SMART *Therapeutics*

SHAPING A MINIMALLY INVASIVE FUTURE

Neuroform™ Microdelivery Stent System

Instructions For Use

Humanitarian Device. Authorized by Federal law for use with embolic coils for the treatment of wide neck, intracranial, saccular aneurysms arising from a parent vessel with a diameter of ≥2mm and ≤4.5mm 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 <2. The effectiveness of this device for this use has not been demonstrated.

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

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

For single patient 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 that, 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.

Resale of this device is prohibited by law.

DEVICE DESCRIPTION

The SMART Therapeutics Neuroform Microdelivery Stent System includes:

- A self-expanding, nitinol Stent with four radiopaque markerbands on each end (distal and proximal).
- A flexible over-the-wire 3F Microdelivery Catheter with a distal tip markerband. The Stent and Peelable Sheath is pre-loaded into the distal end of the 3F Microdelivery Catheter.
- A 2F Stabilizer Catheter with a distal tip markerband. The 2F Stabilizer Catheter maintains the Stent position during deployment.
- A Peelable Sheath to aid in the insertion of the guidewire into the 3F Microdelivery Catheter. The Peelable Sheath is preloaded into the tip of the 3F Microdelivery Catheter.
- Rotating Hemostasis Valves, one provided with the 3F Microdelivery Catheter and one provided with the 2F Stabilizer Catheter

INDICATIONS FOR USE

The Neuroform Microdelivery Stent System is for use with embolic coils for the treatment of wide neck, intracranial, saccular aneurysms arising from a parent vessel with a diameter of ≥2mm and ≤4.5mm 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

- The Neuroform Microdelivery Stent System should only be used by physicians who have received appropriate training in interventional neuroradiology and treatment of intracranial aneurysms.
- Select a Stent size (length and diameter) to maintain a minimum of 4mm on each side of the aneurysm neck along the parent vessel. 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 12mm in length.
- The 3F Microdelivery Catheter or the 2F Stabilizer Catheter is not designed or intended for contrast injections.
- If excessive resistance is encountered during the use of the Neuroform Microdelivery Stent System or any of its components at any time during the procedure, discontinue use of the System. Movement of the System against resistance may result in damage to the vessel or a System component.

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PRECAUTIONS

- The Neuroform Microdelivery Stent System is provided STERILE for single use only. Store in a cool, dry place.
- Use Neuroform Microdelivery Stent System prior to the "Use Before" date printed on the package.
- Carefully inspect the sterile package and Neuroform Microdelivery Stent System prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components.
- The Neuroform Microdelivery Stent System has been shown to be MRI compatible in MRI systems operating at a field strength of 1.5 Tesla or less. MRI laboratory evaluation demonstrated that no significant image distortion or heating was created by the presence of the Stents at scanning sequences commonly used during MRI procedures. MRI compatibility of the embolic coils used in conjunction with the Stent has not been demonstrated by Smart Therapeutics; refer to the specific embolic coil labeling for MRI compatibility information.
- The Neuroform Microdelivery Stent System should not be used for repositioning or recapturing the Stent.
- Exercise caution when crossing the deployed Stent wth adjunct devices.
- Do not excessively insert and retract the guidewire through the undeployed Stent because the motion may remove coating from the guidewire.
- Tighten the Rotating Hemostasis Valves sufficiently to create an adequate hemostasis seal without crushing the 3F Microdelivery Catheter and 2F Stabilizer Catheter shafts. Inadequately tightening the Rotating Hemostasis Valves may lead to premature deployment of the Stent.
- In tortuous vessels, a stiff guidewire may cause binding within the Neuroform Microdelivery Stent System during deployment. In such cases, use only soft guidewires, and position the floppy section of the guidewire within the Stent.
- After deployment, the Stent may foreshorten up to 1.8% in 2.5mm Stents and up to 5.4% in 4.5mm Stents
- Do not steam shape the tip of the 3F Microdelivery Catheter because it could damage the Delivery System or Stent.
- The safety of the Neuroform Microdelivery Stent System in patients below the age of 18 has not been established.

