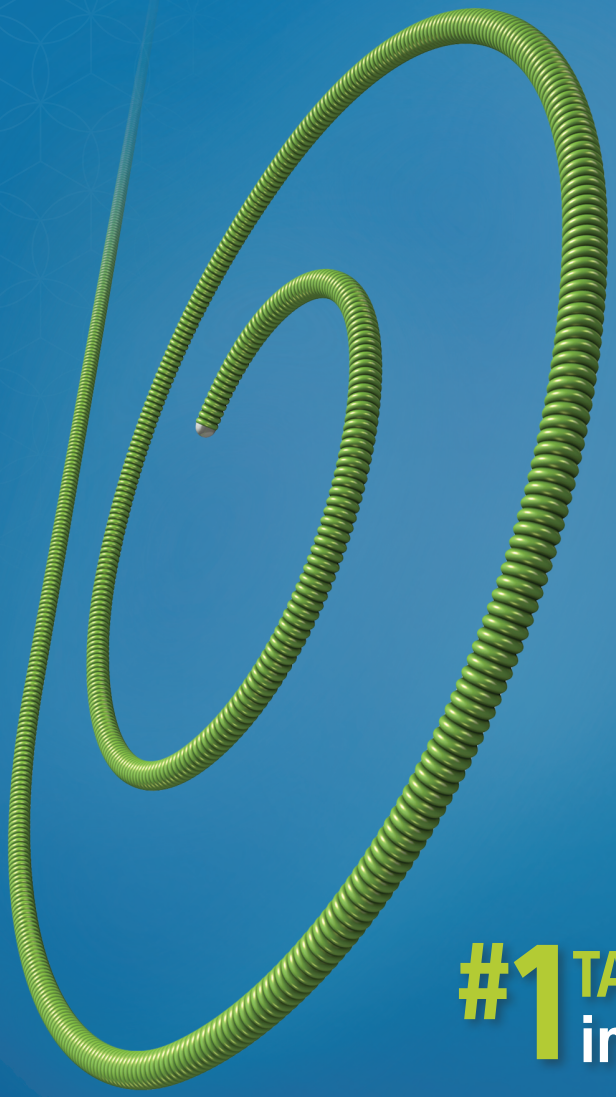
Boston Scientific

Advancing science for life™

# SAFARI²™

## Pre-Shaped Guidewire



# Shaped and Sized for SAFETY

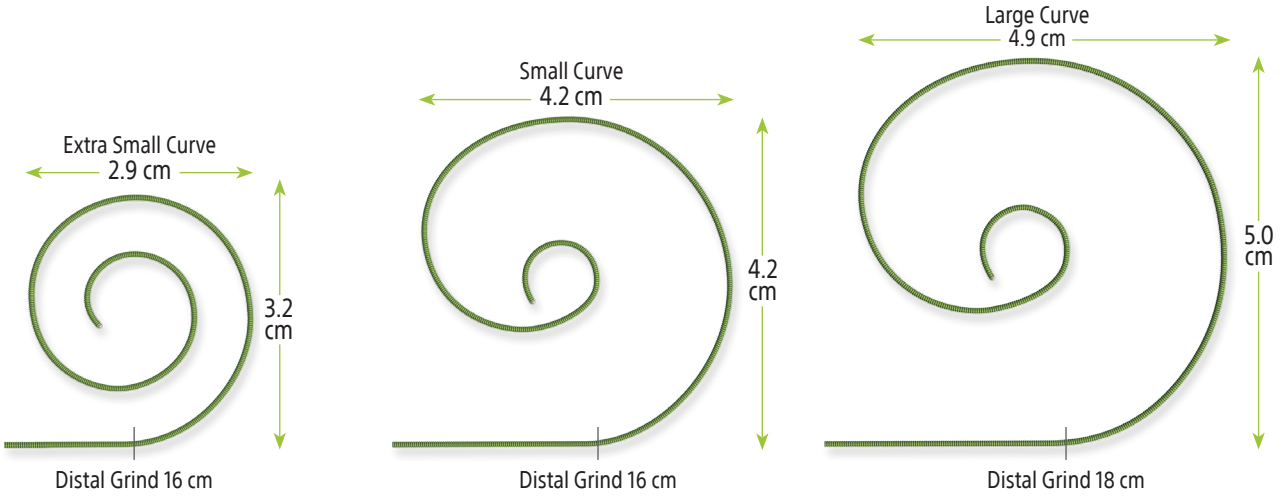
**#1 TAVI Wire in Europe**[1]

