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Boston Scientific

SAFARI²™

PRE-SHAPED TAVR/TAVI

Guidewire

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Black (K) ΔE ≤5.0

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PRE-SHAPED TAVR/TAVI

Guidewire

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

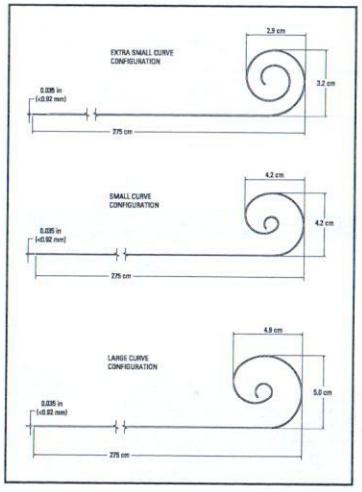
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The SAFARI² Guidewire consists of an 0.035 inch (≤0.92 mm) outside diameter by 275 cm working length guidewire comprised of a spring coil and core. The distal tip has a double-curve. The entire spring coil is coated with a LUBRIGREEN™ PTFE coating. Guidewire Length, Diameter and Curve configurations are indicated on the product label. The SAFARI² Guidewire is packaged with a J-Straightener that is used to aid in the insertion of the guidewire into the delivery catheter.



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Contents

Qty	Material
1	Guidewire
1	J-Straightener

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

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