ADVERSE EVENTS

Potential Adverse Events:

The potential adverse events listed below, as well as others, may be associated with the use of the Neuroform™ Microdelivery Stent System or with the procedure:

Aneurysm perforation or rupture
Cerebral ischemia
Coagulopathy
Coil herniation through Stent into parent vessel
Confusion
Death
Embolic stroke
Hematoma, pain, and/or infection at access site
Incomplete aneurysm occlusion
Intimal dissection
Intracerebral/intracranial hemorrhage
Peripheral thromboembolic events
Post-procedure bleeding
Pseudoaneurysm formation
Renal failure
Stent migration
Stent misplacement
Stent occlusion
Vasospasm
Vessel perforation
Vessel thrombosis

Observed Adverse Events from Clinical Study:

Tables 1 and 2 identify the adverse events observed in the clinical study conducted with the Neuroform™ Microdelivery Stent System. Twenty-nine patients were implanted with the Stent. The tables include all adverse events through 6 months. Of the 29 patients implanted with the Stent, 17 patients had 1 or more adverse events and 5 had 1 or more serious adverse events. There were 12 serious adverse events and 21 other adverse events, all of which occurred prior to or by the time of discharge. None occurred between discharge and the 6-month timepoint. Nine patients had 1 adverse event, 4 patients had 2 adverse events, 1 patient had 3 adverse events, 2 patients had 4 adverse events, and 1 patient had 5 adverse events.

Table 1 summarizes the patient rates for observed serious adverse events. Table 2 summarizes the patient rates for all other observed adverse events.

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Table 1 – Serious Device or Procedure-Related Adverse Events

Serious Adverse Event[1]	n (%)
Death[2]	1 (3.4%)
Aneurysm Perforation[2,3]	2 (6.9%)
Arterial Perforation[4]	1 (3.4%)
Subarachnoid/Interventricular Hemorrhage[2,3]	2 (6.9%)
Thromboembolic Stroke[4]	1 (3.4%)
Intracerebral Hematoma[4]	1 (3.4%)
Left Hemiparesis[4]	1 (3.4%)
Intraparenchymal Bleeding[3]	1 (3.4%)
Retroperitoneal Hematoma[5]	1 (3.4%)
Confusion[6]	1 (3.4%)

[1]Five patients had these 12 serious adverse events. The "n" reflects the number of occurrences of that adverse event. The % is based on 29 patients who were assessed before or at discharge when all adverse events occurred.
[2]One patient had 3 serious adverse events. There was perforation of the aneurysm dome with the micro guidewire during the initial catheterization of the aneurysm resulting in subarachnoid/interventricular hemorrhage and death. Death was due to complications from aneurysm perforation leading to bleeding and pre-existing hepatitis and management of anticoagulation therapy.
[3]One patient had 3 serious adverse events. There was perforation of the aneurysm with the microcatheter during coil placement resulting in subarachnoid hemorrhage and subsequent intraparenchymal bleeding (from the ventricular drainage line).
[4]One patient had 4 serious adverse events. Arterial perforation occurred with the tip of the exchange length guidewire prior to Stent insertion, resulting in an intracerebral hematoma. This patient also had a thromboembolic stroke that led to left hemiparesis.
[5]One patient had a retroperitoneal hematoma.
[6]One patient had confusion. Confusion was categorized by the protocol as a non-serious adverse event; however, it was determined by the clinical study investigator to be a serious adverse event because the patient required a prolonged hospital stay.

Table 2 – Other Device or Procedure-Related Adverse Events

Other Adverse Event[1]	n (%)
Right Hemiparesis	1 (3.4%)
Embolic Event[2]	4 (13.8%)
Vasospasm[3]	5 (17.2%)
Intimal Dissection[4]	1 (3.4%)
Seizure[5]	1 (3.4%)
Access Site Hematoma[6]	2 (6.9%)
Liver Failure	1 (3.4%)
Vomiting	1 (3.4%)
Headache	3 (10.3%)
Fever of Unknown Origin	1 (3.4%)
Urinary Tract Infection	1 (3.4%)

