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Solitaire™ FR Revascularization Device: 4 x 15 mm
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 18

History: 81 year-old female with a history of atrial fibrillation, CAD, and diabetes that was brought in as a stroke alert. She had acute onset of symptoms an hour prior to her presentation. She was at her home and had acute onset of weakness in her left arm, leg, and slurred speech at approximately 10:30. EMS was called and she was transferred to Riverside Methodist for evaluation. CT showed an abrupt cutoff at the right MCA. Patient was given IV tPA and transferred to VIR for possible mechanical embolectomy.

NEUROINTERVENTION DISCUSSION

The initial angiogram noted a complete occlusion of the mid right middle cerebral artery (M2). A 9F balloon guide was used for access and a Solitaire™ FR revascularization device (4 x 15 mm) was advanced into the M2 segment and deployed for four minutes allowing for immediate flow restoration through the stent to the occluded area. The device then was retracted with aspiration to remove a clot from the left middle cerebral artery. Near complete recanalization was achieved.

PATIENT OUTCOME

Post NIHSS: 0
Patient discharged home two days post procedure.

Results may vary - Not all patients achieve the same results.

The Ohio Health Stroke Network features Riverside Methodist Hospital, a comprehensive stroke center that sees more strokes than any other hospital in Ohio. Riverside Methodist can perform interventional procedures for acute stroke patients who aren’t eligible for IV tPA or who fail IV tPA treatment.

Hospital Name: Riverside Methodists
Interventionalist: Dr. Thomas Davis
Neurologist: Dr. Obinna I. Moneme
ED Physician: Dr. John N. Kwak
Stroke Coordinator: Cathy Hulse
Transferring EMS: Columbus Fire Medic 27
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

**PATIENT PRESENTATION**

NIHSS: 6

History: 48 year-old female with history of hypertension, diabetes presented to the ER at 9:00am. She was last seen normal at 7:00am, arrived at home and her family noted speech problems, a right facial droop and some right-sided arm weakness, Initial NIHSS 4 worsened to 6. She was immediately given IV tPA and taken to the angiosuite, procedure started at 10:30am.

**NEUROINTERVENTION DISCUSSION**

The angio also revealed an MCA occlusion. An 8F balloon guide catheter was used for access and a Solitaire™ FR revascularization device (4 x 15 mm) was advanced through a Prowler™ Select Plus™ catheter into the MCA clot for approx. two minutes. On angio, immediate flow restoration was observed after 1 pass with the Solitaire™ FR device. The device was then retracted with aspiration to remove the clot from the MCA. Complete recanalization was achieved. Total procedural time approx. 60 minutes.

**PATIENT OUTCOME**

Patient was discharged from the hospital on day two with no neurological deficits. Her diffusion imaging showed only two small areas of restriction (ischemia).

Results may vary - Not all patients achieve the same results.

Shands at the University of Florida Stroke Program is dedicated to preventing, diagnosing and treating strokes; providing the latest technology and medications; and treating the stroke patient’s entire needs.

Hospital Name: Shands Hospital

Interventionalist: Dr. Chris Firment
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 11

History: 52 year-old female. Patient presented to ER with left hemiplegia and global aphasia within eight hours of symptom onset. Patient was given IV tPA but with no clinical improvement.

NEUROINTERVENTION DISCUSSION

CT scan confirmed MCA occlusion. A Synchro™ wire was passed through a Marksman™ catheter to get past the occlusion. A Solitaire™ FR revascularization device (4 x 15 mm) was deployed, left open for three minutes and provided immediate flow restoration. The clot was pulled into a Shuttle™ sheath, 1 pass with the Solitaire™ FR device with manual 60 cc aspiration. 45 minute interventional procedure time from groin puncture to groin closure.

PATIENT OUTCOME

Patient was kept for observation and sent home two days later. No rehab needed.

Results may vary - Not all patients achieve the same results.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 17

History: 37 year-old female three weeks postpartum delivery of third child. Acute onset of headache while nursing at 2:00am. Went to bed to rest, husband went to work at 6:00am. Her five year-old son found her unresponsive when she didn’t awake to feed the crying baby. He called 911 and she was taken via ambulance to Tacoma General at 7:15am. No impressive HX.

NEUROINTERVENTION DISCUSSION

CT scan was at 7:40am. Dr Nohara found a total occlusion (dissection likely from child birth) of the ICA as well as a M2 clot. Her access was extremely tortuous. A Synchro™ wire was passed through a Marksman™ catheter to get through dissection. The proximal portion was tacked down with a Precise™* carotid stent, followed by 2 Wingspan™* stents around the distal turn. A 6F ReFlex™ catheter was then taken through the construct to capture the Solitaire™ FR revascularization device (4 x 15 mm) and Marksman™ catheter on the distal end. Groin puncture was at 8:30am and M2 recanalization was at 9:15am.

PATIENT OUTCOME

Patient made a full recovery and went home two days post intervention. No rehab.

Results may vary - Not all patients achieve the same results.

St. Joseph Medical Center has earned the prestigious Gold Seal of Approval from the Joint Commission for Primary Stroke Centers. Our team of highly skilled medical professionals is specially trained to stop—or even reverse—the effects of stroke and to help patients recover and get back to the lives they love.

