Novel polymer based Trans Catheter Aortic Valve Implant (TAVI)

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The Direct Flow Medical Transcatheter Aortic Valve System is a novel system utilizing an inflatable cuff with a conforming polymer support structure. Inflatable rings at the top and bottom of the valve are designed to conform and seal above and below the native valve to virtually eliminate aortic regurgitation. The Direct Flow system provides significant advantages over the commercial stented metallic based devices. The lack of a metallic frame allows for a low profile, flexible, fully-sheathed system with the potential to reduce bleeding and vascular complications, particularly in patients with tortuous and variable anatomy. Full-thickness bovine pericardial leaflets are incorporated in the valve design for durability. The valve can be repositioned even after the implant is fully expanded to its final configuration, providing a unique ability to assess clinical outcomes before final deployment. The conforming nature of the Direct Flow device also allows for lower paravalvular leaks when compared to the metallic TAVI devices.

The Direct Flow TAVI system utilizes a novel injectable in-vivo curing polymer to form the conforming support structure of the valve. The polymer is a radiopaque novel epoxy/amine system with unique chemical and mechanical properties designed to meet the demands of a TAVI procedure. The polymer is a two part epoxy amine system which cures in-vivo to form a highly cross-linked thermoset support for the valve. The polymer was designed to meet the unique needs of a TAVI procedure and a permanent implant.

The polymer is mixed ex-vivo and is injected into the nylon inflatable channels within the bioprosthesis through a small inflation needle. The polymer was designed for low viscosity for quick exchange time and with a good working life for the duration of the filling. The polymer was designed to be radiopaque to allow for visualization of the device. Upon filling, the polymer was designed to gel at physiological conditions in less than 2hrs to prevent any leakage. It then quickly achieves its fully cured thermoset properties to provide the rigid support structure for the valve. It was designed to be biocompatible in the both liquid and cured state in case of exposure. The polymer is designed to have excellent fatigue properties and is able to with stand 600 million cycles under physiological loading with significant safety factor. It also has good stability in-vivo with low water absorption, steady tensile strength (60MPA), glass transition temperature (65ºC) and good creep resistance in use.

Methods: The Direct Flow bioprosthesis completed the Discover CE mark study. The study design is a Prospective, multicenter, non-randomized clinical trial of the Direct Flow Medical Percutaneous Aortic Valve 18F System for the treatment of severe aortic stenosis. The primary end point was freedom from all mortality with the secondary end point being device success

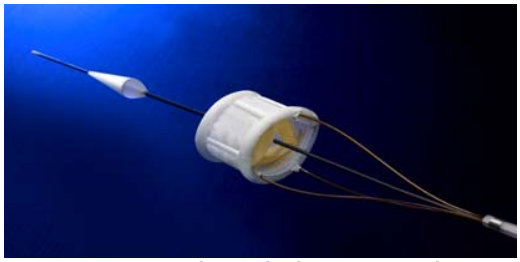
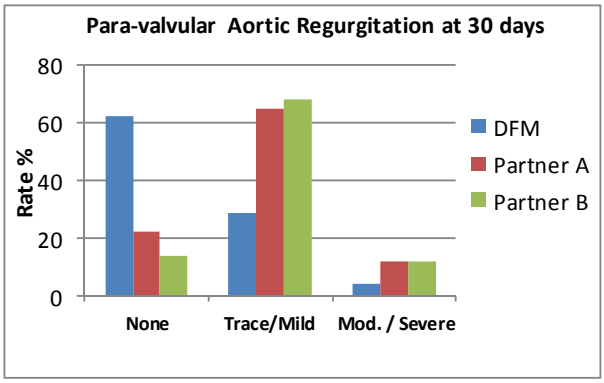


Figure 1. Direct Flow Medical Aortic Bioprosthesis

Results and discussion: The Direct Flow valve achieved 97% freedom from all causes of mortality and 100% freedom from cardiovascular mortality. The study concluded that the DFM valve can be used safely and effectively to treat high and extreme surgical risk patients with aortic stenosis. The DFM valve allowed for controlled positioning, repositioning and retrieval. The performance of the DFM valve was comparable to the published approved Edwards Sapien data. However, rates of paravalvular aortic regurgitation are noticeably lower for the Direct Flow Medical device than that published for the approved Edwards Sapien device and remains stable over time (see figure 2). The Direct Flow Medical received CE mark in January 2013 and US IDE trial was initiated in August 2013. Currently over 200 patients have been treated with the Direct Flow valve with excellent clinical results.



References:
1) Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 2010;363:1597-1607 Supplementary Appendix