[1]Fifteen patients had these 21 adverse events. The "n" reflects the number of occurrences of that adverse event. The % is based on 29 patients who are accounted for and were assessed before or at discharge when all adverse events occurred.
[2]Includes embolic ischemic lesion, small embolic lesion, asymptomatic microemboli to brain detected by MRI, and left prolonged reversible ischemic neurological deficit (PRIND). All embolic events resulted in mild neurological deficits. Three completely resolved, and 1 patient was discharged to a rehabilitation facilty.
[3]Includes 4 mild and 1 moderate case. All completely resolved.
[4]Occurred during placement of the guide catheter in the cervical internal carotid prior to Stent placement, not in the portion of the vessel treated with the device.
[5]One patient with a history of epilepsy experienced a seizure with no permanent sequelae while in the hospital.
[6]Includes 1 mild and 1 moderate case. Both resolved.

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CLINICAL STUDY

This was a European clinical study. The patient inclusion criteria were: (1) wide neck, ruptured or unruptured, saccular, intracranial aneurysm or aneurysm on the level of the skull base, where a wide neck is defined as a dome-to-neck ratio <2 and/or neck length of ≥4mm; (2) aneurysm is in artery with diameter≥1.5mm and ≤5.5mm; (3) patient is ≥18 years old; and (4) patient provided written informed consent.

There were 31 patients entered into the study. Five (16%) were male and 26 (84%) were female. Fifty-two percent of the patients were asymptomatic prior to treatment. Two of the 31 patients did not receive the Stent because of failure to access based on anatomy. The remaining 29 patients enrolled in the study had 30 aneurysms (1 patient had 2 aneurysms that were treated with one Stent). Previous attempts had been made to treat 17 of the 30 aneurysms (57%) using other devices.

Table 3 summarizes the locations of the 30 aneurysms. Table 4 summarizes the sizes of the 30 aneurysms.

Table 3 – Aneurysm Location

Location	n	%
Carotid ophthalmic	7	24%
Posterior communicating artery	7	24%
Carotid cavernous	5	17%
Anterior choroidal	2	7%
Basilar tip	2	6%
Carotid bifurcation	1	3%
Middle cerebral artery	1	3%
Anterior cerebral artery	1	3%
Vertebral artery	1	3%
Posterior inferior cerebellar artery	1	3%
Basilar trunk	1	3%
Other	1	3%

Table 4 – Aneurysm Size

Measurement	n	Mean	SD	Min	Max
Dome width (mm)	30	7.4	4.3	2.1	20.0
Neck length (mm)	30	4.9	1.8	2.1	11.0
Dome to neck ratio	30	1.5	0.5	0.8	2.7
Parent vessel pre-aneurysm (mm)	30	3.6	0.6	2.4	4.8
Parent vessel post-aneurysm (mm)	30	3.2	0.7	1.7	4.4
Parent vessel caliber differential (mm)	30	1.0	1.0	0.3	1.7

The 29 patients were implanted with 39 Stents to treat their 30 aneurysms. Twenty (69%) patients had 1 Stent, 8 (28%) patients had 2 Stents, and 1 (3%) patient had 3 Stents. The Stents implanted ranged from 3.5mm to 4.5mm. One patient required a secondary endovascular procedure to place a second Stent in the correct location because the original Stent was inadvertently not deployed at aneurysm site; this counts for 2 of the Stents. One patient had the original Stent successfully deployed but was removed during the embolic coiling procedure when the clinical study investigator attempted to snare the errant coil loop and dislodged the Stent. A replacement Stent was implanted in its place, and this counts for 2 of the Stents. For 7 patients, multiple Stents were used to treat one aneurysm in cases where (1) the embolic coiling procedure left the tail of an embolic coil in the vessel or (2) the neck of aneurysm was estimated at an incorrect width and a second or third Stent was necessary to cover the neck of the aneurysm.

With regard to patient accounting, 31 patients were originally entered into the study; however, 2 did not receive the Stent. One patient died immediately after the procedure. There are adverse event data on 29 patients, including the one death. Therefore, there were 28 patients of 31 who were expected for evaluation through 6 months. At discharge, 28 of the expected 28 were evaluated for a follow-up rate of 100%. At 6 months, 26 of 28 patients were evaluated for a follow-up rate of 93%.

