stryker®
Neurovascular

Surpass Streamline™

Flow Diverter

Directions for Use

℞ ONLY

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

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Surpass Streamline™ Flow Diverter system is comprised of a self-expandable braided device preloaded in a Delivery System. The Surpass Streamline Flow Diverter system consists of the following components:

- Surpass Flow Diverter (implant)
- Delivery System
  - Surpass Streamline outer
  - Surpass Streamline pusher

The Surpass Flow Diverter is preloaded onto the Surpass Streamline pusher which in turn is locked in place within the Delivery System via a Y-Valve/Rotating Hemostatic Valve (RHV). Each device is shipped sterile and labeled for single use only.

Surpass Flow Diverter

The braided Surpass Flow Diverter is the implant portion of the system. It is shipped preloaded within the Delivery System. These devices come in different sizes and length combinations ranging from 3 mm to 5 mm in diameter and from 15 mm to 50 mm in length. Interwoven within the Surpass Flow Diverter cobalt chromium braids are platinum-tungsten wires for visualization under fluoroscopy.

Once released from the constraint of the Delivery System into the vessel, the Flow Diverter expands to the vessel lumen diameter and can be recaptured and repositioned prior to full deployment, if needed. In its expanded shape, the Surpass Flow Diverter diverts the blood flow away from the intracranial aneurysm.

Surpass Streamline Outer

The Delivery System functions to house and protect the Surpass Flow Diverter during its passage through the arterial system and across the intracranial aneurysm neck. There is a single radiopaque marker located at the distal tip of this Surpass Streamline outer. The distal section of the Surpass Streamline outer has a hydrophilic coating to aid in device tracking in tortuous vessels.

Surpass Streamline Pusher

The Surpass Streamline pusher is a second catheter that resides within the Surpass Streamline outer. It pushes the Surpass Flow Diverter out of the Surpass Streamline outer into the parent artery across the intracranial aneurysm neck and stabilizes the position of Surpass Flow Diverter within the Surpass Streamline outer. A radiopaque marker at the formed tip (Tip marker) marks the tip of the Surpass Streamline pusher.

There is another marker band called the proximal Surpass Streamline pusher marker. The Surpass Flow Diverter is loaded between the proximal Surpass Streamline pusher marker and the tip marker. The length of this section varies such that the different sizes of the Surpass Flow Diverter fit between the two marker bands.

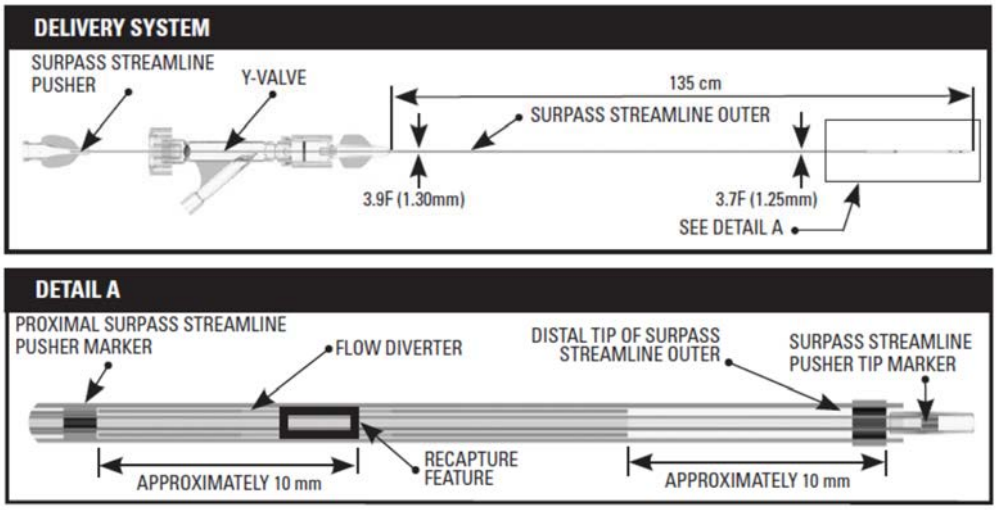


Figure 1. Technical Drawing of Surpass Streamline Flow Diverter

The Surpass Streamline Flow Diverter system is designed for use under fluoroscopy.

INTENDED USE/INDICATIONS FOR USE

The Surpass Streamline Flow Diverter is indicated for use in the endovascular treatment of patients (18 years of age and older) with unruptured large or giant saccular wide-neck (neck width ≥ 4 mm or dome-to-neck ratio < 2) or fusiform intracranial aneurysms in the internal carotid artery from the petrous segment to the terminus arising from a parent vessel with a diameter ≥ 2.5 mm and ≤ 5.3 mm.

CONTRAINDICATIONS

The Surpass Streamline Flow Diverter is contraindicated in the following patient types:

- Patients in whom the parent vessel size does not fall within the indicated range.
- Patients in whom antiplatelet and / or anticoagulation therapy (e.g., aspirin and clopidogrel) is contraindicated.
- Patients who have not received dual anti-platelet agents prior to the procedure.
- Patients with an active bacterial infection.
- Patients in whom the angiography demonstrates the anatomy is not appropriate for endovascular treatment due to conditions such as:
  - Severe intracranial vessel tortuosity or stenosis; and/or
  - Intracranial vasospasm not responsive to medical therapy.

WARNINGS

- This device should only be used by physicians who have received appropriate training in interventional neuroradiology or interventional radiology and preclinical training on the use of this device as established by Stryker Neurovascular.
- Do not use if the package is opened or damaged.
- Persons allergic to nickel, cobalt chromium or platinum tungsten metal may suffer an allergic response to this Flow Diverter implant.
- The system is designed to be manipulated while under high-quality fluoroscopic observation. If resistance is met during manipulation, determine the cause of resistance before proceeding.
- Do not torque or rotate the system.
- Purge the entire Delivery System carefully to avoid the accidental introduction of air into the system.
- If any defects are observed with the Surpass Streamline Flow Diverter system, replace the device.
- If excessive resistance is encountered during the use of the Surpass Flow Diverter at any time during the procedure, discontinue use of the system. Movement of the system against resistance may result in damage to the vessel, a system component, or the patient.
- Repositioning of the Surpass device in the parent vessel without fully retrieving the device is not advised since it could cause vessel damage and/or perforation. After full deployment, do not re-position.
- It is important for the Surpass device to be used with the Stryker Neurovascular AXS Catalyst® 5 (Model UPN M003IC0581150) and one of the following compatible guidewires:
    - Stryker Neurovascular Synchro^{2} ® (e.g., Model UPN M00326410) or
    - Stryker Neurovascular Synchro®-14 (e.g., Model UPN M00313010) or
    - Boston Scientific Transend® EX (e.g., Model UPN M001468050)
- [Clinical Warning] Do not use device for ruptured intracranial aneurysms.
- [Clinical Warning] A decrease in effectiveness has been observed in subjects aged > 65 years old, subjects with history of smoking and history of prior non-target intracranial aneurysm treated.
- [Clinical Warning] Judicious patient selection is important. Patients who fall outside the therapeutic range for antiplatelet testing or at the lower limits have an increased risk of developing stent thrombosis, even with additional doses of antiplatelet medication. Another effective anti-platelet agent should be considered.
- [Clinical Warning] Placement of multiple Surpass devices may increase the risk of ischemic complications.
- [Clinical Warning] Delayed aneurysm rupture may occur with large and giant intracranial aneurysms.

