AXIOS™ Stent and Electrocautery-Enhanced Delivery System
(10x10mm, 15x10mm, 20x10mm and 15x15mm Stents)

Boston Scientific
Advancing science for life™

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.

Device Description

The AXIOS Stent and Electrocautery-Enhanced 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.

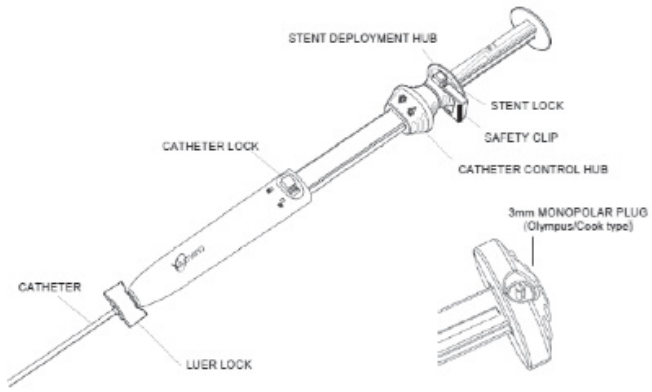

Figure 1. AXIOS Delivery System handle. The catheter control hub advances and retracts the catheter. The stent deployment hub releases the stent from the catheter.

Recommended Stent Selection Method

Select the stent LUMEN diameter based on fluid collection contents via endoscopic ultrasound (EUS) imaging. For example, select 15mm or 20mm in the presence of necrotic material and select 10mm, 15mm or 20mm for 100% fluid contents. The 10mm stent length can accommodate combined GI tract and fluid collection wall thickness up to 10mm as assessed by EUS during the procedure. Warning: The 10mm stent diameter has not been well studied in patients with > 30% solid material in their cysts and may pose an increased risk of infection in these patients. The 15mm stent length can accommodate a combined GI tract and fluid collection wall thickness greater than 10mm and up to 15mm as assessed by EUS during the procedure.

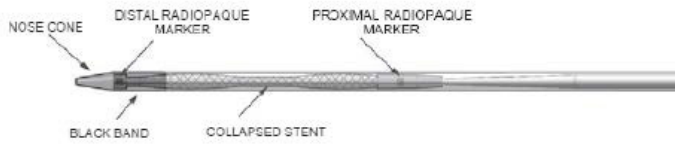

Figure 2. The collapsed stent is contained within the distal end of the catheter. A black band at the end of the catheter is used to position the stent second flange for deployment. Two radiopaque bands indicate the proximal and distal edges of the stent.

Indications for Use/Intended Use

The AXIOS Stent and Electrocautery-Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size, and symptomatic Walled Off Necrosis ≥ 6 cm in size, 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.

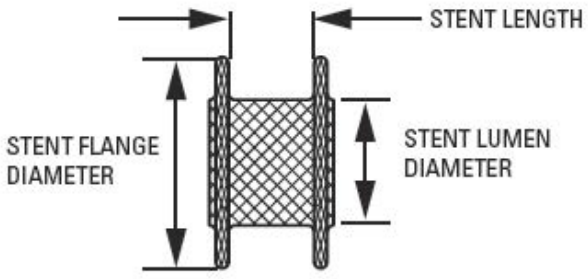

Figure 3. The stent is made of Nitinol wire and fully covered with silicone.

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 insertion location.
- Patients that have allergies or are sensitive to any of the device materials.
- Patients with contraindications to use of electrical devices.

Warnings and Precautions

1. Placement of the AXIOS Stent should be performed by physicians familiar with endoscopic ultrasonography and who have received training for AXIOS Stent placement techniques.
2. Before use, examine the outer surface of devices which are intended to be inserted into a patient or used during procedure. Do not use a device that has unintended rough surfaces, sharp edges or protrusions which may cause harm. Cut, burned or damaged device insulation may cause unsafe currents in either patient or operator.
3. Do not use this device in any echoendoscope with a working channel smaller than 3.7 mm.
4. Do not remove the stent from its delivery system prior to use.
5. This stent must only be placed using the delivery system provided.
6. No modification of this equipment is allowed.
7. Do not use this device for any purpose other than its stated intended use.
8. AXIOS Stent implantation should not exceed 60 days; performance beyond 60 days has not been established.
9. Long-term patency of the AXIOS Stent has not been established. Periodic evaluation of the stent is advised.
10. Do not use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