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The study endpoints were (1) adverse events, (2) technical feasibility, and (3) clinical outcome. The incidence of all adverse events, device or procedure-related, were assessed. Technical feasibility was assessed by the ability to access the aneurysm and place the Stent accurately across the aneurysm neck. Clinical outcome was assessed by percent angiographic aneurysm occlusion.

Adverse events were presented in Tables 1 and 2 in the *Adverse Events* section above.

Table 5 below summarizes the patient rates with regard to technical feasibility.

Table 5 – Technical Feasibility

Technical Feasibility	n (%)
Ability to access aneurysm	29/31 (93.5%) patients[1]
Ability to place Stent across aneurysm neck	29/29 (100%) patients[2,3]

[1]Two patients could not be accessed based on anatomy.
[2]One patient required a secondary endovascular procedure to place a second Stent in the correct location because the original Stent was inadvertently not deployed at aneurysm site.
[3]There were 2 intraoperative device malfunctions involving the markerband of the 2F Stabilizer Catheter inadvertently detaching from the shaft of the 2F Stabilizer Catheter after Stent deployment. In one patient, the 2F Stabilizer Catheter was inside the patient at the time of the device malfunction, and the separated markerband embolized in a small, distal intracranial artery. This patient had no adverse events from this event. In the second patient, the 2F Stabilizer Catheter was outside the patient at the time of the device malfunction. SMART Therapeutics has since increased its markerband bond strength.

Table 6 below summarizes the patient rates with regard to clinical outcome.

Table 6 –Clinical Outcome

Clinical Outcome[1]	n (%)
% occlusion at discharge[2]	
100%	17 (58.6%)
95-99%	13 (44.8%)
% occlusion at 6 months	
100%	18 (69.2%)
95-99%	8 (30.8%)

[1]The "n" reflects the number of occurrences. The % is based on 29 patients at discharge and 26 patients at 6 months.
[2]One patient had 2 aneurysms, each with different resulting % occlusion. Therefore, this patient is reported twice.

Other clinical outcomes included:

- No Stent stenosis or migration.
- No emboli coil migration.
- No parent vessel thrombosis, occlusion, or dissection.
- Neurological status: Of 26 patients evaluated at 6 months, 17 (65%) had an unchanged (normal) neurological assessment as compared to baseline, 3 (16%) had an improved (from abnormal to normal) neurological assessment as compared to baseline, 5 (19%) had an unchanged (abnormal) neurological assessment as compared to baseline, and 1 (4%) had a worsened (abnormal moderate confusion to abnormal severe confusion) neurological assessment as compared to baseline.

PATIENT INFORMATION

You should have already provided the patient with a copy of the Patient Information Booklet so that he/she 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 product 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 compatibility.

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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 Microdelivery Stent System in patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.

PROCEDURE STEPS

Angiographic Assessment of Aneurysm and Stent Selection

1. Using angiography, determine the location of the aneurysm and the size of the aneurysm neck.

2. Select a Stent diameter based on the sizing recommendations in Table 7 and based on the larger vessel diameter (proximal or distal reference vessel diameter).

3. Select a Stent length that is at least 8mm longer than the aneurysm neck to maintain a minimum of 4mm on each side of the aneurysm neck along the parent vessel. Refer to Table 7 for Stent sizing recommendations.

Delivery System Preparation

1. Open and inspect both the 2F Stabilizer Catheter and the 3F Microdelivery Catheter for damage, such as kinks or compromised packaging. The Stent and Peelable Sheath should be preloaded into the distal tip of the 3F Microdelivery Catheter.

2. Flush both the 3F Microdelivery Catheter and the 2F Stabilizer Catheter with sterile, heparinized saline.

NOTE: **Care should be taken when flushing the 3F Microdelivery Catheter so that the jet of saline does not push the Peelable Sheath out of the 3F Microdelivery Catheter.**

3. Insert the 2F Stabilizer Catheter through the Rotating Hemostasis Valve and into the 3F Microdelivery Catheter. Advance the 2F Stabilizer Catheter tip carefully until the tip is adjacent to the proximal end of the Peelable Sheath (at the distal tip).

