

# Wingspan™ Stent System with Gateway™ PTA Balloon Catheter

Delivering New Options for Ischemic Stroke

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

**Humanitarian Device.** The Wingspan™ Stent System with Gateway™ PTA Balloon Catheter is authorized by United States Federal law for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system. The effectiveness of this device for this use has not been demonstrated.

#### Wingspan Stent System Indications for Use

The Wingspan Stent System with Gateway PTA Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system.

#### Contraindications

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Lesions that are highly calcified or otherwise could prevent access or appropriate expansion of the stent.

#### Potential Adverse Effects

The potential adverse events listed below, as well as others, may be associated with the use of the Wingspan Stent System with Gateway PTA Balloon Catheter or with the procedure:

Observed adverse events: infection; TIA; stroke; hematoma; vasospasm; hemorrhagic event; hypertension; peripheral vascular diseases; neurological symptoms; pain; AMI; angina; arrhythmia; creatinine increase; hematuria; hypoglycemia/hyperglycemia; asymptomatic thromboembolic event; bradycardia (35 min); broken middle-foot left/V-fracture; chronic antrum gastritis; death; elevated bilirubin, GOT, GPT; fever; hiatus hernia; hypervolemia; new distal in stent stenosis; pulmonary edema; respiratory failure; seizure; syncope.

Potential adverse events: cerebral aneurysm; coagulopathy; emboli (air, tissue, or thrombotic tissue); intimal dissection; pseudoaneurysm; stent migration; stent misplacement; stent occlusion; stent embolization; stent thrombosis; vessel perforation; vessel rupture; vessel thrombosis; vessel trauma requiring repair or surgical intervention.

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

#### Warnings

- The Wingspan Stent System with Gateway PTA Balloon Catheter should only be used by physicians who have received appropriate training in interventional neuroradiology and treatment of intracranial atherosclerotic disease.
- The Wingspan Stent System is not designed or intended for contrast injections or injections other than heparinized saline.
- If excessive resistance is encountered during the use of the Wingspan Stent System or with the Gateway PTA Balloon Catheter 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.
- In animal evaluations, the severity of vessel stenosis/neointimal thickness appears to be correlated with the degree of trauma inflicted on the arterial walls by stent placement or stent radial expansion.
- Experience with stent implants indicates that there is a risk of restenosis. Subsequent restenosis may require repeat dilation of the vessel segment containing the stent. The risks and long-term outcome following repeat dilation of endothelialized stents is unknown at present.
- If the stent is implanted adjacent to or contacting other implanted metal, such as another stent or embolic coil, the metals should be of similar composition to avoid galvanic corrosion potential.

#### Cautions/Precautions

- The Wingspan Stent System and the Gateway PTA Balloon Catheter are provided STERILE for single use only. Do not resterilize. Store in a cool, dry place.
- Use the Wingspan Stent System and Gateway PTA Balloon Catheter prior to the "Use By" date printed on the package.
- Select a stent size (length and diameter) that extends a minimum of 3 mm on both sides of the lesion.
- Carefully inspect the sterile package and Wingspan Stent System prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components.
- Typical antiplatelet and anticoagulation regimen used for interventional intracranial procedures is an important adjunct to stent treatment. Patients must be advised to take their prescribed medications after the stent is implanted and should be counseled on the risk of not complying with medical therapy. In-stent thrombosis may occur during the procedure if proper antiplatelet and anticoagulation therapy is not administered.
- Do not steam shape the tip of the Wingspan Stent System because it could damage the stent or delivery system.
- Implanting a stent may lead to dissection of the vessel distal or proximal to the stent and may cause other complications (vasospasm/acute closure) of the vessel requiring additional intervention (i.e., further dilation, placement of stents).
- Do not deploy the stent if it is not properly positioned in the vessel.
- Placement of the stent may compromise side branch patency.
- Follow the Wingspan Stent System preparation and use instructions carefully.
- Previous studies have shown that some metal stents may be incompatible with MRI scanning. The Wingspan Stent System has been shown to be MRI compatible in MRI systems operating at field strengths of 3.0 Tesla or lower. 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.
- Do not use the Wingspan Stent System or the Gateway PTA Balloon Catheter for repositioning or recapturing the stent.
- Exercise caution when crossing the deployed stent with guidewires or other devices.
- In tortuous vessels, a stiff guidewire may cause binding within the Wingspan Stent System or the Gateway Balloon Catheter 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 2.4% in 2.5 mm stents and up to 7.1% in 4.5 mm stents.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vasculature and/or the vascular access site. Complications may include bleeding, hematoma, or pseudoaneurysm.

