

**AMRITA SETHI:** Thank you very much. Good evening. Thanks for joining me today to talk about AXIOS, which I really enjoy using and enjoy talking about, actually. And thank you to Boston Scientific for this opportunity to discuss AXIOS. Some of the practices I've used that I think-- and I've also fielded a lot of questions and calls since it's been introduced, and so hopefully this will address some of those.

OK, so we're going to start with some techniques. As most of you know, there are two sizes currently available in terms of the AXIOS stent in the United States, the 15 millimeter and the 10 millimeter. And you do get questions about how to choose which size.

For the most part, I would say the 15 millimeter is really the workhorse for the indications for using AXIOS, particularly large collections that have debris in them, or walled-off necrosis, which is an indication that was approved a little shy of a year ago. And post-surgical collections, also with debris.

In essence, those collections in which you want rapid drainage of thicker material, and also you might anticipate the need for intubation of the stent and the cavity in order to perform further interventions such as necrosectomy.

The 10 millimeter, I think, can oftentimes be reserved for lumens like the duodenum, so a transduodenal placement where having a large opening is not as important, particularly if the cavity is completely fluid-filled and you really don't see any debris. And there's a good chance that you can have rapid drainage and resolution at the time of stent deployment only. So having and maintaining a large opening is not so important. So they tend to be limited indications, but there are places for the 10 millimeter, I think.

So let's move on to deployment. One critical thing when you're preparing for the case in terms of deployment it is to make sure that you have a therapeutic EUS scope. And this is really true for any drainage of any collection, or any interventional EUS procedure, but just an important thing to remember.

So we're going to start with the first step, and when you think about the handle system, it's always a good way to think about it is that the bottom half has to do with the catheter and the top half has to do with the stent. So the first step is going to involve the catheter, basically. So getting the catheter in the right place and getting ready to put it through the collection. So the first step you're going to do is to unlock the catheter, which is the button on the bottom, and advance the catheter forward by pushing down on this handle here until you see some mild tenting on endoscopic ultrasound of the catheter to the tenting of the wall. What this indicates is that you're making good contact so that the cautery be effective, and you can also see the direction that your catheter is going to take and help direct it appropriately to make sure that you have room to advance the catheter once you're inside the cavity.

Next, you will connect this to the generator up here. It's a standard [INAUDIBLE] generator, is what we use. And then you're ready to basically advance the catheter through the wall. So you're going to step on the yellow pedal while steadily advancing the catheter. And it's important to not do this in a skip movements, to start and stop, start and stop, but rather keep your foot on the pedal, advance the catheter through until you feel a given resistance. And you can actually see sometimes the tip of the catheter extend into the cavity itself.

As soon as you see this and as soon as you feel that release of resistance, it's important to actually stop cautery and not keep your foot on the pedal, and that's important because you don't want to continue to advance the catheter and be at risk of cauterizing through in terms of the back wall of the cavity.

So you stop the cautery. You can even disconnect from your generator, but you do want to continue to advance the catheter in until you're about one thumb-width from this gray portion, or until as far as you can go or as far as your cavity will allow. You do want a minimum of three centimeters of catheter inside the cavity in order to ensure proper deployment of the distal flange. And once this step is completed, it's very important to lock your catheter, and this is something that you have to do manually yourself, unlike the top lock, which locks automatically.

OK, so this second step is going to involve actually deploying a portion of the stent. So we're going to be dealing with the top half of the handle. First thing you'll do is remove the yellow safety tag. That's not here, but you normally see that. Just flick that out of the way. And then you're going to unlock the top handle here by moving the black lock this way.

Now, take one look back down at your bottom lock to make sure that you're locked on the catheter side, and then you're ready to deploy. So you're going to pull this up towards the number two position, and you'll hear it lock in place. On EUS, you'll see the distal flange start to deploy, start to open up and take on a disk shape. If you don't see the disk shape developing, there are some tricks that you can do and some cautions that you need to take, and we'll discuss that a little bit later in the talk. But basically, this step is going to be deployment of your distal flange and creation of the disk shape of the stent.

