

Admedus  
www.admedus.com



## Admedus: Superior cardiovascular-tissue-repair products

**Based on its proprietary ADAPT tissue-engineering technology, Admedus is developing an expanding portfolio of next-generation 3D tissue products for cardiovascular repair. The products will expand its range of durable bioscaffolds, which have achieved 10 years without calcification or degradation.**

Admedus is a medical technologies company with a growing portfolio of cardiovascular products based on its proprietary ADAPT tissue-engineering technology. The ADAPT portfolio of implantable tissue bioscaffolds includes CardioCel, CardioCel Neo, CardioCel 3D and Vascel, which are designed for a range of cardiovascular and vascular applications. Surgeons around the world are using these products to treat patients with congenital heart defects and those in need of heart valve, vessel and cardiovascular repairs, and peripheral vascular reconstruction.

"Admedus has developed the first and only bioscaffold with proven resistance to calcification, and the first 3D biological tissue products," said CEO Wayne Paterson. "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 solution for life."

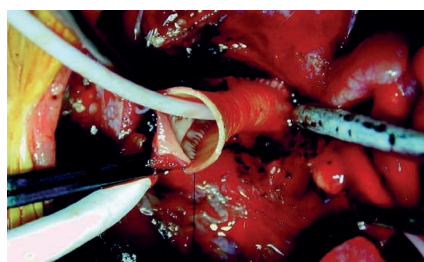
In addition to growing its portfolio, the company is expanding and focusing on key strategic markets and is acquiring global talent to help achieve this. Admedus's leadership team has substantial health-care industry experience, including Paterson, who has 20 years of global pharmaceutical experience, which guides the company's approach to global clinical study programs and clinical publications to support product development.

The company strengthened this expertise recently by appointing Kiran Bhirangi, CMO, to accelerate research projects that will generate new product launches in key areas, including expanding the ADAPT portfolio of products. "Bhirangi's extensive global experience in the cardiovascular area, both as a clinician and corporate executive, will be a great asset to our leadership team as we move the company and our industry-leading technology into a new era of scientific and commercial development," said Paterson.

Admedus has also secured global investors to fund further development of the ADAPT portfolio. Two major investors now hold 50% of the register—SIO Partners, LLC, a US-based health-care-dedicated institutional investment fund, and Hong Kong-based Star Bright Holding Limited. Star Bright will also form a joint venture with Admedus to help resource commercial operations in China and fund clinical development programs.

### ADAPT tissue engineering

Admedus uses its ADAPT technology to transform xenograft tissue (bovine pericardium) into durable bioscaffolds that can be used in the human body for surgical repair in multiple settings, including the



**Fig. 1 | CardioCel 3D used in neonatal arch reconstruction**

aortic and mitral valve. Patented steps in the ADAPT tissue-engineering process include decellularization, molecular crosslinking and antimicrobialization treatment, to reduce the likelihood of calcification (hardening) and improve biocompatibility<sup>1</sup>. ADAPT-treated tissue has been scientifically proven to more closely mimic the characteristics of normal human tissue, which promotes a more tolerant immune response and improved tissue ingrowth<sup>2,3</sup>.

CardioCel—the company's flagship product—is a durable bioscaffold with natural flexibility and elasticity, which not only remains free from calcification but also actively facilitates host tissue regeneration postimplantation. It has delivered positive health outcomes for thousands of patients across a wide range of clinical applications in more than 200 centers worldwide.

The benefits of CardioCel are backed up by extensive clinical data, including a recent study of 30 adult patients that showed promising early results for its use in mitral valve repair<sup>4</sup>. The study showed good, early valve-repair performance, implying good patch biocompatibility and resistance to early degeneration (shrinkage).

In another recent study, CardioCel was used at pediatric cardiac centers in Australia and the UK for the repair of congenital heart defects in 600 patients (830 implants)<sup>5</sup>. The results showed that CardioCel has excellent durability in this setting; with no echocardiographic or radiologic evidence of calcification over a median follow up of 24 months.

The ADAPT portfolio includes CardioCel Neo for use in neonates and Vascel for restorative vascular repair.

### Pre-shaped 3D tissue products

CardioCel 3D (launched in North America in 2018) is the latest ADAPT tissue product and is the world's first curved biological tissue, representing a disruptive technology in the highly complex congenital

defect repair space. CardioCel 3D provides the superior clinical benefits of CardioCel, along with a preshaped curve that enables cardiac surgeons to achieve a more natural shape during aortic arch reconstruction (Fig. 1).

Admedus is also rapidly developing a novel transcatheter aortic valve replacement (TAVR) device. Current TAVR products on the market contain three separate pieces of tissue held together by more than 100 sutures. The Admedus TAVR prototype device features a 3D single-piece molded valve, created using ADAPT technology, which attaches securely to a stent with minimal sutures. ADAPT TAVR will also have an improved delivery system to offer users more control and precise placement. Admedus has patented a sterile hydro-packaging system that substantially reduces TAVR preparation and surgical time.

A leading European reference laboratory is conducting animal trials to test the safety and feasibility of the novel TAVR device, due to be completed in early 2019. Admedus is also exploring a strategic partnership to bring the device to market.

"Our ability to create 3D shaped collagen tissue has opened the door to unprecedented levels of opportunity as we investigate potential new products and applications," said Paterson. "Admedus isn't just looking to create a new TAVR product; our aim is to set a new benchmark in cardiovascular science and technology."

1. Neethling, W. M. et al. *J. Heart Valve Dis.* **19**, 778–785 (2010).
2. Brizard, C. P. et al. *J. Thorac. Cardiovasc. Surg.* **148**, 3194–3201 (2014).
3. Prabhu, S. et al. *Semin. Thorac. Cardiovasc. Surg.* **29**, 356–363 (2017).
4. Tomšič, A. et al. *Ann. Thorac. Surg.* **106**, 1241–1244 (2018).
5. Alphonso, N. et al. Multi-center clinical outcomes for 830 implants of tissue engineered bovine pericardium (CardioCel®) used for the repair of congenital heart defects. Presented at the 7th Congress of the Asia Pacific Pediatric Cardiac Society, Bali, Indonesia, 30 August–1 September 2018.

contact

Wayne Paterson, CEO  
Admedus  
Eagan, MN, USA  
Tel: +1-855-300-1062  
Email: admedus@we-buchan.com