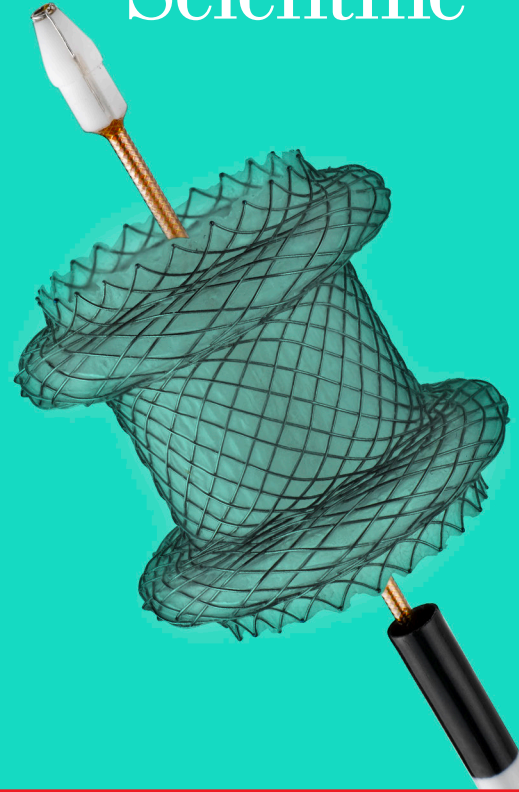
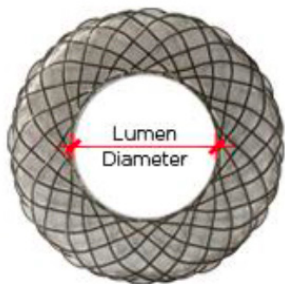


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# AXIOS™ Stent and Electrocautery Enhanced Delivery System

