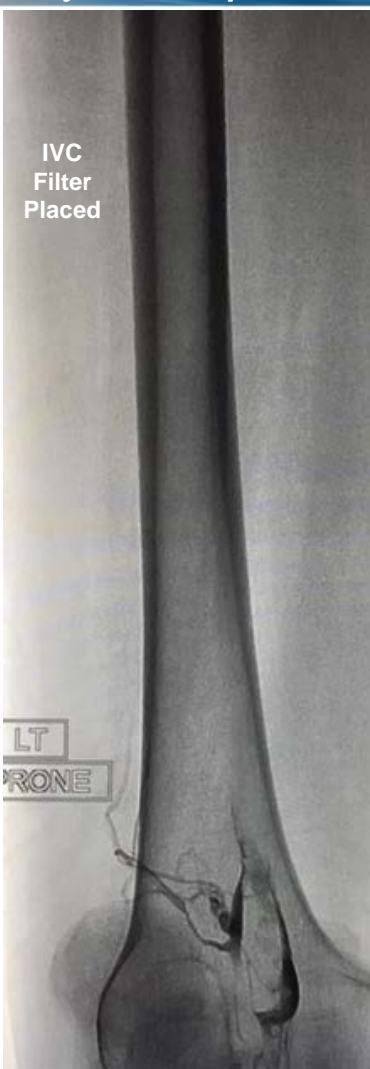


# Pharmacomechanical Revascularization of Extensive IlioFemoral Thrombus

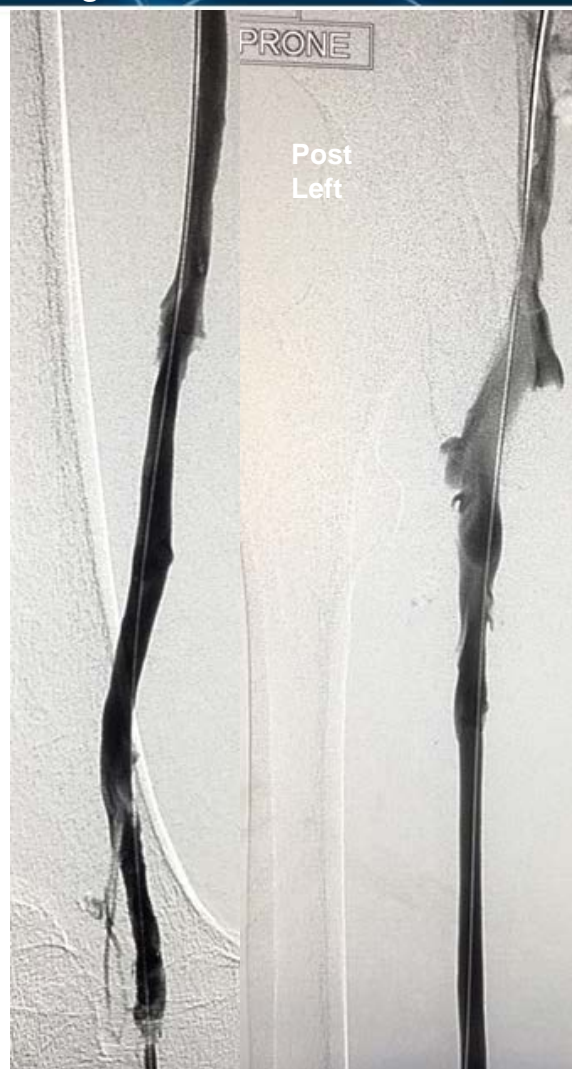
60 y/o female presented with 4 weeks calf pain 1 week swelling



IlioFemoral thrombus pre-treatment



Power Pulse™ delivery 10mg tPA, followed by 20 minute dwell time



Post ZelanteDVT™ Mechanical Thrombectomy



ZelanteDVT runtime 415 seconds  
Total case time 90 minutes

Images Courtesy of Charles Wyble M.D. – Vascular Surgical Associates, Marietta, Georgia–January 5, 2016

# ZelanteDVT™ Thrombectomy Set

## Abbreviated Statement

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

*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  $\geq 6.0$  mm in diameter and
- Upper extremity peripheral veins  $\geq 6.0$  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.

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