# Predictable, Atraumatic Performance Providing Complete Reassurance

- Pre-shaped design for predictable, reliable performance across a broad spectrum of transcatheter devices
- Double curve architecture absorbs contractions of the left ventricle and facilitates stable, atraumatic placement
- Best-in-class rail support and controlled positioning[§,**,††]

# Size Flexibility

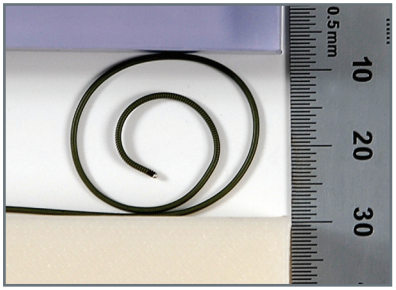
- Multiple curve sizes enable customized selection based on physician preference
- Extra small curve designed for small and/or hypertrophic ventricles



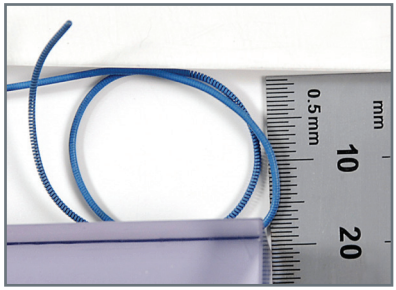
# Best-in-Class Shape Retention

SAFARI2™ Guidewire demonstrates superior curve retention and maintenance of geometry during compression

**Compression Testing**



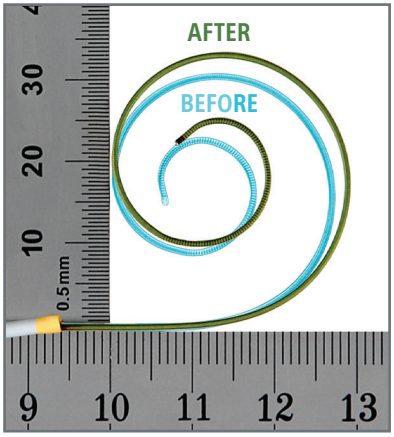

SAFARI2 Guidewire




Amplatz Super Stiff™ Guidewire

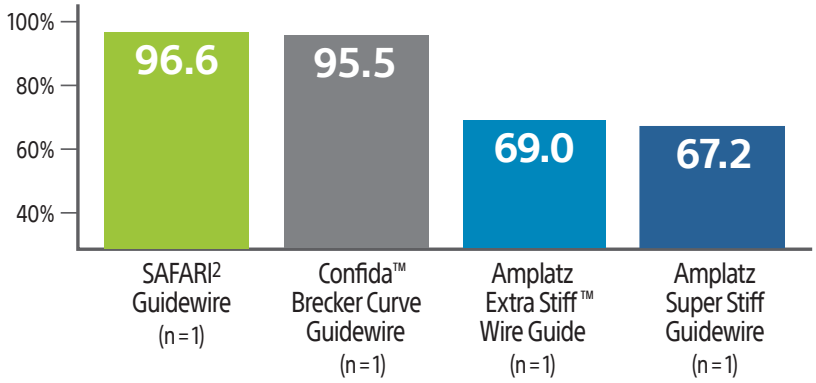
SAFARI2 Guidewire keeps a stable position and curve when subjected to an equivalent compression load simulating the compression in the left ventricle

**Curve Retention Testing**




SAFARI2 Guidewire

**Curve Retention (%)**



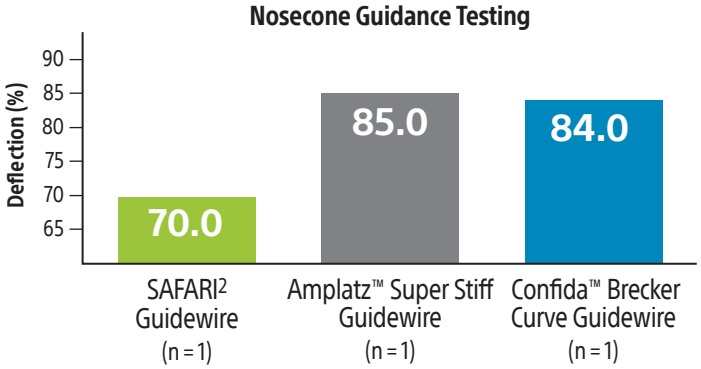

In competitive bench testing the SAFARI2 Guidewire outperformed other wires in shape retention, preserving 96% of its original shape after use

Bench testing performed by Boston Scientific. Bench test results may not necessarily be indicative of clinical performance. Data on file.