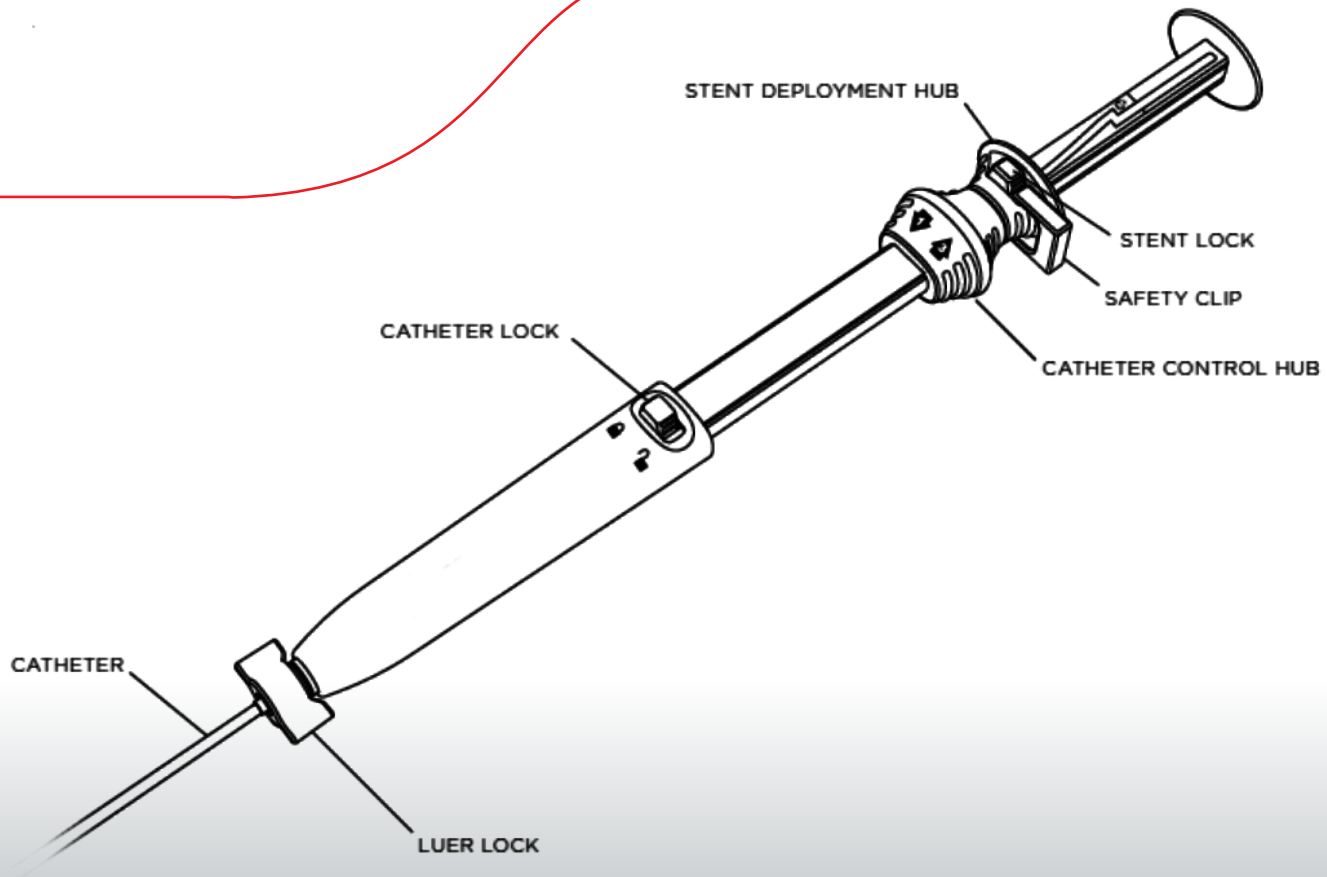
Quick Reference Guide





*AXIOS™ Stent (front and side views)*

| UPN Codes        | Flange Diameter (mm) | Lumen Diameter (mm) | Saddle Length (mm) | Catheter OD (Fr) | Catheter Working Length (cm) | Catheter Total Length (cm) |
|------------------|----------------------|---------------------|--------------------|------------------|------------------------------|----------------------------|
| <b>M00553640</b> | 21                   | 10                  | 10                 | 10.8             | 138                          | 146                        |
| <b>M00553650</b> | 24                   | 15                  | 10                 | 10.8             | 138                          | 146                        |



1

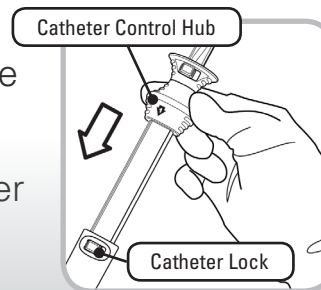
## Prepare AXIOS™ System

- Wet the catheter & insert AXIOS
- Connect AXIOS to generator
- Power on the generator and set to pure cut or auto-cut

2

## Access Target

- Unlock catheter lock & advance catheter control hub until catheter is visible
- Energize the device and advance catheter control hub until catheter is visible in target structure
- ⚠ **Lock catheter lock.** Ensure the catheter is at least 3-4cm into the target structure then lock the catheter
- Power off & disconnect generator

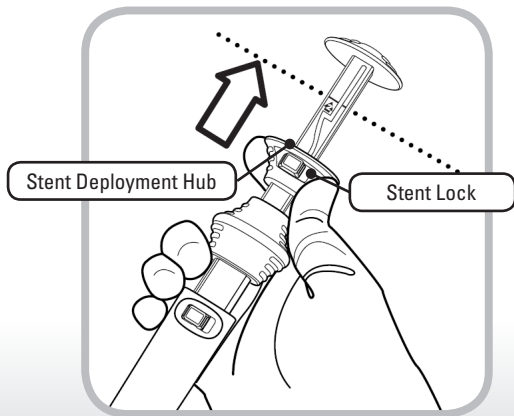


③

3

## Deploy 1st Flange

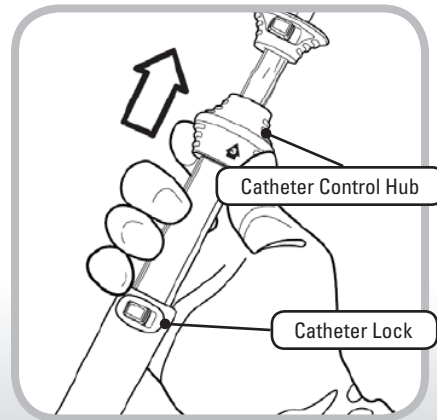
- Unlock the stent lock
- Move stent deployment hub up to the #2 on the handle until it locks in place



# 4

## Retract & Align the Stent

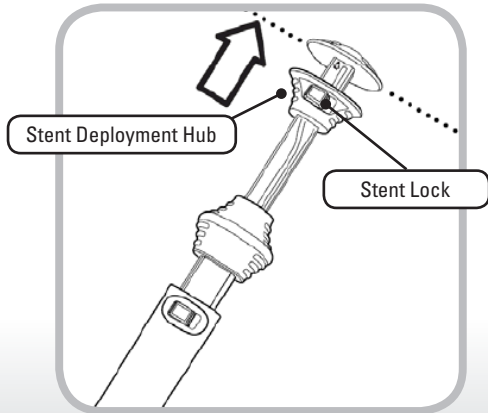
- Switch to endoscopic view
- Unlock catheter lock
- ⚠ Do not advance catheter control hub
- Retract the catheter control hub until 2-3mm of black marker is visible
- ⚠ **Lock the catheter lock**



