# Endovascular Management of Deep Vein Thrombosis: An Expert Panel Discussion

*Endovascular Today* met with a multidisciplinary panel of venous experts to discuss the current status of DVT treatment in the United States and abroad and how the field has evolved in the last 10 years.


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### *EVT:* What is the current state of deep vein thrombosis (DVT) treatment for the majority of patients in the United States?

**Dr. Garcia:** I think the current practice in many ways, somewhat disappointingly, is initially still the same [as it was 10 years ago]. Patients who have acute DVT receive standard-of-care medical treatment. I do think, however, we've come a long way in recognizing the benefits of techniques like pharmacomechanical thrombolysis as well as catheter-directed thrombolysis in aiding these patients and improving their quality of life at the time, but I still think that we have a long way to go. Thankfully, the ATTRACT trial has completed [enrollment], which hopefully will show the benefit of aggressive management with endovascular techniques for DVT.

Even in our institution, where we've developed pretty good algorithms for DVT, there is still a significant

number of patients who receive standard of care despite extensive clot—it really depends on who happens to see them up front. Across the country, I'd be amazed if it's more than a third of the DVT population who could benefit from it who actually receives aggressive DVT therapy.

**Prof. Kucher:** Switzerland has improved a little bit. It's a conservative country, but we have done a lot of work on increasing awareness for DVT, and now we see more patients being referred for catheter-directed thrombolysis and stenting. When we go back 10 or 15 years ago, we were not really aware of the clinical problems of iliofemoral DVT, and we underestimated the risk for these patients to develop postthrombotic syndrome (PTS). Now, I think our knowledge has improved over the last 10 years, and we know that half of the patients at least have an increased risk of developing PTS if they are not being treated.

Ten or 15 years ago, we went out and told our primary care physicians that we don't want to have these patients in the hospital because we had low-molecular-weight heparin and compression treatment, and we have not seen these patients in the hospital because they were managed as outpatients. They were diagnosed and managed by vascular specialists in private care. Now, I think it's our job to go out again and say, "We want patients with iliofemoral DVT back in the hospitals because there is more to do than just anticoagulation and compression therapy."

**Dr. Lookstein:** I would echo Dr. Garcia and Prof. Kucher's points—I think there is, unfortunately, only a minority of patients in the greater New York City area who are being treated with aggressive therapy. I would be surprised if it's greater than 10% of patients with symptomatic lower extremity DVT who were being treated [endovascularly]. One of the major drivers has been a transition to outpatient treatment of DVT. There is not a tremendous public awareness campaign about options that patients can have, and certainly that public awareness campaign hasn't filtered out to primary care physicians or primary hematologists who might be managing these patients in an outpatient setting. I think it behooves all of us as vascular specialists to take that as a challenge to generate data.

There is still a huge opportunity to educate primary care physicians, internists, and hematologists about the risks to their patients. A significant percentage of patients who I see in my practice are learning about these risks on their own, largely due to social media, which is a sad state for the level of public awareness about the potentially devastating consequences of PTS.

**Dr. O'Sullivan:** Most of the time, the focus of the internal medicine specialist or hematologist is not about the patient's leg, it is about the side effects from the medication. [The patients are] asked, "How are the tablets going? Any interactions? Any drug rashes?" Way down the list is, "How's your leg?" and when the [patients] do tell them about the leg, the [physicians] say, "Oh, well that's not my area, we'll have to refer you on."

**Prof. Kucher:** I think that's very much true. I'm often invited to controversy sessions and speak in favor of catheter-directed thrombolysis and stenting, and I'm having difficult discussions with the contrasting speakers because what I often hear from them is that we overestimate PTS. They say it's probably less than 10%, and that's the problem—they don't even check the leg symptoms or look to see if the patient has swelling. There's an additional point: Patients in the early stages of PTS have difficulties explaining their symptoms. Sometimes, you find that they gain weight, they exercise less, but you don't see much on the leg. Often, the leg is not even very swollen. Now imagine a physician has on the last of his list of priorities to check for symptoms and signs of PTS—then it's no surprise to me that it's underestimated. Our conservative colleagues are convinced that we exaggerate the problem, and this is the main concern I have for the future.

