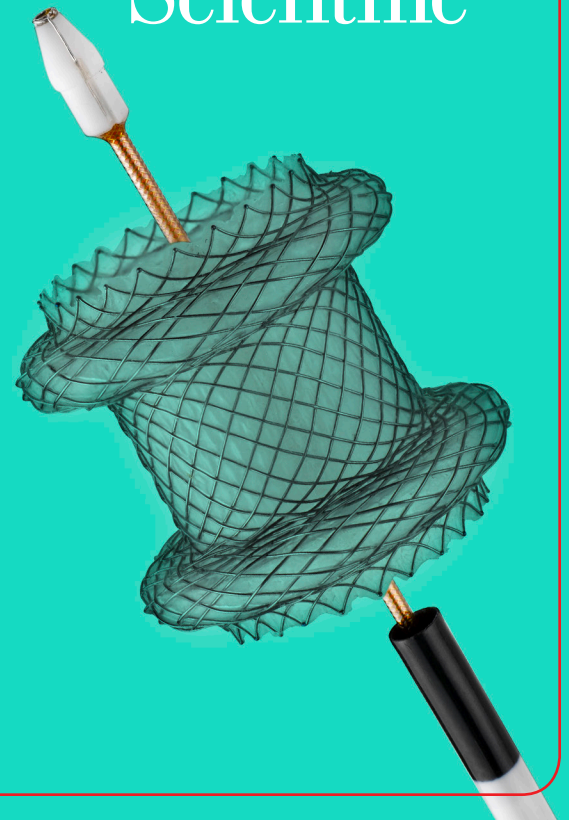
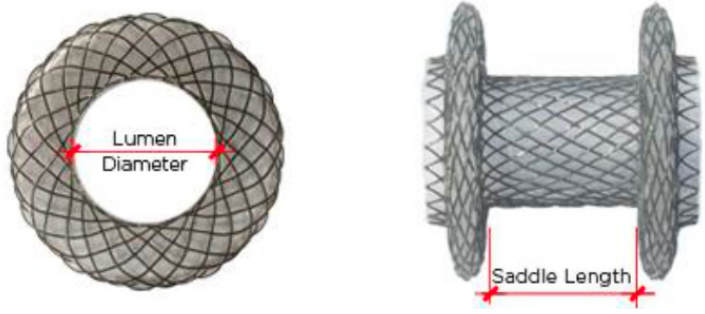
Boston Scientific