#### Gateway PTA Balloon Catheter Indications for Use

The Gateway PTA Balloon Catheter is indicated for balloon dilation of the stenotic portion of intracranial arteries prior to stenting for the purpose of improving intracranial perfusion.

#### Contraindications

The Gateway PTA balloon catheter is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Patients who are judged to have a lesion which prevents effective angioplasty.

#### Potential Adverse Effects

Adverse events (in alphabetical order) may be associated with the use of an intracranial angioplasty in stenotic lesions of the intracranial arteries: death; dissection; drug reactions to antiplatelet agents; contrast medium; distal emboli (air, tissue, or thrombotic emboli); hematoma; hemorrhage, requiring transfusion; hypotension/hypertension; infection and pain at insertion site; ischemia/infarct; perforation; pseudoaneurysm, (femoral and intracranial); restenosis of the dilated vessel; spasm; stroke/TIA; total occlusion of the intracranial artery.

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

#### Warnings

- Since the use of this device carries the associated risk of subacute thrombosis, vascular complication and/or bleeding events, judicious selection of patients is necessary.
- Only physicians who have received training should perform intracranial angioplasty.
- Angioplasty and stenting procedures should only be performed at hospitals where emergency intracranial surgery can be readily performed in the event of a potentially injurious or life-threatening complication.

#### Cautions/Precautions

- Store in a dry, dark, cool place. Do not resterilize.
- Note product "Use By" date.
- Follow the Gateway PTA Balloon Catheter preparation and use instructions carefully.
- Do not prepare or pre-inflate the balloon other than as directed. Use the balloon purging technique described in this Instructions for Use.
- Typical antiplatelet and anticoagulation regimen used for interventional intracranial procedure is an important adjunct to balloon angioplasty treatment. Do not use the Gateway PTA Balloon Catheter in patients in whom antiplatelet and/or anticoagulation therapy is contraindicated. Vessel thrombosis may occur during the procedure if proper antiplatelet and anticoagulation therapy is not administered.
- Angioplasty may lead to dissection of the vessel and may cause other complications (vasospasm/acute closure) of the vessel requiring additional intervention (i.e., further dilation, placement of stents).
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon because it may cause uneven inflation and complications.
- If unexpected difficulty is experienced during inflation, do not continue; remove the device and do not attempt to use it.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the lesser of the vessel diameters just proximal and distal to the stenosis.
- Do not use a guidewire having a diameter greater than 0.014 in/0.36 mm.
- When the delivery catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Infusion of any medium other than a flush of heparinized normal saline through the guidewire lumen may compromise device performance.
- Do not attempt to reposition a partially deployed balloon. Attempted repositioning of a partially deployed balloon may result in severe vessel damage.
- Balloon pressures should be monitored during inflation. Do not exceed rated burst pressure indicated on the product label. Use of pressures higher than those specified on the product label may result in a ruptured balloon and potential intimal damage and dissection. The rated burst pressure is based on the results of *in vitro* testing. At least 99.9% of the balloons (with a 95% confidence interval) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over-pressurization.
- Before withdrawing the device, visually confirm complete balloon deflation by fluoroscopy. If the balloon has already been inflated and difficulty is experienced deflating (a non-deflate), connect a large-barrel syringe and manually attempt to deflate the device.
- In order to achieve optimal performance of Gateway Catheters and Boston Scientific steerable guidewires and to maintain the lubricity of the Bioslide™ surface, it is critical that a continuous flow of appropriate flush solution be maintained between a) the Gateway catheter and guide catheter, and b) the Gateway catheter and any intraluminal device. In addition, flushing aids in preventing contrast crystal formation and/or clotting on both the guidewire and inside the catheter lumen.
- The recommended continuous flush set up requires two stopcocks and two rotating hemostatic valves (RHV); the RHV's provide a fluid tight seal and are attached to the guide catheter and Gateway Catheter. The stopcocks attach to the RHV sidearms, which become infusion ports for appropriate flush or contrast medium injection.

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#### Neurovascular

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Designed  
for Intracranial  
Atherosclerotic  
Disease (ICAD)





# Delivering New Options for Ischemic Stroke

The risk of ischemic stroke in patients with Intracranial Atherosclerotic Disease (ICAD) ranges from 7 to 24%.<sup>1,2</sup> ICAD is caused by build-up of plaque within the blood vessels of the brain. Developed specifically for the treatment of ICAD, the Wingspan Stent System and Gateway PTA Balloon Catheter deliver new options for ischemic stroke.

