CASE STUDY

SmartWise

DESIGN & MANUFACTURE OF A NOVEL INJECTION CATHETER

At Arrotek, we specialise in minimally invasive medical devices, particularly thin-walled catheter solutions and products. We are currently working on a project that involves the design, commercialisation, and manufacture of an innovative thin-walled catheter device.

OVERVIEW

Our client is SmartWise Sweden AB, a research and development company based in Sweden. SmartWise was established to develop a novel endovascular injection catheter called The Extroducer Infusion Catheter System.

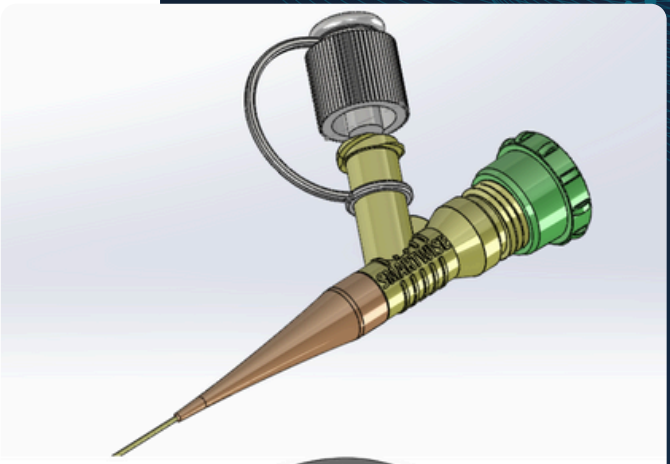
Currently it is a Class II medical device under FDA regulations, but there are plans to further develop the product for heart and brain applications, where it will become a Class III medical device.

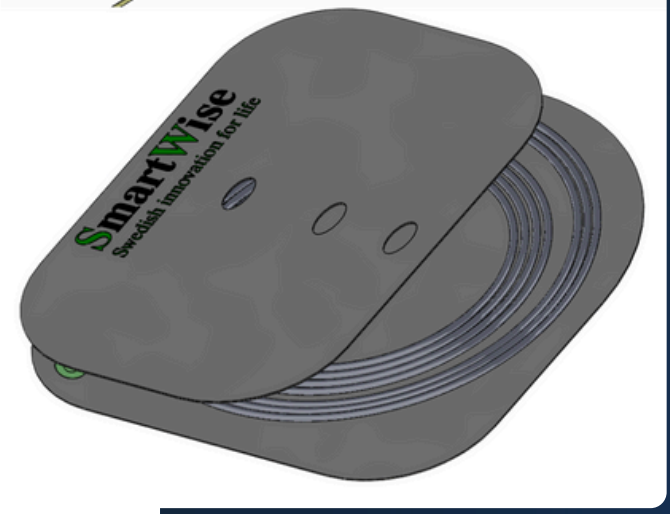
INTENDED USE OF THE NEW EXTRODUCER INFUSION CATHETER SYSTEM

- The infusion of diagnostic or therapeutic solutions into the perivascular area of the peripheral vasculature
- The infusion of diagnostic and therapeutic solutions intraluminally

PROJECT SCOPE

At the start of the project, the new catheter device was at early concept stage as SmartWise AB had produced a hand-made, proof of concept prototype. The Scope of the project involved several elements:





01 DFM (Design for Manufacture) and DFA (Design for Assembly) input

02 Optimise the design and further develop the product to a finalised state

03 Initial product builds for initial trial and evaluation

04 Providing regulatory support during the FDA application process

05 Manufacturing the product through its initial commercialisation launch phase *

* this stage has not yet been reached at the time of writing

> I know the team at Arrotek is thorough, trustworthy, and efficient. Arrotek had everything we needed including the right skillset as well as an established organisation ready to hit the ground running with R&D, regulatory submission preparation, production, etc.
>
> **Jonny Munter, SmartWise**

OBJECTIVES

Design

Take the initial concept and prototype and develop it further to optimise the device and finalise the design ready for regulatory approval. Our responsibilities included project managing the design, product specification development, finalising the device design, DFM, DFA, producing a final prototype, verification, and validation.

