

$\overline{f Z}$ ELANTE $f DVf T^{^{11}}$ paired with f CLOTf HUNTE $f R^{^{11}}$

Thrombectomy Catheter Enhancement

SEEK AND DESTROY DVTs



THERE'S A NEW WAY TO TARGET THROMBUS

CLOTHUNTER

THE FIRST AND ONLY TOOL OF ITS KIND, CLOTHUNTER IS CHANGING HOW TO TARGET ACUTE AND SUB-ACUTE CLOTS

When it comes to treating deep vein thrombosis (DVT), AngioJet™ ZelanteDVT™ Thrombectomy Catheter provides power and flexibility for rapid thrombus removal and quick restoration of blood flow. Now, it offers even greater potential. For more challenging acute and sub-acute cases, pair ZelanteDVT with the ClotHunter™ enhancement for unparalleled control that may provide improved treatment success.



REMOVE MORE CLOT THAN EVER BEFORE

With its improved catheter reach, ClotHunter removes a greater amount of old, sub-acute clot by getting closer to the vessel wall.



Physician-controlled rotational movement combined with a **unique helical shape** broadens the ZelanteDVT treatment area by deflecting the distal end from the traditional straight-wire trajectory to remove tougher thrombus.



Allows for **330-degree sweeps** within a vessel—regardless of its diameter—to attack thrombus.

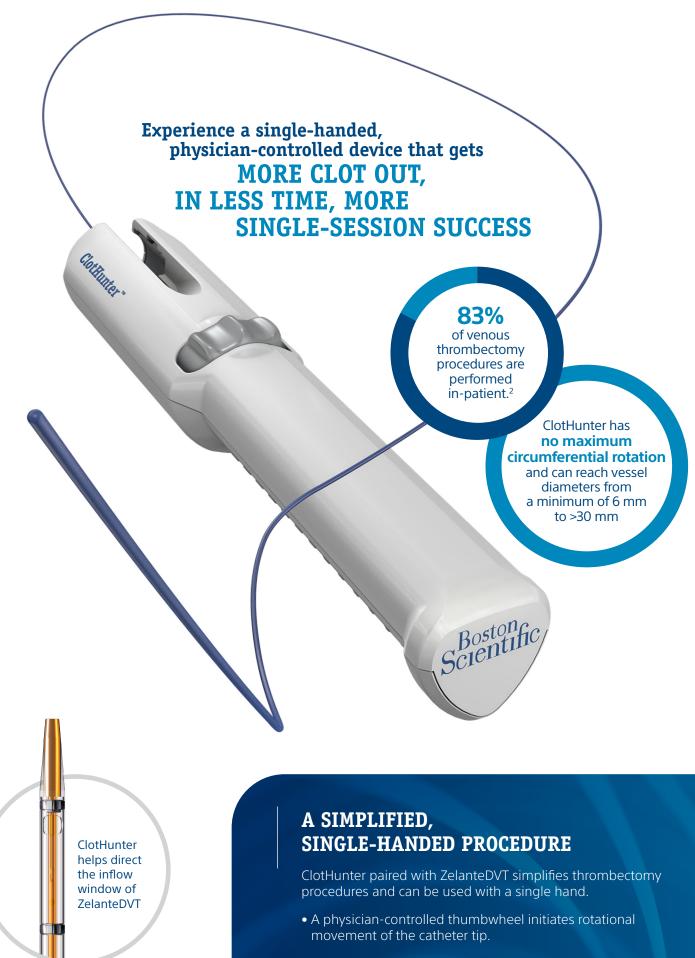


Greater rotational capability provides greater vessel coverage or increased thrombus burden removal.

EXPERIENCE NEW LEVELS OF EFFICIENCY

You want to be as successful as possible with a single DVT treatment. Targeting older clot with ZelanteDVT and ClotHunter can increase your single-session success rate and avoid the need for re-intervention. And the benefits don't stop there. Because ZelanteDVT paired with ClotHunter is designed to increase single-session success rates, in turn it may reduce total procedure time allowing you to treat more DVT patients, increase patient comfort and achieve quicker symptom resolution.

- Research shows that single-session treatment benefits include reduced ICU time, avoiding hospital admission, reducing patient exposure to lytic and reducing procedure room time.¹
- Closer proximity to clot burden is achieved when using ZelanteDVT's Power Pulse™ spray, potentially leading to shorter run times and reduced hemolysis.*



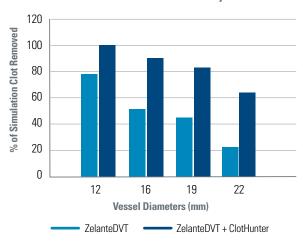
AngioJet™ ZelanteDVT™ Thrombectomy Catheter

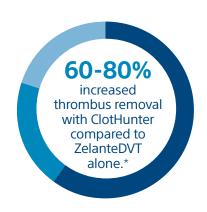
 The catheter inflow window can be pointed precisely next to the vessel wall to increase the amount of exposed clot and maximize removal.

