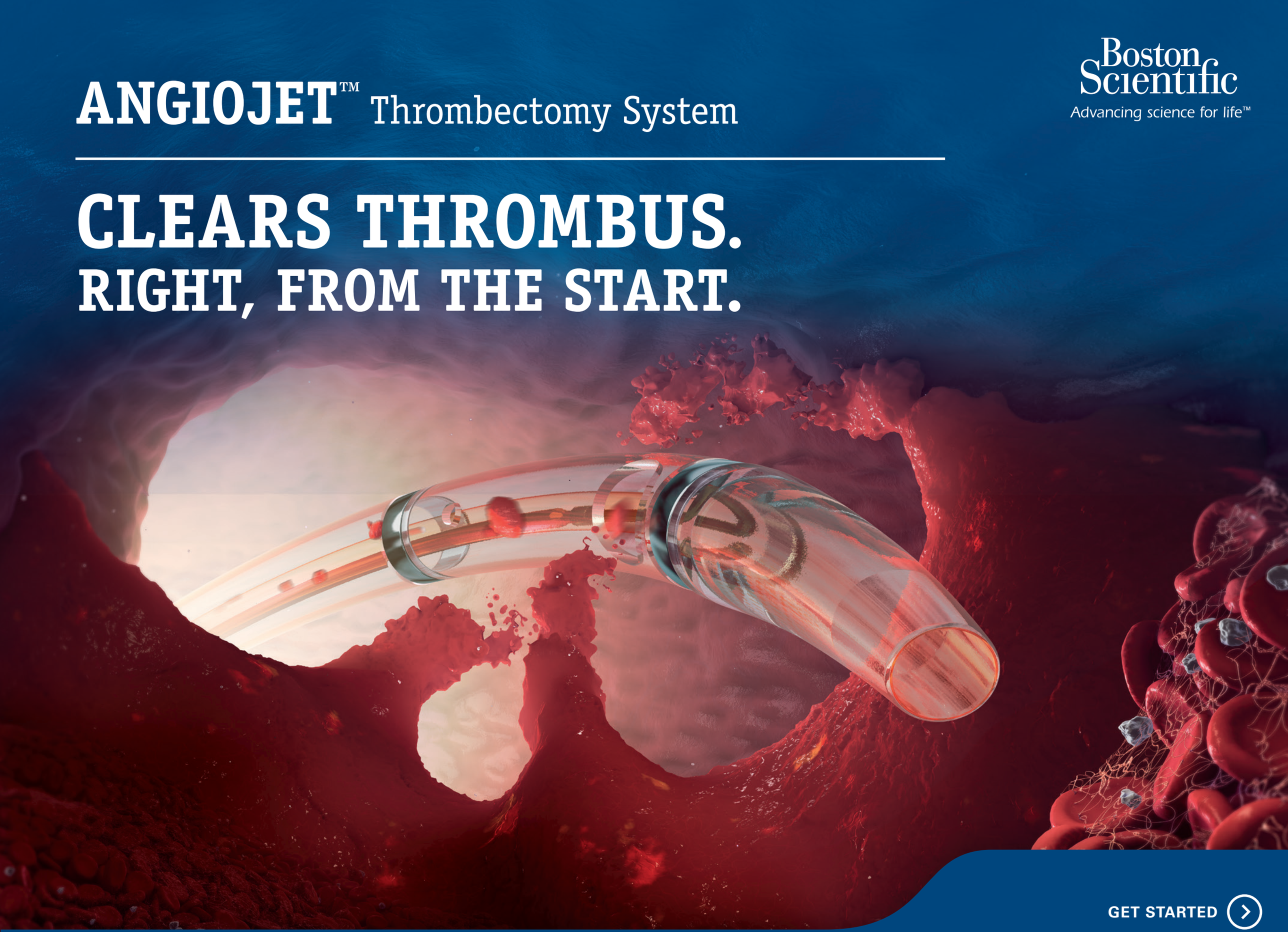
ANGIOJET™ Thrombectomy System

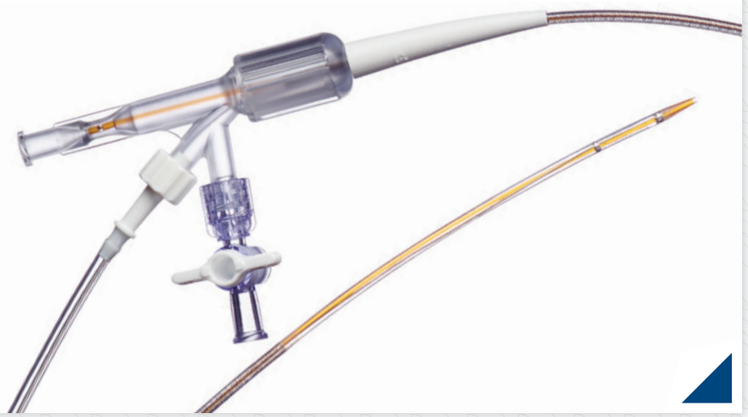
Boston Scientific
Advancing science for life™

CLEARS THROMBUS.
RIGHT, FROM THE START.



