REPAIRING THE HEART WITHOUT OPENING THE BODY - AWESOME

CONTRIBUTED BY

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Figure 1: TAVR access sheaths and dilators enable vascular entry and maintain hemostasis

NOTE TO READERS:
CREGANNA MEDICAL IS NOW PART OF TE CONNECTIVITY (TE)

Creganna Medical has been ranked among the Top 10 global companies in the medical device outsourcing industry and specializes in the design and manufacture of minimally invasive delivery and access devices for a range of therapies. With Creganna now part of the TE family, TE serves the world's leading medical device and life science companies with over 400 companies across 30 countries. Together, we have a global operational footprint with design and manufacturing facilities spanning the US, South America, Europe and Asia.

ADVANCES IN HEART SURGERY: TAVR

The aortic valve of the heart plays a critical role in keeping us alive by returning oxygenated blood to the body. As we get older, this valve may harden making the heart pump blood less effectively, weakening the heart muscle, and ultimately leading to heart failure. Those diagnosed with this progressive valve disease require treatment or face a bleak outcome.

In the past, the only option for many people was invasive open heart surgery where the heart is stopped and a prosthetic surgical valve replaces the diseased valve. Then in 2002, Dr. Alain Cribier pushed the boundaries of what was possible in medicine, performing the first Transcatheter Aortic Valve implantation or TAVR procedure. [1]

During a TAVR procedure, small incisions are made in the groin to access arteries. Through this access point a number of miniature medical devices such as guidewires, balloon catheters and introducer sheaths, many containing TE technologies, are introduced into the body to prepare it for minimally invasive implantation. The replacement valve, framed on a metal scaffold and mounted on a delivery system the diameter of a ballpoint pen, is navigated through the patient's arteries to the heart valve. Once the replacement valve is carefully positioned and deployed, the physician removes the accompanying devices from the patient, closes the entry point in the groin and the patient starts recovery.

THE TECHNOLOGY ENABLING TAVR

From a connectivity standpoint, there are two key devices, which TE develops from subassemblies to full device solutions, that enable the medical devices needed for the TAVR procedure. The first is the **access sheath** that enables the surgeon to enter the body at a small entry point in the femoral artery and then gently expand the artery to accommodate the delivery catheter which carries the replacement valve. It also serves a dual purpose as it maintains hemostasis at the access point, preventing blood from flowing out of the body during the procedure.

The second is the **delivery catheter,** the device conduit responsible for delivering the implant from the access point, through the arterial system, across the aortic arch and into the annulus of the native aortic valve. This delivery system typically comprises inner and outer catheter shafts, a complex deployment handle that remains outside the patient and a system to deploy the prosthetic valve within the patient.

Design of the optimum components for medical subassemblies such as the access sheath and delivery catheter requires balancing multiple performance characteristics; the devices have to be flexible and small enough to maneuver through the complex anatomy of the body yet structurally robust to ensure the replacement valve is safely guided to its location. When designing the components and subassemblies for TAVR, TE engineers focus on three key design areas:

- **SIZE:** The access sheaths and delivery shafts are designed with low profile walls. The incidence of vascular injury is closely related to the diameter of the access and delivery catheters; smaller sized devices significantly decrease access site complications to minimize vascular injury and ensure faster recovery for patients. TE shafts are designed to have an outer diameter as small as possible to complement the current trend for 14 French (14F) equivalent devices.
- **STRUCTURAL INTEGRITY:** The overall structure of the access sheath and delivery catheters needs to be robust. Design of the catheter shaft and the design materials collectively ensure this structural integrity. For example, the choice of material determines the level of pushability, torque and flexibility while design is important in determining the curves, angles of deflection and steerability of the catheter (reference Table 1 for shaft performance characteristics).[2]
- **OPTIMIZING PERFORMANCE:** While the delivery system needs to be highly rigid and robust to manipulate through the body, it also needs to be flexible enough to get around the acute angle of the aortic arch without causing a kink in the shaft or compromising overall structural integrity of the device. TE specifically places emphasis on optimizing sheath design to balance flex and kink performance, thereby providing the optimal overall design to ensure precise navigation of devices throughout the procedure.

Figure 2: Low-profile braided shafts for TAVR valve delivery systems

Desired shaft performance characteristics		
Characteristic	**Definition**	**Essential When**
Pushability	The ability of a shaft to transmit force from the proximal to the distal end of a delivery system	Navigating tortuous anatomy
Kink resistance	A measure of the shaft's ability to maintain its cross-sectional profile during deformation	Navigating a tight radius within the anatomy
Torque	The ability of a shaft to transmit a rotational displacement along its length.	Optimizing accuracy for placement of the treatment device
Flexibility	The ability of a shaft to navigate through difficult anatomy	Accessing complex anatomy
Compression resistance	The ability of the shaft to resist longitudinal compression	Delivery device must not compress during device deployment, particularly when delivering implants incorporating shape memory alloys

Table 1: Desired shaft performance characteristics[3]

As the TAVR market continues to grow, TE is partnering with medical device OEMs to design delivery and access devices that have a lower profile to improve access and reduce risk of vascular complications; allow for easier navigation through the body; and are stronger and even more flexible to improve the overall outcome of the TAVR procedure.

Continuous innovation and testing at every stage of the medical product life cycle helps further enable the advancement of minimally invasive surgery. Our expertise spans the manufacturing and design of the next generation of catheters from product conception to the assembly and field management of finished catheter devices. We offer a comprehensive range of catheter technologies, metal shafts, wire and coil, braided shafts, coiled shafts, extruded shafts and medical balloon molding.

Whether you're looking to develop a new minimally invasive device or another medical solution, TE Connectivity can help design, manufacture, and commercialize the highest quality solutions.

LEARN MORE ABOUT HOW TE ENGINEERS FOR TOMORROW
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