PRECAUTIONS

- Experience with device implants indicates that there is a risk of stenosis. Subsequent stenosis may require dilatation of the vessel segment containing the device. The risks and long-term outcome following dilatation of endothelialized devices is unknown at present.
- Confirm the device labeling reflects the desired size of the target vessel where the device is to be used.
- Do not expose the system to organic solvents (e.g., alcohol).
- Appropriate anti-platelet and anti-coagulation therapy should be employed in accordance with standard medical practice.
- A thrombosing aneurysm may aggravate pre-existing or cause new symptoms of mass effect and may require medical therapy.

- Use product prior to the “Use By” date.
- Do not remove the Surpass Flow Diverter from its Delivery System. The device and Delivery System are intended to perform as a single system and must not be altered.
- Carefully inspect the device packaging and system prior to use. Do not use the Surpass Flow Diverter if any component appears damaged or missing.
- Carefully remove the tray lid and grasp the Delivery System by its RHV and hoop to facilitate removal from the tray.
- Select a device length that is at least 10 mm longer than the intracranial aneurysm neck to maintain a minimum of 5 mm on either side of intracranial aneurysm neck.
- Do not attempt to partially deploy and recapture the Surpass Flow Diverter more than three times.
- Use caution when crossing the deployed device with guidewires or other accessory devices.
- Dispose of all used devices in accordance with hospital policy for biohazardous materials.
- Do not attempt to move the Surpass Flow Diverter more distally once it has begun apposing to the vessel walls.
- Do not apply additional force if significant resistance is experienced while attempting to recapture the flow diverter.
- This device has not been evaluated for pediatric use.
- The safety and effectiveness of the device has not been established in the treatment of small and medium wide-neck intracranial aneurysms.
- Operators should take all necessary precautions to limit X-radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible.
- Lower intracranial aneurysm occlusion rates may be associated with giant intracranial aneurysms (> 25 mm).
- Do not deploy Surpass devices in parallel (side by side).

MRI SAFETY INFORMATION 

Non-clinical testing and analysis have demonstrated the Surpass Flow Diverter is MR Conditional. A patient with this device can be safely scanned immediately after placement in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 2,500 gauss/cm (25 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the Surpass Flow Diverter is expected to produce a maximum temperature rise of less than 3.4 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 10 mm from the Surpass Flow Diverter when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Surpass Flow Diverter. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

The effect of heating in the MRI environment for overlapping stents is not known.

The health state of the patient or the presence of other implants may require reduction of the MRI limits.

HOW SUPPLIED

Stryker Neurovascular products are sterile and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place

PREPARATIONS FOR USE

In addition to the Surpass Flow Diverter the following items are recommended:

- 6F (2.00 mm) or greater Introducer Sheath, appropriately sized
- 0.014 in (0.36 mm) access and/or exchange length Guidewire, specifically the Stryker Neurovascular Synchro^{2} ® (e.g., Model UPN M00326410), Synchro®-14 (e.g., Model UPN M00313010) or the Boston Scientific Transend® EX (e.g., Model UPN M001468050) Guidewires
- 0.053 in (1.35 mm) inner diameter (ID) minimum Guiding Catheter/Intermediate Catheter, max 115 cm long, specifically the Stryker Neurovascular AXS Catalyst® 5 (Model UPN M003IC0581150)
- 2 or more Y connectors / Rotating Hemostasis Valves
- Sterile heparinized saline solution

Surpass Flow Diverter Selection

Appropriate selection of the device is important for patient safety. In order to choose the optimal device for any given intracranial aneurysm neck length and parent artery diameter, examine pre-procedure angiograms.

OPERATIONAL INSTRUCTIONS

Flow Diverter Selection and Preparation

1. Choose a Surpass Flow Diverter with a labeled diameter that approximates the target vessel diameter (Table 1).

Table 1. Device Sizes

Device Diameter (mm)	Device Length (mm)	Unconstrained Implant Outer Diameter (mm)	Maximum vessel diameter (mm)	Recommended minimum vessel diameter (mm)
3	15, 20, 25	> 3.5	3.5	2.5
4	15, 20, 25, 30, 40, 50	> 4.4	4.4	3.4
5	20, 25, 30, 40, 50	> 5.3	5.3	4.3

2. Choose a Surpass Flow Diverter with a labeled length that is at least 10 mm longer than the intracranial aneurysm neck (to maintain a minimum of 5 mm on either side of the neck) and allows for the proximal and distal ends of the Surpass Flow Diverter to land in a straight section of the vessel.

Note: The Surpass Flow Diverter changes in length during deployment. Take this into account

when deploying (Table 2). The Surpass Flow Diverter deployed length will never be shorter than its labeled length, in its indicated vessel diameter, even after foreshortening.

Table 2. Device Deployed Length Changes*

Device Diameter (mm)	Average decrease in length from inside Delivery System to fully expanded (%)
3	33
4	38
5	28

*Based on mathematical calculations

3. Remove the Delivery System from its packaging and inspect the entire system prior to use. Do not use the Surpass Flow Diverter if the packaging and/or any component appears damaged or missing.

   Caution: Carefully remove the tray lid and grasp the Delivery System by its RHV and hoop to facilitate removal from the tray.

4. Flush the dispenser hoop with sterile heparinized saline. Purge the Surpass Streamline outer and Surpass Streamline pusher with sterile heparinized saline.

   Warning: Purge the entire Delivery System carefully to avoid the accidental introduction of air into the system.

5. Confirm that the Surpass Streamline pusher tip extends beyond the tip of the Surpass Streamline outer by approximately 3 mm.

   Note: If the Surpass Streamline pusher tip extends too far from the Surpass Streamline outer, trackability of the system may be impaired.

6. Tighten the RHV on the Surpass Streamline outer to hold the Surpass Streamline pusher in place.

Flow Diverter Positioning

1. Use standard catheter and guidewire access techniques to position an intermediate catheter with an ID of no less than 0.053 in proximal to, or if needed, distal to the intracranial aneurysm neck.
2. Remove the wire used in immediate step 1 above, leaving the intermediate catheter in position.
3. Outside the patient, carefully load the Delivery System onto a 0.014 in access length guidewire.
4. Under fluoroscopic guidance, carefully simultaneously advance both the Delivery System and the guidewire through the intermediate catheter until the Delivery System is past the intracranial aneurysm location.
5. If needed, pull the intermediate catheter back while keeping the Delivery System in place across the neck of the intracranial aneurysm.
6. Confirm the position of the Surpass Flow Diverter by visualizing the radiopaque implant. Ensure the distal end of the implant is at least 5 mm beyond the neck of the intracranial aneurysm.

   Notes:

   - Pulling back on the Delivery System to make final adjustments will ensure that slack has been removed from the Delivery System prior to deployment.
   - Keep the system as straight as possible outside of the patient.
   - If difficulty in access is noticed especially when crossing the neck of the intracranial aneurysm or a bifurcation, ensure the two distal marker bands (Surpass Streamline outer and Surpass Streamline pusher) are aligned with minimal gap by gently retracting or advancing the Surpass Streamline pusher.

- Interchanging forward movements with the intermediate catheter and the Delivery System may improve navigation.
- Anchoring the guidewire tip in a safe location distal to the lesion may help enhance support during deployment.
- Confirm appropriate positioning of the guide catheter and intermediate catheter - retreating catheters can make it more difficult to advance the system.

7. The Surpass Flow Diverter is now ready to be deployed.

Flow Diverter Deployment

1. Loosen the RHV on the Surpass Streamline outer. Begin deployment by unsheathing the Surpass Streamline outer while putting slight forward pressure on the Surpass Streamline pusher until the Surpass Flow Diverter begins to exit the Surpass Streamline outer and starts apposing to the vessel wall.
2. A combination of forward pressure (pushing) on the Surpass Streamline pusher and/or unsheathing of the Surpass Streamline outer (pulling) should enable the operator to keep the distal end of the implant aligned at the desired landing zone.

