Boston Scientific
Advancing science for life™

ANGIOJET™ ZELANTEDVT™ Thrombectomy Catheter

DOMINATE DVTs

ZelanteDVT™ provides the power to remove large venous clot burdens

The AngioJet™ ZelanteDVT thrombectomy catheter is specifically designed to treat deep vein thrombosis (DVT) in large-diameter upper and lower peripheral veins. ZelanteDVT is the most powerful thrombectomy catheter in the market-leading AngioJet portfolio. The catheter makes it possible to more efficiently remove large thrombus burden in veins and restore blood flow, giving you the power to dominate DVTs.

Four times the thrombus-removal power of Solent™ Omni and Solent Proxi catheters

Power Pulse™ enabled for infusion of physician-specified fluids, including thrombolytic agents

Single inflow window for torqueable and directional thrombectomy power

www.bostonscientific.com/zelantedvt

The AngioJet™ Thrombectomy System provides the power and flexibility to remove venous thrombus and restore flow in the most challenging of DVT cases. Recent PEARL Registry data showed[1]:

(ZelanteDVT was not studied in the PEARL Registry)

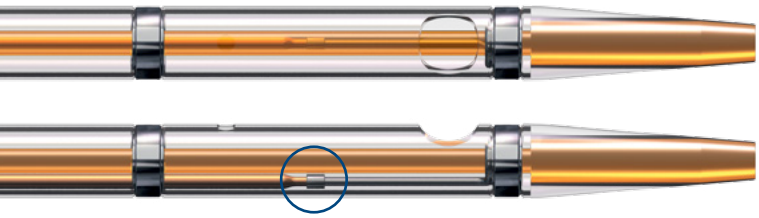
36% of DVT treatments completed in less than 6 hours; **73%** completed in less than 24 hours

No catheter-directed thrombolysis (CDT) in **39%** of venous cases; Lytic delivered by AngioJet (including Power Pulse™) in **87%** of venous cases

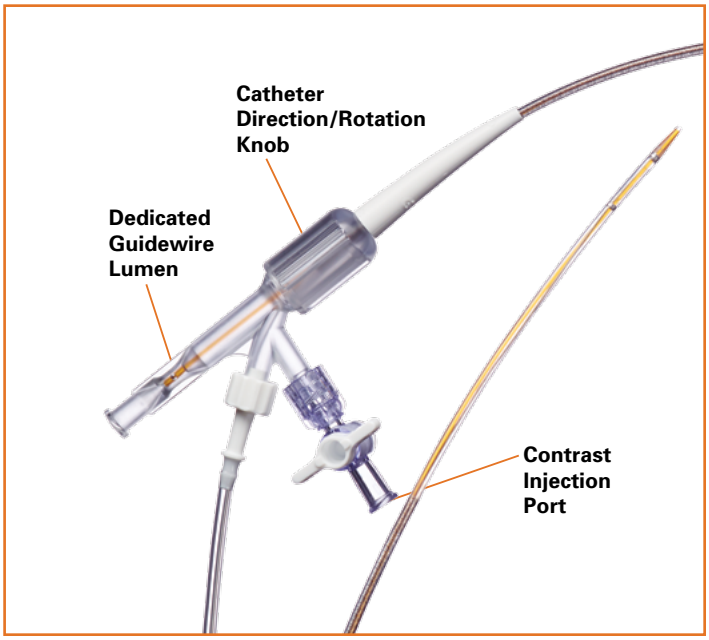
86% of AngioJet venous cases were completed in two or fewer sessions

83% of venous-treated patients had freedom from rethrombosis following 365 days

PEARL



Window Indicator Band



Catheter Specifications

System Compatibility	Ultra
Vessel Diameter	≥ 6 mm (venous)
Working Length	105 cm
Shaft Diameter	8 F (2.7 mm)
Double Marker Band	15 mm
Guidewire Compatibility	0.035" over-the-wire
Sheath Compatibility	8 F
Power Pulse™	Yes

Order Information:

AngioJet™ ZelanteDVT™ Thrombectomy Set Ultra

GTIN (1 per box)	UPN (1 per box)	Catalog (1 per box)
08714729904724	114610-001	114610-001

For use only with the AngioJet Ultra System

Physician's Signature

The C-Code used for the AngioJet ZelanteDVT Thrombectomy Catheter is C1757. C-Codes are used for hospital outpatient device reporting for Medicare and some private payers. Note: Boston Scientific Corporation is not responsible for correct use of codes on submitted claims; this information does not constitute reimbursement or legal advice.

[1]Endovascular Management of Deep Vein Thrombosis with Rheolytic Thrombectomy: Final Report of the Prospective Multicenter PEARL

ZELANTEDVT™ THROMBECTOMY SET

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 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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PI-331201-AB SEP2015