11. Inspect the AXIOS Electrocautery-Enhanced Delivery System, endoscope, and the connector cable for damage prior to use and, especially, the insulation of endoscopic instruments. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.
12. Interference of high frequency medical electrical equipment may adversely influence operation of other electronic equipment.
13. Before use, compatibility with electrosurgical generators, accessories and other endoscopic equipment should be checked according to any criteria for safe use. Using incompatible equipment or equipment not specified by this Instruction for Use can result in patient injury or equipment damage (see Technical Specifications provided in full device IFU).
14. Select cables, patient return electrodes and other medical electrical equipment that are Type BF applied parts. Use of medical electrical equipment other than those specified may result in increased emissions or decreased immunity of the generator.
15. Use caution with endoscopic equipment, accessories, and other medical / non-medical electrical equipment to avoid risks caused by their use together.
16. Any electrosurgical accessory constitutes a potential electrical hazard to the patient and operator. Safe and effective electrosurgery is dependent not only on equipment design but, to a large extent, on factors under the control of the operator.
17. Avoid high frequency output settings where the maximum output voltage may exceed rated accessory voltage (AXIOS Electrocautery-Enhanced Delivery System rated accessory voltage is 750Vp or 1500Vp-p).
18. Patient risks may result from gas embolism caused by over-insufflation of air, inert gas prior to high frequency surgery, or laser assist gas.
19. Do not use in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.
20. Do not place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
21. When energized endoscopes are used with energized endotherapy devices, patient leakage currents may be additive. When applying current, ensure the active tip of the AXIOS™ Electrocautery-Enhanced Delivery System is completely outside the endoscope. Contact between the active element (located on the nose cone) and the echoendoscope may cause grounding, which can result in patient injury, operator injury, or damage to the endoscope.
22. Aspirate fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
23. Do not activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling.
24. The surface of the active electrode may remain hot enough to cause burns after the RF current is turned off.
25. Ensure proper placement of return electrode on patient and connection to generator. Failure to do so could result in harm to patient including burns.
26. Temporary loss of EUS imaging may occur due to electromagnetic interference of the activated catheter tip. Normal EUS operation will resume immediately after deactivation of the catheter tip.
27. Use pure cut generator settings with AXIOS Electrocautery-Enhanced Delivery System. Do not use blended or coagulation generator modes. Blended or coagulation modes may result in failure to access, prolonged time to access, tissue tenting or resistance.
28. Do not attempt to advance or retract the delivery system against resistance until the cause of resistance has been determined.
29. Care is required during dilation, debridement, irrigation, and cystoscopy procedures through the stent, to prevent air/fluid leak and/or stent dislodgement.

30. Ensure correct generator installation. The generator must be installed and put into service according to the EMC information provided in the generator manufacturer's guidance and declaration for electromagnetic compatibility. Refer to the Technical Specifications Table provided in full device IFU to confirm that this device is compatible with the equipment being used.
31. Connect the AXIOS Stent and Electrocautery-Enhanced Delivery System to the electrosurgical unit only when the unit is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.
32. Due to concerns about the carcinogenic and infectious potential of electrosurgical by-products (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used during the procedure
33. Prior to increasing the intensity, check the adherence of the return electrode and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the return electrode or poor contact in its connections.
34. If the electrosurgical device is operated in a mode without the CQM or a CQM compatible monitoring return electrode is not used, loss of safe contact between the return electrode and the patient will not result in an alarm.

35. Device must be used in conjunction with a Type BF or CF generator, see compatible electrosurgical unit or generator information provided in full device IFU.
36. 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 Electrocautery-Enhanced Delivery System may include those often associated with any endoscopic procedure. These complications include:

1. Anesthesia complications.
2. Improper AXIOS Stent placement; incomplete deployment; stent migration into the fluid collection or, GI tract; separation of coating material from stent; stent fracture; coating material wear; coating material failure; puncture of coating material.
3. Tissue ingrowth or overgrowth leading to difficulty or a failure to remove stent.
4. Stent dislodgement.
5. Adverse reaction to implant materials and/or delivery system (e.g., abdominal or back pain, nausea, infection, fever, chronic inflammation or foreign body reaction).
6. Minor or excessive bleeding requiring intervention.
7. Leakage of fluid collection or bowel contents causing inflammation or peritonitis.
8. Stent occlusion.
9. Local infection at the implant site.
10. Tissue damage during stent implantation and/or removal.
11. Ulceration or erosion of mucosal or organ wall linings, or vasculature.
12. Pneumoperitoneum.
13. Sepsis (bacterial, endotoxin or fungal).
14. Perforation.
15. Surgical intervention (endoscopy, transfusion or surgery).
16. Persistent connection to the fluid collection after removal (fistula).
17. Unintended electrical shock, muscle stimulation or burns.
18. Cardiac arrhythmia or arrest.
19. Death.

Clinical Study

CLINICAL STUDY RESULTS FOR TRANSLUMINAL DRAINAGE OF WALLED-OFF NECROSIS (WON) WITH > 30% SOLID COMPONENT

Overview

Objectives and Endpoints:

A prospective, single arm, multi-center clinical trial was conducted to determine the effectiveness and safety of AXIOS Lumen-Apposing Metal Stents in the treatment of Walled-Off Necrosis (WON) with > 30% solid components. The primary effectiveness endpoint was resolution of WON to < 3 cm (assessed radiographically by CT scan or MRI within 60 days from AXIOS stent placement). The primary safety endpoint was AXIOS stent related or WON drainage procedure related serious adverse events.