### HDE Safety Study

The Wingspan Stent System and Gateway PTA Balloon Catheter have been evaluated in a monitored, adjudicated, multicenter study. In this study, half the lesions treated were in the anterior circulation — demonstrating the access capabilities of this groundbreaking system. The clinical performance of the Wingspan Stent System and Gateway PTA Balloon Catheter, as shown in this clinical study, included a procedural success rate of 97.7%.

### HDE Study Results

|                        |                                                                                                                                    |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| Multi-Center Study     | Monitored, adjudicated study at 12 sites; 45 patients enrolled                                                                     |
| Proven Safety          | Procedure success = 97.7% (43/44)<br>0 vessel dissections, 0 vessel ruptures                                                       |
| Access                 | 50% of cases in anterior circulation<br>9 M1 lesions treated                                                                       |
| Clinical Outcomes      | 30-day ipsilateral stroke or death rate = 4.4% (2/45)<br><br>6-month ipsilateral stroke or death rate = 7.0% (3/43)                |
| >50% Stenosis          | 7.5% (3/40) at 6 months<br><br>24 out of 40 patients experienced increase in lumen diameter (post-procedure vs. 6-month follow-up) |
| Symptomatic Restenosis | 0% (0/40) at 6 months                                                                                                              |

## Procedure Overview — Wingspan™ Stent System with Gateway™ PTA Balloon Catheter

### Designed for Neurovascular Access

The Wingspan Stent System features a highly flexible, trackable delivery system designed to facilitate access through challenging neurovascular anatomy.

#### 1 Gentle Pre-Dilation

The Gateway PTA Balloon Catheter features a semi-compliant balloon designed for controlled, low-pressure inflation (6 atm).<sup>\*</sup> Recommended to be undersized to 80% of the target vessel diameter, it provides for gentle pre-dilation prior to stent deployment.

#### 2 Atraumatic Stent Deployment

Engineered for atraumatic deployment, the Wingspan Stent is designed to apply minimal pressure — less than 0.1 atm<sup>\*</sup> — to the vessel wall immediately proximal and distal to the treated lesion.

#### 3 Highly Conformable Stent Design

The Wingspan Stent is a self-expanding design with flexible cells to enhance conformability and vessel wall apposition in curved and tapered vessels.

#### 4 Outward Radial Force

The Wingspan Stent is designed to support the vessel lumen by minimizing vessel recoil following angioplasty and exerting active, controlled, outward radial force.<sup>\*</sup>

<sup>\*</sup>Data on file at Boston Scientific. Bench test results may not be indicative of clinical performance.

<sup>1</sup> Comparison of Warfarin and Aspirin for Symptomatic Intracranial Arterial Stenosis. *N Engl J Med* 352;13, March 31, 2005.  
<sup>2</sup> Failure of Extracranial-Intracranial Arterial Bypass to Reduce the Risk of Ischemic Stroke: Results of an International Randomized Trial. *N Engl J Med* 1985; 313:1191–1200.



# Designed for Gentle Pre-Dilation

## Atraumatic Deployment

The Gateway PTA Balloon Catheter is designed for gentle pre-dilation prior to stent deployment. Undersized no more than 80% of the target vessel diameter, the Gateway PTA Balloon Catheter features a semi-compliant, Over-The-Wire balloon designed for controlled, low-pressure inflation (6 atm).

## Ease of Access

Designed to facilitate neurovascular access, the Gateway PTA Balloon Catheter employs advanced bonding technology, balloon materials, hydrophilic coating, and shaft construction for enhanced crossability and trackability characteristics.

## Over-The-Wire Shaft Construction

The Gateway PTA Balloon Catheter features an Over-The-Wire shaft design that tapers seamlessly from the 2.4F distal shaft to the 3.2F proximal shaft to facilitate lesion crossing. The Gateway PTA Balloon Catheter is compatible with all 0.014" guidewires and guide catheters with an inner lumen of 0.064" diameter.

### System Overview

|                            |                                                      |
|----------------------------|------------------------------------------------------|
| Shaft Configuration        | Over-The-Wire (OTW) dual-lumen catheter              |
| Balloon Diameters (mm)     | 1.5, 2.0, 2.25, 2.5, 2.75, 3.0, 3.25, 3.5, 3.75, 4.0 |
| Balloon Lengths (mm)       | 9, 15, 20                                            |
| Nominal Inflation Pressure | 6 atm                                                |
| Rated Burst Pressure       | 12 atm<br>(14 atm for 2.25–3.25 mm diameters only)   |
| Recommended Guidewire      | 0.014" exchange length (300 cm)                      |
| Recommended Guide Catheter | 6F (minimum 0.064" ID), 90 cm length                 |

# Gateway™ PTA Balloon Catheter

## 0.017" Lesion Entry Profile

The smooth, flexible, tapered distal tip has a low, 0.017" lesion entry profile designed to facilitate access through the lesion.

