AXIOS™
Stent and Delivery System
Prescriptive Information

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

Caution/Rx Only:

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

Warnings:

Contents supplied STERILE usingan 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 AXIOS Stent and Delivery System is an endoscopic device designed to enable the therapeutic endosonographer to deliver a transenteric stent between the gastrointestinal tract and a pancreatic pseudocyst.

The AXIOS Stent is a flexible, MRI Conditional, fullycovered self-expanding metal stent that is preloaded within the Delivery System.

The AXIOS Delivery System is compatible with therapeutic echoendoscopes having a working channel of 3.7 mm diameter or larger.

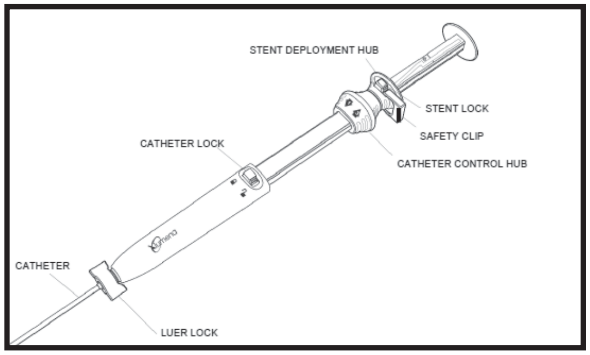

FIGURE 1. AXIOS Delivery System handle. The catheter control hub advances and retracts the catheter. The stent deployment hub releases the stent from the catheter.

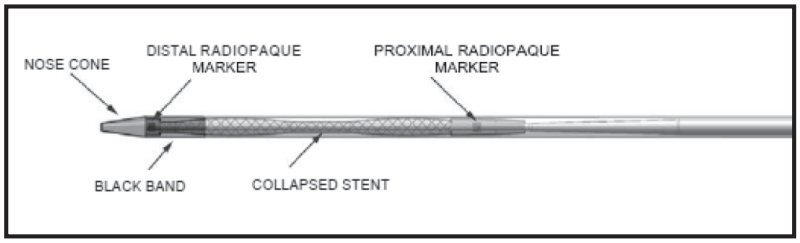

FIGURE 2. The collapsed stent is contained within the distal end of the catheter. A black band at the end of the catheter is used to position the stent second flange for deployment. Two radiopaque bands indicate the proximal and distal edges of the stent.

AXIOS™
Stent and Delivery System
Prescriptive Information

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

Recommended Stent Selection Method

Pseudocyst. Select the stent LUMEN diameter based on pseudocyst contents via endoscopic ultrasound (EUS) imaging. For example, select 15 mm in the presence of necrotic material and select 10 mm (or 15 mm) for 100% fluid contents.

The 10mm stent length can accommodate combined GI tract and pseudocyst wall thickness up to 10mm as assessed by EUS during the procedure.

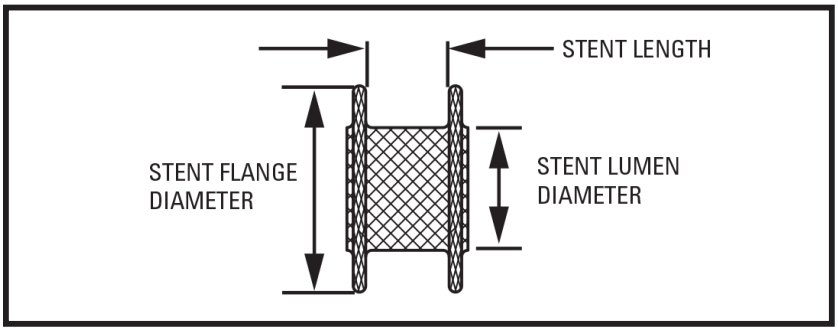

FIGURE 3. The stent is made of Nitinol wire and fully-covered with silicone.

Indications for Use

The AXIOS Stent and Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

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

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

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.

Potential Complications

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

1. Anesthesia complications
2. Tissue ingrowth or overgrowth leading to difficult or a failure to remove stent
3. Stent occlusion
4. Local infection at the implant site
5. Sepsis (bacterial, endotoxin, or fungal)
6. Persistent connection to pseudocyst after removal
7. Cardia arrythmai or arrest
8. Partial or failed stent expansion, stent collapse
9. Device failure, including failure to deliver the stent
10. Stent migration/dislodgement
11. Adverse reaction to implant and/or delivery system (e.g., abdominal or back pain, nausea, infection, fever, chronic inflammation/foreign body reaction)
12. Minor or excessive bleeding (requiring intervention)
13. Leakage of pseudocyst or bowel contents/peritonitis
14. Tissue damage during stent implantation and/or removal
15. Ulceration or erosion of mucosal or organ wall linings
16. Pneumoperitoneum
17. Perforation
18. Surgical intervention (endoscopy, transfustion or surgery)
19. Death

Warranty

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this

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

instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

MRI 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 1.2°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.