stryker®
Neurovascular

Neuroform Atlas™

Stent System

Stryker Neurovascular (DFU Template 8in x 8in EN), DFU, Neuroform Atlas Stent System, EN, NV00020534-01A

Neuroform Atlas™

Stent System

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.

Resale of this device is prohibited by US law.

Humanitarian Device. Authorized by Federal law for use with neurovascular embolic coils in patients who are ≥ 18 years of age for the treatment of wide neck, intracranial, saccular aneurysms arising from a parent vessel with a diameter of ≥ 2 mm and ≤ 4.5 mm that are not amenable to treatment with surgical clipping. Wide neck aneurysms are defined as having a neck ≥ 4 mm or a dome-to-neck ratio < 2. The effectiveness of this device for this use has not been demonstrated.

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 of 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 ≥ 4.5F, 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).

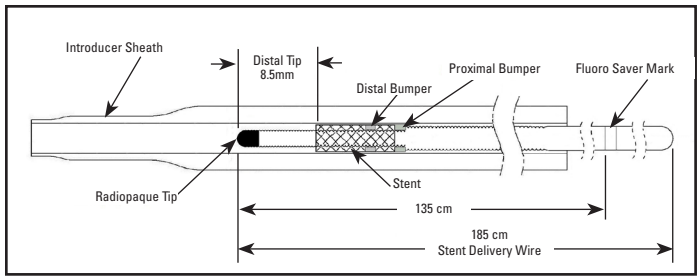

Figure 1: Neuroform Atlas Stent System with tip

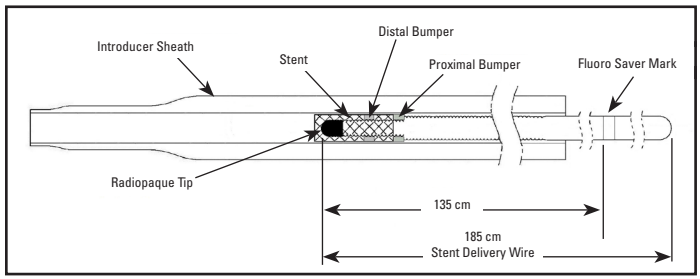

Figure 2: Neuroform Atlas Stent System without tip

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).

INDICATIONS FOR USE

The Neuroform Atlas Stent System is indicated for use with neurovascular embolic coils in patients who are ≥ 18 years of age for the treatment of wide neck, intracranial, saccular aneurysms arising from a parent vessel with a diameter of ≥ 2 mm and ≤ 4.5 mm that are not amenable to treatment with surgical clipping. Wide neck aneurysms are defined as having a neck ≥ 4mm or a dome-to-neck ratio of < 2.

CONTRAINDICATION

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.

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.
- Persons allergic to nickel titanium (Nitinol) may suffer an allergic response to this stent implant.

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.)

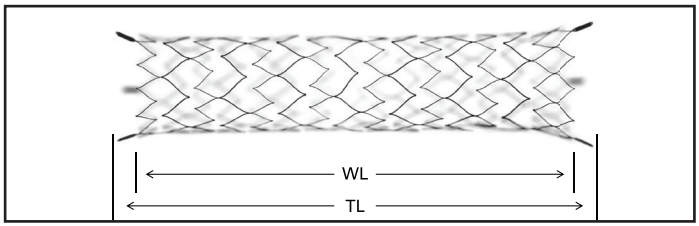

Figure 3: Working Length (WL)/ Total Length (TL)

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.
- The stent delivery microcatheter and the Neuroform Atlas Stent delivery wire should not be used to recapture the stent.
- Exercise caution when crossing the deployed stent with adjunctive devices.
- After deployment, the stent may foreshorten up to 6.3%.
- The max OD of the coiling microcatheter should not exceed the max OD of the stent delivery microcatheter.
- Standard interventional devices with distal tips > 1.8 F may not be able to pass through the interstices of the stent.
- Safety of the Neuroform Atlas Stent System in patients below the age of 18 has not been established.
- In cases where multiple aneurysms are to be treated, start at the most distal aneurysm first.

ADVERSE EVENTS

Potential Adverse Events

Potential complications include, but are not limited to:

- Allergic reaction to Nitinol metal and medications
- Aneurysm perforation/rupture
- Coil herniation through stent into parent vessel
- Death
- Embolus
- Headache
- Hemorrhage
- In-stent stenosis
- Infection
- Ischemia
- Neurological deficit/intracranial sequelae
- Pseudoaneurysm
- Stent fracture
- Stent migration/embolization
- Stent misplacement
- Stent thrombosis
- Stroke
- Transient ischemic attack
- Vasospasm
- Vessel occlusion or closure
- 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.

