

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 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. ■

Mark Hilse, MS, is an AngioJet R&D Manager for Boston Scientific Corporation. He may be reached at mark.hilse@bsci.com.

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