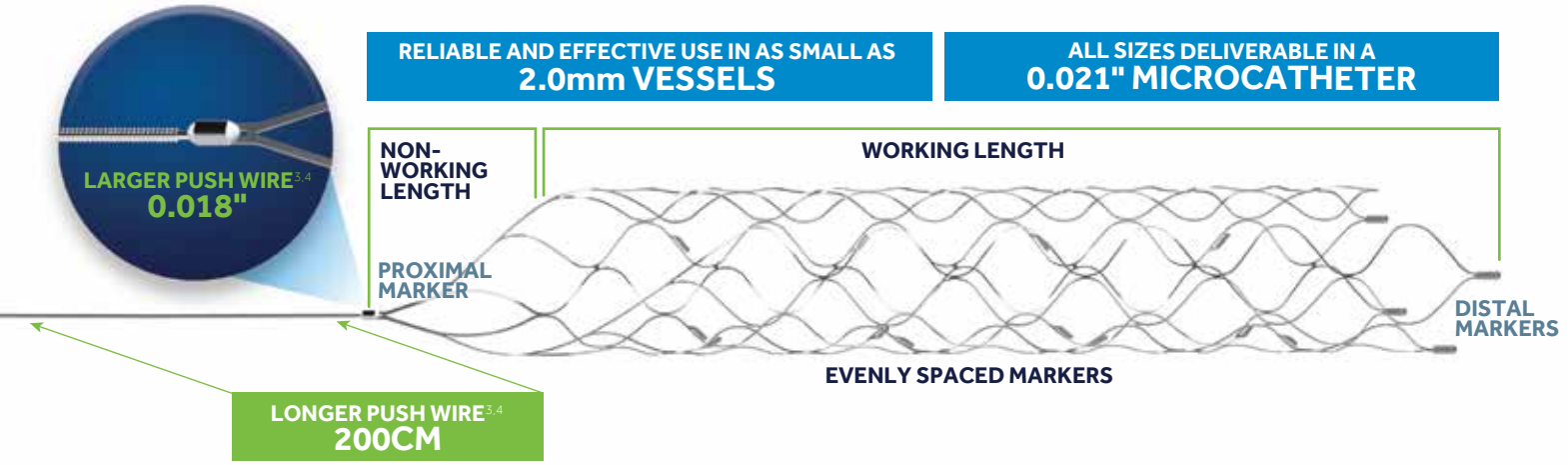
Revascularization Device



SOLITAIRE™ X REVASCULARIZATION DEVICE ORDERING INFORMATION[5]

Model	Recommended Vessel Diameter[A] (mm)		Minimum Microcatheter ID (inch)		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)
SFR4-4-20-05	2.0	4.0	0.021	0.027	200	4.0	20.0	31.0	<130	3	1	5
SFR4-4-40-10	2.0	4.0	0.021	0.027	200	4.0	40.0	50.0	<130	3	1	10
SFR4-6-24-06	2.0	5.5	0.021	0.027	200	6.0	24.0	37.0	<130	4	1	6
SFR4-6-40-10	2.0	5.5	0.021	0.027	200	6.0	40.0	47.0	<130	4	1	10

Up to 3 retrieval passes[5]

1. TR-NV16168 Rev A
2. TR-NV12692 Rev A
3. DWGS31642 Rev A
4. Compared to Solitaire™ Platinum
5. 71042-001 Rev A

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.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu

INDICATIONS: 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. **PRECAUTIONS:** • The Solitaire™ X Revascularization Device should only be used by physicians trained in interventional neuroradiology and treatment of ischemic stroke. • Carefully inspect the sterile package and the Solitaire™ X Revascularization Device prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components. • The Solitaire™ X Revascularization Device is not to be used after the expiration date imprinted on the product label. • Refer to the appropriate intravenous tissue plasminogen activator (IV t-PA) manufacturer labeling for indications, contraindications, warnings, precautions, and instructions for use. • Operators should take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible. • Initiate mechanical thrombectomy treatment as soon as possible. • For indication 3, endovascular therapy with the device should be started within 16 hours of symptom onset. • For indication 3, users should validate their imaging analysis techniques to ensure robust and consistent results for assessing core infarct size. **CONTRAINDICATIONS:** Use of the Solitaire™ X Revascularization Device is contraindicated under these circumstances. • Patients with known hypersensitivity to nickel-titanium. • Patients with stenosis and/or pre-existing stent proximal to the thrombus site that may preclude safe recovery of the Solitaire™ X Revascularization Device. • Patients with angiographic evidence of carotid dissection. **WARNINGS – ALL INDICATIONS:** • The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice. • Administer IV t-PA as soon as possible for all patients who are indicated to receive the drug. Do not cause delays in this therapy. • Per IV t-PA manufacturer labeling, IV t-PA should be administered within 3 hours of stroke symptom onset (IV t-PA use beyond 3 hours is not approved in the United States). • Do not torque the Solitaire™ X Revascularization Device. • For vessel safety, do not perform more than three recovery attempts in the same vessel using Solitaire™ X Revascularization Devices. • For device safety, do not use each Solitaire™ X Revascularization Device for more than three flow restoration recoveries. • For each new Solitaire™ X Revascularization Device, use a new microcatheter. • Solitaire™ X Revascularization Device does not allow for electrolytic detachment. • To prevent device separation: - Do not oversize device, - Do not recover (i.e. pull back) the device when encountering excessive resistance. Instead, resheath the device with the microcatheter and then, remove the entire system under aspiration. If resistance is encountered during resheathing, discontinue and remove the entire system under aspiration, - Do not treat patients with known stenosis proximal to the thrombus site. • This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilization increase the risks of patient infection and compromised device performance. • If excessive resistance is encountered during the delivery of the Solitaire™ X Revascularization Device, discontinue the delivery and identify the cause of the resistance. Advancement of the Solitaire™ X Revascularization Device against resistance may result in device damage and/or patient injury. • If excessive resistance is encountered during recovery of the Solitaire™ X Revascularization Device, discontinue the recovery and identify the cause of the resistance. • Advancing the microcatheter while the device is engaged in clot may lead to embolization of debris. • Do not advance the microcatheter against any resistance. • Do not reposition more than two times. **WARNINGS – INDICATION 1&3 ONLY:** • The safety and effectiveness has not been established for the Solitaire™ X device to reduce disability in patients with the following: Posterior circulation occlusions, More distal occlusions in the anterior circulation, Large core infarct (ASPECTS ≤7).

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