Hospital Name: St. Joseph Medical Center-Tacoma

Interventionalist: Dr. Alison Nohara
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

**PATIENT PRESENTATION**

NIHSS: 21

History: 70 year-old male presented to ED with right hemiparesis and aphasia. Patient was on aspirin, Plavix™* and Coumadin™* for recent coronary stent complicated by a DVT. INR of 2.1 reversed with 3 units of FFP. CTA revealed left Middle Cerebral Artery (M1) occlusion and CTP revealed large penumbra. The patient was taken emergently to IR lab approximately seven hours after symptom onset for possible clot retrieval.

**NEUROINTERVENTION DISCUSSION**

The initial angiogram noted a complete occlusion of the left MCA. A Solitaire™ FR revascularization device (4 x 15 mm) was advanced into the mid M1 segment and deployed for five minutes allowing for immediate flow restoration through the stent to the occluded area. The device then was retracted with aspiration to remove clot from the M1 segment. Revascularization was achieved within 25 minutes of groin puncture.

**PATIENT OUTCOME**

NIHSS: 14
Moving right arm/leg, motor aphasia, to Rehab (RHOW).

Results may vary - Not all patients achieve the same results.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 13

History: 48 year-old male with sudden onset of right MCA stroke symptoms between 7:00am and 8:00am. Patient was transferred from eastern Washington by EMS. He was given IV tPA but with no clinical improvement. On exam the patient was drowsy but arousable with a dense left hemiparesis (arm, face and leg), some left hemineglect with rightward gaze preference, but did speak and follow commands.

NEUROINTERVENTION DISCUSSION

Emergent angio revealed occluded right internal carotid artery and middle cerebral artery vessels. After stenting the carotid artery, a Solitaire™ FR revascularization device (4 x 15 mm) was advanced and deployed across the middle cerebral artery thrombus, which resulted in immediate flow restoration. After three minutes, the Solitaire™ FR device was retrieved under aspiration and the clot was removed.

PATIENT OUTCOME

Post NIHSS: 1
The patient was ambulating the following morning.

At Virginia Mason Stroke Center, we take a coordinated, team-medicine approach to care. The Stroke Center expertly combines the skills and services of the Emergency Department, Radiology, Neurology, Neurosurgery, Rehabilitation, Critical Care Unit (CCU), Telemetry and Neurosciences. The Stroke Center was established in 2004 and is certified as a Primary Stroke Center by The Joint Commission.
Solitaire™ FR Revascularization Device: 4 x 20 mm
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 17

History: 56 year-old male with past medical history of atrial fibrillation (on Warfarin), obesity, and hypertension who presented to UPMC Presbyterian ED for evaluation of sudden onset weakness of the left arm and leg at 4:00pm on day of admission. Neurologic exam on presentation was significant for left hemiplegia, drowsiness, left facial droop, dysarthria, right gaze preference, and left hemianopia. MRI scan at five hours post-symptom onset revealed acute right M1 occlusion (no CT due to weight limit).

NEUROINTERVENTION DISCUSSION

Patient was taken emergently to angiography. 6F radial sheath access was obtained and successful mechanical embolectomy with a Solitaire™ FR revascularization device (4 x 20 mm) opened the occluded right middle cerebral artery with residual superior right MCA occlusion.

PATIENT OUTCOME

Post NIHSS: 8 the morning after intervention, 6 at day five (ambulating with moderate assist). Patient sent to rehab.

Results may vary - Not all patients achieve the same results.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient
Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 38 / 24

History: 65 year-old male was complaining of a headache earlier on the date of admission to a friend. The friend went to the patient's house and found him lying on the floor unresponsive. The friend promptly transported the patient to the UPMC St. Margaret ED. NIHSS was 38. CT/CTA revealed a basilar artery occlusion. Patient transferred to UPMC Presbyterian via Stat MedEvac. NIHSS on arrival was 24.

NEUROINTERVENTION DISCUSSION

Intervention began six hours post symptom onset. Diagnostic angiography demonstrated a proximal basilar artery occlusion (atherosclerotic in origin). The Solitaire™ FR revascularization device (4 x 20 mm) was deployed in the mid PCA allowing for immediate blood flow restoration and then pulled back with aspiration retrieving the clot. The proximal basilar artery was then stented. NIHSS post angio was 13.

PATIENT OUTCOME

TIMI 3 flow and NIHSS was 7 post discharge to rehab.

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

The UPMC Stroke Institute includes 2 facilities, UPMC Presbyterian and UPMC Mercy, which offer services for a full spectrum of cerebrovascular diseases including hemorrhagic and ischemic stroke. Immediate consultation is available 24/7 via Medcall phone: 412-647-7000.

Results may vary - Not all patients achieve the same results.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

**PATIENT PRESENTATION**

NIHSS: 15

History: 63 year-old male with hypertension, hyperlipidemia, diabetes, lupus antibodies, heart failure and atrial fibrillation (on Coumadin™*). Patient was brought in five hours post symptom onset. Patient’s wife found him at home on the floor with left-sided weakness. The patient was brought to UPMC Presbyterian ED where a CT showed hyperdensity in the right MCA.

**NEUROINTERVENTION DISCUSSION**

Patient was taken emergently to angiography where successful mechanical embolectomy with a Solitaire™ FR revascularization device (4 x 20 mm) and manual aspiration were performed achieving TIMI2 and TICI 2b flow.

**PATIENT OUTCOME**

Post NIHSS: 3 the morning after intervention, 1 at five days post-procedure.

