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Advancing science for life™

AngioJet™ Thrombectomy System
In-Service Training

IMPORTANT INFORMATION: These materials are intended to describe common clinical considerations and procedural steps for the on-label use of referenced technologies as well as current standards of care for certain conditions. Of course, patients and their medical circumstances vary, so the clinical considerations and procedural steps described may not be appropriate for every patient or case. As always, decisions surrounding patient care depend on the physician's professional judgment in light of all available information for the case at hand.

BSC does not promote or encourage the use of its devices outside their approved labeling.

The AngioJet™ System Overview

The AngioJet Thrombectomy System is designed to effectively remove thrombus, providing options for improved patient outcomes and decreased complications.

Potential benefits with thrombus removal:

- Quick restoration of flow
- Improved vessel and target lesion visualization
- Decreased risk of distal embolization and resulting complications
- The option of pharmacomechanical combination therapy and the ability to treat thrombus of various age

AngioJet™ Ultra Operation

AngioJet® Ultra Thrombectomy System Mechanism of Action

1 The AngioJet Ultra Console monitors and controls the system.

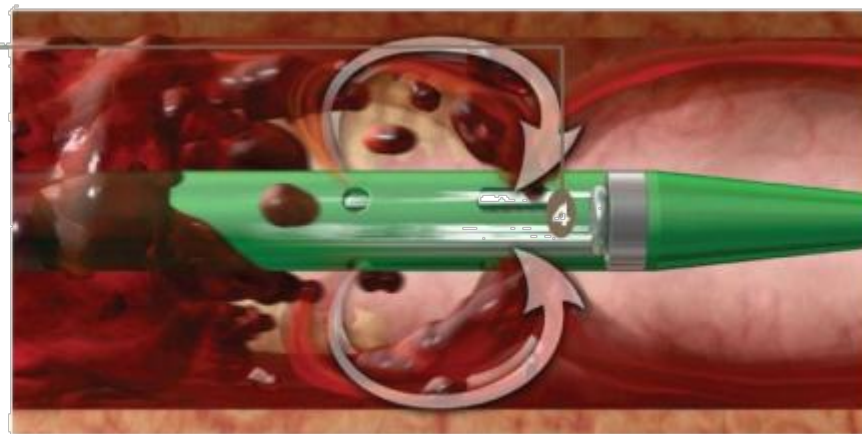
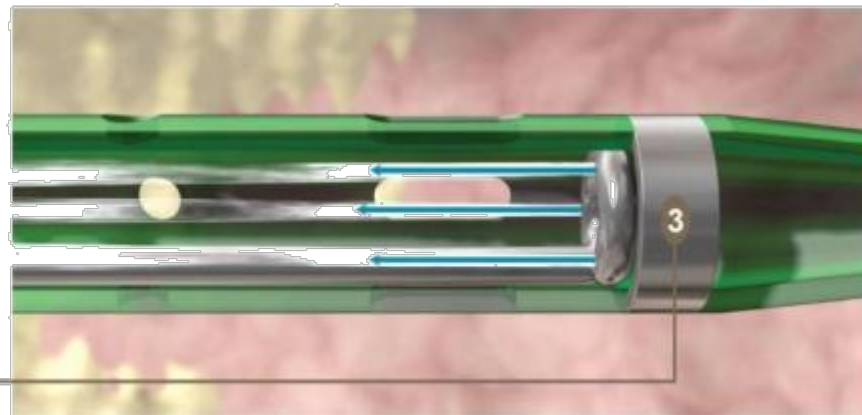


2 The Console energizes the pump, which sends pressurized saline to the catheter tip.

3 Saline jets travel backwards to create a low pressure zone, causing a vacuum effect.

4 Thrombus is drawn into the in-flow windows and the jets push the thrombus back down the catheter.

5 Thrombus is evacuated from the body and into the collection bag.



AngioJet™ & Bernoulli Effect with Hydrodynamics

The AngioJet catheters use the Bernoulli principle for thrombus removal

BERNOULLI EFFECT



Daniel Bernoulli was a
Swiss scientist

BERNOULLI EFFECT

$$P + \frac{1}{2}\rho v^2 + \rho gh = [\text{constant}]$$

Pressure

Fluid Velocity

The Principle: As
velocity increases –
pressure decreases

Where the velocity is the greatest,
the pressure is the lowest

BERNOULLI EFFECT



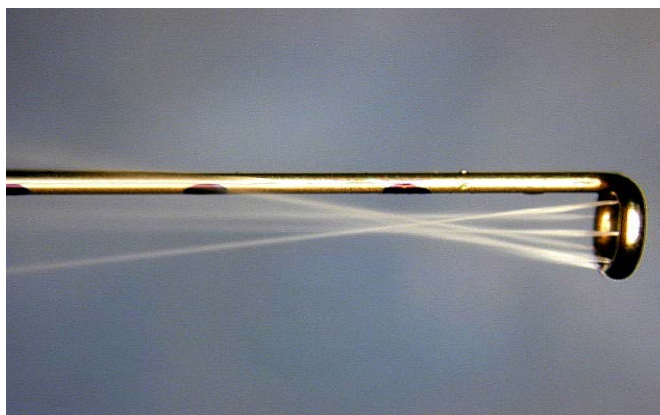
Fluid Velocity →
360 mph

Examples of Bernoulli's principle

- The shower curtain
- Smoke with an open car window
- Airplane flight based on this principle

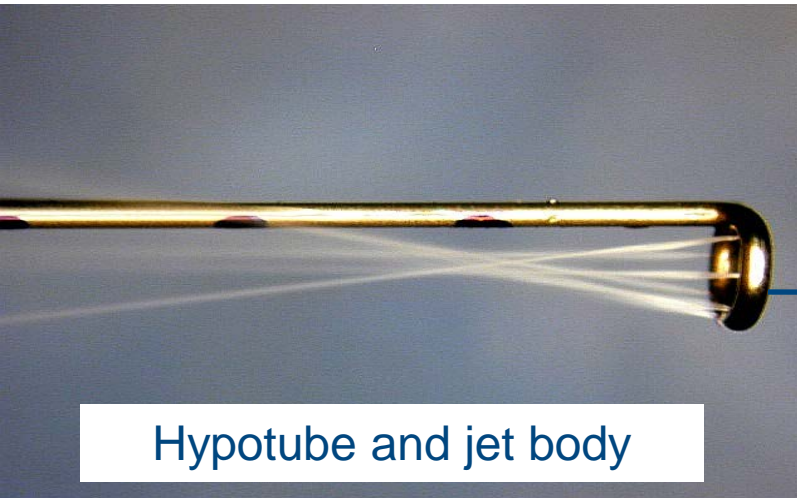
AngioJet™ Catheters – Hydrodynamics

- The pump set generates about (700 kg/cm²) (10,000 psi) to push saline through the jet tube
- These jets are directed backward at high speed – like a shower head
- Saline escapes from the outflow window of the catheter and acts to loosen thrombus and draw it toward the inflow windows – this is called **Entrainment**

