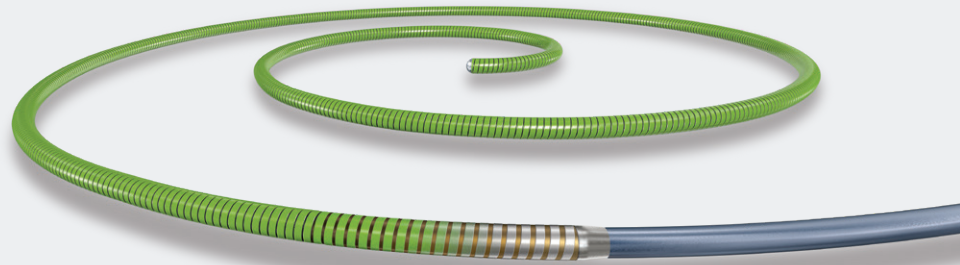


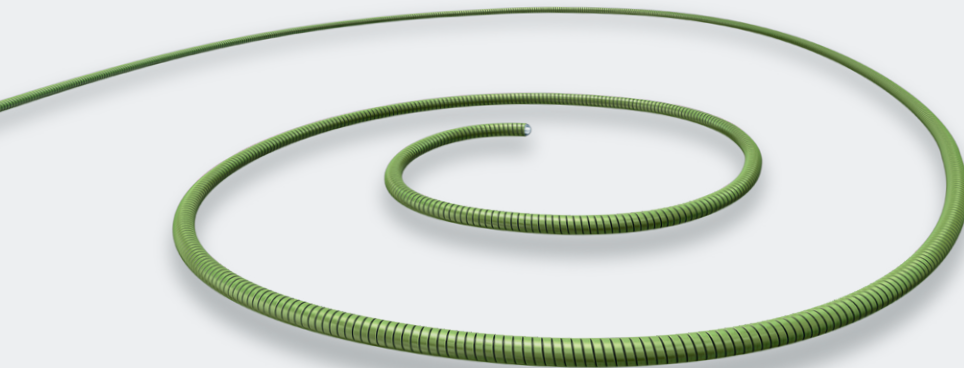


## **SAFARI<sup>2</sup>™ Pre-Shaped Guidewires**

Shaped and  
Sized for  
**Safety**



**SAFARI<sup>2</sup>™ Extra Support Pre-Shaped Guidewire**



**SAFARI<sup>2</sup>™ Pre-Shaped Guidewire**




**#1 TAVI Guidewire<sup>1</sup>**



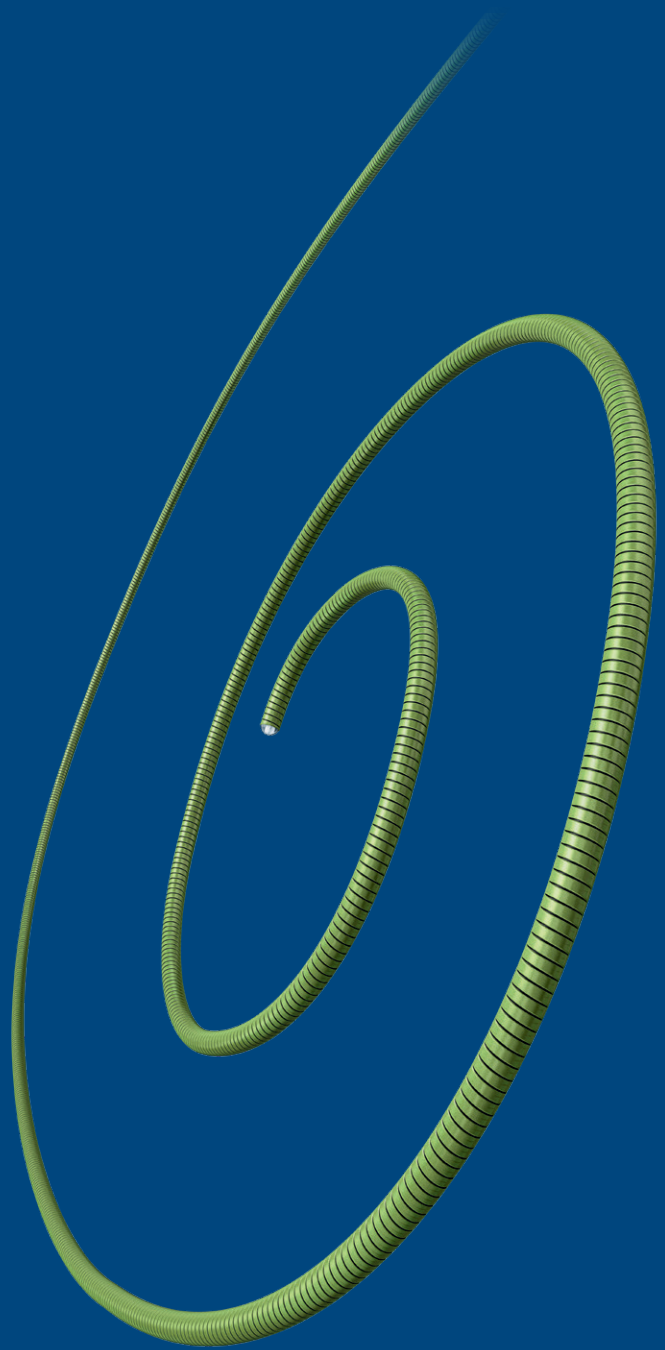
## **Predictable, atraumatic performance providing complete reassurance**

SAFARI<sup>2</sup><sup>™</sup> and SAFARI<sup>2</sup><sup>™</sup> Extra Support  
