Neuroform Atlas® Stent System

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 Neuroform Atlas® Stent System includes:

- A self-expanding, open-cell, nitinol stent with three radiopaque markerbands on each end (proximal and distal) and four interconnects between the central stent segments, designed to provide support for the coil mass within the aneurysm and minimize stent deflection.
- A stent delivery wire and introducer sheath. The stent is pre-loaded on the stent delivery wire and protected by an introducer sheath.
- The stent delivery wire comes in two configurations: 1. With an 8.5 mm distal tip, 2. Without a distal tip. Select a configuration based upon physician preference.
- An accessory pouch containing an optional torque device. The physician may attach the torque device to the proximal end of the stent delivery wire to facilitate handling and stabilization. The stent delivery wire is not designed to be torqued.

Contents

- One (1) Neuroform Atlas Stent System
- One (1) Torque Device

Required Accessories

Standard interventional devices, including rotating hemostatic valves ≥ 4.5 F [1.50 mm (0.059 in)], a guide catheter, guidewire(s), and Stryker Neurovascular microcatheters specifically Excelsior® SL-10® (0.0165 in/0.42 mm ID) or Excelsior® XT-17® (0.017 in/0.43 mm ID). If additional stability is required, consider the use of an intermediate catheter in addition to the microcatheter.

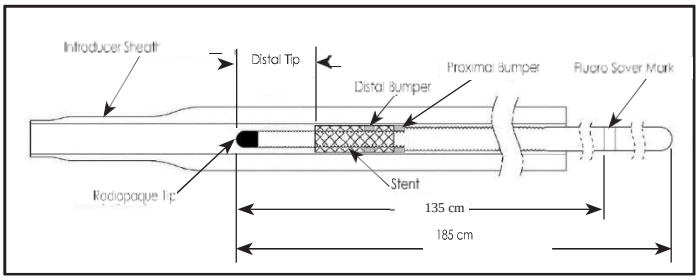

Figure 1: Neuroform Atlas® Stent System with tip

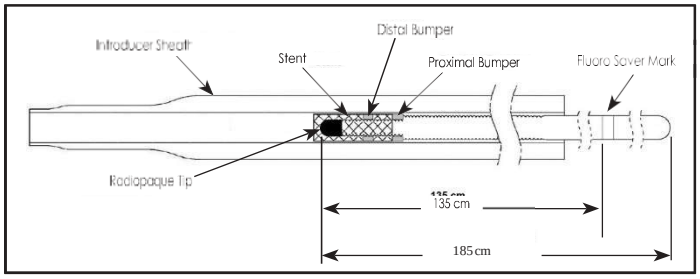

Figure 2: Neuroform Atlas Stent System without tip

Table 1. Sizing Table

Labeled Stent Diameter (mm)	Unconstrained Stent Diameter (mm)	Recommended Parent Vessel Diameter (mm)[1]
3.0	3.5	≥ 2.0 and < 3.0
4.0	4.5	≥ 3.0 and < 4.0
4.5	5.0	≥ 4.0 and ≤ 4.5

[1] Select a stent diameter based on the sizing recommendations in Table 1 and based on the larger vessel diameter (proximal or distal reference vessel diameter).

Table 2. Stent Sizing

Stent Label Diameter: 3.0 mm

Labeled Stent Length								
	15 mm		21 mm		24 mm		30 mm	
Vessel Diameter (mm)	WL (mm)	TL (mm)	WL (mm)	TL (mm)	WL (mm)	TL (mm)	WL (mm)	TL (mm)
2.0	15.4	17.6	22.6	24.4	25.5	27.3	31.5	33.6
2.5	15.4	17.6	22.3	24.3	25.0	27.2	31.1	33.3
3.0	15.2	17.4	22.0	24.2	24.7	26.8	30.8	33.1

Stent Label Diameter: 4.0 mm

Labeled Stent Length								
	15 mm		21 mm		24 mm		30 mm	
Vessel Diameter (mm)	WL (mm)	TL (mm)	WL (mm)	TL (mm)	WL (mm)	TL (mm)	WL (mm)	TL (mm)
3.0	15.1	17.3	21.7	23.6	24.5	26.6	30.8	32.9
3.5	14.8	17.1	21.0	23.2	24.1	26.3	30.4	32.6
4.0	14.6	16.8	20.4	22.5	23.8	25.4	29.2	31.4

Stent Label Diameter: 4.5 mm

Labeled Stent Length								
	15 mm		21 mm		24 mm		30 mm	
Vessel Diameter (mm)	WL (mm)	TL (mm)	WL (mm)	TL (mm)	WL (mm)	TL (mm)	WL (mm)	TL (mm)
4.0	14.6	16.3	20.8	23.1	23.7	25.8	29.9	32.3
4.5	14.3	16.1	20.0	22.2	23.1	25.2	29.5	31.8

WL = Working Length, TL = Total Length (Refer to Figure 3.)

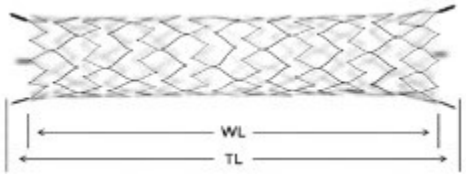

Figure 3: Working Length (WL)/ Total Length (TL)

INTENDED USE/INDICATIONS FOR USE

The Neuroform Atlas® Stent System is indicated for use with neurovascular embolization coils in the anterior and posterior circulation of the neurovasculature for the endovascular treatment of patients ≥ 18 years of age with saccular wide-necked (neck width ≥ 4 mm or a dome-to-neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of ≥ 2.0 mm and ≤ 4.5 mm.

CONTRAINDICATIONS

- 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 anti-platelet agents prior to stent implantation.
- Patients with an active bacterial infection.
- Patients in whom angiography demonstrates the anatomy is not appropriate for endovascular treatment due to conditions such as:
  - Severe intracranial vessel tortuosity or stenosis;
  - Intracranial vasospasm not responsive to medical therapy.
- Patients in whom a pre-existing stent is in place in the parent artery at the target intracranial aneurysm location.

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.
- Select a stent size (length) to maintain a minimum of 4 mm on each side of the aneurysm neck along the parent vessel (see Table 2 for size information). An incorrectly sized stent may result in damage to the vessel or stent migration. Therefore, the stent is not designed to treat an aneurysm with a neck greater than 22 mm in length.
- If excessive resistance is encountered during the use of the Neuroform Atlas® Stent System or any of its components at any time during the procedure, discontinue use of the stent system. Continuing to move the stent system against resistance may result in damage to the vessel or a system component.
- Use the Neuroform Atlas Stent System with compatible microcatheters. If repeated friction is encountered during device delivery, verify microcatheter is not kinked or in extremely tortuous anatomy. Confirm that the microcatheter does not ovalize. Confirm that there is adequate sterile flush solution.
- Do not torque the delivery wire while advancing or retracting the Neuroform Atlas Stent System.
- Do not attempt to re-position the Neuroform Atlas stent post-deployment.
- The stent delivery microcatheter and the Neuroform Atlas Stent delivery wire should not be used to recapture the stent.
- Persons allergic to nickel titanium (Nitinol) may suffer an allergic response to this stent implant.
- Higher adverse event rates may be experienced for distal aneurysms located in the anterior and middle cerebral arteries.
- The safety and effectiveness of the device has not been established in the treatment of ruptured intracranial aneurysms.

PRECAUTIONS

- Use the Neuroform Atlas® Stent System prior to the “Use By” date printed on the package.
- Carefully inspect the sterile package and Neuroform Atlas Stent System prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components; contact your Stryker Neurovascular representative.
- In cases where multiple aneurysms are to be treated, start at the most distal aneurysm first.
- After deployment, the stent may foreshorten up to 6.3%.
- The maximum outer diameter (OD) of the coiling microcatheter should not exceed the maximum OD of the stent delivery microcatheter.
- Standard interventional devices with distal tips > 1.8 F [0.60 mm (0.024 in)] may not be able to pass through the interstices of the stent.
- Exercise caution when crossing the deployed stent with adjunctive devices.
- Take all necessary precautions to limit X-ray radiation doses to clinical operators by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible.
- The Neuroform Atlas stent may create local field inhomogeneity and susceptibility artifacts during magnetic resonance angiography (MRA), which may degrade the diagnostic quality to assess effective intracranial aneurysm occlusion.
- Safety and effectiveness of the Neuroform Atlas Stent System in patients below the age of 18 has not been established.
- The benefits may not outweigh the risks of device use in patients with small and medium asymptomatic extradural intracranial aneurysms, including those located in the cavernous internal carotid artery.
- Carefully weigh the benefits vs. risks of device treatment for each individual patient based on their medical health status and risk factors for intracranial aneurysm rupture during their expected life time such as age, comorbidities, history of smoking, intracranial aneurysm size, location, and morphology, family history, history of prior asymptomatic subarachnoid hemorrhage (aSAH), documented growth of intracranial aneurysm on serial imaging, presence of multiple intracranial aneurysms, and presence of concurrent pathology. The benefits may not outweigh the risks associated with device use in certain patients; therefore, judicious patient selection is recommended based on clinical practice guidelines or tools to assess the life time risk of intracranial aneurysm rupture.

POTENTIAL ADVERSE EVENTS

Potential complications include, but are not limited to:

- Aphasia
- Allergic reaction to Nitinol metal and medications
- Aneurysm perforation/rupture, leak or contrast extravasation
- Blindness
- Cardiac arrhythmia
- Coil herniation through stent into parent vessel
- Cranial neuropathy
- Death
- Embolus
- Headache
- Hemiplegia
- Hemorrhage (i.e., intracerebral, subarachnoid, retroperitoneal, or in other locations)
- Hydrocephalus
- In-stent stenosis
- Infection
- Ischemia
- Mass effect
- Myocardial infarction
- Neurological deficit/intracranial sequelae
- Pseudoaneurysm
- Reaction to radiation exposure (i.e., alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, or delayed neoplasia)
- Reactions to anti-platelet/anti-coagulant agents
- Renal failure
- Seizure
- Stent fracture, migration/embolization, or misplacement
- Stent thrombosis
- Stroke
- Transient ischemic attack
- Vasospasm
- Vessel occlusion or closure including parent vessel or non-target side-branches
- Vessel perforation/rupture, dissection, trauma or damage
- Vessel thrombosis
- Visual impairment
- Other procedural complications including but not limited to anesthetic and contrast media risks, hypotension, hypertension, access site complications (including pain, hematoma, local bleeding, local infection, and injury to the artery (i.e. dissection), vein, or adjacent nerves)
- Unplanned intervention

Refer to the appropriate neurovascular embolization coil instructions for use for other complications that may occur due to coil embolization.

SUMMARY OF ADVERSE EVENTS IN ATLAS STUDY

The ATLAS study utilized a Clinical Events Committee/Data Safety Monitoring Board (CEC/DSMB) that adjudicated pre-specified clinical events, as they occurred throughout the study, in accordance with a ratified charter. The CEC/DSMB committee members adjudicated the adverse event term, stroke severity (if applicable), and event relatedness to the device, procedure, and/or concomitant medications. No unanticipated adverse device effects (UADE) occurred during this study. Adverse event (AE) summaries for the two cohorts in the ATLAS study (anterior-circulation and posterior-circulation) are presented in separate sections below.

SUMMARY OF ADVERSE EVENTS – ANTERIOR CIRCULATION COHORT

An overall summary of all AEs that occurred in the Anterior-Circulation Cohort, referred to as the Anterior Cohort herein, is shown in Table 3. A total of 207 events were reported during the peri-procedural period in 98 subjects. After 30 days (31 days to 12 months), 251 events occurred in 104 subjects.

Table 3. Site-reported Overall Summary of Adverse Events - mITT Population, Anterior Cohort

Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Adverse Event Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Any Adverse Event (AE)	207	53.8% (98/182)	251	57.1% (104/182)
Blood and lymphatic system disorders	3	1.6% (3/182)	5	2.2% (4/182)
Anemia	1	0.5% (1/182)	2	1.1% (2/182)
Increased tendency to bruise	2	1.1% (2/182)	0	0.0% (0/182)
Leukocytosis	0	0.0% (0/182)	1	0.5% (1/182)
Microcytic anemia	0	0.0% (0/182)	1	0.5% (1/182)
Thrombocytopenia	0	0.0% (0/182)	1	0.5% (1/182)
Cardiac disorders	2	1.1% (2/182)	5	2.7% (5/182)
Arrhythmia	0	0.0% (0/182)	2	1.1% (2/182)
Cardiomyopathy	0	0.0% (0/182)	2	1.1% (2/182)
Sinus bradycardia	1	0.5% (1/182)	0	0.0% (0/182)
Supraventricular tachycardia	0	0.0% (0/182)	1	0.5% (1/182)
Tachycardia	1	0.5% (1/182)	0	0.0% (0/182)
Ear and labyrinth disorders	0	0.0% (0/182)	1	0.5% (1/182)
Deafness bilateral	0	0.0% (0/182)	1	0.5% (1/182)
Eye disorders	11	4.9% (9/182)	11	4.9% (9/182)
Blepharospasm	0	0.0% (0/182)	1	0.5% (1/182)
Corneal abrasion	1	0.5% (1/182)	0	0.0% (0/182)
Diplopia	0	0.0% (0/182)	2	1.1% (2/182)
Glaucoma	0	0.0% (0/182)	1	0.5% (1/182)
Macular degeneration	0	0.0% (0/182)	1	0.5% (1/182)
Ocular discomfort	1	0.5% (1/182)	0	0.0% (0/182)
Photophobia	1	0.5% (1/182)	3	1.6% (3/182)