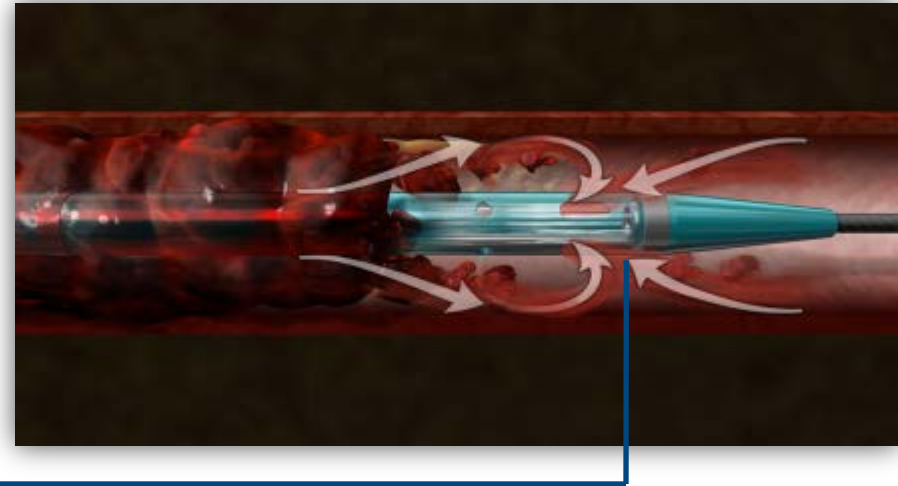


AngioJet™ Catheter Design

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Hypotube and jet body



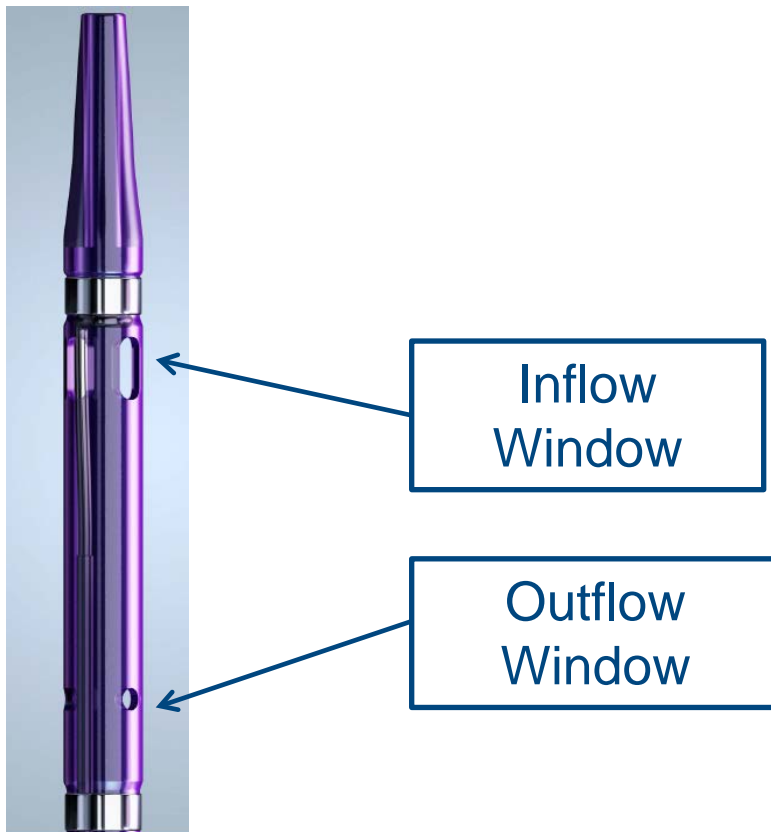
AngioJet
tip on a
Penny



Jet hole
compared to a
human hair

AngioJet™ Catheter Design

- The thrombus is then **captured** through the inflow windows
- The thrombus is **fragmented** within the AngioJet catheter and **evacuated** through the catheter



AngioJet thrombectomy is isovolumetric –which means unchanging volumes. Thus, the volume of saline that is delivered equals ($\pm 8\%$) the fluid volume that is removed from the patient

- Must consider the size of the catheter or sheath - and the size of the guidewire – 0.014 or 0.035 wire compatibility systems
- The lesion is crossed with the guide wire
- The AngioJet catheter is loaded onto the back end of the guidewire – or “back loaded”
- Do not retract the guidewire into the catheter during operation.
- Solent™ PROXI and OMNI allow guidewire swapability
- The guidewire should extend at least 3 cm past the catheter tip at all times. If retraction of the guidewire into the catheter occurs, it may be necessary to remove both the catheter and the guidewire from the patient in order to re-load the catheter over the guidewire.

Refer to each catheter *Information for Use* for specific indication and use

AngioJet™ Ultra Console Overview

The AngioJet™ Ultra Console

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The AngioJet System offers reliable and predictable performance to treat a wide range of thrombosed vessels. With single-package disposables and an intuitive console, the AngioJet Thrombectomy System simplifies setup and user controlled thrombectomy power.



The AngioJet™ Thrombectomy System

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The AngioJet Ultra was designed to facilitate setup and operation:

1. Prepare the console
2. Install the thrombectomy set
3. Prime the system



Please review the AngioJet Ultra operation manual for full set up instructions.

Prepare the Console

Hang a bag of heparinized saline on the side hook and Turn on Power

THE DFU Recommends 5000u of heparin in a 1000ml bag of saline



The display panel will light while the system runs a self check



The catheter drawer opens indicating a successful self-test



Installing the Thrombectomy Set

Open / hand off sterile catheter and pump set to the scrub personnel.
Scrub removes the pump from the package and hand off to the circulator

1. Insert pump into the pump block
2. Spike the saline bag
3. Align waste tubing in the roller pump
4. Push the drawer button to close the drawer

The console will load the pump and use the bar code information to identify the thrombectomy set and instruct the user to prime the catheter



Prime the Catheter

- The scrub personnel submerges the catheter tip into sterile, heparinized saline
- Step on the foot pedal to prime
- Priming is complete when display reads “Prime Complete” and value is zero

Priming varies between catheters - appropriate pump strokes for priming volume is noted on the display screen When the value reaches zero the prime is complete



Ultra is ready for use when the display reads “Ready” and you have a green light



Thrombectomy procedural information

The AngioJet™ Ultra Console displays time and volume of fluid infused



AngioJet catheter models have indications for specific maximum run times – refer to the Information for Use for catheter specific run times

AngioJet™ Catheter Selection

Catheter Reference & Ordering Information



										Maximum Run times	
Model	Order Information	Indication	Power Pulse™ Enabled	Delivery Platform	Guide Wire	Minimum Vessel Diameter	Catheter Length	Catheter Diameter	Introducer Sheath	Total Run Time	Run time with Blood Flow
ZelanteDVT™	114610-001	Peripheral Venous	YES	OTW	0.035"	6 mm	105cm	8 F	8 F	480 sec	240 sec
Solent™ Omni	109681-001	Peripheral Arterial and Venous, AV Access	YES	OTW	0.035"	3 mm	120 cm	6 F	6 F	480 sec	240 sec
Solent™ Proxi	109676-001	Peripheral Arterial and Venous, AV Access	YES	OTW	0.035"	3 mm	90 cm	6 F	6 F	480 sec	240 sec
Solent™ Dista	111303-001	Peripheral Arterial	YES	OTW	0.014"	1.5 mm	145 cm	4 F / 3 F distal	4 F	600 sec	300 sec
AVX™	105039-001	AV Access	NO	OTW	0.035"	3 mm	50 cm	6 F	6 F	600 sec	300 sec