## Laser-Bonded TrakTip™ Design

The distal tip is laser-bonded to the shaft for a smooth, flexible transition between the tip and balloon, designed to facilitate access in challenging neurovascular anatomy.

## Semi-Compliant Balloon

Fabricated of soft, semi-compliant LEAP® or SoftLEAP™ balloon material, Gateway PTA Balloons are designed for gentle pre-dilation (6 atm nominal inflation pressure).

## Dual Swaged Marker Bands

Dual marker bands are swaged, not glued, for a smoother transition between the marker bands and catheter shaft. The marker bands are designed to facilitate positioning of the balloon relative to the lesion by defining the working area of the balloon.

Note: 1.5 mm balloons have a single marker band

## Swaged Profile vs. Adhesive Bond



## Bioslide® Hydrophilic Coating

The catheter shaft features Bioslide Hydrophilic Coating, designed to facilitate advancement and negotiation of challenging anatomy.

## XTRA® Silicone Coating

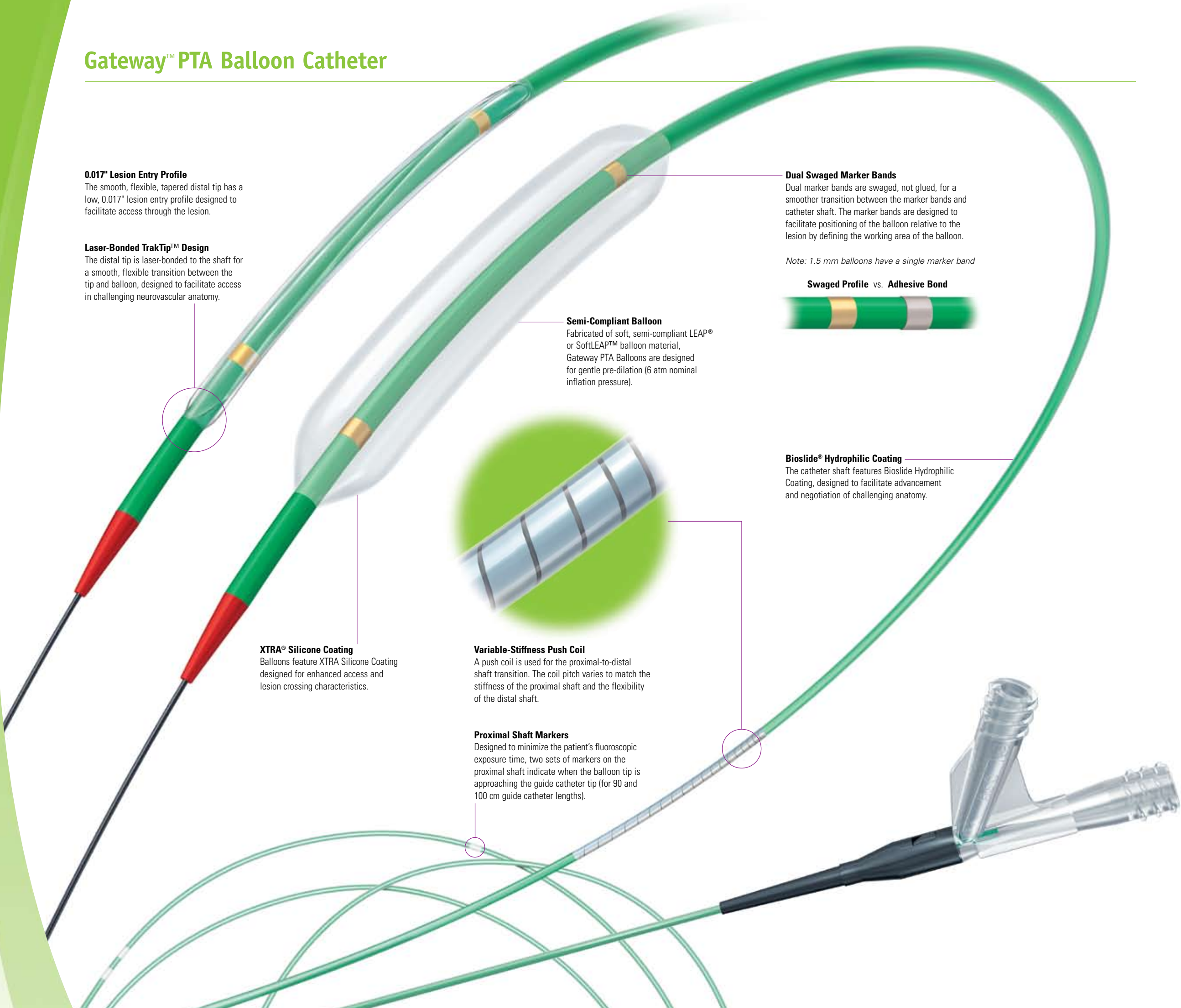
Balloons feature XTRA Silicone Coating designed for enhanced access and lesion crossing characteristics.

