Expert Panel Discussion on Atherectomy and Vessel Prep: What Roles Do They Play In My Practice?

Endovascular Today sat down with a multidisciplinary panel of esteemed interventionists to discuss their current practice paradigms for atherectomy, including the hot topic of Vessel Prep prior to drug-coated balloons and other adjunctive therapies.

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All physicians were compensated for their time associated with this panel discussion and/or article.

EVT: **In your practice, have you treated enough patients using the combination of atherectomy and drug-coated balloons (DCBs) (or other adjunctive therapies) to be able to say if your outcomes are better, worse, or about the same compared to treatment with other contemporary therapies such as stenting, specialty balloons, etc.?**

Dr. Mustapha: Luckily for us, we use ultrasound 100% in terms of bettering our therapy. One of the things that we've done so far [that] we've seen a difference with is debulk-

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ing the target vessel pretty much to the wall, where you can actually go in, prep the vessel, deliver the DCB, and see under ultrasound that the DCB is actually in complete contact with the vessel wall, giving you a 1:1 ratio between the DCB and the vessel wall. I've got to tell you, for the first time, we have seen fewer patients coming back with restenosis since DCBs have been out, and atherectomy does make a big difference in those patients if you want to get a proper vessel prep prior to [using a] DCB.

Dr. Shimshak: I think the problem is, like all the trials, [what we see in the] real world is different in terms of the endpoints and the patient population that we deal with day in and day out. I think if we limit the scope of DCBs to short or intermediate-length lesions, there is clear benefit. What I struggle with is making the leap for long superficial femoral artery (SFA) disease—chronic total occlusions that are 20 or 30 cm. That is a huge amount of disease that you're dealing with. In those patients, I think atherectomy, coupled with whatever other device, gives you optimal luminal gain and is the way to go. That's why I think vessel preparation is so key. You may be able to achieve [good results in a long lesion] with a DCB, but I think that's a good place for stenting, and I still believe stenting has a role in those long segments of disease.

Dr. Davis: When we were in the DCB trials, we were treating a very different population of patients' lesions. Historically, I can say that I know a few patients who have come back when I've just used DCBs [to treat them]. I haven't seen many of the [patients treated with] atherectomy and DCBs, at least in my own sense of it, but we are collecting our data, and I think at the 1-year mark we'll know a little bit better. I think we need a little bit more time to go by to have a better answer to that question.

I think back over the European data and what Professor Thomas Zeller sees, and you've got to take what he says with a lot of stock. He truly is a believer in [atherectomy and DCB], and that's what he does in his practice.

ATHERECTOMY AND DCBs: A Q+A WITH DR. NICOLAS W. SHAMMAS

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EVT: In your practice, in which lesion types are you choosing to perform vessel prep with atherectomy prior to DCBs?

Dr. Shammas: I use atherectomy frequently prior to DCBs or plain old balloon angioplasty in any lesion > 10 cm long, any total occlusions (if you cross intraluminally), or calcified plaque—irrespective of length.

Why do I do this? We have seen that these particular lesions are high risk for dissections and stenting, and I try to use a no-stent strategy in my lab as much as possible to keep the vessel intact for potential future treatments and avoid potential stent-related problems. With that no-stent strategy, atherectomy has become very important in my lab. If you look at the lesions that have the highest predictor for the need for stenting and the lesions that are more likely to dissect, they are calcified long lesions, total occlusions, and complex lesions (TASC C and D). With that in mind, these particular vessels are treated with atherectomy in my lab almost routinely. I have been performing atherectomy for over 15 years now, which has reduced my stenting rate to < 10%. Atherectomy is quite the tool to allow me to have the best acute procedural success.

EVT: Do you think thrombus is underappreciated in peripheral artery lesions? How important is clearing the thrombus barrier prior to utilizing DCBs?

Dr. Shammas: Clots can be of different ages, and different age clots bind paclitaxel in different ways and allow diffusion of the drug in different ways, creating a milieu that is highly unpredictable to how much drug can penetrate into the vessel

Dr. Beasley: You see some tremendous results. Early on, I remember a couple of my patients who I treated with atherectomy and DCBs when they first became available. Those patients have not shown any restenosis, reocclusion, or redevelopment of plaque that I can see, and these are patients that I follow closely on external ultrasound in the office.

