Boston Scientific
Advancing science for life™

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[1] 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 thrombus[1]
- Quick restoration of blood flow[2,3]
- Resolution of symptoms[2,3]

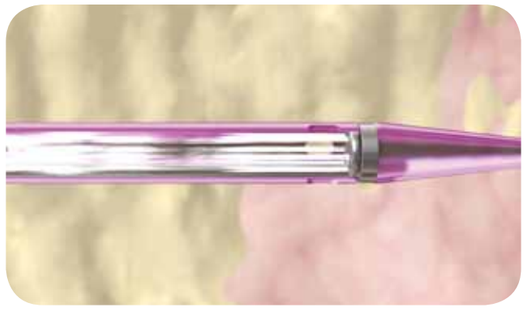
With single-package disposables and an intuitive console, the AngioJet Thrombectomy System simplifies setup and user controlled thrombectomy power

ADVANCED, USER-FRIENDLY CONSOLE

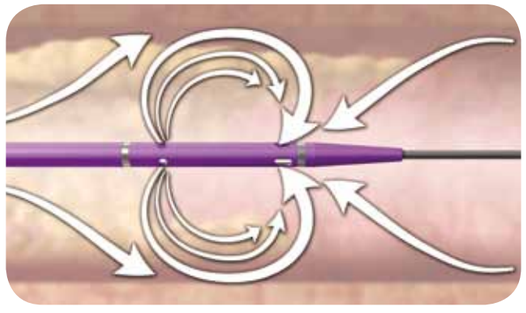
- Control system automates set-up and monitors operation
- Step-by-step interface for procedural efficiency
- Automated system self-configures to each catheter
- Compact, highly mobile console

A powerful, yet controlled, mechanism of action

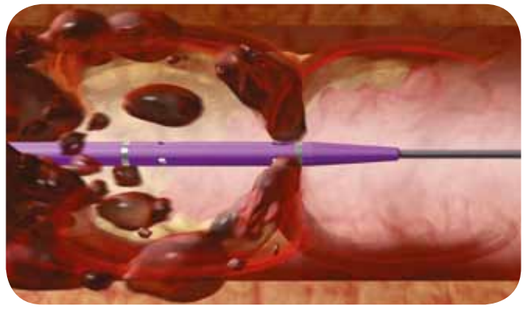
For Large and Small Thrombus Burden



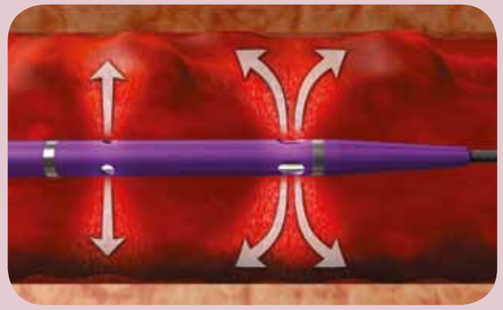
Saline jets travel backward within the catheter at high speed creating a powerful vacuum effect



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



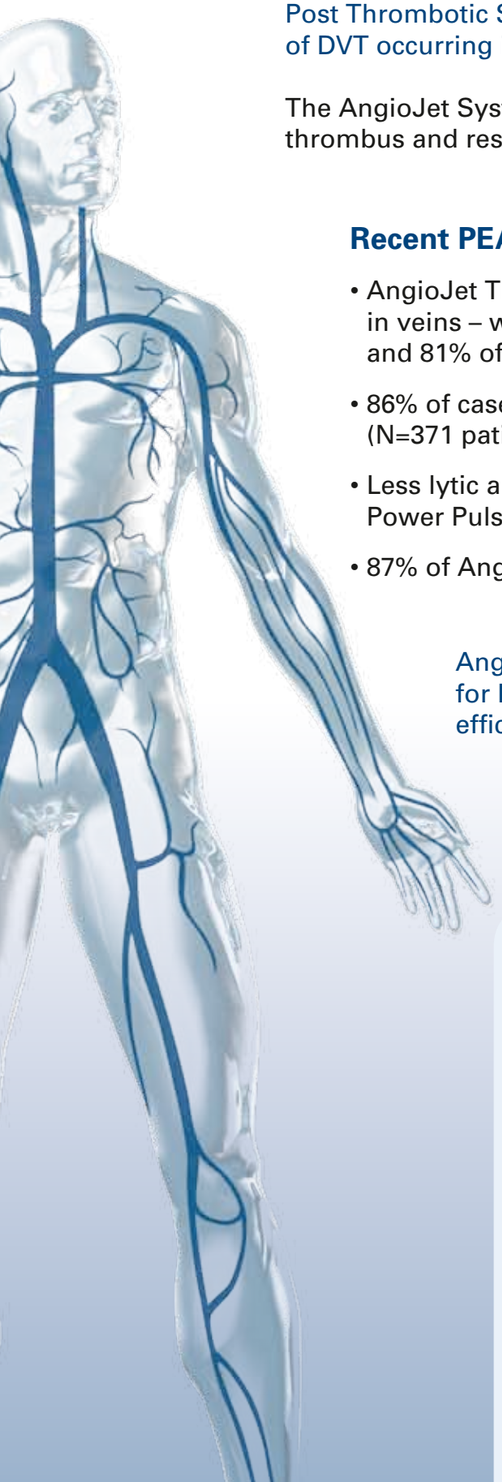
Thrombus is drawn into the catheter where it is fragmented and evacuated from the body