Retinal tear	0	0.0% (0/182)	1	0.5% (1/182)
Scleral hemorrhage	0	0.0% (0/182)	1	0.5% (1/182)
Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Adverse Event Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Vision blurred	6	3.3% (6/182)	0	0.0% (0/182)
Visual impairment	1	0.5% (1/182)	0	0.0% (0/182)
Vitreous floaters	1	0.5% (1/182)	1	0.5% (1/182)
Gastrointestinal disorders	13	6.0% (11/182)	20	8.2% (15/182)
Abdominal discomfort	0	0.0% (0/182)	1	0.5% (1/182)
Abdominal pain	0	0.0% (0/182)	2	1.1% (2/182)
Abdominal pain lower	0	0.0% (0/182)	1	0.5% (1/182)
Abdominal pain upper	1	0.5% (1/182)	0	0.0% (0/182)
Colitis ischemic	1	0.5% (1/182)	0	0.0% (0/182)
Constipation	1	0.5% (1/182)	1	0.5% (1/182)
Crohn's disease	1	0.5% (1/182)	0	0.0% (0/182)
Diarrhea	0	0.0% (0/182)	2	1.1% (2/182)
Diverticulitis intestinal hemorrhagic	0	0.0% (0/182)	1	0.5% (1/182)
Dysphagia	0	0.0% (0/182)	2	1.1% (2/182)
Functional gastrointestinal disorder	1	0.5% (1/182)	0	0.0% (0/182)
Gastritis	0	0.0% (0/182)	1	0.5% (1/182)
Gastrointestinal hemorrhage	0	0.0% (0/182)	1	0.5% (1/182)
Glossitis	0	0.0% (0/182)	1	0.5% (1/182)
Hemorrhoidal hemorrhage	0	0.0% (0/182)	1	0.5% (1/182)
Hemorrhoids	0	0.0% (0/182)	1	0.5% (1/182)
Nausea	7	3.3% (6/182)	3	1.6% (3/182)
Rectal hemorrhage	1	0.5% (1/182)	0	0.0% (0/182)
Vomiting	0	0.0% (0/182)	2	1.1% (2/182)
General disorders and administration site conditions	25	8.8% (16/182)	12	5.5% (10/182)
Administration site pain	2	1.1% (2/182)	0	0.0% (0/182)
Adverse drug reaction	2	0.5% (1/182)	0	0.0% (0/182)
Application site hematoma	6	3.3% (6/182)	0	0.0% (0/182)
Application site hemorrhage	1	0.5% (1/182)	0	0.0% (0/182)
Asthenia	0	0.0% (0/182)	3	1.6% (3/182)
Catheter site hemorrhage	2	1.1% (2/182)	0	0.0% (0/182)
Chest pain	1	0.5% (1/182)	3	1.6% (3/182)
Facial pain	1	0.5% (1/182)	0	0.0% (0/182)
Fatigue	2	1.1% (2/182)	1	0.5% (1/182)
Hypothermia	1	0.5% (1/182)	0	0.0% (0/182)
Local swelling	0	0.0% (0/182)	2	1.1% (2/182)
Pain	1	0.5% (1/182)	0	0.0% (0/182)
Procedural pain	0	0.0% (0/182)	1	0.5% (1/182)
Pyrexia	0	0.0% (0/182)	1	0.5% (1/182)
Seroma	0	0.0% (0/182)	1	0.5% (1/182)
Wound secretion	6	3.3% (6/182)	0	0.0% (0/182)
Immune system disorders	2	1.1% (2/182)	0	0.0% (0/182)

Hypersensitivity	2	1.1% (2/182)	0	0.0% (0/182)
Infections and infestations	8	3.3% (6/182)	25	10.4% (19/182)
Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Adverse Event Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Acute sinusitis	0	0.0% (0/182)	3	1.6% (3/182)
Bronchitis	0	0.0% (0/182)	2	1.1% (2/182)
Cellulitis	0	0.0% (0/182)	1	0.5% (1/182)
Enterocolitis viral	0	0.0% (0/182)	1	0.5% (1/182)
Groin infection	1	0.5% (1/182)	0	0.0% (0/182)
Herpes zoster	0	0.0% (0/182)	2	1.1% (2/182)
Influenza	0	0.0% (0/182)	1	0.5% (1/182)
Infusion site infection	1	0.5% (1/182)	0	0.0% (0/182)
Pelvic abscess	0	0.0% (0/182)	1	0.5% (1/182)
Peritonitis	0	0.0% (0/182)	1	0.5% (1/182)
Pharyngitis	0	0.0% (0/182)	1	0.5% (1/182)
Pneumonia	0	0.0% (0/182)	1	0.5% (1/182)
Sinusitis	1	0.5% (1/182)	2	1.1% (2/182)
Skin candida	0	0.0% (0/182)	1	0.5% (1/182)
Upper respiratory tract infection	0	0.0% (0/182)	1	0.5% (1/182)
Urinary tract infection	3	1.6% (3/182)	7	3.8% (7/182)
Viremia	1	0.5% (1/182)	0	0.0% (0/182)
Vulvovaginal mycotic infection	1	0.5% (1/182)	0	0.0% (0/182)
Injury, poisoning and procedural complications	8	3.8% (7/182)	13	6.6% (12/182)
Animal bite	0	0.0% (0/182)	1	0.5% (1/182)
Arterial restenosis	0	0.0% (0/182)	1	0.5% (1/182)
Catheter site discharge	1	0.5% (1/182)	0	0.0% (0/182)
Catheter site hemorrhage	1	0.5% (1/182)	0	0.0% (0/182)
Contusion	0	0.0% (0/182)	1	0.5% (1/182)
Fall	1	0.5% (1/182)	2	0.5% (1/182)
Incision site pain	2	0.5% (1/182)	0	0.0% (0/182)
Injury	0	0.0% (0/182)	1	0.5% (1/182)
Ligament sprain	0	0.0% (0/182)	1	0.5% (1/182)
Post procedural diarrhea	0	0.0% (0/182)	1	0.5% (1/182)
Post-traumatic headache	0	0.0% (0/182)	1	0.5% (1/182)
Procedural complication	1	0.5% (1/182)	0	0.0% (0/182)
Radius fracture	0	0.0% (0/182)	1	0.5% (1/182)
Skin injury	1	0.5% (1/182)	0	0.0% (0/182)
Soft tissue injury	0	0.0% (0/182)	1	0.5% (1/182)
Subdural hematoma	0	0.0% (0/182)	1	0.5% (1/182)
Toxicity to various agents	0	0.0% (0/182)	1	0.5% (1/182)
Vessel perforation	1	0.5% (1/182)	0	0.0% (0/182)
Investigations	1	0.5% (1/182)	1	0.5% (1/182)
Hemoglobin decreased	1	0.5% (1/182)	0	0.0% (0/182)
Occult blood	0	0.0% (0/182)	1	0.5% (1/182)
Metabolism and nutrition disorders	7	3.3% (6/182)	4	2.2% (4/182)

Decreased appetite	1	0.5% (1/182)	0	0.0% (0/182)
Dehydration	0	0.0% (0/182)	1	0.5% (1/182)
Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Adverse Event Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Diabetes mellitus inadequate control	0	0.0% (0/182)	1	0.5% (1/182)
Hypokalemia	5	2.7% (5/182)	0	0.0% (0/182)
Hypomagnesemia	1	0.5% (1/182)	0	0.0% (0/182)
Inappropriate antidiuretic hormone secretion	0	0.0% (0/182)	1	0.5% (1/182)
Vitamin D deficiency	0	0.0% (0/182)	1	0.5% (1/182)
Musculoskeletal and connective tissue disorders	3	1.6% (3/182)	23	10.4% (19/182)
Arthralgia	0	0.0% (0/182)	3	1.6% (3/182)
Back pain	1	0.5% (1/182)	5	2.7% (5/182)
Contusion	0	0.0% (0/182)	1	0.5% (1/182)
Groin pain	0	0.0% (0/182)	1	0.5% (1/182)
Hip fracture	0	0.0% (0/182)	1	0.5% (1/182)
Ligament sprain	0	0.0% (0/182)	1	0.5% (1/182)
Muscle hemorrhage	1	0.5% (1/182)	0	0.0% (0/182)
Musculoskeletal pain	1	0.5% (1/182)	1	0.5% (1/182)
Neck pain	0	0.0% (0/182)	3	1.6% (3/182)
Osteopenia	0	0.0% (0/182)	1	0.5% (1/182)
Pain in extremity	0	0.0% (0/182)	4	2.2% (4/182)
Rotator cuff syndrome	0	0.0% (0/182)	1	0.5% (1/182)
Wrist fracture	0	0.0% (0/182)	1	0.5% (1/182)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.5% (1/182)	5	2.7% (5/182)
Basel cell carcinoma	0	0.0% (0/182)	1	0.5% (1/182)
Gallbladder cancer	0	0.0% (0/182)	1	0.5% (1/182)
Lung adenocarcinoma	0	0.0% (0/182)	1	0.5% (1/182)
Malignant melanoma	0	0.0% (0/182)	1	0.5% (1/182)
Ovarian cyst	0	0.0% (0/182)	1	0.5% (1/182)
Prostate cancer	1	0.5% (1/182)	0	0.0% (0/182)
Nervous system disorders	84	33.5% (61/182)	71	29.7% (54/182)
Amnesia	0	0.0% (0/182)	2	1.1% (2/182)
Aphasia	1	0.5% (1/182)	1	0.5% (1/182)
Balance disorder	2	1.1% (2/182)	1	0.5% (1/182)
Carpal tunnel syndrome	0	0.0% (0/182)	1	0.5% (1/182)
Cerebral artery embolism	1	0.5% (1/182)	0	0.0% (0/182)
Cerebral infarction	3	1.6% (3/182)	0	0.0% (0/182)
Cerebral thrombosis	1	0.5% (1/182)	0	0.0% (0/182)
Cerebral vasoconstriction	14	7.7% (14/182)	0	0.0% (0/182)
Cervical myelopathy	0	0.0% (0/182)	1	0.5% (1/182)
Cognitive disorder	0	0.0% (0/182)	2	1.1% (2/182)
Complicated migraine	0	0.0% (0/182)	1	0.5% (1/182)
Confusional state	1	0.5% (1/182)	0	0.0% (0/182)
Convulsion	2	1.1% (2/182)	2	1.1% (2/182)
Dizziness	2	1.1% (2/182)	7	3.8% (7/182)

Hemorrhage intracranial	1	0.5% (1/182)	0	0.0% (0/182)
Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Adverse Event Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Headache	35	18.7% (34/182)	23	11.5% (21/182)
Hypoesthesia	3	1.1% (2/182)	5	2.7% (5/182)
Intracranial aneurysm	1	0.5% (1/182)	0	0.0% (0/182)
Ischemic stroke	4	2.2% (4/182)	5	2.7% (5/182)
Memory impairment	1	0.5% (1/182)	0	0.0% (0/182)
Migraine	0	0.0% (0/182)	2	1.1% (2/182)
Migraine with aura	1	0.5% (1/182)	0	0.0% (0/182)
Muscular weakness	0	0.0% (0/182)	2	1.1% (2/182)
Neuropathy peripheral	0	0.0% (0/182)	1	0.5% (1/182)
Ophthalmoplegic migraine	0	0.0% (0/182)	1	0.5% (1/182)
Paresthesia	0	0.0% (0/182)	3	1.6% (3/182)
Peripheral nerve lesion	1	0.5% (1/182)	0	0.0% (0/182)
Presyncope	1	0.5% (1/182)	1	0.5% (1/182)
Ruptured cerebral aneurysm	2	1.1% (2/182)	0	0.0% (0/182)
Sciatica	1	0.5% (1/182)	0	0.0% (0/182)
Speech disorder	1	0.5% (1/182)	0	0.0% (0/182)
Status migrainosus	0	0.0% (0/182)	1	0.5% (1/182)
Subarachnoid hemorrhage	2	1.1% (2/182)	1	0.5% (1/182)
Syncope	1	0.5% (1/182)	2	1.1% (2/182)
Transient ischemic attack	1	0.5% (1/182)	5	1.6% (3/182)
Unresponsive to stimuli	1	0.5% (1/182)	0	0.0% (0/182)
Visual field defect	0	0.0% (0/182)	1	0.5% (1/182)
Psychiatric disorders	0	0.0% (0/182)	9	4.9% (9/182)
Anxiety	0	0.0% (0/182)	2	1.1% (2/182)
Delirium	0	0.0% (0/182)	2	1.1% (2/182)
Depression	0	0.0% (0/182)	2	1.1% (2/182)
Insomnia	0	0.0% (0/182)	1	0.5% (1/182)
Panic attack	0	0.0% (0/182)	1	0.5% (1/182)
Phonophobia	0	0.0% (0/182)	1	0.5% (1/182)
Renal and urinary disorders	2	1.1% (2/182)	7	3.3% (6/182)
Acute prerenal failure	0	0.0% (0/182)	1	0.5% (1/182)
Dysuria	0	0.0% (0/182)	1	0.5% (1/182)
Enuresis	0	0.0% (0/182)	1	0.5% (1/182)
Hematuria	2	1.1% (2/182)	0	0.0% (0/182)
Nephrogenic anemia	0	0.0% (0/182)	1	0.5% (1/182)
Nephrolithiasis	0	0.0% (0/182)	1	0.5% (1/182)
Renal failure	0	0.0% (0/182)	1	0.5% (1/182)
Renal tubular necrosis	0	0.0% (0/182)	1	0.5% (1/182)
Respiratory, thoracic and mediastinal disorders	10	5.5% (10/182)	9	4.4% (8/182)
Acute respiratory failure	0	0.0% (0/182)	1	0.5% (1/182)
Chronic obstructive pulmonary disease	1	0.5% (1/182)	0	0.0% (0/182)
Cough	0	0.0% (0/182)	2	1.1% (2/182)

