

Admedus

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## Superior cardiovascular tissue repair solutions improve outcomes for patients

**ADAPT biomaterial scaffolds outperform all competitors, having achieved 9 years without calcification or degradation and delivering positive health benefits to patients around the world.**

Admedus is a global healthcare company that develops, commercializes and distributes next-generation medical technologies and devices. The company's ADAPT engineering process produces implantable tissue bioscaffolds for a range of cardiovascular and vascular applications. These products, which include CardioCel, CardioCel Neo, CardioCel 3D and VasculCel, are currently used by surgeons around the world to treat patients with congenital heart defects and those in need of heart valve, vessel and cardiovascular repairs and peripheral vascular reconstruction.

Admedus's clinically superior ADAPT biomaterial scaffolds are the only products of their kind with 9 years of clinical data that demonstrate zero calcification or degradation. Moreover, ADAPT-treated tissue has been scientifically proven to more closely mimic the characteristics of normal human tissue, promoting a more tolerant immune response and improved tissue ingrowth without toxicity. The lack of calcification or toxicity provides significant benefit to patients who would otherwise be forced to undergo recurrent valve replacement operations.

With the potential for a product lifespan free from calcification, physicians can potentially intervene across a broader age spectrum and provide their patients with a lifelong solution. "Our mission is to provide patients around the world with a better quality of life through access to our innovative technology and products," said Admedus president and CEO Wayne Paterson. "The potential of our ADAPT technology is almost beyond measure, as we continuously expand its purpose and application."

### Clinically superior tissue engineering technology

The company's flagship product, CardioCel, is an implantable bioprosthetic scaffold that has delivered positive health outcomes for thousands of patients across a wide range of clinical applications in more than 200 centers worldwide. CardioCel is used to repair congenital heart deformities and more complex heart defects, and to reconstruct dysfunctional heart valves and valve leaflets. The durable bioscaffold is easier to handle and use, owing to its natural flexibility and elasticity, and actively facilitates host tissue regeneration and blood flow postimplantation. It is also available as CardioCel Neo for use in neonatology.

The ADAPT portfolio also includes VasculCel—a next-generation collagen scaffold for restorative vascular repair. Similar to all ADAPT products, it offers optimized healing and clinical performance,



Research being carried out at the Admedus laboratories.

enhanced procedural efficiency and improved handling for a broad spectrum of vascular surgical procedures.

In February, Admedus was pleased to launch its latest cutting-edge product, CardioCel 3D—the world's first curved biological tissue product and a disruptive technology in the highly complex congenital defect repair space. At the forefront of cardiovascular science, it has a unique preshaped curve that provides physicians immediate access to an off-the-shelf, optimized arch reconstruction solution with a nonantigenic response and unique calcification resistance.

Current alternative products are limited in their abilities to meet all patient and physician needs, often requiring a compromise in terms of clinical benefit and outcome. With CardioCel 3D, such trade-offs are not required. Surgeons can achieve a more natural shape, allowing for optimal compliance and dynamics, while simultaneously providing the superior clinical benefits of ADAPT technology to deliver transformative healing. 3D is an area of significant interest to Admedus as it looks to develop a range of new preshaped tissue products.

The company recently entered into an agreement with a major compliant group purchasing organization, giving Admedus direct access to promote its ADAPT products in more than 1500 hospitals in the United States and the potential to claim a greater share of the cardiovascular surgery and tissue repair market.

CardioCel is approved or cleared for sale in countries across Europe, North America, Asia and the Middle East and North Africa (MENA) region. Admedus is currently working through approvals processes in Mexico and China and expects to receive regulatory approval in Australia during 2018, which will help expedite the approvals processes in the Association of Southeast Asian Nations (ASEAN) and the MENA region. VasculCel and CardioCel 3D are currently available in North America.

### Expanding opportunities

Last October, the company submitted two separate intellectual property applications in the United States for the development of its novel ADAPT transcatheter aortic valve replacement (TAVR) device. During TAVR procedures, a valve is placed into the heart via a catheter (usually inserted through the leg) to replace the aortic valve, eliminating the need for open-heart surgery. The less invasive TAVR procedure is considered the best alternative treatment for patients who are not suitable candidates for traditional valve replacement surgery and therefore represents a significant commercial opportunity.

Current TAVR products on the market contain three separate pieces of tissue held together by more than 100 sutures. In comparison, the Admedus TAVR prototype device features a three-leaflet, single-piece, 3D-molded valve created using the ADAPT technology, which securely attaches to a stent with minimal sutures. Admedus has also patented a sterile hydropackaging system that substantially reduces TAVR preparation and surgical time. Through these innovations, Admedus aims to create the best TAVR device on the market—one that is less expensive to produce, more efficient to use and, most importantly, delivers optimal health outcomes for patients.

All ADAPT products are created at the company's state-of-the-art manufacturing facility in Australia which has substantial capacity to expand and includes an in-house research laboratory for the development and testing of new products. "Admedus loves innovation and cutting-edge science. We're always looking for new opportunities to grow, expand and transform our business," said Paterson. "By investing in world-class research and building collaborative partnerships with global leaders in the medical community, Admedus is emerging as a credible force within the medtech sector, delivering unique and clinically superior healthcare solutions."

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