Cohort Information

Patients:

Forty (40) patients with WON due to severe or moderately acute necrotizing pancreatitis were enrolled.

Demographics and Primary Outcomes:

The mean patient age was 54 (sd 12.4 years) and 26 patients (65%) were male. The median total procedure time was 22.6 minutes. 97.5% of patients (39/40) met the primary effectiveness endpoint after 60 days. The primary safety endpoint (SAE due to AXIOS stent or WON drainage procedure) had an observed rate of 7.5% (3/40).

AXIOS Stent Placement

Device	Number Implanted
AXIOS 15 x 10 mm	20
AXIOS 20 x 10 mm	25

Overall Summary of Clinical Outcomes in Relation to Effectiveness and Safety Endpoints

Primary Effectiveness Endpoint	ITT Subjects (n=40)
Resolution of WON to ≤ 3 cm (assessed radiographically by CT scan or MRI within 60 days from AXIOS stent placement)[1]	97.5% (39/40) [86.8%, 99.9%]

Primary Safety Endpoint	
AXIOS™ stent related or WON drainage procedure related serious adverse events	7.5% (3/40) [1.6%, 20.4%]
Additional Endpoints	
Reduction of WON-related symptoms	
Final WON assessment visit	75.0% (30/40)
6-month WON recurrence assessment visit	85.3% (29/34)
Technical success	
AXIOS stent placement	100.0% (40/40)
AXIOS stent removal	100.0% (40/40)
Drainage procedure time (min)	
Total	22.6±11.3 (40) (1.0, 51.0)
Initial Axios stent	21.8±11.0 (40) (1.0, 51.0)
Second Axios stent	10.0±3.5 (3) (8.0, 14.0)
Resolution of WON by 6-month post-stent removal[2] Resolution before AXIOS removal – not lost to 6-month follow-up (34/34) Resolution before AXIOS removal – lost to 6-month follow-up (6/6)	100.0% (40/40)
Time to WON resolution of ≤ 3 cm (days)	34.1±16.8 (40) (4.0, 100.0)
Recurrence of WON from initial resolution to 6 months post-AXIOS stent removal	0.0% (0/34)
Stent lumen patency	
Drainage through Axios stent visualized from the stomach or bowel	
After stent placement	100.0% (40/40)
Before stent removal	65.0% (26/40)
Visual confirmation of Axios stent lumen patency	
After stent placement	100.0% (40/40)
Before stent removal	97.5% (39/40)
Fluoroscopy time per endoscopic procedure (min)	4.6±6.1 (38) (1.0, 33.0)
Incidence of new organ failure from drainage procedure to WON resolution[3]	2.6% (1/39)

Change of SF-12 score from baseline to:	
Axios stent removal[4]	23.6±20.5 (37) (-26.1, 67.2)
End of study[5]	40.9±24.3 (27) (-12.5, 81.3)

NOTE: Numbers in the table above are either percent (# events/# of patients) or mean ± standard deviation (sample size) (minimum, maximum).

1. One subject reached WON size < 3 cm 100 days after AXIOS stent placement.
2. All subjects (including those that were later lost to follow-up) had resolution of WON by 100 days after AXIOS stent placement and before AXIOS stent removal, i.e. by 6 month post-stent removal.
3. Organ failure assessment not collected for 1 subject.
4. Short Form Patient Health Survey (SF-12) quality of life assessment not collected for 3 subjects at time of stent removal.
5. SF-12 not collected for 7 subjects at 6-month WON assessment visit.

Advanix™ 7 F Double Pigtail Stent Placement

Per protocol, some clinicians opted to place a 7 F Advanix double pigtail stent through the AXIOS stent to prevent occlusion of the drainage lumen. The use of the pigtail stent was at the discretion of the practitioner. Twenty-five 7 F Advanix double pigtail stents were placed through AXIOS stents during the study. There were no adverse events related to the Advanix stents.

Stent Removability

AXIOS and Advanix stent removal was successful in 100% (40/40) of subjects.

Adverse Events

There were no unanticipated adverse device effects reported. There were a total of 49 adverse events (AEs) observed in 24 subjects. Of the 49 adverse events, 36 were recorded as Serious Adverse Events (SAEs). The table below shows AEs and SAEs related to the AXIOS stent, AXIOS stent placement or removal, and necrosectomy:

	Related to AXIOS Stent	Related to AXIOS Stent Placement or Removal Procedure	Related to Necrosectomy
All Adverse Events	3	3	7
Serious Adverse Events	2	1	4

There were no AEs related to the use of the Advanix 7 F double pigtail plastic stent.

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.

A person with the Axios Stent may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Magnetic Resonance Conditional

Device Name	Axios Stent
Static magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Cylindrical Whole-body Coil Cylindrical Head Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration / Temperature Rise	Under scan conditions defined above, Axios Stent is expected to have a temperature rise of less than 4°C and can be used for 60 minutes of continuous RF
MR Image Artifact	Image artifact caused by device may extend approximately 10 mm from the stent with a gradient echo pulse sequence

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 aswell 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.

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