

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
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.

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 fluid collection (i.e. a pancreatic pseudocyst or a walled-off necrosis). 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.

Recommended Stent Selection Method (See Stent Size Table)

Select the stent LUMEN diameter based on fluid collection 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 10 mm stent length can accommodate combined GI tract and fluid collection wall thickness up to 10mm as assessed by EUS during the procedure.

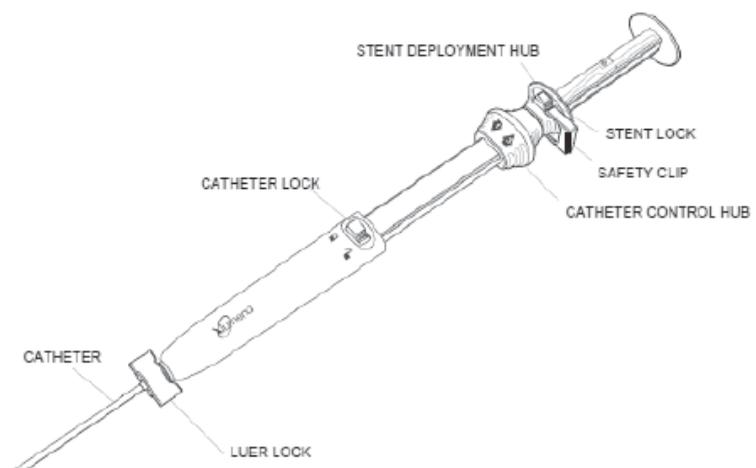


Figure 1. AXIOS Delivery System handle. The catheter control hub advances and retracts the catheter. The stent deployment hub releases the stent from the catheter.

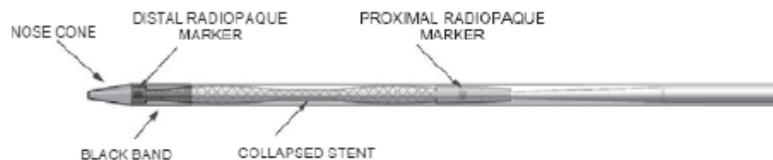


Figure 2. The collapsed stent is contained within the distal end of the catheter. A black band at the end of the catheter is used to position the stent second flange for deployment. Two radiopaque bands indicate the proximal and distal edges of the stent.

Indications for Use/ Intended Use

The AXIOS Stent and Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size and walled-off necrosis ≥ 6 cm in size with $\geq 70\%$ 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 or walled-off necrosis 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 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.

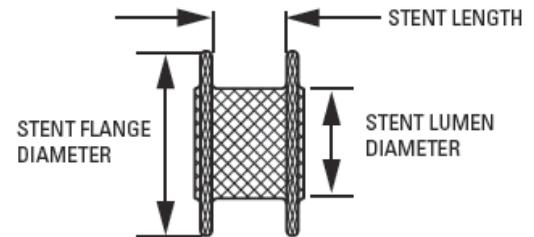


Figure 3. The stent is made of Nitinol wire and fully covered with silicone.

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 fluid collection after removal
- Cardia arrhythmias 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 (requiring intervention)
- Leakage of fluid collection 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

Clinical Study

Results from a multi-center clinical study demonstrate the safety and effectiveness of the AXIOS Stent and Delivery System. An overview of the study protocol is provided in the table below.

Study Objective	To demonstrate the safety and effectiveness of the AXIOS Stent and Delivery System for endoscopic drainage of symptomatic pancreatic pseudocysts
Device Name	AXIOS Stent and Delivery System
Study Design	Protestive, multi-center, non-blinded, single-arm (nonrandomized)
Subjects Enrolled	33 (18 male and 15 female)
Number of Sites	Seven (7) investigational sites
Safety Endpoint	Freedom from major complications through the duration of AXIOS Stent implantation and 1-week post-stent removal
Effectiveness Endpoint	Acceptable rate of stent lumen patency; stent removability; technical and clinical success at 30 days and/or 60 days
Study Population	Subjects between 18 and 75 years of age, suitable for transluminal drainage of symptomatic pancreatic pseudocysts that are greater than or equal to 6 cm in diameter and adherent to the bowel wall are candidates for study treatment.
Assessments: Pre-Op	General/physical health and abdominal imaging were assessed to identify condition(s) that would affect the planned course of the treatment (e.g., co-morbidities, medications etc.)
IntraOP	Endoscopy with endosonography (EUS)
PostOP	At 30 days, 60 days and 1 week post stent removal: General/physical health, endoscopy and/or radiographic imaging; subsequent intervention. At 3 months and 6 months: Telephone follow-up regarding General/physical health; subsequent intervention
Adverse Events	Monitored throughout study

Patient Selection Criteria

Inclusion Criteria: Subjects must meet all criteria.

1. Age between 18 and 75 years old, male or female.
2. Eligible for endoscopic intervention.
3. Acceptable candidate for endoscopic transluminal pancreatic pseudocyst drainage.
4. Symptomatic pancreatic pseudocyst having the following characteristics:
 - a. Greater than or equal to 6 cm in size (based upon the maximum cross-sectional area in the CT scan),
 - b. Adherent to bowel wall, and
 - c. ≥70% fluid content.

5. Subject understands the study requirements and the treatment procedures and provides written Informed Consent using a form that has been approved by the local Institutional Review Board or Ethics Committee before any study-specific tests or procedures are performed.
6. Subject is willing to comply with all specified follow-up evaluations, including willingness to undergo a pre/post CT imaging study.

Exclusion Criteria: Subjects meeting any of the following criteria were excluded from study.