The UPMC Stroke Institute includes 2 facilities, UPMC Presbyterian and UPMC Mercy, which offer services for a full spectrum of cerebrovascular diseases including hemorrhagic and ischemic stroke. Immediate consultation is available 24/7 via Medcall phone: 412-647-7000.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

**PATIENT PRESENTATION**

NIHSS: 15

History: 58 year-old female with history of tobacco abuse. Presented to Samaritan Regional Health with aphasia and right-sided weakness, administered IV tPA. The patient was then transferred to Riverside Methodist and arrived clinically worse with NIHSS stroke scale approaching 17-20. CT scan and CTA showed persistent left middle cerebral artery occlusion and possible severe stenosis of left internal carotid artery. Patient was taken emergently to angiography where the initial angiogram showed a critical 95-99% stenosis of the left internal carotid artery and proximal to mid complete occlusion of the left middle cerebral artery.

**NEUROINTERVENTION DISCUSSION**

A 9F balloon guide was used for access and balloon angioplasty was performed in the left ICA. The Solitaire™ FR revascularization device (4 x 20 mm) was advanced into the mid M1 segment and deployed for five minutes allowing for immediate flow restoration through the stent to the occluded area. The device then was retracted with aspiration to remove clot from the proximal M1. A second pass in the distal M1 segment with the 4 x 20 mm Solitaire™ FR device and aspiration removed the remaining clot. A small anterior division distal embolus remained.

**PATIENT OUTCOME**

Post NIHSS: 0

Discharged home in two days with no deficit.

The Ohio Health Stroke Network features Riverside Methodist Hospital, a comprehensive stroke center that sees more strokes than any other hospital in Ohio. Riverside Methodist can perform interventional procedures for acute stroke patients who aren’t eligible for IV tPA or who fail IV tPA treatment.

Results may vary - Not all patients achieve the same results.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 11

History: 70 year-old male was having a heart cath at an outside hospital for shortness of breath when he was found to be aphasic and not moving his right side well, due to a left MCA branch occlusion. Cardiologist transferred the patient immediately and because he had just had a heart cath he was not a good candidate for IV or IA tPA. Patient arrived at Riverside approx. 4:49pm (onset of symptoms at 12:20pm) and was aphasic.

NEUROINTERVENTION DISCUSSION

Diagnostic angiography demonstrated a complete occlusion of the left middle cerebral artery (M2). The Solitaire™ FR revascularization device (4 x 20 mm) was deployed in the left MCA allowing for immediate blood flow restoration. The Solitaire™ device was left deployed for five minutes and then pulled back with aspiration retrieving the clot.

PATIENT OUTCOME

TICI 3 flow achieved and the patient was talking in full sentences two days post-procedure.

Results may vary - Not all patients achieve the same results.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 8

History: 57 year-old female with history of hypertension who presented within one hour of new onset of difficulty speaking, aphasia and confusion. Patient’s husband heard her grunting as she was having trouble talking at 9:00am and called EMS. IV tPA administered at Grant Medical Center and then patient transferred to Riverside. CTA showed left ICA terminus thrombus. The patient was taken immediately to VIR for possible mechanical embolectomy.

NEUROINTERVENTION DISCUSSION

The initial angiogram noted a complete occlusion of the carotid terminus extending into the left middle cerebral artery. A 9F balloon guide was used for access and a Solitaire™ FR revascularization device (4 x 20 mm) was advanced into the mid M1 segment and deployed for four minutes allowing for immediate flow restoration through the stent to the occluded area. The device then was retracted with aspiration to remove a large amount of clot from the proximal M1 and ICA. Near complete recanalization was achieved.

PATIENT OUTCOME

Post NIHSS: 0

Patient had marked improvement and only had slight word-finding difficulty.

Results may vary - Not all patients achieve the same results.

The Ohio Health Stroke Network features Riverside Methodist Hospital, a comprehensive stroke center that sees more strokes than any other hospital in Ohio. Riverside Methodist can perform interventional procedures for acute stroke patients who aren’t eligible for IV tPA or who fail IV tPA treatment.

Referring Hospital: Grant Medical Center
Hospital Name: Riverside Methodist
Interventionalist: Dr. Ron Budzik
Neurologist: Dr. Emily T. Klatte, Dr. Adam N. Ueberroth
Stroke Coordinator: Cathy Hulse
Transferring EMS to Grant: Columbus Fire Medic 21
Transferring EMS to Riverside: Columbus Connection MICU
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 18

History: 38 year-old male with onset of acute right hemisphere stroke syndrome at 8:00am. Arrived at Riverside ED via Marion General ED 4.5 hours after symptom onset. Symptoms included left facial weakness, left visual field loss, PERRL, and speech mildly dysarthric. Dense left hemiplegia. CTA showed right carotid terminus occlusion. The patient was taken immediately to VIR for possible mechanical embolectomy.

NEUROINTERVENTION DISCUSSION

A 9F balloon guide was used for access and sluggish flow in the right ICA was noted. The Solitaire™ FR revascularization device (4 x 20 mm) was advanced into the mid M1 segment and deployed for four minutes allowing for immediate flow restoration through the stent to the occluded area. The device then was retracted with aspiration to remove a large amount of clot from the proximal M1 and ICA. Near complete recanalization was achieved.

PATIENT OUTCOME

Post NIHSS: 0
Patient discharged three days post procedure.

Results may vary - Not all patients achieve the same results.