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 challenging DVT cases.

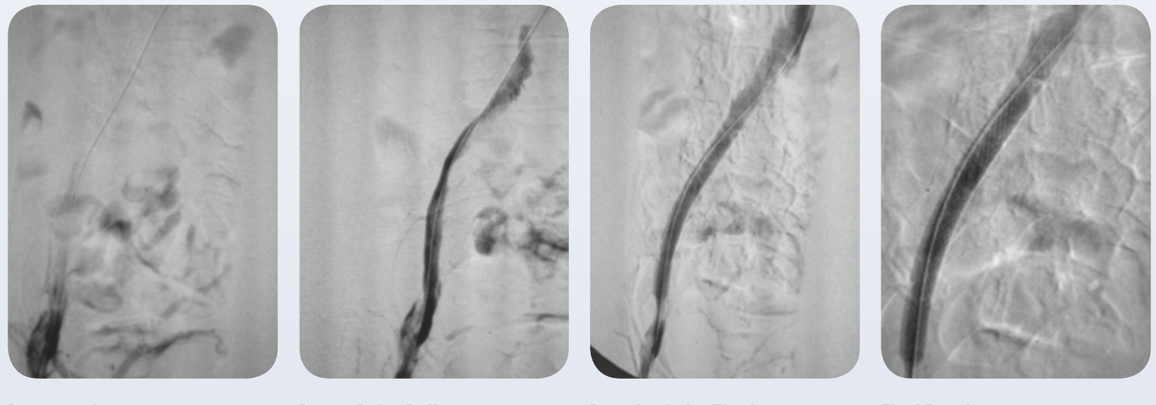
Recent PEARL Registry data showed:[1]

- 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

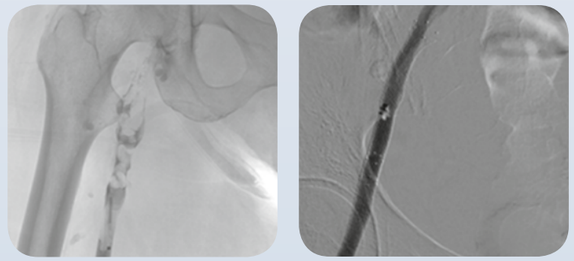
Power Pulse Delivery
Post Power Pulse Delivery with AngioJet Solent Proxi; 10 mg tPA in 500ml bag, 30 minute dwell time

Post-AngioJet Throbectomy
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

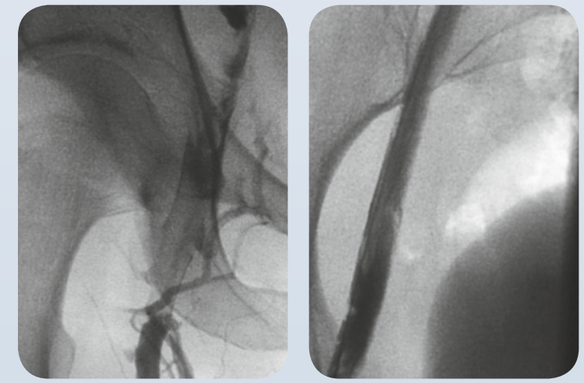


Baseline
48-year-old woman with a history of metastatic cervical cancer with new left lower swelling.

