

ANGIOJET™ ULTRA Thrombectomy System

ENHANCING YOUR OPTIONS FOR RESTORING FLOW



When you need the versatility and power to restore flow

Refined from experience in over 700,000 cases worldwide, today's AngioJet System offers the reliable and predictable performance needed to treat the widest range of thrombotic occlusions—including clots from vessels as small as 1.5mm to the largest clot burdens in iliofemoral veins.

Some of the potential benefits of using AngioJet Thrombectomy include:

- Rapid removal of thrombus¹
- Quick restoration of blood flow^{2,3}
- Resolution of symptoms^{2,3}

With single-package disposables and an intuitive console, the AngioJet Thrombectomy System simplifies setup and user controlled thrombectomy power

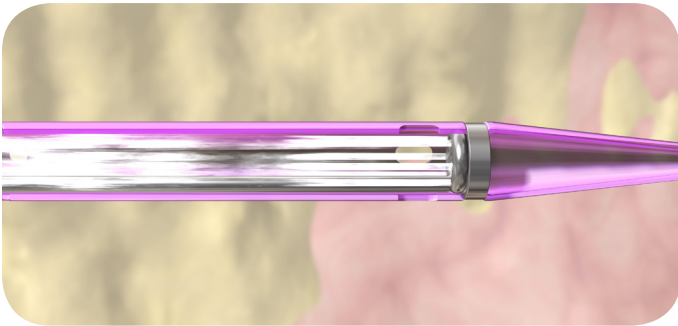
ADVANCED, USER-FRIENDLY CONSOLE

- Control system automates set-up and monitors operation
- Step-by-step interface for procedural efficiency
- Automated system self-configures to each catheter
- Compact, highly mobile console

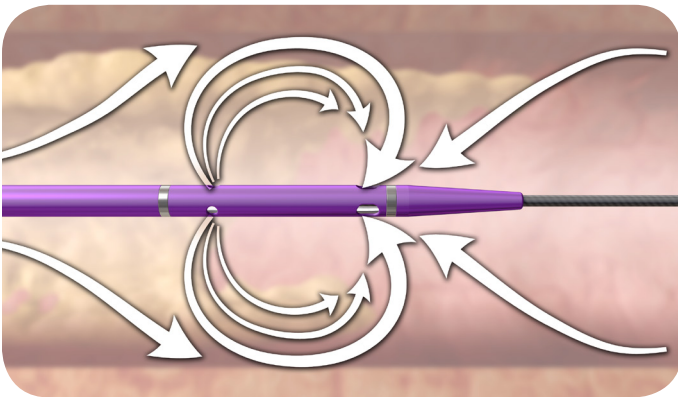


A powerful, yet controlled, mechanism of action

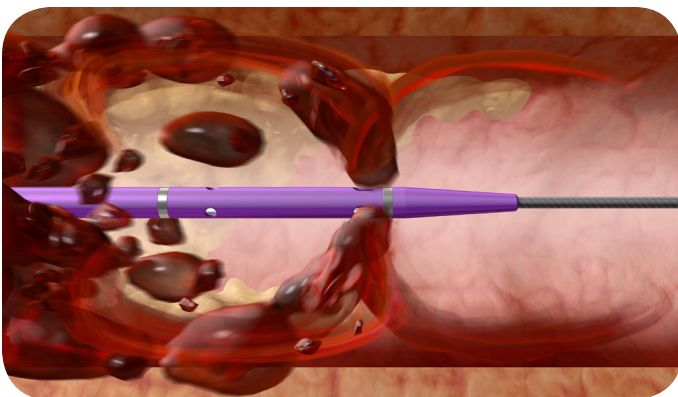
Ideal for Large and Small Thrombus Burden



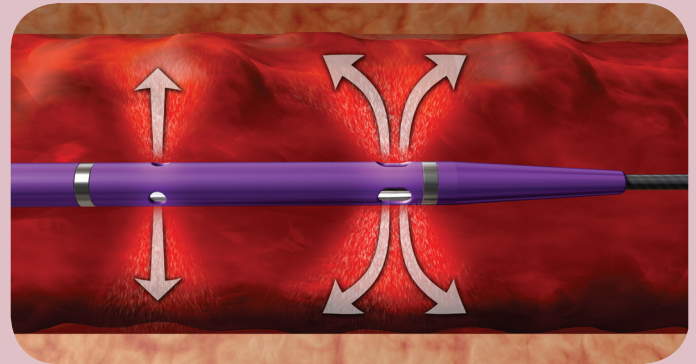
Saline jets travel backward within the catheter at high speed creating a powerful vacuum effect



Cross-Stream™ flow is specially designed to optimize thrombus removal



Thrombus is drawn into the catheter where it is fragmented and evacuated from the body



Power Pulse™ Lytic Delivery

Available on Solent™ family of peripheral catheters, Power Pulse™ Delivery enables lytic delivery for thrombus treatment

Delivers medication directly into the clot, where it's most effective, saturating and softening tough thrombus to facilitate removal

Peripheral Venous Thrombus

Post Thrombotic Syndrome (PTS) is a chronic, debilitating complication of DVT occurring in 20-50% of patients following a proximal DVT.⁴

The AngioJet System provides the power and flexibility to remove thrombus and restore flow in even the most challenging DVT cases.