# Optimal Nosecone Guidance

The SAFARI²™ Guidewire is designed for optimal nosecone guidance and control during valve positioning and delivery‡,††

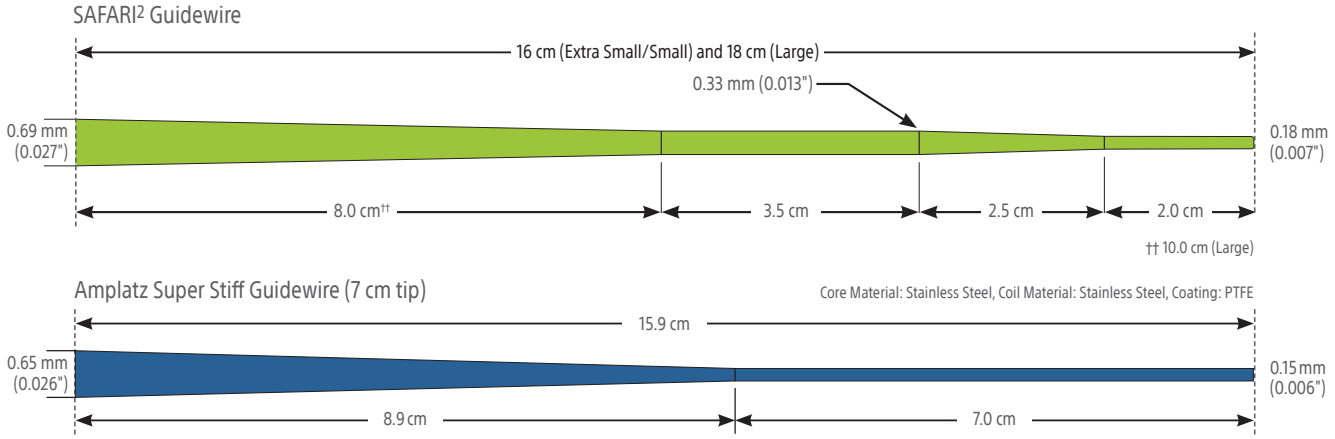
Tests measure the degree of deflection of the distal curve when tracking valve nosecone




SAFARI² Guidewire deflected less than the Amplatz Super Stiff or Confida wire when tracking valve nosecone over the proximal part of the curve

# Distal Curve Designed for Atraumatic Valve Procedures

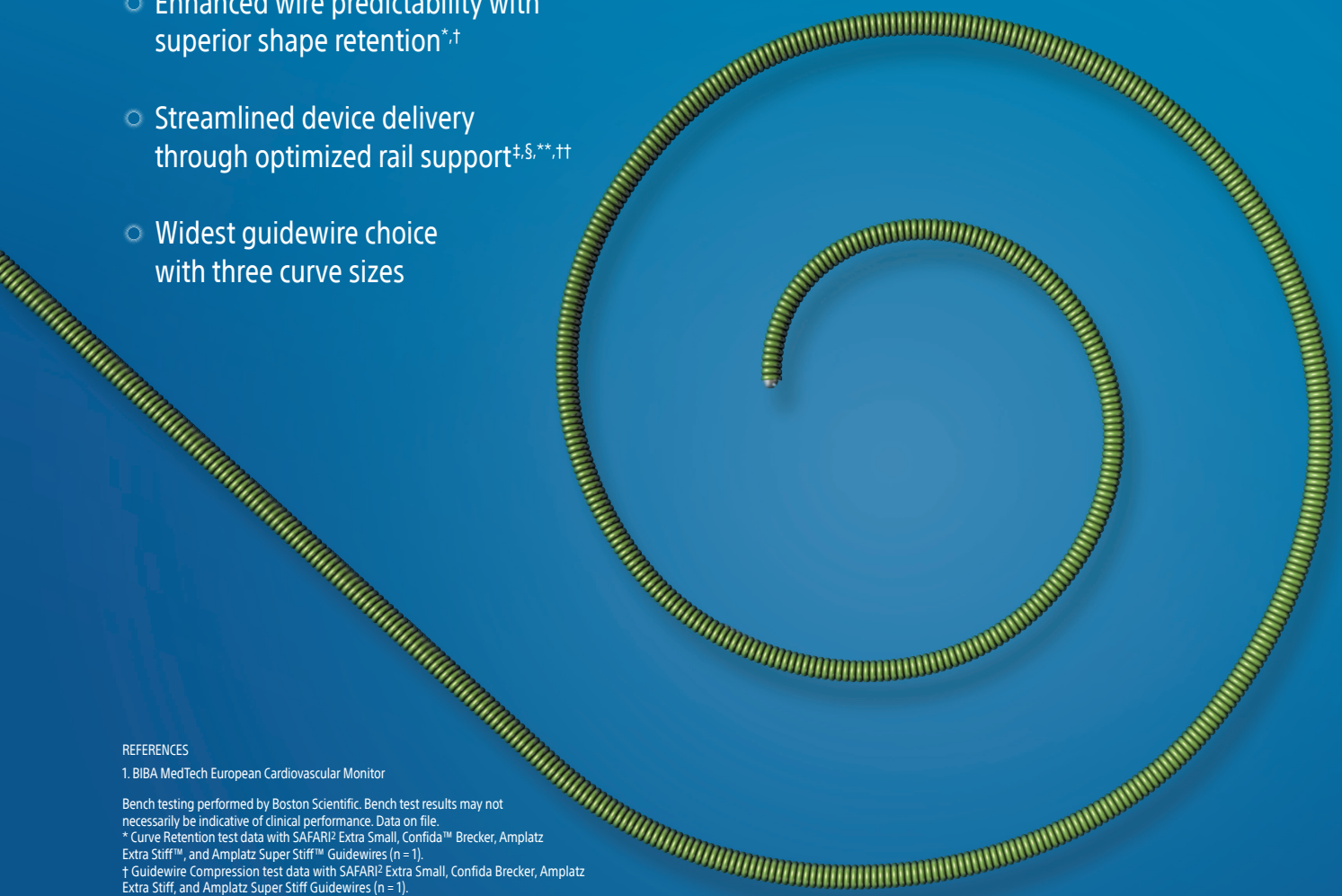
Smooth tapering of the distal core for optimal distal tip rail support