   Note: During deployment, to improve apposition, tighten the RHV on the Surpass Streamline outer and advance the system to maintain slight forward pressure on the Surpass Flow Diverter.

3. If positioning is not satisfactory, the Surpass Flow Diverter can be recaptured and repositioned. To recapture the Surpass Flow Diverter, simultaneously advance the Surpass Streamline outer and pull the Surpass Streamline pusher. Once recaptured, the Delivery System can be repositioned both distally and proximally.
   Note: The Surpass Flow Diverter can be recaptured as long as the gap between Surpass Streamline outer tip marker and proximal Surpass Streamline pusher marker is at least 11 mm.

   Caution: Do not attempt to partially deploy and recapture the Surpass Flow Diverter more than three times.

   Caution: Do not attempt to move the Surpass Flow Diverter more distally once it has begun apposing to the vessel walls.

   Caution: Do not apply additional force if significant resistance is experienced while attempting to recapture the flow diverter.

4. If the position of the Delivery System is satisfactory, refer back to Flow Diverter Deployment Steps 1/2 to begin deployment. After about 10 mm of the Surpass Flow Diverter has been exposed, its distal end will begin to flare and appose to the vessel walls.
5. After the distal end of the Surpass Flow Diverter has successfully expanded and begun apposing to the vessel walls, deploy the remainder of the Surpass Flow Diverter by alternately pushing the Surpass Streamline pusher and unsheathing the Surpass Streamline outer. Carefully monitor the Surpass Streamline pusher tip under fluoroscopy during deployment of the Surpass Flow Diverter.
6. After the entire Surpass Flow Diverter has deployed, confirm full expansion under fluoroscopy to ensure that it has completely apposed the vessel wall. If the device is not fully apposed, consider using a balloon catheter to fully open it.
7. Advance the Surpass Streamline outer over the Surpass Streamline pusher until the radiopaque marker on the Surpass Streamline pusher tip is aligned with the distal radiopaque marker on the Surpass Streamline outer. Tighten the Surpass Streamline outer RHV.
8. Carefully remove the Delivery System and accessories as a unit and discard.

9. Verify that the device has remained patent and properly positioned.
10. After completing the procedure, withdraw and discard all applicable accessory devices.

POTENTIAL ADVERSE EVENTS

Risks that may be associated with the use of the Surpass Flow Diverter in the intracranial arteries include:

- Allergic reaction
- Adverse reaction to anesthesia, contrast or antiplatelet/anticoagulation agents
- Aphasia
- Cardiac arrhythmia
- Cranial neuropathy
- Confusion, coma, change in mental status
- Death
- Device migration, fracture, misplacement
- Dissection or perforation of the parent artery
- Embolism (air, clots, device fragments)
- Groin injury (bleeding, pain, vessel/nerve damage)
- Headache
- Hemiplegia
- Hydrocephalus
- Implant or parent vessel stenosis
- Implant thrombosis/occlusion
- Infection
- Intracerebral bleeding
- Mass effect
- Myocardial infarction
- Neurological deficits
- Perforation or rupture of aneurysm
- Progressive neurologic symptoms related to intracranial aneurysm (IA)
- Pseudoaneurysm formation
- Reaction to radiation exposure (i.e., alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, delayed neoplasia)
- Renal failure
- Retroperitoneal hematoma
- Seizure
- Stroke
- Subarachnoid hemorrhage
- Thromboembolism from device
- Thrombosis of parent artery or branch vessel
- Transient ischemic attack (TIA)
- Vasospasm

Risks that are eye related with the use of the Surpass Flow Diverter may include:

- Amaurosis fugax/transient blindness
- Blindness
- Diplopia
- Reduced visual acuity/field
- Retinal artery occlusion
- Retinal ischemia
- Retinal infarction
- Vision impairment

Please notify your Stryker Neurovascular representative immediately if a device malfunctions or patient complication or injury is experienced or suspected. Please make every attempt to retain any suspect device, its associated components and their packaging for return to Stryker Neurovascular.

CLINICAL TRIAL RESULTS

SCENT Trial (The Surpass IntraCranial Aneurysm EmbolizatioN System Pivotal Trial to treat large OR giant wide neck aneurysms)

Purpose

The purpose of the SCENT Trial was to evaluate the effectiveness and safety of the Surpass Streamline Flow Diverter Stent System for the endovascular treatment of patients with unruptured large or giant intracranial aneurysms (IA) of the internal carotid artery to the terminus.

Design

The SCENT Trial was a prospective, multi-center, single-arm, open label clinical study that enrolled 236 patients from 25 sites in the US and 1 site outside of the US. All patients were required to receive aspirin 75 to 325 mg daily 5 days pre-procedure and thereafter for life, and Clopidogrel/Plavix 75 mg daily 5 days pre-procedure and post procedure for 6 months.

Inclusion Criteria

Candidates considered for treatment in the study met the following criteria:

1. Age 19 to 80 years
2. Subject or legal representative is willing and able to give informed consent
3. Subject has a single targeted intracranial aneurysm that:
    a. Is located in the internal carotid artery (ICA) distribution up to the terminus
    b. Is able to be crossed with a standard 0.014" guide wire
    c. Has a neck ≥ 4 mm or no discernible neck and an aneurysm size ≥ 10 mm (including saccular, fusiform and dissecting configuration)
    d. Has a vessel diameter between 2.5 mm and 5.3 mm at both the proximal and distal segments where the implant will be placed
4. Subject agrees to return to the treating Investigator for all scheduled follow up visits and is capable of returning to the hospital for follow up

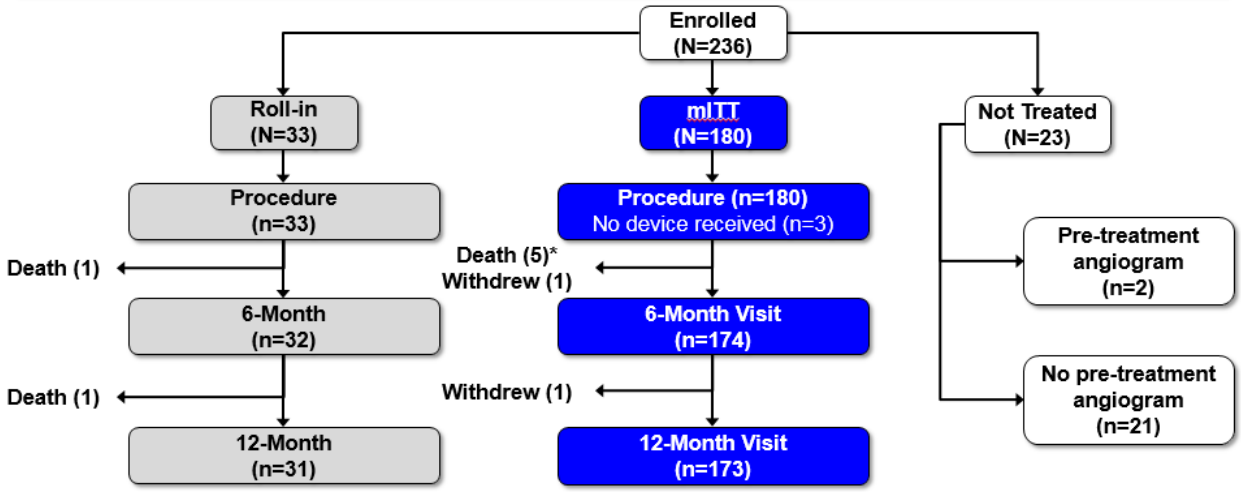
Exclusion Criteria

Candidates excluded from the study met the following criteria:

1. Known allergy or contraindication to aspirin, clopidogrel/Plavix, heparin, local or general anesthesia
2. Subject has documented resistance to clopidogrel/Plavix
3. Platelet count < 100 x 10^3 cells/mm^3 or known platelet dysfunction
4. Subject has a history of bleeding diathesis or coagulopathy, international normalized ratio (INR) greater than 1.5, or will refuse blood transfusions
5. Subject has a need for long-term use of anticoagulants (i.e. Warfarin, Dabigatran)
6. Known history of life threatening allergy to contrast dye
7. Known allergy to nickel, chromium cobalt, tungsten or platinum
8. Major surgery within previous 30 days or planned in the next 120 days after enrollment date
9. Previous intracranial implant associated with the symptomatic distribution within the past 12 weeks prior to treatment date
10. Stenting, angioplasty, or endarterectomy of an extracranial (carotid or vertebral artery) or intracranial artery within 30 days prior to treatment date
11. Any previous stenting of parent artery at or proximal to the aneurysm where it would interfere with the placement and proper apposition of the device
12. Any previous coiling where it would interfere with the placement and proper apposition of the device
13. More than one intracranial aneurysm (IA) that requires treatment within 12 months
14. Asymptomatic extradural aneurysms requiring treatment
15. Contraindication to CT scan or MRI
16. Severe neurological deficit that renders the subject incapable of living independently
17. Unstable neurological deficit (i.e., worsening of clinical condition in the last 30 days)
18. Evidence of active infection at the time of treatment
19. Dementia or psychiatric problem that prevents the subject from completing required follow up
20. Co-morbid conditions that may limit survival to less than 24 months
21. Serum creatinine ≥ 2.5 mg/dL
22. Female subjects who are pregnant or planning to become pregnant within the study period (all females of child bearing age must take a pregnancy test within 24 hours of treatment) and who are unwilling or unable to take adequate method of contraception for at least until the 12 months study follow up
23. Subject with anatomy not appropriate for endovascular treatment due to severe intracranial vessel tortuosity or stenosis
24. Extra-cranial stenosis or parent vessel with stenosis > 50% in the area proximal to the aneurysm
25. Other known serious concurrent medical conditions such as heart disease (e.g. atrial fibrillation/pacemaker, recent myocardial infarction, symptomatic congestive heart failure, or carotid stenosis), pulmonary disease, uncontrolled diabetes, progressive neurologic disorders, vasculitis, or subjects using immunosuppressants including corticosteroids
26. History of intracranial vasospasm not responsive to medical therapy
27. Subject with an intracranial mass (tumor, except meningioma, abscess, or other infection), or is undergoing radiation therapy for carcinoma or sarcoma of the head or neck region

28. Subject had a subarachnoid hemorrhage within 30 days prior to the enrollment date
29. Subject has a non-treated arterio-venous malformation (AVM) in the territory of the target aneurysm
30. Inability to understand the study or a history of non-compliance with medical advice
31. Current use of illicit substance
32. Enrollment in another trial involving an investigational product

Figure 2 is a subject accountability flowchart that details the total number of patients enrolled and patient disposition through 12 month follow-up.



*mITT deaths (N = 5): 4 Neurologic, 1 Unrelated. One additional death occurred post 12-month follow-up (on day 898).

Figure 2. Subject Accountability Flowchart

Study success was determined by meeting both the primary effectiveness and safety endpoint success criteria in the modified intent to treat (mITT) primary analysis population. The mITT population was defined to include all enrolled subjects for whom the investigational device entered the body. Primary effectiveness was defined as a composite of complete target intracranial aneurysm occlusion at the time of 12 month cerebral angiography in the absence of use of other treatments, the absence of major (> 50%) stenosis of the parent artery, and no retreatment. The primary effectiveness endpoint was assessed by the angiographic core laboratory. The primary safety endpoint was defined as the occurrence of major ipsilateral stroke or neurologic death by 12 months as adjudicated by a clinical events committee (CEC).

Based on information derived from pre-study review of available medical literature, the SCENT Trial was designed to be considered a success if the primary effectiveness endpoint rate was statistically > 50% and the primary safety endpoint rate was statistically < 20%.

Demographics and Baseline Intracranial Aneurysm Characteristics are presented in Table 3.

Table 3. Demographic and Baseline Characteristics - mITT (N=180)

Variable	mITT N=180
Age (yr)	
Mean ± SD (n)	61.0 ± 9.9 (180)
Median (Minimum, Maximum)	61.5 (38.0, 80.0)
Sex, % (n/N)	
Female	91.7% (165/180)
Race, % (n/N) [1]	
American Indian/Alaska Native	1.1% (2/180)
Asian	3.3% (6/180)
Black or African American	14.4% (26/180)
White	77.8% (140/180)
Other	1.1% (2/180)
Not reported	3.3% (6/180)
Ethnicity, % (n/N)	
Hispanic or Latino	7.8% (14/180)
Not Hispanic or Latino	87.8% (158/180)
Unknown	3.3% (6/180)
Not reported	1.1% (2/180)
Height (in)	
Mean ± SD (n)	64.8 ± 3.2 (180)
Median (Minimum, Maximum)	65.0 (52.0, 75.0)
Weight (lbs)	
Mean ± SD (n)	166.0 ± 40.2 (180)
Median (Minimum, Maximum)	158.4 (83.6, 281.6)
BMI (lbs/in^2)	
Mean ± SD (n)	27.8 ± 6.1 (180)
Median (Minimum, Maximum)	27.0 (16.0, 49.0)
Smoking Status/Alcohol Use, % (n/N) [2]	
Current Smoker	20.0% (36/180)
Past Smoker	43.9% (79/180)
Current consumer of Alcohol	50.6% (91/180)

[1] Patients may contribute toward more than one criterion for race. The total count may exceed the number of study patients in each study cohort.
[2] Patients may contribute toward more than one criterion for smoking status.

Table 4 presents site reported pre-procedure target IA size. Aneurysm size ≥ 10 mm was used to determine patient eligibility. The majority of intracranial aneurysms (92.8%; 167/180) were between 10 to 25 mm in size. Giant (≥ 25 mm) aneurysms occurred in 7.2% (13/180) of the study population.

Table 4. Site Reported Pre-procedure IA Measurement/Characteristics - mITT (N=180)

Measurement / Characteristic	mITT N=180
Number Assessed [1]	100.0% (180/180)
Parent Vessel Diameter (mm)	
Proximal to Aneurysm Neck	
mean ± SD (n)	3.9 ± 0.6 (180)
median (min, max)	4.0 (2.6, 5.3)
Distal to Aneurysm Neck	
mean ± SD (n)	3.4 ± 0.6 (180)
median (min, max)	3.4 (2.5, 5.1)
Aneurysm Sac Size (mm)	
Dome Height	
mean ± SD (n)	13.4 ± 5.7 (178)
median (min, max)	11.8 (1.3, 43.0)

