Tech Offer Write-up

Title

Smart Fistula Needle For Safe Fistula Cannulation And Other Vascular Procedures

Technology Overview (

This invention relates to a smart vessel wall penetration detection needle device for fistula cannulation and other various vascular procedures; and the corresponding method to operate this smart vessel wall penetration detection needle device, to reliably detect vessel wall penetration and avoid accidental puncturing of the opposing vessel wall during the cannulation procedure.

Many vascular procedures such as central venous catheter insertion, dialysis catheter insertion, arterial angiograms, etc. are conducted daily across the globe. Such vascular procedures require a skilled medical person to complete the task. Even so, there would be times where a skilled medical person may accidentally insert the needle too deep after puncturing the front vessel wall and puncturing through the opposing side of vessel wall while inserting the needle further upstream. Therefore, those skilled in the art are striving to provide an improved device for penetrating the vessel wall during cannulation to eliminate the inadvertent puncturing of the opposing vessel wall and improve the safety of the cannulation procedure.

The Smart vessel wall penetration detection system that enables surgeons/nurses to gauge the intravascular position of distal end of the needle and automatically deploys a smart sensing stylet after needle puncture of fistula wall / vessel wall to prevent accidental back-walling during further needle travel.

The Smart vessel wall penetration detection system protects against needlestick accidents and accidental back walling of fistula wall.

A brief summary or description of the invention - What is the problem solved by this technology?
Who is going to buy this technology? How is this IP addressing a need/problem in the marketplace?

Keywords

Fistula Cannulation, Vascular Procedures, Detection

Specify some keywords that can help others to quickly search for your technology.

Technology Readiness Level (TRL)

Level 5

*Refer to **Annex A** - **Technology Readiness Level Reference Table** for details.*

Technical Features & Specifications

Smart fistula needle with smart sensing vessel wall penetration detection system for fistula cannulation and other vascular procedures.

The proposed smart vessel wall penetration detection system consists of a spring actuated smart sensing stylet to prevent accidental back walling of the fistula wall during cannulation, and a flashback chamber to gauge the intravascular position of the needle during puncture. The trigger engages the said stylet, retracting and release to expose or shield the needle during the cannulation process respectively. Two haemostasis valves are incorporated into the device: one located at the trigger housing to prevent blood leakage into said trigger; the other in the catheter housing to reduce and prevent blood leakage during

needle removal. Both needle and said stylet will be removed from the device while retaining the flexible catheter tube inside the fistula to proceed with the dialysis session.
In summary, the proposed system has these key features:

1. Smart sensing stylet is in extended mode prior to use to protect user from accidental needlestick compared to conventional fistula needles.
2. Sensing means (flashback chamber) to gauge the intravascular position of the distal end of the needle.
3. Spring actuated trigger that conceals smart stylet to enable puncture of fistula wall followed by automatic propulsion of said stylet upon release of trigger.
4. Removable needle and said stylet to provide a safer and more comfortable dialysis session

The computer aided design (CAD) completed, and prototypes fabricated. Verification phase completed with trials on fistula dummy arm using the prototypes.

What does the technology consist of? E.g. Video camera, software algorithm
Who is/are the ideal collaboration partner(s) in the value chain? E.g. medical institutions, device manufacturers

Potential Applications

Potential commercialization of device for hospitals and dialysis centres where vascular procedures are routinely performed.

In which industry can this technology be deployed? What applications do you foresee that this technology can be applied in? What products can be marketed based on this technology?

Market Potential (Optional)

The device can be used for safer cannulation procedures performed for fistula and other vascular procedures.

Estimate for Singapore Market:

- number of dialysis patients – 9000
- dialysis per patient/per week – 3
- 2 Device per dialysis session
- no of device use per patient per month = 24

Total Quantity per month = 216,000 devices.

Worldwide, there are over 2 million people worldwide currently receive treatment with dialysis, so the market is large just for fistula cannulation.

What is the approximate market size for this technology? What makes this technology attractive to the market?

Unique Value Proposition

The improved cannulation procedure protects patients from accidental back walling of vascular vessels and bleeding during fistula and other vascular procedures to make such procedures inherently safer.

How is this technology an improvement over the current "State-of-the-Art"?
What is the Unique Value Proposition (UVP) in comparison to the current "State-of-the-Art"?

Technology Categories

E.g. Chemicals; Electronics; Energy; Environment; Clean Air & Water; Foods; Green Building; Healthcare; Infocomm; Life Sciences; Logistics; Manufacturing; Materials; Personal Care; Waste Management & Recycling

Preferred Business Model:

☐ R&D Collaboration	☒ Licensing	☐ IP Acquisition
☒ Test-Bedding		

Ideal Collaboration Partner:

Dialysis centres, Hospitals for test bedding.

Indicate the top 3 competitors of your technology and describe your UVP over theirs.

Others:

Please provide any additional information about this Tech Offer, or any information that you want to include in the TechInnovation website here.

Please indicate if you would like to pitch this technology at Crowdpitching segment on 1 Nov 2023:

No

Annex A: Technology Readiness Level (TRL) Reference Table

TRL	Physical Sciences & Engr	Healthcare (Pharmaceutical)	Healthcare (Medtech)	Healthcare (Diagnostics)	Simplified
1	Basic principles observed	Basic principles observed	Basic principles observed	Basic principles observed	Proof-of-Concept
2	Technology concept formulated	Technology concept formulated	Technology concept formulated	Technology concept formulated	Proof-of-Concept
3	Experimental proof of concept	Experimental proof of concept in vitro and in vivo research models	Experimental proof of concept in vitro and in vivo research models	Experimental proof of concept in vitro	Proof-of-Concept
4	Technology validated in lab	Proof of concept demonstrated in defined laboratory/animal models	Proof of concept demonstrated in defined laboratory/animal models	Analytical validation	Prototype in Lab
5	Technology validated in relevant environment	Non-clinical and pre-clinical research studies, & initial demonstration of feasibility and efficacy	Product Development Plan		
6	Technology demonstrated in relevant environment	Phase 1 clinical trials	Phase 1 clinical trials		
7	System prototype demonstration in operational environment	Phase 2 clinical trials	Clinical safety and effectiveness trials in operational environment	Clinical validation in 1 site	Prototype in Live Environment
8	System complete and qualified	Phase 3 clinical trials	Overall risk-benefit Trials		
9	Actual system proven in operational environment	Pharmaceutical can be distributed or marketed	Medical device can be distributed or marketed	Clinical validation in multi-site	Ready-to-Market

Return to TRL section