Disease State Treatments & Peripheral Offerings

DVT, PAD, & AV Access Declot

ARTERIAL

Upper Extremity

SOLENT™
Omni / Proxi

Lower Extremity ATK

SOLENT
Omni / Proxi

Below Extremity BTK

SOLENT Dista

AV Access

AVX™-CI
Catheter

VENOUS

Upper Extremity

SOLENT
Omni / Proxi

ZELANTEDVT™

Lower Extremity ATK

ZELANTEDVT

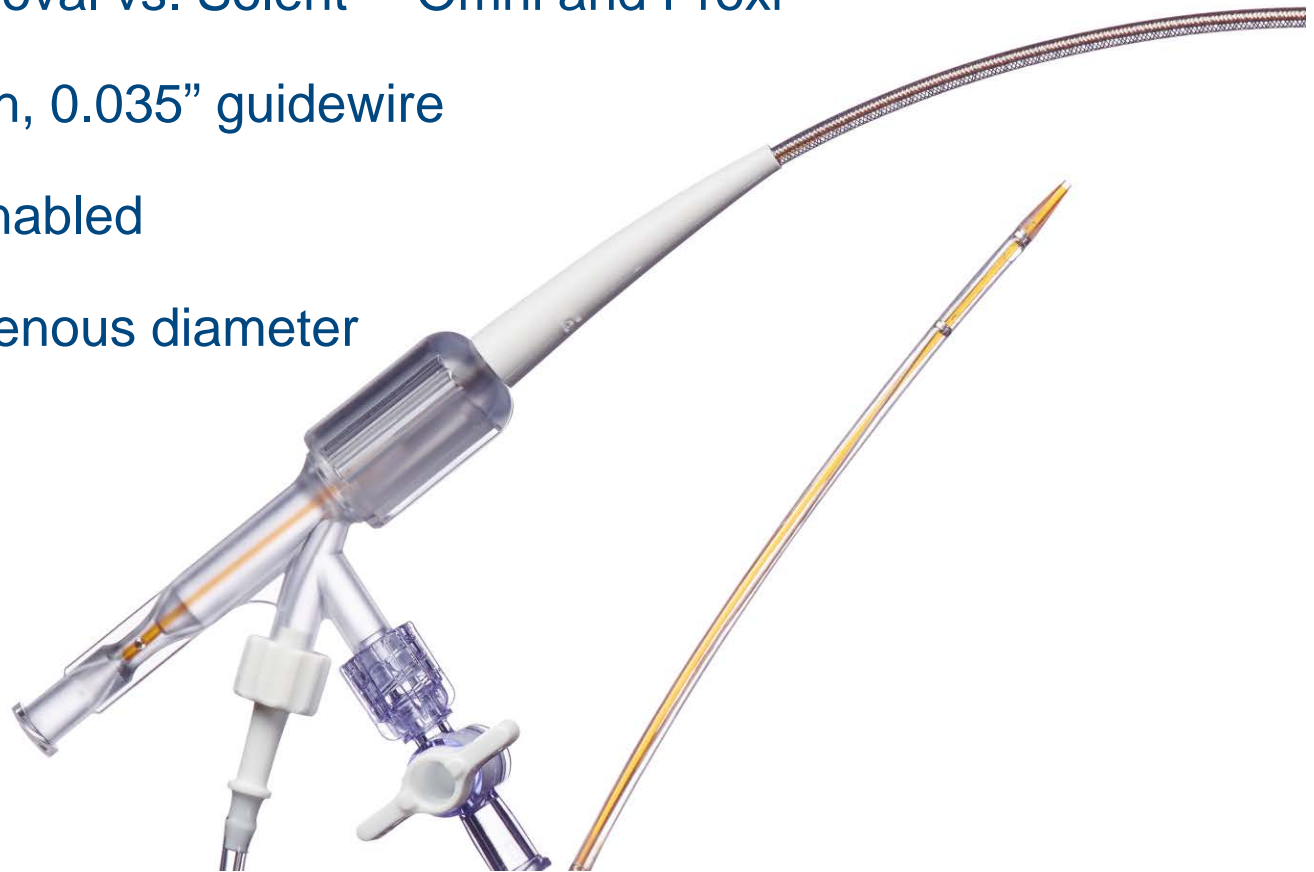
SOLENT
Omni / Proxi

AngioJet™ *VENOUS* Catheter

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ZelanteDVT™

- ~4x thrombus removal vs. Solent™ Omni and Proxi¹
- 8 F, 105 cm length, 0.035" guidewire
- Power Pulse™ enabled
- 6 mm minimum venous diameter



¹Bench testing results may not necessarily be indicative of clinical performance

AngioJet Catheter Comparison

Product Feature(s)	Solent™ Omni / Proxi	ZelanteDVT™
Indication	Arterial and Venous	Venous Only
Minimum Vessel Diameter	3 mm	6 mm
Sheath Compatibility	6F	8F
Working Length	120 cm / 90 cm	105 cm
Thrombectomy Power		~4x thrombus removal power than Omni & Proxi ¹
Power Pulse™ enabled	Yes	
Contrast Injection Port	Yes	
Wire Compatibility	0.035"	
Guide Wire Swappable	Yes	
Run Times (No Flow / Flow)	8 minutes / 4 minutes	8 minutes / 4 minutes
Power Pulse™ Delivery	0.6 mL / pump stroke	0.6 mL / pump stroke

¹Bench testing results may not necessarily be indicative of clinical performance

A **NEW** Direction for DVT Thrombectomy

- Directional control over the thrombus removal power
- One single (larger) inflow window
- Similar hemolysis profile to Solent™ Omni

One inflow window

One outflow window



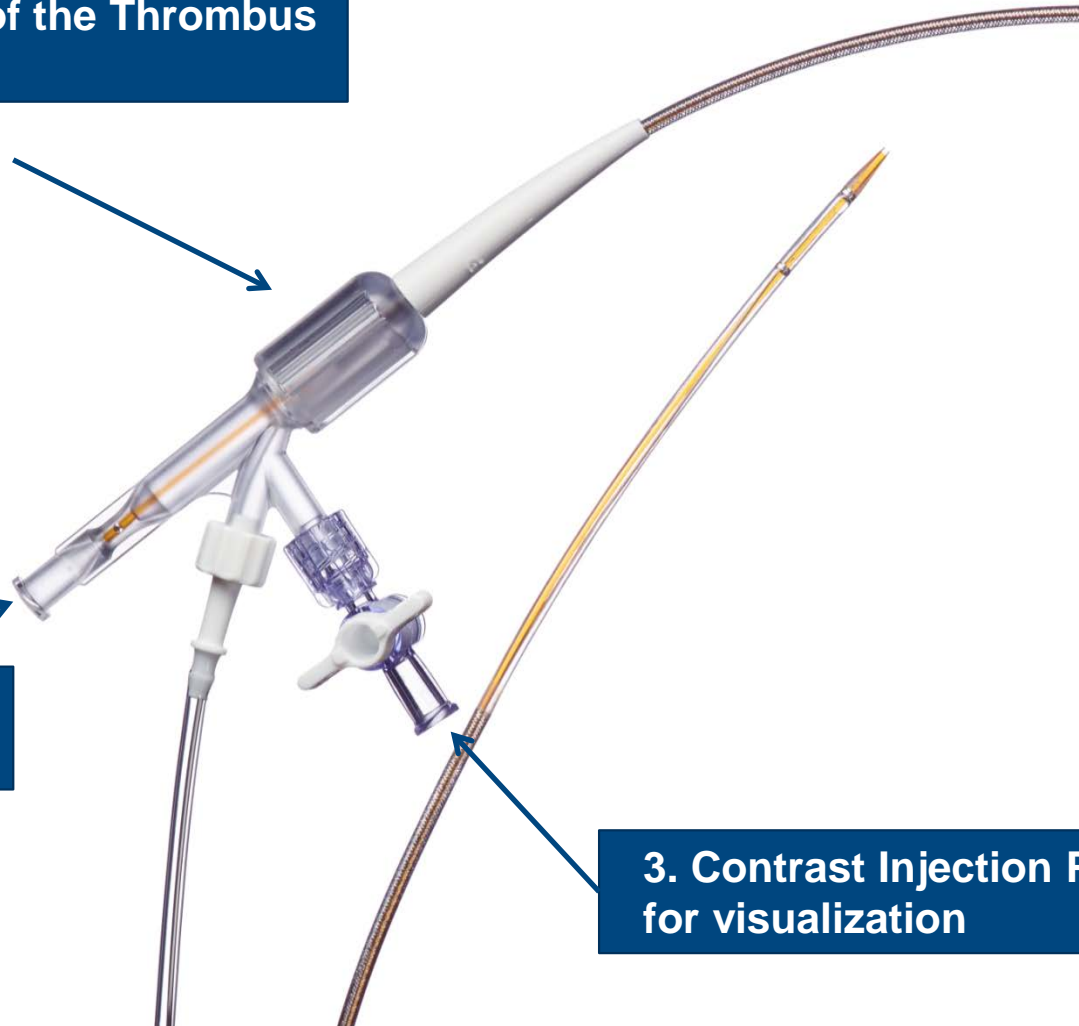
ZELANTE DVT™ Hub Overview

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1. Catheter direction / rotation knob
Directional control of the Thrombus Removal Power

2. Dedicated guidewire lumen (over the wire)

3. Contrast Injection Port for visualization



The POWER of ZELANTE DVT™

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THE CHALLENGE: Using fiber clot in a 22 mm tube