Dyspnea	0	0.0% (0/182)	1	0.5% (1/182)
Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Adverse Event Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Epistaxis	4	2.2% (4/182)	2	1.1% (2/182)
Hemoptysis	3	1.6% (3/182)	0	0.0% (0/182)
Laryngitis	0	0.0% (0/182)	1	0.5% (1/182)
Pneumonia aspiration	1	0.5% (1/182)	1	0.5% (1/182)
Pulmonary edema	1	0.5% (1/182)	1	0.5% (1/182)
Skin and subcutaneous tissue disorders	7	3.8% (7/182)	3	1.6% (3/182)
Cellulitis	1	0.5% (1/182)	0	0.0% (0/182)
Eczema	0	0.0% (0/182)	1	0.5% (1/182)
Pruritus generalized	0	0.0% (0/182)	1	0.5% (1/182)
Rash	4	2.2% (4/182)	0	0.0% (0/182)
Skin irritation	1	0.5% (1/182)	0	0.0% (0/182)
Skin ulcer	0	0.0% (0/182)	1	0.5% (1/182)
Urticaria	1	0.5% (1/182)	0	0.0% (0/182)
Surgical and medical procedures	3	1.6% (3/182)	18	8.2% (15/182)
Angioplasty	0	0.0% (0/182)	1	0.5% (1/182)
Colostomy	0	0.0% (0/182)	1	0.5% (1/182)
Eye operation	0	0.0% (0/182)	1	0.5% (1/182)
Hernia repair	0	0.0% (0/182)	1	0.5% (1/182)
Intra-cerebral aneurysm operation	0	0.0% (0/182)	9	3.8% (7/182)
Laryngeal polypectomy	0	0.0% (0/182)	1	0.5% (1/182)
Peripheral artery stent insertion	1	0.5% (1/182)	0	0.0% (0/182)
Renal stone removal	1	0.5% (1/182)	0	0.0% (0/182)
Rheumatoid nodule removal	0	0.0% (0/182)	1	0.5% (1/182)
Skin neoplasm excision	0	0.0% (0/182)	1	0.5% (1/182)
Spinal operation	0	0.0% (0/182)	1	0.5% (1/182)
Ureteral catheterization	1	0.5% (1/182)	0	0.0% (0/182)
Wound treatment	0	0.0% (0/182)	1	0.5% (1/182)
Vascular disorders	17	7.7% (14/182)	9	4.4% (8/182)
Arteriosclerosis	0	0.0% (0/182)	1	0.5% (1/182)
Arteriovenous fistula	1	0.5% (1/182)	0	0.0% (0/182)
Blood pressure fluctuation	1	0.5% (1/182)	0	0.0% (0/182)
Contusion	2	1.1% (2/182)	1	0.5% (1/182)
Deep vein thrombosis	0	0.0% (0/182)	1	0.5% (1/182)
Hemorrhage	0	0.0% (0/182)	1	0.5% (1/182)
Hypertension	0	0.0% (0/182)	3	1.6% (3/182)
Hypotension	6	2.7% (5/182)	0	0.0% (0/182)
Malignant hypertension	1	0.5% (1/182)	0	0.0% (0/182)
Retroperitoneal hemorrhage	1	0.5% (1/182)	0	0.0% (0/182)
Thrombosis in device	2	1.1% (2/182)	1	0.5% (1/182)
Tracheal hemorrhage	0	0.0% (0/182)	1	0.5% (1/182)
Vasospasm	1	0.5% (1/182)	0	0.0% (0/182)
Venous thrombosis limb	2	0.5% (1/182)	0	0.0% (0/182)

Serious adverse events (SAEs) that were CEC-adjudicated to be related to the device are summarized in Table 4. Ten events were reported to occur peri-procedurally in 8 subjects in the Anterior Cohort. After 30 days, an additional 10 events were reported to occur in 7 subjects.

Table 4. Serious Adverse Events Adjudicated to be Related to the Device - mITT Population, Anterior Cohort

Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Adverse Event Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Any Adverse Event (AE)	10	4.4% (8/182)	10	3.8% (7/182)
Nervous system disorders	9	4.4% (8/182)	5	2.2% (4/182)
Cerebral artery embolism	1	0.5% (1/182)	0	0.0% (0/182)
Hemorrhage intracranial	1	0.5% (1/182)	0	0.0% (0/182)
Headache	1	0.5% (1/182)	0	0.0% (0/182)
Ischemic stroke	3	1.6% (3/182)	2	1.1% (2/182)
Ruptured cerebral aneurysm	1	0.5% (1/182)	0	0.0% (0/182)
Subarachnoid hemorrhage	2	1.1% (2/182)	0	0.0% (0/182)
Transient ischemic attack	0	0.0% (0/182)	3	1.1% (2/182)
Surgical and medical procedures	0	0.0% (0/182)	5	2.2% (4/182)
Intra-cerebral aneurysm operation	0	0.0% (0/182)	5	2.2% (4/182)
Vascular disorders	1	0.5% (1/182)	0	0.0% (0/182)
Thrombosis in device	1	0.5% (1/182)	0	0.0% (0/182)

Procedure-related SAEs are summarized in Table 5. Twenty events were reported to occur peri-procedurally in 12 subjects. After 30 days, an additional 9 events were reported to occur in 5 subjects.

Table 5. Site-reported Procedure-related Serious Adverse Events - mITT Population, Anterior Cohort

Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Adverse Event Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Any Adverse Event (AE)	20	6.6% (12/182)	9	2.7% (5/182)
Gastrointestinal disorders	0	0.0% (0/182)	1	0.5% (1/182)
Gastrointestinal hemorrhage	0	0.0% (0/182)	1	0.5% (1/182)
General disorders and administration site conditions	1	0.5% (1/182)	0	0.0% (0/182)
Application site hematoma	1	0.5% (1/182)	0	0.0% (0/182)
Infections and infestations	1	0.5% (1/182)	0	0.0% (0/182)
Groin infection	1	0.5% (1/182)	0	0.0% (0/182)
Injury, poisoning and procedural complications	2	1.1% (2/182)	0	0.0% (0/182)
Procedural complication	1	0.5% (1/182)	0	0.0% (0/182)
Vessel perforation	1	0.5% (1/182)	0	0.0% (0/182)
Musculoskeletal and connective tissue disorders	1	0.5% (1/182)	0	0.0% (0/182)

Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Adverse Event Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Muscle hemorrhage	1	0.5% (1/182)	0	0.0% (0/182)
Nervous system disorders	12	4.9% (9/182)	3	1.1% (2/182)
Cerebral artery embolism	1	0.5% (1/182)	0	0.0% (0/182)
Convulsion	1	0.5% (1/182)	0	0.0% (0/182)
Headache	1	0.5% (1/182)	0	0.0% (0/182)
Intracranial aneurysm	1	0.5% (1/182)	0	0.0% (0/182)
Ischemic stroke	4	2.2% (4/182)	0	0.0% (0/182)
Ruptured cerebral aneurysm	2	1.1% (2/182)	0	0.0% (0/182)
Subarachnoid hemorrhage	2	1.1% (2/182)	0	0.0% (0/182)
Transient ischemic attack	0	0.0% (0/182)	3	1.1% (2/182)
Surgical and medical procedures	0	0.0% (0/182)	5	2.2% (4/182)
Intra-cerebral aneurysm operation	0	0.0% (0/182)	5	2.2% (4/182)
Vascular disorders	3	1.6% (3/182)	0	0.0% (0/182)
Retroperitoneal hemorrhage	1	0.5% (1/182)	0	0.0% (0/182)
Thrombosis in device	1	0.5% (1/182)	0	0.0% (0/182)
Venous thrombosis limb	1	0.5% (1/182)	0	0.0% (0/182)

Incidence of Ischemic and Hemorrhagic Adverse Events, Anterior Cohort

The incidence of all CEC adjudicated ischemic or hemorrhagic adverse events (i.e., ischemic and hemorrhagic, ipsilateral and contralateral, of all severities, at all times after enrollment, and of any duration, including TIAs) that occurred in the study was 11.3% (18/160) and 9.1% (2/22) in the subject cohorts with unruptured and ruptured aneurysms, respectively (Table 6). For all subjects, the overall event rate was 11.0% (20/182; unadjusted 95% CI: 6.8%, 16.5%).

Table 6. mITT Subjects with Cerebrovascular Events during Study Period – Anterior Cohort

		Unruptured			Ruptured		
CEC-adjudicated Categories [1]	Adverse Event Term [2]	# of Events	# of Subjects	% Subjects (n/N)	# of Events	# of Subjects	% Subjects (n/N)
Stroke, minor		8	8	5.0% (8/160)	0	0	0.0% (0/22)
	Aphasia	1	1	0.6% (1/160)	0	0	0.0% (0/22)
	Ischemic stroke	2	2	1.3% (2/160)	0	0	0.0% (0/22)
	Muscular weakness	1	1	0.6% (1/160)	0	0	0.0% (0/22)
	SAH	1	1	0.6% (1/160)	0	0	0.0% (0/22)
	Ruptured cerebral aneurysm	1	1	0.6% (1/160)	0	0	0.0% (0/22)
	TIA	2	2	1.3% (2/160)	0	0	0.0% (0/22)
Ischemic stroke, major		6	6	3.8% (6/160)	2	2	9.1% (2/22)
	Confusional state	1	1	0.6% (1/160)	0	0	0.0% (0/22)
	Ischemic stroke	4	4	2.5% (4/160)	2	2	9.1% (2/22)
	TIA	1	1	0.6% (1/160)	0	0	0.0% (0/22)
SAH or SAH/aneurysm rupture		7	7	4.4% (7/160)	0	0	0.0% (0/22)
	ICH	1	1	0.6% (1/160)	0	0	0.0% (0/22)
	SAH	3	3	1.9% (3/160)	0	0	0.0% (0/22)

	Ruptured cerebral aneurysm	2	2	1.3% (2/160)	0	0	0.0% (0/22)
	Vessel perforation	1	1	0.6% (1/160)	0	0	0.0% (0/22)
Not a stroke/ SAH/aneurysm rupture		3	2	1.3% (2/160)	0	0	0.0% (0/22)
	TIA	3	2	1.3% (2/160)	0	0	0.0% (0/22)
Overall		22	18	11.3% (18/160)	2	2	9.1% (2/22)

[1] AEs could be adjudicated into more than one CEC category; therefore, event/subject counts across CEC categories are not additive. A total of 24 separate AEs occurred in 20 subjects.
[2] ICH: intracranial hemorrhage; SAH: subarachnoid hemorrhage; TIA: transient ischemic attack

SUMMARY OF ADVERSE EVENTS - POSTERIOR CIRCULATION COHORT

An overall summary of all AEs that occurred in the Posterior-Circulation Cohort, referred to as the Posterior Cohort herein, is shown in Table 7. A total of 137 events were reported during the peri-procedural period in 64 subjects. After 30 days (31 days to 12 months), 188 events occurred in 67 subjects.

Table 7. Site-reported Overall Summary of Adverse Events - mITT Population, Posterior Cohort

Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Preferred Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Any Adverse Event(AE)	137	55.2% (64/116)	188	57.8% (67/116)
Blood and lymphatic system disorders	4	3.4% (4/116)	3	2.6% (3/116)
Anemia	1	0.9% (1/116)	0	0.0% (0/116)
Increased tendency to bruise	3	2.6% (3/116)	2	1.7% (2/116)
Myelodysplastic syndrome	0	0.0% (0/116)	1	0.9% (1/116)
Cardiac disorders	2	1.7% (2/116)	3	2.6% (3/116)
Atrial fibrillation	0	0.0% (0/116)	1	0.9% (1/116)
Cardiac failure congestive	0	0.0% (0/116)	1	0.9% (1/116)
Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Preferred Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Chest pain	1	0.9% (1/116)	0	0.0% (0/116)
Myocardial infarction	0	0.0% (0/116)	1	0.9% (1/116)
Sinus tachycardia	1	0.9% (1/116)	0	0.0% (0/116)
Ear and labyrinth disorders	2	1.7% (2/116)	4	3.4% (4/116)
Ear pain	1	0.9% (1/116)	2	1.7% (2/116)
Tinnitus	1	0.9% (1/116)	1	0.9% (1/116)
Vertigo	0	0.0% (0/116)	1	0.9% (1/116)
Endocrine disorders	0	0.0% (0/116)	2	1.7% (2/116)
Hypothyroidism	0	0.0% (0/116)	1	0.9% (1/116)
Pituitary cyst	0	0.0% (0/116)	1	0.9% (1/116)
Eye disorders	10	8.6% (10/116)	9	7.8% (9/116)
Corneal abrasion	1	0.9% (1/116)	0	0.0% (0/116)
Diplopia	1	0.9% (1/116)	1	0.9% (1/116)
Eye pain	1	0.9% (1/116)	0	0.0% (0/116)
Eyelid disorder	1	0.9% (1/116)	0	0.0% (0/116)