## Variable-Stiffness Push Coil

A push coil is used for the proximal-to-distal shaft transition. The coil pitch varies to match the stiffness of the proximal shaft and the flexibility of the distal shaft.

## Proximal Shaft Markers

Designed to minimize the patient's fluoroscopic exposure time, two sets of markers on the proximal shaft indicate when the balloon tip is approaching the guide catheter tip (for 90 and 100 cm guide catheter lengths).





# Designed for Access, Conformability, Support

## Ease of Access

Developed specifically for use within the neurovasculature, the Wingspan Stent System features a highly flexible and trackable delivery system designed for ease of access. In this Over-The-Wire system, the stent is fully enclosed prior to deployment to minimize the risk of vessel trauma during access.

## Highly Conformable Stent Design

The Wingspan Stent System employs an extra-flexible, self-expanding stent design. This highly conformable stent is designed to promote good vessel wall apposition in curved and tapered vessels and to accommodate the natural variation present in vessel morphology.

## Atraumatic Deployment

Engineered to apply minimal pressure (<0.1 atm) to the vessel wall immediately proximal and distal to the lesion, Wingspan Stents feature a self-expanding stent design for gentle, atraumatic deployment.

## Outward Radial Force

The outward radial force exerted by Wingspan Stents is designed to support the vessel lumen to minimize vessel recoil following angioplasty. The outward radial force is engineered to provide controlled expansion up to the fully expanded stent diameter.

### System Overview

|                              |                                                              |
|------------------------------|--------------------------------------------------------------|
| Configuration                | 3.5F unified Over-The-Wire (OTW) self-expanding stent system |
| Nominal Stent Diameters (mm) | 2.5, 3.0, 3.5, 4.0, 4.5                                      |
| Stent Lengths (mm)           | 9, 15, 20                                                    |
| Recommended Guidewire        | 0.014" exchange length (300 cm)                              |
| Recommended Guide Catheter   | 6F (minimum 0.064" ID), 90 cm length                         |

# Wingspan™ Stent System

### Fully Sheathed Stent

The stent is fully sheathed within the outer body. This design is intended to facilitate access, protect the stent, and minimize the risk of vessel trauma.

### Flexible 3-Connector Cell Design

A flexible 3-connector cell design promotes conformability and good vessel wall apposition. It is also designed to enhance access and delivery characteristics, especially with longer stent lengths.

### Distal Marker Band

A platinum marker band on the distal end of the outer body is designed to facilitate positioning and visualization of the delivery system.

### Proximal Bumper and Marker

A proximal bumper on the inner body is designed to maintain stent position during deployment. A platinum marker band provides for visualization.

### 3.5F Coil Reinforced Shaft

The outer delivery catheter shaft is reinforced with stainless steel coil is designed to limit kinking and ovalization for enhanced trackability.

### Hydropass® Hydrophilic Coating

Ultra-lubricious outer surface is designed to facilitate advancement and negotiation of the delivery system through challenging neurovascular anatomy.

### Radiopaque Markers

Four platinum markers distally and proximally is designed to provide for visualization of stent position within the outer body and following deployment.

### Dual-Tapered Tip

The inner body has a dual-tapered tip is designed to facilitate crossing of the lesion and retraction of the delivery system following stent deployment. The inner body tip tapers gradually both distally and proximally (0.046" diameter crossing profile).

### Hypotube Proximal Shaft

The inner body features a stainless-steel proximal hypotube shaft is designed to transmit force to the proximal shaft for enhanced support during stent deployment.

### Rotating Hemostatic Valve (RHV)

Designed to maintain hemostasis, the integrated RHV allows the outer body to be locked to the inner body during advancement.

### Continuous Guidewire Lumen

The inner body provides a continuous guidewire lumen, designed for compatibility with 0.014" guidewires to maintain guidewire access throughout the procedure.