The Need to More Efficiently Treat Large Vein Thrombus

Conceptualizing the new 8-F AngioJet™ ZelanteDVT™ Catheter.

BY MARK HILSE, MS

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 ZELANTEDVT 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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*When compared to current 6-F AngioJet catheters. Bench test data on file. Bench test results may not necessarily be indicative of clinical performance.

ABBREVIATED STATEMENTS

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

SOLENT CATHETERS COMBINED W/CONSOLE

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INDICATIONS AND USAGE

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 peripheral arteries ≥ 3.0mm in diameter,
- upper extremity peripheral veins ≥ 3.0mm in diameter,
- ileofemoral and lower extremity veins ≥ 3.0mm in diameter,
- A-V access conduits ≥ 3.0mm 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 AngioJet SOLENT dista Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:
- upper and lower extremity peripheral arteries 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 (unless accompanied by a separate coronary IFU).
- 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 nonhealed injury due to recent mechanical intervention, in the vessel to be treated, to avoid further injury, dissection, or hemorrhage.
- Do not use the Thrombectomy Set in vessels smaller than minimum vessel diameter for each Thrombectomy Set model as listed in Table 1 (in 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.
- Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the IFU) 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 hemoglobinemia 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.
- Large thrombus burdens in peripheral veins and other vessels may result in significant hemoglobinemia which should be monitored to manage possible renal, pancreatic, or other adverse events.
- Monitor thrombotic debris/fluid flow exiting the Thrombectomy Set via the waste tubing during use. If blood is not visible in the waste tubing during AngioJet Ultra System activation, the catheter may be occlusive within the vessel; verify catheter position, vessel diameter and thrombus status. Operation under occlusive conditions may increase risk of vessel injury.
- Do not exchange the guide wire. Do not retract the guide wire into the catheter during 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. (Dista only)
- Use of a J-tip guide wire is not recommended as it is possible for the tip of the guide wire to exit through a side window on the distal end of the catheter. (Omni, Proxi only)
- Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, remove the catheter together with the sheath or guide catheter as a unit to prevent possible tip separation.
- If resistance is felt during the 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.

(Below is Omni, Proxi only)
- Hand injection of standard contrast medium may be delivered through the thrombectomy catheter via the manifold port stopcock. Follow the steps to remove air from the catheter when delivering fluid through the catheter stopcock.
- Fluids should be injected only under the direction of a physician and all solutions prepared according the manufacturer instructions.
- The Thrombectomy Set waste lumen is rated for 50psi. Delivering a hand injection of contrast medium with excessive force can create injection pressures greater than 50psi, potentially causing leaks in the waste lumen of the catheter.
- Do not use a power injector to deliver contrast medium through the catheter stopcock. Power injectors can deliver pressures greater than 50psi, potentially causing leaks in the waste lumen of the catheter.
- Some fluids, such as contrast agents, can thicken in the catheter lumen and block proper catheter operation if left static too long. The catheter should be operated to clear the fluid within 15 minutes of injection.

Console WARNINGS and PRECAUTIONS:
- Use the AngioJet Ultra Console only with an AngioJet Ultra Thrombectomy Set. This Console will not operate with a previous model pump set and catheter.
- Do not attempt to bypass any of the Console safety features.
- If the catheter is removed from the patient and/or is inoperative, the waste tubing lumen, guide catheter, and sheath should be flushed with sterile, heparinized solution to avoid thrombus formation and maintain lumen patency. Reprime the catheter by submerging the tip in sterile, heparinized solution and operating it for at least 20 seconds before reintroduction to the patient.
- Refer to the individual AngioJet Ultra Thrombectomy Set Information for Use manual for specific warnings and precautions.
- Do not move the collection bag during catheter operation as this may cause a collection bag error.
- Monitor thrombotic debris/fluid flow exiting the catheter through the waste tubing during use. If blood is not visible during console activation, the catheter may be occlusive within the vessel or the outflow lumen may be blocked.
- Ensure adequate patient anticoagulation to prevent thrombus formation in outflow lumen.
- Refer to individual Thrombectomy Set Instructions for Use manual for specific instructions regarding heparinization of the Thrombectomy Set.
- The Console contains no user-serviceable parts. Refer service to qualified personnel.
- Removal of outer covers may result in electrical shock.
- This device may cause electromagnetic interference with other devices when in use. Do not place Console near sensitive equipment when operating.
- Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Where the "Trapping Zone Hazard for Fingers" symbol is displayed on the console, there exists a risk of trapping or pinching fingers during operation and care must be exercised to avoid injury.
- Do not reposition or push the console from any point other than the handle designed for that purpose. A condition of overbalance or tipping may ensue.
- The AngioJet Ultra Console should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the AngioJet Ultra Console should be observed to verify normal operation in the configuration in which it will be used.
- Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
- The use of accessories and cables other than those specified, with the exception of accessories and cables sold by Bayer HealthCare as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Ultra Console.
- MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding Electro-Magnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the tables provided in the IFU.

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

AMPLATZ SUPER STIFF GUIDEWIRE

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INTENDED USE/INDICATIONS FOR USE

The Amplatz Super Stiff guidewire facilitates catheter placement and exchange during diagnostic or interventional procedures. Not intended for use in coronary arteries. The tip of the guidewire is not designed to be reshaped. Reshaping of the tip could result in damage to the guidewire. Attention should be paid to guidewire movement in the vessel. Always advance or withdraw a wire slowly. Never push, auger, or withdraw a guidewire which meets resistance. Resistance may be felt tactilely or noted by tip buckling during fluoroscopy. When reintroducing a guidewire into a catheter within a vessel, confirm that the catheter tip is free within the lumen (i.e. not against the vessel wall). Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

CONTRAINDICATIONS

None known.

WARNINGS:

This device 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 the use of the device include but are not limited to:
Air Embolism/Thromboembolism, Allergic Reaction, Amputation, Arteriovenous (AV) Fistula, Death, Embolism, Hematoma, Hemorrhage, Hemoglobinuria, Infection or Sepsis/Infection, Myocardial Ischemia and/or Infarction, Pseudoaneurysm, Stroke (CVA)/Transient Ischemic Attacks (TIA), Thrombus, Vessel Occlusion, Vessel Perforation/ Dissection/Trauma, Vessel Spasm, Wire Entrapment/Entanglement, Foreign body/Wire Fracture. Some of the stated potential adverse events may require additional surgical intervention.