Pre-Shaped Guidewires are designed for  
predictable performance across a broad  
spectrum of transcatheter devices.



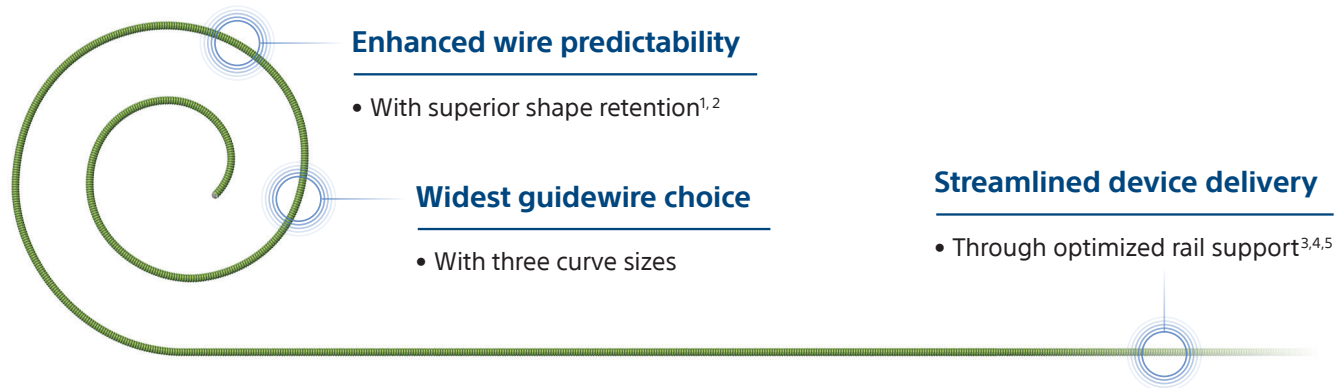
## Enables safe treatment of a broad range of patients with valvular disease

- Enhanced wire predictability with superior shape retention<sup>1,2</sup>
- Widest guidewire choice with three curve sizes and two stiffness profiles
- Optimized rail support for streamlined device delivery—SAFARI<sup>2</sup> for standard of care; SAFARI<sup>2</sup> Extra Support for torturous anatomies