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

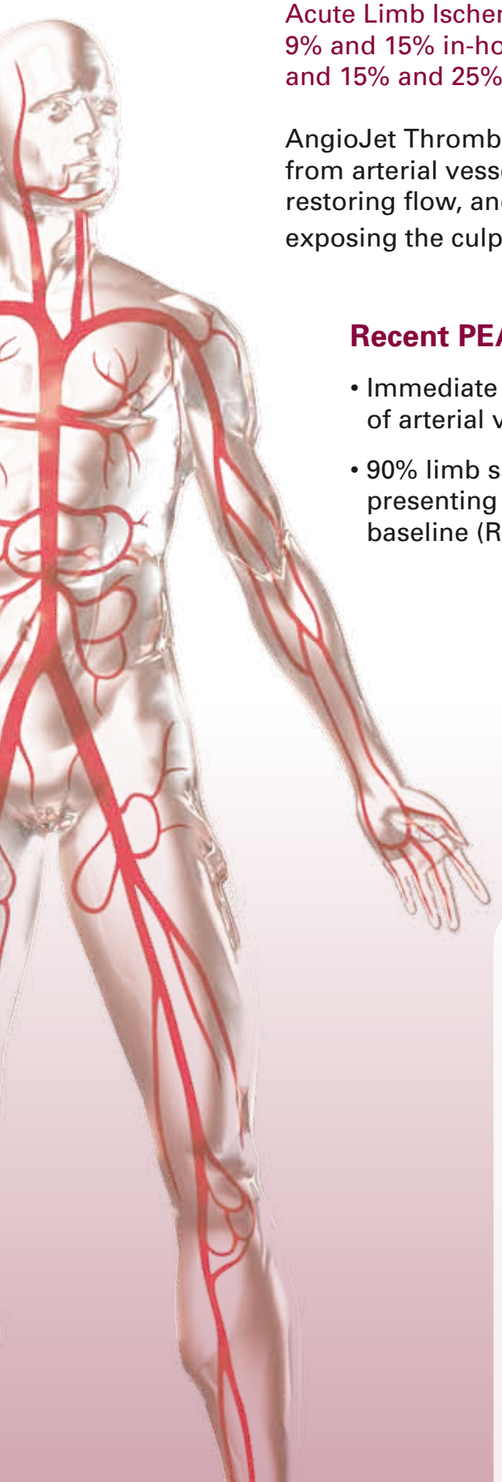


1 Pass AngioJet Solent Proxi Catheter
Distal Iliac and Common Femoral

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 1.5 mm – restoring flow, and resolving symptoms while exposing the culprit lesion, facilitating treatment.

Solent family catheters

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)

AV Access Conduits

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

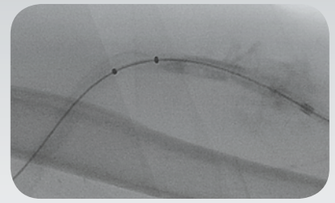
Used for thrombectomy of both synthetic grafts and natural fistulae, the AngioJet System utilizes powerful Cross-Stream technology to remove thrombotic materials from the dialysis access conduit with minimal vessel wall trauma, potentially decreasing the risk for future thrombotic events.

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

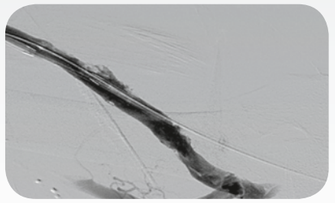
Recent PEARL Registry data showed:[1]

- 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

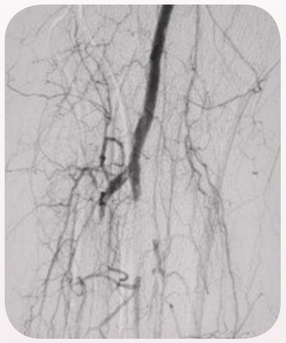


Pre-procedure AngioJet catheter positioned in thrombosed AV graft.



