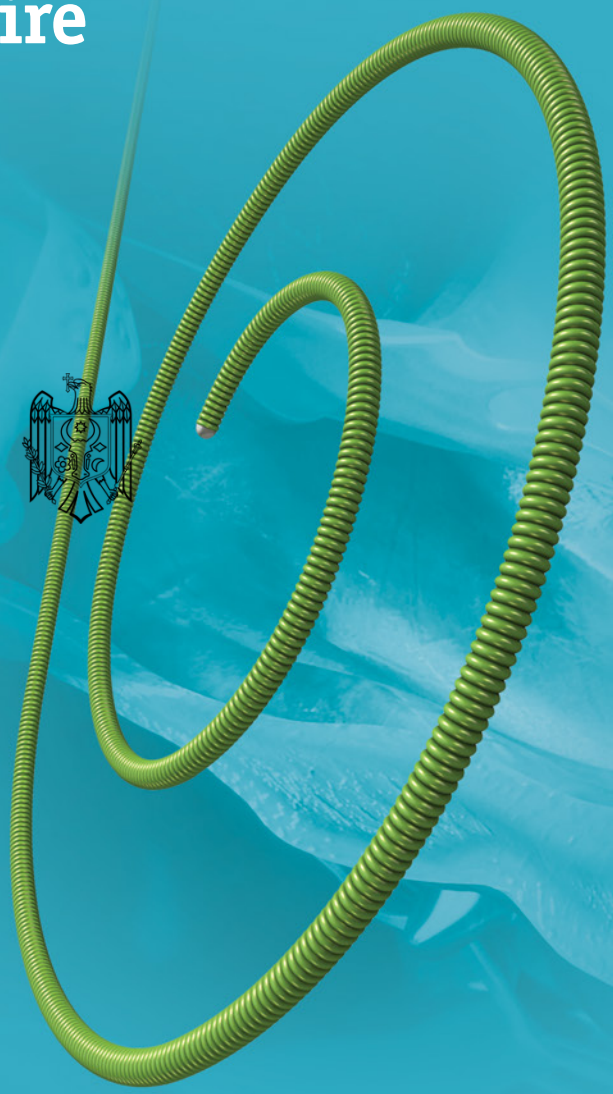
Boston Scientific
Advancing science for life™

Safari²™
Pre-Shaped Guidewire



Shaped and Sized for Safety

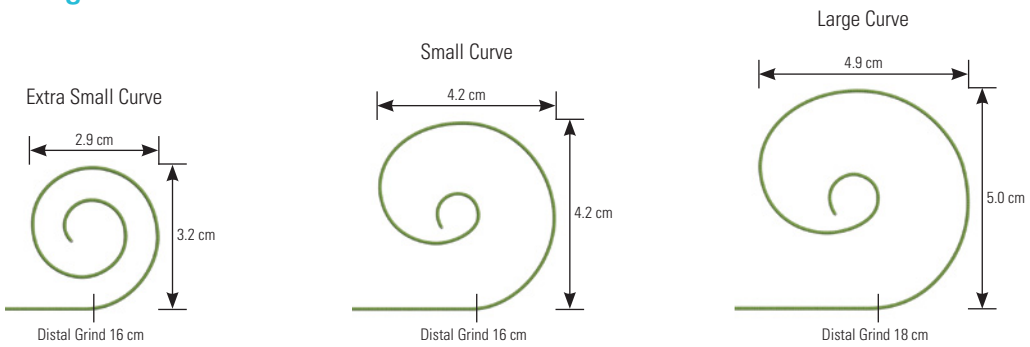
The Safari² Pre-Shaped Guidewire enables safe treatment of a broad range of patients with valvular disease

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

AVAILABLE IN EXTRA SMALL SIZE

Safari²™
Pre-Shaped Guidewire

Curve Tip Configuration



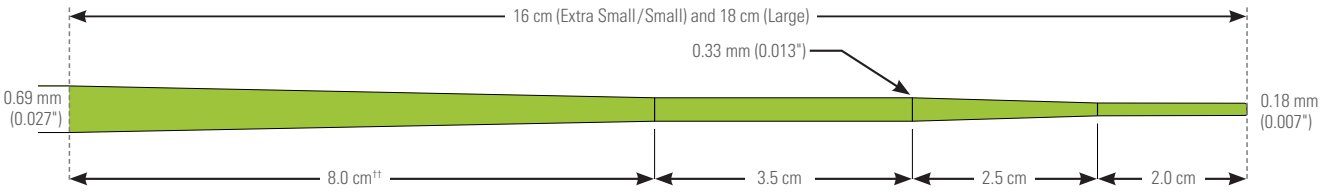
Guidewire Specifications

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.
Outer Diameter	0.035" (0.889 mm)
Length	275 cm
Core Material	Stainless Steel
Spring Coil Material	Stainless Steel
Spring Coil Coating	LUBRIGREEN™ PTFE

Configurations	Extra Small Curve	Small Curve	Large Curve
Distal Grind	16 cm	16 cm	18 cm
Curve Height	3.2 cm	4.2 cm	5.0 cm
Curve Width	2.9 cm	4.2 cm	4.9 cm

Package Contains	Guidewire, J-Straightener
Use	Single use - not for reuse, reprocessing or resterilization
Sterilization	Ethylene Oxide
Shelf Life	3 years

Smooth Tapered Core Wire Design



†† 10.0 cm (Large)

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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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 Displacment with Evolut™ R with Safari² Extra Small and Confida Brecker Guidewires (n = 3).

The Safari² Guidewire is manufactured by Lake Region Medical and distributed by Boston Scientific Corporation.
Illustrations for information purposes – not indicative of actual size or clinical outcome.

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 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.

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.

Rev AA

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