In my lab, I'm using [multiple DCBs] at a time on a patient and hopefully getting a 70% to 80% success rate, where we don't have to place a stent. If we do have to place a stent, then you're placing a bare-metal stent over an area that already has drug on it.

EVT: What is the role of atherectomy in your current practice? Does it depend on the type of adjunctive therapy you are using?

Dr. Beasley: I use atherectomy in almost every case that has anything to do with any type of peripheral vascular disease—any type of critical ischemia or revascularization model. If [the vessel] has plaque, an occlusion, or a stenosis, I use atherectomy to prepare the vessel.

I'm a user of pretty much all the atherectomy devices, so depending on the location of the lesion, the position of the lesion, and the type of the lesion, I'll use a particular atherectomy device. I know with DCBs, you want to debulk and expose the vessel wall to that drug. With stenting, you want to give the stents a chance so that the stent's drug can appose itself to the wall the best possible way it can. So, I pretty much use atherectomy at all times.

Dr. Noor: I started using atherectomy early in my fellowship training so I took to it really easily—it wasn't as difficult to learn when you have already adopted other techniques, and at that time, it was really just angioplasty and stenting. I really like the philosophy of atherectomy, which has luminal gain and removal of the plaque, allowing the vessel to be more compliant with minimal trauma. Everything else that we do to the vessel in order to get luminal gain causes more injury and trauma and sets you back a year from now, when you have disease recurrence.

I use atherectomy, depending on the lesion, almost everywhere. In the femoral, popliteal, or below-the-knee distribution, atherectomy is probably my first line of defense. It then allows you to decide how you want to treat after. I'm not a big stenter; however, I will use focal stenting, depending on how much lesion or disease is left behind. I think it's a great platform for DCBs and possibly drug-eluting stents (DESs) once we have a little bit more data.

Dr. Mustapha: I try to marry each atherectomy device wall. In my mind, the presence of a thrombus is equal to unpredictability of drug absorption into the vessel wall. If we can take care of the thrombus and remove it as much as possible, I think that would create more homogeneous, predictable drug diffusion into the target lesion.

With that in mind, I use the JETSTREAM™ Atherectomy System (Boston Scientific Corporation), because it's also approved for thrombectomy. I use it to treat both fibrous plaque and thrombus, and I try to remove as much of this plaque-thrombus burden as I can safely. The presence of a thrombus is also a high predictor for distal embolization, so particularly in total occlusions, I tend to use filters on a routine basis because we know very well that embolic debris will likely occur during the treatment.

EVT: How important is creating concentric lumens or circumferential lumens with atherectomy in order to create a uniform landing zone for DCB?

Dr. Shammas: My own particular preference is to maintain the rotational cutting within the intima and the superficial media rather than go deep into the media and the adventitia. There is a very interesting study that was recently published in the *Journal of Endovascular Therapy* that discussed the impact of deeper cuts into the media and the adventitia.[1] Strikingly, it showed that a very high rate of patency loss would occur when you cut very deep into the media and adventitia, supporting the hypothesis that restenosis, to a large degree, originates from the outer and deeper layers of the artery. To me, atherectomy is about vessel modification and about getting the least amount of deeper trauma into the vessel wall. I think this is a very important concept and raises the question of whether rotational cutting may lead to less restenosis than random directional cutting.

EVT: What type of clinical data would you like to see in the future regarding atherectomy and DCB?

Dr. Shammas: Peripheral vascular intervention lags behind the coronary world by years, and the reason for that is the lack of good, randomized data. I'd like to start seeing a move from just registries—which are also important—but, we need to move into the world of randomized trials that are powered enough to prove a point.