# SAFARI<sup>2</sup> Overview

## ▶ SAFARI<sup>2</sup>™ Guidewire



## ▶ SAFARI<sup>2</sup>™ Extra Support Guidewire

### **Proximal wire stiffness<sup>6</sup>**

- Extra rail support in tortuous anatomy



### **Proximal guidewire stiffness comparison<sup>7</sup>**

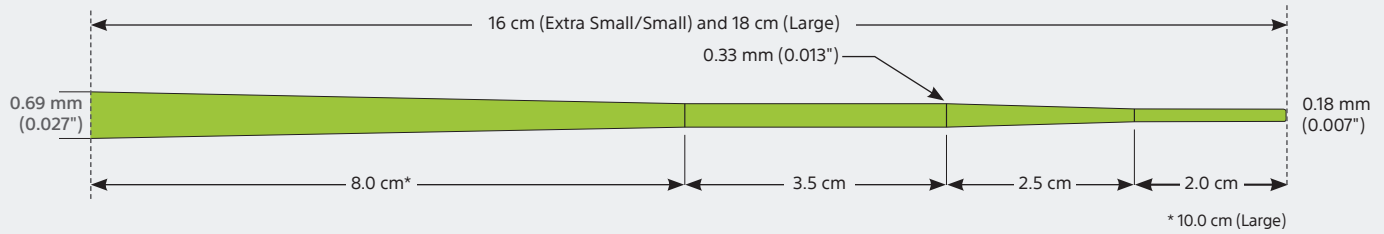


1. Curve Retention test data with SAFARI<sup>2</sup> Extra Small, Confida™ Brecker, Amplatz Extra Stiff™, Amplatz Super Stiff™ Guidewires, Lunderquist (n = 1). 2. Guidewire Compression test data with SAFARI<sup>2</sup> Extra Small, Confida Brecker, Amplatz Extra Stiff, Amplatz Super Stiff Guidewires, Lunderquist (n = 1). 3. Nosecone Tracking test data with SAFARI<sup>2</sup> Extra Small, Confida Brecker, Amplatz Extra Stiff, and Amplatz Super Stiff Guidewires (n = 1). 4. Simulated Use Friction, Dynamic Friction, and Distal Curve Displacement with Evolut™ R with SAFARI<sup>2</sup> Extra Small and Confida Brecker Guidewires (n = 3). 5. Per VAR 550 342 ACURATE neo™ and SAFARI validation testing the performance of ACURATE neo TF delivery system is compatible with the SAFARI<sup>2</sup> Guidewire in a representative simulated use environment. Bench testing performed by Boston Scientific. 6. Three Point Bend Test, January 2022, performed by Lake Region Medical, BSC data on file. Bench test results may not necessarily be indicative of clinical performance.

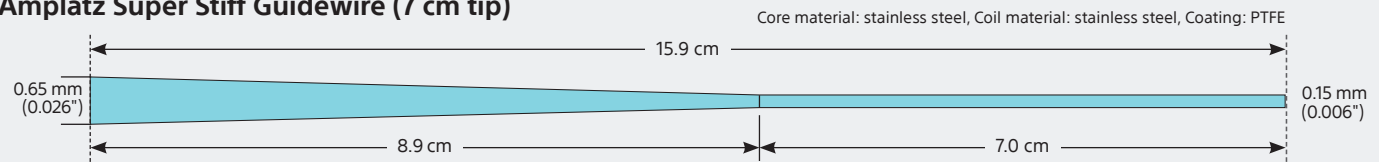
# Distal Curve designed for atraumatic valve procedures

Smooth tapering of the distal core provides optimal rail support and safety for the patient

