stryker®
Neurovascular

# Neuroform EZ®

## Stent System




Stryker Neurovascular (DFU Template 8in x 8in Global, 90106041AL), DFU, Neuroform EZ, EN, 90685463-01C

# Neuroform EZ®

## Stent System

**℞ 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.

**Resale of this device is prohibited by US law.**

**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 ≥ 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 EZ Stent System includes:

- A self-expanding, open cell, nitinol stent with four radiopaque markerbands on each end (proximal and distal) and 3 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. The stent is pre-loaded on the stent delivery wire and protected by an introducer sheath.
- An accessory pouch containing an optional guidewire introducer and an optional torque device. The physician may attach the torque device to the proximal end of the stent delivery wire, which may facilitate handling and stabilization. The stent delivery wire is not designed to be torqued. The guidewire introducer should not be used with the stent delivery wire. If the microcatheter must be repositioned with a guidewire (as described in procedure step 18), the guidewire introducer may be used to facilitate introduction into the microcatheter.

**Contents**

- One (1) Neuroform EZ Stent System
- One (1) Torque Device
- One (1) Guidewire Introducer

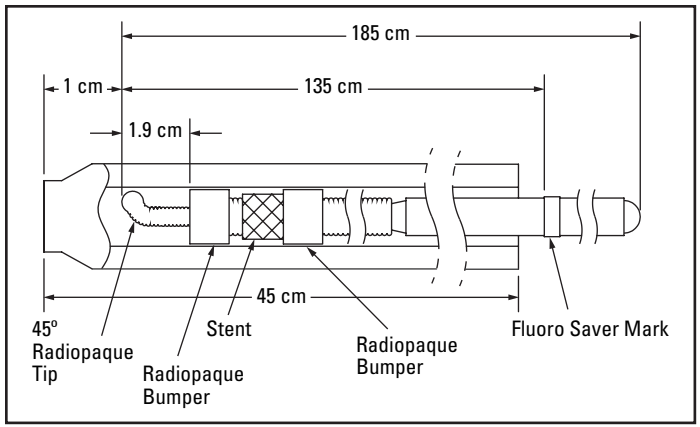


**Figure 1. Neuroform EZ Stent System**

**Table 1. Sizing Table**

| Labeled Stent Diameter (mm) | Self Expanded Stent Diameter (mm) | Recommended Vessel Diameter[1] (mm) |
|---|---|---|
| 2.5 | 3.0 | > 2.0 and ≤ 2.5 |
| 3.0 | 3.5 | > 2.5 and ≤ 3.0 |
| 3.5 | 4.0 | > 3.0 and ≤ 3.5 |
| 4.0 | 4.5 | > 3.5 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).

**INTENDED USE/INDICATIONS FOR USE**

The Neuroform EZ Stent System is intended for use with embolic coils 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 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 and diameter) to maintain a minimum of 4 mm 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 22 mm in length.
- If excessive resistance is encountered during the use of the Neuroform EZ 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.

## PRECAUTIONS

- The Neuroform EZ® Stent System is provided STERILE for single use only.
- Use the Neuroform EZ Stent System prior to the "Use By" date printed on the package.
- Carefully inspect the sterile package and Neuroform EZ Stent System prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components.
- For MRI information, please refer to the "MRI Information" section.
- The Neuroform EZ Stent System should not be used for recapturing the stent.
- Exercise caution when crossing the deployed stent with adjunct devices.
- After deployment, the stent may foreshorten up to 1.8% in 2.5 mm stents and up to 5.4% in 4.5 mm stents.
- The safety of the Neuroform EZ 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.
- The safety of "Y" stenting or techniques of passing a guidewire through stent interstices to access other vessels for the purpose of stenting has not been clinically established.

## ADVERSE EVENTS

### Potential Adverse Events

Potential complications include, but are not limited to:

- allergic reaction
- aneurysm perforation/rupture
- coil herniation through stent into parent vessel
- death
- embolus
- hemorrhage
- in-stent stenosis
- infection
- ischemia
- neurological/intracranial sequelae
- pseudoaneurysm
- stent fracture
- stent migration/embolization
- stent misplacement
- stent thrombosis
- stroke
- transient ischemic attack
- vasospasm
- vessel occlusion or closure
- vessel thrombosis
- vessel perforation/rupture, dissection, trauma or damage
- 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.