We need to be able to prove and get the message out there that atherectomy devices added to a DCB can be highly effective in reducing acute failure, and at the same time will likely have an impact on the long-term patency and reduction of target lesion revascularization. I would also like to see a trial of atherectomy with DCB versus DCB only that is powered and large enough to at least show that the additional vessel prep and the additional vessel modification would lead to better outcomes acutely as well as in the long term. ■

1. Tarricone A, Ali Z, Rajamanickam A, et al. Histopathologicial evidence of adventitial or medial injury is a strong predictor of restenosis during directional atherectomy for peripheral artery disease. J Endovasc Ther. 2015;22:712-715.

with the type of lesion or plaque that I'm facing at the time. In our institution, we use extravascular ultrasound, and that has been extremely helpful. We evaluate the plaque that we're dealing with and actually make a decision on which type of atherectomy device we're going to use based on what we saw. [Under fluoroscopy,] we tend to undersize the vessel significantly, especially in the SFA/popliteal and tibial vessels. Based on what we see on ultrasound, we are able to debulk or modify the vessel [plaque] more accurately.

Dr. Shimshak: For me, it really comes down to plaque burden. When you begin to look at these vessels from a physical standpoint, you begin to realize why balloon angioplasty has failed at the most basic level. Remember, you cannot achieve an adequate lumen just by compressing that material. By the same token, even if you are an aggressive stenter, you [may] not be able to achieve optimal luminal dimensions of the stent even with the highest-performing stents today without preparing that vessel, in my opinion. I think balloon angioplasty is not enough. As Dr. Noor said, there is no question that as we begin to embark on preparing the vessel with balloon angioplasty when these vessels are highly calcified, there's a high incidence of dissections that are generated, which impacts patency and the durability of whatever intervention you perform.

Dr. Davis: To add onto that complexity, as years go on, we all push the envelope in terms of the types of vessels we're willing to treat. As the complexity of lesions increases, I think atherectomy really is almost imperative in those types of lesions—long calcified lesions, thrombotic, and mixed lesions. As we push the limit, that's where we need it more.

Dr. Mustapha: Intimal calcification is different than medial calcification. Intimal calcification is the one that actually causes the problem for us, in particular if you deploy a stent without prepping the vessel properly—this is where you see the stent kinked. Intimal calcification has a significantly higher density of calcium deposit in it versus medial calcification. This is where the term "debulking" versus modifying the plaque comes into play. Knowing what kind of lesion you're dealing with is extremely important. Sometimes you may not be able to debulk it, so you modify it, and you will be able to dilate it.

Dr. Shimshak: To Dr. Mustapha's point, 360° calcification cannot be approached with angioplasty or any other device short of debulking. In my practice, the other traditional subset, as Dr. Davis alluded to, that we backed off from and now are pushing the envelope on, would be common femoral disease. I don't think every [case of] common femoral disease needs to be treated with end-

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arterectomy. I think there are subsets that can be treated with endovascular techniques, and I think intravascular ultrasound (IVUS) is the guide for that, correlated with angiograms.

EVT: Despite a lack of level 1 data, what inspires your confidence in using atherectomy prior to DCB? What would you say to peers of yours who have not yet incorporated vessel prep with atherectomy into their practice, prior to using DCB in certain lesion types?

Dr. Noor: It's unfortunate that atherectomy doesn't have good level 1 evidence. It's probably a failure on all of our parts that there isn't good level 1 evidence that allows you to compare such a good modality of treatment with other standard modalities out there. But if I had to do every case with level 1 evidence, I would only get half my cases done, realistically.

It does take time. The problem with atherectomy is that there is a learning curve, and it's a steep learning curve. There are multiple devices out now, so it's difficult to be able to learn each one of them, but if you would pick one or two, you could use it. It's not as easy and fast as angioplasty and stenting—it's a labor of love—but I think you offer your patients a very good solution.

Dr. Beasley: When you take a look at IVUS and see the concentric luminal gain after atherectomy, and you take the Fanelli results into account, and then the dispersion of the balloon and paclitaxel into the wall, when you improve the wall apposition—it's an argument you make without level 1 evidence, but it's an argument that I think that most reasonable folks can understand.

