



SAFARI²
Pre-Shaped Guidewire

Wired for Safety



#1

TAVR
GUIDEWIRE

Stable. Predictable. Reliable.

Shaped and sized for safety, the SAFARI²™ Pre-Shaped Guidewire gives you the optimized rail support¹⁻³ and unmatched curve retention⁴ you rely on to effectively treat patients. Approved for a broad spectrum of structural heart disease uses, it streamlines device delivery¹⁻³ and offers enhanced wire predictability⁴ – making it the #1 TAVR guidewire.⁵

MORE THAN
500,000
patients
worldwide





Sized for patient safety

Three curve sizes, including extra-small for small or hypertrophic ventricles, fit a broad range of patient anatomies, giving you the versatility to treat nearly any patient

Streamlined device delivery

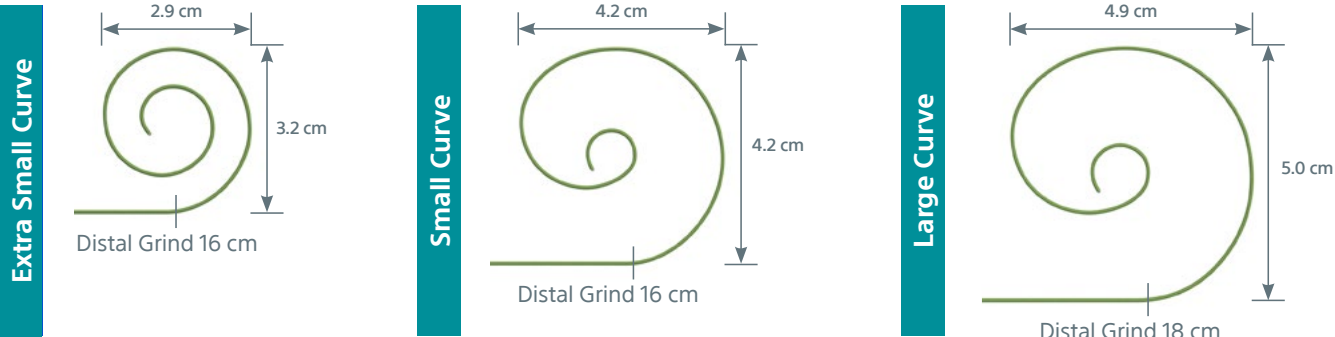
Wire stiffness optimizes rail support¹⁻³ even in tortuous anatomies, allowing you to treat even the most difficult cases

Best-in-class curve retention

Preserves 96% of its original shape – the top performer in competitive bench testing⁴ – maintaining stability you can rely on while tracking