GET STARTED

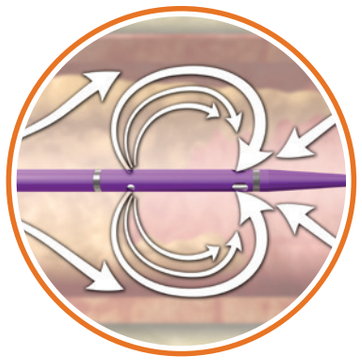
System Overview



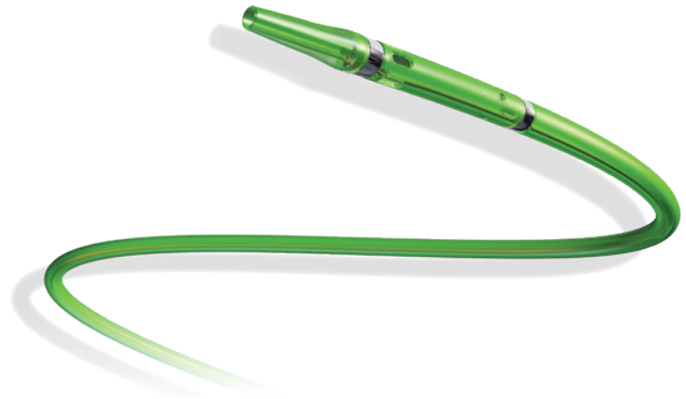
Console Overview

Power Pulse™

Mechanism of Action

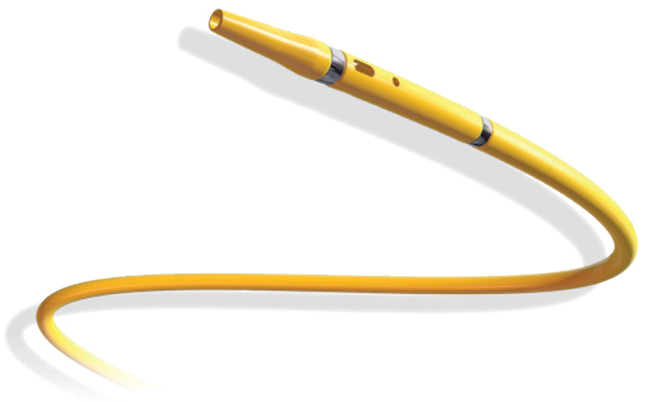


Arterial



Venous

AV Access

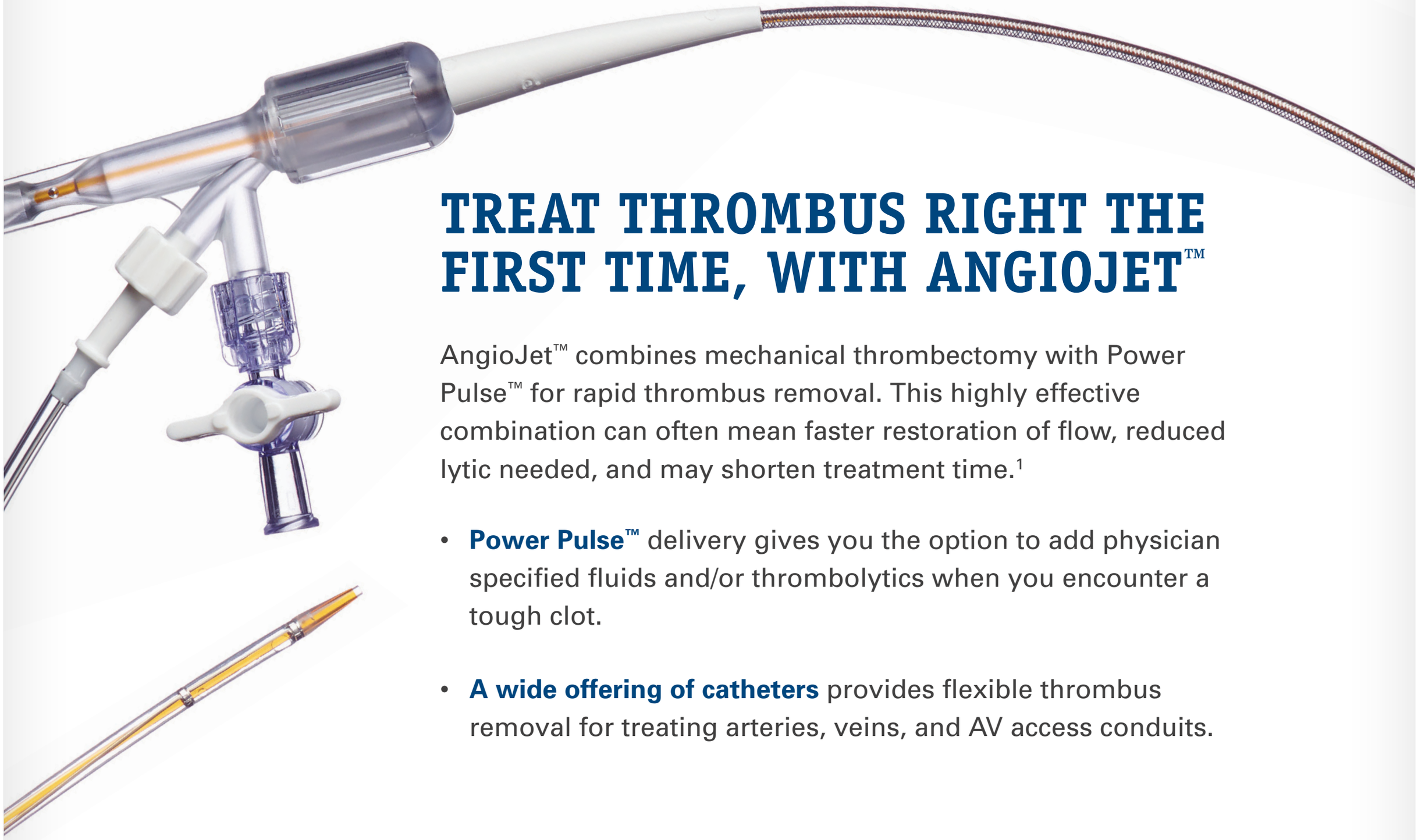


Specifications Chart

Frequently Asked Questions

Abbreviated Statements

Videos



TREAT THROMBUS RIGHT THE FIRST TIME, WITH ANGIOJET™

AngioJet™ combines mechanical thrombectomy with Power Pulse™ for rapid thrombus removal. This highly effective combination can often mean faster restoration of flow, reduced lytic needed, and may shorten treatment time.[1]

- **Power Pulse™** delivery gives you the option to add physician specified fluids and/or thrombolytics when you encounter a tough clot.

