



Amplatz Super Stiff Guidewire Brief Summary Document

Overview

Product

Amplatz Super Stiff Guidewire – 51753269

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

REUSE WARNING: For single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or sterilization 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 sterilization 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.

Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.

Content

INTENDED USE/INDICATIONS FOR USE

The Boston Scientific Amplatz Super Stiff Guidewire is indicated for use throughout the alimentary tract, tracheobronchial tree as well as for selective cannulation of the pancreatico-biliary system including the common bile, pancreatic duct, cystic duct, and right and left hepatic ducts. The endoscopic guidewire is designed to be used during gastrointestinal procedures, bronchoscopic procedures, and endoscopic pancreatico-biliary procedures for introduction, exchange, and placement of diagnostic and therapeutic devices.

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.

WARNINGS

- Do not manipulate, advance and/or withdraw the guidewire through a metal cannula or needle. Manipulation, advancement, and/or withdrawal through a metal device may result in destruction and/or separation of the outer polymer jacket requiring retrieval.
- Do not reshape the guidewire by any means. Attempting to reshape the wire may cause damage, resulting in the release of wire fragments into the alimentary tract, or the pancreaticobiliary anatomy, and may result in patient harm.
- The guidewire should be advanced through the scope using short, deliberate 2-3 cm movements to prevent inadvertent damage to the device or injury to the patient.
- Do not use a guidewire which has been damaged or if any defect is found during inspection. Damage will prevent a guidewire from performing with accurate torque or tactile response and may cause injury. Return any defective product to Boston Scientific for replacement.

PRECAUTIONS

- Any use of this device, other than those indicated in these instructions is not recommended.
- Free movement of the guidewire within a catheter is an important feature of a guidewire because it gives the user valuable tactile information. Test the system for any resistance prior to use.
- Do not forcibly advance or withdraw a guidewire. To do so may result in complications. If resistance is encountered, STOP, determine the cause and take remedial action before continuing. If necessary, remove guidewire and ancillary device or scope as a complete unit to avoid complications.

POTENTIAL ADVERSE EVENTS

- Edema
- Hemorrhage
- Hemothorax
- Infection
- Inflammation
- Obstruction
- Pancreatitis
- Perforation
- Peritonitis
- Pleural Effusion
- Pneumothorax
- Tissue Damage

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France. 2025 Copyright © Boston Scientific Corporation or its affiliates. All rights reserved.