Measurement / Characteristic	mITT N=180
Dome Width	
mean ± SD (n)	12.3 ± 5.7 (179)
median (min, max)	10.8 (1.3, 33.0)
Dome Depth (if not spherical)	
mean ± SD (n)	11.1 ± 6.4 (151)
median (min, max)	10.8 (0.0, 26.2)
Neck Width	
mean ± SD (n)	6.7 ± 2.8 (169)
median (min, max)	6.0 (0.0, 27.1)
Aneurysm Size (mm)	
< 10 mm	0.0% (0/180)
10 to < 25 mm	92.8% (167/180)
25 mm or larger	7.2% (13/180)
Aneurysm Type	
Saccular	70.0% (126/180)
Fusiform	18.3% (33/180)
Blister	0.0% (0/180)
Segmental	5.0% (9/180)
Focal	0.0% (0/180)
Dissecting	0.6% (1/180)
Dysplastic	6.1% (11/180)
Aneurysm Location	
Petrous Segment	2.2% (4/180)
Cavernous Segment	23.3% (42/180)
Carotid Cavernous Artery	1.1% (2/180)
Carotid-Ophthalmic	31.1% (56/180)
Superior Hypophyseal Artery	5.0% (9/180)
Supraclinoid Carotid Artery	25.0% (45/180)
Cerebral Segment (not otherwise specified)	1.1% (2/180)
Anterior Choroidal Artery	0.6% (1/180)
Other	10.6% (19/180)
Aneurysm Side	
Right	45.6% (82/180)
Left	54.4% (98/180)
[1] Includes subjects with a completed angiogram	

Technical Results

Technical success was achieved in 176 of 180 (97.8%) SCENT Trial patients (**Table 5**). A mean of 1.1 Surpass devices were implanted per patient (**Table 6**).

Table 5. Technical and Surpass System Success – mITT (180)

	mITT N=180	
Success	% (n/N)	95% CI [3]
Technical Success (per patient) [1]	97.8% (176/180)	(94.4, 99.4)
Surpass System Success (per device) [2]	89.6% (198/221)	(84.8, 93.3)
[1] On a per patient basis, technical success is determined when the entire neck of the target aneurysm is covered using as many as two Surpass implants; per protocol, implantation of more than two devices is a technical failure. [2] On a per device basis, success is determined when the Surpass device enters the patient and is successfully deployed to target location. [3] The confidence intervals are calculated without multiplicity adjustment. As such, the confidence intervals are provided to show the variability only and should not be used to draw any statistical conclusions.		

Table 6. Number of Surpass Devices Implanted per Patient - mITT

# of Surpass devices implanted	n (%)
0	3 (1.7%)
1	156 (86.7%)
2	21 (11.7%)
Total # of Surpass devices Implanted (N)	198
Mean (range)	1.1 (0 - 2)

Procedural Duration

As reported in **Table 7**, the median procedural duration in the mITT cohort was 43.0 minutes (range: 3.0 – 266.0).

Table 7. Procedure Duration - mITT (N=180)

Procedure Duration (minutes) [1]	mITT N=180
Mean ± SD (n)	53.6 ± 42.9 (180)
Median (Q1, Q3)	43.0 (25.0, 68.0)
Min, Max	3.0, 266.0
[1] Time of Surpass System insertion to time last guidewire was removed	

Patient Follow-Up

Of the 180 patients in the mITT primary analysis population, 175 were theoretically available to complete 12 month follow-up. Clinical and angiographic follow-up was obtained in 92% (161/175) of available patients.

Study Results

The primary effectiveness composite success rate in the mITT population was 62.8% (113/180; 95% CI: 55.3, 69.9) and statistically greater than the predetermined threshold of 50% (p-value = < 0.001). The primary effectiveness endpoint was therefore met (**Table 8**).

Table 8. Primary Effectiveness through 12 Month Follow-up - mITT (N=180)

	% (n/N) (95% CI) [3, 4]	p-value [5]
Primary Effectiveness Composite Success [1, 2]	62.8% (113/180) (55.3, 69.9)	< 0.001
[1] Primary effectiveness endpoint success defined as Grade 1 Raymond Class without clinically significant stenosis of the parent artery or retreatment of the target intracranial aneurysm. [2] mITT patients missing 12 month follow-ups (n=11) were imputed as failures. [3] The confidence intervals are calculated without multiplicity adjustment. As such, the confidence intervals are provided to show the variability only and should not be used to draw any statistical conclusions. [4] Clopper-Pearson exact confidence interval. [5] One-sided Fisher's Exact test of success against the PG of > 0.50 (α=0.025).		

Sub-components of the primary effectiveness composite success endpoint (Raymond Class I, Parent Artery Stenosis > 50%, and no aneurysm retreatment) were also evaluated at 6 and 12 months for patients in the mITT and per protocol (PP) cohorts (PP includes patients in whom no pre-defined major protocol violations occurred, an investigational device was implanted, and a core lab assessable angiographic image was available) and summarized in **Table 9**; Secondary Effectiveness Endpoints through 12 Month Follow-up. Changes in mRS scores were also secondary effectiveness endpoints, and are summarized in **Table 17**.

Table 9. Secondary Effectiveness Endpoints through 12 Month Follow-up - mITT (N=180) / PP (n=164)

	mITT		PP	
	6 Months % (n/N) 95% CI [3]	12 Months [1] % (n/N) 95% CI [3]	6 Months % (n/N) 95% CI [3]	12 Months [1] % (n/N) 95% CI [3]
Aneurysm Rupture	2.2% (4/180) (0.6, 5.6)	2.2% (4/180) (0.6, 5.6)	1.8% (3/164) (0.4, 5.3)	1.8% (3/164) (0.4, 5.3)
Raymond Class [2]				
Grade 1	59.4% (107/180) (51.9, 66.7)	66.1% (119/180) (58.7, 73.0)	62.2% (102/164) (54.3, 69.6)	70.7% (116/164) (63.1, 77.6)
Grade 2	17.2% (31/180) (12.0, 23.5)	9.4% (17/180) (5.6, 14.7)	18.9% (31/164) (13.2, 25.7)	10.4% (17/164) (6.2, 16.1)
Grade 3	15.0% (27/180) (10.1, 21.1)	15.0% (27/180) (10.1, 21.1)	15.9% (26/164) (10.6, 22.4)	16.5% (27/164) (11.1, 23.0)
Grade Not Available	8.3% (15/180) (4.7, 13.4)	9.4% (17/180) (5.6, 14.7)	3.0% (5/164) (1.0, 7.0)	2.4% (4/164) (0.7, 6.1)
Complete Aneurysm Occlusion (Grade 0 Consensus Scale)	59.4% (107/180) (51.9, 66.7)	68.3% (123/180) (61.0, 75.1)	62.2% (102/164) (54.3, 69.6)	73.2% (120/164) (65.7, 79.8)
Implant Stenosis > 50%	6.7% (12/180) (3.5, 11.4)	2.8% (5/180) (0.9, 6.4)	7.3% (12/164) (3.8, 12.4)	3.0% (5/164) (1.0, 7.0)
Parent Artery Stenosis > 50%	7.2% (13/180) (3.9, 12.0)	3.3% (6/180) (1.2, 7.1)	7.9% (13/164) (4.3, 13.2)	3.7% (6/164) (1.4, 7.8)
Incidence of Retreatment	0.6% (1/180) (0.0, 3.1)	0.6% (1/180) (0.0, 3.1)	0.0% (0/164) (0.0, 2.2)	0.0% (0/164) (0.0, 2.2)

[1] Includes angiographic imaging completed between 10 and 15 months. If complete data was missing during this window, angiographic imaging from an expanded time window was used to evaluate aneurysm occlusion (from a 6-15 month window) and parent artery stenosis (from 10+ months), where available.
[2] Per protocol, Raymond Class at 6 month follow-up is a secondary effectiveness endpoint and Raymond Class at 12 month follow-up is a sub-component of primary effectiveness composite success; Raymond Class at both time intervals are presented herein for completeness.
[3] The confidence intervals are calculated without multiplicity adjustment. As such, the confidence intervals are provided to show the variability only and should not be used to draw any statistical conclusions.