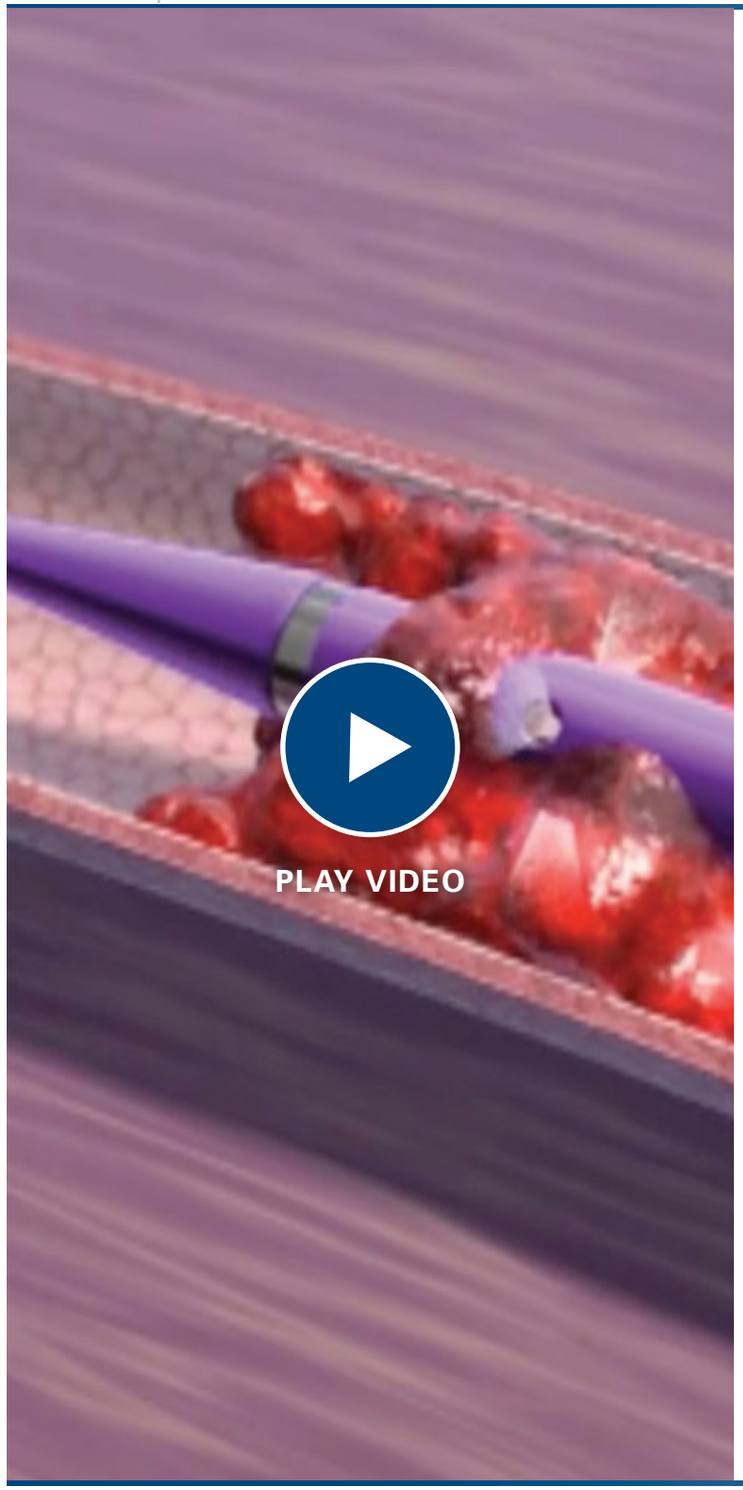
- **A wide offering of catheters** provides flexible thrombus removal for treating arteries, veins, and AV access conduits.

[1] The PEARL Registry study

CONSOLE OVERVIEW

THE VERSATILITY AND POWER TO RESTORE FLOW

- **Intuitive console automatically adjusts** its settings based on the AngioJet™ catheter used.
- Simple **set up** for staff efficiency.
- **Step-by-step interface** for procedural efficiency.
- Console is **compact** and highly mobile.
- Fewer single-use components mean **lower costs** per procedure.



POWER PULSE™:

ADDING OPTIONAL LYTIC DELIVERY TO YOUR THROMBECTOMY ARSENAL

- In addition to mechanical thrombectomy, the AngioJet™ Power Pulse™ spray allows physicians the **flexibility to deliver lytic** directly into the thrombus.
- Delivers lytic where it's most effective, **directly into the clot**, helping break up the fibrin and softening tough thrombus to facilitate removal.

MECHANISM OF ACTION

High speed saline jets inside the catheter create a powerful vacuum effect at the tip of the catheter for **efficient thrombus removal.**

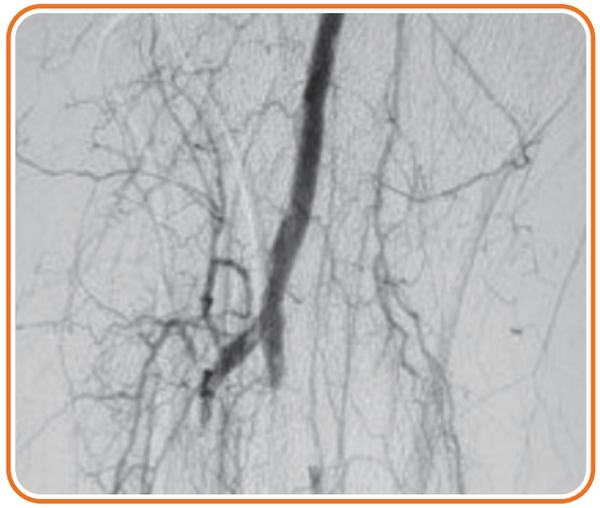
Thrombus is drawn into the catheter **and evacuated from the body** and into the console's collection bag.

WITH PERIPHERAL ARTERIAL THROMBUS EVERY MINUTE COUNTS

With a 30-day mortality rate of 15% and a 30-day amputation rate of 25%, Acute Limb Ischemia is a critical condition.[2]

- AngioJet™ with or without Power Pulse™ offers **quick restoration of flow** and **resolution of symptoms** in acute limb ischemia patients.
- Allows for **quick treatment** of acute intra-procedural thromboembolic complications.
- **May reduce** the need for prolonged lytic therapy and procedure time, leading to a **potential cost benefit.**[3]

Post CDT Arteriogram of Posterior and Anterior Tibial.



PT and AT remained occluded following overnight CDT infusion of lytic.

Acute onset of leg pain revealed SFA occlusion. Wire passed easily, thrombus is present.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

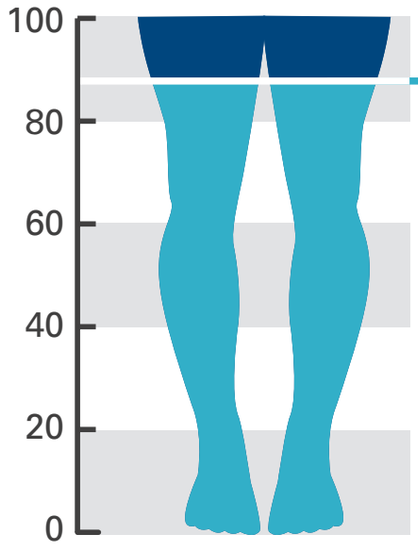
[2] Dormandy J, Heeck L, Vig S. Acute limb schemia. Semin Vasc Surg 1999;12:148–153.

[3] Presented by Dr. Ali Amin at Charing Cross 2014; Final PEARL Data Aug 2013

PEARL REGISTRY SHOWS ANGIOJET™ CAN SAVE TIME AND LIMBS

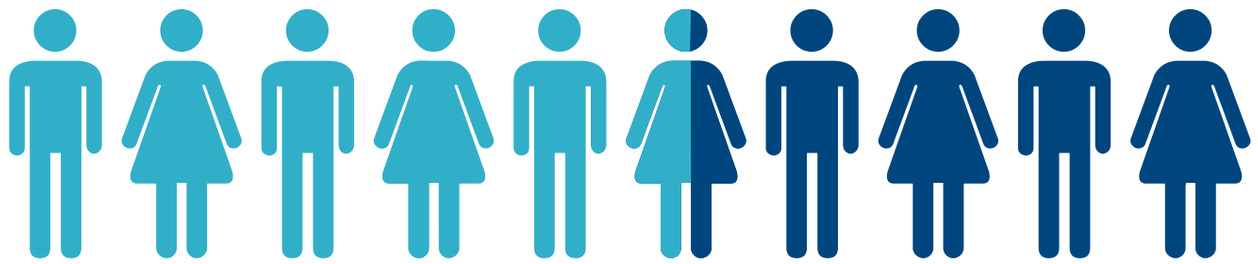
Arterial Limb Ischemia Patient Results[4]