Refer to the appropriate embolic coil DFU for other complications that may occur due to coil embolization.

Summary of Observed Adverse Events from Clinical Study

There were no unanticipated adverse events (UADE) during the study. There were three events adjudicated by the CEC as either major (n=1) or minor stroke (n=2). There was one subject with suspected confusion as a "manifestation of contrast induced encephalopathy," right-sided weakness, aphasia, and evidence of a small stroke on MRI exam with no residual symptoms at the time of discharge. NIHSS was not performed and therefore this was designated as a major stroke related to the procedure and not related to the device. There were two minor strokes adjudicated by the CEC. One subject experienced an intra-procedural target aneurysm rupture attributed to coil packing and a minor stroke that was determined to be related to the procedure and not related to the device. One subject with a minor stroke developed new onset aphasia 12 hours after the procedure which resolved within 24 hours and was determined to be unrelated to both the device and the procedure. The stroke events and aneurysm rupture are summarized in Table 3.

Table 3. CEC Adjudicated Safety Endpoints

CEC Adjudication/ Description	Number of Occurrences (Peri-Procedural)	Subjects with Events (%) (n=30)
Major Stroke	1	1 (3.3%)
Minor Stroke[1]	2	2 (6.7%)
Ruptured Cerebral Aneurysm[1]	1	1 (3.3%)

[1]One subject experienced both a ruptured cerebral aneurysm related to the coiling procedure and post-procedure aphasia determined to be a minor stroke.

As shown in **Table 4**, 30 procedure/device-related AEs occurred in 12 subjects (12/30 or 40.0%). The most frequently site reported procedure-related AEs were categorized as nervous system disorders (N=20) and, of these, all were non-serious with one exception. These non-serious AEs included 11 reports of headaches in 10 subjects (10/30 or 33.3%), one report of migraine with aura (1/30 or 3.3%), one report of ophthalmoplegic migraine (1/30 or 3.3%), and one report of mental confusion (1/30 or 3.3%) that was deemed by the site to be related to the contrast media used in the procedure. The second most commonly reported procedure-related AEs in nervous system disorders were 6 cerebral vasoconstriction events occurring in 5 subjects (5/30 or 16.7%). Three subjects (3/30 or 10.0%) experienced 4 access site-related AEs (application site hematoma (2) and catheter site hemorrhage (2)) categorized as general disorders and administration site conditions. In addition, two subjects (2/30 or 6.7%) experienced eye disorders (diplopia, visual impairment), one subject (1/30 or 3.3%) experienced procedural complication (arterial restenosis), and one subject (1/30 or 3.3%) experienced two respiratory disorders (cough, laryngitis). All of these AEs were reported as non-serious and all resolved with no residual effects. All events listed in Table 4 were classified by the site as having a Related, Probable, or Possible relationship to the study procedure.

Table 4. Site Reported Procedure /Device Related AEs by Medical Dictionary for Regulatory Activities (MedDRA) Codes

	Serious AE		Non-Serious AE		All AEs	
MedDRA* System Organ Class/ Preferred Term	Events Related to Procedure/ Atlas Device	Subjects with Events [n (% Based on N=30)]	Events Related to Procedure/ Atlas Device	Subjects with Events [n (% Based on N=30)]	Events Related to Procedure/ Atlas Device	Subjects with Events [n (% Based on N=30)]
Any AE	1	1 (3.3%)	29	11 (36.7%)	30	12 (40.0%)
Eye disorders	0	0	2	2 (6.7%)	2	2 (6.7%)
Diplopia	0	0	1	1 (3.3%)	1	1 (3.3%)
Visual impairment	0	0	1	1 (3.3%)	1	1 (3.3%)
General disorders and administration site conditions	0	0	4	3 (10.0%)	4	3 (10.0%)
Application site hematoma	0	0	2	2 (6.7%)	2	2 (6.7%)
Catheter site hemorrhage	0	0	2	2 (6.7%)	2	2 (6.7%)
Injury, poisoning and procedural complications	0	0	1	1 (3.3%)	1	1 (3.3%)
Arterial restenosis	0	0	1	1 (3.3%)	1	1 (3.3%)
Nervous system disorders	1	1 (3.3%)	20	11 (36.7%)	21	12 (40.0%)
Cerebral vasoconstriction	0	0	6	5 (16.7%)	6	5 (16.7%)
Confusional state	0	0	1	1 (3.3%)	1	1 (3.3%)
Headache	0	0	11	10 (33.3%)	11	10 (33.3%)
Migraine with aura	0	0	1	1 (3.3%)	1	1 (3.3%)
Ophthalmoplegic migraine	0	0	1	1 (3.3%)	1	1 (3.3%)
Ruptured cerebral aneurysm	1	1 (3.3%)	0	0	1	1 (3.3%)
Respiratory, thoracic and mediastinal disorders	0	0	2	1 (3.3%)	2	1 (3.3%)
Cough	0	0	1	1 (3.3%)	1	1 (3.3%)
Laryngitis	0	0	1	1 (3.3%)	1	1 (3.3%)

