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Advent Access receives CE Mark for av-Guardian Vascular Access System

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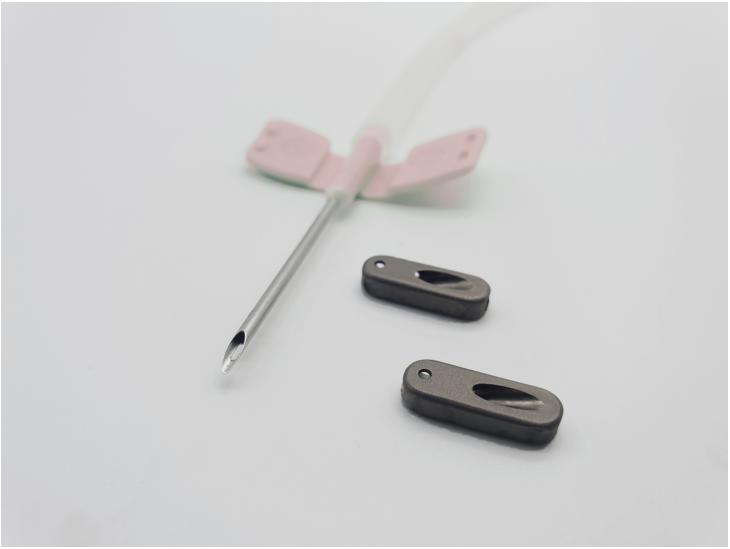
The world's first implant technology to facilitate dialysis needles to optimally access the dialysis vein without the implant being in contact with the vein in patients undergoing hemodialysis.



Singapore based medtech startup Advent Access, on 3 July 2019, announced receipt of the CE Mark certificate for its award-winning av-Guardian™ vascular access system. The certificate indicates av-Guardian™'s conformity with health, safety, and environmental protection standards set by the European Union for a device to be distributed into the European Economic Area.

The av-Guardian™ is the world's first implant technology to pioneer the concept of establishing a "guardian guide-door" to facilitate dialysis needles to optimally access the dialysis vein, an arteriovenous fistula (AV fistula), without being in contact with the vein. The technology is compatible with patients undergoing haemodialysis in various treatment settings – in dialysis centres or at home, regardless of the types of dialysis machine being used.

Providing reliable access to the AV fistula remains one of the most stressful and challenging parts of haemodialysis. Moreover, during this usually painful procedure, many complications can often arise due to poor needling, leading to inadequate dialysis or vascular access related hospitalizations.

Peh Ruey Feng, CEO and Founder of Advent Access, said: "Receiving CE Mark approval for av-Guardian™ is an important milestone in our mission to provide a more comfortable treatment for patients suffering long term end-stage kidney disease and to reduce the cost burden of maintenance dialysis. Our focus now is to work with high-quality manufacturing and distribution partners to realize the impact we can make in potentially changing the way haemodialysis patients receive treatment either in the centre or at home."

The av-Guardian™ technology was recently evaluated in a first-in-man study conducted at Singapore General Hospital and National University Hospital of Singapore, with support from the National Kidney Foundation. The study was a non-randomized, prospective clinical investigation to assess the safety and clinical performance of the av-Guardian™ across 216 haemodialysis sessions in patients with native AV fistulas. The study showed that av-Guardian™ met all safety and performance endpoints. In particular, the av-Guardian™ achieved 94% - 98% successful access to the AV fistula, with

86% - 90% success at the first needle attempt.

Enabling Haemodialysis Patients for the Future of Home Care

Today, an estimated 2.5 million patients suffer from end-stage renal disease (ESRD) and it is estimated that this figure will more than double to 5.5 million patients worldwide by 2030. 89% of ESRD patients rely on haemodialysis to sustain their lives until a kidney transplant is received. The haemodialysis market is valued at USD$71 billion in 2017 and is forecasted to be worth USD$99 billion by 2025.

Advent Access is focused on developing solutions to address the rising cost of operating in-centre haemodialysis and the limited scalability of dialysis centres when they reach maximum capacity. An effective solution is to empower more patients the freedom to perform haemodialysis at home or independently. However, the foremost barrier freeing the patient from the dialysis centre and the nurse is the patient’s ability to self-needle with confidence.