The primary safety endpoint was met in the primary analysis population and the null hypothesis was rejected ($p < 0.001$). The incidence of primary safety failure (major ipsilateral stroke and/or neurological death) in the mITT population was 10.6% (19/180; 95% CI: 6.5, 16.0).

The subcomponents of the composite primary safety endpoint, the incidence of major ipsilateral stroke and the rate of neurological death, were 10.6% (19/180) and 2.8% (5/180), respectively. Five of the 19 subjects who experienced major ipsilateral stroke also suffered neurologic death (**Table 10**).

Table 10. Pre-specified Primary Safety Endpoint Events through 12 Month Follow-up - mITT (N=180)

Event Type [1]	% of Patients with Observations (n/N) (95% CI) [2]	p-value [3]
Major ipsilateral stroke [4]	10.6% (19/180) (6.5, 16.0)	
Neurological death [4]	2.8% (5/180) (0.9, 6.4)	
Primary Safety Failure (major ipsilateral stroke or neurological death)	10.6% (19/180) (6.5, 16.0)	<0.001

[1] Occurrence from enrollment date through 365 days post-procedure
[2] Clopper-Pearson exact confidence interval
[3] One-sided Fisher's Exact test of success against the performance goal of <0.20 at 12 months (α=0.025)
[4] Individual subjects may have experienced both major ipsilateral stroke and neurological death. The overall safety failure rate includes 15 major ipsilateral strokes as adjudicated by the CEC and 4 strokes that were determined to meet the definition of primary safety failure post CEC-review.

An additional *post-hoc* analysis was performed wherein the mITT population was analyzed using a composite safety endpoint definition of disabling stroke (modified Rankin Scale (mRS) score of ≥ 3 at a minimum of 90-days post-stroke event) or neurological death. Using this modified definition, the primary safety failure rate within 12 months post-treatment with the Surpass device was 6.1% (11/180) (Table 11).

Table 11: *Post-hoc* Primary Safety Endpoint of Disabling Stroke or Neurologic Death through 12 Month Follow-up – mITT (N=180)

Event [1]	% of Patients with Observations (n/N) 95% CI [2]
Disabling Stroke or Neurologic Death	6.1% (11/180) (3.1, 10.7)
Neurologic Death [3]	2.8% (5/180) (0.9, 6.4)
Disabling Stroke [3]	6.1% (11/180) (3.1, 10.7)

[1] Debilitating Stroke defined as mRS of 3 or higher measured at least 90 days after stroke
[2] Unadjusted Clopper-Pearson exact confidence interval. The confidence intervals are calculated without multiplicity adjustment. As such, the confidence intervals are provided to show the variability only and should not be used to draw any statistical conclusions
[3] Individual subjects may have experienced both disabling stroke and neurological death.

Subgroup Analyses

The following preoperative characteristics were evaluated for potential association with outcomes: intracranial aneurysm size (large vs. giant), anatomical location, age, subject baseline characteristics. Subgroup analyses of the primary safety endpoint events did not show statistically significant differences based on intracranial aneurysm size (large vs. giant), age, anatomical location of the treated intracranial aneurysm, or subject baseline characteristics due to the low rate of safety events. Therefore, no statistical conclusions can be made for safety of the device and treatment from these subgroup analyses.

For effectiveness, Table 12 shows the predictive variables that were assessed to determine whether they could affect the primary effectiveness endpoint success in the mITT population. In addition, Tables 13-15 shows the primary effectiveness endpoint rates based on the subgroups of age (< 65 years old vs. ≥ 65 years old), anatomical location of the intracranial aneurysm treated, and intracranial aneurysm size (large vs. giant). The subgroup analysis based on age (Table 13) does show that there is a statistically significant difference in the primary effectiveness endpoint success rate that favors effectiveness of the subject device and treatment in patients < 65 years old [70.2% (80/114)] as compared to patients ≥ 65 years old [50.0% (33/66)] in the mITT population in the SCENT trial.

Table 12. Full Multivariate Model for Primary Effectiveness Endpoint Success in the mITT Population

Predictive Variable	Odds Ratio (95% CI) [1]	Wald Chi-Square	Pr > Chi-Square [2]
Intercept	--	15.269	<.001
Aneurysm Location (compared to Carotid-ophthalmic Segment)			
Superior Hypophyseal Artery	7.56 (0.59-96.4)	2.423	0.120
Petrous Segment	3.41 (0.20-58.0)	0.719	0.396
Supraclinoid Carotid Artery	0.61 (0.19-1.96)	0.688	0.407
Posterior Communicating Artery	1.34 (0.51-3.54)	0.350	0.554
Cavernous Segment	1.29 (0.52-3.21)	0.294	0.588
Age 65 and Older vs. Under Age 65	0.30 (0.15-0.61)	10.785	0.001
History of Stroke	0.14 (0.04-0.46)	10.294	0.001
History of Aneurysm	0.25 (0.08-0.80)	5.411	0.020
Aneurysm Size (mm)	0.94 (0.89-1.00)	4.038	0.044
Black or African-American	0.58 (0.22-1.54)	1.186	0.276
[1] The confidence intervals are calculated without multiplicity adjustment. As such, the confidence intervals are provided to show the variability only and should not be used to draw any statistical conclusions. [2] Pr = Probability.			

Table 13. Subgroup Analysis of Primary Effectiveness Endpoint Based on Subject Age ≥ 65 Years versus < 65 Years in mITT Population

	Under Age 65 N=114		Age 65 and Older N=66	
Outcomes	% (n/N)	95% CI*	% (n/N)	95% CI*
Primary Effectiveness Endpoint	70.2% (80/114)	(60.9, 78.4)	50.0% (33/66)	(37.4, 62.6)
*The confidence intervals are calculated without multiplicity adjustment. As such, the confidence intervals are provided to show the variability only and should not be used to draw any statistical conclusions.				

Table 14 shows the subgroup analysis for the primary effectiveness endpoint based on intracranial aneurysm location. There does not appear to be a statistically significant difference in device effectiveness based on the intracranial aneurysm location treated. Table 15 shows the subgroup analysis of the primary effectiveness endpoint based on giant vs. large intracranial aneurysms treated in the mITT population. The results show that there is decreased effectiveness with the subject device and treatment in giant intracranial aneurysms [46.2% (6/13)] compared to large intracranial aneurysms [64.1% (107/167)] but the difference is not statistically significant.

Finally, the secondary effectiveness endpoints of Raymond-Roy intracranial aneurysm occlusion classifications at 12-month follow-up were compared in subgroups of patients who had full apposition of the device to the vessel wall and those who did not, per Core Lab imaging findings (Table 16). The rate of complete intracranial aneurysm occlusion (Raymond-Roy Class I) at 12-months post-procedure was statistically significantly higher among patients who had full device apposition (79.2%; 99/125) compared to those who did not (50.0%; 17/34).

