Neurologic outcomes are measured as mRS ≤ 2 and are compared to the significant historical registries of Merci and penumbra including Merci, Multi-Merci, Merci Registry, Penumbra Study, POST, Penumbra 054 Speed.

Simplicity claims based on devices required per Instructions per Use.

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.

REFERENCES:
5. Miami Miller School of Medicine, Gordon Center for Research in Medical Education
9. Clinical claims based on 17.2% mortality rate from the SWIFT study (Solitaire™ FR with the Intention for Thrombectomy (SWIFT) Study SWIFT IDE # G090082 FD2963.) and 96% TICI 2a-3 rate from the Solitaire™ FR Device Retrospective Study (Solitaire Retrospective (Retrospective, single arm, N=141): Castaño C, Mendes Pereira V . et. al. Solitaire FR Revascularization Device: A Retrospective Study as a First Line Device for Acute Ischemic Stroke. Presented at WFITN 2010.) Comparisons made to significant historical registries from Concentric and Penumbra including Penumbra POST, Penumbra 054 Speed and Merci Registry.
Covidien Neurovascular

Covidien Neurovascular is committed to advancing the treatment of Acute Ischemic Stroke. Through technological innovations such as the Solitaire™ FR revascularization device, and a comprehensive approach to clinical research, Covidien is dedicated to improving patient outcomes. Our approach, however, extends beyond devices and our goal is to be your ally in improving the treatment pathway — from onset to recovery. Covidien’s Ischemic Stroke Therapy Team is at your disposal to provide and help implement a series of programs, in an effort to help your facility treat more victims of Ischemic Stroke safely and effectively.
Stroke Protocol Roadmap

Covidien’s Stroke Protocol Roadmap below addresses the most effective and efficient care continuum for acute ischemic stroke.

1. Family recognizes stroke symptoms
   - Call 911
   - EMS Assess
   - EMS Identifies Stroke
   - EMS Departs for Hospital
   - Go to ER

2. Patient arrives at comprehensive stroke center ER
   - Symptom onset ≤ 3 hrs (4.5 hrs)
     - TPA Eligible YES
       - CT/MR Imaging
       - Start IV TPA
       - CTP/CTA/MRP/MRA
       - Large Mismatch
       - To Angio
       - Small Mismatch or No Mismatch
       - To MedTX
     - TPA Eligible No
   - Symptom onset > 3 hrs (4.5 hrs)

3. Patient arrives in angiography suite
   - General anesthesia
   - Carotid Access Easy
     - Rapid flow restored
   - Carotid Access Difficult
     - Clot retrieval
   - Conscious sedation
   - Needle stick
   - Patient prep
What is Ischemic Stroke?

An ischemic stroke occurs as a result of a blood clot in an artery blocking the flow of blood to the brain. Often referred to as brain attack, stroke is the fourth leading cause of death behind coronary heart disease and cancer and is the leading cause of long term disability in the U.S. Each year, about 795,000 people suffer a stroke, the equivalent of one stroke every 40 seconds.¹

Acute ischemic stroke can be a serious and devastating condition. Knowing all of the treatment options may help ensure the best possible outcome.

Public Awareness

As reported by The American Heart Association, 795,000 individuals in the United States suffer a stroke annually. It is the 4th leading cause of death, killing over 134,000 people each year. Stroke is also a leading cause of functional impairments, with 20% of survivors requiring institutional care after 3 months and 15% – 30% being permanently disabled. In 2010, the cost of stroke was estimated at $73.7 billion. Recognizing the symptoms and acting fast can make the difference between a rapid resolution and neurologic disability or death. Covidien’s Ischemic Stroke Therapy Team is prepared to help your institution reach out to the public and provide awareness of your hospital’s cutting edge stroke team and therapy options.

Few in the U.S. know the warning signs of stroke. Learning them – and acting FAST when they occur – could save your life or the life of a loved one. Use the FAST test to remember warning signs of stroke.

F = FACE  Ask the person to smile. Does one side of the face droop?
A = ARMS  Ask the person to raise both arms. Does one arm drift downward?
S = SPEECH Ask the person to repeat a simple sentence. Does the speech sound slurred or strange?
T = TIME  If you observe any of these signs (independently or together), call 9-1-1 immediately.