The Ohio Health Stroke Network features Riverside Methodist Hospital, a comprehensive stroke center that sees more strokes than any other hospital in Ohio. Riverside Methodist can perform interventional procedures for acute stroke patients who aren’t eligible for IV tPA or who fail IV tPA treatment.

Referring Hospital: Marion General
Hospital Name: Riverside Methodist
Interventionalist: Dr. Ron Budzik
Neurologist: Diane Masciangelo ACNP-BC
ED Physician: Dr. Adam N. Ueberroth
Stroke Coordinator: Cathy Hulse
Transferring EMS: Medflight 2
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 16

History: 55 year-old female with history of hypertension, CVA, diabetes presented with acute onset right side weakness and speech difficulty. Patient was vacuuming at 12:30pm when she swayed and fell to floor. She developed a rigid hand, was swaying, eyes remained open but unresponsive and head turned to the left. The patient was taken by family to Southern Ohio Medical Center (Portsmouth, OH) where she received CT and then transferred to Riverside Methodist. No IV tPA was given due to patient’s elevated INR.

NEUROINTERVENTION DISCUSSION

The initial angiogram noted an occlusion of the left middle cerebral artery. A 9F balloon guide was used for access and a Solitaire™ FR revascularization device (4 x 20 mm) was advanced into the proximal M1 segment. The device was deployed for four minutes and immediate flow restoration was seen through the stent to the occluded area. The device then was retracted with aspiration to remove the entire clot from the middle cerebral artery.

PATIENT OUTCOME

Post NIHSS: 0
Overall significant improvement, back to baseline at two days.

Results may vary - Not all patients achieve the same results.

The Ohio Health Stroke Network features Riverside Methodist Hospital, a comprehensive stroke center that sees more strokes than any other hospital in Ohio. Riverside Methodist can perform interventional procedures for acute stroke patients who aren’t eligible for IV tPA or who fail IV tPA treatment.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

**PATIENT PRESENTATION**

NIHSS: 11

History: 91 year-old male with a history of atrial fibrillation on Coumadin™*. Patient had fallen at home around 1:30pm and found to have left-sided weakness and garbled speech. Patient seemed to get worse between 4:00pm and 6:00pm and taken to Grant Medical Center ER. Patient was transferred to Riverside Methodist. CT upon arrival revealed a right middle cerebral artery occlusion.

**NEUROINTERVENTION DISCUSSION**

The initial angiogram showed an occlusion of the right middle cerebral artery. A 9F balloon guide was used for access and a Solitaire™ FR revascularization device (4 x 20 mm) was advanced into the proximal M1 segment. The device was deployed for five minutes and then was retracted with aspiration to remove several large clots. Clot was still present, so the Solitaire™ FR device was deployed again which allowed for immediate flow restoration through the stent to the occluded area and after retraction resulted in complete recanalization.

**PATIENT OUTCOME**

Patient improved immediately with much clearer speech and significant movement of his affected left upper extremity, but unfortunately suffered a delayed reperfusion hemorrhage two days later.

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The Ohio Health Stroke Network features Riverside Methodist Hospital, a comprehensive stroke center that sees more strokes than any other hospital in Ohio. Riverside Methodist can perform interventional procedures for acute stroke patients who aren’t eligible for IV tPA or who fail IV tPA treatment.
**PATIENT PRESENTATION**

NIHSS: 11

History: 73 year-old male developed expressive aphasia and right-sided hemiparesis while driving. He flagged down another motorist, called EMS, and was transported to St. John’s River District Hospital. His presenting NIHSS was 11. Through the St. John’s Stroke Network, robotic technology was utilized to visually evaluate the patient. IV tPA was administered and the patient was transferred to St. John’s Main Hospital via Tri-Hospital EMS.

**NEUROINTERVENTION DISCUSSION**

Diagnostic angiography demonstrated a complete occlusion of the left middle cerebral artery just past the origin. The Solitaire™ FR revascularization device (4 x 20 mm) was deployed in the left MCA allowing for immediate blood flow restoration. The Solitaire™ device was then pulled back retrieving the clot.

**PATIENT OUTCOME**

TICI 3 flow achieved, only slight residual numbness and no paralysis.

Results may vary - Not all patients achieve the same results.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 13

History: 89 year-old female with a history of coronary artery disease as well as afib was admitted with stroke symptoms at St. John Providence – Providence Park. Patient experienced sudden onset of left-sided weakness around 7:30am. CT showed no acute findings. Patient had no movement of the left arm or leg, difficulty with articulation, mild dysarthria and sensory loss on the left side. IV tPA was given with initial improvement, but patient had worsening lower extremity weakness. CT perfusion showed a large right MCA territory penumbra and patient was taken emergently to Angio.

NEUROINTERVENTION DISCUSSION

The initial angiogram showed an occlusion of the right middle cerebral artery. A Solitaire™ FR revascularization device (4 x 20 mm) was advanced into the proximal M1 segment. The device was deployed for five minutes allowing for immediate flow restoration. The device was then retracted with aspiration to remove the entire clot resulting in complete recanalization.

PATIENT OUTCOME

Post NIHSS: 2
Discharged to home with recommendation for outpatient rehabilitation.

Results may vary - Not all patients achieve the same results.

The St. John Providence Health System includes 3 Comprehensive Stroke Centers across the Detroit area. All 3 hospitals offer services for a full spectrum of cerebrovascular diseases including hemorrhagic and ischemic stroke. Patients are treated by a highly specialized team including 3 endovascular trained Neurosurgeons. Immediate consultation is available 24/7 via the NeuroOnCall hotline at 1-888-885-STAT (7828).