### *EVT:* What is the referral pattern for your practice? Where are the DVT patients coming from?

**Dr. Wang:** That's probably been the biggest change over the last half a decade. There [used to be] a lot of referrals for DVT that came through the hospital, where the patients were initially sent. [A vascular surgeon] would potentially capture some of the patients that need intervention at that point because you'd be asked to see them and may even be involved in their anticoagulation regimens.

The referral pattern now typically comes through the outpatient setting. A primary care physician may see the patient and say, "Hmm, this patient has a swollen leg," so we make ourselves available to do ultrasounds so the patients will find their way to our office.

I started doing thrombectomy procedures for iliofemoral DVTs [in patients in the hospital who were having difficulty walking]. The patients would then go back to their primary care doctors, and I would seize every advantage or opportunity to help with the education process. I would go out and essentially do grassroots educational programs in doctors' offices, which is ultimately how we were able to build a referral base for these types of procedures.

**Dr. Lookstein:** One thing I would add is that the major transformation in primary care physicians' and internists' willingness to accept this aggressive procedure is a commitment to provide it in the ambulatory setting. Historically, when we all used to treat patients with DVT 15 years ago, that required an inpatient stay of 2 to 3 days on average, sometimes much longer. Because this procedure using pharmacomechanical techniques is an outpatient procedure, there has been a greater acceptance of the procedure's benefits for the patient population at large and a lower threshold to refer patients. When they know the patient will be home the same day and be safe, referring physicians feel much more comfortable sending the patients to you.

**Dr. Garcia:** In our institution, I found that by educating the hospitalists (because the hospitalists do the admission and initial patient evaluations), they're much less resistant to endovascular therapies for people suffering from acute DVT. The amazing thing I find is that the hematologists still resist, despite the fact that every one of them had patients who were dealing with extensive DVT and phlegmasia whom we've treated and had great successes. Their field in general, like oncology, is very scientific, and they need tens of thousands of patients to show a benefit in randomized trials to convince them differently.

Many of the referring physicians don't recognize that by the advancement of our pharmacomechanical and debulking techniques, we've limited the amount of tPA. They keep bringing up numbers of giving tPA with astronomical bleeding rates, which we just don't see. There's been some ignorance to what we've actually been able to obtain across the world with these newer techniques.

### *EVT:* What is your preferred treatment algorithm when a DVT patient comes to your office?

**Dr. Garcia:** [If they're not suffering from phlegmasia], usually we do serial ultrasounds for several weeks [to see if they are resolving the clot] … but we found that if we get to [these patients] within 4 weeks, we're almost always successful in completely recanalizing and resolving the clot.

Once we know we're going to treat, we get every patient on Lovenox starting the day before, and we use a technique called "rapid lysis" that we've been doing since 1997. We think that [technique] has completely changed our ability to rapidly restore flow, get wall-to-wall apposition, clean out the vast majority of clot, and preserve the vein function, as well as the valve function. In over half of our population, [we perform a single] session, and those who may undergo additional catheter-directed therapy, it's for a short period of time because you've debulked the clot. That technique, spiraling through the venous system and through the clot, is really our mainstay of treatment and has worked incredibly well.

**Prof. Kucher:** First of all, we have to say that not all DVT patients are candidates for interventional treatment. We have a flow chart in our hospital emergency department across all walls. When there is a DVT diagnosed in which the upper leg is swollen and at least the common femoral vein or a higher-located vein is thrombosed, those patients are candidates for interventional treatment, which I would say is approximately 20% of all DVTs. Most DVTs are confined to the thigh or the lower leg, and those patients are not candidates for interventional treatment because their risk of PTS is very low. We have learned that the common femoral vein is the most important functional inflow vessel, where three veins of the leg come together. Functionally, if this vein or a higher vein is thrombosed, those patients have the highest risk of PTS. It's fivefold higher than when any other vein is thrombosed, and those patients should be treated.