Resources

Public Awareness Resources offered by Covidien Ischemic Stroke Therapies:
- Solitaire™ FR Device Patient Education Brochure
- Awareness Campaigns through the Covidien Media Kit and Corporate Communications Department
- Attendance and support of Local, Regional and National events for stroke awareness and education

Please contact your Covidien Regional Stroke Zone Manager or Stroke Implementation Representative for assistance.
Ischemic Stroke Therapies

Emergency Medical Services

When somebody suffers an ischemic stroke, recognizing symptoms, calling 911, rapid response by EMS, and transportation to a stroke center with diagnostic and treatment capabilities can make a significant impact in a successful outcome. Rapid assessment and knowing what level of stroke care each hospital offers is paramount in optimizing a stroke victim's chances of a good outcome.4

The goal of the Covidien Ischemic Stroke Therapy Team is to help your facility work with EMS to improve diagnosis in the field and to help divert patients to your facility, ensuring optimal care and the fastest revascularization when possible.
Ischemic Stroke Therapies

Emergency Medical Services

RESORCE GUIDE

Ischemic Stroke Therapies

Please contact your Covidien Regional Stroke Zone Manager or Stroke Implementation Representative for assistance.

Stroke Alert Checklist

Prehospital identification is a vital initial step in the emergency medical management of stroke. A symptoms-based screening tool, like the one depicted, facilitates rapid, standardized, symptomatic clinical assessment. Based on the assessment, routing the stroke victim to the most appropriate treatment facility which offers the latest therapies and interventional technologies, including the Solitaire™ FR device, will increase good neurologic outcome for patients.

Resources

Resources offered to Emergency Medical Services by Covidien Ischemic Stroke Therapies:

- EMS Outreach In-Service Programs
- Bring EMS personnel into hospital
- Educational visits at EMS sites
- Partner with the hospital’s outreach department
- Share documented case reports with transporting EMS personnel
- EMS Brochure
- EMS Roundtable Programs with Covidien faculty lectures
Emergency Department & Neurology

Once an acute ischemic stroke patient is transported to the Emergency Department, a series of protocols are initiated. Rapid neurological assessment, expedited clinical evaluation, imaging to rule out hemorrhage and locate blockage, and an assessment of the amount of reversible penumbra are all essential elements to be performed by the team. The goal of the Covidien Ischemic Stroke Therapy Team is to provide resources to help improve treatment protocols and benchmark performance data to ensure continuous improvement in door-to-needle times, and access to revascularization therapy with the Solitaire™ FR device.6
Once an acute ischemic stroke patient is transported to the Emergency Department, a series of protocols are initiated. Rapid neurological assessment, expedited clinical evaluation, imaging to rule out hemorrhage and locate blockage, and an assessment of the amount of reversible penumbra are all essential elements to be performed by the team. The goal of the Covidien Ischemic Stroke Therapy Team is to provide resources to help improve treatment protocols and benchmark performance data to ensure continuous improvement in door-to-needle times, and access to revascularization therapy with the Solitaire™ FR device.

### Resources

**Resources offered to the Emergency Department by Covidien Ischemic Stroke Therapies:**
- Advanced Stroke Treatment Summit Program
- Emergency Department Brochure
- Emergency Department In-Service Programs
- Evening Roundtable Programs
- Attendance and support of regularly scheduled ED meetings

**Resources offered to the Neurologist by Covidien Ischemic Stroke Therapies:**
- Advanced Stroke Treatment Summit Program
- Emergency Department Brochure
- Emergency Department/Neurology In-Service Programs
- Evening Roundtable Programs
- Attendance and support of regularly scheduled Neurology meetings

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Please contact your Covidien Regional Stroke Zone Manager or Stroke Implementation Representative for assistance.
Interventionalists

The Solitaire™ FR revascularization device is the leading mechanical thrombectomy device in the United States and around the world. With over 20,000 procedures performed and over 2 years of clinical experience the Solitaire™ FR device offers effective and rapid revascularization and category leading safety and efficacy clinical data. The goal of the Covidien Ischemic Stroke Therapy Team is to provide in-servicing to the entire interventional staff on the use of the Solitaire™ FR device and our array of innovative access technologies. In addition, the Covidien team will help educate all of the care-givers and administrators involved in the stroke protocol of the interventional team’s Solitaire™ FR revascularization results, and the ever improving patient outcomes.
Resources