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<tr>
<td>Interventionalist</td>
<td>Dr. Richard Fessler</td>
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<tr>
<td>ED Physician</td>
<td>Dr. Jennifer Boukouris</td>
</tr>
<tr>
<td>Neurologist</td>
<td>Dr. Bruce H. Kole</td>
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<td>Stroke Coordinator</td>
<td>Dr. Vickie Gordon</td>
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<td>Transferring EMS</td>
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The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

**PATIENT PRESENTATION**

NIHSS: 20

History: 69 year-old male who presented to ED with chest pain. Cardiology was assessing him for admission, presumably for unstable angina when he suddenly developed right-sided hemiplegia and aphasia. Onset 12:10pm and NIHSS = 20. CT revealed possible hyper-dense left MCA. Patient had been taken off Coumadin™* due to recent surgery, and thus was contraindicated for IV tPA.

**NEUROINTERVENTION DISCUSSION**

Diagnostic angiography demonstrated a complete occlusion of the left middle cerebral artery. The Solitaire™ FR revascularization device (4 x 20 mm) was deployed in the left MCA along with a balloon inflatable guide catheter with aspiration. A 1 cm thrombus was retrieved. Time from groin puncture to device deployment was 24 minutes. Time to complete recanalization was 29 minutes.

**PATIENT OUTCOME**

TICI 3 flow achieved and three hours post procedure NIHSS = 1.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 14, then improved to 8

History: 81 year-old male with a history of dyslipidemia, hypertension and atrial fibrillation woke at 8:00am with right-sided weakness. He was last known well at 10:00pm the evening prior. He presented to a local hospital where his NIHSS was 14 and transferred to Saint Luke’s Hospital (SLH) in Kansas City for further evaluation. NIHSS 8, slightly improved, upon arrival to SLH. CT angiogram revealed an occlusion (TICI 0) of the left middle cerebral artery (MCA). CT Perfusion showed a large perfusion defect within the left MCA territory.

NEUROINTERVENTION DISCUSSION

The Solitaire™ FR revascularization device (4 x 20 mm) was advanced into the M2 segment of the left MCA. The device was deployed twice for five minutes and immediate flow restoration (TICI 3) was seen through the stent to the occluded area. The device then was retracted with aspiration to remove the entire clot from the middle cerebral artery. TICI 3 flow.

PATIENT OUTCOME

Post NIHSS: 0 immediately post-procedure

Stroke work-up revealed a patent foramen ovale (PFO) and possible sleep apnea. Secondary stroke prevention plan: Coumadin™* for atrial fibrillation and the patent foramen ovale and outpatient evaluation for sleep apnea. Discharged home seven days later.

Results may vary - Not all patients achieve the same results.

Saint Luke’s is a comprehensive stroke center that sees more strokes than any other hospital in Missouri. Saint Luke’s can perform interventional procedures for acute stroke patients who aren’t eligible for IV tPA or fail IV tPA treatment.

eDocOnecall - 816-932-6200 / 877-932-6200

Hospital Name: Saint Luke’s Hospital
Interventionalist: Dr. William Holloway
Neurologist: Dr. Christine Boutwell
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 24

History: 36 year-old male with a history of dilated cardiomyopathy and renal insufficiency was being worked up for heart transplant. At 6:30pm he developed slurred speech and a facial droop. The stroke team was activated and he worsened to complete left hemiplegia while in MRI. He was not a candidate for IV tPA due to recent embolic events on MRI.

NEUROINTERVENTION DISCUSSION

Cerebral arteriogram revealed a complete occlusion of the right middle cerebral artery. An 8F balloon guide was used for access and a Solitaire™ FR revascularization device (4 x 20 mm) was advanced into the proximal M1 segment. The device was deployed twice for five minutes and immediate flow restoration was seen through the stent to the occluded area. The device then was retracted with aspiration to remove clot from the middle cerebral artery. A second pass with the 4 x 20 mm device in the anterior temporal branch removed the remaining clot. TICI 2b flow.

PATIENT OUTCOME

Post NIHSS: 7 and 1 at 24 hours

Stoke work-up revealed a large apical thrombus. Secondary stroke prevention plan: Coumadin™* was added to his medication regimen; continued cardiac transplant work-up. Discharged home five days later.

Results may vary - Not all patients achieve the same results.

Saint Luke’s is a comprehensive stroke center that sees more strokes than any other hospital in Missouri. Saint Luke’s can perform interventional procedures for acute stroke patients who aren’t eligible for IV tPA or fail IV tPA treatment.

eDocOnecall - 816-932-6200 / 877-932-6200

Hospital Name: Saint Luke’s Hospital

Interventionalist: Dr. William Holloway

Neurologist: Dr. Suzanne Crandall
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

**PATIENT PRESENTATION**

NIHSS: 22

History: 85 year-old male with a history of atrial fibrillation (and recently taken off Coumadin™* due to a fall), dyslipidemia, hypertension, CAD with CABG, renal insufficiency and dementia. He arrived at the emergency room with left-sided weakness and dysarthria. CT angiogram revealed an occlusion of the basilar artery at the apex. He was not a candidate for IV tPA due to prior cerebral hemorrhage.