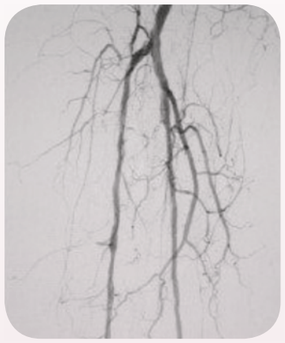
Post Procedure Imaging post-AngioJet System activation in both venous and arterial side of AV graft

CLI with Right Foot Ulcer Thrombectomy



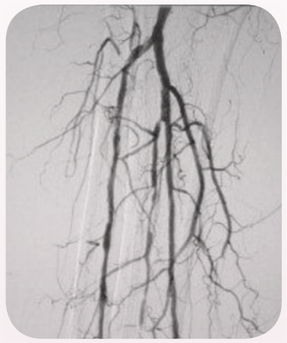
Arteriogram of Posterior and Anterior Tibial – post CDT

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



Pharmacomechanical thrombecomty with AngioJet Solent Dista

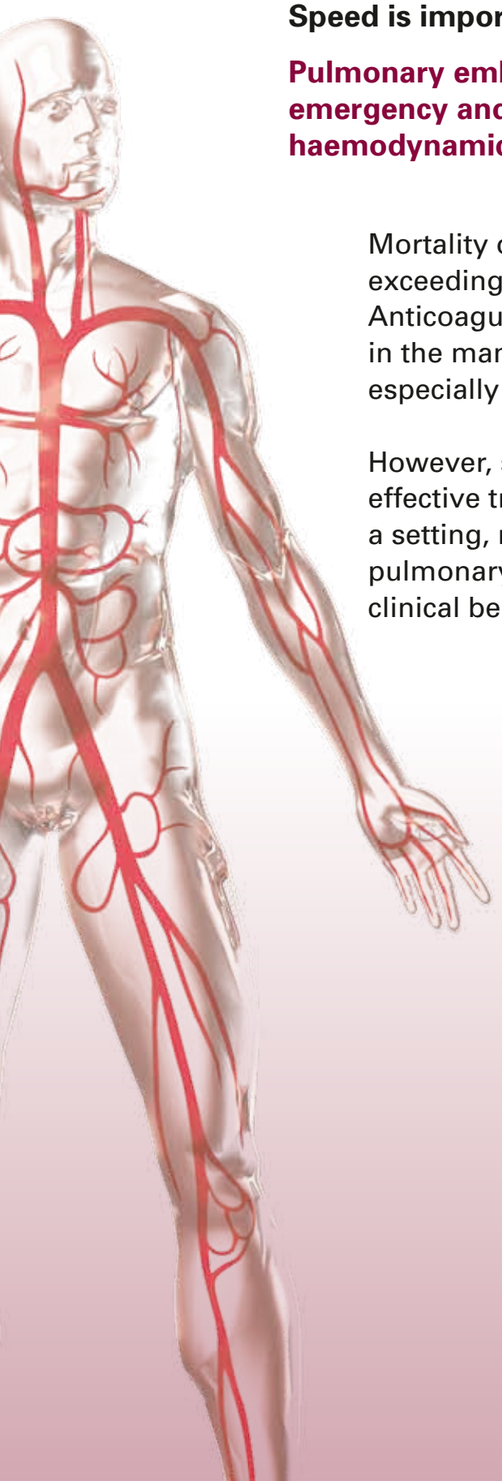
AngioJet Solent Dista Catheter used in Power Pulse mode in both AT and PT. 30 min dwell in AT and 45 min dwell in PT. Followed by Solent Dista Catheter used in thrombectomy mode.



Post Procedure Arteriogram

Image following ballooning of small focal lesion in PT.

Pulmonary Embolism



Speed is important!

Pulmonary embolism (PE) can be a life-threatening emergency and requires fast diagnosis and rapid haemodynamic stabilization.

Mortality of massive pulmonary embolism remains exceedingly high despite thrombolytic therapy. Anticoagulant and thrombolytic therapies are a mainstay in the management of acute pulmonary embolism (PE), especially when hemodynamic compromise is present.

However, systemic drugs cannot achieve timely and effective treatment of acute PE in all patients. In such a setting, mechanical removal of thrombus from the pulmonary circulation holds the promise of significant clinical benefits.

