

Delivery Apparatus: Central Venous Catheter (CVC)

Opportunity

A next generation introducer needle or delivery device has been developed for ultrasound-guided interventions to enhance the quality and safety in patient care.

The device is generic with potential for wider use across most of the ultrasound-guided interventions; for example vascular needles and catheters, nerve block needles, percutaneous tracheostomy tubes, and minimal access surgery introducers.

A manufacturing prototype design for single lumen catheters, midline catheters and cannulae has already been developed. The University Hospitals of Leicester NHS Trust is looking for a commercial partner.

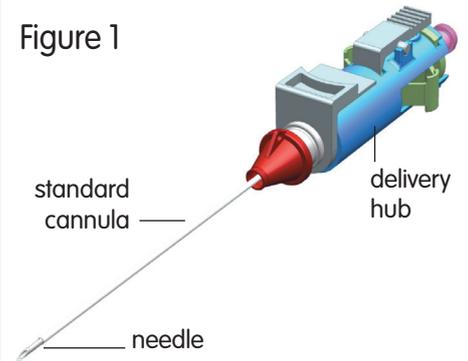
The problem

The Seldinger technique is traditionally a landmark-guided intervention used since the 1950s. A guidewire is used to secure the initial access for further insertion of a cannula. The Seldinger technique is employed, for example, when securing central venous access, which is required for drug delivery, parenteral nutrition, percutaneous cardiac interventions and pressure monitoring. However, landmark-guided techniques pose a risk of complications such as injury to adjacent tissues, arterial puncture, catheter malposition, pneumothorax, stroke or guidewire-related complications.

With around 5 million CVCs being inserted every year in intensive care alone in the US¹, a substantial number of patients are placed at risk. Therefore the Agency for Healthcare Research and Quality, USA (2001) and the National Institute for Clinical Excellence UK (2002) recommend that ultrasound be used to guide the placement of CVCs to improve patient safety.

This presents a difficulty when using devices with ultrasound that were originally developed for landmark-guided techniques. The multi-step process to insert the needle and feed the guidewire requires both hands of the operator to hold the

Figure 1



Manufacturing prototype device.

A standard cannula is used in conjunction with a novel delivery hub without the need for a guidewire.

needle/catheter at certain points, resulting in interruptions in imaging, as the ultrasound probe must be put to one side repeatedly. This may leave the patient at risk due to certain parts of the procedure being carried out unsighted. There would also be an increased risk of slight movements that could cause localised tissue damage. Therefore makeshift use of landmark-guided catheters for ultrasound-guided procedures increases complexity and risk of the procedure.

The solution

A novel single hand operable device has been designed for gaining access without the use of a guidewire. The device converts a complex process into a guidewire-free, single step procedure with uninterrupted

use of ultrasound guidance. This allows the clinician to monitor the procedure using ultrasound continuously, thus limiting the potential for injuries. Serious complications related to guidewire retention, 'a never

event', would also be eliminated. The device is made operator friendly and improves the time and workflow efficiencies with reduced risk of infection.

Market

The market for ultrasound-guided interventions including vascular access is growing, in no small part due to the increase in incidence of cancer, cardiac disease, overall complexity of medical management and ageing population.

The catheter securement market, which includes CVCs, is cited to be particularly strong, with CAGR of 7.3 per cent to 2020 and a market forecast of US\$2.3 billion by 2019 (Global Intravenous Access Market 2015-2019). CVC insertions are in the region

of 16 million each year worldwide². The device has wider applicability for other ultrasound-guided procedures therefore adding the potential to reach a broader healthcare market.

Technology readiness

- A prototype has been developed and a manufacturing prototype design is ready.
- UK patent has been obtained, and European and American patent applications are in process.

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