We just published our series of 90 patients with iliofemoral DVT. In most cases, we use catheter-directed thrombolysis and a fixed-dose regimen of tPA (20 mg over 15 hours), and then we bring the patient back to the cath lab and do a venogram. Our stenting rate is 80%; I think this is a very critical point because one of the problems from earlier studies was that the stenting rate was very low. For example, in the CAVENT study, it was 17%, and that's the main reason that one-third of the vessels were closed at 6 months, and their PTS rate was 40% in the treated arm. In our series, the patency rate at 1 year was 96%, and the PTS rate was 6% and only mild PTS forms.

**Dr. Lookstein:** Most patients who are seeing me in the office have already received medical therapy and don't feel that it's giving them enough symptomatic relief. If patients come into my office seeking more aggressive therapy or if they've told their primary care provider they want more aggressive therapy, as part of the consent process of reviewing their options, we typically risk stratify them by obtaining cross-sectional imaging of their pelvis and lower abdomen to determine whether or not there is a mechanical cause for their iliofemoral DVT.

In the majority of patients with symptomatic iliofemoral DVT, there is, in fact, a mechanical cause,

and that goes into the risk stratification conversation. Most times, when patients find out that they do have a mechanical cause for their DVT, they're much more enthusiastic about having that mechanical cause corrected, and they're willing to undergo the pharmacomechanical thrombectomy procedure.

These procedures are scheduled electively based on the patient's convenience. Typically, the patients will come in early in the morning and have a fairly rapid Power Pulse™ spray thrombectomy procedure that usually takes about an hour, and then they'll go to our recovery room and receive a short duration of catheter-directed thrombolysis for anywhere from 4 to 6 hours. Then they'll come back into a procedure room and have the offending lesion, typically in the pelvis, corrected with a stent, as Prof. Kucher mentioned. As soon as the stent is implanted and it's dilated, all the sheaths and equipment are removed from the patient. They will get an injection of Lovenox, as Dr. Garcia said, and they'll go home in a few hours.

**Dr. O'Sullivan:** That's exactly where we should be going in my view—we want this to be a 1-day case, we want it to be safe; it is safe. Cross-sectional imaging looking for an offending lesion typically near the confluence of the iliac veins is critical. Once you get the thrombus out and you stent that lesion—and the vast majority of patients *do* need a stent—their leg is almost normal in a day or two, and they go back to full activity quickly.

**Dr. Wang:** I [treat my patients] in an office-based lab, so there are some considerations that you need to make sure you take there. I also Power Pulse™ lytic, leave a lytic catheter mainly to hold my place, put the patients in the holding area, do some other cases, and then bring them back and do secondary intervention.

The most important thing in making sure you have a successful, stress-free experience for your patients is to make sure that you give them significant education that their urine will turn brown or red, and that they need to be well hydrated so it disappears in 24 hours. For male patients, this is exceedingly important. If they do not stay well hydrated, there are untoward complications you can have that you don't want.

**Dr. Garcia:** I have only one additional cautionary comment: in patients who present with either chronic or acute renal insufficiency, we back off from doing pharmacomechanical therapy only because of the risk of worsening their renal condition. We have found that clearly there is a direct correlation to worsening kidney failure and using pharmacomechanical technique. In that population, we may go to the "standard of care," if you want to call it that, with catheter-directed lytic therapy to try to obviate any of the renal complications that may occur from hemolysis and hemoglobinuria.

**Prof. Kucher:** I also have one additional cautionary comment on sending patients home after thrombolytic therapy the same day. If you do catheter-directed thrombolysis with 50 mg over 50 hours as it was done in the CAVENT study, there was a major bleeding rate of 9%. This is one of the reasons our medical community is still conservative and says, "For stable disease like DVT, if you have a major bleeding rate of 9% with your intervention, then we will not refer patients to you." They are correct, and that's why if you do catheter-directed thrombolysis, you should stop your treatment and terminate your lysis at 24 hours, maybe even earlier. We stop at 15 hours in all cases, but you still have a 2% to 3% major bleeding rate if you do this. Especially if you also treat fragile patients, those with an increased risk of bleeding, or those who had postsurgical thrombosis—there is a risk of bleeding, and I would not send patients home the same day who have received thrombolytic treatment. This is a potentially dangerous drug, and I will always keep the patients in the hospital at least one night, even if I have done a single-session procedure.

### *EVT:* How has the new 8-F AngioJet™ ZelanteDVT™ Catheter (Boston Scientific Corporation) impacted your practice so far?