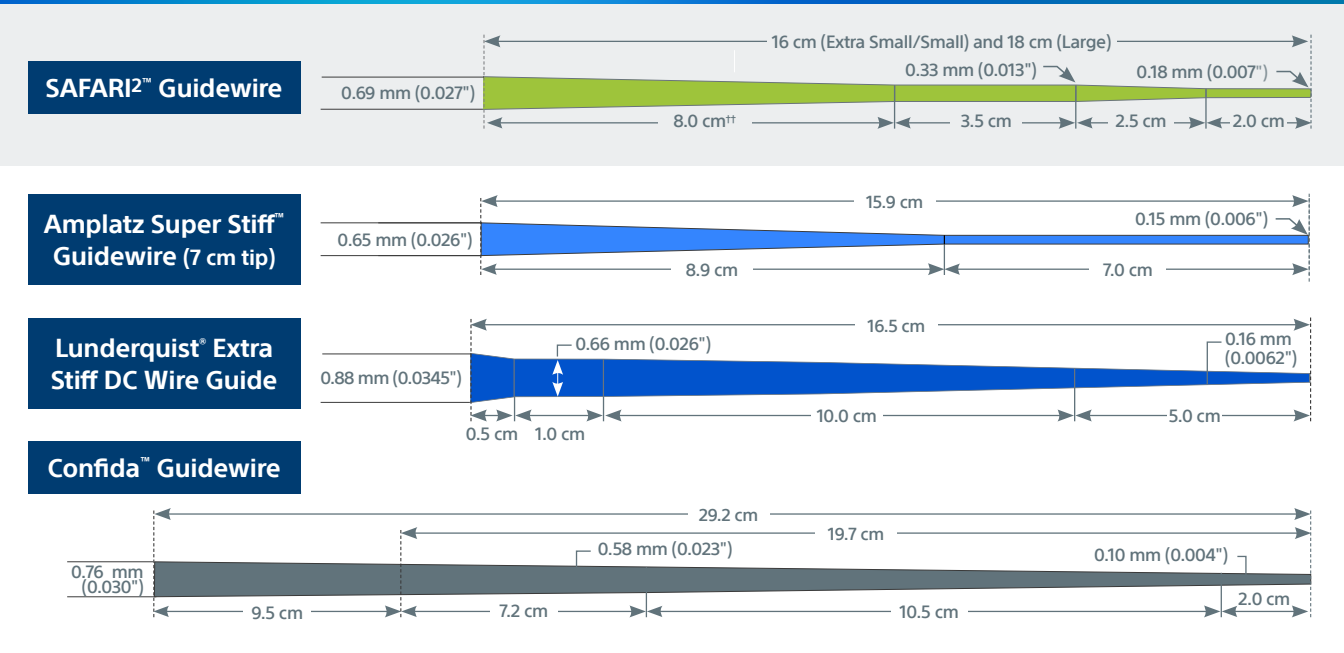
Size Flexibility

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



Distal Curve Designed for Atraumatic Valve Procedures

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

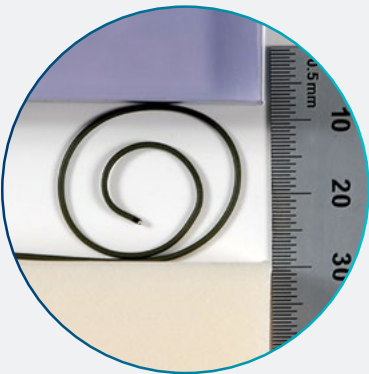


^{††} 10.0 cm (Large)