The most important feature of mechanical thrombectomy for massive PE is the immediate improvement of the cardiac output, PO2, and clinical situation, overcoming the first critical hours after massive PE.[7]

European Society of Cardiology guidelines identify mechanical thrombectomy as “an alternative to thrombolysis when there are absolute contraindications, as an adjunctive therapy when thrombolysis has failed to improve haemodynamics or as an alternative to surgery if immediate access to cardiopulmonary bypass is unavailable…”[8]

“Substantial improvement in pulmonary blood flow may result from what appears to be only modest angiographic change.” In fact, haemodynamic improvement may be a more indicative clinical parameter.[14]

The AngioJet PE Thrombectomy Set is intended for use with the AngioJet System for removal of thrombus from main pulmonary and lobal arteries ≥ 6mm.[9]

AngioJet Thrombectomy has been proposed in several publications as a treatment option for patients with massive and submassive pulmonary embolism, with the potential of providing rapid and significant haemodynamic improvement with encouraging results at both early and long-term follow-up.[10, 11, 12, 13]

Pulmonary Embolism

Case Studies

Thrombectomy of High Risk Pulmonary Embolism

Pre Treatment
Patient with active GI bleeding precluding the use of lytic. Main pulmonary artery angiography (more selective to the right) performed with an angulated 6 F (2 mm) pigtail catheter, showing the presence of a large thrombus within the right and left pulmonary arteries and respective lobar branches.

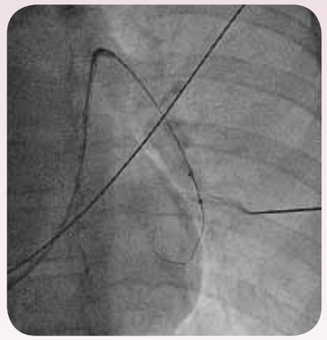
AngioJet® Thrombectomy
Rheolytic thrombectomy performed with AngioJet® PE catheter through a 0.035" (0.089 mm) hydrophilic guide wire, starting in the left pulmonary artery and inferior lobar branch. Procedure was repeated in the right pulmonary artery and corresponding lobar branches. Procedure was terminated because of bradyarrhythmia. Furthermore, total activation time was near the recommended limit (4 minutes).

Post Thrombectomy
Despite large volume of thrombus removed, final angiogram shows only a mild improvement of obstruction. However, the treatment goal is to simply restore flow and not remove all thrombus since even this modest angiographic result was accompanied with significant hemodynamic and gas exchange recovery.

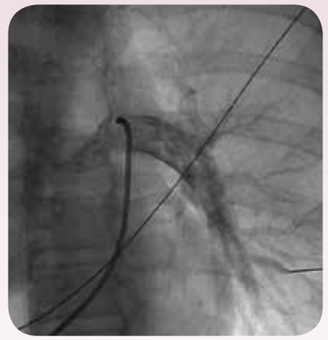
Rita Faria, Gaia Hospital Center, Cardiology Department, Vila Nova de Gaia, Portugal

Thrombectomy of Left Pulmonary Artery

Baseline pulmonary angiography
Left pulmonary angiography performed with an angulated 6 F (2 mm) pigtail catheter, demonstrating the presence of thrombus within the left pulmonary artery and the upper, middle and lower lobar branches.



AngioJet® Thrombectomy
Rheolytic thrombectomy performed with the AngioJet® PE catheter through an 8 F (2.67 mm) multipurpose guiding catheter and a 0.035" (0.089 mm) hydrophylic guide wire.

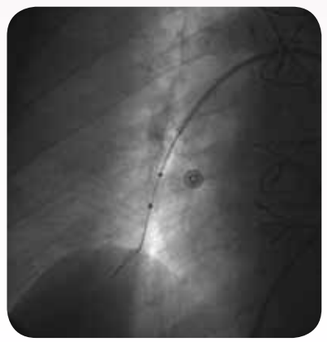


Final pulmonary angiography
Left pulmonary angiography performed after rheolytic thrombectomy showing the improvement of the obstruction and perfusion index.

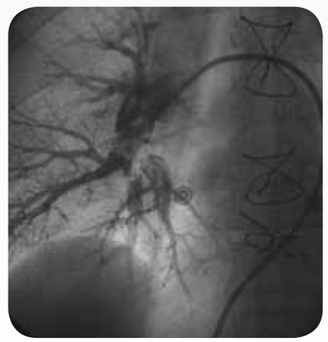
Massimo Margheri, Vecchio Sabine, Cardiology Department, Ravenna, Italy

Thrombectomy of Right Pulmonary Artery

Baseline pulmonary angiography
Right pulmonary angiography performed with an angulated 6 F (2 mm) pigtail catheter, demonstrating the presence of a large thrombus within the right pulmonary artery and the upper, middle and lower lobar branches.