And then you're ready for step three, which again, is returning to the catheter portion of the handle. So again, anytime we're using the catheter portion, we're going to unlock the catheter down here. And basically, what this step is about is bringing the distal flange up to the wall in order to help oppose the two lumens of the collection that you're draining. So now you're going to pull the catheter, or push-- whichever is comfortable for your hand. You're going to pull it up this way and you will see the disk shape start to move towards the lumen, towards the wall. You want to pull it up until it takes a deformity that looks like an oval or a football, but essentially, what that's indicating is that it's starting to hit the wall and create a little resistance.

This is a good spot for you because you will have enough stent on the gastric side, for example-- if you're doing it trans-gastrically-- to deploy the proximal flange. So once you find this position and you're done pulling the catheter up, you'll lock the catheter again. And now we're ready to move on to step four.

Step four is where we can divide into performing this by EUS guidance and performing it by endoscopy, and we'll talk a little later, again, about the pros and cons of both. The actual step is basically deployment of your proximal flange. So let's first talk about EUS-guided, which I do for most of my cases.

But basically, you're going to remember returning to the top half of the handle, because you're talking about doing something with a stent and you're going to unlock the top lock here. And you're going to move back-- move this portion here up until the two handles here are flush. Now, if you're performing this by EUS guidance, you actually will see nothing happen, because what's happening is the stent is actually getting deployed within the channel of the scope. So it's important to maintain your scope position, don't worry if you don't see anything on EUS, don't worry if you don't see anything on fluoroscopy if that's what you're using, but just do this maneuver.

Then you are ready to switch to endoscopy, which you can do to basically confirm that your stent has been deployed and that the proximal end is on the gastric side. So the switchover to endoscopy, you can move away from the wall a little bit, you can big wheel away from you, torque to the right, and you should be able to see the proximal flange deployed.

Let's talk about if you want to do this by endoscopy guidance. So for endoscopy guidance, after step three-- or actually during step three-- when you're pulling back on the catheter. Remember that means that this is unlocked and you're pulling back on the catheter in order to bring the distal flange up against the cavity side of the lumen. You're going to pull this up until you see the black mark, and you can see that there in an insert. You see that black mark on the gastric side or on the proximal side of the lumen, and what that indicates is that you have enough so that the proximal flange is on the proximal side-- the proximal lumen are on the gastric side. It's critical-- if you're going to do this endoscopically guided-- that you see that black mark. That's when you know that you're ready to deploy the proximal flange.

At that moment, you're going to lock this in place and then, again, do the same step here. Now, with the EUS guidance, I mentioned just it's a very quick automatic calling this up, and you're not going to see anything happen. When you perform this by endoscopy, you do want to make sure that you're seeing the stents come out as you are deploying, as you're moving these two handles up, just to ensure that you actually are seeing stents and that the stent hasn't migrated in.

One of the tips in terms of performing endoscopy-- using endoscopy for guidance-- is sometimes getting yourself away from the lumen of the wall in order to actually be able to see that black mark and to see the stent come out. And so tips for that include big wheeling away and torquing to the right. It can be an uncomfortable move for some people because you feel like you might fall out of place, but it is sometimes necessary in order to be able to actually visualize the catheter and the black mark. So that's the stent deployment.

Let's just talk now about wire-guided versus freehand. Actually, just to finish that off-- some people say, should I stick a wire through there, which can be done by placing that up through the top handle, and dilate. We'll talk a little bit about post-stent dilation, but that would be the point before you pull this out. If you do want to put a wire in to secure your place, you can put it in through the top of the handle here, and then essentially, you're just going to unscrew this from the catheter up on the scope and just pull the entire thing out.