**Prof. Kucher:** I see an advantage in comparison to a 6-F device. I have the feeling it's more powerful, not only because of the bigger device lumen, [but also the] rotational thrombectomy. With the [other] current devices, you are not able to torque the device and change the angulation where the clot is being sucked in at the tip. I think it's very important because in many cases, the catheter is not centrally located in the vessel, and often the catheter is at the vessel wall. Now, by changing the angulation of the device, you will reach the clot even in eccentric positions of your device. I think this is probably one of the main advantages that [makes] the 8-F ZelanteDVT catheter more effective. Especially in combination with Power Pulse™ thrombolysis, I think the device is very effective.

**Dr. Lookstein:** I think the new catheter is uniquely designed to address the anatomic issues that we're facing as we move more proximally in the lower extremity. In the last several years, we've been able to identify that

the iliac vein diameter, especially in the setting of acute thrombus, can range anywhere from 14 mm to even 20 mm. There was clearly an unmet clinical need for a catheter with the ability to extract clot from a large luminal surface.

The 8-F system is clearly moving toward addressing that space, and the goal is that you'll be able to extract a greater percentage of the thrombus in those patients in a single session. I think the goal here is to try and get 90%-plus clot removal using a reliable, efficient method. This is a step in the right direction.

**Dr. O'Sullivan:** It's been very successful. Dr. Garcia showed me that by putting the 6-F AngioJet device inside an 8-F torque catheter, you could generate what I would call *rotational thrombectomy*. A lot of the focus at the moment in arteries is directional atherectomy—this is directional thrombectomy. With the 8-F device, you can do it without the 8-F catheter as an adjunct, and you can get over 90% [clot removal] in probably under 20 minutes.

**Dr. Wang:** I do think that being more confident in the device's ability to extract thrombus may lead toward modification to what we do now. As the technology progresses, people are going to modify their practice patterns if given additional tools to do better in that situation.

**Dr. O'Sullivan:** [For me to change my practice pattern], it really has to happen in 2 hours. ICU beds are very difficult to come by. What they do in Bern as Professor Kucher describes, where the patients stay overnight … is a great technique, I just don't have access to it. So for me, it has to work in 2 hours, and it does with this.

**Dr. Lookstein:** I think that any time you're admitting somebody overnight, it accelerates the cost of the procedure so much that it becomes unpalatable to a health care delivery system. The only way that this is going to catch on, if you want to look at health care economics in the United States, is to move it into the ambulatory space. If you are not utilizing such intensive hospital resources, then it becomes palatable to a health system.

**Dr. Garcia:** Early results suggest a more efficient thrombus removal aided by the size and directionality of the catheter. This highlights a very important point in our data review. One of the things that we looked at was the cost benefit of a successful single-session pharmacomechanical thrombolysis versus the cost of overnight lytic therapy in the ICU compared to infusion in our step down… Everyone who has done these procedures knows that infusions can sometimes go 2 or 3 days in those who don't use pharmacomechanical techniques. All of our patients for the last 3 or 4 years have gone to the vascular floor bed—they no longer go to the ICU for overnight infusion if it happens.

One thing we looked at was the [single] session, which is what the AngioJet rapid lysis technique was allowing us to do, and we calculated the cost savings, since one of the complaints that has been written about is the upfront cost of these devices. We found that in 147 patients, if you were to take that single session and do an overnight infusion, we were seeing an approximate savings of $1.5 million—just in that small population.

The benefits from increased upfront costs of using this device can be seen downstream by minimizing the need for catheter thrombolysis by increasing the efficiency of pharmacomechanical thrombolysis as is seen early with the ZelanteDVT.

**Dr. Lookstein:** The cost of an ICU [stay] can be upwards of 10 times the cost of a thrombectomy catheter—that's the hidden truth. So you're paying a slight modicum of cost up front, but you're saving a tremendous amount by keeping the patients' care at the same level of intensity and not escalating their care overnight.