Eyelid ptosis	0	0.0% (0/116)	1	0.9% (1/116)
Halo vision	1	0.9% (1/116)	0	0.0% (0/116)
Macular hole	0	0.0% (0/116)	1	0.9% (1/116)
Photophobia	1	0.9% (1/116)	1	0.9% (1/116)
Photopsia	1	0.9% (1/116)	0	0.0% (0/116)
Vision blurred	1	0.9% (1/116)	1	0.9% (1/116)
Visual acuity reduced	0	0.0% (0/116)	1	0.9% (1/116)
Visual impairment	2	1.7% (2/116)	2	1.7% (2/116)
Vitreous floaters	0	0.0% (0/116)	1	0.9% (1/116)
Gastrointestinal disorders	8	6.0% (7/116)	16	7.8% (9/116)
Abdominal distension	0	0.0% (0/116)	1	0.9% (1/116)
Abdominal pain upper	0	0.0% (0/116)	2	1.7% (2/116)
Constipation	1	0.9% (1/116)	2	1.7% (2/116)
Diarrhea	0	0.0% (0/116)	1	0.9% (1/116)
Dysphagia	1	0.9% (1/116)	3	2.6% (3/116)
Flatulence	0	0.0% (0/116)	1	0.9% (1/116)
Gastric ulcer	1	0.9% (1/116)	0	0.0% (0/116)
Gastrointestinal hemorrhage	0	0.0% (0/116)	1	0.9% (1/116)
Hematemesis	1	0.9% (1/116)	0	0.0% (0/116)
Hematochezia	0	0.0% (0/116)	1	0.9% (1/116)
Inguinal hernia	0	0.0% (0/116)	1	0.9% (1/116)
Nausea	1	0.9% (1/116)	2	1.7% (2/116)
Esophageal stenosis	1	0.9% (1/116)	0	0.0% (0/116)
Vomiting	2	1.7% (2/116)	1	0.9% (1/116)
General disorders and administration site conditions	11	9.5% (11/116)	5	3.4% (4/116)
Application site hematoma	3	2.6% (3/116)	1	0.9% (1/116)
Asthenia	1	0.9% (1/116)	0	0.0% (0/116)
Chest pain	0	0.0% (0/116)	3	2.6% (3/116)
Device dislocation	1	0.9% (1/116)	0	0.0% (0/116)
Fatigue	2	1.7% (2/116)	0	0.0% (0/116)
Local swelling	0	0.0% (0/116)	1	0.9% (1/116)
Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Preferred Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Puncture site erythema	1	0.9% (1/116)	0	0.0% (0/116)
Wound secretion	3	2.6% (3/116)	0	0.0% (0/116)
Immune system disorders	1	0.9% (1/116)	0	0.0% (0/116)
Hypersensitivity	1	0.9% (1/116)	0	0.0% (0/116)
Infections and infestations	11	7.8% (9/116)	15	9.5% (11/116)
Bronchitis	0	0.0% (0/116)	1	0.9% (1/116)
Conjunctivitis	1	0.9% (1/116)	0	0.0% (0/116)
Cystitis	0	0.0% (0/116)	1	0.9% (1/116)
Ear infection	0	0.0% (0/116)	1	0.9% (1/116)
Herpes zoster	0	0.0% (0/116)	1	0.9% (1/116)
Human anaplasmosis	0	0.0% (0/116)	1	0.9% (1/116)
Pharyngitis	1	0.9% (1/116)	0	0.0% (0/116)
Pneumonia bacterial	0	0.0% (0/116)	1	0.9% (1/116)
Pneumonia staphylococcal	1	0.9% (1/116)	0	0.0% (0/116)
Sinusitis	1	0.9% (1/116)	0	0.0% (0/116)

Upper respiratory tract infection	1	0.9% (1/116)	3	1.7% (2/116)
Urinary tract infection	6	5.2% (6/116)	3	2.6% (3/116)
Vaginal infection	0	0.0% (0/116)	1	0.9% (1/116)
Viral infection	0	0.0% (0/116)	1	0.9% (1/116)
Viral sinusitis	0	0.0% (0/116)	1	0.9% (1/116)
Injury, poisoning and procedural complications	8	6.0% (7/116)	14	9.5% (11/116)
Arterial restenosis	0	0.0% (0/116)	1	0.9% (1/116)
Catheter site hemorrhage	2	1.7% (2/116)	0	0.0% (0/116)
Contrast encephalopathy	1	0.9% (1/116)	0	0.0% (0/116)
Corneal abrasion	1	0.9% (1/116)	0	0.0% (0/116)
Craniocerebral injury	0	0.0% (0/116)	1	0.9% (1/116)
Face injury	0	0.0% (0/116)	1	0.9% (1/116)
Fall	0	0.0% (0/116)	7	4.3% (5/116)
Femoral nerve injury	1	0.9% (1/116)	0	0.0% (0/116)
Head injury	0	0.0% (0/116)	1	0.9% (1/116)
Laceration	0	0.0% (0/116)	1	0.9% (1/116)
Post procedural complication	0	0.0% (0/116)	1	0.9% (1/116)
Procedural nausea	1	0.9% (1/116)	0	0.0% (0/116)
Subdural hematoma	0	0.0% (0/116)	1	0.9% (1/116)
Vascular pseudoaneurysm	2	1.7% (2/116)	0	0.0% (0/116)
Investigations	2	1.7% (2/116)	1	0.9% (1/116)
Hemoglobin decreased	1	0.9% (1/116)	0	0.0% (0/116)
Pulmonary physical examination abnormal	0	0.0% (0/116)	1	0.9% (1/116)
Weight increased	1	0.9% (1/116)	0	0.0% (0/116)
Metabolism and nutrition disorders	5	4.3% (5/116)	6	1.7% (2/116)
Dehydration	1	0.9% (1/116)	0	0.0% (0/116)
Diabetes mellitus	0	0.0% (0/116)	1	0.9% (1/116)
Diabetic ketoacidosis	0	0.0% (0/116)	2	0.9% (1/116)
Electrolyte imbalance	1	0.9% (1/116)	0	0.0% (0/116)
Hyperglycemia	0	0.0% (0/116)	1	0.9% (1/116)
Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Preferred Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Hypokalemia	3	2.6% (3/116)	1	0.9% (1/116)
Hyponatremia	0	0.0% (0/116)	1	0.9% (1/116)
Musculoskeletal and connective tissue disorders	6	4.3% (5/116)	15	10.3% (12/116)
Arthralgia	0	0.0% (0/116)	1	0.9% (1/116)
Back pain	1	0.9% (1/116)	1	0.9% (1/116)
Hemarthrosis	1	0.9% (1/116)	0	0.0% (0/116)
Muscle spasms	0	0.0% (0/116)	4	3.4% (4/116)
Musculoskeletal pain	0	0.0% (0/116)	1	0.9% (1/116)
Neck pain	3	2.6% (3/116)	2	1.7% (2/116)
Osteoarthritis	0	0.0% (0/116)	1	0.9% (1/116)
Pain in extremity	1	0.9% (1/116)	2	1.7% (2/116)
Periarthritis	0	0.0% (0/116)	2	0.9% (1/116)
Rheumatoid arthritis	0	0.0% (0/116)	1	0.9% (1/116)
Neoplasms benign, malignant and unspecified (incl cysts and	0	0.0% (0/116)	3	2.6% (3/116)

Basal cell carcinoma	0	0.0% (0/116)	1	0.9% (1/116)
Benign neoplasm of thyroid gland	0	0.0% (0/116)	1	0.9% (1/116)
Small cell lung cancer recurrent	0	0.0% (0/116)	1	0.9% (1/116)
Nervous system disorders	51	31.9% (37/116)	54	33.6% (39/116)
Balance disorder	0	0.0% (0/116)	1	0.9% (1/116)
Brain edema	1	0.9% (1/116)	0	0.0% (0/116)
Cerebral artery thrombosis	1	0.9% (1/116)	0	0.0% (0/116)
Cerebral infarction	2	1.7% (2/116)	2	1.7% (2/116)
Cerebral vasoconstriction	12	10.3% (12/116)	1	0.9% (1/116)
Convulsion	1	0.9% (1/116)	2	1.7% (2/116)
Disturbance in attention	0	0.0% (0/116)	1	0.9% (1/116)
Dizziness	2	1.7% (2/116)	6	5.2% (6/116)
Dysarthria	0	0.0% (0/116)	1	0.9% (1/116)
Embolic stroke	0	0.0% (0/116)	1	0.9% (1/116)
Gait disturbance	0	0.0% (0/116)	2	1.7% (2/116)
Generalised tonic-clonic seizure	1	0.9% (1/116)	1	0.9% (1/116)
Hand-eye coordination impaired	1	0.9% (1/116)	0	0.0% (0/116)
Headache	18	15.5% (18/116)	11	8.6% (10/116)
Hemiparesis	1	0.9% (1/116)	2	1.7% (2/116)
Hydrocephalus	0	0.0% (0/116)	1	0.9% (1/116)
Hyperesthesia	0	0.0% (0/116)	1	0.9% (1/116)
Hypoesthesia	4	2.6% (3/116)	2	0.9% (1/116)
Intracranial aneurysm	0	0.0% (0/116)	1	0.9% (1/116)
Ischemic stroke	2	1.7% (2/116)	2	1.7% (2/116)
Lethargy	1	0.9% (1/116)	0	0.0% (0/116)
Memory impairment	0	0.0% (0/116)	1	0.9% (1/116)
Migraine	0	0.0% (0/116)	1	0.9% (1/116)
Migraine with aura	0	0.0% (0/116)	1	0.9% (1/116)
Paresthesia	0	0.0% (0/116)	2	1.7% (2/116)
Presyncope	0	0.0% (0/116)	1	0.9% (1/116)
Subarachnoid hemorrhage	2	1.7% (2/116)	0	0.0% (0/116)
Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Preferred Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Subdural hygroma	0	0.0% (0/116)	1	0.9% (1/116)
Transient ischemic attack	1	0.9% (1/116)	5	3.4% (4/116)
Tremor	0	0.0% (0/116)	1	0.9% (1/116)
Vertebral artery dissection	1	0.9% (1/116)	3	2.6% (3/116)
Psychiatric disorders	1	0.9% (1/116)	2	1.7% (2/116)
Nervousness	1	0.9% (1/116)	0	0.0% (0/116)
Post-traumatic stress disorder	0	0.0% (0/116)	1	0.9% (1/116)
Staring	0	0.0% (0/116)	1	0.9% (1/116)
Renal and urinary disorders	1	0.9% (1/116)	5	2.6% (3/116)
Hydronephrosis	0	0.0% (0/116)	1	0.9% (1/116)
Proteinuria	1	0.9% (1/116)	0	0.0% (0/116)
Renal atrophy	0	0.0% (0/116)	1	0.9% (1/116)
Renal failure acute	0	0.0% (0/116)	2	0.9% (1/116)
Urinary retention	0	0.0% (0/116)	1	0.9% (1/116)
Reproductive system and breast disorders	0	0.0% (0/116)	1	0.9% (1/116)
Benign prostatic hyperplasia	0	0.0% (0/116)	1	0.9% (1/116)

Respiratory, thoracic and mediastinal disorders	6	5.2% (6/116)	5	4.3% (5/116)
Bronchospasm	1	0.9% (1/116)	0	0.0% (0/116)
Cough	1	0.9% (1/116)	0	0.0% (0/116)
Dyspnea	1	0.9% (1/116)	0	0.0% (0/116)
Epistaxis	2	1.7% (2/116)	1	0.9% (1/116)
Hypoxia	0	0.0% (0/116)	1	0.9% (1/116)
Oropharyngeal pain	1	0.9% (1/116)	1	0.9% (1/116)
Pneumonia aspiration	0	0.0% (0/116)	1	0.9% (1/116)
Sleep apnea syndrome	0	0.0% (0/116)	1	0.9% (1/116)
Skin and subcutaneous tissue disorders	1	0.9% (1/116)	7	4.3% (5/116)
Acne	0	0.0% (0/116)	1	0.9% (1/116)
Alopecia	0	0.0% (0/116)	2	1.7% (2/116)
Dermatitis contact	0	0.0% (0/116)	1	0.9% (1/116)
Pruritus	1	0.9% (1/116)	0	0.0% (0/116)
Rash	0	0.0% (0/116)	2	1.7% (2/116)
Swelling face	0	0.0% (0/116)	1	0.9% (1/116)
Surgical and medical procedures	1	0.9% (1/116)	14	11.2% (13/116)
Carotid artery stent insertion	0	0.0% (0/116)	1	0.9% (1/116)
Coronary artery bypass	0	0.0% (0/116)	1	0.9% (1/116)
Intra-cerebral aneurysm operation	1	0.9% (1/116)	10	8.6% (10/116)
Percutaneous coronary intervention	0	0.0% (0/116)	1	0.9% (1/116)
Vertebroplasty	0	0.0% (0/116)	1	0.9% (1/116)
Vascular disorders	6	5.2% (6/116)	4	3.4% (4/116)
Carotid artery stenosis	0	0.0% (0/116)	1	0.9% (1/116)
Hypertension	1	0.9% (1/116)	1	0.9% (1/116)
Hypotension	1	0.9% (1/116)	0	0.0% (0/116)
Peripheral ischemia	1	0.9% (1/116)	0	0.0% (0/116)
Retroperitoneal hemorrhage	1	0.9% (1/116)	1	0.9% (1/116)
Thrombosis in device	2	1.7% (2/116)	1	0.9% (1/116)

Serious adverse events (SAEs) that were CEC-adjudicated to be related to the device are summarized in Table 8. Seven events were reported to occur peri-procedurally in 7 subjects in the Posterior Cohort. After 30 days, an additional 15 events were reported to occur in 13 subjects.

Table 8. Serious Adverse Events Adjudicated to be Related to the Device - mITT Population, Posterior Cohort

Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Adverse Event Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Any Adverse Event (AE)	7	6.0% (7/116)	15	11.2% (13/116)
Injury, poisoning and procedural complications	0	0.0% (0/116)	1	0.9% (1/116)
Subdural hematoma	0	0.0% (0/116)	1	0.9% (1/116)
Nervous system disorders	5	4.3% (5/116)	5	3.4% (4/116)
Cerebral infarction	1	0.9% (1/116)	0	0.0% (0/116)
Embolic stroke	0	0.0% (0/116)	1	0.9% (1/116)
Ischemic stroke	1	0.9% (1/116)	1	0.9% (1/116)

Subarachnoid hemorrhage	2	1.7% (2/116)	0	0.0% (0/116)
Transient ischemic attack	1	0.9% (1/116)	3	1.7% (2/116)
Respiratory, thoracic and mediastinal disorders	0	0.0% (0/116)	1	0.9% (1/116)
Pneumonia aspiration	0	0.0% (0/116)	1	0.9% (1/116)
Surgical and medical procedures	0	0.0% (0/116)	8	6.9% (8/116)
Intra-cerebral aneurysm operation	0	0.0% (0/116)	8	6.9% (8/116)
Vascular disorders	2	1.7% (2/116)	0	0.0% (0/116)
Thrombosis in device	2	1.7% (2/116)	0	0.0% (0/116)

Procedure-related SAEs are summarized in Table 9. Fourteen events were reported to occur peri-procedurally in 12 subjects. After 30 days, an additional 9 events were reported to occur in 9 subjects.