**NEUROINTERVENTION DISCUSSION**

The Solitaire™ FR revascularization device (4 x 20 mm) was advanced into the basilar artery. The device was deployed for five minutes and immediate flow restoration was seen through the stent to the occluded area. The device then was retracted with aspiration to remove the entire clot from the middle cerebral artery in one pass.

**PATIENT OUTCOME**

Post NIHSS: 10

Secondary stroke prevention plan: Coumadin™* added to his medication regimen. Discharged to in-patient rehabilitation seven days later. He went home with home health after 30 days of rehabilitation – NIHSS 2.

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Hospital Name: Saint Luke’s Hospital
Interventionalist: Dr. Coleman Martin
Neurologist: Dr. Steve Arkin

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Results may vary - Not all patients achieve the same results.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient
Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

**PATIENT PRESENTATION**

NIHSS: 22

History: 92 year-old male with a history of atrial fibrillation, diabetes, hypertension, aortic stenosis, dyslipidemia, MI, and recent UTI was at mass in the Saint Luke’s Hospital chapel when his stroke symptoms started (left facial droop, left upper extremity paralysis, and left hemi-ballistic movement). The stroke team was activated and the patient was immediately taken to the ED. CT head was negative for hemorrhage and labs unremarkable. He was given IV tPA 45 minutes following stroke onset. CT Angiogram showed thrombus within the proximal right middle cerebral artery (MCA) and minimal flow in the distal right MCA branches.

**NEUROINTERVENTION DISCUSSION**

The Solitaire™ FR revascularization device (4 x 20 mm) was advanced into the proximal M1 segment of the right MCA. The device was deployed twice for five minutes. The device then was retracted with aspiration to remove clot from the middle cerebral artery on both passes. Complete restoration (TICI 3) of cerebral blood flow achieved.

**PATIENT OUTCOME**

Admitting NSICU NIHSS: 2, 24 hrs NIHSS: 0
Secondary stroke prevention plan: Coumadin™ * was added to his medication regimen. Discharged home six days later.

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Saint Luke’s is a comprehensive stroke center that sees more strokes than any other hospital in Missouri. Saint Luke’s can perform interventional procedures for acute stroke patients who aren’t eligible for IV tPA or fail IV tPA treatment.

eDocOnecall - 816-932-6200 / 877-932-6200

Hospital Name: Saint Luke’s Hospital
Interventionalist: Dr. Coleman Martin
Neurologist: Dr. Christine Boutwell
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 18

History: 49 year-old male collapsed in a downtown skyway while taking a walk near his workplace. Hennepin EMS was immediately at the scene and a stroke code was called. The patient presented to HCMC with complete paralysis and loss of sensation on the left side of his body, including partial vision loss and slurred speech. The patient had a CT that revealed a right MCA occlusion.

NEUROINTERVENTION DISCUSSION

11:40am: puncture groin, access via 6F 90 cm shuttle sheath.
12:03pm: immediate flow restoration with the Solitaire™ FR revascularization device (4 x 20 mm).
12:26pm: 2nd pass in inferior division of M1 and large clot retrieved.
12:48pm: 3rd pass in lower division and another clot retrieved.
1:10pm: division of MCA open.

PATIENT OUTCOME

Post NIHSS: 0-1 immediately post-procedure
Patient went back to work within a couple of weeks.

Results may vary - Not all patients achieve the same results.

Hennepin Stroke Center is a nationally certified Stroke Center with some of the fastest stroke delivery treatment times in the country — averaging 50.7 minutes from “door-to needle” — far beating the national average of 60 minutes. HCMC’s neurology/neurosurgery service is available 24/7 to provide rapid consultation, referral and treatment for strokes and other neurological conditions. For more information about Hennepin Stroke Center, go to hcmc.org/stroke.
Solitaire™ FR Revascularization Device: 6 x 20 mm
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 10

History: 56 year-old female, transported from another hospital five hours after onset of symptoms at 2:00am. Patient felt disoriented, dizzy and could not keep balance to get from the couch to bed.

NEUROINTERVENTION DISCUSSION

No IV tPA available in ER. A gold tip .016 wire, Marksman™ catheter, Envoy™* catheter and a Solitaire™ FR revascularization device (6 x 20 mm) were used. 3 passes — basilar terminous and left P1 and P2. Flow restoration was not achieved on initial terminous pass, however was achieved on each PCA pass. Intervention started 7.5 hours after onset of symptoms. Total intervention time was 42 minutes.

PATIENT OUTCOME

Patient made a full recovery. Some initial rehab was needed on an outpatient basis for balance and gait. Patient went home two days after intervention.

The Joint Commission has certified Swedish Medical Center as a Primary Stroke Center. This designation recognizes the expertise and dedication of the Swedish stroke team, which includes physicians, nurses, imaging and lab staff, available 24 hours a day, seven days a week to respond within minutes of a patient’s arrival in the Emergency Department.

Hospital Name: Swedish Medical Center

Interventionalist: Dr. Joe Eskridge
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 18

History: 51 year-old male with history of coronary artery disease, hypertension and HLD who presented with left-sided weakness and slurred speech that evolved to unresponsiveness during transfer from Southern Ohio Medical Center to Riverside. CT showed an abrupt occlusion of the basilar artery. Patient was transferred to VIR for possible mechanical embolectomy. Patient presented within eight hours of symptom onset.

