

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 Boston Scientific Amplatz Super Stiff Guidewire is intended to cannulate and/or facilitate insertion and manipulation of catheters and instruments during endoscopic procedures in the GI systems, including the biliary and alimentary tracts. The Amplatz Super Stiff Guidewire is also indicated to aid in the placement of diagnostic and therapeutic devices during bronchoscopic procedures..

Contraindications

Bronchoscopy: Placement of a guidewire should not be attempted in any patient whose general medical condition and degree of respiratory failure would not allow that patient to tolerate bronchoscopy (rigid or fiberoptic) and/or the manipulation required to perform the procedure.

Adverse Events

Potential adverse events which may result from the use of the device include but are not limited to:

- Perforation
- Bleeding
- Septicemia
- Tissue trauma
- Infection
- Peritonitis
- Wire fracture
- Failure to pass
- Hemorrhage
- Edema
- Pancreatitis
- Pneumothorax

Precautions

- The Amplatz Super Stiff™ Guidewire should only be used by or under the supervision of trained physicians.
- Any use of this device, other than those indicated in these instructions is not recommended.
- Do not use the Amplatz Super Stiff Guidewire with a metal tip catheter.