AXIOS™ Stent and Electrocautery Enhanced Delivery System

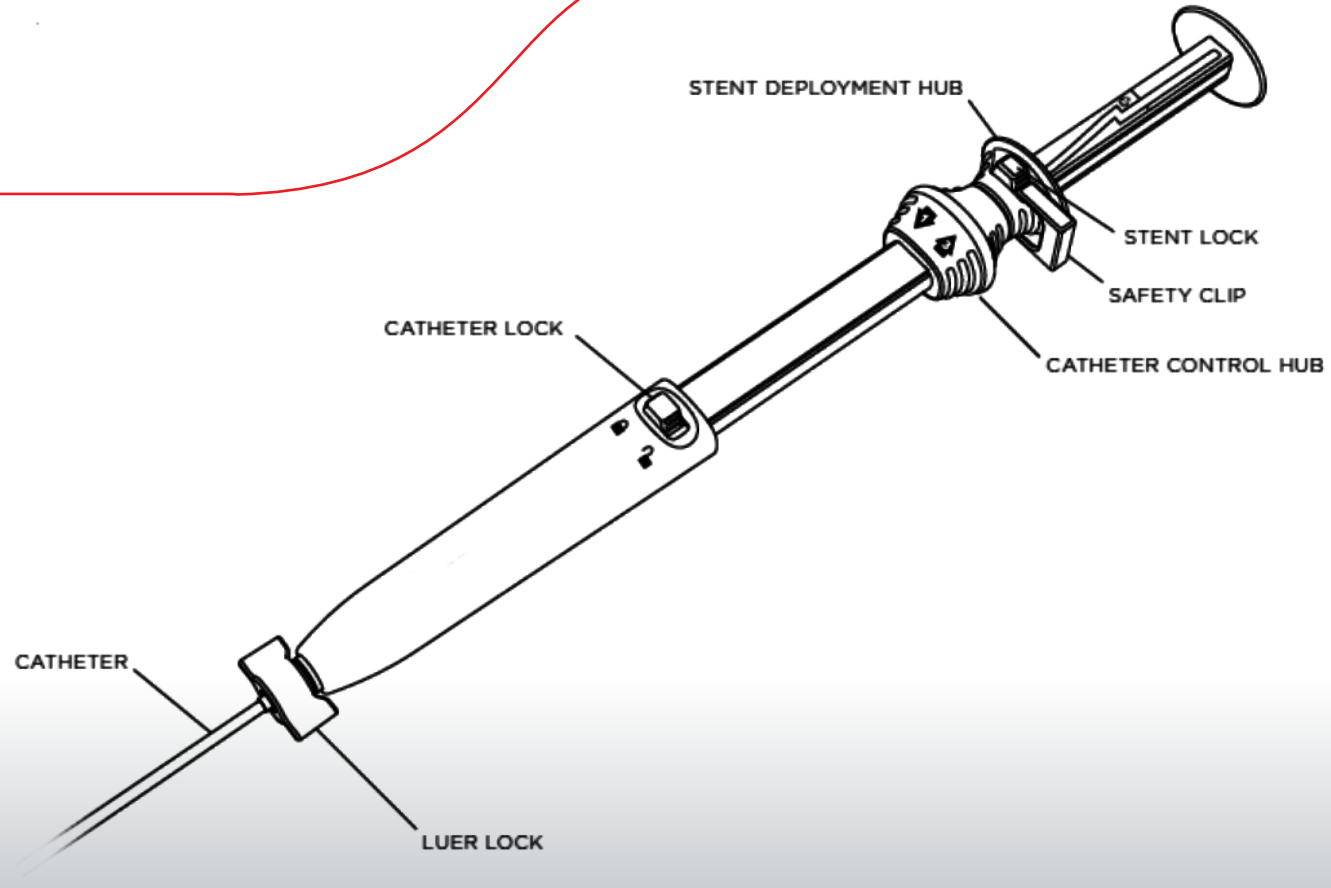
Quick Reference Guide





AXIOS™ Stent (front and side views)

UPN Codes	Flange Diameter (mm)	Lumen Diamter (mm)	Saddle Length (mm)	Catheter OD (Fr)	Catheter Working Length (cm)	Catheter Total Length (cm)
M00553640	21	10	10	10.8	138	146
M00553650	24	15	10	10.8	138	146


STENT DEPLOYMENT HUB
STENT LOCK
SAFETY CLIP
CATHETER CONTROL HUB
CATHETER LOCK
CATHETER
LUER LOCK

1 Prepare AXIOS™ System

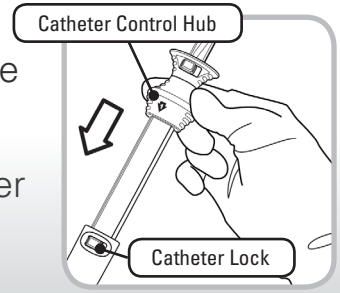
- Wet the catheter & insert AXIOS
- Connect AXIOS to generator
- Power on the generator and set to *pure cut*