ZELANTE DVT –
Shows its POWER¹

*Removing 4X's more
thrombus than our
standard AngioJet™
Peripheral Catheter*



¹Bench testing results may not necessarily be indicative of clinical performance

Bench Simulation¹ Power Pulse™ Delivery

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Solent Omni

ZelanteDVT

COMBINATION THERAPY¹

¹Bench testing results may not necessarily be indicative of clinical performance

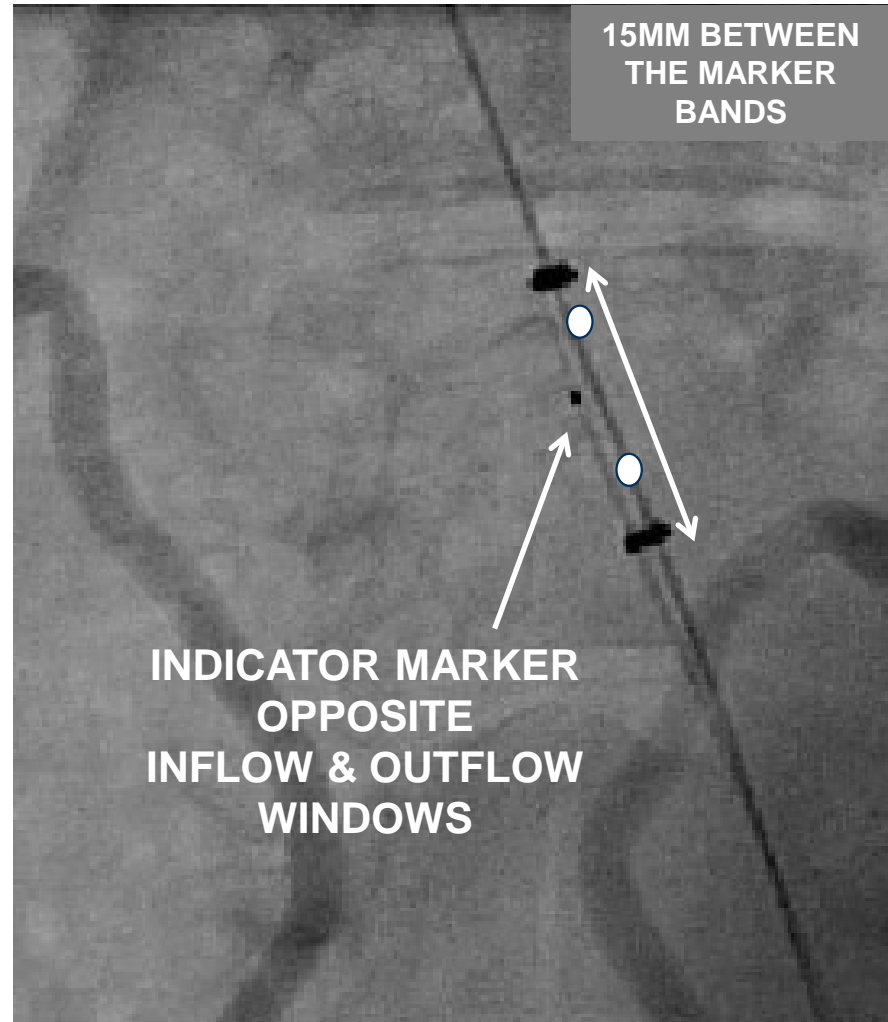
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PI-468201-AA

ZELANTE DVT™ Catheter Tip

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- Standard 15 mm between marker bands facilitating a reference to location of windows
- NEW – Indicator marker located on the hypo-tube
 - Designed to help identify window direction and Location
 - Places midway between inflow and outflow windows



Solent™ Proxi – 90cm

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High-speed saline jets inside the Solent catheter create a powerful low pressure zone to pull thrombus into the catheter and removes it from the body. Cross-Stream™ technology can treat larger arteries without vessel wall contact.

Improved Site Access

- Guidewire swapability to allow changing guide wires during a procedure
- Spiral cut proximal shaft offering increased flexibility for reduced kinking
- Distal shaft has hydrophilic coating to reduce drag and ensure smooth delivery

Improved Visibility

Contrast injection port allows contrast to be delivered directly to the treatment site without disrupting treatment.

Power Pulse™ delivery

Solent Proxi is Power Pulse enabled for difficult-to-remove thrombus.

CATHETER SPECIFICATIONS

System Compatibility	Ultra
Vessel Diameter	≥ 3mm
Working Length	90cm
Shaft Diameter	6F
Double Marker Band	15 mm
Guidewire Compatibility	OTW 0.035"
Guide Compatibility	8F ≥ 0.086"
Sheath Compatibility	6F

ORDER INFORMATION

Solent Proxi Thrombectomy Set
US part number 109676-001
For use only with the AngioJet Ultra System

Solent™ Omni – 120cm

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Solent Omni–High Thrombus Removal Power in a Longer Length

High-speed saline jets inside the Solent catheter create a powerful low pressure zone to pull thrombus into the catheter and removes it from the body. Cross-Stream™ catheter technology can treat larger arteries without vessel wall contact.

Improved Site Access

- Guidewire swapability to allow exchanging of the guide wire during a procedure
- Spiral cut proximal shaft offering increased flexibility
- Distal shaft with hydrophilic coating to reduce drag and ensure smooth delivery

Improved Visibility

The Solent Omni catheter has a contrast injection port that allows the delivery of contrast through the catheter directly to the lesion site.

Power Pulse™ Delivery

Solent Omni is Power Pulse enabled for difficult-to-remove thrombus.

CATHETER SPECIFICATIONS

System Compatibility	Ultra
Vessel Diameter	≥ 3mm
Working Length	120cm
Shaft Diameter	6F
Double Marker Band	15 mm
Guidewire Compatibility	OTW 0.035"
Guide Compatibility	8F ≥ 0.086"
Sheath Compatibility	6F

ORDER INFORMATION

Solent Omni Thrombectomy Set
US part number 109681-001
For use only with the AngioJet Ultra System

Solent™ Dista – 145cm

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Solent Dista – High Thrombus Removal Power in our Longest Length and Smallest Diameter – for Arterial use only

High-speed saline jets inside the Solent catheter create a powerful low pressure zone to pull thrombus into the catheter and removes it from the body. Cross-Stream™ catheter technology can treat larger arteries with minimal vessel wall contact.

Improved Site Access

- Nitinol 3F distal section allowing access to smaller, tortuous vasculature
- Braided shaft design offering pushability to access lesions
- Distal shaft with hydrophilic coating to reduce drag and facilitate smooth delivery

Power Pulse™ Delivery

Solent Dista is Power Pulse enabled for difficult-to-remove thrombus.

Catheter Specifications

System Compatibility	AngioJet Ultra
Vessel Diameter	≥ 1.5mm
Working Length	145cm
Shaft Diameter	4F (130cm) / 3F (15cm)
Double Marker Band	15 mm
Guidewire Compatibility	OTW 0.014"
Sheath Compatibility	4F

Order Information

AngioJet Solent Dista Thrombectomy Set
Part number 111303-001
For use only with the AngioJet Ultra System



An Excellent Choice for Vascular Access Management

Performance

- The AngioJet™ AVX endovascular System is designed to remove thrombus from AV grafts and fistulas.
- Removal of the thrombus reduces the need for thrombolytics and may eliminate their use altogether.¹
- Minimal wall contact reduces vessel trauma that could increase the potential for a future thrombotic event.

Versatile

- The AngioJet AVX System is the only mechanical thrombectomy device indicated for both native fistulas and synthetic grafts.
- Its 0.035" guide wire compatibility and tapered, flexible tip facilitates navigation through the AV access conduit.

Convenient

- Allows injection of contrast via the manifold for vessel visualization.
- The system offers quick and easy set-up, with standardized steps and prompt menus.

Catheter Specifications

System Compatibility	AngioJet Ultra
Vessel Diameter	≥ 3mm
Working Length	50cm
Shaft Diameter	6F
Guidewire Compatibility	OTW 0.035"
Guide Compatibility	8F ≥ 0.086"
Sheath Compatibility	6F

Order Information

AngioJet Ultra AVX Thrombectomy Set

Customer order number 105039

For use only with the AngioJet Ultra System

1. Bush RL, Lin PH, Lumsden AB. Management of thrombosed dialysis access: thrombectomy versus thrombolysis. Seminars in Vascular Surgery 2004; 17:32-39.