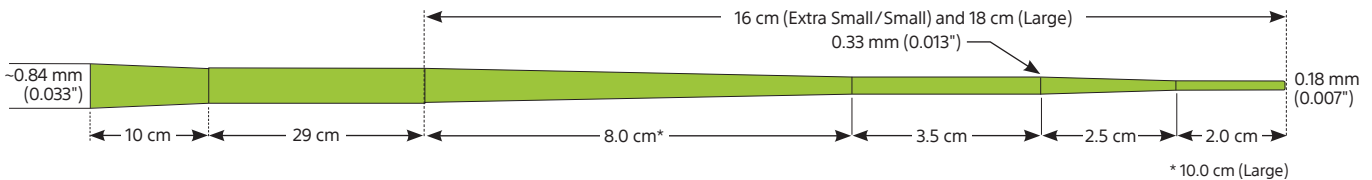
## ▶ SAFARI<sup>2</sup>™ Guidewire



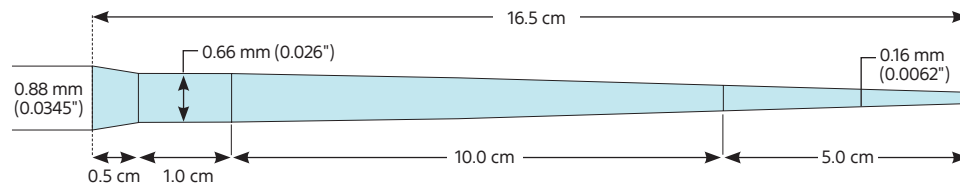
## Amplatz Super Stiff Guidewire (7 cm tip)



## ▶ SAFARI<sup>2</sup>™ Extra Support Guidewire



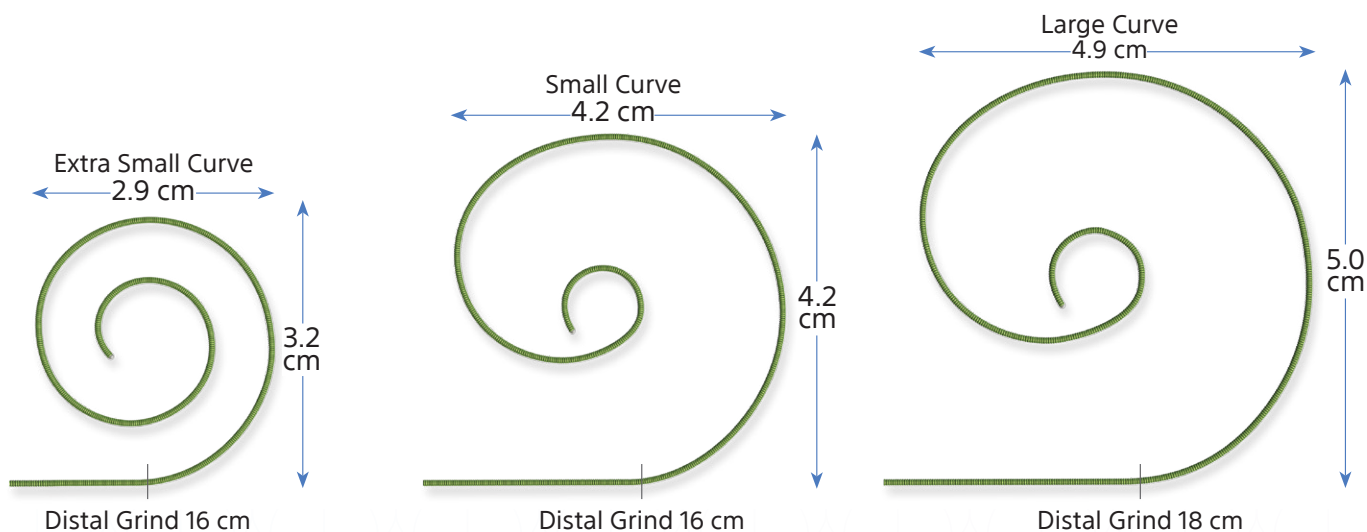
## Lunderquist<sup>®</sup> Extra Stiff DC Wire Guide



\*Per VAR 550 342 ACURATE neo™ and SAFARI validation testing the performance of ACURATE neo TF delivery system is compatible with the SAFARI<sup>2</sup> Guidewire in a representative simulated use environment. Guidewire Specifications. Data on file.

