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.

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 thrombectomy catheters were used during treatment of pulmonary embolism.

Indications and Usage: The ZelanteDVT Thrombectomy Set is intended for use with the AngioJet Ultra Device to break apart and remove thrombus, including thrombus occluding the femoral or popliteal vessels, and to provide temporary antegrade blood flow in the presence of femoral, iliac, or mesenteric artery embolization. The ZelanteDVT Thrombectomy Set is also intended for use with the AngioJet Ultra System for the treatment of iliofemoral, and infrapopliteal deep vein thrombosis (DVT) and for the treatment of iliofemoral and infrapopliteal venous occlusions in the management of deep vein thrombosis (DVT) and venous outflow obstruction due to chronic venous valvular insufficiency. 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 thrombus particulates debris.

Contraindications: Cautions and Warnings: The ZelanteDVT Thrombectomy Set is contraindicated in the presence of a patient with 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 AngioJet Ultra System in patients who have a hemothorax (hemothorax is a serious adverse event). • Do not use the AngioJet Ultra System in patients who have a hemothorax (hemothorax is a serious adverse event). • Do not use the AngioJet Ultra System in patients who have a hemothorax (hemothorax is a serious adverse event).

Adverse Events: Serious adverse events, including death, are associated with use of the AngioJet Ultra System. 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 thrombectomy catheters were used during treatment of pulmonary embolism. • Systematic heparinization is indicated 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 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. • If a patient has a hemothorax (hemothorax is a serious adverse event), the catheter may cause a vessel dissection or perforation. • Do not use the AngioJet Ultra System in patients who have a hemothorax (hemothorax is a serious adverse event).
The AngioJet™ ZelanteDVT 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.

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

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:

- 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

www.bostonscientific.com/zelantedvt
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**INDICATIONS AND USAGE** The ZelanteDVT Thrombectomy Set is intended for use with the AngioJet Ultra to break apart and remove thrombus, including thrombi that are not amenable to other thrombectomy systems. The ZelanteDVT Thrombectomy Set includes a catheter to deliver the AngioJet Ultra System, which uses a controlled and selective infusion of drug or saline solution to disrupt and remove thrombus.

**ORDER INFORMATION:**

For use only with the AngioJet Ultra System

**Catheter Specifications**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Compatibility</td>
<td>Ultra</td>
</tr>
<tr>
<td>Vessel Diameter</td>
<td>≤ 6 mm (venous)</td>
</tr>
<tr>
<td>Working Length</td>
<td>105 cm</td>
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<tr>
<td>Shaft Diameter</td>
<td>8 F (2.7 mm)</td>
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<tr>
<td>Double Marker Band</td>
<td>15 mm</td>
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<tr>
<td>GuideWire Compatibility</td>
<td>0.035” over-the-wire</td>
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<tr>
<td>Sheath Compatibility</td>
<td>8 F</td>
</tr>
<tr>
<td>Power Pulse®</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**ADVERSE EVENTS:**

Potential adverse events which may be associated with use of the AngioJet Ultra Thrombectomy System include, but are not limited to:

- Cardiac arrhythmias
- Coronary artery spasm
- Coronary artery dissection or perforation
- Hemolysis
- Hypotension or hypertension
- Hypothermia
- Intravascular catheterization
- Myocardial infarction
- Pulmonary embolism
- Thrombosis or partial occlusion
- Vascular perforation
- Venous thrombosis

**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 or safely navigated

**WARNINGS and PRECAUTIONS:**

The ZelanteDVT Thrombectomy Set has not been evaluated for treatment of pulmonary embolism. There are reports of various adverse events, including death, associated with cases where endovascular 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.
- The potential for pulmonary thromboembolism should be carefully considered when the ZelanteDVT Thrombectomy Set is used to break up and remove peripheral venous thrombi.

- If resistance is felt during the advancement of the ZelanteDVT Thrombectomy Set into the lesion site, do not force or torque the catheter excessively as this may result in deterioration or tip separation leading to embolization.

**Catheter Directions/Rotation Positions**

- Dedicated GuideWire Lumen
- Dedicated GuideWire Knob
- Dedicated Window Indicator Band
- Dedicated Injection Port

**Order Information:**

<table>
<thead>
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<th>GTIN (1 per box)</th>
<th>UPN (1 per box)</th>
<th>Catalog (1 per box)</th>
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