Dr. Shimshak: I think it's a leap at this point; we don't have the robust datasets that we want. I think it will come, but the message I would convey to people who are not yet embracing atherectomy, to help them understand the power of that therapy, would be to begin to use IVUS if they're not using IVUS. I think that is the key element in

understanding the utility of this approach. Then, be guided by atherectomy coupled with other new technologies that do have more proven efficacy.

Dr. Mustapha: Stents did not always have level 1 evidence. Eventually, atherectomy will have level 1 evidence, and operators who don't use atherectomy today will hopefully see the value of atherectomy then. We had an atherectomy study [DEFINITIVE LE, Medtronic] that had a patency rate similar to stenting, so you already have something that tells you atherectomy is as effective as stenting in certain situations.

Many operators are reluctant to make the shift toward atherectomy utilization. In part, it could be due to the ease of use of a stent and/or not wanting to invest the time using atherectomy. In my opinion, atherectomy is the first tool to think of when trying to achieve the most effective vessel prep.

Dr. Davis: I go back to my Stone Age days when I was just using balloon angioplasty in the coronary [arteries], and then stents came out, and we always [thought] we shouldn't stent all the time, we should do bailout stenting. [Then] all of a sudden, stenting became this phenomenal thing. Then DESs came out, but because of the cost, you only used them in certain areas and at certain times. Now, if you don't put a DES in there, you're committing malpractice unless there's a good reason not to. So I think part of this is cost—costs have come down, and I think we've gotten used to the outcomes there.

I think drug delivery is here to stay, and right now, we have DCBs as our delivery system. Who knows where the technology is going to go and what's going to be the best delivery system, but that's what our system is.

EVT: How are you currently making the decision on which atherectomy device to use for vessel prep prior to using a DCB?

Dr. Shimshak: Calcium is critical to remove and prepare the vessel, but I also think it's plaque burden. Whatever device offers you the ability to debulk varying morphologies is my go-to device. There aren't very many that fit that bill. Most of the atherectomy devices are better for some things than others, but in my clinical practice, the JETSTREAM™ Atherectomy System (Boston Scientific Corporation) gives you predictability for varying lesion morphologies. Even for the non-IVUS users, I think there's comfort in that, if you don't understand the extent of disease, the device will perform admirably regardless of what kind of morphology you've encountered—soft plaque, eccentric, concentric, varying degrees of calcium, thrombus—it provides functionality for all those lesion morphologies.

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>
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In my practice, I would say over 90% [of the time, the] atherectomy device that I select off the shelf is JETSTREAM, for the reasons that I've already discussed. It gives me high performance for varying lesion morphologies, it's predictable, and it has a safety profile that's desirable. The aspiration is key, and I find it to be very desirable regardless of where I am.

Dr. Noor: Any time you performed a peripheral vascular intervention and you're concerned about thrombus, it's almost a contraindication to do anything because before, if you embolized the thrombus, we didn't have a lot of options. We had to lyse it and then you had to go back in and treat the underlying lesion.

But with newer technology, you can still go in and lyse it or use the AngioJet™ Thrombectomy System (Boston Scientific Corporation) and then treat it with atherectomy, or use JETSTREAM, which allows you to do both [atherectomy and thrombectomy, due to JETSTREAM having an indication for both]. The concept of being able to treat the thrombus and the underlying disease at the same time is very attractive not only for the patient and the time spent in the lab, but also from a cost standpoint. There are a lot of advantages to doing that, and your complication rate hopefully is lower with or without a filter, depending on how comfortable you are using one or not.

Dr. Davis: There is a lot more thrombotic disease that we just don't recognize in these lesions. Dr. Shimshak, as you've noticed, too, that's why by IVUS, with the virtual histology, you see it. When you do an OCT, the thrombotic areas are much more evident. A surgeon would probably recognize it more than we would, but as interventionists, you don't really recognize exactly how much thrombus you're dealing with on occlusive disease in the SFA.