Resources offered to the Interventional Team by Covidien Ischemic Stroke Therapies:

- Advanced Stroke Treatment Summit Program
- Solitaire™ FR Device In-Service Programs
- Procedural Animations for physician clinical rounds
- Patient Case Report Template and Follow-up Tool
- Regional Case Report Template
- Evening Roundtable Programs
- Solitaire™ FR Device Media Kit

* Good neurological outcome defined as mRS ≤ 2, or equal to the prestroke mRS if the prestroke mRS was higher than 2, or NIHSS score improvement of 10 points or more.

Please contact your Covidien Regional Stroke Zone Manager or Stroke Implementation Representative for assistance.
Caring for patients suffering from stroke takes a concerted effort of many medical specialties as well as technology to optimize the care for this service line. In order to have a successful stroke service line, the executive board must consider the following: manpower, imaging and angiography equipment, a neuro-critical care unit, and marketing for the new service line. The comprehensive stroke center should also consider networking with outside institutions to offer telemedicine or stroke neurology consultation services and air/ground transportation of patients as a “hub and spoke model”.\(^\text{10}\) In addition there must be a collaborative effort to involve the physicians with the stroke service line imperatives to measure quality, resource utilization, efficiency, and market development. The benefits of committing to a stroke service line include the ability to serve the community, to bring more patients into the institution, as well as the potential to obtain additional revenue.
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Resources

Resources offered to Administrators & Executives by Covidien Ischemic Stroke Therapies:

- Reimbursement Guide and 877.278.7482 Hotline
- Advanced Stroke Treatment Summit Programs
- Stroke Service Line Benchmark Tool
- Stroke Center of Excellence Site Visit Program
- Solitaire™ FR Device Media Kit

Please contact your Covidien Regional Stroke Zone Manager or Stroke Implementation Representative for assistance.
Advanced Stroke Treatment (AST) Programs

Hosted by Covidien Professional Affairs and Clinical Education Department (PACE), the Advanced Stroke Treatment Programs are held regionally throughout the year to educate your team of interventionalists, ER staff, stroke nurses and neurologists.

The intent of the AST programs is to learn from world renowned faculty who engage in a comprehensive approach to the treatment of acute ischemic stroke — from symptom onset to recovery. Our esteemed faculty will identify rapid assessment, diagnosis, imaging, and treatment options from lytics and best-medical management, to best-practices around the use of the Solitaire™ FR device and mechanical revascularization. The Covidien Ischemic Stroke Therapy Team will notify the staff at your facility of upcoming programs and provide targeted course options to specific functions in the stroke treatment pathway.

Please contact neuroeducation@covidien.com, your Covidien Regional Stroke Zone Manager or your Stroke Implementation Representative for assistance.
Our Ischemic Stroke Therapy Team provides the following personnel and resources:

**Territory Managers** are certified to provide in-service and technical case support to interventionalists and angiograph suite staff on the safe and effective use of the Solitaire™ FR device and related technologies.

**Regional Stroke Managers** are certified to provide in-service and technical case support to interventionalists and angiograph suite staff on the safe and effective use of the Solitaire™ FR device and related technologies. The Regional Stroke Managers also deliver resources aimed to educate the public and the stroke service line experts on ischemic stroke and the treatment options available.

**Stroke Program Implementation Manager** are certified to provide in-service and technical case support to interventionalists and their staff in the safe and effective use of the Solitaire™ FR device and related technologies. The stroke implementation managers also collaborate with emergency medical services and emergency room professionals to bridge the knowledge of the latest breakthroughs in ischemic stroke treatment.

Please contact your Covidien Regional Stroke Zone Manager or Stroke Implementation Representative for assistance.
Neurologic outcomes are measured as mRS ≤ 2 and are compared to the significant historical registries of Merci and penumbra including Merci, Multi-Merci, Merci Registry, Penumbra Study, POST, Penumbra 054 Speed.

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