Contrast Injection with AngioJet™ Catheter*

- DO NOT inject fluids through the stopcock unless the catheter has operated for at least 30 seconds
- DO NOT use negative pressure from a syringe to try to purge the catheter
- FIRST, purge the Tru-Seal hemostasis valve of the manifold by orienting the valve toward the ceiling then depressing the horn in the 'open' position until 3cc of blood has escaped the manifold. Pull the horn into a closed position
- SECOND, rotate the manifold until the stopcock is toward the ceiling and open until 3cc of blood has escaped through the stopcock.
- Make a fluid to fluid connection between the injecting syringe and stopcock leg prior to delivery of contrast.

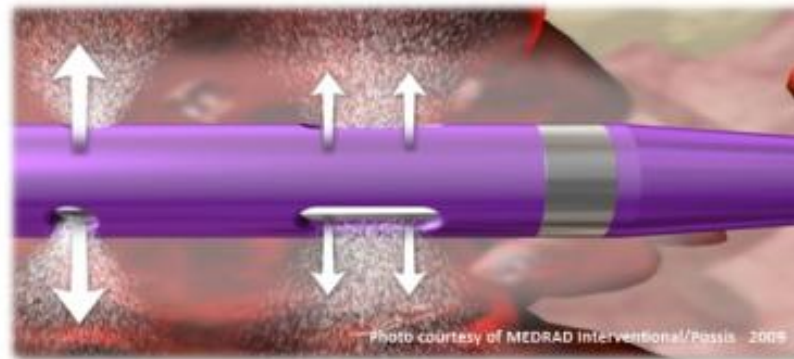
* Refer to the Technical Bulletin on contrast injection and AngioJet catheter *Information for Use*



Power Pulse™ Overview

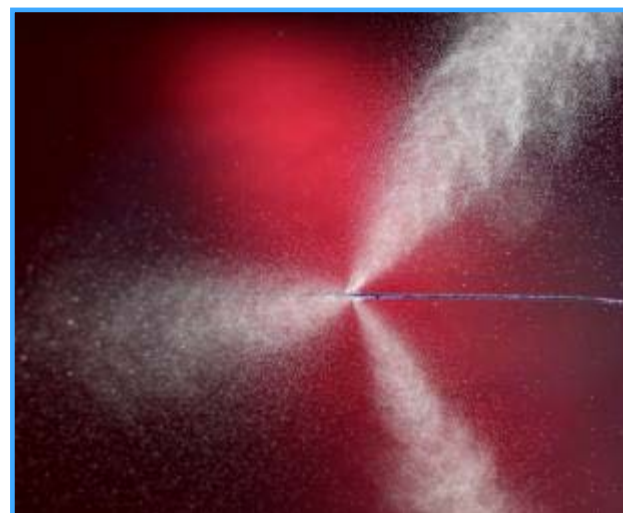
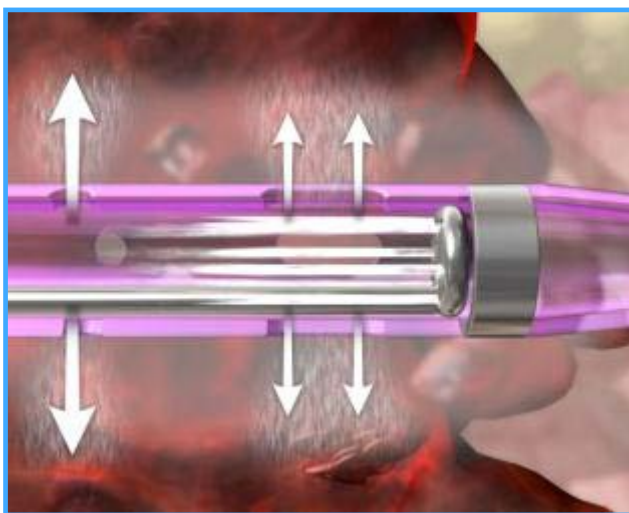
Power Pulse delivery enables you to infuse medication directly into the thrombus, making it softer and facilitating removal.

By infusing the lytic directly into the clot, physicians can often reduce the duration and dose of this medication. With the AngioJet® Ultra device, Power Pulse Mode is activated easily with Power Pulse volume and time automatically displayed on the Ultra device screen.



Mechanism of Action

INFUSION of physician-specified fluid (PSF)



In Power pulse Mode:

- Inflow remains open
- Outflow lumen is occluded

PSF pulsed through distal windows & PSF delivered directly into thrombus

How Power Pulse Delivery Works

1. The outflow lumen of the AngioJet™ Catheter is closed off.
2. This allows the fluid to be pulsed through the catheter, penetrating and disrupting the thrombus.
3. Using the Y-spike set, the physician can switch between heparinized saline (normally used for thrombectomy) and a second fluid, usually a lytic.
4. After the lytic has been allowed to work on the thrombotic lesion, the stopcock is opened, the catheter is primed and flushed with saline and reintroduced into the clot.
5. After opening the outflow lumen for normal thrombectomy, the powerful Cross-Stream™ action of the approved AngioJet catheter can remove the clot.



Safe and simple conversion

Components

1. Sterile Y-Set with 2 tube clamps:
 - Short tubing for saline
 - Long tubing for PSF
2. Distal flexible tubing to accommodate AngioJet spike
3. Instructions for use

5 Kits per carton
Packaged Sterile
Catalog #104834-002

Engaging AngioJet™ Ultra Console Power Pulse™ Delivery Mode

Push the CATHETER button twice

Note: Only those Thrombectomy Sets that have a Power Pulse Delivery indication will allow entry into Power Pulse Delivery mode



Use arrow to select YES

Push CATHETER button once more to confirm



Console is ready for Power Pulse Delivery



Exit Power Pulse™ Delivery Mode

To exit Power Pulse Delivery infusion mode and begin thrombectomy:

1. Open heparinized Saline flow clamp
2. Close PSF flow clamp
3. Push alarm reset to exit PPD mode on the AngioJet Ultra Drive unit

To exit Power Pulse Delivery:
Push ALARM RESET
button once



Moving between PPD and Thrombectomy

Initiate Power Pulse™ Delivery Mode

1. Push the **CATHETER** button twice

Note: Only those Thrombectomy Sets that have a Power Pulse Delivery indication will allow entry into Power Pulse Delivery mode



2. Open PSF tubing clamp
3. Close HepNS bag Clamp
4. Insure catheter is primed

Initiate Thrombectomy Mode

1. To exit Power Pulse Delivery:
Push **ALARM RESET** button once



2. Close PSF tubing clamp
3. Open HepNS Clamp
4. Insure catheter is primed

Potential benefits (acute & chronic)

1. Can be used with other treatment strategies
2. Improved visualization of vessel lesion
3. Less lytic use
4. Quick restoration of flow
5. Favorable long term limb salvage*

* Drs. Gary Ansel, Charles Botti, and Mitchell Silver; Treatment of Acute Limb Ischemia with a Percutaneous Mechanical Thrombectomy-Based Endovascular Approach: 5-Year Limb Salvage And Survival Results from a Single Center Series; *Catheterization and Cardiovascular Interventions*; 72:325-550(2008)

AngioJet™ Catheters

some Warnings and Cautions during use

Cardiac arrhythmias during peripheral 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.¹

An interrupted activation technique with short activation times (5 sec on, 5 sec off) has been used successfully to avoid transient arrhythmias in the Jetstent study.²

¹ZelanteDVT DFU

²Migliorini A1, Stabile A, Rodriguez AE, Gandolfo C, Rodriguez Granillo AM, Valenti R, Parodi G, Neumann FJ, Colombo A, Antoniucci D; JETSTENT Trial Investigators.

Comparison of AngioJet rheolytic thrombectomy before direct infarct artery stenting with direct stenting alone in patients with acute myocardial infarction. The JETSTENT trial. J Am Coll Cardiol. 2010 Oct 12;56(16):1298-306. doi: 10.1016/j.jacc.2010.06.011. Epub 2010 Aug 5.