CLOTHUNTER™ COMPARED TO ZELANTEDVT™ ALONE

Enhance the trusted power of ZelanteDVT™ with ClotHunter™ to achieve more single-session success. In a head-to-head comparison, ClotHunter was able to remove more clot compared to ZelanteDVT alone.

Sub-acute Simulation Clot Removal Percentage in 4 Minutes of Thrombectomy Runtime"





IMPROVE YOUR REACH FOR GREATER SUCCESS

Find out how ZelanteDVT paired with ClotHunter can increase your single-session success.

ZelanteDVT ClotHunter

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. INTENDED USE/INDICATIONS FOR USE: The ZelanteDVT Thrombectomy System, which includes the ZelanteDVT Thrombectomy Set and the ClotHunter Helical Rotation Device, is intended for use with the AngioJet Ultra Console to break apart and remove thrombus, including deep vein thrombus (DVT), from: \bullet iliofemoral and lower extremity veins \geq 6.0 mm in diameter and \bullet upper extremity peripheral veins \geq 6.0 mm in diameter. The ZelanteDVT Thrombectomy System 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 ZelanteDVT Thrombectomy System in patients: • who are contraindicated for endovascular procedures. • in whom the lesion cannot be accessed with the quidewire. • who cannot tolerate contrast media. WARNINGS: • The Thrombectomy System 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 System has not been evaluated for use in the carotid or cerebral vasculature. • The Thrombectomy System has not been evaluated for use in the coronary vasculature. • The Thrombectomy System has not been evaluated for use in the pediatric populations. • 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, can be employed, if needed. • Do not use the AngioJet™ Ultra System in patients who have an injury in the target vessel to avoid further vessel injury or hemorrhage. • Do not use the Thrombectomy System in vessels smaller than minimum vessel diameter as listed in Table 1 (in the eIFU); such use may increase risk of vessel injury. • In addition to the heparin added to the saline supply bag systemic heparinization is advisable to avoid pericatheter thrombus and acute rethrombosis. • Use of the Thrombectomy Set in peripheral vessels may result in significant hemolysis which should be monitored to manage possible renal, pancreatic, or other adverse events. Excessive hemolysis may require additional intervention such as blood transfusion, dialysis. Table 1 (in the eIFU) 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 hemolysis 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. • Obstructed lesions that are difficult to cross with the catheter may be predilated with low pressure (≤ 2 atm). Failure to predilate 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 Set is used to break up and remove peripheral venous thrombus. PRECAUTIONS: • Use the Thrombectomy System only with the AngioJet Ultra Console. • The Thrombectomy Set waste tubing 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 tubing of the Thrombectomy Set.

can create injection pressures greater than 100 psi, potentially causing leaks in the waste tubing of the Thrombectomy Set. **POTENTIAL ADVERSE EVENTS:** Potential adverse events (in alphabetical order) which may be associated with use of the Angiolet Ultra Thrombectomy System are similar to those associated with other interventional procedures and include, but are not limited to: • Allergic reaction (to drug, contrast, device or other) • Aneurysm • Arrhythmia • Bleeding/hemorrhage • Cerebrovascular accident (CVA), stroke, transient ischemic attack (TIA) • Death • Embolism (air, plaque, thrombus, device or other) • Hematoma

- Hemolysis Hypotension/hypertension Infection/sepsis Myocardial infarction Need for urgent intervention or surgery

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- Pain Pancreatitis Renal insufficiency/failure Thrombus/thrombosis Vasospasm Vessel injury (perforation, trauma, rupture, dissection, pseudoaneurysm Vessel occlusion Rev. 92619777 A. 1

rupture, dissection, pseudoaneurysm • Vessel occlusion Rev. 92619777 A. 1

*Bench Test results may not necessarily be indicative of clinical performance

- **Clot removal bench test with ClotHunter vs. ZelanteDVT in various sized tubes (x-axis) using sub-acute simclot. Both devices conducted thrombectomy mode for 3.5 mins and percentage of clot removed (y-axis) was measured at the end of each runtime. No lytic agents were used in the bench tests.

 1. All data from double-blinded survey of 61 interventional cardiologists, interventional radiologists and vascular surgeons
- All data from double-blinded survey of 61 interventional cardiologists, interventional radiologists and vascular surgeons completed summer 2017.
- 2. 2018 Hospital Medicare Claims Data PSPSF.

The testing was performed by or on behalf of BSC. Data on file. All trademarks are the property of their respective owners.

ORDER INFORMATION:

ClotHunter™	
GTIN (1/box)	08714729968740
UPN (1/box)	114690-001
Catalog (1/box)	114690-001

ZelanteDVT™		
GTIN (1/box)	08714729904724	
UPN (1/box)	114610-001	
Catalog (1/box)	114610-001	



Peripheral Interventions

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To order product or for more information contact customer service at 1.888.272.1001

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