4. Flush the Rotating Hemostasis Valves and connect to the proximal hub of the Catheters, one to the 2F Stabilizer Catheter and one to the 3F Microdelivery Catheter.

5. Connect the 2F Stabilizer Catheter and the 3F Microdelivery Catheter to a pressurized sterile heparinized saline flush.

6. Tighten the hemostasis valve on the 3F Microdelivery Caheter to hold the 2F Stabilizer Catheter in place during advancement of the Neuroform Microdelivery Stent System. Do not overtighten the hemostasis valve because the 2F Stabilizer Catheter could be crushed.

Guidewire Positioning

1. Position an access wire across the aneurysm neck using standard microcatheter and guidewires techniques. Recommended guiding catheter specifications include 90 cm length and minimum ID of .050".

2. Replace the access guidewire with an exchange length 0.014" guidewire, and remove the microcatheter. Leave the exchange guidewire across the aneurysm neck. Soft guidewires are recommended rather than support guidewires.

Stent Positioning and Deployment

1. Carefully backload the 3F Microdelivery Catheter onto the .014" guidewire. Ensure that the guidewire does not push the Peelable Sheath inside the tip of the 3F Microdelivery Catheter.

2. Once a sufficient length of the guidewire is inside the 3F Microdelivery Catheter and through the 2F Stabilizer Catheter, carefully sliding the Peelable Sheath out of the 3F Microdelivery Catheter and along the guidewire. Care should be taken to ensure the Stent does not move. If necessary slight pressure on the 3F Microdelivery Catheter in the area of the Stent will ensure the Stent does not move.

3. Remove the Peelable Sheath from the guidewire and 3F Microdelivery Catheter by tightly gripping both ends of the Peelable Sheath and slide the ends toward the center of the Peelable Sheath. This will cause the Peelable Sheath to buckle in the center. Carefully grasp the buckled center of the Peelable Sheath and remove it from the guidewire. Ensure that the entire Peelable Sheath is removed from the guidewire.

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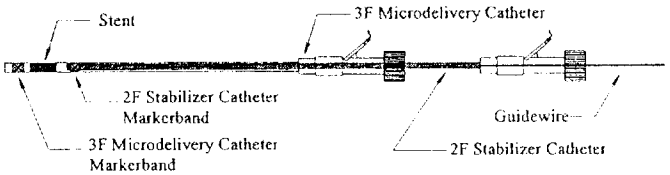
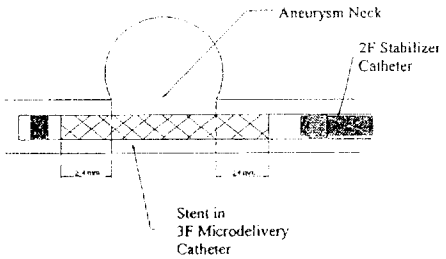
4. Carefully advance the Neuroform Microdelivery Stent System as one unit into the guiding catheter.

5. Adjust the hemostasis valve on the 3F Microdelivery Catheter to hold the 2F Stabilizer Catheter in place during advancement of the Neuroform Microdelivery Stent System. Do not overtighten the hemostasis valve because the 2F Stabilizer Catheter could be crushed.



6. Holding the Neuroform Microdelivery Stent System in one hand, and the guidewire in the other, advance the Neuroform Microdelivery Stent System like a typical microcatheter by manipulating the Neuroform Microdelivery Stent System and the guidewire. Advance the Neuroform Microdelivery Stent System so that the undeployed Stent crosses the aneurysm neck.



NOTE: **Advancing the 2F Stabilizer Catheter independently from advancing the 3F Microdelivery Catheter may cause premature deployment of the Stent. Do not use the 2F Stabilizer Catheter to push the Stent out of the Delivery System.**

NOTE: **Initially during advancement of the Neuroform Microdelivery Stent System, it is helpful to have an assistant hold the end of the wire while the Neuroform Microdelivery Stent System is advanced into the body. However, as the System approaches the intracranial circulation, a single operator should advance both the System and the guidewire.**

7. Gently pull back on the guidewire and Neuroform Microdelivery Stent System until the excess guidewire slack is removed from the System and the tip of the 3F Microdelivery Catheter begins to move. Advance the 2F Stabilizer Catheter (slightly loosening the rotating hemostasis valve may be necessary) so that its tip contacts the Stent and moves the Stent slightly within the 3F Microdelivery Catheter.