Bench testing performed by Boston Scientific. Bench test results may not necessarily be indicative of clinical performance. Data on file.

# Enables Safe Treatment of a Broad Range of Patients with Valvular Disease

- Enhanced wire predictability with superior shape retention*,†
- Streamlined device delivery through optimized rail support‡,§,**,††
- Widest guidewire choice with three curve sizes



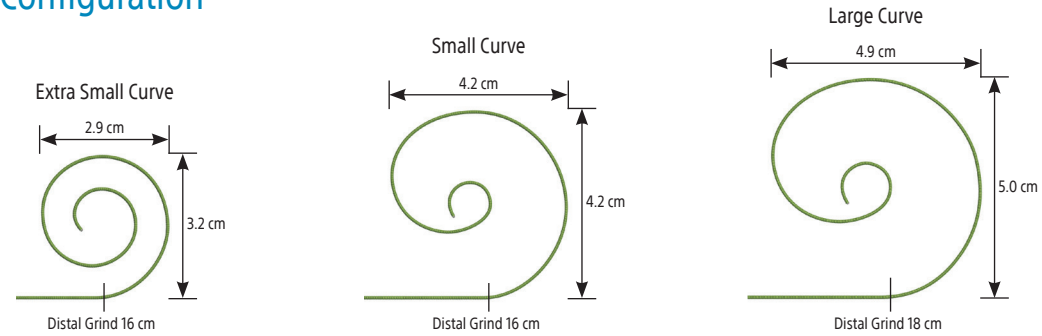

REFERENCES

1. BIBA MedTech European Cardiovascular Monitor


Bench testing performed by Boston Scientific. Bench test results may not necessarily be indicative of clinical performance. Data on file.
* Curve Retention test data with SAFARI² Extra Small, Confida™ Brecker, Amplatz Extra Stiff™, and Amplatz Super Stiff™ Guidewires (n = 1).
† Guidewire Compression test data with SAFARI² Extra Small, Confida Brecker, Amplatz Extra Stiff, and Amplatz Super Stiff Guidewires (n = 1).
‡ Nosecone Tracking test data with SAFARI² Extra Small, Confida Brecker, Amplatz Extra Stiff, and Amplatz Super Stiff Guidewires (n = 1).
§ Simulated Use Static Friction, Dynamic Friction, and Distal Curve Displacement test data with LOTUS™ Valve System with SAFARI Large and Amplatz Super Stiff Guidewires (n = 4).
** Simulated Use Friction, Dynamic Friction, and Distal Curve Displacement with Evolut™ R with SAFARI² Extra Small and Confida Brecker Guidewires (n = 3).
†† Per VAR 550 342 ACURATE *neo*™ and SAFARI validation testing the performance of ACURATE *neo* TF delivery system is compatible with the SAFARI² Guidewire in a representative simulated use environment.

