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INSPIRE-S

A neurovascular registry to study innovative AIS approved devices

Innovative NeurovaScular Product Surveillance REgistry-Acute Ischemic Stroke (INSPIRE-S) Registry



Study design

- Prospective, global registry¹
- >800 AIS patients enrolled to date, across 33 sites worldwide, including Europe, Asia, and South America²
- Core-lab adjudicated
- Clinical events committee (CEC) adjudicated
- 3 cohorts based on first pass technique:



Stent retriever only

Solitaire[™] X revascularization device and Solitaire™ Platinum revascularization device[†]



Aspiration only

React[™] 68/71 catheters



Combination therapy

Solitaire[™] revascularization device[†] and React[™] 68/71 catheters (or market-approved aspiration catheter)

Purpose

To present the results for 397 patients from the combination therapy cohort.

Primary objectiveGood functional outcomes as measured by a modified Rankin Scale (mRS) score of 0-2 or return to pre-stroke mRS at 90 days post-intervention.

Additional outcomes

Final successful revascularization, first pass revascularization, and safety outcomes.



Procedural characteristics

Combination therapy % (n/Total N)

Thrombectomy devices used on 1st pass	
Solitaire™ X and Platinum	100% (397/397)
React [™]	76.1% (302/397)
React™ 68	37.8% (150/397)
React [™] 71	38.3% (152/397)
Other aspiration catheter§	23.9% (95/397)
Balloon guide catheter used at 1st pass	39.5% (157/397)

Preliminary Results

Final successful revascularization[‡]

Combination therapy % (n/total N)

eTICI ≥ 2b50	93.4% (367/393)
eTICI ≥ 2b67	88.8% (349/393)
eTICI ≥ 2c	75.6% (297/393)
eTICI = 3	52.7% (207/393)

- † Includes Solitaire™ X revascularization device, primarily, with Solitaire™ Platinum revascularization device
- ‡ A total of 393 patients had core lab data available for revascularization.
- § Enrollment guide was updated in March 2022 to include use of other market-approved aspiration catheters in conjunction with the SolitaireTM device as the primary treatment device.
- 1. INSPIRE-S Analysis Plan V3.0.
- 2. Medtronic data on file for INSPIRE-S Registry.

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™ 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™ 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™ 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, <25cc 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.

The React™ 68 Catheter and React™ 71 Catheter are indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral M1 and M2 segments, basilar, and vertebral arteries) 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.

Ribó M, Möhlenbruch M, Cognard C, Sanjeev N, Mordasini P. Combination therapy using Solitaire™ revascularization device and primarily the React™ catheter in mechanical thrombectomy: Experience from INSPIRE-S registry. Poster at: International Stroke Conference; February 7-9, 2024; Phoenix, AZ.

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9775 Toledo Way Irvine, CA 92618 USA Tel 1-800-716-6700 Fax 763-526-7888

Preliminary results[‡]

First pass revascularization

61.1% eTICL>2b50

56.5% eTICI ≥2b67

48.6% eTICI ≥2c

35.9%

397

Patients treated with Combination Therapy

100%

Solitaire[™] X and Platinum used at 1st pass

76.1%

React[™] used at 1st pass

93.4%

Final Revascularization eTICI ≥ 2b50

48.6%

First pass eTICl≥2c

1.5%

Rate of symptomatic Intracranial Hemorrhage

54.1%

mRS 0-2