Clinical Study

The 30 subjects in the ATLAS Study were enrolled in a prospective, multi-center, single arm study at eight institutions in the United States. Data collected from this cohort of 30 subjects was used to demonstrate the safety and probable benefit of the Neuroform Atlas™ Stent System. Subjects were eligible if they presented with a wide-necked, intracranial, saccular aneurysm arising from a parent vessel with a diameter of 2.0 – 4.5 mm in either the distal anterior or posterior intracranial circulation that is accessible for endovascular treatment. Wide necked was defined as having a neck ≥ 4mm or a dome-to-neck ratio <2. The age of eligible patients ranged from 18 to 80 years of age.

The Inclusions/Exclusion criteria for enrollment in the ATLAS clinical study was as follows. Patients were required to meet all inclusion criteria and none of the exclusion criteria to be considered eligible for study participation.

Inclusion 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.

Exclusion 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.

The primary safety endpoint of this study is any major ipsilateral stroke or neurological death within 12 months. The primary effectiveness endpoint of this study is complete aneurysm occlusion (Raymond Class 1) of the treated target lesion on 12-month angiography in the absence of retreatment at the target location or parent artery stenosis (>50%).

The cohort is sized to provide a characterization of the adverse event profile associated with the device and to summarize its performance using traditional statistical techniques. The sample size for this trial was not derived via traditional power methods as no formal statistical hypothesis testing was planned. A total of 30 subjects were implanted with the device, providing an adequate sample size to allow for the calculation of confidence limits for the probable benefit performance endpoint that is meaningful and interpretable. A sample of 30 subjects is also adequate to provide a characterization of the safety profile associated with the device.

The device safety profile was based on the occurrence of any major ipsilateral stroke or neurological death within 12 months. The 12-month results from this 30-subject cohort demonstrated that use of the Neuroform Atlas Stent in patients with wide neck aneurysms is safe. There was one minor stroke, one aneurysm rupture with minor stroke and one major stroke, all unrelated to the device.

Performance was evaluated based on the endpoint of complete aneurysm occlusion (Raymond Class 1) of the treated target lesion on 12-month angiography in the absence of retreatment or parent artery stenosis (>50%) at the target location. Three subjects did not have evaluable 12-month data, so the last observation was carried forward. Probable benefit at 12 months is demonstrated by the high rate of complete aneurysm occlusion (83.3%, 25/30; Binomial exact 95% CI: 65.3-94.4%).

Table 5 summarizes the locations of the 30 aneurysms. Table 6 summarizes the sizes of the 30 aneurysms.

Table 5. Aneurysm Location

Location	n	%
Anterior Communicating Artery	13	43%
Middle Cerebral Artery Bifurcation	3	10%
Supraclinoid Carotid Artery	3	10%
Basilar apex	3	10%
ICA Ophthalmic Artery	2	7%
ICA Posterior Communicating Artery	1	3%
ICA Bifurcation/Terminus	1	3%
Superior hypophyseal	1	3%
Basilar trunk	1	3%
Superior Cerebellar Artery	1	3%
Vertebrobasilar junction	1	3%

Table 6. Aneurysm Size

Measurement	n	Mean	SD	Min	Max
Aneurysm Size (mm)	30	5.3	1.7	2.5	9.0
Neck length (mm)	30	3.9	1.1	1.6	7.0
Dome to neck ratio	28	1.1	0.2	0.6	1.5
Parent vessel pre-aneurysm (mm)	30	2.9	0.6	2.0	4.4
Parent vessel post-aneurysm (mm)	30	2.6	0.6	2.0	4.5

Thirty patients were implanted with 33 stents to treat their 30 aneurysms. Twenty-seven (90%) patients had 1 stent and 3 (10%) patients had 2 stents placed in a Y-configuration. The stents implanted ranged from 3.0 mm to 4.5 mm.

The study endpoints were (1) adverse events, (2) technical success, and (3) clinical outcome. The incidence of all adverse events, device- or procedure- related, were assessed. Procedural technical success was determined based on the ability to successfully deliver and deploy the stent at the target location. Clinical angiographic outcome was based on angiographic aneurysm occlusion and evaluated by an independent core lab.