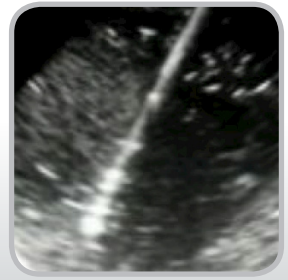
2 Access Target

- 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

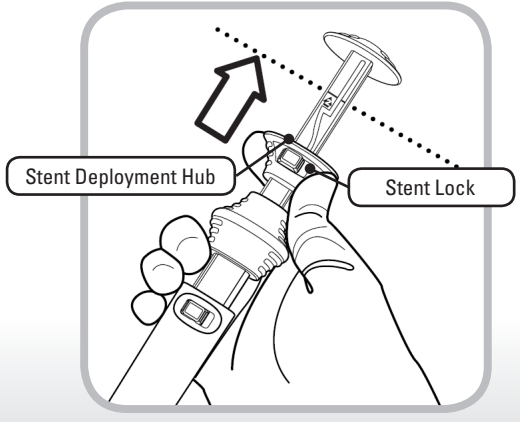


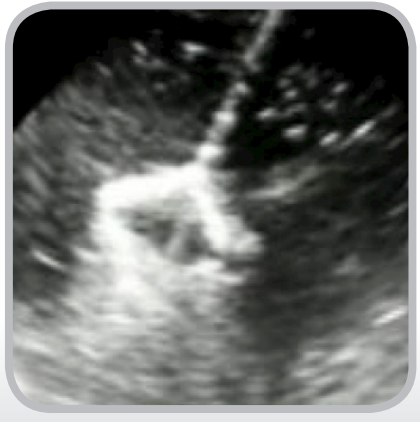


3

Deploy 1st Flange

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





4

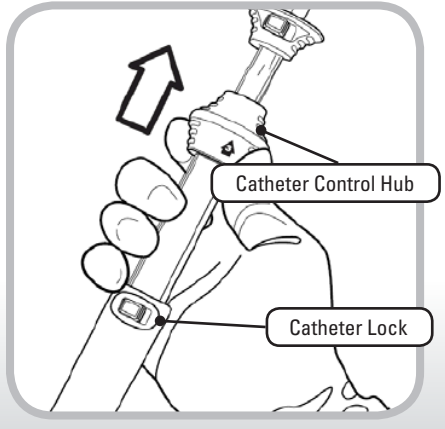
Retract & Align the Stent

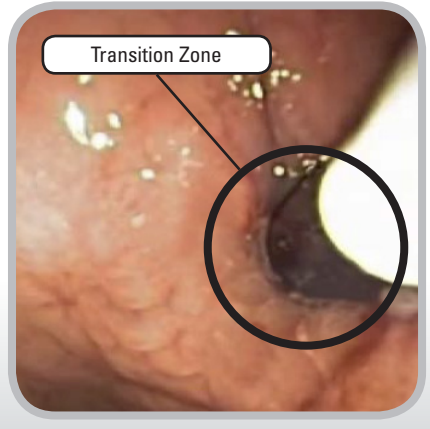
- Switch to endoscopic view
- Unlock catheter lock

⚠ Do not advance catheter control hub

- Retract the catheter control hub until 2-3mm of black marker is visible

⚠ **Lock the catheter lock**

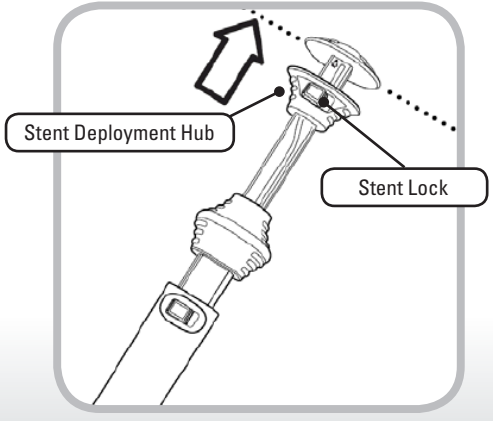




5

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.	• <2 cm from fully inserted, lower the elevator and straighten the scope. • <10 cm from fully inserted, straighten the scope. • >10 cm from being fully inserted, remove it and pass another tool to see if the working channel is obstructed
The catheter cannot be advanced from its post-insertion position.	• Unlock catheter and lower (open) the echoendoscope elevator & straighten scope • Remove the catheter and confirm that it is not kinked and nose cone is contiguous with the catheter. • Lubricate catheter and reinsert it
The catheter can be advanced but it does not enter the pseudocyst.	• Adjust/realign the scope position. • Ensure proper electrical connection between generator and AXIOS Delivery System • Ensure the patient is properly grounded. • Check generator to ensure appropriate settings
The second stent flange does not deploy even though the stent deployment hub has been retracted to the top of the handle.	• Unlock the catheter lock and slowly advance the catheter control hub to push the second flange out of the scope working channel.

Troubleshooting

Resistance makes it difficult to retract the stent deployment hub.	• Lower (open) the elevator • Straighten the scope • 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.
The first flange is not deployed even though the stent deployment hub has clicked into position (is at the #2 arrow line).	• Elevator is open (lowered). • Straighten the scope position. • Unlock the catheter lock, advance the catheter control hub, and confirm the first flange deployment. Retract and advance the catheter control hub as necessary. Relock the catheter lock. • 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 first flange has deployed. DO NOT RETRACT MORE THAN 1 cm. CAUTION: Retracting the deployment hub too far may result in the entire stent deploying inside the pseudocyst.
The black mark on the endo image cannot be seen on endo view when deploying second flange.	• Deploy under EUS guidance. Using the EUS view, retract the catheter control hub so that the first flange is seen tugging against the inner pseudocyst wall. Deploy the second flange.

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

INDICATIONS FOR USE

The Xlumena Hot AXIOS™ Stent and Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of a pancreatic pseudocyst or the biliary tract.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

Information not intended for distribution in France.

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