So in terms of wire-guided versus freehand, [AUDIO OUT] Well to be quite honest, I have been performing AXIOS-- hot AXIOS procedures-- pretty much 100% freehand since I started using them. And there are a couple of reasons for that, and I think that, for one thing, it's a very, very fast procedure when you do this freehand. For cases in which the freehand are particularly advantageous are when you have thick debris, such as in walled off necrosis, when you can't actually advance the wire far in enough to have enough purchase to be able to perform all of the wire-guided exchanges that are involved in wire placement in wire guidance.

In addition, for a large fluid collections when the collection is immediately adjacent to the lumen wall-- when you see the tenting of the catheter up against the wall, you can actually see the two lumens really pressed together. And when you apply the cautery it's a very quick and very safe entry into-- and fistula creation-- into that cavity. You're really not at risk of separation of the two walls, particularly if you have a good stable scope position.

And for large collections in which the catheter can be fully advanced-- so if you have like a big seven centimeter collection, you know that you have the safety of the entire catheter within the cavity. You don't have to worry about slipping out, losing your position, and in those cases a wire is not necessary.

Cases in which wire-guidance would be helpful-- for those in which there might be a slightly increased space between the cavity wall and the lumen wall; if your scope is in an unstable position and you're worried about falling away, making sure that you have a way to maintain that access with a wire is helpful; and then also, again, a smaller cavity or target space where you don't have the safety of being able to advance a good portion of that catheter in and making sure that the distal flange opens within the cavity. For that, you might want to be able to maintain access with a wire. So those would be cases.

What about the role of fluoroscopy? it's an interesting evolution of collection drainage and how it's progressed from endoscopy-only to EUS-guided and fluoroscopy, and I think that this current iteration of the AXIOS system has actually-- does allow for potentially doing this completely without fluoroscopy. All of the components have something that can be seen by [AUDIO OUT] and so that's really an advantage, particularly--

[AUDIO OUT]

--when you need to confirm optimal positioning. For example, if you know that you're going to do further intervention such as necrosectomy, sometimes you want to see what the scope position going in, or what will further scope positions be like entering the cavity? If you have to do a lot of retroflexion with a scope to follow, this might not be the most optimal position.

If you're performing it EUS-guided and you notice that the catheter and the flange deployment are very clear, very clearly each step can be visualized, you really don't need any fluoroscopy for that, but if you're deploying, for example, the distal flange, and you don't see a take on that disc shape, that might be a time that fluoroscopy is helpful because you want to make sure that that's starting to form before you really pull on it. Because if the disc has not formed and you don't have a safe way of ensuring that the lumens are going to be opposing each other, then you're at risk of pulling the entire stent out at the time of proximal flange deployment. So those would be times when fluoroscopy is particularly helpful.

But this certainly can be done by EUS guidance only, and if you're in emergency situations, for example, or in the ICU, that's a good place to forego the fluoroscopy.

So this seems to be a hot topic. Should we dilate these stents after placement, and when should we dilate? So I always dilate. I always dilate up to the maximum size of the stent. So if it's a 10 millimeter, I dilate up to 10, if it's 15, up to 15. And I go straight to that target size, I don't do it in increments. For ex-- well--

[AUDIO OUT]

--wire through the stent, and then placing your balloon over the wire, so wire-guided. Or you can do it freehand if you have good visualization of the lumen of the stent. But if there's a lot of debris, or if there is a lot of blood and it's hard to visualize that, then you might want to place the wiring

[AUDIO OUT]

--the patency of the stent. If there's thick debris, sometimes that can keep the stent [AUDIO OUT] closed. And the other is to pull the flanges together to help approximate the walls even more. So as you dilate, it actually brings the two flanges together, and you have very good approximation. But for the most part, I always dilate and have not yet had a problem, but I do make sure that I don't dilate beyond the lumen of the stent-- the lumen-- the stent size.