Refer to each catheter *Information for Use* for specific indication and use

AngioJet™ Catheters

some Warnings and Cautions during use

Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Observe 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. ¹

Intravenous Sodium BiCarb is sometimes used to decrease the risk of PFH precipitation.^{2,3}

NOTE: Hemoglobinuria should NOT be confused with Hematuria³

¹ Solent Proxi/Omni DFU

² Robert A. Lookstein, MD ,Treating Deep Vein Thrombosis; p66 Endovascular Today 2007 Buyer's Guide

³ Andre Biuckians; George H. Meier III, Treatment of Symptomatic Lower Extremity Acute Deep Venous Thrombosis: Role of Mechanical Thrombectomy, Vascular. 2007;15(5):297-303.

Refer to each catheter *Information for Use* for specific indication and use

Suggestions for minimizing potential for adverse events

- Utilize AngioJet catheters only in indicated vessels, according to the DFUs.
- Use the interrupted activation technique to avoid transient arrhythmias .
 - If the patient experiences an arrhythmia, step off the pedal for a few seconds, until normal rhythm returns, then step on the pedal again to continue.
- Hydrate the patient prior to, during, and after the procedure.
- Closely monitor run times and/or infused saline volume.
 - Adjust run times appropriately when activating AngioJet in vessels with potentially high blood flow, such as large veins; these are rarely completely occluded.
 - If utilizing Power Pulse, include the Power Pulse run time as part of the total run time, especially in large vessels, or vessels which are not completely occluded.
- The AngioJet catheters which are indicated for venous applications are the most powerful AngioJet catheters available today, and may have a higher potential for causing hemolysis and arrhythmias.
 - Utilize extra caution when using AngioJet catheters in large veins.
 - Take into consideration other important factors surrounding the condition of each patient, such as preexisting compromised kidney function, total case contrast exposure, age and size of thrombus burden.

Clinical Data Overview



CLINICAL STUDY

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, and Peter A. Soukas, MD

JVIR Vol 26, Issue 6, June 2015, Pages 777-785

- **329 venous AngioJet patients; 32 study sites**
- **86% of procedures required no more than 2 cath lab sessions**
- **12 month freedom from rethrombosis rate: 83%**

“...rheolytic PCDT treatment of DVT is safe and effective, and can potentially reduce the need for concomitant CDT and intensive care.”

PEARL Registry: DVT Duration of Procedure



N=355*

Time Period	Frequency
≤ 6 Hrs	133 (38%)
> 6 Hrs & ≤ 12 Hrs	37 (10%)
> 12 Hrs & ≤ 24 Hrs	97 (27%)
> 24 Hrs	88 (25%)

*(355/371 had times recorded)

Procedure = time from introduction of sheath to completion of all endovascular treatments

38% completed in ≤ 6 hrs
75% completed in ≤ 24 hrs

PEARL Registry: DVT Number of Lab Sessions



N = 359*

# of Sessions	N(%)
1	123 (34%)
2	189 (53%)
3	40 (11%)
>3	7 (2%)

*(359/371 had # sessions recorded)

Session = In and out of the interventional suite

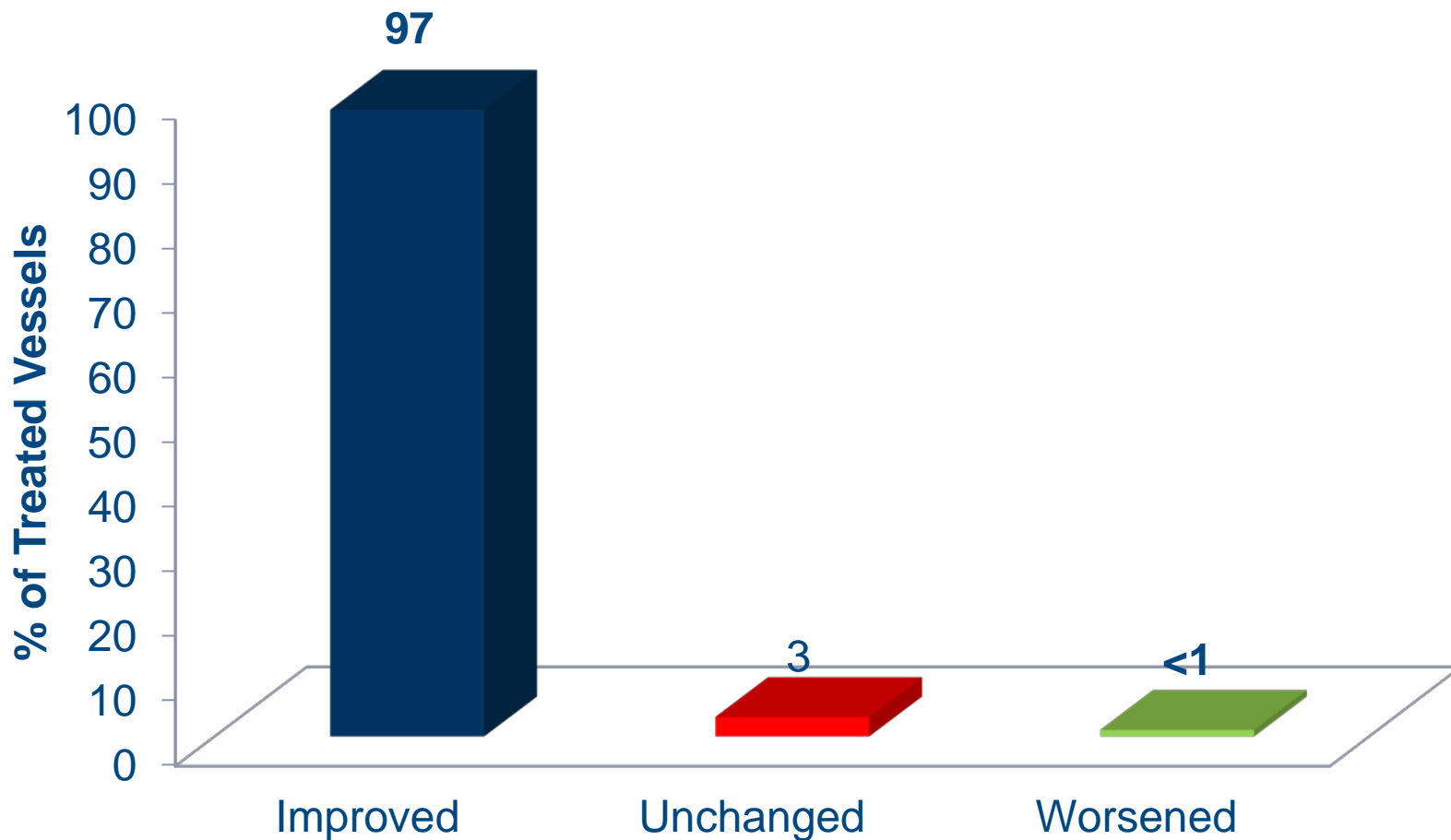
87% had 2 or less sessions

Venographic Results

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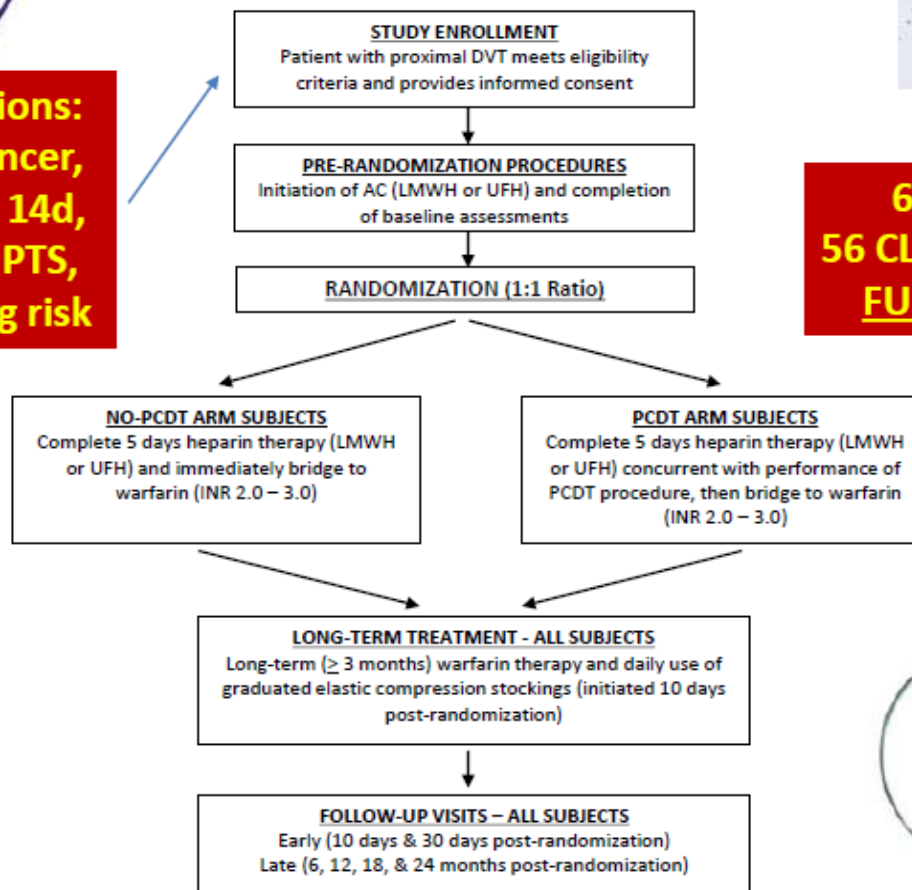
N=1295 vessels treated ($p < 0.0001$)