# SAFARI²™
## Pre-Shaped Guidewire

## Curve Tip Configuration




## Order Information

| Order Number (GTIN) | Ref/Catalog Number | Description | Outer Diameter (inches) | Outer Diameter (mm) | Length | Quantity per Box |
|---|---|---|---|---|---|---|
| 08714729887614 | H749 **39406XS** 1 | SAFARI² Guidewire Extra Small Curve | 0.035 | 0.889 | 275 cm | 5 Pack |
| 08714729887591 | H749 **39406S** 1 | SAFARI² Guidewire Small Curve | 0.035 | 0.889 | 275 cm | 5 Pack |
| 08714729887577 | H749 **39406L** 1 | SAFARI² Guidewire Large Curve | 0.035 | 0.889 | 275 cm | 5 Pack |
| 08714729887638 | H749 **39407XS** 0 | SAFARI² Guidewire Extra Small Curve | 0.035 | 0.889 | 275 cm | 1 Single |
| 08714729887652 | H749 **39407S** 0 | SAFARI² Guidewire Small Curve | 0.035 | 0.889 | 275 cm | 1 Single |
| 08714729887645 | H749 **39407L** 0 | SAFARI² Guidewire Large Curve | 0.035 | 0.889 | 275 cm | 1 Single |

The C-code used for this product is C11769 Guidewires. C-codes are used for hospital outpatient device reporting for Medicare and some private payers. Boston Scientific is not responsible for the correct use of codes on submitted claims; this information does not constitute reimbursement or legal advice.

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**SAFARI² Pre-Shaped TAVR TAVI Guidewire**
**Intended Use/Indications for Use:** The SAFARI² Guidewire is intended to facilitate the introduction and placement of interventional devices within the chambers of the heart including those used within transcatheter aortic valve procedures. **Contraindications:** This wire is not intended for use in the cerebrovasculature or coronary arteries. **Warnings:** • The SAFARI² Guidewire should be used only by physicians trained in the introduction and placement of interventional devices including those used within transcatheter aortic valve procedures. • Carefully read all instructions prior to use. Observe all warnings and precautions. Failure to do so may result in complications. • Prior to use, inspect for damage. If damaged, DO NOT USE. • Monitor wire position throughout the procedure for proper placement of curve and distal tip. • Do not torque this guidewire. • Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated. • Inserting the distal end of the guidewire through a Tuohy-Borst Adapter may result in damage to the tip of the guidewire. • If contrast agents are used, use extreme caution in patients who have had a severe reaction to contrast agents and who cannot be adequately premedicated. • When advancing or removing the guidewire, always use fluoroscopic guidance with radiographic equipment that provides high-resolution images. Never position the guidewire blindly, as this may result in misplacement, dissection or perforation. • Exercise care in handling of the guidewire during a procedure to reduce the possibility of accidental breakage, bending, kinking, or coil separation. Resulting guidewire fractures might require additional percutaneous intervention or surgery. • Never advance the guidewire against the resistance without first determining the reason for resistance under fluoroscopy. Excessive force against resistance may result in damage to the catheter or vessel/organ. Care should be taken when advancing a guidewire after device deployment. • The wire should only be introduced into or withdrawn from the ventricle through a catheter already positioned in the ventricle.• The curve of the SAFARI² Guidewire should be constrained within a catheter during insertion into or withdrawal from the body or treatment site. • The SAFARI² Guidewire is manufactured with a double curve; attempts to modify may alter its performance. Alterations to curve may lead to complications including Perforation or Dissection, Mitral Valve Regurgitation, Pericardial Effusion, Cardiac Tamponade, Cardiac Arrest and Guidewire Replacement. • Clinical data showing use of this device in pregnant/breastfeeding women is not available. **Adverse Events:** • Access site complication • Additional Surgical Procedure • Air Embolism/Thromboembolism • Allergic Reaction • Amputation • Aorta Complications • Arteriovenous (AV) Fistula • Arrhythmia • Bleeding • Cardiac and/or Septal Perforation • Death • Embolism • Hematoma • Hemorrhage • Hemoglobinuria • Hypovolemia • Infection or Sepsis • MACCE • Myocardial Ischemia and/or Infarction • Pericardial Effusion • Pseudoaneurysm • Renal Failure or Injury • Stroke or other Neurologic event • Tamponade • Thrombus • Valve Complications • Vascular Complication • Vessel Occlusion • Vessel Perforation, Dissection, Trauma, or Damage • Vessel Spasm • Wire Entrapment/ Entanglement • Foreign Body/Wire Fracture. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
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SH-322921-AF-US