Table 9. Site-reported Procedure-related Serious Adverse Events - mITT Population, Posterior Cohort

Adverse Event	Peri-Procedure		Post-Procedure	
System Organ Class/Adverse Event Term	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Any Adverse Event (AE)	14	10.3% (12/116)	9	7.8% (9/116)
General disorders and administration site conditions	2	1.7% (2/116)	0	0.0% (0/116)
Application site hematoma	2	1.7% (2/116)	0	0.0% (0/116)
Injury, poisoning and procedural complications	2	1.7% (2/116)	0	0.0% (0/116)
Vascular pseudoaneurysm	2	1.7% (2/116)	0	0.0% (0/116)
Musculoskeletal and connective tissue disorders	1	0.9% (1/116)	0	0.0% (0/116)
Neck pain	1	0.9% (1/116)	0	0.0% (0/116)
Nervous system disorders	6	4.3% (5/116)	3	2.6% (3/116)

Adverse Event System Organ Class/Adverse Event Term	Peri-Procedure		Post-Procedure	
	# Events	% Subjects with Event (n/N)	# Events	% Subjects with Event (n/N)
Cerebral infarction	1	0.9% (1/116)	0	0.0% (0/116)
Headache	0	0.0% (0/116)	1	0.9% (1/116)
Ischemic stroke	1	0.9% (1/116)	1	0.9% (1/116)
Subarachnoid hemorrhage	2	1.7% (2/116)	0	0.0% (0/116)
Transient ischemic attack	1	0.9% (1/116)	1	0.9% (1/116)
Vertebral artery dissection	1	0.9% (1/116)	0	0.0% (0/116)
Surgical and medical procedures	0	0.0% (0/116)	6	5.2% (6/116)
Intra-cerebral aneurysm operation	0	0.0% (0/116)	6	5.2% (6/116)
Vascular disorders	3	2.6% (3/116)	0	0.0% (0/116)
Peripheral ischemia	1	0.9% (1/116)	0	0.0% (0/116)
Thrombosis in device	2	1.7% (2/116)	0	0.0% (0/116)

Incidence of Ischemic and Hemorrhagic Adverse Events, Posterior Cohort

The incidence of all CEC adjudicated ischemic or hemorrhagic adverse events (i.e., ischemic and hemorrhagic, ipsilateral and contralateral, of all severities, at all times after enrollment, and of any duration, including TIAs) that occurred in the study was 17.5% (18/103) and 7.7% (1/13) in the posterior cohort subjects with unruptured and ruptured aneurysms, respectively (Table 10). For all subjects, the overall event rate was 16.4% (19/116; unadjusted 95% CI: 10.2%, 24.4%).

Table 10. mITT Subjects with Cerebrovascular Events during Study Period – Posterior Cohort

		Unruptured			Ruptured		
CEC-adjudicated Categories	Adverse Event Term [1]	# of Events	# of Subjects	% Subjects (n/N)	# of Events	# of Subjects	% Subjects (n/N)
Stroke, minor		10	10	9.7% (10/103)	1	1	7.7% (1/13)
	Cerebral infarction	2	2	1.9% (2/103)	0	0	0.0% (0/13)
	Dizziness	1	1	1.0% (1/103)	0	0	0.0% (0/13)
	Embolic stroke	0	0	0.0% (0/103)	1	1	7.7% (1/13)
	Hyperesthesia	1	1	1.0% (1/103)	0	0	0.0% (0/13)
	Ischemic stroke	3	3	2.9% (3/103)	0	0	0.0% (0/13)
	TIA	2	2	1.9% (2/103)	0	0	0.0% (0/13)
	Visual impairment	1	1	1.0% (1/103)	0	0	0.0% (0/13)
Ischemic stroke, major		4	3	2.9% (3/103)	0	0	0% (0/13)
	Brain edema	1	1	1.0% (1/103)	0	0	0.0% (0/13)

		Unruptured			Ruptured		
CEC-adjudicated Categories	Adverse Event Term [1]	# of Events	# of Subjects	% Subjects (n/N)	# of Events	# of Subjects	% Subjects (n/N)
	Contrast encephalopathy	1	1	1.0% (1/103)	0	0	0.0% (0/13)
	Ischemic stroke	1	1	1.0% (1/103)	0	0	0.0% (0/13)
	Thrombosis in device	1	1	1.0% (1/103)	0	0	0.0% (0/13)
SAH or SAH/aneurysm rupture		2	2	1.9% (2/103)	0	0	0% (0/13)
	SAH	2	2	1.9% (2/103)	0	0	0.0% (0/13)
Not a stroke/SAH/aneurysm rupture		4	4	3.9% (4/103)	0	0	0% (0/13)
	TIA	4	4	3.9% (4/103)	0	0	0.0% (0/13)
Overall [2]		20	18	17.5% (18/103)	1	1	7.7% (1/13)

[1] ICH: intracranial hemorrhage; SAH: subarachnoid hemorrhage; TIA: transient ischemic attack.
[2] AEs could be adjudicated into more than one CEC category; therefore, event/subject counts across CEC categories are not additive. Subjects could experience more than one event, a total of 21 separate AEs occurred in 19 subjects (18 unruptured and 1 ruptured subjects).

SUMMARY OF ATLAS CLINICAL TRIAL RESULTS

ATLAS trial (SAfety and Effectiveness of the Treatment of Wide Neck, Saccular IntracraniaL Aneurysms with the Neuroform Atlas® Stent System)

Purpose

The purpose of the ATLAS trial was to evaluate the safety and effectiveness of the Neuroform Atlas Stent System compared to established performance goals in the treatment of wide-neck intracranial aneurysms.

Design

The ATLAS trial was designed as a multi-center, prospective, non-randomized 2-cohort trial (anterior-circulation and posterior-circulation) to evaluate the safety and effectiveness of the Neuroform Atlas Stent System against objective performance criteria. The pivotal study included follow-up at post-implant, 2 months, 6 months, and 12-months post-procedure.

Subject Inclusion Criteria

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

1. Subject is between 18 and 80 years of age.
2. Documented wide neck (neck ≥ 4 mm or a dome-to-neck ratio of < 2) intracranial, saccular aneurysm arising from a parent vessel with a diameter of ≥ 2 mm and ≤ 4.5 mm, which will be treated with bare metal coils.
3. Subject or legal representative is willing and able to provide informed consent.
4. Subject is willing and able to comply with protocol follow-up requirements.

Subject Exclusion Criteria

Candidates excluded from the study met the following criteria:

1. Known multiple untreated cerebral aneurysms, other than non-target blister aneurysm, infundibulum, or aneurysm measuring < 3 mm for each of three dimensions assessed (height, width, and depth) that will not require treatment during the study period.
2. Target lesion is a blister aneurysm, infundibulum, or aneurysm measuring < 3 mm for each of three dimensions assessed (height, width, and depth).
3. Target aneurysm that will require an Investigator to intentionally leave a neck remnant in order to preserve blood flow in a bifurcation or branch.
4. Coiling or stenting of a non-target intracranial aneurysm within 30 days prior to study treatment.
5. Target aneurysm is in the anterior circulation proximal to the superior hypophyseal internal carotid artery (ICA).
6. Acute target aneurysm rupture less than 14 days prior to study treatment.
7. Hunt and Hess score ≥ 3 or a pre-morbid mRS score ≥ 4.
8. An admission platelet count of < 50,000, any known coagulopathy, or an International Normalized Ratio (INR) > 3.0 without oral anticoagulation therapy.
9. A known absolute contraindication to angiography.
10. Evidence of active cancer, terminal illness or any condition which, in the opinion of the

treating physician, would/could prevent subject from completing the study (e.g., a high risk of embolic stroke, atrial fibrillation, co-morbidities, psychiatric disorders, substance abuse, major surgery ≤ 30 days pre-procedure, etc.).
11. Known absolute contraindication to the use of required study medications or agents (e.g., heparin, aspirin, clopidogrel, and radiographic contrast agents, etc.).
12. Female subject who is pregnant or intends to become pregnant during the study.
13. Moya-Moya disease, arteriovenous malformation(s), arteriovenous fistula(e), intracranial tumor(s), or intracranial hematoma(s) (unrelated to target aneurysm).
14. Significant atherosclerotic stenosis, significant vessel tortuosity, vasospasm refractory to medication, unfavorable aneurysm morphology or vessel anatomy, or some other condition(s) that, in the opinion of the treating physician, would/could prevent or interfere with access to the target aneurysm and/or successful deployment of the Neuroform Atlas® Stent.
15. Previous treatment (e.g., surgery, stenting) in the parent artery that, in the opinion of the treating physician, would/could prevent or interfere with successful use of the Neuroform Atlas® Stent System and/or successful adjunctive deployment of embolic coils.
16. Previous stent-assisted coiling of the target aneurysm.

Study success was determined by meeting 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. For both the Anterior and Posterior Cohorts, primary effectiveness was defined as a composite of complete target intracranial aneurysm occlusion at the time of 12-month angiography in the absence of retreatment, or significant parent artery stenosis (> 50%) at the target location as evaluated by an independent 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). An ipsilateral stroke was defined as an acute episode of focal or global neurological dysfunction due to brain or retinal infarction, or due to an intracranial hemorrhage inclusive of subarachnoid, intraventricular or intraparenchymal hemorrhage, occurring in the same hemisphere as the target intracranial aneurysm. A major ipsilateral stroke was defined as an ipsilateral stroke that is associated with an increase of 4 or more points on the NIHSS at 24 hours after symptom onset.

Based on information derived from pre-study review of available medical literature, the ATLAS trial was designed to be considered a success in the Anterior Cohort if the primary effectiveness endpoint rate was statistically > 50% and the primary safety endpoint rate was statistically < 20%. For the Posterior Cohort, trial success was declared if the primary effectiveness endpoint rate was statistically > 50% and the primary safety endpoint rate was statistically < 25%.

Trial results for the Anterior Cohort and Posterior Cohort are presented separately below.

Subject Accountability

Figure 4 is a subject accountability flowchart that details the total number of subjects enrolled in the Anterior Cohort and subject disposition through 12-month follow-up.

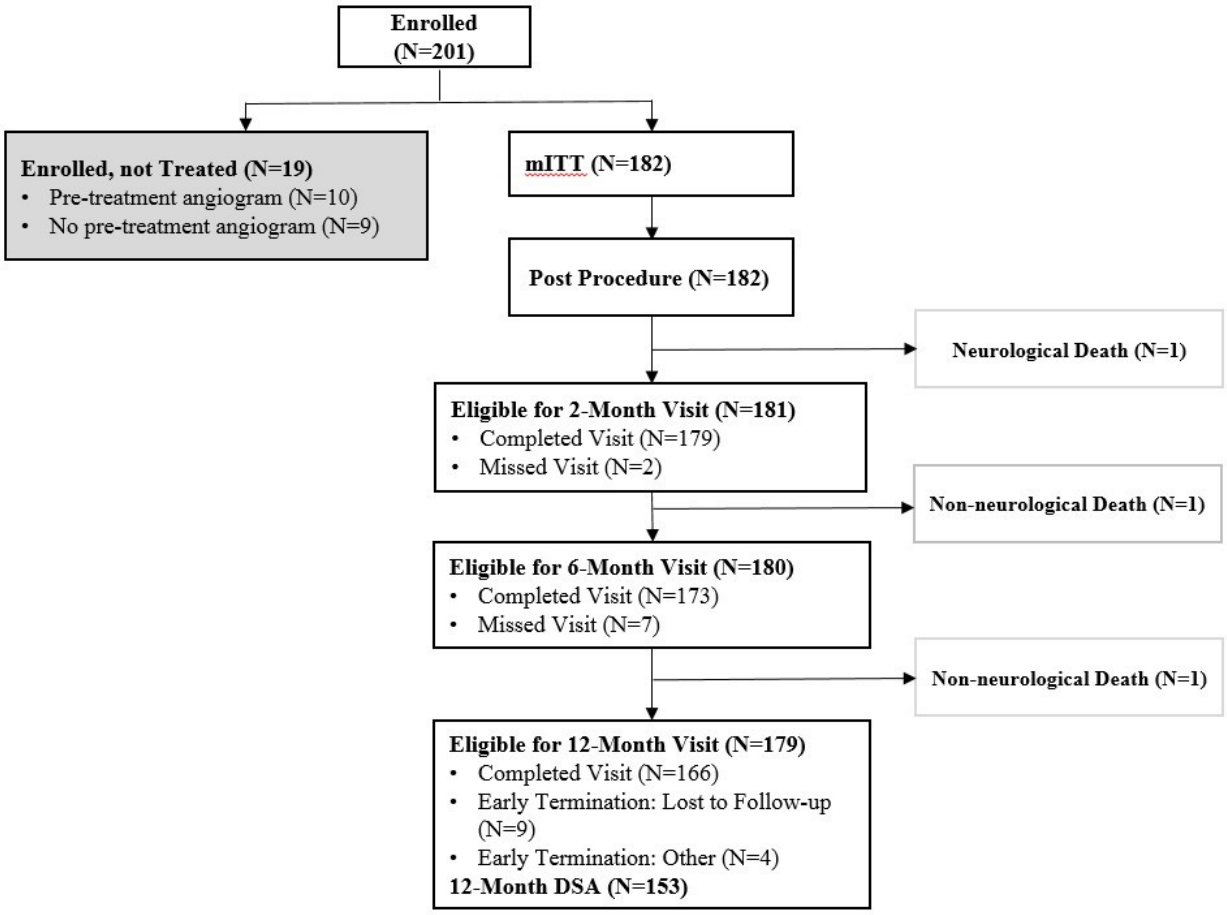

Figure 4. Subject Accountability Flowchart – Anterior Cohort

Figure 5 is a subject accountability flowchart that details the total number of subjects enrolled in the Posterior Cohort and subject disposition through 12-month follow-up.