N = 410 patients



89%
Limb Salvage Rate at 1 year

80%
of procedures were completed in **less than 24 hours**



56% of patients treated in a single session

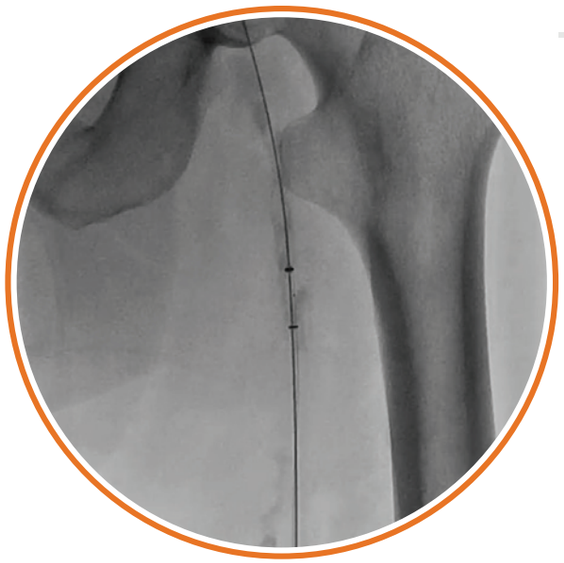
[4] Presented by Dr. Ali Amin at Charing Cross 2014; Final PEARL Data Aug 2013 Rheolytic

RAPID THROMBUS REMOVAL OF DEEP VEIN THROMBOSIS PROVIDES IMPROVED QUALITY OF LIFE[5]

The AngioJet™ 6F and 8F thrombectomy catheters are designed and indicated to treat deep vein thrombosis (DVT) in upper and lower extremity peripheral veins.

Power Pulse™ delivery gives you the option to add lytic when you encounter a tough clot.

May reduce the need for prolonged lytic and **hospital stays,** minimizing potential complications.[5]



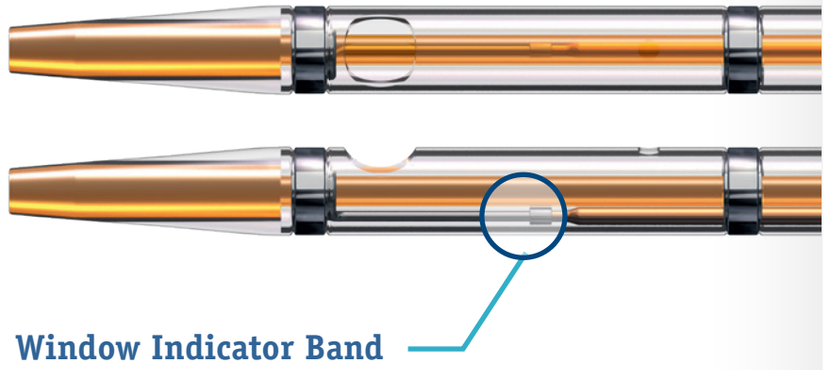
Extensive Acute on Chronic DVT

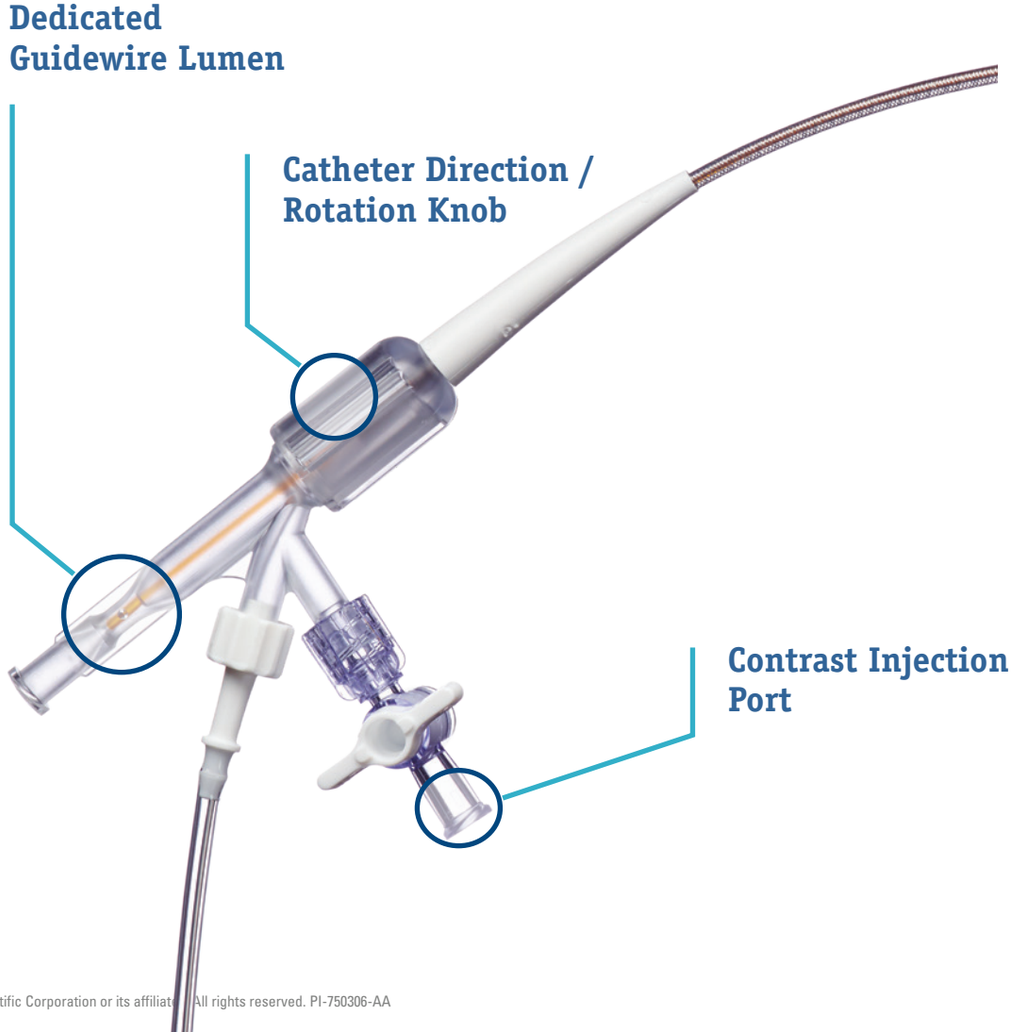
The directional ability of ZelanteDVT enabled targeted aspiration of the acute thrombus.