1. The fluid collection to be drained is an immature pseudocyst.
2. The fluid collection to be drained is a cystic neoplasm.
3. The fluid collection to be drained is a pseudoaneurysm.
4. The fluid collection to be drained is a duplication cyst.
5. The fluid collection to be drained is a non-inflammatory fluid collection.
6. There is more than one pseudocyst requiring drainage.
7. Abnormal coagulation:
 - a. INR > 1.5 and not correctable
 - b. presence of a bleeding disorder
 - c. platelets < 50,000/mm³
8. Altered anatomy that precludes the physician's ability to deliver the stent (decision on a case by case basis).
9. Intervening gastric varices or vessels within a one centimeter radius of the needle (visible using endoscopy or endoscopic ultrasound).
10. Any prior true anaphylactic reaction to contrast agents, nitinol (nickel titanium), silicone or any other materials contacting the patient.
11. Female of childbearing potential with a positive pregnancy test prior to the procedure or intends to become pregnant during the study.
12. Currently participating in another investigational drug or device study that has not completed the primary endpoint or that clinically interferes with the endpoints of this study.

Study Results

The Intent-to-Treat study group consisted of 33 subjects who provided consent and treated with the AXIOS™ Stent and Delivery System. The group included one subject who received two stents for two distinct pseudocysts. Three (3) patients not receiving stents, and an additional patient who had pigtail stents and a nasocystic tube placed alongside the AXIOS Stent (through a second cystgastrostomy) were excluded from the Per-Protocol analysis. A modified Intent to-Treat subset (n=30) included all subjects who received an AXIOS Stent during the index procedure (i.e., underwent successful AXIOS Stent placement). Patients (55% male) were 53 years of age (average). Eighty-five percent (85%) of study subjects had a history of pancreatitis. Gallstone disease and alcohol abuse were present in 20% of subjects. Pancreatic pseudocysts with average diameter of 9.0 cm (stdev 3.3 cm) were treated. Effectiveness: Thirty (30) stents were placed in 33 subjects with no intra-operative complications. AXIOS Stent patency was confirmed with drainage visualized for all stents placed. The overall effectiveness demonstrated for AXIOS Stent and Delivery System is summarized in the table on the preceding page.

AXIOS Overall Effectiveness

Effectiveness Measure	Study Subset	Overall Effectiveness by Endpoint
Technical Success , defined as Placement of the AXIOS Stent, and Removal of the AXIOS Stent using a standard endoscopic tools.	Intent-to-Treat	90.9% (30/33)
	Modified Intent-to-Treat	96.7% (29/30)
Stent Lumen Patency Debridements Supplemental stenting (stent-in-stent)	Per-Protocol	93.1% (27/29) 31.0% (9/29) 10.3% (3/29)
	Per-Protocol	86.2% (25/29)
Clinical Success , defined as at least a 50% decrease in pseudocyst size, based on radiographic analysis	Per-Protocol	86.2% (25/29)
Overall Effectiveness	Per-Protocol	86.2% (25/29)

Immediate post procedure endoscopic exams, as well as exams at stent removal noted no injury to surrounding tissue at the AXIOS Stent site. Resolution of the treated pancreatic pseudocysts was achieved in a majority of the subjects. For some subjects, debridement, lavage, irrigation and cystoscopy was required and performed through the AXIOS Stent as an access port. AXIOS Stent removal was readily performed using standard endoscopic tools (snare, forceps, etc.) with no injury to the treatment site.

Safety: The pivotal study results demonstrated that there were no unanticipated events related to the use of the device or the echoendoscopic approach in its deployment. Serious adverse events deemed related to the AXIOS device or the index procedure were the same type of events as those generally associated with endoscopic pancreatic pseudocyst drainage with commercially available stents and delivery systems (see table below).

Serious Adverse Events

Events	%(n/N)
Access site-related bleeding requiring transfusion	0
Access site-related infection requiring IV/IM antibiotics and extended hospitalization	3.0% (1/33)
Surgery for access-site related perforation	0
Stent migration dislodgement into the pseudocyst or enteral lumen	3.0% (1/33)
Tissue injury *ulceration to the submucosa at site of stent implant as observed to persist through 1-week post-stent removal	0
Back pain due to drainage leak/peritonitis	3.0% (1/33)
Pseudoaneurysm requiring embolization	3.0% (1/33)
Fever and prolonged hospitalization	3.0% (1/33)
Abdominal pain requiring endoscopy	3.0% (1/33)
Overall Rate	15.2% (5/33)

*Rates based on Intent-to-Treat; Subjects may experience more than one event.

Conclusion

The AXIOS™ Stent design and construction is optimized for controlled placement, maintaining patency, preventing migration and easy removal. Once placed, the stent provides a large diameter conduit and the bi-flange design secures access to the pseudocyst. The stent is provided fully covered to minimize tissue ingrowth. The study of the AXIOS Stent and Delivery System demonstrated the AXIOS devices to be predictable and easy to use. There were no intraoperative adverse events during AXIOS Stent placement or removal. There were no unanticipated complications or new risks related to the implantation and removal of the AXIOS Stent. The AXIOS Stent and Delivery System is deployed using current strategies and techniques for clinical assessment and treatment. In conclusion, the AXIOS devices were safe and effective for the endoscopic transenteric drainage of symptomatic pancreatic pseudocysts.

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.

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:



**Magnetic Resonance
Conditional**

- 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.

Warranty

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

AXIOS™ Stent and Delivery System

The AXIOS™ Stent and Electrocautery-Enhanced Delivery System Indications for Use:

US: The AXIOS Stent and Electrocautery-Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts 6cm in size, with $\geq 70\%$ 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.

All trademarks are the property of their respective owners.

Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

Caution: US Federal law restricts this device to sale by or on the order of a physician.