Recent PEARL Registry data showed:¹

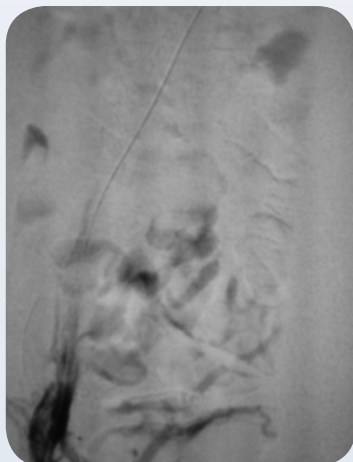
- AngioJet Thrombectomy removed a mean of 95% thrombus burden in veins—with 76% of DVT treatments completed in less than 24 hours and 81% of patients remaining free of rethrombus at 12 months
- 86% of cases utilized Power Pulse and/or Rapid Lysis approach (N=371 patients)
- Less lytic and shorter procedure times using either Power Pulse or Power Pulse plus CDT than with CDT alone with AngioJet
- 87% of AngioJet venous cases were completed in 2 or less sessions

AngioJet Percutaneous Mechanical Thrombectomy for DVT can result in less treatment time and cost efficiencies compared to traditional CDT.²



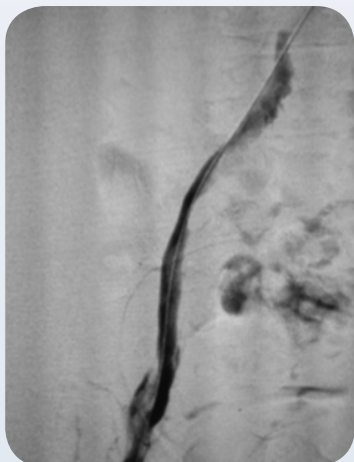
The Solent Omni and Proxi catheters were designed with a stronger thrombectomy power for clearing larger thrombus burden than other AngioJet catheter models. Power Pulse Delivery can infuse lytic into the clot. Contrast injection capability and guidewire swappability increase treatment efficiencies.

Pharmacomechanical treatment of left iliac DVT



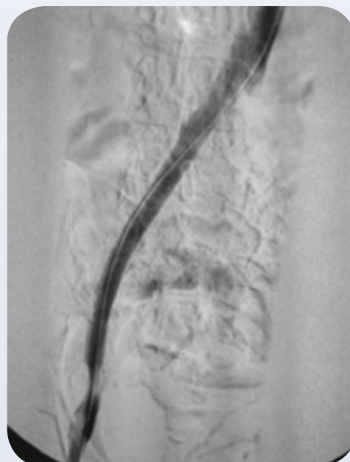
Pre-procedure venogram

Pre treatment image following left popliteal stick



Power Pulse Delivery

Post Power Pulse Delivery with AngioJet Solent Proxi; 10mg tPA in 500ml bag, 30 minute dwell time



Post-AngioJet Thrombectomy

4 passes with Solent Proxi catheter followed by PTA



Final Result

Post PTA of common Iliac and the external Iliac

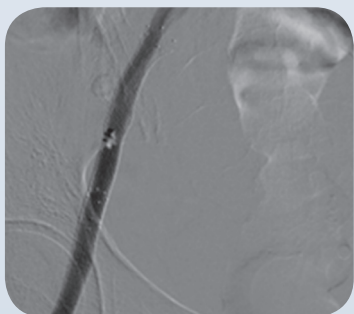
Dr. Ravi Rajani, Vascular Surgeon
Grady Hospital, Atlanta, Georgia
Procedure Date: October 30, 2013

Acute DVT left lower extremity swelling



Baseline

48-year-old woman with a history of metastatic cervical cancer with new left lower swelling.

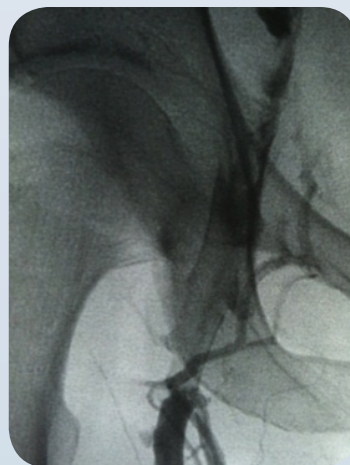


Final Result

Treatment with AngioJet Solent Omni Thrombectomy catheter. No Power Pulse Delivery used. Final venogram after PTA.