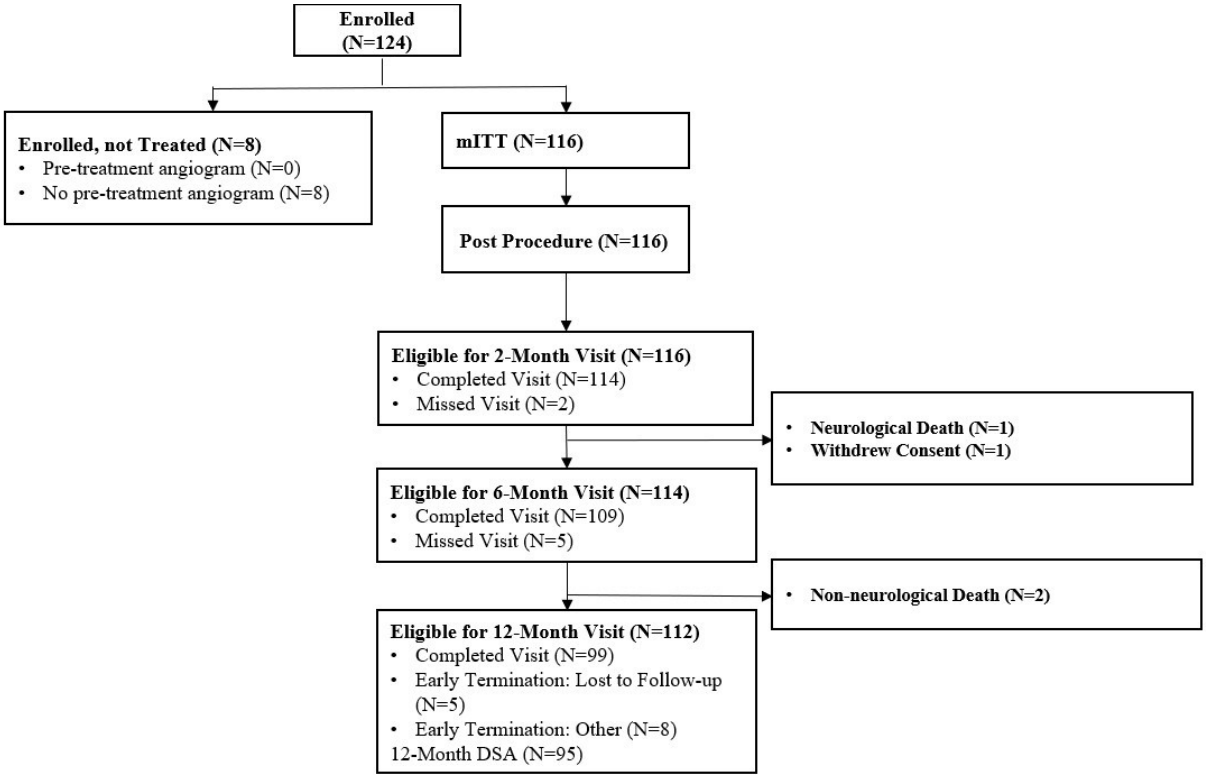

Figure 5. Subject Accountability Flowchart – Posterior Cohort

Demographics

Subject demographic and baseline characteristics for the Anterior and Posterior Cohorts are presented in Table 11. Tables 12, 13, 14, 15 and 16 present the location, measurement characteristics, and rupture status of the intracranial aneurysms treated in the ATLAS trial based on the baseline (pre-procedure) digital subtraction angiogram (DSA) that is site-reported.

Table 11. Demographic and Baseline Characteristics – mITT Population

Characteristic	mITT Subjects (Anterior Cohort) (N=182)	mITT Subjects (Posterior Cohort) (N=116)
Age (yrs)		
Mean ± SD (N)	60.3 ± 11.4 (182)	60.2 ± 10.5 (116)
Median (Q1 - Q3)	61.0 (53.0 - 69.0)	61.0 (53.5 - 67.5)
Min – Max	23.0 - 80.0	37.0 - 80.0
Height (cm)		
Mean ± SD (N)	166.2 ± 9.9 (182)	165.6 ± 8.8 (116)
Median (Q1 - Q3)	165.1 (160.0 - 171.0)	165.0 (160.0 - 170.1)
Min – Max	138.0 - 195.6	149.9 - 193.0
Weight (kg)		
Mean ± SD (N)	79.8 ± 19.2 (182)	77.2 ± 17.4 (116)

Characteristic	mITT Subjects (Anterior Cohort) (N=182)	mITT Subjects (Posterior Cohort) (N=116)
Median (Q1 - Q3)	79.4 (65.8 - 91.0)	74.9 (63.9 - 88.5)
Min – Max	36.3 - 157.0	47.0 - 131.2
BMI (kg/m²)		
Mean ± SD (N)	28.8 ± 6.2 (182)	28.1 ± 5.8 (116)
Median (Q1 - Q3)	28.2 (24.5 - 32.3)	27.8 (23.6 - 31.5)
Min – Max	16.2 - 55.0	17.8 - 45.2
Gender		
Female	73.1% (133/182)	81.0% (94/116)
Male	26.9% (49/182)	19.0% (22/116)
Race		
White	80.8% (147/182)	91.4% (106/116)
Black or African American	13.7% (25/182)	7.8% (9/116)
Asian	2.7% (5/182)	0.0% (0/116)
Native Hawaiian or other Pacific Islander	0.5% (1/182)	0.0% (0/116)
American Indian or Alaskan Native	0.0% (0/182)	0.9% (1/116)
Other [1]	2.2% (4/182)	0.0% (0/116)
Ethnicity		
Not Hispanic or Latino	93.4% (170/182)	97.4% (113/116)
Hispanic or Latino	6.6% (12/182)	2.6% (3/116)
[1] Specified as Arabic (n=1), Portuguese (n=1), Hispanic (n=1), and mixed race (n=1)		

Table 12. Target Aneurysm Location – mITT Population, Anterior Cohort

Target Aneurysm Location	mITT Population (N=182)
Anterior Cerebral Artery	2.2% (4/182)
Anterior Communicating Artery	35.2% (64/182)
Middle Cerebral Artery Bifurcation	14.8% (27/182)
Middle Cerebral Artery-M1	2.7% (5/182)
Middle Cerebral Artery-M2	1.6% (3/182)
Internal Carotid Artery—Ophthalmic	15.9% (29/182)
Internal Carotid Artery-Anterior Choroidal Artery	0.5% (1/182)
Internal Carotid Artery-Posterior Communicating Artery	13.2% (24/182)
ICA Bifurcation/Terminus	4.9% (9/182)
Supraclinoid Carotid Artery	3.3% (6/182)
Superior Hypophyseal	3.3% (6/182)
Other [1]	2.2% (4/182)
[1] ICA paraclinoid (n = 1), para-ophthalmic ICA (n = 1), and fetal PCA origin (n = 2)	

Table 13. Target Aneurysm Location – mITT Population, Posterior Cohort

Target Aneurysm Location	mITT Population (N=116)
Internal Carotid Artery-Posterior Communicating Artery	0.9% (1/116)
Basilar Apex	75.9% (88/116)
Basilar Trunk	6.0% (7/116)
Superior Cerebellar Artery	4.3% (5/116)
Posterior Inferior Cerebellar Artery	4.3% (5/116)
Vertebral Artery	4.3% (5/116)
Vertebrobasilar Junction	1.7% (2/116)
Other [1]	2.6% (3/116)
[1] Persistent Trigeminal Artery Origin (n=1), Fetal Posterior Cerebral Artery (n=1), and Posterior Cerebral (n=1)	

Table 14. Pre-implant Target Aneurysm Characteristics (Site-reported) – mITT Population

	N=182 mITT Subjects (Anterior Cohort)	N=116 mITT Subjects (Posterior Cohort)
Subjects with number of Target Aneurysms		
1	100.0% (182/182)	100.0% (116/116)
Type of imaging used		
1.DSA	83.5% (152/182)	87.1% (101/116)
2.CTA/MRA/Other	16.5% (30/182) [1]	12.9% (15/116) [2]
Aneurysm height (mm) (superior inferior on AP or lateral)		
Mean ± SD (N)	5.4 ± 2.2 (182)	6.1 ± 2.9 (116)
Median (Q1 - Q3)	5.1 (4.0 - 6.1)	5.5 (4.0 - 7.5)
Min - Max	1.8 - 16.3	1.7 - 20.2
Aneurysm width (mm) (horizontal on AP)		
Mean ± SD (N)	5.2 ± 2.0 (182)	6.1 ± 2.8 (116)
Median (Q1 - Q3)	5.0 (4.0 - 6.1)	5.5 (4.0 - 7.1)
Min - Max	1.9 - 19.0	1.7 - 18.2
Aneurysm depth (mm) (AP or lateral)		
Mean ± SD (N)	5.0 ± 1.8 (182)	6.1 ± 2.5 (116)
Median (Q1 - Q3)	4.9 (3.9 - 6.0)	5.8 (4.2 - 7.4)
Min - Max	1.5 - 12.8	1.4 - 17.0
Aneurysm neck width (mm)		
Mean ± SD (N)	4.1 ± 1.2 (182)	4.7 ± 1.7 (116)
Median (Q1 - Q3)	4.0 (3.3 - 4.7)	4.3 (3.6 - 5.5)
Min - Max	1.6 - 8.7	1.9 - 12.2

	N=182 mITT Subjects (Anterior Cohort)	N=116 mITT Subjects (Posterior Cohort)
Aneurysm Size (mm) [3]		
Mean ± SD (N)	6.1 ± 2.2 (182)	7.1 ± 3.0 (116)
Median (Q1 - Q3)	6.0 (4.8 - 7.0)	6.5 (5.0 - 8.2)
Min - Max	2.3 - 19.0	2.6 - 20.2
Dome/Neck Ratio [4]		
Mean ± SD (N)	1.2 ± 0.3 (182)	1.2 ± 0.3 (116)
Median (Q1 - Q3)	1.1 (1.0 - 1.3)	1.1 (1.0 - 1.4)
Min - Max	0.4 - 2.1	0.3 - 3.2
Parent vessel diameter proximal to the aneurysm neck (mm)		
Mean ± SD (N)	3.0 ± 0.7 (182)	2.9 ± 0.6 (116)
Median (Q1 - Q3)	2.9 (2.4 - 3.6)	3.0 (2.5 - 3.3)
Min - Max	2.0 - 4.5	1.9 - 4.5
Parent vessel diameter distal to the aneurysm neck (mm)		
Mean ± SD (N)	2.7 ± 0.7 (182)	2.4 ± 0.5 (116)
Median (Q1 - Q3)	2.5 (2.1 - 3.2)	2.3 (2.0 - 2.7)
Min - Max	1.6 - 4.4	1.6 - 4.5
Parent vessel stenosis pre-implant		
No	96.7% (176/182)	97.4% (113/116)
Yes	3.3% (6/182)	2.6% (3/116)
% stenosis:		
25% or less	83.3% (5/6)	33.3% (1/3)
26% - 50%	16.7% (1/6)	66.7% (2/3)

[1] Other includes CTA only (n = 19), MRA only (n = 10), and CTA + MRA + MRI (n = 1)
[2] This includes 8 CTA, 7 MRA, and no other imaging
[3] The aneurysm size is defined as the maximum of three dimensions (AP plane, lateral plane, height)
[4] The dome size is defined as the minimum of two widths (AP plane, lateral plane)

Table 15. Target Aneurysm Rupture Status at Baseline and Prior Target Aneurysm Treatment - mITT Population, Anterior Cohort

Measure	mITT Population (N=182) (Anterior Cohort)		
	Ruptured	Unruptured	Total
Previous target aneurysm status	12.1% (22/182)	87.9% (160/182)	100.0% (182/182)
Days from last rupture to index procedure			
Mean ± SD (N) [1]	642.6 ± 1352.8 (19)		
Median (Q1 - Q3)	274.0 (105.0 - 530.0)		
Min - Max	23.0 - 6128.0		
Prior Treatment/Intervention			
Coiling only	72.7% (16/22)	3.8% (6/160)	12.1% (22/182)
Balloon assisted coiling	4.5% (1/22)	0.0% (0/160)	0.5% (1/182)
Other [2]	22.7% (5/22)	1.9% (3/160)	4.4% (8/182)

[1] Data on the days from last rupture to index procedure was missing for three subjects.
[2] Five subjects with previously ruptured target aneurysms underwent clipping (n = 4) or partial embolization (n = 1). All 3 subjects with unruptured target aneurysms who received prior treatment underwent clipping.

Table 16. Target Aneurysm Rupture Status at Baseline and Prior Target Aneurysm Treatment - mITT Population, Posterior Cohort

Measure	mITT Population (N=116) (Posterior Cohort)		
	Ruptured	Unruptured	Total
Previous target aneurysm status	11.2% (13/116)	88.8% (103/116)	100.0% (116/116)
Days from last rupture to index procedure			
Mean ± SD (N) [1]	800.4 ± 1171.5 (12)		
Median (Q1 - Q3)	189.0 (120.5 - 1257.0)		
Min - Max	5.0 - 3927.0		
Prior Treatment/Intervention			
Coiling only	76.9% (10/13)	3.9% (4/103)	12.1% (14/116)
Balloon assisted coiling	15.4% (2/13)	0.0% (0/103)	1.7% (2/116)
Other [2]	0.0% (0/13)	1.0% (1/103)	0.9% (1/116)
None	7.7% (1/13)	95.1% (98/103)	85.3% (99/116)

[1] Data on the days from last rupture to index procedure was missing for one subject.
[2] One subject with an unruptured target intracranial aneurysm underwent clipping prior to the index procedure.

SUMMARY OF ATLAS TRIAL RESULTS – ANTERIOR CIRCULATION COHORT

Technical Results (Anterior Cohort)

The average procedure duration was 110.2 ± 47.0 minutes (Table 17) in the Anterior Cohort. Procedural technical success was a secondary effectiveness endpoint and was achieved in

100.0% (182/182) of mITT subjects. All subjects were implanted with either 1 Atlas device (84.1%; 153/182) or 2 Atlas devices (15.9%; 29/182). On a per device basis, 93.0% (211/227) of attempted device implantations were successful.