PLAY VIDEO

[5] Presented by Dr. Mark Garcia at CIRSE 2013; Final PEARL Data Aug 2013 Endovascular Managment of Deep Vein Thrombosis With Rheolytic Thrombectomy: Final Report of the Prospective Multicenter PEARL (Peripheral Use of AngioJet Rheolytic Thrombectomy with a Variety of Catheter Lengths) Registry. Mark J. Garcia, MD, MS, et al. JVIR, Volume 26, Number 6, June 2015.

ZelanteDVT™ GIVES YOU THE POWER TO REMOVE LARGE VENOUS CLOT BURDENS





- **The 8F AngioJet™ ZelanteDVT** is purpose built for efficient treatment of large vein DVTs.
- **4 times** the thrombus-removal **power.**[6]
- **ZelanteDVT** has a large, single .090” inflow window for torqueable and **directional thrombectomy power—** where it is needed the most.

[6] When compared to current 6F AngioJet catheters. Bench test data on file. Bench test results may not necessarily be indicative of clinical performance.

PEARL REGISTRY CONFIRMS ANGIOJET™ CAN SAVE TIME AND LYTIC DOSE

Less < Total Lytic Dose

When using Power Pulse or Rapid Lysis (with/without CDT) vs. CDT alone

Deep Vein Thrombosis Patient Results[7]

N = 371 patients

34% of patients treated in a single session

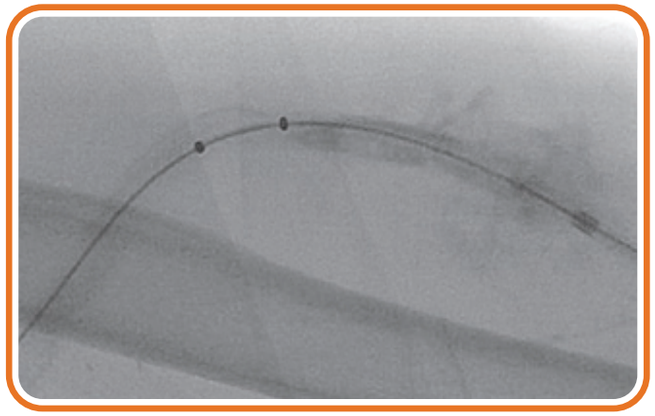
75% of procedures were completed in **less than 24 hours**

[7] Presented by Dr. Mark Garcia at CIRSE 2013; Final PEARL Data Aug 2013 Endovascular Managment of Deep Vein Thrombosis With Rheolytic Thrombectomy: Final Report of the Prospective Multicenter PEARL (Peripheral Use of AngioJet Rheolytic Thrombectomy with a Variety of Catheter Lengths) Registry. Mark J. Garcia, MD, MS, et al. JVIR, Volume 26, Number 6, June 2015.

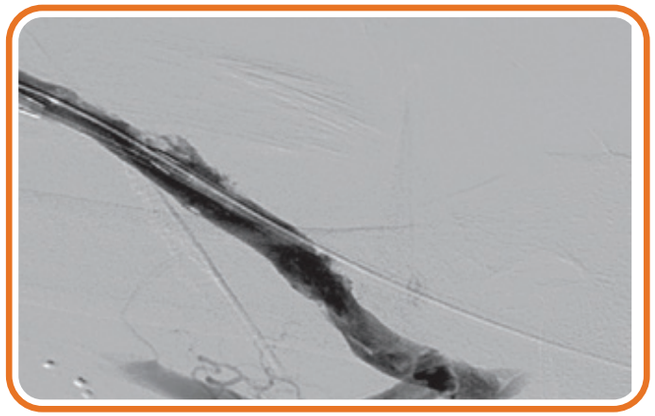
QUICK THROMBUS RESOLUTION IN AV ACCESS CONDUITS

Thrombus narrowing or restricting flow within AV access fistulas and grafts can prevent a patient from undergoing life supportive dialysis treatment.

AngioJet™ is designed to offer quick removal of thrombotic materials from the dialysis access conduit, potentially **improving long-term patency.**



Pre-procedure: AngioJet catheter positioned in thrombosed AV graft.



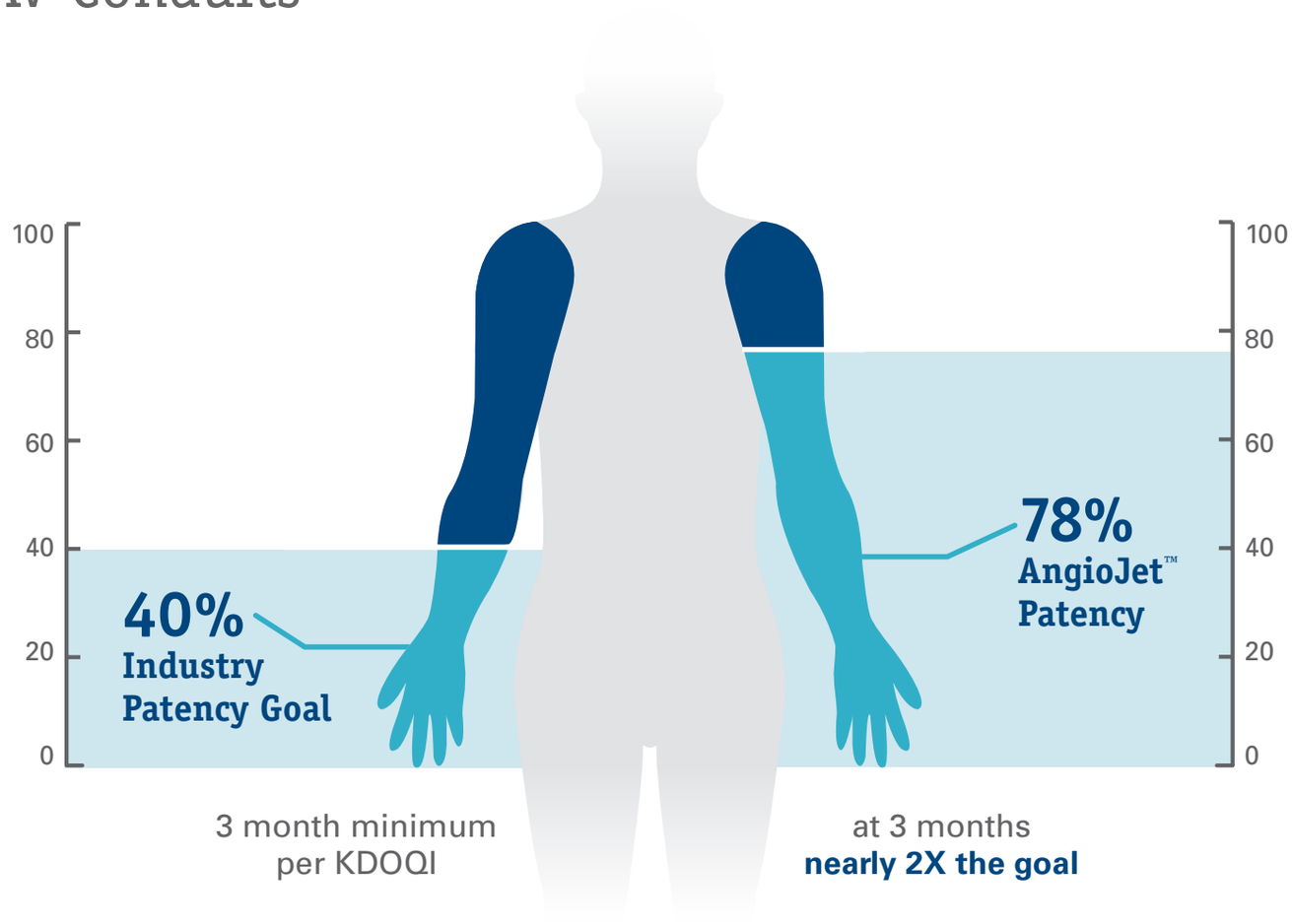
Post-procedure: Imaging post-AngioJet™ System activation in both venous and arterial side of AV graft.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

