AXIOS™ Stent and Electrocautery-Enhanced Delivery System
(6x8mm, 8x8mm)

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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 ultrasound trained interventional endoscopist to deliver a transenteric stent between the gastrointestinal tract and a fluid collection (i.e. a pancreatic pseudocyst). The AXIOS Stent is a flexible, MRI Conditional, fully-covered self-expanding metal stent that is preloaded within the Delivery System preloaded within the Electrocautery-Enhanced Delivery system.

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

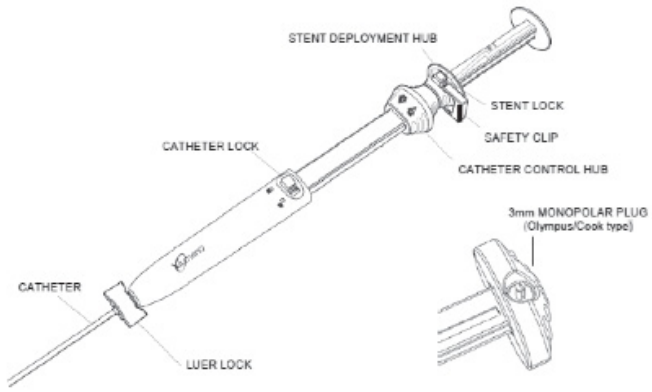

Figure 1. AXIOS Delivery System handle. The catheter control hub advances and retracts the catheter. The stent deployment hub releases the stent from the catheter. Monopolar plug for connection to electrosurgical generator.

Recommended Stent Selection Method

6mm and 8mm stents are indicated for the drainage of pancreatic pseudocysts with 100% fluid contents. Physicians may choose either 6 mm or 8 mm stent to drain the pancreatic pseudocyst based on anatomical or procedural considerations.
Perform a high definition CT scan and/or comprehensive endoscopic ultrasound (EUS) prior to the use of this device in order to rule out the presence of solid debris.
The 6 mm and 8 mm diameter stents both have an 8 mm stent LENGTH which can accommodate combined GI tract and fluid collection wall thickness up to 8 mm as assessed by EUS during the procedure.

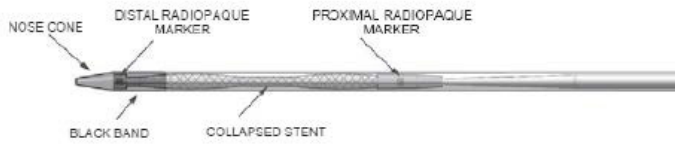

Figure 2. The collapsed stent is contained within the distal end of the catheter. A black band at the end of the catheter is used to position the stent second flange for deployment under direct visualization. Two radiopaque bands indicate the proximal and distal edges of the stent.

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, that are adherent to the gastric or bowel wall and are free of solid debris. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

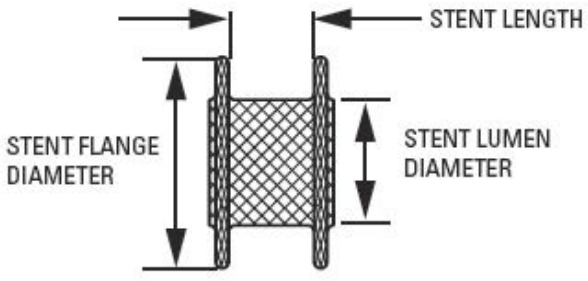

Figure 3. The stent is made of Nitinol wire and fully covered with silicone.

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. Evaluation of stent patency is advised and should be performed under endoscopic and/or radiographic imaging of the pancreatic pseudocyst if and when symptoms worsen or fail to improve.
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. 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.

30. 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.
31. 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
32. 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.
33. 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.
34. Device must be used in conjunction with a Type BF or CF generator, see compatible electrosurgical unit or generator informatio provided in full device IFU.
35. 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.
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.

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.

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