### Observed Adverse Events from Clinical Study

Tables 2 and 3 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 2 summarizes the patient rates for observed serious adverse events. Table 3 summarizes the patient rates for all other observed adverse events.

**Table 2. 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 3. 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 facility.

[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.

## 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 ≥ 4 mm; (2) aneurysm is in artery with diameter ≥ 1.5 mm and ≤ 5.5 mm; (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 4 summarizes the locations of the 30 aneurysms. Table 5 summarizes the sizes of the 30 aneurysms.

**Table 4. Aneurysm Location**

| Location | n | % |
|---|---|---|
| Carotid ophthalmic | 7 | 24% |
| Posterior communicating artery | 7 | 24% |
| Carotid cavernous | 5 | 17% |
| Anterior choroidal | 2 | 7% |
| Basilar tip | 2 | 7% |
| 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 5. 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 3.5 mm to 4.5 mm. 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%.

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 2 and 3 in the ***Adverse Events*** section above.

Table 6 below summarizes the patient rates with regard to technical feasibility.

**Table 6. 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. Stryker Neurovascular has since increased its markerband bond strength.

Table 7 below summarizes the patient rates with regard to clinical outcome.

**Table 7. 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 (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 Patient Information Booklet, 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 EZ® Stent System in patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.

## MRI INFORMATION

### Magnetic Resonance Conditional

Non-clinical testing and analysis have demonstrated that Neuroform® Stent is MR Conditional alone, or when overlapped with a second stent, and adjacent to a Stryker Neurovascular coil mass. A patient with Neuroform 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
- spatial gradient field up to 2500 Gauss/cm (25 Tesla/m)
- normal operational mode for gradients and SAR (maximum whole body averaged specific absorption rate (SAR) of lower than 2.0 W/kg and maximum head SAR of lower than 3.2 W/kg) for a total active MR scan time (with RF exposure) of 15 minutes or less per scan sequence.

In an analysis based on the temperature rises in non-clinical testing of stents and the calculated SAR in the patient during an MR scan, Neuroform Stents were determined to produce an in-vivo temperature rise of 4°C or lower for 15 minutes of MR scanning in normal operational mode in 1.5 T and 3 T MR systems. The Neuroform Stent should not migrate in this MRI environment.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. In Spin Echo and Gradient Echo sequence evaluations Neuroform stent image artifact extended approximately 2 mm from the device. Lumen of the stent was partially obscured by the artifact. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

## HOW SUPPLIED

### Minimum Materials Required (Not included in the Neuroform EZ Stent System package)

| Quantity | Material |
|---|---|
| 1 | Appropriate guiding catheter(s) [0.064 in (1.63 mm) minimum ID] |
| 3 | Sterile Heparinized normal saline (HepNS) flush lines 1000 U/500 mL (500 cc) |
| 1 | 0.014 in (0.36 mm) guidewire access length |
| 1 | 0.014 in (0.36 mm) guidewire exchange length |
| 1 | Sterile Contrast |
| 1 | Arterial sheath and dilator set |
| 1 | 20 mL (20 cc) syringe with luer-lock |
| 3 | Three way stopcock |
| 1 | 0.027 in (0.69 mm) ID Microcatheter, 135 or 150 cm length |

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 Boston Scientific or Stryker Neurovascular microcatheter (0.027 in (0.69 mm) ID and 135 or 150 cm length) with a neurovascular indication. Establish and maintain continuous flush with sterile heparinized saline 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 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 EZ® Stent System based on the sizing recommendations in Table 1 and based on the larger reference vessel diameter. Select a stent that is at least 8 mm longer 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

5. Carefully inspect the stent system packaging for damage. Do not use if damage is found; call your Stryker Neurovascular representative.
6. Peel open the pouch using aseptic technique.
7. Carefully place the dispenser hoop into the sterile field.
8. Release the stent delivery wire from the clip on the dispenser hoop. Hold the stent delivery wire and proximal end of the introducer sheath together, then carefully remove the system from the dispenser hoop.