AngioJet® Thrombectomy
Rheolytic thrombectomy performed with the AngioJet® PE catheter through an 8 F (2.67 mm) multipurpose guiding catheter and a 0.035" (0.089 mm) hydrophylic guide wire, in the middle and lower lobar branches.



Fina l pulmonary angiography
Right pulmonary angiography performed after rheolytic thrombectomy showing the improvement of the obstruction and perfusion indexes.

Massimo Margheri, Vecchio Sabine, Cardiology Department, Ravenna, Italy

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	111303-003	OTW	1.5 mm	145 cm	0.014″ 0.035 mm	Yes		
								
Solent™ Omni	109681-004	OTW	3 mm	120 cm	0.035″ 0.089 mm	Yes	Yes	Yes
								
Solent™ Proxi	109676-004	OTW	3 mm	90 cm	0.035″ 0.089 mm	Yes	Yes	Yes
								
AVX™	105039-003	OTW	3 mm	50 cm	0.035″ 0.089 mm		Yes	
								
PE	107171-003	OTW	6 mm	120 cm	0.035″ 0.089 mm	Yes		
								
AngioJet™ Console	105650							
Power Pulse™ Delivery Kit of 5	104834-0031	Delivers medication directly into the clot, where it's most effective, saturating and softening tough thrombus to facilitate removal						

1 The PEARL Registry: Endovascular Management 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; Robert Lookstein, MD; Rahul Malhotra, MD; Ali Amin, MD, RVT; Lawrence R. Blitz, MD; Daniel A. Leung, MD; Eugene J. Simoni, MD; Peter A. Soukas, MD

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 ofpharmacomechanical 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 schemia. *Semin Vasc Surg* 1999;12:148–153.

7 Reekers JA1, Baarslag HJ, Koolen MG, Van Delden O, van Beek EJ. Mechanical thrombectomy for early treatment of massive pulmonary embolism. Cardiovasc Intervent Radiol. 2003 May-Jun;26(3):246-50.

8 Torbicki A, Perrier A, Konstantinides S, Agnelli G, Galiè N, Pruszczyk P et al. Guidelines on the diagnosis and management of acute pulmonary embolism. The task force for the diagnosis and management of acute pulmonary embolism of the European Society of Cardiology (ESC). European Heart Journal, 2008;29:2276–2315.

9 AngioJet PE Thrombectomy Set Instructions for Use

10 Iskander A, Nayak A, Chauhan MS. Submassive pulmonary embolism and paradoxical embolic stroke treated with percutaneous rheolytic thrombectomy and closure of the patent foramen ovale. Catheter Cardiovasc Interv 2005;64(3):356–360.

11 Siablis D, Karnabatidis D, Katsanos K, Kagadis GC, Zabakis P, Hahalis G. AngioJet rheolytic thrombectomy versus local intrapulmonary thrombolysis in massive pulmonary embolism: A retrospective data analysis. Journal of Endovascular Therapy 2005;12(2):206-214.

12 Margheri M. Percutaneous rheolytic thrombectomy with AngioJet for pulmonary embolism: methods and results in the experience of a high-volume center. Italian Journal of Cardiology 2008;9(5):355-363

13 Arzamendi D, Bilodeau L, Ibrahim R, Noble S, Gallo R, Lavoie-L'Allier P et al. Role of rheolytic thrombectomy in massive pulmonary embolism with contraindication to systemic thrombolytic therapy. EuroIntervention 2009;5:716-721

14 Jaff M, McMurty S, Archer S, Cushman M, Goldenberg N, Goldhaber S et al. Management of massive and submassive pulmonary embolism, iliofemoral deep vein thrombosis, and chronic thromboembolic pulmonary hypertension. A scientific statement from the American Heart Association. Circulation 2011;123:1788-1830.

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

PI-323002-AA JUN 2015

Boston Scientific

Advancing science for life™

www.bostonscientific.eu

DINPER4665EA