So in terms of best practices, if we look at optimal access in scope positioning, it's very similar to other EUS-guided drainages. As straight a scope position as you can obtain is always best, because you'll have less resistance passing any instruments through the channel of your scope. And again, you do want to think about post-stent deployment interventions.

When you're initially placing the catheter up against the lumen and getting ready to go through the wall, it's about a near perpendicular approach, similar to the FNA needle. You don't want it to be skimming along the wall of the collection as you go in, which as one knows from conventional techniques, can happen, and that would mean deployment of the stent between the collection and the wall of the stomach, for example. And again, considering the need for further interventions like necrosectomy.

What are some limita-- I mentioned that I do everything freehand for the most part. So what are the limitations? I think for wire-guided access, it's that really it's mostly that it adds significant length to this procedure. The more practice you have using the hot AXIOS, things become second nature, and this procedure can literally take one minute. Whereas if you're doing things over a wire, each step requires wire exchange and it really does add a significant amount of time, coordination between yourself and the tech or the nurse. You do really have to use fluoroscopy if you're doing wire-guided. Some wires can be seen on EUS, but in terms of confirming placement and during the exchange, you need fluoroscopy, so that's another limitation.

I do find that it can change the angle of the catheter, if you're not holding tension on the wire, and you do want to be careful about that in terms of entering the collection and making sure that you're going all the way through the two walls. And I've had experience where the cautery can actually damage the wire, particularly if there is an angulation, and this will prevent further [AUDIO OUT] --there and/or other instruments over the wire, so that can happen.

And then, the last thing is if the lumen tends to be small or is at a distance from the gastric wall, remember that the wires can be stiff, and if you're pushing the wire up against the distal wall of the cavity, it can have a tendency to push the cavity away from the gastric wall, for example. So you want to be careful about that if you are performing wire-guided access.

And then I mentioned, what are some pros/cons of when should we do EUS-guided and when endoscopic guided? Really, the most important thing is to feel comfortable with the method that you're going to use, and really commit to that approach, particularly when you're performing step three. Because remember, if you're going to do endoscopic guidance, you want to switch to endoscopy and you want to ensure that you see that black mark. If you're able and willing to do EUS-guided, you want to make sure you're maintaining a good EUS position so that you can visualize the flange up against the wall. But then, you're not going to see anything when you actually deploy the proximal flange.

I think that EUS-guided allows for such rapid deployment that it's particularly good for emergent situations, like if you're in the ICU or there is an infected collection and a patient is decompensating and you really don't have that much time to perform the procedure. It's also good if you can't really have established a good endoview. That step of really torquing away, torquing to the right, big wheel away, is an uncomfortable maneuver when we used to do this with conventional methods, and if you can't find a good position or there's too much fluid and there's too much debris and you're just not able to see anything, EUS guidance is a really good way to do this.

In general, I firmly believe that deployment of that is really performed the most safely [AUDIO OUT] --guidance, because again, you're deploying this stent within the scope and the scope you know is on the proximal side within the proximal lumen. And so, there's no way for the proximal flange to actually enter the distal lumen or the cavity, because once it comes out of the scope, it will already be in a deployed position. So it's really the safest way to deploy these stents.

What are a few watch-outs? These come around things like cautery. Always make sure that you're connected, that the generator's on the right settings. There is an issue about the wires that are being used for it to connect to the cautery generators. Older generators have a smaller cable. So it's a three millimeter socket that you need, so you might want to take a look at that or talk to your rep about making sure that you have the right cable. And then, when you're actually stepping on the cautery, as with any cautery, on EUS, you can have echogenic interference.

And this is kind of important, because I think sometimes you can get nervous if suddenly there's cautery effect and you get that sort of echogenic interference and you can't see the tip of the catheter. And you just need to remember, it's more of a feel, and just continue-- despite the interference-- continue to advance the catheter until you feel the release of that resistance. In fact, if you can continue to see the tip of the catheter very clearly and you can see tenting of the gastric wall, this means something's wrong. That means either the cautery's not working-- you're not going through that wall, and you have to stop, reassess, bring back the catheter, get that tenting out of the way, and start again. So really, don't get distracted or turned off by seeing some of that interference.