Table 14. Primary Effectiveness Endpoint Success Based on Intracranial Aneurysm Location – mITT Population

	Aneurysm Size (mm) (CORE LAB)		Primary Effectiveness Success	
Aneurysm Location	Mean (SD) (min, max)		% (n/N)	95% CI [1]
Petrous Segment	14.2 (4.8) (8.3,20.1)		75.0% (3/4)	[19.4, 99.4]
Cavernous Segment	17.6 (7.4) (4.9,41.7)		59.6% (31/52)	[45.1, 73.0]
Carotid-Ophthalmic	13.1 (5.2) (3.9,28.3)		63.3% (38/60)	[49.9, 75.4]
Posterior Communicating Artery	12.2 (5.0) (3.4,27.0)		65.8% (25/38)	[48.6, 80.4]
Supraclinoid Carotid Artery	13.5 (4.4) (6.7,25.1)		55.0% (11/20)	[31.5, 76.9]
Superior Hypophyseal Artery	10.5 (3.1) (5.5,13.9)		83.3% (5/6)	[35.9, 99.6]
[1] The confidence intervals are calculated without multiplicity adjustment. As such, the confidence intervals are provided to show the variability only and should not be used to draw any statistical conclusions.				

Table 15. CEC Adjudicated Primary Effectiveness Endpoint Outcomes for Giant and Non-Giant (Large) Intracranial Aneurysms through 12 Month Follow-Up – mITT Population (N=180)

	All Intracranial Aneurysm Sizes Except Giant N=167		Giant Intracranial Aneurysms N=13	
Outcome	% (n/N) of Patients with Outcome	[95% CI]*	% (n/N) of Patients with Outcome	[95% CI]*
Primary Effectiveness Success	64.1% (107/167)	[56.3, 71.3]	46.2% (6/13)	[19.2, 74.9]
*The confidence intervals are calculated without multiplicity adjustment. As such, the confidence intervals are provided to show the variability only and should not be used to draw any statistical conclusions.				

Table 16. Raymond-Roy Score per Core Lab Assessment Based on Device Apposition at 12 Months Post-Procedure – mITT Population

	Device Not Fully Apposed to Vessel Wall at 12 Months N=34		Device Fully Apposed to Vessel Wall at 12 Months N=125	
Adjudicated Raymond Score at 12 Months [1]	% (n/N)	[95% CI][2]	% (n/N)	[95% CI] [2]
Raymond-Roy I	50.0% (17/34)	[32.4, 67.6]	79.2% (99/125)	[71.0, 85.9]
Raymond-Roy II	8.8% (3/34)	[1.9, 23.7]	11.2% (14/125)	[6.3, 18.1]
Raymond-Roy III	41.2% (14/34)	[24.6, 59.3]	9.6% (12/125)	[5.1, 16.2]
[1] Complete 12-month angiographic data not available for 21 mITT subjects [2] The confidence intervals are calculated without multiplicity adjustment. As such, the confidence intervals are provided to show the variability only and should not be used to draw any statistical conclusions.				

Baseline and 12-month mRS scores were obtained on all subjects to evaluate long-term clinical outcome. The shifts in numerical mRS scores from baseline to the 12-month follow-up visit were analyzed on a per subject basis (Table 17).

The majority of subjects in the mITT population (82.2%; 148/180) had unchanged or improved functional outcomes compared to baseline. A total of 107 out of 180 subjects (59.4%) had unchanged mRS scores, and 41 of the 180 subjects (22.8%) had improved mRS scores at 12 months. There were 23 subjects with worsened mRS scores (23/180; 12.8%). For 9 subjects, the mRS assessment was not performed due to confirmed missed visits (6), subject withdrawal (2), and protocol deviation (1).

Table 17. Change in Modified Rankin Scale Score through 12 Month Follow-up Compared to Baseline – mITT Population

	Score at 12 Month Follow-up Visit [1]								
Score at Baseline	ND [2]	0	1	2	3	4	5	6	Total
0	7	86	12	3	0	0	1	3	112
1	0	22	16	1	1	0	0	2	42
2	1	11	4	3	0	0	0	0	19
3	1	0	1	2	0	0	0	0	4
4	0	1	0	0	0	1	0	0	2
5	0	0	0	0	0	0	1	0	1
Total	9	120	33	9	1	1	2	5	180
[1] Each cell indicates score frequency at 12 month follow-up relative to baseline score frequency. Gray-shaded cells show subjects who worsened. [2] mRS exams were not done (ND) on 9 subjects at the 12-month follow-up visit for the following reasons: confirmed missed visit (6), subject withdrawal (2), and protocol deviation (1)									

Adverse events were reviewed by the CEC to determine whether individual events met the criteria for minor stroke designation (**Table 18**). A minor stroke was defined as a stroke associated with an increase in NIHSS score ≤ 3. As adjudicated by the CEC, the minor stroke rates in the mITT and Roll-in populations were 6.7% (12/180) and 3.0% (1/33), respectively.

Table 18. CEC Adjudicated Rate of Minor Strokes through 12 Month Follow-up (mITT and Roll-in)

	mITT Population N=180		Roll-in Population N=33	
Outcome	% (n/N) of Subjects with Outcome	[95% CI] [2]	% (n/N) of Subjects with Outcome	[95% CI] [2]
Minor Stroke [1]	6.7% (12/180)	[3.5, 11.4]	3.0% (1/33)	[0.1, 15.8]

[1] Minor strokes in the first 12 months, as adjudicated by the CEC

[2] The confidence intervals are calculated without multiplicity adjustment. As such, the confidence intervals are provided to show the variability only and should not be used to draw any statistical conclusions.

Observed Adverse Events

Table 19 reports serious adverse events (SAEs) and non-serious adverse events through one year follow-up.

Table 19. Adverse Events with >1% Overall Frequency Through 12 Months Post-procedure by MedDRA* Codes - mITT (N=180)

MedDRA Classification		Serious Adverse Events		Non-serious Adverse Events		All Adverse Events	
System/Organ Class	Preferred Term	Total Events (Patients)	Rate of Patients with Event (N=180)	Total Events (Patients)	Rate of Patients with Event (N=180)	Total Events (Patients)	Rate of Patients with Event (N=180)
Blood and Lymphatic System Disorders	Anaemia	1 (1)	0.6%	1 (1)	0.6%	2 (2)	1.1%
Cardiac Disorders	Arrhythmia	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Atrial Fibrillation	1 (1)	0.6%	1 (1)	0.6%	2 (2)	1.1%
	Cardiac Arrest	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
Ear and Labyrinth Disorders	Tinnitus	0 (0)	0.0%	3 (2)	1.1%	3 (2)	1.1%
	Ear Pain	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
Eye Disorders	Visual Impairment	2 (2)	1.1%	15 (14)	7.8%	17 (16)	8.9%
	Diplopia	2 (2)	1.1%	7 (7)	3.9%	9 (9)	5.0%
	Eye Pain	0 (0)	0.0%	8 (8)	4.4%	8 (8)	4.4%
	Vision Blurred	0 (0)	0.0%	7 (7)	3.9%	7 (7)	3.9%
	Vitreous Floaters	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Blepharitis	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Cataract	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%

Table 19. Adverse Events with >1% Overall Frequency Through 12 Months Post-procedure by MedDRA* Codes - mITT (N=180)