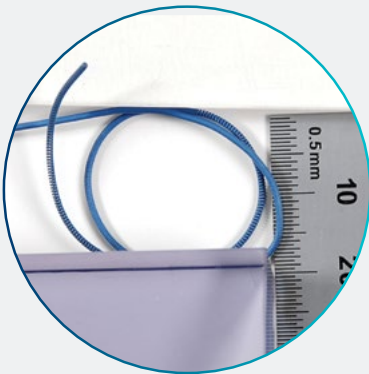
Best-in-Class Shape Retention

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

Compression Testing



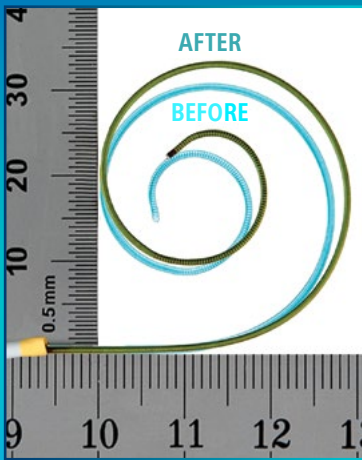
SAFARI² Guidewire



Amplatz Super Stiff™ Guidewire

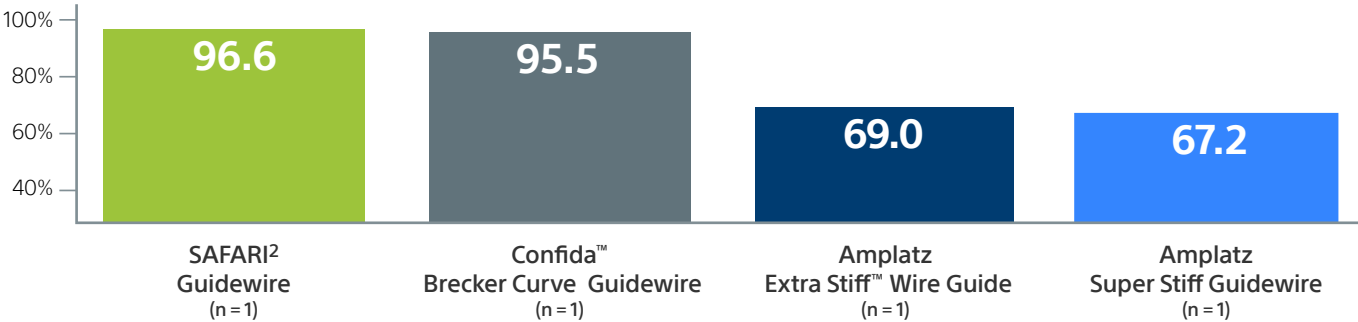
SAFARI² Guidewire keeps a stable position and curve when subjected to an equivalent compression load simulating the compression in the left ventricle

Curve Retention Testing



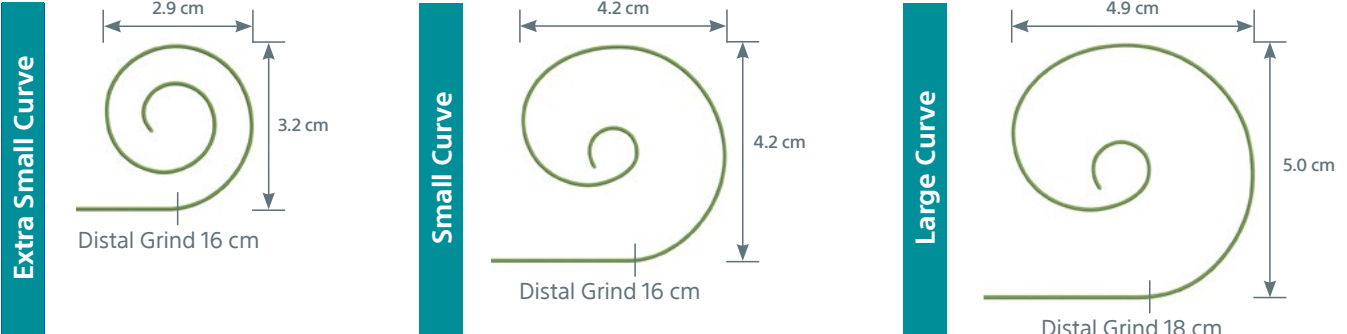
SAFARI² Guidewire

Curve Retention (%)



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

Curve Tip Configuration



Ordering Information

Order Number (GTIN)	Ref/Catalog Number	Description	Outer Diameter		Length	Quantity per Box
			(inches)	(mm)		
08714729887614	H749 39406XS 1	SAFARI ² Guidewire Extra Small Curve	0.035	0.889	275 cm	5 Pack
08714729887591	H749 39406S 1	SAFARI ² Guidewire Small Curve	0.035	0.889	275 cm	5 Pack
08714729887577	H749 39406L 1	SAFARI ² Guidewire Large Curve	0.035	0.889	275 cm	5 Pack
08714729887638	H749 39407XS 0	SAFARI ² Guidewire Extra Small Curve	0.035	0.889	275 cm	1 Single
08714729887652	H749 39407S 0	SAFARI ² Guidewire Small Curve	0.035	0.889	275 cm	1 Single
08714729887645	H749 39407L 0	SAFARI ² Guidewire Large Curve	0.035	0.889	275 cm	1 Single

The C-code used for this product is C1769, (Guidewire used in other medical items or services). 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.

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).
2. Simulated Use Friction, Dynamic Friction, and Distal Curve Displacement with Evolut™ R with SAFARI² Extra Small and Confida Brecker Guidewires (n = 3).
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.
4. Curve Retention test data with SAFARI² Extra Small, Confida™ Brecker, Amplatz Extra Stiff™, and Amplatz Super Stiff™ Guidewires (n = 1).
5. In2ition Market Data. Data on file.

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SAFARI² Preshaped 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. 91075696 AB

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