Device and procedure-related adverse events were presented in Tables 3 and 4 in the Adverse Events section above.

Table 7 below summarizes the procedural technical success rates.

Table 7. Technical Success

Procedural Outcomes	Results [% (n/N)]
Procedural Technical Success (per subject)[1]	100.0% (30/30)
Number of Subjects with One Stent Successfully Implanted	90.0% (27/30)
Number of Subjects with Two Stents Successfully Implanted	10.0% (3/30)
Neuroform Atlas Stent Implantation Success (per device)	97.1% (33/34)
Neuroform Atlas Stent Implantation Failure (per device)[2]	2.9% (1/34)

[1]Procedural technical success is defined as the proportion of subjects in whom the stent was successfully delivered to, and deployed at, the target location.
[2]One subject had one Neuroform Atlas Stent system removed due to difficult delivery and stent was not deployed; a second stent was delivered and deployed successfully.

Probable benefit was judged based on angiographic core lab assessment provided in Table 8.

Table 8. Core Lab Clinical Angiographic Outcomes

Clinical outcome	Post-Procedure n=30	6 Months n=16	12 Months n=30[1]
Raymond Class			
Complete (100% Occlusion)	60.0% (18/30) [40.6%, 77.3%]	81.3% (13/16) [54.4%, 96.0%]	86.7% (26/30) [69.3%, 96.2%]
With Stenosis ≤ 50%	60.0% (18/30) [40.6%, 77.3%]	81.3% (13/16) [54.4%, 96.0%]	83.3% (25/30) [65.3%, 94.4%]
With Stenosis > 50%	0.0% (0/30) [0.0%, 11.6%]	0.0% (0/16) [0.0%, 20.6%]	3.3% (1/30) [0.1%, 17.2%]
Residual Neck	26.7% (8/30) [12.3%, 45.9%]	12.5% (2/16) [1.6%, 38.3%]	0.0% (0/30) [0.0%, 11.6%]
Residual Aneurysm	10.0% (3/30) [2.1%, 26.5%]	0% (0/16) [0.0%, 20.6%]	10.0% (3/30) [2.1%, 26.5%]
Not assessable[2]	3.3% (1/30) [0.1%, 17.2%]	6.3% (1/16) [0.2%, 30.2%]	3.3% (1/30) [0.1%, 17.2%]
Parent Artery Stenosis w/Last Observation Carried Forward (LOCF) for 12m			
0-25%	100.0% (30/30) [88.4%, 100%]	87.5% (14/16) [61.7%, 98.4%]	93.3% (28/30) [77.9%, 99.2%]
26-50%	0% (0/30) [0.0%, 11.6%]	12.5% (2/16) [1.6%, 38.3%]	3.3% (1/30) [0.1%, 17.2%]
51-70%	0% (0/30) [0.0%, 11.6%]	0.0% (0/16) [0.0%, 20.6%]	0.0% (0/30) [0.0%, 11.6%]
70-99%	0% (0/30) [0.0%, 11.6%]	0.0% (0/16) [0.0%, 20.6%]	3.3% (1/30) [0.1%, 17.2%]
100%	0% (0/30) [0.0%, 11.6%]	0.0% (0/16) [0.0%, 20.6%]	0.0% (0/30) [0.0%, 11.6%]

[1]Three missing subjects in 12 month follow up were imputed by using LOCF.
[2]Image type or image quality preclude reliable interpretation by core lab.

Other clinical outcomes included:

- No stent migration.
- No aneurysm retreatment.

Primary Safety Endpoint

The primary safety endpoint was any major ipsilateral stroke or death within 12 months as shown in Table 9.

Table 9. Primary Safety Endpoint at 12 months Follow up

Endpoint	% Subjects (n/N)	95% Conf. Interval[1]
Any major ipsilateral stroke or neurologic death	3.3% (1/30)	[0.1%, 17.2%]
Major ipsilateral stroke[2]	3.3% (1/30)	[0.1%, 17.2%]
Neurologic death	0.0% (0/30)	[0.0%, 11.6%]

[1] Clopper-Pearson Exact Confidence Interval

[2] One reported stroke with minor neurological symptoms of aphasia and right sided weakness lasted < 48 hours and was designated as a major stroke as an NIHSS was not performed.

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) 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.

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). 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.

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 increases from a 2.5 mm PCA (posterior communicating artery) to a 3.5 mm basilar artery.

A: Choose the stent sized for the larger vessel. In this example, choose the 4.0 mm stent. This stent can be deployed safely in the smaller PCA and will be well anchored in the basilar artery.

Q: I have accidentally 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.

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