



Advancing cardiovascular safety with Three Peaks Medical's expandable sheath



Providing micro and nano fabrication facilities for Australia's researchers, students and industry.

Innovative Adelaide MedTech startup, Three Peaks Medical, is revolutionising interventional cardiology with a cutting-edge solution designed to overcome the hurdles of large-bore device procedures and enhance patient outcomes.

Designed to reduce vascular injury and bleeding during complex cardiovascular procedures, such as Transcatheter Aortic Valve Implantations (TAVIs), the company's innovative introducer sheath features a unique expandable and retractable mechanism that improves procedural safety.

Providing critical elements to the development of Three Peaks Medical's sheath, the South Australian node of the Australian National Fabrication Facility (ANFF-SA) facilitated access to cutting edge 3D printing capabilities and expertise through their Industry 4.0 Testlab, located at the University of South Australia's Mawson Lakes campus.

Adam DiFiore, Three Peaks Medical's Technologies' Engineering Manager said ANFF-SA has been pivotal in the device's prototyping and testing phases supporting the optimisation of the prints and materials used in the sheath.

"Early access to ANFF-SA's cleanrooms and rapid prototyping capabilities has enabled the efficient and cost-effective development of our sheath," said Adam.

"This has been crucial for fine-tuning the device's design and ensuring its functionality before our clinical trials."

This support has enabled Three Peaks Medical to swiftly iterate their design and validate their concepts, significantly accelerating their development timeline.

In November 2023, the Three Peaks' sheath was used in five TAVI cases at the Victorian Heart Hospital with the trials demonstrating exceptional results: no major vascular complications were reported, and the sheath's expansion and retraction functions performed as intended.

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**Adam DiFiore,
Three Peaks Medical**

ANFF-SA Director, Professor Craig Priest, said providing Three Peaks Medical with access to cutting-edge additive manufacturing capabilities and expert support exemplifies ANFF-SA's pivotal role in expediting product development.

"This collaboration not only showcases how advanced resources can

significantly accelerate innovation but also illustrates ANFF-SA's commitment to bridging the gap between early-stage MedTech startups and the industry's rigorous demands," said Prof Priest. "This support is crucial for driving forward the next generation of medical technologies and ensuring they reach the market more efficiently."

Three Peaks Medical's dedication to quality and innovation was recently validated by achieving ISO 13485:2016 certification for Medical Device Quality Management Systems. This milestone underscores the company's commitment to meeting rigorous international standards and delivering safe, effective products.

Three Peaks Medical's innovative expandable sheath platform is designed to transform large-bore device interventional cardiology procedures. With support from ANFF-SA, this technology has the ability to enhance procedural safety and efficiency by addressing key challenges in large-bore access.

ANFF-SA is a world-class micro and nanofabrication facility providing open access to cutting-edge equipment housed in state-of-the-art facilities with support from world-leading experts.

If you require support or assistance with your project or research, contact us on 08 8302 5226 or visit anff-sa.com.

Expandable sheath platform that accommodates large-bore devices with controlled and reliable expansion and retraction.



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