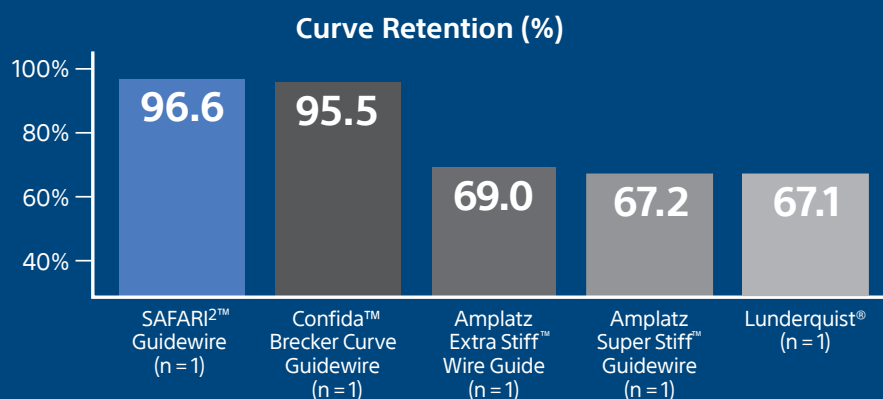
## Size flexibility to fit procedure

- ▶ Multiple curve sizes enable customized selection based on physician preference and patient anatomy
- ▶ Extra small curve designed for small and/or hypertrophic ventricles
- ▶ Double curve architecture absorbs contractions of the left ventricle and facilitates stable, atraumatic placement



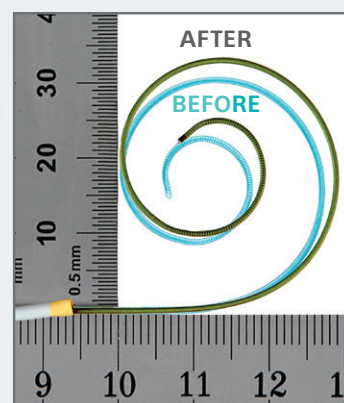
## Best-in-class shape retention

SAFARI<sup>2</sup>™ Distal Curve with best-in-class shape retention provides predictable performance.<sup>1</sup>



In competitive bench testing the SAFARI<sup>2</sup> Guidewires outperformed other wires in shape retention, preserving 96% of its original shape after use.

### Curve retention testing



SAFARI<sup>2</sup> Pre-Shaped Guidewires keep a stable position and curve when subjected to devices tracking over the wire.

1. Curve Retention test data with SAFARI<sup>2</sup> Extra Small, Amplatz Extra Stiff™ and Amplatz Super Stiff™, Confida, Lunderquist. N = 1 of each wire, data on file.  
Bench testing performed by Boston Scientific. Bench test results may not necessarily be indicative of clinical performance. Data on file.

# Ordering Information

## SAFARI<sup>2</sup>™ Extra Support Pre-Shaped Guidewire

Order number (GTIN)	Ref/catalog number	Description	Outer diameter		Length	Quantity per box
			Inches	mm		
10816349012607	H749 39597ESL 1	SAFARI <sup>2</sup> Extra Support GW Large Curve	0.035	0.889	275 cm	5 Pack
10816349012614	H749 39597ESS 1	SAFARI <sup>2</sup> Extra Support GW Small Curve	0.035	0.889	275 cm	5 Pack
10816349012621	H749 39597ESXS 1	SAFARI <sup>2</sup> Extra Support GW Extra Small Curve	0.035	0.889	275 cm	5 Pack
00816349012631	H749 39598ESL 0	SAFARI <sup>2</sup> Extra Support GW Large Curve	0.035	0.889	275 cm	1 Single
00816349012648	H749 39598ESS 0	SAFARI <sup>2</sup> Extra Support GW Small Curve	0.035	0.889	275 cm	1 Single
00816349012655	H749 39598ESXS 0	SAFARI <sup>2</sup> Extra Support GW Extra Small Curve	0.035	0.889	275 cm	1 Single

