

Neuroform³[™] Microdelivery Stent System

Confidence Begins with Control

Engineered to provide enhanced performance throughout the system, Neuroform³ Microdelivery Stents offer a new level of control.*

Intracranial Access

An all-new, stabilizer catheter features advanced hypotube shaft construction designed for improved access and controlled deployment.*

Guidewire Control

A familiar, over-the-wire system allows for independent manipulation of the guidewire distal to the stent. This feature is designed to facilitate access for system support, and ultimately control.*

Stent Conformability

Neuroform³ Stents employ a highly flexible, hybrid cell design for better tracking during access and greater conformability within a variety of vessel morphologies.*

Clinical Experience

Since its introduction in 2002, Neuroform[®] Stents have been selected by physicians to treat more than 8,000 intracranial aneurysms worldwide.

Pre-Assembled for Convenience

Designed to reduce procedural time and the risk of system damage or inadvertent deployment during assembly, Neuroform³ Stents are now packaged pre-assembled for convenience.*

Hybrid Cell Design

Optimized for Greater Scaffolding

The Neuroform³ hybrid cell design is engineered to provide greater scaffolding for coil mass support and sufficient radial force to generate stability within the vessel.*

Developed for Tapered Vessel Applications

A highly conformable, segmented stent design allows for vessel apposition in tapered vessel applications and simplifies sizing of the stent to the dimensions of the target vessel.

Designed to Minimize Foreshortening

Neuroform³ Stents employ segmented cell geometry engineered to minimize foreshortening during deployment. Stent foreshortening ranges from 1.8% to 5.4% of total length.* **

* Compared to the Neuroform and Neuroform² Stent Systems.

** Bench testing conducted by Boston Scientific. Data on file. Bench test results are not necessarily indicative of clinical performance.

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Delivery Catheter Construction

Fiber and Platinum Braid

The microdelivery catheter features a continuous fiber and platinum braid construction for exceptional flexibility, trackability, and kink resistance.

PTFE Inner Lumen

An ultra-smooth inner lumen surface enhances manipulation of the stabilizer catheter within the microdelivery catheter and aids in deployment of the stent.

New Stabilizer Catheter

83% Reduction in Guidewire Friction**

A new, enlarged PTFE inner lumen (.0165" diameter) reduces system friction by 83% to facilitate manipulation of guidewires within the stabilizer catheter.*

.014" Guidewire Compatibility

Compatible with all .014" guidewires, the stabilizer catheter allows for use of preferred guidewires for familiar "feel" and greater control.

Stabilizer Proximity Marker Band

A laser-etched marker band indicates the proximity of the distal tip of the stabilizer catheter to the proximal end of the stent.

Stabilizer Catheter Construction

Hypotube Proximal Shaft

Stainless steel hypotube proximal shaft offers enhanced trackability and support.*

Spiral-Cut Transition Zone

Hypotube proximal shaft is spiral-cut distally to provide a flexible transition to the braided mid-shaft.

Braided Mid-Shaft

Continuous flat-wire braid reinforcement and a two-layer polymer shaft body for support and lumen integrity.

Braided Distal Shaft

Single-layer polymer shaft body over continuous flat-wire braiding provides lumen integrity with greater distal flexibility.*

* Compared to the Neuroform and Neuroform² Stent Systems.

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Neuroform³™ Microdelivery Stent System

Prod. No.	Diameter x Length	Min. Guiding Catheter ID	Max. Guidewire Diameter
SNF34530	4.5 x 30 mm	.050 in	.014 in
SNF34030	4.0 x 30 mm	.050 in	.014 in
SNF33530	3.5 x 30 mm	.050 in	.014 in
SNF33030	3.0 x 30 mm	.050 in	.014 in
SNF34520	4.5 x 20 mm	.050 in	.014 in
SNF34020	4.0 x 20 mm	.050 in	.014 in
SNF33520	3.5 x 20 mm	.050 in	.014 in
SNF33020	3.0 x 20 mm	.050 in	.014 in
SNF32520	2.5 x 20 mm	.050 in	.014 in
SNF34515	4.5 x 15 mm	.050 in	.014 in
SNF34015	4.0 x 15 mm	.050 in	.014 in
SNF33515	3.5 x 15 mm	.050 in	.014 in
SNF33015	3.0 x 15 mm	.050 in	.014 in
SNF32515	2.5 x 15 mm	.050 in	.014 in
SNF34510	4.5 x 10 mm	.050 in	.014 in
SNF33510	3.5 x 10 mm	.050 in	.014 in

Neuroform²® Microdelivery Stent System

Prod. No.	Diameter x Length	Min. Guiding Catheter ID	Max. Guidewire Diameter
S245030	4.5 x 30 mm	.050 in	.014 in
S240030	4.0 x 30 mm	.050 in	.014 in
S235030	3.5 x 30 mm	.050 in	.014 in
S245020	4.5 x 20 mm	.050 in	.014 in
S240020	4.0 x 20 mm	.050 in	.014 in
S235020	3.5 x 20 mm	.050 in	.014 in
S245015	4.5 x 15 mm	.050 in	.014 in
S240015	4.0 x 15 mm	.050 in	.014 in
S235015	3.5 x 15 mm	.050 in	.014 in

Microdelivery Catheter Usable Length: 131 cm

Microdelivery Catheter OD: 2.8F Distal; 3F Proximal

Stabilizer Catheter Usable Length: 150 cm

Stabilizer Catheter OD: 2F

Recommended Guide Catheter: Guider Softip® XF Guide Catheter, 90 cm, 5F

Stent Interstices Size: 2.0F–2.5F

Stent Foreshortening: 1.8%–5.4%

Recommended Guidewire: Transend® 300 Floppy Guidewire

Neuroform® Stent Accessories

Prod. No.	Description
SNF3STA	Stabilizer

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See package insert for complete indications, contraindications, warnings, and instructions for use.

Indications 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 ≥ 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.

Contraindication

Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated

Potential Adverse Effects

Potential complications include but are not limited to: 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

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 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.
- 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.

Cautions/Precautions

- Federal Law (USA) 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 Boston Scientific representative.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise 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.
- 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 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 Boston Scientific; 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 with 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 2.5 mm stents and up to 5.4% in 4.5 mm 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.
- Testing on the 30 mm length stents and 3 interconnect stents was performed in the lab but not in animals or humans. However, probable benefit is still expected.

Trademark

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