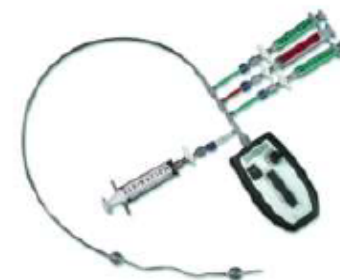


Main Exclusions:
Age > 75, cancer,
symptoms > 14d,
established PTS,
high bleeding risk

ATTRACT STUDY SCHEMA



692 PATIENTS
56 CLINICAL CENTERS
FULLY ENROLLED



Study Outcomes *Short-Term Effects of PCDT*

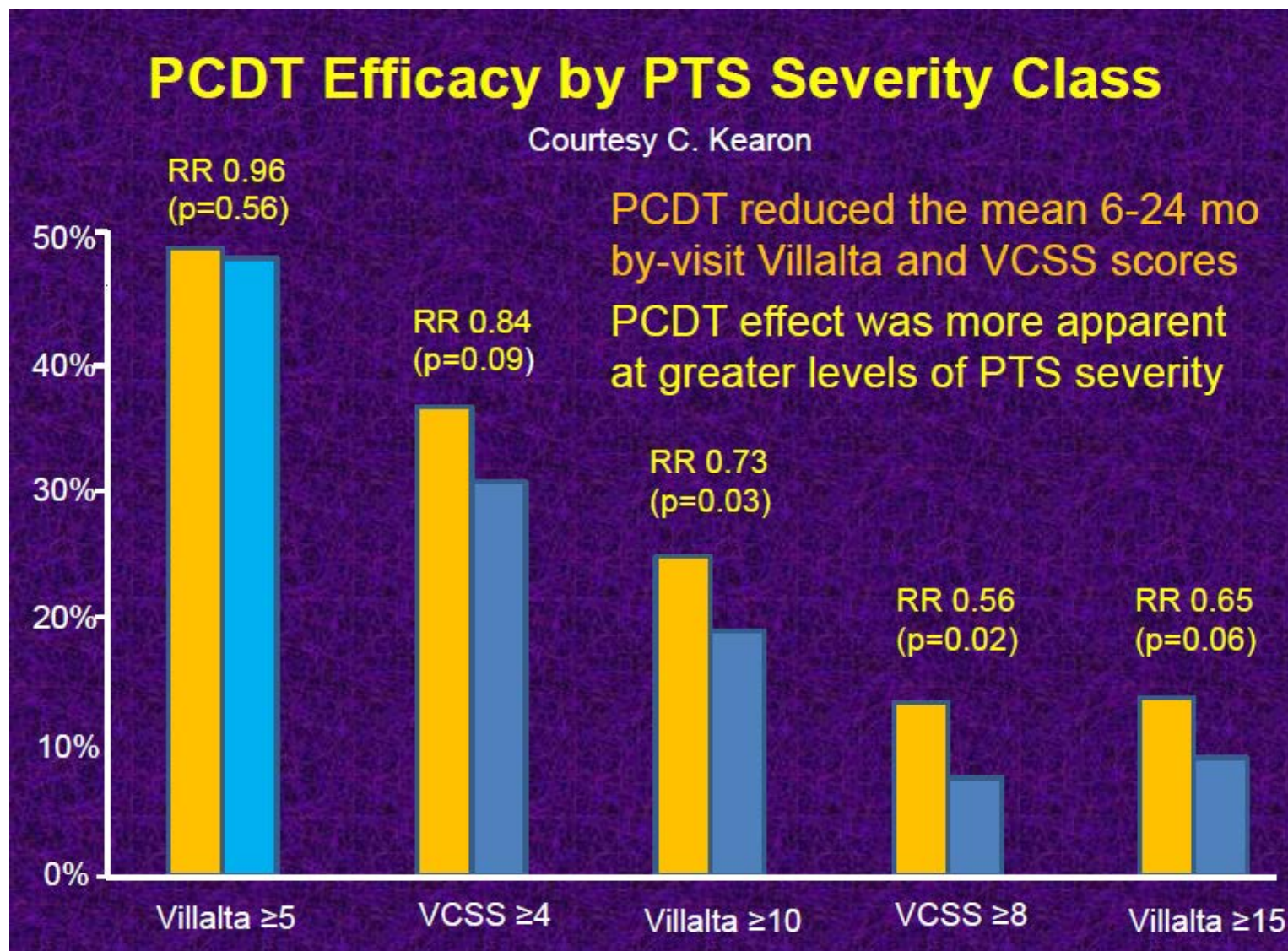
Outcome	PCDT (n=336)	No-PCDT (n=355)	P Value
Major Bleeding (10 days)	1.7%	0.3%	0.049
Any Bleeding (10 days)	4.5%	1.7%	0.034
Leg Pain (10d)	-1.62	- 1.29	0.019
Leg Pain (30d)	-2.17	- 1.83	0.026
Leg Swelling (10d)	-0.26	+0.27	0.024
Leg Swelling (30d)	-0.74	-0.28	0.051