[The CAVENT trial] really answered the open vein hypothesis. Patients with an open vein did dramatically better in terms of their quality of life afterward. How can we get more patients' veins open to improve their quality of life? At least among the practitioners here, I think that involves the use of a thrombectomy system. ■

## ABBREVIATED STATEMENTS

**ZELANTEDVT THROMBECTOMY SET**

***CAUTION:*** *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

**INDICATIONS AND USAGE**

The ZelanteDVT Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus, including deep vein thrombus (DVT), from:
- Iliofemoral and lower extremity veins ≥ 6.0 mm in diameter and
- Upper extremity peripheral veins ≥ 6.0 mm in diameter.

The ZelanteDVT Thrombectomy Set is also intended for use with the AngioJet Ultra Power Pulse® technique for the controlled and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

**CONTRAINDICATIONS**

Do not use the catheter in patients:
- Who are contraindicated for endovascular procedures
- Who cannot tolerate contrast media
- In whom the lesion cannot be accessed with the guidewire

**WARNINGS and PRECAUTIONS**

The ZelanteDVT Thrombectomy Set has not been evaluated for treatment of pulmonary embolism. There are reports of serious adverse events, including death, associated with cases where other thrombectomy catheters were used during treatment of pulmonary embolism.
- The ZelanteDVT Thrombectomy Set has not been evaluated for use in the carotid or cerebral vasculature.
- The ZelanteDVT Thrombectomy Set has not been evaluated for use in the coronary vasculature.
- Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vessel occlusion, which may further result in hypoperfusion or tissue necrosis.
- Cardiac arrhythmias during catheter operation have been reported in a small number of patients. Cardiac rhythm should be monitored during catheter use and appropriate management, such as temporary pacing, be employed, if needed.
- Use of the catheter may cause a vessel dissection or perforation.
- Do not use the AngioJet Ultra System in patients who have a non-healed injury due to recent mechanical intervention, in the vessel to be treated, to avoid further injury, dissection, or hemorrhage.
- Do not use the ZelanteDVT Thrombectomy Set in vessels smaller than minimum vessel diameter as listed in Table 1 of the IFU; such use may increase risk of vessel injury.
- Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. This is in addition to the heparin added to the saline supply bag. Physician discretion with regard to the use of heparin is advised.
- Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, remove the catheter together with the sheath as a unit to prevent possible tip separation.
- If resistance is felt during the advancement of the ZelanteDVT Thrombectomy Set to lesion site, do not force or torque the catheter excessively as this may result in deformation of tip components and thereby degrade catheter performance.
- The potential for pulmonary thromboembolism should be carefully considered when the ZelanteDVT Thrombectomy Set is used to break up and remove peripheral venous thrombus

**ADVERSE EVENTS**

Potential adverse events which may be associated with use of the AngioJet Ultra Thrombectomy System are similar to those associated with
other interventional procedures and include, but are not limited to:
• abrupt closure of treated vessel • acute myocardial infarction • acute renal failure • bleeding from access site • cerebrovascular accident • death • dissection • embolization, proximal or distal • hematoma • hemolysis • hemorrhage, requiring transfusion • hypotension/hypertension • infection at the access site • pain • pancreatitis • perforation • pseudoaneurysm • reactions to contrast medium • thrombosis/occlusion • total occlusion of treated vessel • vascular aneurysm • vascular spasm • vessel wall or valve damage

**SOLENT CATHETERS COMBINED W/CONSOLE**

***CAUTION:*** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

**INDICATIONS AND USAGE**

The AngioJet SOLENT proxi & omni Thrombectomy Sets are intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:
- upper and lower extremity peripheral arteries ≥ 3.0mm in diameter,
- upper extremity peripheral veins ≥ 3.0mm in diameter,
- ileofemoral and lower extremity veins ≥ 3.0mm in diameter,
- A-V access conduits ≥ 3.0mm in diameter and
- for use with the AngioJet Ultra Power Pulse technique for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

The AngioJet SOLENT dista Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:
- upper and lower extremity peripheral arteries and
- for use with the AngioJet Ultra Power Pulse technique for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

The minimum vessel diameter for each Thrombectomy Set model is listed in Table 1 (in the IFU).