5

## Deploy 2nd Flange

- Unlock the stent lock
- Move stent deployment hub up to the #4 on the handle
- Confirm deployment with endoscopic view
- Unlock luer fitting and remove delivery system



# Troubleshooting

Some scope and elevator positions result in excess friction between the catheter and the working channel. This impacts the performance of the AXIOS™ Delivery System and is why the solutions below include both lowering the elevator and straightening the scope.

| Problem   | Possible Solutions   |
|---|--|
| Excessive resistance when trying to pass the catheter through the working channel.  | <ul style="list-style-type: none"><li>• &lt;2 cm from fully inserted, lower the elevator and straighten the scope.</li><li>• &lt;10 cm from fully inserted, straighten the scope.</li><li>• &gt;10 cm from being fully inserted, remove it and pass another tool to see if the working channel is obstructed</li></ul> |
| The catheter cannot be advanced from its post-insertion position.   | <ul style="list-style-type: none"><li>• Unlock catheter and lower (open) the echoendoscope elevator &amp; straighten scope</li><li>• Remove the catheter and confirm that it is not kinked and nose cone is contiguous with the catheter.</li><li>• Lubricate catheter and reinsert it</li></ul>                       |
| The catheter can be advanced but it does not enter the pseudocyst.  | <ul style="list-style-type: none"><li>• Adjust/realign the scope position.</li><li>• Ensure proper electrical connection between generator and AXIOS Delivery System</li><li>• Ensure the patient is properly grounded.</li><li>• Check generator to ensure appropriate settings</li></ul>                             |
| The proximal stent flange does not deploy even though the stent deployment hub has been retracted to the top of the handle. | <ul style="list-style-type: none"><li>• Unlock the catheter lock and slowly advance the catheter control hub to push the proximal flange out of the scope working channel.</li></ul>   |



# Troubleshooting

|  |  |
|--|--|
| <p>Resistance makes it difficult to retract the stent deployment hub.</p>  | <ul style="list-style-type: none"><li>• Lower (open) the elevator</li><li>• Straighten the scope</li><li>• Remove the catheter from the scope and insert a guidewire through it. The guidewire should extend out of the distal tip 6 inches (this prevents the inner catheter from being damaged). Keep catheter straight, while retracting the stent deployment hub until 5 mm of the stent's distal end is visible. This will loosen the stent within the catheter. Then push the nose cone distally until it is seated against the catheter (as it was originally). Remove the guidewire and reinsert the catheter into the working channel.</li></ul>  |
| <p>The distal flange is not deployed even though the stent deployment hub has clicked into position (is at the #2 arrow line).</p> | <ul style="list-style-type: none"><li>• Elevator is open (lowered).</li><li>• Straighten the scope position.</li><li>• Unlock the catheter lock, advance the catheter control hub, and confirm the distal flange deployment. Retract and advance the catheter control hub as necessary. Relock the catheter lock.</li><li>• To limit deployment hub travel, grasp the handle at 5 - 10 mm above the #2 line. Unlock the stent lock and carefully retract the stent deployment hub while closing monitoring the EUS view. Stop retracting the hub immediately when the distal flange has deployed. <b>DO NOT RETRACT MORE THAN 1 cm.</b> CAUTION: Retracting the deployment hub too far may result in the entire stent deploying inside the pseudocyst.</li></ul> |
| <p>The black mark on the endo image cannot be seen on endo view when deploying proximal flange.</p>                                | <ul style="list-style-type: none"><li>• Deploy under EUS guidance. Using the EUS view, retract the catheter control hub so that the distal flange is seen tugging against the inner pseudocyst wall. Deploy the proximal flange.</li></ul>   |

*To remove the AXIOS™ Stent after the implant period, place an endoscopic snare over the proximal stent flange, tighten until the stent lumen is collapsed and pull the snare away from the GI wall.*

AXIOS™ Stent and Delivery System Indications for Use: The AXIOS Stent and Delivery System is indicated for use to facilitate transenteric endoscopic drainage of symptomatic pancreatic pseudocysts  $\geq 6$ 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 resolution.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

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Boston Scientific Corporation  
300 Boston Scientific Way  
Marlborough, MA 01752  
[www.bostonscientific.com/gastro](http://www.bostonscientific.com/gastro)

**Ordering Information**  
**1.800.225.3226**

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