## SAFARI<sup>2</sup>™ Pre-Shaped Guidewire

Order number (GTIN)	Ref/catalog number	Description	Outer diameter		Length	Quantity per box
			Inches	mm		
08714729887614	H749 39406XS 1	SAFARI <sup>2</sup> Guidewire Extra Small Curve	0.035	0.889	275 cm	5 Pack
08714729887591	H749 39406S 1	SAFARI <sup>2</sup> Guidewire Small Curve	0.035	0.889	275 cm	5 Pack
08714729887577	H749 39406L 1	SAFARI <sup>2</sup> Guidewire Large Curve	0.035	0.889	275 cm	5 Pack
08714729887638	H749 39407XS 0	SAFARI <sup>2</sup> Guidewire Extra Small Curve	0.035	0.889	275 cm	1 Single
08714729887652	H749 39407S 0	SAFARI <sup>2</sup> Guidewire Small Curve	0.035	0.889	275 cm	1 Single
08714729887645	H749 39407L 0	SAFARI <sup>2</sup> 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.

### SAFARI<sup>2</sup> and SAFARI<sup>2</sup> Extra Support Pre-Shaped TAVR/TAVI Guidewires

**Intended Use/Indications for Use:** The SAFARI<sup>2</sup>™ and SAFARI<sup>2</sup>™ Extra Support Guidewires are intended to facilitate the introduction and placement of interventional devices within the chambers of the heart, including those used during transcatheter aortic valve procedures. **Contraindications:** The guidewires are not intended for use in the cerebral vasculature or coronary arteries.

**Warning:** • The SAFARI<sup>2</sup> guidewires 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. • Guidewire stiffness should be considered. Carefully read labelling to ensure selection of correct guidewire stiffness and SAFARI<sup>2</sup> Extra Support curve dimensions. • Do not torque this guidewire. • Inserting the distal end of the guidewire through a Tuohy-Borst Adapter without using the J-straightener will 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 guidewire should only be introduced into or withdrawn from the heart through a catheter already positioned in the ventricle. • The SAFARI<sup>2</sup> guidewires are manufactured with a pre-formed double curve; attempts to modify the double curve may alter its performance and/or compromise coating integrity. Alterations to curve may lead to complications including perforation or dissection, mitral valve regurgitation, pericardial effusion, cardiac tamponade, cardiac arrest and guidewire replacement. • This device contains nickel. Persons with allergic reaction to this metal may have an allergic reaction. • Manipulation, advancement, and/or withdrawal past sharp or beveled edges may result in destruction and/or separation of the outer coating, which may lead to clinical adverse events, resulting in coating material remaining in the vasculature or device damage. • Use appropriate anticoagulation to prevent or reduce device thrombosis, as this device has not been tested in the absence of anticoagulation. **Precautions:** The safety and effectiveness of this guidewire for temporary pacing in the ventricle has not been established. **Adverse Events:** • Access site complication (pseudoaneurysm, hematoma, AV fistula) • Additional surgical/endovascular procedure • Allergic reaction/anaphylaxis • Amputation • Aorta Complications • Arrhythmia • Bleeding (hemorrhage, hematoma) • Cardiac damage and/or septal perforation • Death • Device related thrombus • Embolism (air, thrombus, plaque, device fragments) • Foreign Body/Wire Fracture • Guidewire entrapment/entanglement • Hemoglobinuria • Hypovolemia • Infection or sepsis • MAACE • Myocardial ischemia and/or infarction • Pericardial effusion or cardiac tamponade • Renal failure or injury • Stroke (cerebral infarction), TIA or other neurologic event • Valve Complications • Vascular Complications • Vessel occlusion, perforation, dissection, trauma, spasm or damage

**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.

SH-1592604-AA

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**Interventional Cardiology**  
300 Boston Scientific Way  
Marlborough, MA 01752-1234  
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