8. While holding the 3F Microdelivery Catheter in one hand and the 2F Stabilizer Catheter in the other hand, carefully pull both Catheters together as a unit until the Stent is in the desired position. Position the markerband on the 3F Microdelivery Catheter so that it is a minimum of 4mm distal to the aneurysm neck.

NOTE: **The best fluoroscopic view for positioning the Stent for deployment is the view that shows the vessel distal to the aneurysm. This view may not be the same view as that used as the working position for aneurysm embolization.**

9. When the distal end of the Stent is in the desired location, deploy the Stent by holding the 2F Stabilizer Catheter steady with one hand while continuing to carefully withdraw the 3F Microdelivery Catheter with other hand. This will deploy the Stent.

10. As the tip of the 3F Microdelivery Catheter passes the Stent, you will see the markerbands on the distal end of the Stent spread out from one another. This is the Stent opening. Continue deploying the Stent in one continuous smooth motion. Do not attempt to move the Stent after it has begun to deploy. Be careful not to advance the 3F Microdelivery Catheter as the Stent is deploying.

11. After the Stent is completely deployed, remove the Delivery System.

Aneurysm Embolization

1. The aneurysm embolization can begin immediately. Standard microcatheters accepting .010", .014", or .018" guidewires with distal tip ≤ 2.0F may be carefully placed through the interstices of the Stent to place embolic coils in the aneurysm.

   NOTE: Carefully watch the Stent markerbands when passing through the deployed Stent with embolic coiling microcatheters to avoid dislodging the Stent.

2. Perform a standard embolic coiling procedure using accepted embolic coiling practices.

TABLE 7 – Neuroform Microdelivery Stent System
Product Numbers and Recommended Sizing Guidelines

Product Number	Labeled Stent Diameter (mm)	Labeled Stent Length[1] (mm)	Self Expanded Stent Diameter (mm)	Recommended Vessel Diameter[2] (mm)	Useable 3F Microdelivery Catheter Length	Useable 2F Stabilizer Catheter Length	Maximum Guidewire Diameter	Minimum Guide Catheter ID
FA-00001-01	2.5 mm	10 mm	3.0	>2.0 and ≤2.5	131 cm	161 cm	0.014 in	0.050 in
FA-00001-02	2.5 mm	15 mm	3.0	>2.0 and ≤2.5				
FA-00001-03	2.5 mm	20 mm	3.0	>2.0 and ≤2.5				
FA-00002-01	3.0 mm	10 mm	3.5	>2.5 and ≤3.0				
FA-00002-02	3.0 mm	15 mm	3.5	>2.5 and ≤3.0				
FA-00002-03	3.0 mm	20 mm	3.5	>2.5 and ≤3.0				
FA-00003-01	3.5 mm	10 mm	4.0	>3.0 and ≤3.5				
FA-00003-02	3.5 mm	15 mm	4.0	>3.0 and ≤3.5				
FA-00003-03	3.5 mm	20 mm	4.0	>3.0 and ≤3.5				
FA-00004-01	4.0 mm	10 mm	4.5	>3.5 and ≤4.0				
FA-00004-02	4.0 mm	15 mm	4.5	>3.5 and ≤4.0				
FA-00004-03	4.0 mm	20 mm	4.5	>3.5 and ≤4.0				
FA-00005-01	4.5 mm	10 mm	5.0	>4.0 and ≤4.5				
FA-00005-02	4.5 mm	15 mm	5.0	>4.0 and ≤4.5				
FA-00005-03	4.5 mm	20 mm	5.0	>4.0 and ≤4.5				

[1]Select a Stent length that is at least 8mm longer than the aneurysm neck to maintain a minimum of 4mm on each side of the aneurysm neck along the parent vessel.
[2]Select a Stent diameter based on the sizing recommendations in Table 7 and based on the larger vessel diameter (proximal or distal reference vessel diameter).