MedDRA Classification		Serious Adverse Events		Non-serious Adverse Events		All Adverse Events	
System/Organ Class	Preferred Term	Total Events (Patients)	Rate of Patients with Event (N=180)	Total Events (Patients)	Rate of Patients with Event (N=180)	Total Events (Patients)	Rate of Patients with Event (N=180)
	Dry Eye	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Eye Pruritus	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Photophobia	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Retinal Artery Occlusion	1 (1)	0.6%	1 (1)	0.6%	2 (2)	1.1%
	Retinal Haemorrhage	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Retinal Infarction	2 (2)	1.1%	0 (0)	0.0%	2 (2)	1.1%
Gastrointestinal Disorders	Nausea	0 (0)	0.0%	10 (10)	5.6%	10 (10)	5.6%
	Constipation	0 (0)	0.0%	6 (6)	3.3%	6 (6)	3.3%
	Gastrointestinal Haemorrhage	6 (5)	2.8%	0 (0)	0.0%	6 (5)	2.8%
	Vomiting	0 (0)	0.0%	6 (6)	3.3%	6 (6)	3.3%
	Dysphagia	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Mouth Haemorrhage	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Rectal Haemorrhage	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Abdominal Pain	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Dyspepsia	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Haematochezia	1 (1)	0.6%	1 (1)	0.6%	2 (2)	1.1%
	Retroperitoneal Haematoma	1 (1)	0.6%	1 (1)	0.6%	2 (2)	1.1%
General Disorders and Administration Site Conditions	Fatigue	0 (0)	0.0%	11 (10)	5.6%	11 (10)	5.6%
	Thrombosis In Device	4 (4)	2.2%	2 (2)	1.1%	6 (6)	3.3%
	Catheter Site Haemorrhage	0 (0)	0.0%	4 (4)	2.2%	4 (4)	2.2%
	Chest Pain	3 (3)	1.7%	1 (1)	0.6%	4 (4)	2.2%
	Oedema Peripheral	0 (0)	0.0%	4 (4)	2.2%	4 (4)	2.2%
	Gait Disturbance	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Implant Site Pain	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
Infections and Infestations	Urinary Tract Infection	0 (0)	0.0%	11 (10)	5.6%	11 (10)	5.6%
	Pneumonia	1 (1)	0.6%	3 (3)	1.7%	4 (4)	2.2%
	Sinusitis	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Bronchitis	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
Injury, Poisoning and Procedural Complications	Contusion	0 (0)	0.0%	9 (9)	5.0%	9 (9)	5.0%
	Fall	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Traumatic Haematoma	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Vascular Injury	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Vascular Pseudoaneurysm	1 (1)	0.6%	1 (1)	0.6%	2 (2)	1.1%
Investigations	Neurological Examination Abnormal	0 (0)	0.0%	4 (4)	2.2%	4 (4)	2.2%
	Carotid Bruit	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
Metabolism and Nutrition Disorders	Hyponatraemia	1 (1)	0.6%	2 (2)	1.1%	3 (3)	1.7%
	Decreased Appetite	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
Musculoskeletal and Connective Tissue Disorders	Pain In Extremity	0 (0)	0.0%	7 (6)	3.3%	7 (6)	3.3%
	Back Pain	0 (0)	0.0%	6 (6)	3.3%	6 (6)	3.3%

Table 19. Adverse Events with >1% Overall Frequency Through 12 Months Post-procedure by MedDRA* Codes - mITT (N=180)

MedDRA Classification		Serious Adverse Events		Non-serious Adverse Events		All Adverse Events	
System/Organ Class	Preferred Term	Total Events (Patients)	Rate of Patients with Event (N=180)	Total Events (Patients)	Rate of Patients with Event (N=180)	Total Events (Patients)	Rate of Patients with Event (N=180)
	Neck Pain	0 (0)	0.0%	4 (4)	2.2%	4 (4)	2.2%
	Arthralgia	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Groin Pain	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Muscular Weakness	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Plantar Fasciitis	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
Nervous System Disorders	Headache	3 (3)	1.7%	57 (52)	28.9%	60 (54)	30.0%
	Dizziness	1 (1)	0.6%	13 (12)	6.7%	14 (13)	7.2%
	Reversible Ischaemic Neurological Deficit	0 (0)	0.0%	12 (12)	6.7%	12 (12)	6.7%
	Ischaemic Stroke	11 (11)	6.1%	0 (0)	0.0%	11 (11)	6.1%
	Hypoaesthesia	0 (0)	0.0%	9 (7)	3.9%	9 (7)	3.9%
	Transient Ischaemic Attack	3 (3)	1.7%	4 (3)	1.7%	7 (6)	3.3%
	Subarachnoid Haemorrhage	5 (5)	2.8%	0 (0)	0.0%	5 (5)	2.8%
	Amnesia	1 (1)	0.6%	3 (3)	1.7%	4 (4)	2.2%
	Embolic Stroke	3 (3)	1.7%	1 (1)	0.6%	4 (4)	2.2%
	Haemorrhagic Stroke	4 (4)	2.2%	0 (0)	0.0%	4 (4)	2.2%
	Memory Impairment	0 (0)	0.0%	4 (4)	2.2%	4 (4)	2.2%
	Migraine	0 (0)	0.0%	4 (4)	2.2%	4 (4)	2.2%
	Syncope	4 (4)	2.2%	0 (0)	0.0%	4 (4)	2.2%
	Aphasia	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Presyncope	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Ataxia	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Carotid Artery Occlusion	1 (1)	0.6%	1 (1)	0.6%	2 (2)	1.1%
	Hemiparesis	1 (1)	0.6%	1 (1)	0.6%	2 (2)	1.1%
	Hydrocephalus	1 (1)	0.6%	1 (1)	0.6%	2 (2)	1.1%
	IIIrd Nerve Paralysis	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Paraesthesia	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Restless Legs Syndrome	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Tremor	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
Psychiatric Disorders	Anxiety	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Confusional State	1 (1)	0.6%	2 (2)	1.1%	3 (3)	1.7%
	Depression	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Insomnia	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Mental Status Changes	1 (1)	0.6%	1 (1)	0.6%	2 (2)	1.1%
Renal and Urinary Disorders	Urinary Retention	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
Respiratory, Thoracic and Mediastinal Disorders	Epistaxis	1 (1)	0.6%	5 (5)	2.8%	6 (6)	3.3%
	Cough	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Dyspnoea	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Haemoptysis	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
	Respiratory Failure	2 (2)	1.1%	0 (0)	0.0%	2 (2)	1.1%
	Sleep Apnoea Syndrome	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%
Skin and Subcutaneous Tissue Disorders	Ecchymosis	0 (0)	0.0%	3 (3)	1.7%	3 (3)	1.7%
	Rash	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%

Table 19. Adverse Events with >1% Overall Frequency Through 12 Months Post-procedure by MedDRA* Codes - mITT (N=180)

MedDRA Classification		Serious Adverse Events		Non-serious Adverse Events		All Adverse Events	
System/Organ Class	Preferred Term	Total Events (Patients)	Rate of Patients with Event (N=180)	Total Events (Patients)	Rate of Patients with Event (N=180)	Total Events (Patients)	Rate of Patients with Event (N=180)
Surgical and Medical Procedures	Intra-Cerebral Aneurysm Operation	3 (3)	1.7%	0 (0)	0.0%	3 (3)	1.7%
Vascular Disorders	Hypotension	0 (0)	0.0%	12 (10)	5.6%	12 (10)	5.6%
	Haematoma	1 (1)	0.6%	7 (7)	3.9%	8 (8)	4.4%
	Vasospasm	0 (0)	0.0%	7 (6)	3.3%	7 (6)	3.3%
	Haemorrhage	2 (2)	1.1%	3 (3)	1.7%	5 (5)	2.8%
	Hypertension	1 (1)	0.6%	4 (4)	2.2%	5 (5)	2.8%
	Deep Vein Thrombosis	1 (1)	0.6%	1 (1)	0.6%	2 (2)	1.1%
	Embolism	2 (2)	1.1%	0 (0)	0.0%	2 (2)	1.1%
	Orthostatic Hypotension	0 (0)	0.0%	2 (2)	1.1%	2 (2)	1.1%

*Medical Dictionary for Regulatory Activities

Conclusions

The SCENT Trial met the primary effectiveness and safety endpoints with a high degree of statistical significance ($p < 0.001$).

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