Table 17. Procedural Duration and Technical Success – mITT Population, Anterior Cohort

Variable	% of Subjects (n/N) (N=182 Subjects/ 227 Devices)
Procedural Duration (minutes)	
Mean ± SD (N)	110.2 ± 47.0 (182)
Min - Max	40.0 - 370.0
Procedural Technical Success (per subject)	100.0% (182/182)
Number of Subjects with One Stent Implanted	84.1% (153/182)
Number of Subjects with Two Stents Implanted	15.9% (29/182)
Atlas Stent Implanted (per device)	93.0% (211/227)
Atlas Stent not Implanted (per device)	7.0% (16/227)

Subject Follow-up

Of the 182 subjects in the mITT primary analysis population, 180 were theoretically available to complete 12-month follow-up and 2 subjects died from non-neurologic causes prior to 12 months. Clinical and angiographic follow-up was obtained in 85% (153/180) of available subjects in the Anterior Cohort.

Safety Data

The incidence of primary safety failure (major ipsilateral stroke or neurological death) in the mITT population was 4.4% (8/182; 95% CI: 1.9%, 8.5%) and statistically less than the predetermined threshold of less than 20% ($p < 0.001$). The primary safety endpoint success criterion was therefore met in the Anterior Cohort.

The subcomponents of the composite primary safety endpoint, the incidence of major ipsilateral stroke and the rate of neurological death, were 4.4% (8/182) and 0.5% (1/182), respectively. One of the 8 subjects who experienced major ipsilateral stroke also suffered neurologic death (Table 18).

Table 18. Pre-specified Primary Safety Endpoint at 12-month Follow-up – mITT Population, Anterior Cohort

	mITT Population (N=182)		
Endpoint	% of Subjects with Events (n/N)	95% CI [1]	P-value [2]
Any Major Ipsilateral Stroke or Neurologic Death [3]	4.4% (8/182)	[1.9%, 8.5%]	<.001
Major Ipsilateral Stroke [4]	4.4% (8/182)	[1.9%, 8.5%]	
Neurologic Death [4]	0.5% (1/182)	[0.0%, 3.0%]	

[1] Clopper-Pearson exact confidence interval
[2] One-sided Fisher's Exact test of success against the performance goal of < 0.20 at 12 months (α=0.025)
[3] Does not account for 7 subjects with missing data within 1-year follow-up.
[4] One subject experienced both major ipsilateral stroke and neurological death

Baseline and 12-month Modified Rankin Scale (mRS) scores were obtained by study personnel 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. The results for subject cohorts with unruptured aneurysms and ruptured aneurysms in the anterior circulation are shown in Table 19 and Table 20, respectively.

Among those subjects with unruptured aneurysms (n=160) who had 12-month mRS data available, the majority (90.5%; 133/147) had unchanged or improved functional outcomes compared to baseline (Table 19). A total of 109 subjects (74.1%) had unchanged mRS scores and 24 subjects (16.3%) had improved mRS scores at 12 months compared to their baseline mRS. There were 14 subjects with worsened mRS scores (14/147; 9.9%). For 13 subjects, the mRS assessment was not performed due to loss-to-follow-up (n = 8), study discontinuation (n = 4), and protocol deviation (n = 1).

Four of the 14 subjects with worsened 12-month mRS scores experienced ischemic or hemorrhagic adverse events (i.e., neurologic death [mRS score = 6], major stroke [mRS score = 5], subarachnoid hemorrhage [mRS score = 1], aneurysm rupture/minor stroke [mRS score = 1]). Six subjects had a mRS score change of 1 at 12 months compared to baseline; none of these subjects experienced a neurological SAE and all had good neurological outcomes, with mRS scores of 1 (n = 5) or 2 (n = 1). Two subjects with baseline mRS scores of 1 had worsened mRS scores of 3 at the 12-month follow-up that were not associated with new neurological deficit. One of these subjects, who experienced no SAEs during the study period, had a medical history significant for panic disorder, anxiety, depression, chronic headache/migraine, post-concussive syndrome and mitral valve prolapse. The second subject suffered a left hip fracture treated with intramedullary nailing. Two subjects died prior to the 12-month visit due to non-neurological causes (i.e., gallbladder cancer, cardiac arrest secondary to acute fentanyl intoxication).

Table 19. Change in mRS Score through 12-month Follow-up Compared to Baseline – mITT Population with Previously Unruptured Aneurysm, Anterior Cohort

	Score at 12 Month Follow-up Visit*								
Score at Baseline	ND	0	1	2	3	4	5	6	Total
0	8	86	7	0	0	0	1	2	104
1	3	19	21	1	2	0	0	0	46
2	2	2	1	1	0	0	0	0	6
3	0	0	1	1	1	0	0	1	4
Total	13	107	30	3	3	0	1	3	160

*Grey = no change

Similarly, among those subjects with ruptured aneurysms (n=22) who had 12-month mRS data available, the majority (78.9%; 15/19) had unchanged or improved functional outcomes compared to baseline (Table 20). Nine subjects (47.4%) had unchanged mRS scores and 6

subjects (31.6%) had improved mRS scores at 12 months compared to their baseline mRS. Four subjects (21.1%) had worsened mRS scores (4/19; 21.1%). For 3 subjects, the mRS assessment was not performed due to loss-to-follow-up (n = 1), or protocol deviation (n = 2).

One of the 4 subjects with worsened mRS scores experienced a major stroke and had a mRS score of 3 at 12 months. Three subjects had a 1-point change in mRS score, from 0 to 1 (n =2) or 1 to 2 (n = 1), at the 12-month follow-up; none of these subjects experienced a neurological SAE.

Table 20. Change in mRS Score through 12-month Follow-up Compared to Baseline – mITT Population with Previously Ruptured Aneurysm, Anterior Cohort

	Score at 12 Month Follow-up Visit*								
Score at Baseline	ND	0	1	2	3	4	5	6	Total
0	0	3	2	0	1	0	0	0	6
1	1	3	5	1	0	0	0	0	10
2	0	0	2	0	0	0	0	0	2
3	2	0	0	1	1	0	0	0	4
Total	3	6	9	2	2	0	0	0	22

*Grey = no change

Effectiveness Data

Primary Endpoint

Key effectiveness outcomes for the Anterior Cohort are presented in Table 21. The pre-specified primary effectiveness analysis was performed on the mITT population using regression methods to impute missing endpoint data. The primary effectiveness composite success rate in the mITT population was 84.7% (95% CI: 78.6%, 90.9%) and statistically greater than the predetermined threshold of 50% (p-value < 0.001). The primary effectiveness endpoint success criterion was therefore met in the Anterior Cohort.

Table 21: Primary Effectiveness at 12-month Follow-up – mITT Population (N=182), Anterior Cohort

Primary Effectiveness Composite Success [1]	%(n/N) (95% CI) [5]	P-value [6]
Primary Effectiveness Analysis		
mITT Population with Regression Imputation [2]	84.7% [78.6%, 90.9%]	<0.001
Additional Analyses of Primary Effectiveness Endpoint		
mITT Population without Imputation [3]	84.5% (131/155) [77.8%, 89.8%]	<0.001
Worst Case Analysis [4]	72.0% (131/182) [64.9%, 78.4%]	<0.001

[1] Primary effectiveness endpoint defined as Grade 1 Raymond Class in the absence of retreatment, or significant parent artery stenosis (>50%) at the target location. One subject who suffered neurological death was imputed as a failure.
[2] Missing endpoint data was imputed using regression methods. The five separate imputed data sets were constructed.
[3] Two subjects without 12-month DSA, one retreatment and one neurological death, were imputed as effectiveness failures and included in the denominator.
[4] All missing endpoint data (n=27) imputed as failure.
[5] Clopper-Pearson exact confidence interval.
[6] One-sided Fisher's Exact test of success against the performance goal of > 0.50 at 12 months (α=0.025).

Secondary Endpoints

Secondary effectiveness endpoints included: proportion of aneurysms with occlusion of Raymond Class 1, 2 or 3, proportion of aneurysms with Raymond Class 1 and 2 combined, incidence of progressive aneurysm occlusion at the target aneurysm location, incidence of parent artery stenosis (> 50%) at the target aneurysm location, incidence of stent migration based on follow-up angiogram, incidence of recanalization, and the incidence of retreatment. Twelve-month results are summarized in Table 22.

Table 22. Secondary Effectiveness Endpoints at 12-month Follow-up– mITT Population, Anterior Cohort

Endpoint	mITT Population (N =182) mITT Subjects with Available DSA or Retreatment (N=154) or DSA Only (N=153) % (n/N) (Unadjusted 95% CI) [1]
Raymond Class (Core Lab)	
1	88.2% (135/153) [82.0%, 92.9%]
2	7.8% (12/153) [4.1%, 13.3%]
3	3.9% (6/153) [1.5%, 8.3%]
Proportion of aneurysms with occlusion of Raymond Class 1 and 2 combined	96.1% (147/153) [91.7%, 98.5%]
Recanalization [2]	5.8% (9/154) [2.7%, 10.8%]
Incidence of progressive occlusion at the target aneurysm location (Core Lab)	
Same	60.1% (92/153) [51.9%, 67.9%]
Better	34.6% (53/153) [27.1%, 42.7%]

Endpoint	mITT Population (N =182) mITT Subjects with Available DSA or Retreatment (N=154) or DSA Only (N=153) % (n/N) (Unadjusted 95% CI) [1]
Worse	5.2% (8/153) [2.3%, 10.0%]
Parent artery stenosis > 50% (Core Lab)	1.3% (2/153) [0.2%, 4.6%]
Incidence of stent migration (Core Lab)	0.0% (0/153) [0.0%, 2.4%]
Incidence of retreatment (Site-reported) [3, 4]	3.8% (7/182) [1.6%, 7.8%]
[1] 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. [2] Recanalization is defined as Raymond score of 3 at 12-month visit or retreatment due to recanalization. [3] Two of the 7 subjects had pre-planned staged procedures. [4] Denominator is full mITT cohort.	

Conclusions

The ATLAS trial met the primary effectiveness and safety endpoints with statistical significance ($p < 0.001$) for the Anterior Cohort.

SUMMARY OF ATLAS TRIAL RESULTS - POSTERIOR CIRCULATION COHORT

Technical Results (Posterior Cohort)

The average procedure duration was 118.4 ± 46.0 minutes (Table 23) in the Posterior Cohort. Procedural technical success was a secondary effectiveness endpoint and was achieved in 100.0% (116/116) of mITT subjects. All subjects were implanted with either 1 Atlas device (65.5%; 76/116) or 2 Atlas devices (34.5%; 40/116). On a per device basis, 94.5% (156/165) of attempted device implantations were successful.

Table 23. Procedural Duration and Technical Success – mITT Population, Posterior Cohort

Variable	% of Subjects (n/N) (N=116)
Procedural Duration (minutes)	
Mean ± SD (N)	118.4 ± 46.0 (116)
Min - Max	39.0 - 282.0
Procedural Technical Success (per subject)	100.0% (116/116)
Number of Subjects with One Stent Implanted	65.5% (76/116)
Number of Subjects with Two Stents Implanted	34.5% (40/116)
Atlas Stent Implanted (per device)	94.5% (156/165)
Atlas Stent not Implanted (per device) [1]	5.5% (9/165)
[1] Nine device failures occurred during 5 procedures. None of the devices entered the body and all 5 cases were successfully completed with additional devices.	

Subject Follow-up

Of the 116 subjects in the mITT primary analysis population, 114 were theoretically available to complete 12-month follow-up (1 subject withdrew consent and 1 subject died from non-neurologic causes prior to 12 months). Clinical and angiographic follow-up was obtained in 83.3% (95/114) of available subjects in the Posterior Cohort.

Safety Data

The incidence of primary safety failure (major ipsilateral stroke or neurological death) in the mITT population was 4.3% (5/116; 95% CI: 1.4%, 9.8%) and statistically less than the predetermined threshold of less than 25% ($p < 0.001$). The primary safety endpoint success criterion was therefore met in the Posterior Cohort.

The subcomponents of the composite primary safety endpoint, the incidence of major ipsilateral stroke and the rate of neurological death, were 3.4% (4/116) and 0.9% (1/116), respectively (Table 24). The subject who experienced neurological death had developed severe aspiration pneumonia following a fall on postoperative day 60 (during which the subject sustained a subdural hematoma), and subsequently expired 15 days later.

Table 24. Pre-specified Primary Safety Endpoint at 12-month Follow-up – mITT Population, Posterior Cohort

	mITT Population (N=116)		
	% of Subjects with Events (n/N)	95% CI [1]	P-value [2]
Any Major Ipsilateral Stroke or Neurologic Death [3]	4.3% (5/116)	[1.4%, 9.8%]	< 0.001
Major Ipsilateral Stroke	3.4% (4/116)	[0.9%, 8.6%]	
Neurologic Death	0.9% (1/116)	[0.0%, 4.7%]	

[1] Clopper-Pearson exact confidence interval
[2] One-sided Fisher's Exact test of success against the performance goal of <0.25 at 12 months (α=0.025).
[3] This is not a worst-case analysis accounting for 5 missing data subjects as failures.

Baseline and 12-month Modified Rankin Scale (mRS) scores were obtained by study personnel 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. The results for subjects in the Posterior Cohort are shown in Table 25.

Among those subjects who had 12-month mRS data available, the majority (90.2%; 92/102) had unchanged or improved functional outcomes compared to baseline (Table 25). A total of 73 subjects (71.6%) had unchanged mRS scores and 19 subjects (18.6%) had improved mRS scores at 12 months compared to their baseline mRS. There were 10 subjects with worsened mRS scores (10/102; 9.8%). For 14 subjects, the mRS assessment was not performed due to loss-to-follow-up (n = 5), study discontinuation (n = 8), and subject withdrawal of consent (n = 1).