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QUESTIONS AND ANSWERS

Q: The Neuroform Microdelivery Stent System seems to be binding with the guidewire, making it difficult to advance the System. What should I do?

A: Use soft guidewires rather than support guidewires because soft guidewires facilitate maneuverability of the Neuroform Microdelivery Stent System and deployment of the Stent. Excess tension can build up in the guidewire resulting in increased friction in the System. Alleviate the friction by slightly retracting the guidewire and 3F Microdelivery Catheter to remove any accumulated tension. If excessive friction continues, confirm that the 3F Microdelivery Catheter saline flush is functioning. With use, guidewires can become kinked and loose their lubricious coatings. If excessive friction persists, consider removing and discarding the guidewire and Neuroform Microdelivery Stent System and replacing it with a new one.

Generally, once the Neuroform Microdelivery Stent System is tracking forward over the guidewire, take advantage of the momentum and continue tracking to a target site that is distal to the aneurysm neck. It is easier to move the Neuroform Microdelivery Stent System from a distal to proximal location across the aneurysm neck instead of trying to reposition it by advancing the Neuroform Microdelivery Stent System.

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 normal areas of the parent vessel. The Stent will be more stable if each end of the Stent is anchored in at least 4-6mm of normal vessel. For example, for aneurysms 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, so that the distal end of the Stent can be accurately deployed with respect to the aneurysm. This view may be different from the view used to advance the Neuroform Microdelivery Stent System, or the view used as a working position for aneurysm embolization.

Deploy the distal end of the Stent as precisely as possible with respect to the aneurysm neck to assure at least 4mm of each end of the Stent lies along the parent vessel. Ensure accurate measurement of the aneurysm neck so that, when the Stent is properly sized per Table 7, the proximal end of the Stent will deploy at the correct location, even if it is difficult to see it because of curves in the vessel.

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: *Vessel increases from 2mm PCA (posterior communicating artery) to a 3.4mm basilar.*

A: Choose the Stent sized for the larger vessel. In this example, choose the 3.5mm Stent. This Stent can be deployed safely in the smaller PCA and will be well anchored in the basilar artery.

Q: Is there any problem with deploying the Stent across a branch vessel? Can the Stent be safely deployed across the anterior choroidal artery? What about lenticulostriate arteries or perforators arising from the basilar?

A: No adverse events resulting from branch vessel occlusion or emboli to "jailed" vessels have been observed in the limited clinical study conducted on this Stent (26 patients followed through 6 months). Stents have been placed extending from the M1 (middle cerebral artery, first segment) to the ICA (internal carotid artery) without problems.

Q: A coil was placed only partially into the aneurysm and won't retract back into the embolization microcatheter. Part of the coil is outside the aneurysm. What should I do?

A: Do not attempt to remove the partially deployed coil in this situation. The best solution is to place a second Neuroform Microdelivery Stent System in the parent vessel and parallel to the embolization microcatheter, gently pull back the microcatheter containing the coil to unroll, but not stretch, the coil. Then deploy the second Stent to hold the unrolled coil against the vessel wall, and finally detach the coil. This may be safer than trying to forcibly remove the coil and risk dislodging the coil mass and Stent into the parent vessel. Strict attention to heparinization and antiplatelet medication is important.

Q: A loop, or several loops, of a coil (especially a small diameter coil such as 2mm) are protruding through the interstices of the Stent, and I am unable to reposition it. What should I do?

A: If the risk of leaving part of the coil in the parent vessel is unacceptable, place a second Stent inside the first Stent to pin the herniated coil portion against the wall of the vessel. Three-dimensional angiography using an orthogonal view (i.e., "down the

barrel") may be helpful to assess whether or not a coil loop is inside the lumen of the Stent, in the parent vessel, or between the wall of the vessel and the Stent. Strict attention to heparinization and antiplatelet medication is important.

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

A: The safest course of action generally is not to try repositioning the Stent, but to 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: Leave the guidewire in place, remove the 3F Microdelivery Catheter and 2F Stabilizer Catheter, and insert and deploy a second Stent starting from inside from the first Stent to the normal portion of the parent vessel (telescoping Stents). The second Stent should be of the same diameter or larger than the first.

WARRANTY

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