**CONTRAINDICATIONS**

Do not use the catheter in patients:
- Who are contraindicated for endovascular procedures
- Who cannot tolerate contrast media
- In whom the lesion cannot be accessed with the guide wire

**WARNINGS AND PRECAUTIONS**

- The Thrombectomy Set has not been evaluated for treatment of pulmonary embolism. There are reports of serious adverse events, including death, associated with cases where the catheter was used in treatment of pulmonary embolism.
- The Thrombectomy Set has not been evaluated for use in the carotid or cerebral vasculature.
- The Thrombectomy Set has not been evaluated for use in the coronary vasculature (unless accompanied by a separate coronary IFU).
- Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vessel occlusion, which may further result in hypoperfusion or tissue necrosis.
- Cardiac arrhythmias during catheter operation have been reported in a small number of patients. Cardiac rhythm should be monitored during catheter use and appropriate management, such as temporary pacing, be employed, if needed.
- Use of the catheter may cause a vessel dissection or perforation.
- Do not use the AngioJet Ultra System in patients who have a nonhealed injury due to recent mechanical intervention, in the vessel to be treated, to avoid further injury, dissection, or hemorrhage.
- Do not use the Thrombectomy Set in vessels smaller than minimum vessel diameter for each Thrombectomy Set model as listed in Table 1 (in the IFU); such use may increase risk of vessel injury.
- Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. This is in addition to the heparin added to the saline supply bag.
- Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the IFU) lists maximum recommended run times in a flowing blood field and total operating time for each Thrombectomy Set. Evaluate the patient's risk tolerance for hemoglobinemia and related sequelae prior to the procedure. Consider hydration prior to, during, and after the procedure as appropriate to the patient's overall medical condition.
- Large thrombus burdens in peripheral veins and other vessels may result in significant hemoglobinemia which should be monitored to manage possible renal, pancreatic, or other adverse events.
- Monitor thrombotic debris/fluid flow exiting the Thrombectomy Set via the waste tubing during use. If blood is not visible in the waste tubing during AngioJet Ultra System activation, the catheter may be occlusive within the vessel; verify catheter position, vessel diameter and thrombus status. Operation under occlusive conditions may increase risk of vessel injury.
- Do not exchange the guide wire. Do not retract the guide wire into the catheter during operation. The guide wire should extend at least 3 cm past the catheter tip at all times. If retraction of the guide wire into the Thrombectomy Set occurs, it may be necessary to remove both the Thrombectomy Set and the guide wire from the patient in order to re-load the catheter over the guide wire. (Dista only)
- Use of a J-tip guide wire is not recommended as it is possible for the tip of the guide wire to exit through a side window on the distal end of the catheter. (Omni, Proxi only)
- Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, remove the catheter together with the sheath or guide catheter as a unit to prevent possible tip separation.
- If resistance is felt during the advancement of the Thrombectomy Set to lesion site, do not force or torque the catheter excessively as this may result in deformation of tip components and thereby degrade catheter performance.
- Obstructing lesions that are difficult to cross with the catheter to access thrombus may be balloon dilated with low pressure (≤ 2 atm). Failure to pre-dilate difficult-to-cross lesions prior to catheter operation may result in vessel injury.
- The potential for pulmonary thromboembolism should be carefully considered when the Thrombectomy Sets are used to break up and remove peripheral venous thrombus.

(Below is Omni, Proxi only)
- Hand injection of standard contrast medium may be delivered through the thrombectomy catheter via the manifold port stopcock. Follow the steps to remove air from the catheter when delivering fluid through the catheter stopcock.
- Fluids should be injected only under the direction of a physician and all solutions prepared according the manufacturer instructions.
- The Thrombectomy Set waste lumen is rated for 50psi. Delivering a hand injection of contrast medium with excessive force can create injection pressures greater than 50psi, potentially causing leaks in the waste lumen of the catheter.
- Do not use a power injector to deliver contrast medium through the catheter stopcock. Power injectors can deliver pressures greater than 50psi, potentially causing leaks in the waste lumen of the catheter.
- Some fluids, such as contrast agents, can thicken in the catheter lumen and block proper catheter operation if left static too long. The catheter should be operated to clear the fluid within 15 minutes of injection.