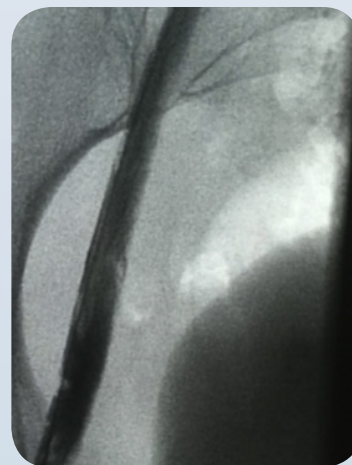
Reginald Baker, MD
Baptist Cardiac and Vascular Institute Miami, Florida
Procedure Date: November 18, 2011

Thrombectomy in May-Thurner Syndrome DVT



1 Pass AngioJet Solent Proxi Catheter

Distal Iliac and Common Femoral



Post Power Pulse Delivery and AngioJet Thrombectomy

30 minute dwell time of lytics and 3 minute 10 seconds of AngioJet Thrombectomy

Dr. Ramana Yedavalli
Silver Cross Hospital
New Lenox, IL
Procedure Date: December 12, 2012

Peripheral Arterial Thrombus

Acute Limb Ischemia (ALI) remains a life-threatening condition with 9% and 15% in-hospital and 30-day mortality rates, respectively; and 15% and 25% amputation rates at discharge and 30 days.^{5,6}

AngioJet Thrombectomy removes clot burden from arterial vessels as small as 1.5mm—restoring flow, and resolving symptoms while exposing the culprit lesion, facilitating treatment.

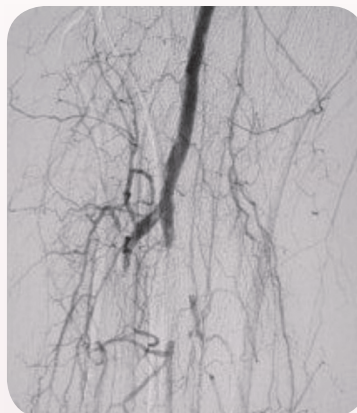
Recent PEARL Registry data showed:¹

- Immediate improvement in 93% of arterial vessels treated
- 90% limb salvage rate for patients presenting with threatened limbs at baseline (Rutherford scoring)



Solent family catheters

CLI with Right Foot Ulcer Thrombectomy



Arteriogram of Posterior and Anterior Tibial - post CDT

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

AV Access Conduits

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

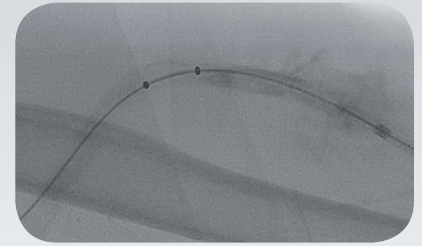
Used for thrombectomy of both synthetic grafts and natural fistulae, the AngioJet System utilizes powerful Cross-Stream technology to remove thrombotic materials from the dialysis access conduit with minimal vessel wall trauma, potentially decreasing the risk for future thrombotic events.

Catheters with AV access indication include: AVX, Solent Proxi and Solent Omni

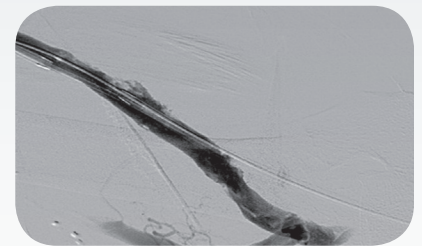
Recent PEARL Registry data showed:¹

- Patency and functionality rate of 78% at 3 months compared to KDOQI guidelines target of 40%
- Procedural success reported in 125/135 (93%)
- 3 month follow up completed in 112/130 (86%); Patency maintained in 76/112 (68%)

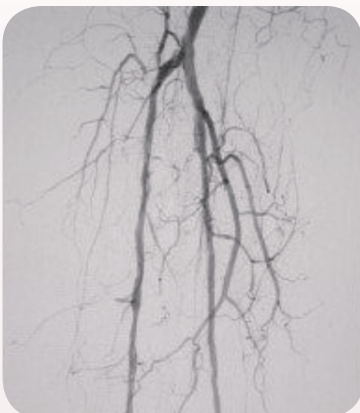
Thrombectomy of left brachial artery-axillary vein graft



Pre-procedure AngioJet catheter positioned in thrombosed AV graft.