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

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

9. Inspect the stent 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. Do not use if damage is found; call your Stryker Neurovascular representative.
10. Partially insert the distal end of the introducer sheath into the RHV (3.5F compatible RHV) connected to the microcatheter. Tighten the RHV. Open the y-connector valve of the RHV that is connected to the sterile heparinized saline flush 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.

**Note:** Partial insertion of the introducer sheath into the RHV is necessary to ensure a flow path for flush.

11. Loosen the RHV. Advance the introducer sheath until the colored tip is fully inserted into the microcatheter hub, then tighten the RHV firmly. Pull gently on the introducer sheath to ensure that it is secure. The introducer sheath tip should not move.

**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 colored 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.

12. 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 indicate an inadequately tightened RHV and may result in premature deployment of the stent within the microcatheter hub.

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

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

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

### Stent Positioning and Deployment

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

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

17. Withdraw the microcatheter slightly to remove any slack from the stent system and to position the stent for deployment by aligning the stent radiopaque markers across the target aneurysm.

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

18. Before stent deployment, if the microcatheter must be repositioned with a guidewire, the stent and the stent delivery wire must be pulled back into the introducer sheath as follows: Tighten the RHV firmly to hold the stent delivery wire and the microcatheter together, then reposition the distal flexible segment of the catheter until it is in a relatively straight segment of the artery. Load the introducer sheath over the proximal end of the stent delivery wire into the RHV attached to the microcatheter, and ensure that the colored tip is fully inserted into the microcatheter hub. Tighten the RHV firmly. Pull gently on the introducer sheath to ensure that it is secure. The introducer sheath tip should not move.

    Carefully retract the stent delivery wire so that the stent is pulled back into the introducer sheath proximal to the colored tip section. Verify that the sterile heparinized saline flush exits the introducer sheath to ensure that no blood products remain in the sheath. Ensure that the distal tip of the stent delivery wire is fully inside the introducer sheath, then loosen the RHV and remove the stent system from the RHV. Once the stent system is removed from the microcatheter, place the stent system in sterile heparinized saline for reuse after microcatheter repositioning. Re-insert the access length guidewire to reposition the microcatheter, using the guidewire introducer if desired.

**Note:** At least 50 cm of the stent delivery wire should be proximal to the RHV in order to load the introducer sheath.

**Note:** Be careful that the introducer sheath is loaded in the correct orientation – the colored tip should be fully inserted into the hub of the microcatheter.

**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:** Ensure that the introducer sheath does not move while retracting the stent delivery wire. Movement of the introducer sheath during stent retraction may indicate an inadequately tightened RHV and may result in premature deployment of the stent within the microcatheter hub.

19. If stent positioning is satisfactory, carefully retract the microcatheter in a continous movement, while maintaining the position of the stent delivery wire to allow the stent to deploy across the neck of the aneurysm. The stent's distal markers will expand as it exits the microcatheter. Confirm deployed stent position.

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

**Note:** The physician may attach the optional torque device to the proximal end of the stent delivery wire, which may 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.

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

20. Prior to removing the stent delivery wire, position the microcatheter distal to the stent to maintain access through the stent. Remove and discard the Neuroform EZ® Stent System.

21. Advance an exchange length guidewire through the microcatheter.

22. Remove the 0.027 in microcatheter while maintaining the position of the exchange length guidewire, and replace with an appropriate microcatheter to begin aneurysm embolization.

**Aneurysm Embolization**

23. The aneurysm embolization can begin immediately. Standard microcatheters accepting 0.25 mm (0.010 in), 0.36 mm (0.014 in), or 0.46 mm (0.018 in) guidewires with distal tip ≤ 2F 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.

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

**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 normal areas of the parent vessel. The stent will be more stable if each end of the stent is anchored in at least 4-6 mm 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 EZ 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 4 mm 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 1, 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 2 mm PCA (posterior communicating artery) to a 3.4 mm basilar.*

A: Choose the stent sized for the larger vessel. In this example, choose the 3.5 mm 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 loop, or several loops, of a coil (especially a small diameter coil such as 2 mm) 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: Remove the Neuroform EZ® Stent System from the microcatheter while maintaining the position of the microcatheter. 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.

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