NEUROINTERVENTION DISCUSSION

The initial angiogram noted an abrupt occlusion of the basilar artery approx. 8 to 9 mm beyond the origin. An 8F balloon guide catheter was used for access and a Solitaire™ FR revascularization device (4 x 20 mm) was advanced into the right basilar segment and deployed twice for four minutes. The device was retracted with aspiration to remove clot from the right basilar artery and a severe stenosis of the mid to distal basilar was identified. A final deployment with a Solitaire™ FR device (6 x 20 mm) for 15 minutes revealed complete patency of the basilar artery. A 2 x 9 mm balloon was used to PTA the stenosis.

PATIENT OUTCOME

Discharged to SNF by his home six days post procedure with some paralysis of arm.

The Ohio Health Stroke Network features Riverside Methodist Hospital, a comprehensive stroke center that sees more strokes than any other hospital in Ohio. Riverside Methodist can perform interventional procedures for acute stroke patients who aren’t eligible for IV tPA or who fail IV tPA treatment.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 22

History: 64 year-old male was walking to the car at 11:00am when he apparently collapsed to the ground. His wife states that he was normal moments prior. EMS was called and he was transferred to Riverside Methodist for evaluation at 12:00pm. He was unable to move right side and had difficulty speaking. CT showed an abrupt cutoff at the origin of the left MCA. Patient was given IV tPA and transferred to VIR for possible mechanical embolectomy.

NEUROINTERVENTION DISCUSSION

The initial angiogram noted a complete occlusion of the left middle cerebral artery (M1). A 9F balloon guide was used for access and a Solitaire™ FR revascularization device (6 x 20 mm) was advanced into the M1 segment and deployed for four minutes allowing for immediate flow restoration through the stent to the occluded area. The device was retracted with aspiration to remove a large clot plug from the left MCA. Complete recanalization was achieved.

PATIENT OUTCOME

Post NIHSS: 8

Patient discharged to in-patient rehab. Has some expressive aphasia and left-sided weakness, but is doing much better.

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The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 20

History: 63 year-old male with history of hypertension, coronary artery disease and hypercholesterolemia presented with acute left-sided facial droop, weakness and paralysis. Symptom onset was approx. 8:15pm. Patient had CT and a right ICA occlusion was noted. The patient was given IV tPA at 10:05pm. Symptoms did not improve, so the patient was taken emergently to angiography.

NEUROINTERVENTION DISCUSSION

The initial angiogram noted an occlusion of the right carotid artery at the cervical level and thrombus noted in the A1 and M1 segments. A 9F balloon guide was used for access and a Solitaire™ FR revascularization device (6 x 20 mm) was advanced into the proximal M1 segment. The device was deployed for four minutes and retracted to remove clot from the ICAT. Persistent clot in the distal M1 segment was removed via 2 more passes with a (4 x 20 mm) Solitaire™ FR device.

PATIENT OUTCOME

Patient released to a SNF three days post-procedure showing great improvement.

The Ohio Health Stroke Network features Riverside Methodist Hospital, a comprehensive stroke center that sees more strokes than any other hospital in Ohio. Riverside Methodist can perform interventional procedures for acute stroke patients who aren’t eligible for IV tPA or who fail IV tPA treatment.
Solitaire™ FR Revascularization Device: 6 x 30 mm
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

**PATIENT PRESENTATION**

NIHSS: 15

History: 53 year-old male with history of hypertension, two myocardial infarctions, and the patient has been blind since birth. He is allergic to Coumadin™* and Levaquin™*. Current medications: Atenolol, Zocor™* and Lasix™*. The patient was found at 11:45am with left-sided weakness and slurred speech. His wife called 911 and EMS arrived on the scene at 11:56am. Last known normal was 7:15am. Patient arrived at St. Dominic’s at 12:20pm with left-sided paralysis, slurred speech and confusion.

**NEUROINTERVENTION DISCUSSION**

Patient arrived to Interventional Radiology at 2:10pm. Diagnostic angiography demonstrated an occlusion of the right middle cerebral artery (RMCA). The Solitaire™ FR revascularization device (6 x 30 mm) was deployed in the RMCA allowing for immediate restoration. The Solitaire™ device was deployed for five minutes and then pulled back with aspiration to successfully remove the clot. One retrieval was required.

**PATIENT OUTCOME**

Post NIHSS: 6 at day seven

Patient has some facial weakness and his speech is mildly dysarthric. His sensation is mildly impaired on the left. His strength is normal in all four extremities. He is ambulatory and cognitively intact.

Results may vary - Not all patients achieve the same results.

St. Dominic’s, located in Jackson Mississippi, is capable of delivering the full spectrum of care to seriously ill patients with stroke and cerebrovascular disease. St. Dominic’s Certified Primary Stroke Center offers rapid diagnosis, high-tech intervention, expert care and intensive rehabilitation in a caring, compassionate setting.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 21

History: 58 year-old male with acute onset right MCA syndrome at 12:15pm, presented with left-sided weakness and right gaze preference. Received IV tPA at outside hospital then transferred to Jackson Memorial Hospital. MRI showed moderate basal ganglia infarct. Groin puncture was at 5:00pm.

NEUROINTERVENTION DISCUSSION

Evaluation revealed complete occlusion of right petrous ICA with acute thrombus superimposed on a chronic atherosclerotic stenosis measuring 70% after clot removal. A Solitaire™ FR revascularization device (6 x 30 mm) was deployed across the RICA clot for 5 minutes, then angio performed, showing immediate revascularization and clot was retrieved after one pass. The Solitaire™ FR device was removed along with syringe aspiration through the 8F balloon guide catheter. Balloon angioplasty was also done and a residual petrous ICA stenosis measuring 38% remained. A Prowler™ Select Plus™ catheter was placed in the mid M1 segment of right MCA distal to the clot and a Solitaire™ FR device (4 x 20 mm) was deployed for five minutes. After one pass, post thrombectomy, there was recanalization of M1 segment with complete restoration of distal MCA branch filling. TIMI grade 3 & TICI grade 3.