One of the 10 subjects with worsened 12-month mRS scores experienced a major ipsilateral stroke on the day of the index procedure and had a mRS score of 2 at the 12-month follow-up. One subject experienced a fall and subsequently developed pneumonia aspiration that led to

neurological death; 1 subject experienced a myocardial infarction; and 1 subject experienced a congestive heart failure that led to non-neurological deaths. Six subjects had a mRS score change from 0 at baseline to 1 at 12 months; 2 of these 6 subjects experienced minor strokes at 18 and 40 days post-procedure while the remainder experienced no neurological SAEs.

Table 25. Change in mRS Score through 12-month Follow-up Compared to Baseline – mITT Population, Posterior Cohort

	Score at 12 Month Follow-up Visit								
Score at Baseline	ND	0	1	2	3	4	5	6	Total
0	12	63	6	1	0	0	0	2	84
1	2	14	8	0	0	0	0	0	24
2	0	3	1	1	0	0	0	0	5
3	0	0	0	1	1	0	0	1	3
Total	14	80	15	3	1	0	0	3	116

*Grey = no change

Effectiveness Data

Primary Endpoint

Key effectiveness outcomes for the Posterior Cohort are presented in Table 26. The pre-specified primary effectiveness analysis was performed on the mITT population using regression methods to impute missing endpoint data. The primary effectiveness composite success rate in the mITT population was 76.7% (95% CI: 67.0%, 86.5%) and statistically greater than the predetermined threshold of 50% ($p < 0.001$). The primary effectiveness endpoint success criterion was therefore met in the Posterior Cohort.

Table 26: Primary Effectiveness at 12-month Follow-up – mITT Population (N=116), Posterior Cohort

Primary Effectiveness Composite Success [1]	%(n/N) (95% CI)[4]	P-value [5]
Primary Effectiveness Analysis		
mITT Population with Regression Imputation [2]	76.7% [67.0%, 86.5%]	< 0.001
Additional Analyses of Primary Effectiveness Endpoint		
Complete-Case Analysis	77.0% (77/100) [67.5%, 84.8%]	< 0.001
mITT Population Worst Case Analysis [3]	66.4% (77/116) [57.0%, 74.9%]	< 0.001

[1] Primary effectiveness endpoint defined as Grade 1 Raymond Class in the absence of retreatment, or parent artery stenosis (>50%) at the target location. Subject who suffered neurological death was imputed as failure.
[2] Missing endpoint data was imputed using regression methods. The five separate imputed data sets were constructed.
[3] Missing endpoint data was imputed as failure.
[4] Clopper-Pearson exact confidence interval.
[5] One-sided Fisher's Exact test of success against the performance goal of > 0.50 at 12 months (α=0.025).

Per pre-established protocol requirement, one Core Lab reader adjudicated the intracranial aneurysm occlusion results. Therefore, these results may be subject to assessment variability for intracranial aneurysm occlusion scores presented in Table 26.

The ATLAS study protocol did not pre-specify or guide site investigators on the packing of the intracranial aneurysm with adjunctive neurovascular embolization coils. Coil packing is dependent on clinical practice with utilization of currently marketed neurovascular embolization coils, and can vary based on intracranial aneurysm size, location, morphology and shape.

The primary effectiveness endpoint results presented in Table 26 are presented with multiple imputations, complete-case and worst-case analyses. These results may vary in clinical practice.

Conclusions

The ATLAS trial met the primary effectiveness and safety endpoints with statistical significance ($p < 0.001$) for the Posterior Cohort.

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.

OPERATIONAL INSTRUCTIONS

Initial Access, Angiographic Assessment and Stent Selection

1. Gain vascular access according to standard practice. Select a recommended microcatheter (see Required Accessories section on Page 2). If additional stability is required, consider the use of an intermediate catheter in addition to the microcatheter. Establish and maintain continuous flow of appropriate flush solution through the microcatheter per standard vascular practice. Using angiography, determine the location of the aneurysm and the size of the aneurysm neck.
2. Navigate the stent delivery microcatheter over an access length guidewire at least 1.2 cm distal to the aneurysm neck.

Note: The microcatheter tip must be placed sufficiently distal to the aneurysm neck to allow for slack to be removed from the system after the stent is advanced, while maintaining adequate stent length (approximately 4 mm) distal to the aneurysm neck. Excessive tortuosity may necessitate microcatheter tip placement more than 1.2 cm distal to the aneurysm neck.

3. Remove the guidewire.
4. Select an appropriate Neuroform Atlas® Stent based on the largest reference vessel diameter and the sizing recommendations in Tables 1 and 2. Select a stent that is at least 8 mm longer (referenced off the working length, WL) than the aneurysm neck to maintain a minimum of 4 mm on each side of the aneurysm neck along the parent vessel.

Delivery System Preparation and Stent Transfer

Note: Coiling can be performed by placing the microcatheter into the aneurysm prior to or after stent deployment, per physician preference.

5. Carefully inspect the stent delivery system packaging for damage.
6. Peel open the pouch using aseptic technique and remove the (sterile) dispenser hoop.

7. Carefully place the dispenser hoop into the sterile field.
8. Using two hands, one on each side of the wire retention clip, release the stent delivery wire from the wire retention clip on the dispenser hoop.
9. Remove the device from the dispenser hoop by grabbing the stent delivery wire and the proximal end of the introducer sheath; holding them together, slowly and carefully remove the entire wire and introducer sheath.

Note: The stent delivery wire and proximal end of the introducer sheath must be held together when removing the Neuroform Atlas® Stent System from the dispenser hoop to prevent stent movement and premature deployment.

Note: Ensure that the stent delivery wire does not move relative to the introducer sheath during removal of the stent system from the dispenser hoop.

10. Inspect the stent delivery system. Confirm that the tip of the stent delivery wire is entirely within the introducer sheath. Confirm that the stent delivery wire is not kinked and that the introducer sheath tip is not damaged.
11. Partially insert the distal end of the introducer sheath into the RHV that is connected to the microcatheter. Tighten the RHV to secure the introducer sheath.

Note: Partial insertion of the introducer sheath into the RHV is necessary to ensure a flow path for flush. Ensure that the tip of the introducer sheath is inserted into the middle of the RHV.

Note: Under-tightening the RHV may result in inadequate flushing. Over- tightening the RHV may crush the introducer sheath and may result in inadequate flushing.

12. Open the y- connector valve of the RHV that is connected to the appropriate flush solution and verify that fluid exits the proximal end of the introducer sheath.

Warning: Purge the system carefully to avoid the accidental introduction of air into the stent system.

13. Loosen the RHV, then advance the introducer sheath until the tip is fully inserted into the microcatheter hub. Tighten the RHV firmly.

Warning: Confirm there are no air bubbles trapped anywhere in the stent system.

Note: After tightening the RHV firmly, the introducer sheath tip should not move when pulled

gently. Failure to secure the introducer sheath may result in premature deployment of the stent within the microcatheter hub or difficulty in transferring the stent.

Note: The introducer sheath tip must be fully inserted into the microcatheter hub to enable the stent to move into the microcatheter. Over-tightening the RHV may crush the introducer sheath, while under-tightening the RHV may result in premature deployment of the stent.

14. Advance the stent delivery wire to transfer the stent from the introducer sheath into the microcatheter.

Note: Ensure that the introducer sheath does not move while advancing the stent delivery wire. Movement of the introducer sheath during stent advancement may result in premature deployment of the stent within the microcatheter hub.

15. Continue advancing the stent delivery wire into the microcatheter until the distal edge of the fluoro saver mark enters the introducer sheath. The fluoro saver mark is 135 cm from the stent delivery wire distal tip. When the fluoro saver mark enters the introducer sheath, the stent is approximately 90 cm inside the microcatheter.
16. Loosen the RHV on the stent delivery microcatheter, remove the introducer sheath from the proximal end of the stent delivery wire while holding the stent delivery wire fixed in place, and set the introducer sheath aside.

Note: At this point, fluoroscopy may be used at the physician's discretion.

17. If desired, place torque device on proximal end of wire (at least 5 cm from proximal end of fluoro saver marker).

Note: The torque device may be attached to the proximal end of the stent delivery wire to facilitate handling and stabilization. Be sure to tighten the torque device to secure the stent delivery wire. Do not use the torque device to torque the stent delivery wire as it is not designed to be torqued.

18. Slowly advance the delivery wire and stent until the distal edge of the stent delivery wire fluoro saver mark reaches the stent delivery microcatheter's RHV.

Note: If resistance is encountered at any point during stent manipulation, do not apply undue force. Withdraw the microcatheter, stent, and stent delivery wire as a unit and repeat the procedure with new devices.

Stent positioning and Deployment

19. Under fluoroscopy, advance the stent delivery wire until the stent's distal radiopaque markers are 1 – 2 mm proximal of the distal tip marker of the stent delivery microcatheter.

Note: Maintain adequate stent length (approximately 4 mm) on each side of the aneurysm neck to ensure appropriate neck coverage.

20. Withdraw the microcatheter slightly to remove any slack from the stent system and position the stent for deployment by aligning the stent radiopaque markers across the target aneurysm.
21. If stent delivery microcatheter positioning is satisfactory, carefully retract the stent delivery microcatheter in a continuous movement while maintaining the position of the stent delivery wire. This will allow the stent to deploy across the neck of aneurysm. The stent's distal radiopaque markers will expand as the stent exits the stent delivery microcatheter.

Note: Do not use the stent delivery wire to push the stent out of the microcatheter while deploying.

Note: Do not deploy the stent if it is not properly positioned in the vessel.

22. Confirm deployed stent position using fluoroscopy.
23. If stent did not adequately cover aneurysm, withdraw the stent delivery wire from the stent delivery microcatheter. Place additional Neuroform Atlas® Stents as needed.
24. Once the aneurysm is adequately covered, remove stent delivery wire and stent delivery microcatheter from patient and establish hemostasis.
25. Perform coiling procedure per appropriate coiling device DFU.
26. Discard used devices.

Additional Information

Patient Information

You should have already provided the patient with a copy of the Patient Information Booklet so that (s)he has had adequate time to review the information and ask any questions.

Immediately after the procedure, complete the Patient Information Card, which is included in the carton box, and provide the card to the patient before the patient leaves the hospital. The Patient Information Card includes important information about the stent that was used and includes a statement regarding MRI information.

Concomitant Medical Therapy

Typical antiplatelet and anticoagulation regimen used for interventional intracranial procedure is recommended at the discretion of the treating physician. Do not use the Neuroform Atlas® Stent System in patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.

MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

Safety Information Magnetic Resonance Conditional

Non-clinical testing and analysis have demonstrated that the Neuroform Atlas Stent is MR Conditional alone, or when overlapped with a second stent, and adjacent to a Stryker Neurovascular coil mass. A patient with the Neuroform Atlas Stent can be safely scanned immediately after placement of this implant, under the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla
- Maximum spatial gradient field up to 2500 Gauss/cm (25 Tesla/m)
- Maximum MR system reported whole body averaged specific absorption rate of 2 W/kg (Normal Operating Mode) and head averaged specific absorption rate of 3.2 W/kg.

Under the scan conditions defined above, the Neuroform Atlas Stent is expected to produce a maximum temperature rise of 4 °C after 15 minutes of continuous scanning. The Neuroform Atlas Stent should not migrate in this MRI environment.

In non-clinical testing, the image artifact caused by the device extends approximately 2 mm from the Neuroform Atlas Stent when imaged with a spin echo pulse sequence and 3 Tesla MRI System. The artifact may obscure the device lumen. It may be necessary to optimize MR imaging parameters for the presence of this implant. See additional precaution related to the image artifact from the implant in the “Precautions” section of this labeling.

QUESTIONS AND ANSWERS

Q: What is the optimal position of the stent with respect to the aneurysm?

A: Generally, try to position the stent so that each end of the stent is secured in relatively straight areas of the parent vessel. The stent will be more stable if each end of the stent is anchored in at least 4 mm of normal vessel. For example, if an aneurysm is located in the supraclinoid carotid, it may be better to secure the stent by deploying the distal end in the M1 (middle cerebral artery, first segment) than trying to deploy it in the few millimeters between the aneurysm and the ICA (internal carotid artery) bifurcation. When deploying the stent, care should be taken to use a view that best shows the parent vessel distal to the aneurysm; this enables the distal end of the stent to be accurately deployed with respect to the aneurysm. This view may be different from the view used to advance the Neuroform Atlas Stent System, or the view used as a working position for aneurysm embolization.

Q: Which stent size should I choose if I intend to place the stent in a vessel that has a different diameter between the proximal and distal ends of the stent? Example: A vessel proximal diameter decreases from a 4.0 mm at the right ICA bifurcation terminus to a 2.5 mm MCA distal diameter.

A: Choose the stent sized for the larger vessel. In this example, choose the 4.0 or 4.5 mm stent. This stent can be deployed safely in the smaller MCA and will be well anchored in the ICA terminus.

Q. I have accidently started to deploy the stent, but it is not in the location that I wanted. What should I do?

A. In general the safest course of action is not to try repositioning the stent. Rather, continue to deploy the stent where it is and then deploy a second stent at the desired location. Safely deploying a stent – even in an undesired location – will minimize vascular injury. Animal studies have demonstrated that the stent endothelializes in less than 30 days.

Q: I misjudged the positioning of the stent and have deployed it with one end adjacent to the aneurysm rather than in the normal part of the parent vessel. What should I do?

A: Remove the spent stent delivery wire from the microcatheter while maintaining the position of the microcatheter. Insert and deploy a second Neuroform Atlas® Stent starting from inside of the first stent to the normal portion of the parent vessel (in a telescoping fashion). The second stent should be of the same diameter or larger than the first.

Warranty

Stryker Neurovascular warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Stryker Neurovascular's control directly affect the instrument and the results obtained from its use. Stryker Neurovascular's obligation under this warranty is limited to the repair or replacement of this instrument and Stryker Neurovascular shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Stryker Neurovascular neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. Stryker Neurovascular assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

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