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.

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

**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.

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

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.

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

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

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)

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%)
Treat the Full Range of Thrombus

<table>
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<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>
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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 periarterialization 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, hemoptysis, 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.

AngioJet, Solent, AVX, Power Pulse and Cross-Stream are trademarks of Boston Scientific.

The PEARL Registry


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