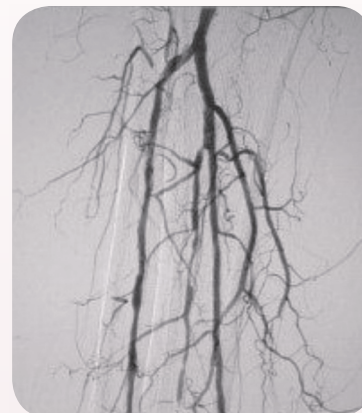


Post Procedure Imaging post-AngioJet System activation in both venous and arterial side of AV graft



Pharmacomechanical thrombectomy with AngioJet Solent Dista

AngioJet Solent Dista Catheter used in Power Pulse mode in both AT and PT. 30 min dwell in AT and 45 min dwell in PT. Followed by Solent Dista Catheter used in thrombectomy mode.



Post Procedure Arteriogram

Image following ballooning of small focal lesion in PT.

Treat the Full Range of Thrombus

Model	Catalog Number	Platform	Minimum Vessel Diameter	Catheter Length	Guide Wire	Power Pulse™ Delivery	Contrast Injection Port	Guidewire Swappability
Solent™ Dista	111303	OTW	1.5mm	145cm	0.014"	Yes		
								
Solent™ Proxi	109676	OTW	3mm	90cm	0.035"	Yes	Yes	Yes
								
Solent™ Omni	109681	OTW	3mm	120cm	0.035"	Yes	Yes	Yes
								
AVX™	105039	OTW	3mm	50cm	0.035"		Yes	
								
AngioJet™ Console	105650							
Power Pulse™ Delivery Kit of 5	104834	Delivers medication directly into the clot, where it's most effective, saturating and softening tough thrombus to facilitate removal						

¹ The PEARL Registry

² Lin, P.H. et al. Catheter-direct thrombolysis versus pharmacomechanical thrombectomy for treatment of symptomatic lower extremity deep venous thrombosis. *The American Journal of Surgery* 192 (2006):782–788

³ Hager, E et al. Anatomic and functional outcomes of pharmacomechanical and catheter-directed thrombolysis of iliofemoral deep venous thrombosis. *J Vasc Surg: Venous and Lym Dis* 2014;2:246-52.

⁴ Kahn SR. The post-thrombotic syndrome. *Hematology Am Soc Hematol Educ Program* 2010; 2010:216–220.

⁵ Ouriel K, Veith FJ, Sasahara AA. A comparison of recombinant urokinase with vascular surgery as initial treatment for acute arterial occlusion of the legs. Thrombolysis or Peripheral Arterial Surgery (TOPAS) Investigators. *N Engl J Med* 1998;338:1105–1111.

⁶ Dormandy J, Heeck L, Vig S. Acute limb ischemia. *Semin Vasc Surg* 1999;12:148–153.

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

AngioJet™ Thrombectomy Systems

GENERAL INDICATIONS/CONTRAINDICATIONS: AngioJet System peripheral indications include: breaking up and removing thrombus from infra-inguinal peripheral arteries, upper and lower extremity peripheral arteries, upper extremity peripheral veins, iliofemoral, infra-iliac and lower extremity veins, A-V access conduits, and for use with the AngioJet Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system. AngioJet System coronary indications include: removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions prior to balloon angioplasty or stent placement. Do not use in patients: who are contraindicated for intracoronary or endovascular procedures, who cannot tolerate contrast media, and in whom the lesion cannot be accessed with the wire guide.

GENERAL WARNINGS AND PRECAUTIONS: The System has not been evaluated for treatment of pulmonary embolism in the US and some other countries or for use in the carotid or cerebral vasculature. Some AngioJet devices have not been evaluated for use in coronary vasculature. Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Cardiac arrhythmias may occur and cardiac rhythm should be monitored during catheter use and appropriate management employed, if needed. Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. Operation of the System causes transient hemolysis. Large thrombus burdens may result in significant hemoglobinemia which should be monitored. Consider hydration, as appropriate. Before coronary AngioJet treatment, verify the presence of thrombus because routine use of AngioJet in every STEMI patient, without proper selection for thrombus, has been associated with increased mortality risk. Do not use the system in the coronary vasculature without placing a temporary pacing catheter to support the patient through hemodynamically significant arrhythmias which may occur.

POTENTIAL ADVERSE EVENTS: Potential adverse events (in alphabetical order) which may be associated with use of the system are similar to those associated with other interventional procedures and include but are not limited to the following: abrupt closure of treated vessel, acute myocardial infarction, acute renal failure, arrhythmias (including VF and VT), bleeding from access site, death, dissection, embolization (proximal or distal), emergent CABG, hematoma, hemolysis, hemorrhage requiring transfusion, hypotension/hypertension, infection at access site, myocardial ischemia, pain, pancreatitis, perforation, pseudoaneurysm, reactions to contrast medium, stroke/CVA, thrombosis/occlusion, total occlusion of treated vessel, vascular aneurysm, vascular spasm, vessel wall or valve damage.

Indications, operating specifications and availability may vary by country. Check with local product representation and country-specific Information For Use for your country.

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician.

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Peripheral Interventions

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