WALLSTENT™

Super Stiff Guidewire

Boston Scientific
Advancing science for life™

Refer to the device directions for use for complete instructions on device use.

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.

Intended Use/ Indications For Use

The WALLSTENT Super Stiff Guidewire is intended to cannulate and/or facilitate device exchange during gastrointestinal (GI) procedures. WALLSTENT Guidewire is not intended for coronary artery, vascular or neurological use.

Contraindications

None known.

Precautions

- The sterile packaging and device should be inspected prior to use. Do not use if packaging is open or damaged.
- Do not attempt to withdraw guidewire from an endoscope when the elevator is in a flexed position.
- Do not withdraw guidewire through a metal trocar or a metal needle.
- Do not advance or withdraw guidewire against resistance until the cause of the resistance has been determined. Excessive force against resistance may result in damage to the guidewire and instrument.
- Boston Scientific Corporation does not recommend a particular technique for the use of this device. The steps contained in the preceding directions are for information purposes only. Each physician should evaluate the preceding directions according to individual patient condition and his or her medical training and experience.

Adverse Events

Complications which can result from the use of guidewires in pancreaticobiliary applications include, but are not limited to:

- Additional Surgical Intervention
- Cholangitis
- Cholecystitis
- Death
- Elevated Enzyme Levels
- Pain
- Pancreatitis
- Perforation
- Sepsis

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