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 thrombus
- Quick restoration of blood flow
- Resolution of symptoms

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

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

Recent PEARL Registry data showed:

- 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.

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.
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. 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.

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%)

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 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.

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

Post Procedure Arteriogram
Image following ballooning of small focal lesion in PT.
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

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.

Pulmonary Embolism

Speed is important!

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

“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 lobar 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
**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.

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**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) hydrophilic guide wire.

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

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**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) hydrophilic guide wire, in the middle and lower lobar branches.

**Final pulmonary angiography**
Right pulmonary angiography performed after rheolytic thrombectomy showing the improvement of the obstruction and perfusion indexes.
## Treat the Full Range of Thrombus

<table>
<thead>
<tr>
<th>Model</th>
<th>Catalog Number</th>
<th>Platform</th>
<th>Minimum Vessel Diameter</th>
<th>Catheter Length</th>
<th>Guide Wire</th>
<th>Power Pulse™ Delivery</th>
<th>Contrast Injection Port</th>
<th>Guidewire Swappability</th>
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<tbody>
<tr>
<td>Solent™ Dista</td>
<td>111303-003</td>
<td>OTW</td>
<td>1.5 mm</td>
<td>145 cm</td>
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<td>109681-004</td>
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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; All Amin, MD, RVT; Lawrence R. Blitz, MD; Daniel A. Leung, MD; Eugene J. Simoni, MD; Peter A. Soukas, MD
9 AngioJet PE Thrombectomy Set Instructions for Use

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