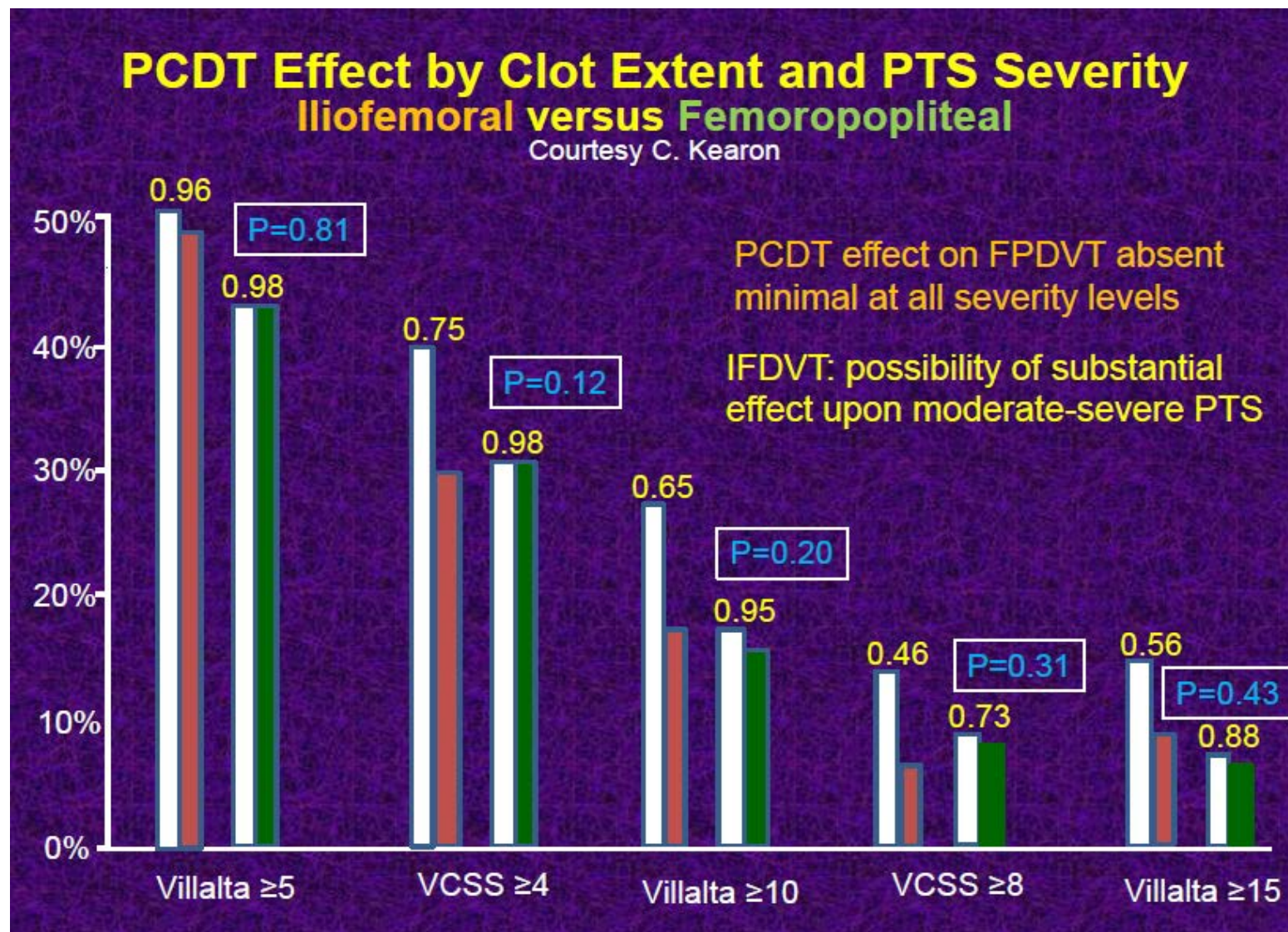
No fatal or intracranial bleeds in either arm
PCDT Arm: 3/4 transfusions & 2 embolizations

Study Outcomes *Long-Term Effects of PCDT*

Outcome (24 months)	PCDT (n=336)	No-PCDT (n=355)	P Value
Any PTS	46.7%	48.2%	0.56
Recurrent VTE	12.5%	8.5%	0.087
Generic QOL (SF-36 PCS)	11.8	10.06	0.37
Venous QOL (VEINES)	27.67	23.47	0.08
Moderate or severe PTS	17.9%	23.7%	0.035
MS-PTS: IFDVT	18.4%	28.2%	
MS-PTS: FPDVT	17.1%	18.1%	

PCDT was less effective in patients ≥ 65 years old ($p = 0.038$)





Abbreviated Statement

ANGIOJET SOLENT DISTA

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 “Instructions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

INDICATIONS AND USAGE: 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 IFU).

CONTRAINDICATIONS: Do not use the catheter in patients: • Who are contraindicated for endovascular procedures • Who cannot tolerate contrast media • In whom the lesion cannot be accessed with the guide wire

WARNINGS AND PRECAUTIONS: • 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 (unless accompanied by a separate coronary IFU). • 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 nonhealed 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 IFU); 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. • Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the IFU) 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. • 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. • 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. • 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. • 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. **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 • 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 **REV AA**

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Abbreviated Statement

ANGIOJET SOLENT OMNI PROXI

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INDICATIONS AND USAGE: 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 ≥ 3.0 mm in diameter, • upper extremity peripheral veins ≥ 3.0 mm in diameter, • iliofemoral and lower extremity veins ≥ 3.0 mm in diameter, • A-V access conduits ≥ 3.0 mm 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.

CONTRAINDICATIONS: Do not use the catheter in patients: • Who are contraindicated for endovascular procedures • Who cannot tolerate contrast media • In whom the lesion cannot be accessed with the guide wire **WARNINGS AND PRECAUTIONS:** • 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 (unless accompanied by a separate coronary IFU). • 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 nonhealed 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 IFU); 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. • Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the IFU) 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. • Thrombotic debris/fluid flow exiting the catheter manifold via the waste tubing should be monitored continually during use. If the effluent fluid is primarily saline (clear in appearance), AngioJet Ultra System operation should be stopped and the catheter should be repositioned. Clear fluid indicates that the catheter may be occlusive within the vessel or operating in an area cleared of clot. Prolonged operation under occlusive conditions may result in tissue injury. • Do not retract the guide wire into the catheter during operation. The catheter is not designed to operate without the guide wire in place. • 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. • 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. • 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. • 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. • 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 to 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. **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 • 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 **REV AA**

Abbreviated Statement

ANGIOJET AVX

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

INDICATIONS AND USAGE: 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 AND PRECAUTIONS:** • 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. • Use the Thrombectomy Set only with the multiple-use AngioJet Ultra Console. • 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 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 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. • Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the IFU) 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. • 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. • 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. • 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. • 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. • 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• 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 **REVA**

Abbreviated Statement

ANGIOJET ULTRA POWER PULSE KIT

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 “Instructions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

INDICATIONS AND USAGE: The AngioJet Ultra Power Pulse Kit is intended for use only with AngioJet Ultra Thrombectomy Sets indicated for the control and selective infusion of physician-specified fluids, including thrombolytic agents, into the peripheral vascular system using the AngioJet Ultra System. **CAUTION:** See Product Labeling for the AngioJet Ultra Console and AngioJet Ultra Thrombectomy Set Before Using the AngioJet Ultra Power Pulse Kit. • The AngioJet Ultra Power Pulse Kit assembly should only be used with those AngioJet Ultra Thrombectomy Sets which are indicated for use with Power Pulse Technique. • This system has NOT been tested for use in administering contrast medium. **Do not administer contrast medium using this System.** • The guide wire/catheter must traverse beyond the targeted treatment zone prior to infusion of physician-specified fluid. • Never leave the device unattended while running. Patient injury may occur. • Refer to the product insert supplied with the physician-specified fluid used during Ultra Power Pulse Technique for contraindications, side effects, warnings and precautions. **CONTRAINDICATIONS:** Do not use the Thrombectomy Set in patients: • Who are contraindicated for endovascular procedures; • Who cannot tolerate contrast media; • In whom the lesion cannot be accessed with the guide wire. **WARNINGS AND PRECAUTIONS:** The Ultra Power Pulse Kit is not intended for use in the pulmonary, carotid, cerebral or coronary vasculature (unless indicated in a specific AngioJet Thrombectomy Set Information for Use). **ADVERSE EVENTS:** Potential adverse events (in alphabetical order) which may be associated with use of the AngioJet Ultra Power Pulse Technique in peripheral vessels are similar to those associated with other interventional procedures and include but are not limited to: • death • dissection • embolization • hemolysis • hemorrhage • hypotension/hypertension • infection at the access site • pain • perforation • pseudoaneurysm • thrombosis/occlusion • total occlusion of treated vessel • vascular aneurysm • vascular spasm **REVA**

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Abbreviated Statement

AngioJet™ Ultra 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 Console is intended for use only in conjunction with an AngioJet Ultra Thrombectomy Set. Refer to the individual Thrombectomy Set *Information for Use* manual for specific clinical applications. **CONTRAINDICATIONS:** Refer to the individual Thrombectomy Set *Information for Use* manual for specific contraindications.

WARNINGS and PRECAUTIONS: • Use the AngioJet Ultra 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 *Information 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 *Instructions 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 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 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 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 IFU. **ADVERSE EVENTS** Refer to the individual Thrombectomy Set *Information for Use* manual for specific observed and/or potential adverse events. **REVA**

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Abbreviated Statement

ZelanteDVT™ THROMBECTOMY SET

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INDICATIONS AND USAGE: 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 • Who cannot tolerate contrast media • In whom the lesion cannot be accessed with the guidewire

WARNINGS and PRECAUTIONS: 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 IFU; 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. • 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. • 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. • The potential for pulmonary thromboembolism should be carefully considered when the ZelanteDVT Thrombectomy Set is used to break up and remove peripheral venous thrombus

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 • 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

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