STENT AND DELIVERY SYSTEM

UPN

M00553440, M00553450

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.

Indications for Use/Intended Use

The AXIOS Stent and Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of a pancreatic pseudocyst or a walled-off necrosis with ≥ 70% fluid content.

CAUTION:

The AXIOS stent should be removed upon confirmation of pseudocyst or WON resolution and is intended for implantation up to 60 days.

Contraindications

• All cardiovascular applications.

• Cystic neoplasms.

• Pseudoaneurysms.

• Duplication cysts.

• Non-inflammatory fluid collections.

• Patients with abnormal coagulation or who require ongoing complete anticoagulation at the time of implantation and post stent placement have an increased possibility of bleeding.

• Patients with altered anatomy that precludes the physician's ability to deliver the stent.

• Patients with intervening gastric varices or vessels within a one centimeter radius of the device needle.

• Patients with any prior true anaphylactic reaction to contrast agents, nitinol (nickel titanium), silicone or any other materials contacting the patient.

Warnings and Precautions

• Placement of the AXIOS™ Stent should be performed by physicians familiar with endoscopic ultrasonography and received training for endoscopic stent placement techniques.

• Do not use this device in any echoendoscope with a working channel smaller than 3.7 mm.

• The stent cannot be resheathed once deployment has been initiated. • The AXIOS Stent implantation should not exceed 60 days. Performance beyond 60 days has not been established.

• Long-term patency of this stent has not been established. Periodic evaluation of the stent is advised.

• Do not remove the stent from its delivery system prior to use.

• This stent must only be placed using the delivery system provided.

• Do not use this device for any purpose other than its stated intended use.

• Care is required during dilation, debridement, irrigation, and cystoscopy procedures through the stent, to prevent air/fluid leak and/or stent dislodgement.

• Examine all components to be used during procedure. Do not use a device that has been cut, burned or damaged.

• This device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

Adverse Events

Possible Adverse Events associated with the use of the AXIOS Stent and Delivery System may include those often associated with any endoscopic procedure. These complications include:

• Anesthesia complications

• Tissue ingrowth or overgrowth leading to difficult or a failure to remove stent

• Stent occlusion

• Local infection at the implant site

• Sepsis (bacterial, endotoxin, or fungal)

• Persistent connection to target structure after removal

• Cardia arrythmai or arrest

• Partial or failed stent expansion, stent collapse

• Device failure, including failure to deliver the stent

• Stent migration/dislodgement

• Adverse reaction to implant and/or delivery system (e.g., abdominal or back pain, nausea, infection, fever, chronic inflammation/foreign body reaction)

• Minor or excessive bleeding because of Indication (requiring intervention)

• Leakage of pseudocyst or bowel contents/peritonitis

• Tissue damage during stent implantation and/or removal

• Ulceration or erosion of mucosal or organ wall linings

• Pneumoperitoneum

• Perforation

• Surgical intervention (endoscopy, transfusion or surgery)

• Death

MRI Safety Information

The delivery system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of delivery system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Magnetic Resonance Conditional

Non-clinical testing demonstrated that the AXIOS™ Stent is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

• Static magnetic field of 1.5-Tesla and 3-Tesla, only.

• Maximum spatial field gradient of 4,000-Gauss/cm (40 T/m).

• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/kg (Normal Operating Mode)

MRI-Related Heating

Under the scan conditions defined above, the AXIOS Stent is expected to produce a maximum temperature rise of 2.9 °C after 15-minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the AXIOS Stent extends approximately 10 mm from the AXIOS Stent when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.