PEARL REGISTRY DEMONSTRATES NEARLY DOUBLE THE PATENCY

Results in AV Conduits[8]

N = 145 patients



[8] Presented by Dr. Eugene Simoni at VEITH 2013; Final PEARL Data Aug 2013 Simoni. PEARL Registry Hemodialysis Access. VEITH 2013

SPECIFICATIONS

TREAT THE FULL RANGE OF THROMBUS

Model	Indication	Minimum Vessel Diameter	Catheter Length	Catheter Diameter	Guidewire Wire	Introducer Sheath	Power Pulse™ Delivery Enabled	Contrast Injection Port	Flow Rate	Maximum Rate Times: Total Run Time	Maximum Rate Times: Runtime with Blood Flow	Catalog Number
AngioJet™ Console												105650-001
Solent™ Dista 	Peripheral Arterial	1.5 mm	145 cm	4F/3F	.014″	4 F	YES	Yes	23mL/min	600 sec	300 sec	111303-001
Solent™ Omni 	Peripheral Arterial and Venous, AV Access	3 mm	120 cm	6 F	.035″	6 F	YES	Yes	60mL/min	480 sec	240 sec	109681-001
Solent™ Proxi 	Peripheral Arterial and Venous, AV Access	3 mm	90 cm	6 F	.035″	6 F	YES	Yes	60mL/min	480 sec	240 sec	109676-001
AVX™ 	AV Access Grafts and Fistula	3 mm	50 cm	6 F	.035″	6 F	–	Yes	60mL/min	600 sec	300 sec	105039-001
ZelanteDVT™ 	Venous	6 mm	105 cm	8 F	.035″	8 F	YES	Yes	60mL/min	480 sec	240 sec	114610-001
Power Pulse™ Delivery Kit of 5 												104834-002

For full catheter specification refer to the Instructions for Use.

FREQUENTLY ASKED QUESTIONS

What is the PEARL Registry?

The 2-phase PEARL Registry was established to document the procedural and patient outcomes of endovascular treatment of arterial, venous and AV access sites utilizing the AngioJet™ catheter system. It included a total of 952 patients, and 34 enrolling sites.

- PEARL I followed patients for 3 months with documentation of symptomatic improvement after AngioJet™ thrombectomy.
- PEARL II followed patient outcomes through 12 months after AngioJet™ thrombectomy.

What's the definition of a single session in PEARL?

A session as defined in the PEARL registry is treatment provided within the interventional suite. Therefore, a single session means the patient was able to have the procedure completed by being in the interventional suite only one time.

The PEARL Registry Demonstrated a Reduction in Lytic Used. How is that defined?

In the PEARL Registry, arterial and venous patients received a lower lytic dose when the AngioJet™ was used for lytic delivery (Power Pulse™ and /or Rapid Lysis) than if lytic was delivered via CDT only with comparable angiographic/venographic results.

In the DVT arm, even when CDT was combined with the use of AngioJet™ Power Pulse™ (PP) or Rapid Lysis (RL), there was a significant reduction in lytic dose compared to when CDT was used without PP/RL.

Total Lytic by Lytic Treatment Group	Alteplase Only (mg)
Lytic delivered by AJ only (Power Pulse and/or Rapid Lysis)	12.8 ± 15.1 (10.0) N=53
Lytic delivered by CDT only	37.7 ± 21.4 (37.1) N=18
Lytic delivered by AJ (PPS and/or RL) and CDT	27.2 ± 18.8 (26.2) N=145

FREQUENTLY ASKED QUESTIONS

The PEARL Registry Demonstrated Shorter Treatment Time. How is that defined?

In the DVT arm for example, when patients were treated with AngioJet™ with or without Power Pulse™ as well as AngioJet™ Power Pulse™ + CDT, the mean treatment time was lower than the mean treatment time when patients were treated with a lytic delivered via CDT alone.

Treatment (LE Only)	Frequency	Median Time in Hours
AngioJet Thrombectomy (no lytic)	13 (4%)	1.4
AngioJet + Lytic by AngioJet "PMT"	115 (35%)	2
AngioJet Thrombectomy + CDT	29 (9%)	41
AngioJet "PMT" + CDT	172 (52%)	22

For more details on the PEARL Registry and its data set, please refer to the PEARL Registry interactive PDF (PI-315422)

What does KDOQI stand for and what is it?

KDOQI stands for Kidney Disease Outcomes Quality Initiative. This is an initiative developed by the National Kidney Foundation. It provides evidence-based guidelines on the treatment of chronic kidney disease.

What are the current KDOQI accepted industry standards for AV access patency rates?

The KDOQI provides clinical practice guidelines for vascular access. Guideline 8 details clinical outcome goals for thrombosis and patency rates for both fistulas and grafts. KDOQI minimum goal for percutaneous thrombectomy is 40% unassisted patency and functionality at 3 months.

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 "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

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 • In whom the lesion cannot be accessed with the guidewire • Who cannot tolerate contrast media

WARNINGS

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 DFU; 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.
- The potential for pulmonary thromboembolism should be carefully considered when the ZelanteDVT Thrombectomy Set is used to break up and remove peripheral venous thrombus

PRECAUTIONS

- 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.
- 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.
- 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.

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 • arrhythmia • 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

ABBREVIATED STATEMENTS

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 "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

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 DFU).

CONTRAINDICATIONS

Do not use the catheter/Thrombectomy set in patients:

- Who are contraindicated for endovascular procedures • In whom the lesion cannot be accessed with the guide wire • Who cannot tolerate contrast media

WARNINGS

- 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.
- 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 Thrombectomy Set in vessels smaller than minimum vessel diameter for each Thrombectomy Set model as listed in Table 1 (in the DFU); 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.
- Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the DFU) 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.
- 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.