**Console WARNINGS and PRECAUTIONS:**
- Use the AngioJet Ultra Console only with an AngioJet Ultra Thrombectomy Set. This Console will not operate with a previous model pump set and catheter.
- Do not attempt to bypass any of the Console safety features.
- If the catheter is removed from the patient and/or is inoperative, the waste tubing lumen, guide catheter, and sheath should be flushed with sterile, heparinized solution to avoid thrombus formation and maintain lumen patency. Reprime the catheter by submerging the tip in sterile, heparinized solution and operating it for at least 20 seconds before reintroduction to the patient.
- Refer to the individual AngioJet Ultra Thrombectomy Set Information for Use manual for specific warnings and precautions.
- Do not move the collection bag during catheter operation as this may cause a collection bag error.
- Monitor thrombotic debris/fluid flow exiting the catheter through the waste tubing during use. If blood is not visible during console activation, the catheter may be occlusive within the vessel or the outflow lumen may be blocked.
- Ensure adequate patient anticoagulation to prevent thrombus formation in outflow lumen.
- Refer to individual Thrombectomy Set Instructions for Use manual for specific instructions regarding heparinization of the Thrombectomy Set.
- The Console contains no user-serviceable parts. Refer service to qualified personnel.
- Removal of outer covers may result in electrical shock.
- This device may cause electromagnetic interference with other devices when in use. Do not place Console near sensitive equipment when operating.
- Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Where the "Trapping Zone Hazard for Fingers" symbol is displayed on the console, there exists a risk of trapping or pinching fingers during operation and care must be exercised to avoid injury.
- Do not reposition or push the console from any point other than the handle designed for that purpose. A condition of overbalance or tipping may ensue.
- The AngioJet Ultra Console should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the AngioJet Ultra Console should be observed to verify normal operation in the configuration in which it will be used.
- Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
- The use of accessories and cables other than those specified, with the exception of accessories and cables sold by Bayer HealthCare as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Ultra Console.
- MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding Electro-Magnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the tables provided in the IFU.

**ADVERSE EVENTS**

Potential adverse events which may be associated with use of the AngioJet Ultra Thrombectomy System are similar to those associated with
other interventional procedures and include, but are not limited to:
• abrupt closure of treated vessel • acute myocardial infarction • acute renal failure • bleeding from access site • cerebrovascular accident • death • dissection • embolization, proximal or distal • hematoma • hemolysis • hemorrhage, requiring transfusion • hypotension/hypertension • infection at the access site • pain • pancreatitis • perforation • pseudoaneurysm • reactions to contrast medium • thrombosis/occlusion • total occlusion of treated vessel • vascular aneurysm • vascular spasm • vessel wall or valve damage

**AMPLATZ SUPER STIFF GUIDEWIRE**

***CAUTION:*** *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

**INTENDED USE/INDICATIONS FOR USE**

The Amplatz Super Stiff guidewire facilitates catheter placement and exchange during diagnostic or interventional procedures. Not intended for use in coronary arteries. The tip of the guidewire is not designed to be reshaped. Reshaping of the tip could result in damage to the guidewire. Attention should be paid to guidewire movement in the vessel. Always advance or withdraw a wire slowly. Never push, auger, or withdraw a guidewire which meets resistance. Resistance may be felt tactilely or noted by tip buckling during fluoroscopy. When reintroducing a guidewire into a catheter within a vessel, confirm that the catheter tip is free within the lumen (i.e. not against the vessel wall). 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.

**CONTRAINDICATIONS**

None known.

**WARNINGS:**

This device should be used only by physicians with a thorough understanding of angiography and percutaneous interventional procedures. Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated.

**ADVERSE EVENTS**

Potential adverse events which may result from the use of the device include but are not limited to:
Air Embolism/Thromboembolism, Allergic Reaction, Amputation, Arteriovenous (AV) Fistula, Death, Embolism, Hematoma, Hemorrhage, Hemoglobinuria, Infection or Sepsis/Infection, Myocardial Ischemia and/or Infarction, Pseudoaneurysm, Stroke (CVA)/Transient Ischemic Attacks (TIA), Thrombus, Vessel Occlusion, Vessel Perforation/ Dissection/Trauma, Vessel Spasm, Wire Entrapment/Entanglement, Foreign body/Wire Fracture. Some of the stated potential adverse events may require additional surgical intervention.