Q50 Stent Graft Balloon Catheter Case Study

Customer Challenge

A medium-sized global medical device distributor wanted a catheter with a large balloon diameter to treat abdominal aortic aneurysms (AAAs). The distributor's customer did not have a balloon catheter large enough for their patients' anatomy. The balloon had to be strong enough when expanded to iron out the stent graft without bursting during the Endovascular Aneurysm Repair (EVAR) procedure. The global medical device distributor came to Via Biomedical for a timely, cost-effective, and quality medical solution.

The challenge of the project was to build a balloon that was larger than other competitors on the market, in addition to combining the capabilities of two separate balloons into a singular balloon. Although the balloon needed to have more capabilities, it still had to fit the client's original profile requirements.

The balloon needed to be strong enough to fully expand, seal aortic stent grafts in patients, and work in all anatomy sizes. Like similar devices, the catheter would be trackable and have a compliant balloon that would inflate and deflate rapidly to give physicians more control.

Via Solution

The distributors engineer(s) met with the Via Biomedical production team to develop a marketing specification and prepare a design/development plan. After identifying the product, they worked with Via's team to produce a design freeze, which took three months. Via communicated with the client in weekly conference calls to discuss the progress of the product.

Via filed a 510(K) with the FDA to demonstrate that the catheter to be marketed was substantially equivalent, with the same intended use and technological characteristics as other legally marketed catheters not subject to premarket approval. Throughout the process, Via kept records of the history, build, data, medical device testing, and material pedigrees so that the device would be defendable to the FDA. Via also signed a contract with the distributors, who would return with any field complaints. Via was responsible for providing manufacturing data of the finished medical device related to medical complaints. Via engineers worked to meet the requirements of the design:

- Compatible with a 12Fr introducer
- Balloon capability of 60 cc of fluid
- Balloon diameter range of 10mm to 50mm

The next step involved developing a catheter balloon mold for the device and acquiring initial catheter tubing material. Via Biomedical chose materials that were compatible with one another and blended them with thermal bonding. Through bonding, welding, and folding, Via's catheter designers created a one-unit device that offered a seamless stent delivery system.

In the balloon forming process, Via had to tighten up the standard deviation on the volume of the balloon burst. This was to ensure that all the balloons would burst with the same tendencies so that the customer could rely on the balloon performance. Via worked to find a reliable plastic material that was

strong enough to withstand the volume of fluid needed to expand the stent grafts against the vessel walls. The team chose a soft balloon that uses volume to expand and performed characterization testing on the prototype. Via documented and performed all mechanical testing and review of the prototype.

The team worked closely with the client to create a balloon catheter according to their original vision. After Via presented the design freeze, the client decided they wanted an additional balloon design and asked Via to present a new product as quickly as possible. All redesign and 510(K) testing was completed within a month.

Resolution

Via designed many iterations of prototypes and improved the device each time. Via Biomedical finished the product within the client's timeline. Via designed, tested, packaged, labeled, and shipped the product within the client's budget and specifications. As the owner of the 510(K) contract, Via Biomedical brought the product from concept to distribution, performing and organizing all services including

- Documenting, reviewing catheter design inputs, and developing test plans.
- Testing the product, reviewing test results, and processing validations.
- Organizing biocompatibility, medical device sterilization, and shelf-life testing through another vendor on behalf of the client.
- Building the product at the Via Biomedical lab and releasing it to distributors.
- Creating commercial packaging and designing labels.
- Packaging and shipping to medical device distributors.

The resulting full stent graft balloon catheter met the 510(K) requirements with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, and standards. The device was cleared for commercial distribution and was received well in the marketplace on all accounts. Any reported incidents in the field were not because of device malfunction, but rather, off-label use by a physician.

The Q50® Stent Graft Balloon Catheter consists of:

- Multi-lumen catheter shaft
- Compliant polyurethane balloon
- Radiopaque marker bands
- Strain relief
- Integral extension with 3-way stopcock

The device is a tri-lumen polyurethane balloon catheter that can expand to 50 mm at 60 cc. The catheter accommodates a 0.038" diameter guidewire that runs through the medical tubing and has two radiopaque marker bands inside the balloon that facilitate placement of the balloon in the vessel. It offers a short, flexible tip with optimized catheter trackability through challenging anatomy, and a robust polyurethane balloon with exceptional inflation control.

The Q50® Stent Graft Balloon Catheter is compatible with standard guidewires and low-profile introducer sheaths. This product offers a broad diameter range and low profile for use with aortic stent grafts that treat abdominal and thoracic aneurysms (AAA/TAA) and is also ideal for occlusion of large vessels. Though the device has changed distributors, it is available in the US, Canada, and Europe.

The Q50® Stent Graft Balloon Catheter became the leading aortic endograft molding balloon for complex and straightforward procedures. Via Biomedical brought the product from a napkin sketch to 510(K) approval and FDA clearance. Eventually, Via Biomedical negotiated the transfer of ownership for the Q50® Stent Graft Balloon Catheter to the distributor who stills sell this product today.