PRECAUTIONS

- 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.
- 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)
- 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.

ABBREVIATED STATEMENTS

Solent Catheters combined w/console (continued…)

(Below is Omni, Proxi 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)
- 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 5000A 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 Directions 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 Directions 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 5000A 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 radio frequency (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 5000A 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 Operator’s Manual.

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 • arrhythmia • 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

ABBREVIATED STATEMENTS

AngioJet Ultra AVX

INTENDED USE/INDICATIONS FOR USE

The AngioJet Ultra AVX Thrombectomy Set is intended for use with the AngioJet Ultra System in breaking apart and removing thrombus from A-V access conduits ≥ 3.0 mm in diameter.

CONTRAINDICATIONS

Do not use the Thrombectomy Set in patients:

• Who are contraindicated for endovascular procedures • In whom the lesion cannot be accessed with the guide wire • Who cannot tolerate contrast media

WARNINGS

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.

- 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.
- 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 catheter in vessels smaller than 3.0 mm in diameter which may increase risk of vessel injury.
- 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.
- 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.
- Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the DFU) 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 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.

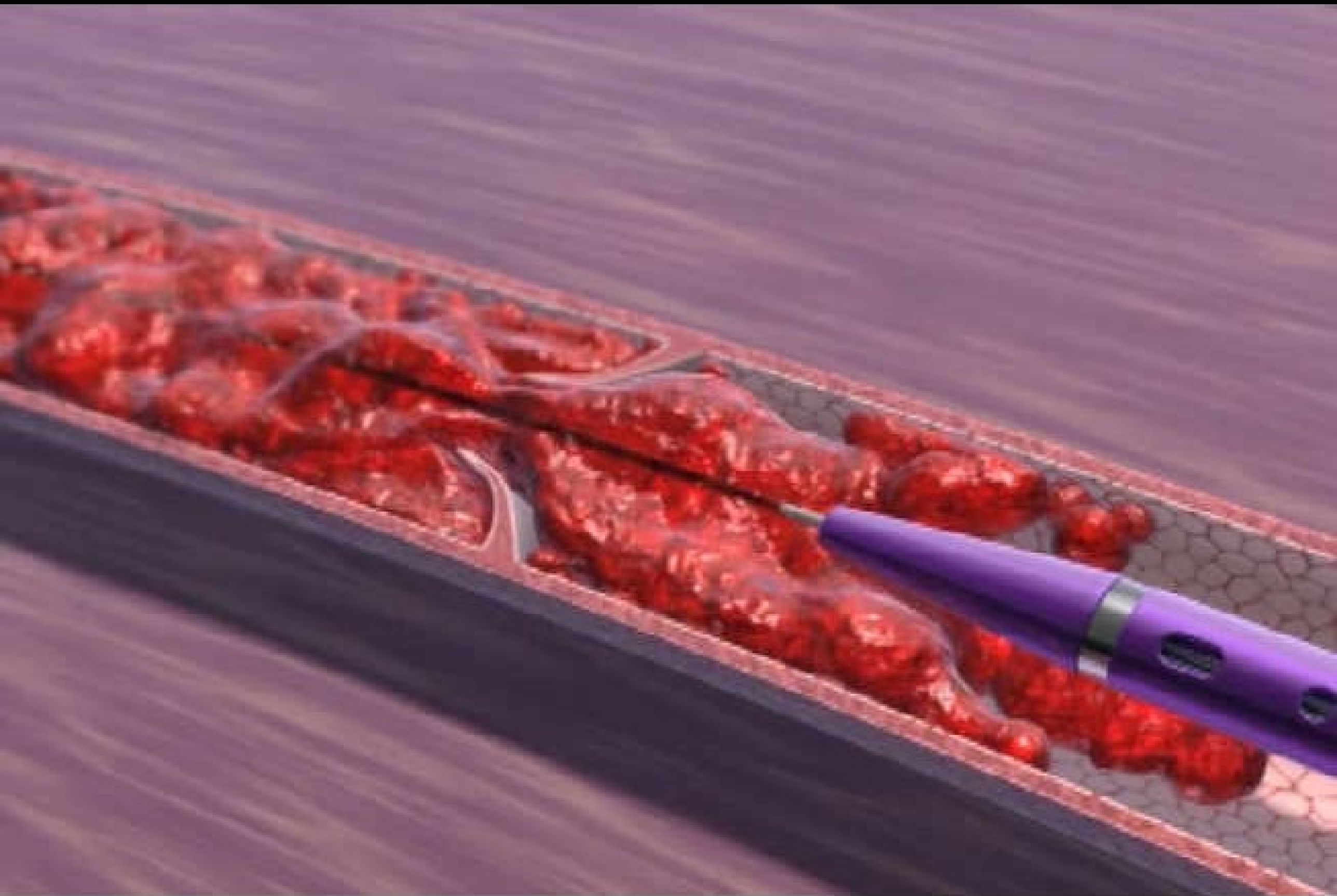
PRECAUTIONS

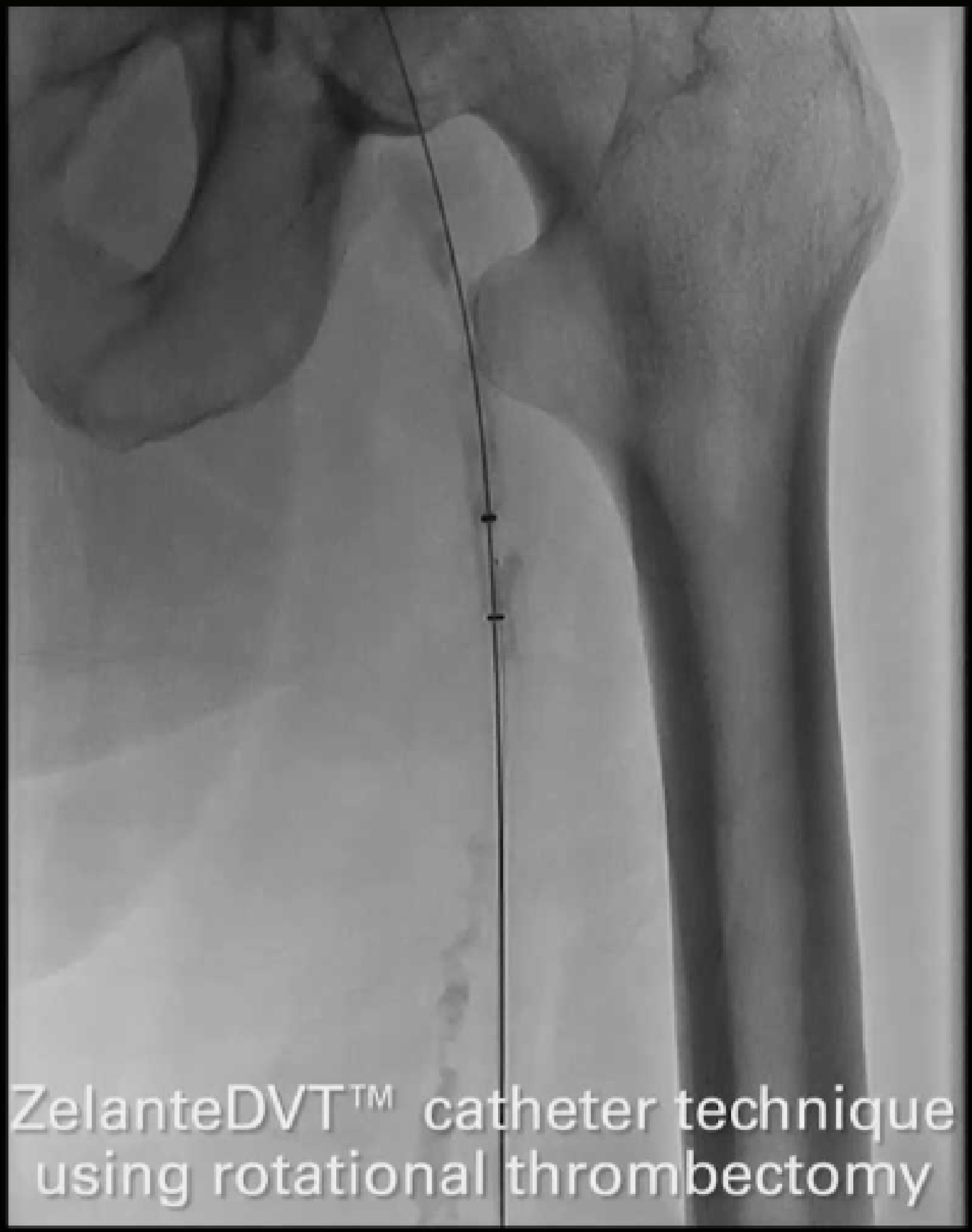
- Use the Thrombectomy Set only with the multiple-use AngioJet Ultra Console.
- The catheter should be operated over a 0.035" guide wire. Attempting to use a larger guide wire will damage the catheter and the guide wire.
- If resistance is felt during the advancement of the Thrombectomy Set to lesion site, do not force or torque the catheter excessively as this may result in deformation of tip components and thereby degrade catheter performance.
- 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.
- 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
- 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 100 psi. Delivering a hand injection of contrast medium with excessive force can create injection pressures greater than 100 psi, 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 100 psi, 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.

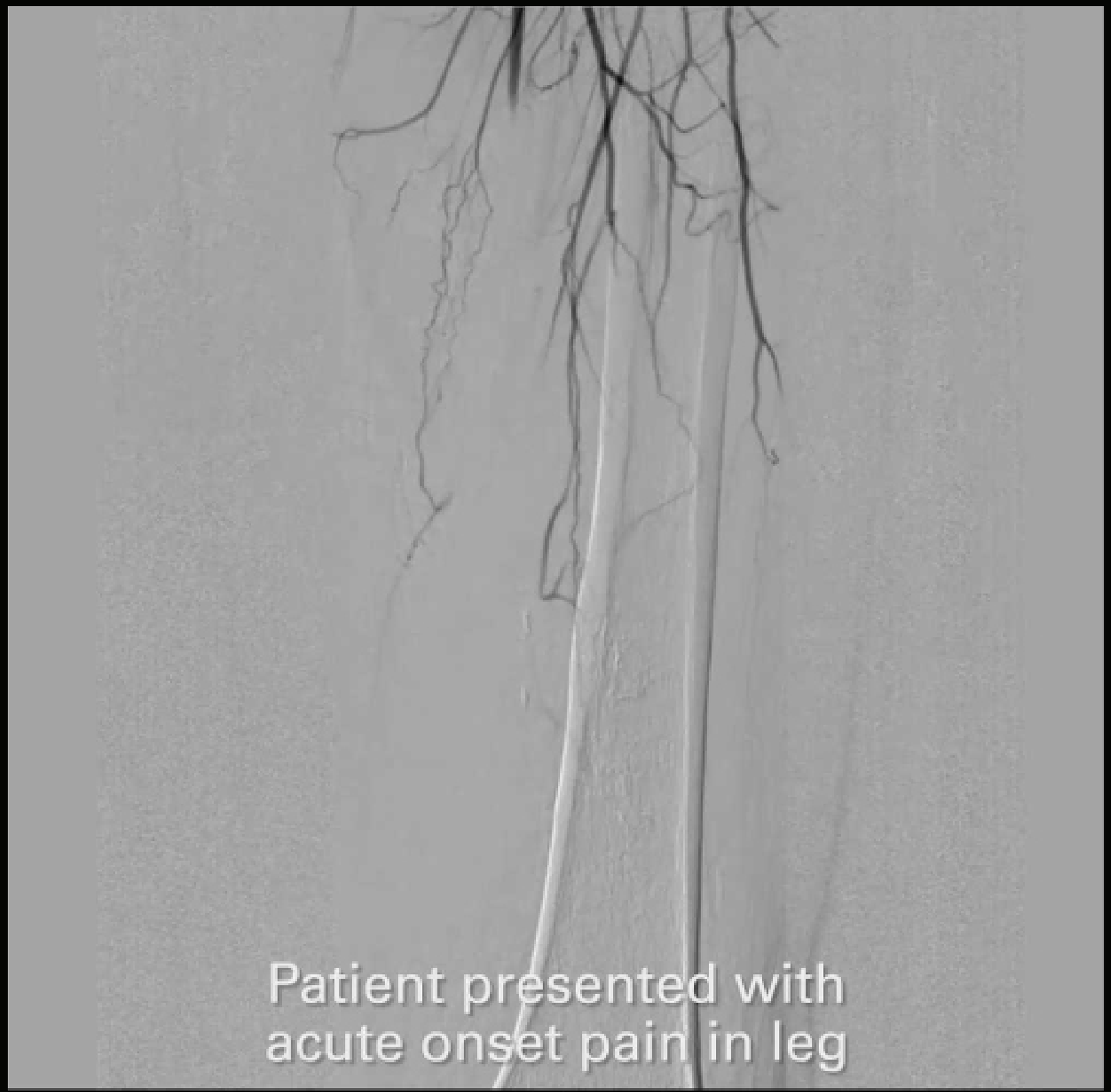
ADVERSE EVENTS

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 • arrhythmia • 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




ZelanteDVT™ catheter technique
using rotational thrombectomy


Patient presented with
acute onset pain in leg