Clearing the Clot

Over the years, physicians using the AngioJet™ Thrombectomy System for deep vein thrombosis (DVT) treatment expressed their need to more efficiently address the large thrombus burden that is often found in the iliofemoral veins. Specifically, physicians treating DVTs in the iliofemoral veins found that a significant number of cases still required an overnight thrombolytic drip to achieve a more complete resolution of thrombus. This resulted in the need for a new AngioJet catheter: the ZelanteDVT™ (Boston Scientific Corporation), with power that could remove the thrombus burden in large venous vessels, aiding in decreased treatment times.

DESIGN CONSIDERATIONS FOR THE NEW ANGIOJET CATHETER

One of the barriers to removing large, organized thrombus is the inflow window size of the current 6-F AngioJet catheters (Solent Omni and Solent Proxi). The unique mechanism of action within the AngioJet catheters is based on the high-speed jets that create a near-perfect vacuum to pull in and break up the thrombus. Because the inflow window size on the 6-F catheters only allows relatively small-sized thrombus to enter, Boston Scientific aimed to specially design a catheter to address large, organized thrombus burden, which meant having a larger inflow window. The resulting design demonstrated that having one large inflow window instead of three or four small windows, as on predicate catheters, enables this catheter to most optimally remove the thrombus burden found in larger iliofemoral and upper extremity peripheral veins. Because the inflow window pulls in thrombus from one side of the catheter, the outflow jet, which liberates the thrombus from the vessel wall, was shifted to the inflow window side of the catheter. Therefore, the design includes only one outflow window located on the same side as the large inflow window. The outflow jet is also more powerful than the 6-F AngioJet models, which aids this catheter in more efficient removal of tough thrombus from the vessel walls.

In addition, the unidirectional design of the windows drove the need for a rotating hub, so the single window could be swept around the vessel in order to clear thrombus on all sides. To facilitate improved visualization of the window orientation, a marker band was added opposite the window and is visible under fluoroscopy. When using the rotating hub, the inflow window directional design allows the user to direct the thrombus removal power where it is needed most. The Power Pulse™ feature remains on the ZelanteDVT catheter but is also directionally controllable, which may aid in more uniform distribution of the physician-specified fluid.

Lastly, from a design standpoint, a dedicated guidewire lumen was created to ensure that the 0.035-inch guidewire could not potentially exit through the now much-larger inflow window. Developing a catheter with a dedicated guidewire lumen also provides the user with easy guidewire exchanges and eliminates the need for a hemostasis valve. As a result, a larger 8-F lumen was required to accommodate these requirements.

THE ZELANTE DVT CATHETER WAS BORN

The AngioJet ZelanteDVT catheter design has a single inflow window with a surface area that is 60% larger than the combined area of four inflow windows on the Solent Omni and Proxi. The larger window combined with a more powerful outflow jet has created a catheter that can remove four times more thrombus* in the same amount of time as the Solent catheters.

With its more powerful action, it is limited to a minimum indicated vessel diameter of 6 mm, whereas the Solent Omni and Proxi are ideal catheters when treating vessels of 3 mm in diameter. Preclinical testing showed that in its vessel size range, the ZelanteDVT’s safety profile is the same as the Solent Omni catheter. Hemolysis with the ZelanteDVT is also similar to the Solent catheters for its respective indicated vasculature. Therefore, the ZelanteDVT catheter allows more efficient treatment of large DVT while maintaining its safety profile.

ZelanteDVT was designed specifically to fill an unmet physician need to address larger, more organized thrombus. This new catheter enables physicians to more efficiently treat large vein DVTs.

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

INDICATIONS AND USES

• The Zelante DVT Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus, including venous thrombus (DVT), from:
  - Femoral and lower extremity veins ≥ 8.0 mm in diameter and
  - Upper extremity peripheral veins

The Zelante DVT Thrombectomy Set is also intended 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 Zelante DVT 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 Zelante DVT Thrombectomy Set has not been evaluated for use in the carotid or cerebral vasculature.
• The Zelante DVT Thrombectomy Set has not been evaluated for use in the coronary vasculature (unless accompanied by a separate coronary IFU).
• Use of standard contrast medium can be delivered through the thrombectomy catheter via the manifold port stopcock.

ADVERSE EVENTS

Potential adverse events which may be associated with use of the AngioJet Ultra Console System are similar to those associated with other interventional procedures and include, but are not limited to:

• Abnormal blood pressure, 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 Zelante DVT Thrombectomy Set in vessels smaller than minimum vessel diameter as listed in Table 1 of the AngioJet Thrombectomy Sets Instructions for Use for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

INDICATIONS and USES

The AngioJet SOLENT proxi & omni Thrombectomy Sets are intended for use with the AngioJet Ultra Console only with an AngioJet Ultra Thrombectomy Set. This Console will not operate with any other interventional tools or components.

• 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 System are similar to those associated with other interventional procedures and include:

• 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 • hypotension • injury to the lumen (i.e. not against the vessel wall) • laceration • perforation • pseudoaneurysm • reactions to contrast medium • thrombosis/occlusion • total occlusion of treated vessel • vascular aneurysm • vessel wall necrosis.

SOLENT catheter COMBINED W/CONSOLE

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INDICATIONS AND USES

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 veins ≤ 13.0 mm in diameter
• Upper extremity peripheral veins ≤ 10.0 mm in diameter
• Femoral and lower extremity veins ≤ 13.0 mm in diameter
• AV A/Access conduits ≤ 13.0 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.

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. There are reports of severe adverse events which may be associated with use of the AngioJet Ultra System are similar to those associated with other interventional procedures and include:

• 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 • hypotension • injury to the lumen (i.e. not against the vessel wall) • laceration • perforation • pseudoaneurysm • reactions to contrast medium • thrombosis/occlusion • total occlusion of treated vessel • vascular aneurysm • vessel wall necrosis.

AMPLATZ SUPER STIFF GUIDEWIRE

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INTENDED USES/INDICATIONS FOR USE

The Amplatz Super Stiff guidewire facilitates catheter placement and exchange during diagnostic or interventional procedures, and may be used in conjunction with the AngioJet Ultra System.

CONTRAindications

None known.

WARNINGS:

Thrombectomy Sets should be used only by physicians with a thorough understanding of angiography and percutaneous interventional procedures. Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated.

ADVERSE EVENTS

Potential adverse events which may result from use of the device include but are not limited to:

• Air Embolism
• Thromboembolism, Allergic Reaction, Amputation, Arteriovenous (AV) Fistula, Death, Embolism, Hematoma, Hemorrhage, Hepatic Insufficiency, Infusion or Sepsis/Infusion, Myocardial ischemia and/or Infarction, Pseudoaneurysm, Stroke (CVA)/Transmural Ischemic Attacks (TIA), Thrombus, Vessel Occlusion, Vessel Perforation/ Dissection/Trauma, Vessel Spasm, Wire Entrapment/Entanglement, Foreign body/Wire

Do not use the stated potential adverse events may require additional surgical intervention.

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blood is not visible in the waste tubing during AngioJet Ultra System activation, the catheter may be occlusive within the vessel when the catheter position, vessel diameter and thrombus status. Operation under occlusive conditions may increase risk of vessel injury.

Do not leave the guide wire in the catheter guide wire in the catheter during the 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. (Dexta only)

• Use of a tip guide wire is not recommended as it is possible for the tip of the guide wire to exit through a catheter lesion. If resistance is felt during 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.