PATIENT OUTCOME

Patient greatly improved after intervention and was able to regain strength on his left side. Patient was discharged home nine days after procedure.

The UM Jackson Memorial Hospital is a comprehensive stroke center that sees more strokes than any other hospital in Miami. Jackson Memorial can perform interventional procedures for acute stroke patients who aren’t eligible for IV tPA or who fail IV tPA treatment.

Referring Hospital: Lee Memorial, Fort Myers
Hospital Name: UM, Jackson Memorial Hospital
Interventionalist: Dr. Dileep Yavagal
Neurologist: Dr. Mowzoon
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 21

History: 37 year-old female. Patient presented to ER in atrial fibrillation. Patient was given IV tPA but with no clinical improvement. Her symptom onset was three hours prior to arrival.

NEUROINTERVENTION DISCUSSION

CT scan confirmed MCA occlusion. A Synchro™ wire was passed through a Marksman™ catheter to get past the occlusion. A Solitaire™ FR revascularization device (6 x 30 mm) was deployed, left open for four minutes and provided immediate flow restoration. The clot was pulled into a Shuttle™ sheath after 1 pass with the Solitaire™ FR device and manual 60 cc aspiration. 25 minute interventional procedure time from groin puncture to groin closure.

PATIENT OUTCOME

Patient was kept for observation and sent home three days later. No rehab needed.

Since 2004, Sacred Heart has continuously earned the Gold Seal of Approval from the Joint Commission for its Primary Stroke Program. Sacred Heart is working toward the next level of certification – a Comprehensive Stroke Center – which is capable of handling the most severe stroke patients, with the technology and specialists on hand to perform interventional procedures.

Hospital Name: Sacred Heart Medical Center
Interventionalist: Dr. Chris Zylak

Results may vary - Not all patients achieve the same results.
The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

**PATIENT PRESENTATION**

NIHSS: 13

History: 76 year-old male found with slurred speech and left-sided weakness. Daughter called 911. Patient presented within eight hours of symptom onset. History of hypertension, hypercholesterolemia and type 2 diabetes.

**NEUROINTERVENTION DISCUSSION**

CT scan confirmed ICA occlusion. A gold tip .016 wire was passed through a Marksman™ catheter to get past the occlusion. A Solitaire™ FR revascularization device (6 x 30 mm) was deployed, left open for five minutes and provided immediate flow restoration. The clot was pulled into an Envoy™* catheter after 1 pass with the Solitaire™ FR device. 32 minute interventional procedure time from groin puncture to groin closure.

**PATIENT OUTCOME**

Patient was kept for observation and sent home the following day.

The Joint Commission has certified Swedish Medical Center as a Primary Stroke Center. This designation recognizes the expertise and dedication of the Swedish stroke team, which includes physicians, nurses, imaging and lab staff, available 24 hours a day, seven days a week to respond within minutes of a patient’s arrival in the Emergency Department.

**Hospital Name:** Swedish Medical Center

**Interventionalist:** Dr. Joe Eskridge

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The Clinical Benefits of Solitaire™ FR Device Embolectomy in an Acute Stroke Patient

Patients who are ineligible for IV t-PA or who fail IV t-PA therapy could still be candidates for mechanical intervention.

PATIENT PRESENTATION

NIHSS: 22

History: 45 year-old female RN with history of HBP who collapsed while on duty at Memorial Regional Hospital, onset 10:00am, presented with right-sided weakness, aphasia and became unresponsive. The patient was intubated and taken immediately to angio suite for possible mechanical embolectomy. She was also given IV tPA.

NEUROINTERVENTION DISCUSSION

The initial angiogram showed a 99% occlusion of the carotid artery which was ballooned and then stented with a Precise stent™*. The angio also revealed an MCA occlusion. A .070 Neuron™* and Marksman™ catheter was used for access and a Solitaire™ FR revascularization device (6 x 30 mm) was advanced into the MCA clot for five minutes. Immediate flow restoration was observed after 1 pass. More clot was observed in some distal/parietal branches. Clot in a parietal branch was retrieved with an additional pass of the 6 x 30 mm device then using a .021 micro catheter and a Solitaire™ FR device (4 x 20 mm), a moderate amount of clot was retrieved from a frontal parietal branch. The MCA and three parietal branches were successfully recanalized.

PATIENT OUTCOME

Three days post procedure, patient is talking and has some right-sided weakness, but can move right side.

Results may vary - Not all patients achieve the same results.

Medical expertise and facilities make Memorial’s Neurointervention Program among the best in the nation. The Joint Commission has certified Memorial Regional Hospital as a Comprehensive Stroke Center, and the hospital’s Brain Attack Team — emergency personnel, specially trained doctors and nurses, and neuroimaging and laboratory services — is available 24 hours a day.

Hospital Name: Memorial Regional
Interventionalist: Dr. Hoang Duong
Results may vary - Not all patients achieve the same results.

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.

Indications, contraindications, warnings and instructions for use can be found on the product labeling supplied with each device.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.