Dr. Beasley: For the great majority of the SFA, [I use] rotational atherectomy because you have the benefit of not only being able to get a really nice channel, but also a very concentric luminal gain that you can then use for your adjunctive treatment modality, be it DCBs or stenting. You also have that aspirational component where you can at least be sure of yourself that you're pushing through and debulking this plaque. ■

ABBREVIATED STATEMENTS

JETSTREAM CATHETERS COMBINED WITH 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.
Catheter INDICATIONS
The Jetstream System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.
Console INDICATIONS
The PV Console is designed for use only with the Jetstream Catheter and Control Pod. See the current revision of the applicable Catheter and Control Pod Instructions for Use for further information.
CONTRAINDICATIONS
No known contraindications.
Catheter WARNINGS/PRECAUTIONS
- The Jetstream Catheter and Control Pod may only be used with the PV Console.
- Take care to avoid being pinched when closing the aspiration and infusion pump doors.

Use room temperature infusate only. Use of heated infusate may lead to wrinkling, ballooning and/or bursting of the outer catheter sheath.
- Do not bend or kink the Catheter during setup or during the procedure. This may damage the device and lead to device failure.
- Operating the Catheter over a kinked guidewire may cause vessel damage or guidewire fracture.
- During treatment, do not allow the Catheter tip within 10.0 cm of spring tip portion of the guidewire. Interaction between the Catheter Tip and this portion of the guidewire may cause damage to or detachment of the guidewire tip or complicate guidewire management.
- The guidewire must be in place prior to operating the Catheter in the patient. Absence of the guidewire may lead to inability to steer the Catheter and cause potential vessel damage.
- Do not inject contrast while the device is activated.
- If the guidewire is accidentally retracted into the device during placement or treatment, stop use, and remove the Catheter and the guidewire from the patient. Verify that the guidewire is not damaged before re-inserting the guidewire. If damage is noticed, replace the guidewire.
- Check the infusate bag frequently and replace when needed. Do not run the JETSTREAM System without infusate as this may cause device failure.
- Hold the guidewire firmly during Catheter retraction process. Failure to do so may result in guidewire rotation within the vessel.
- Do not manipulate the Catheter against resistance unless the cause for that resistance has been determined.
- Use only listed compatible guidewires and introducers with the Jetstream System. The use of any supplies not listed as compatible may damage or compromise the performance of the Jetstream System.

Prior to use of the Jetstream System, confirm the minimum vessel diameter proximal to the lesion per the following:
Jetstream SC Atherectomy Catheter 1.6 Minimum Vessel Diameter Proximal to Lesion 2.5 mm
Jetstream SC Atherectomy Catheter 1.85 Minimum Vessel Diameter Proximal to Lesion 2.75 mm
Jetstream XC Atherectomy Catheter2.1-3.0 Minimum Vessel Diameter, Blades Down 3.0 mm; Minimum Vessel Diameter, Blades Up 4.0 mm
Jetstream XC Atherectomy Catheter2.4-3.4 Minimum Vessel Diameter, Blades Down 3.5 mm; Minimum Vessel Diameter, Blades Up 4.5 mm
Console WARNINGS/PRECAUTIONS
- WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Do not open either pump door during operation of the System. Doing so could result in loss of aspiration and/or infusion and will halt device activation.
- Ensure the PV Console display is visible during the entire procedure.
- Observe normal safety practices associated with electrical/electronic medical equipment.
- Avoid excessive coiling or bending of the power cables during storage.
- Store the PV Console using appropriate care to prevent accidental damage.
- Do not place objects on the PV Console.
- Do not immerse the PV Console in liquids.

ADVERSE EVENTS
Potential adverse events associated with use of this device and other interventional catheters include, but are not limited to the following (alphabetical order):
• Abrupt or sub-acute closure • Amputation • Bleeding complications, access site • Bleeding complications, non-access site • Death • Dissection • Distal emboli • Hypotension • Infection or fever • Perforation • Restenosis of the treated segment • Vascular complications which may require surgical repair • Thrombus • Vasospasm

SOLENT CATHETERS COMBINED W/CONSOLE
SOLENT OMNI, SOLENT PROXI THROMBECTOMY CATHETERS
SOLENT DISTA THROMBECTOMY CATHETER
ANGIOJET ULTRA 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

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. This material is not for use or distribution in France.