Other issues involve the catheter. Remember that that catheter always has to be locked at the end of step one and step three. If you fail to lock that, you can have premature deployment of the stent within the cavity, for example. If you're having difficulty advancing the catheter, either through the scope just on initially going down, or when you get to the end of the scope and you're trying to get it out of scope, take it out, flush the channel, re-wet the catheter. What this probably indicates is some friction between the catheter and the inside of the scope channel, and what it's going to do is it's going to start to deploy the stent while it's going through the scope.

If you, again, notice that the flange is delayed in taking on that disc shape when you're deploying, for example, the distal flange. Just wait a minute, stop, check your fluoro, do a little bit of jiggling, because you really need to establish that disc to make sure that that stent doesn't get pulled through the cavity when you're going to move on to step four.

And in fact, you can also-- if you're having a little difficulty-- unscrew the catheter. It's a little bit of an advanced move, but unscrew the catheter from the scope because it gives you a little extra catheter here to play with in terms of just moving back and forth. And so that's one maneuver. And again, if you have a small space and you find that you're really not able to have enough space to get at least three centimeters of the catheter in or there's a lot of thick debris, you can actually inject some saline, either before with an FNA needle to expand the space a little bit and give you some more room to optimally deploy the stent.

And lastly, in terms of stent dislodgement-- if it occurs during your indexed cystoscopy, for example. So you've deployed the stent and you're going through it for the first time with a scope, just go ahead and establish wire access. Dilate the collection up so you know that you're ensuring your access, and then consider replacing the AXIOS after the necrosectomy.

If you're doing the initial placement and there's some mis-deployment, the important thing is to maintain access. So quickly get a wire down there, and if you find, for example, that the stent has completely deployed within the cavity, as long as you have wire access, you can just take this out-- wire exchange it out-- and you can put in another stent. You can put in a biliary sent, for example. A 10 by 6 is a good stent to use, and that will actually either go through the lumen of the AXIOS, or it will just push the AXIOS out of the way. But that's a good salvage maneuver.

And once you deploy the stent, if you notice that the proximal flange is starting to migrate in and you're worried about it getting buried in the wall or actually migrating into the cavity itself, just grab some grabbers, pull it out until you see the shelf of the proximal flange flush against the proximal lumen. And that's really it, and I think we'll take some questions. Great.

**SPEAKER 2:** Thank you so much Dr. Sethi. We have time for a couple of questions. The first one that came in is, how do you determine whether to admit the patient after the procedure or to send them home, and what course of antibiotics do you prescribe pre and post placement?

**AMRITA SETHI:** So in terms of the antibiotics, I'll answer that first. I give antibiotics for any interventional EUS procedure, or so, and I usually do Levaquin at our hospital as a good standard antibiotic. Ciprofloxacin works just as well, and I prescribe it depending on the fluid content. So if it's just clear fluid, for about five days-- three to five days. If it's thicker infected looking material, I'll oftentimes take some of that material and send it off for culture, and adjust the antibiotics accordingly.

For infected collections, those patients are either inpatients to start with, or if they're not and I see infected material, I will definitely admit them-- and not only admit them, but plan for early re-intervention to get back in to start the necrosectomy process. And dilating, I think, is pretty important at that time, again, to make sure that the stent is patent and that you have established good drainage.

But I think for a lot of these patients, they do tend to be inpatients. So I keep them inpatient for not long. Otherwise, just one or two days, and if they're stable they can go home. One thing-- a key tip-- is that I do keep patients off of PPIs immediately after stent replacement, particularly if there's a lot of necrotic material, because I think that helps induce early dissolving of the product material.

**SPEAKER 2:** Excellent, thank you. Our next question from the audience is, do you wait for a cyst to collapse completely 100% or significantly drop in size sufficient before removing AXIOS?