Regulatory Approval

Approval would be for markets in the USA and EU. The device needed to be approved for use with multiple fluids, drugs, and cells with various viscosity.

Manufacturing

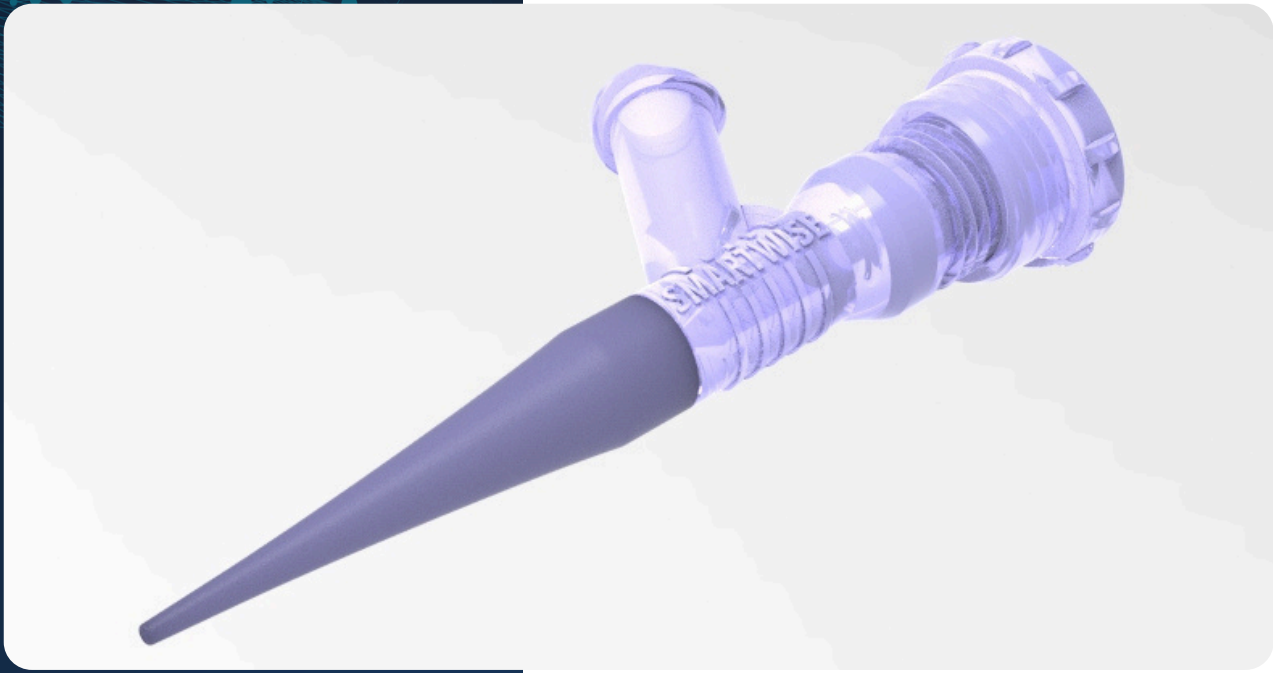
Manufacturing the device in our Sligo facility for distribution to the EU and/or US markets. This includes developing a supply chain and manufacturing process, sourcing raw materials and components, ensure full traceability, creating manufacturing parameter specifications, manufacturing process validation, packing and packaging validation, labelling, and more

FAST TRACK DEVELOPMENT

A key aspect of the project is that it is a fast track development. This is to fit in with the SmartWise AB business plan and to achieve various objectives and milestones. As a result, it took less than 12 24 months from the project starting in October 2019 to being ready to submit a Pre-Request for Designation to the FDA.

With a significant focus on timescales, we needed to get it right the first time. So, our experience and years of expertise have been essential.

Shane O'Doherty,
Arrotek Project Manager



CURRENT PROGRESS

We have had considerable successes to date, reaching all key milestones. The product development phase took two years and FDA regulatory approval was obtained within six months.

Jonny Munter from SmartWise said it was a “massive achievement getting a Class II device to this stage so quickly”.

Note: we will continue to update this case study as the project progresses through the design and regulatory approval stages and into commercial production.

Contact Arrotek

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