**AMRITA SETHI:** So I usually wait for the collection to completely collapse. I find that they collapse very rapidly with these large-- the large lumens of the AXIOS stents, and particularly if it's mostly fluid, just a little bit of debris. So I usually leave them in for at least two weeks, actually. If I don't anticipate having to go back in and doing necrosectomy, getting a scan-- a CT scan, for example. I haven't had any issues removing the stents in terms of-- I haven't seen tissue in-growth or significant bleeding because of that.

A caveat to all of that is kind of having a sense of what's inside that cavity. It is important to inspect your scan prior to stent deployment, and if you see, for example, that there's a risk of vessels being exposed within the cavity or there's some really thick material, then it's important to get back in there quickly, inspect. And I would say after a couple of cases now, if you see vessels or signs of vessels within that cavity, I actually get that stent out earlier, because I don't want to leave such a large hole, particularly leaving those vessels exposed to stomach acids.

**SPEAKER 2:** Thank you. Our next question from the audience is, do you ever perform irrigation or debridement at the index procedure? Why or why not, and with which tools?

**AMRITA SETHI:** Yeah, so that's a great question. I have in the past if the collection is very thick. First of all, if it's really thick and there's a lot of pus and the patient is sick, septic, I might put in a-- I'll irrigate, I'll suction, and then at the end, leave a nasocystic drain in there. If it's thick material, I have on occasion just put a gastroscope in. It's a good idea-- if you have time and the patient's stable-- is actually to go ahead and put a gastroscope right inside the lumen. You don't have to investigate it very deeply, but just take a look at what the contents are. Again, look for anything that looks suspicious for a vessel.

If it just looks like a lot of thick debris, I have irrigated with hydrogen peroxide, for example, irrigate with about 120 CCs. I'll let it sit for a few minutes and then do some suctioning. I do think it's important to suction that hydrogen peroxide, particularly if you're not planning on doing necrosectomy at that time, because you don't want the patient to aspirate those fluid contents. So I'll let it sit, I'll let it start the process. If it's really thick and the patient is septic and I have a good scope position, I'm not concerned about dislodging the stent, I might start to do some initial necrosectomy, but for the most part, I wait till a second procedure and there's good stabilization of that stent within the lumen before I start performing any significant interventions.

**SPEAKER 2:** Great, thank you.

**AMRITA SETHI:** Actually, let me just say one thing. You do want to be careful about your choice of instruments with respect to the dislodging the stent. So there are often times people will use the tripod grabbers or grabbers themselves. Those do have a tendency to get caught in the stent, and you are at risk for pulling the stent out. So I would say probably avoid that until you are completely within the cavity and you can be sure that you're not going to open that within the lumen of the stent.

**SPEAKER 2:** Great, thank you. And our last question-- you spoke about dilation during your presentation. How long do you leave the balloon inflated post-dilation?

**AMRITA SETHI:** About a minute. If I have fluoro-- I look for the waste, which is seen, and it gets faced pretty quickly. But about a minute is typically the dilation. There's no good data behind that, but I think that's just our standard practice from dilations of other strictures and whatnot. But it dilates pretty quickly to the balloon. The balloon waste goes away very quickly.

**SPEAKER 2:** And we had one last question come in. So how and when, in relation to AXIOS deployment, do you decide to aspirate cyst fluid content from microbiology and culture?

**AMRITA SETHI:** If patients are septic I will do that. And if they are on strong antibiotics and there's a question of resistance, for example, or patients are immunocompromised, sometimes I'll actually-- before stent deployment, if the ability of the patient allows-- actually puncture with an FNA needle and aspirate that way. So it's not fluid that is contaminated with a lot of gastric contents that I'm aspirating for culture. But if I see thick fluid, pus, the patient's unstable, or they're on a number of antibiotics, I usually will send that because that specificity can be important in terms of speciation.