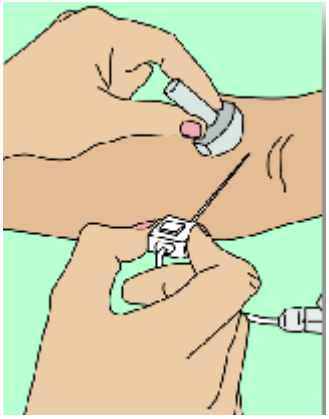
Regional Anaesthesia Delivery System (RADS)

A patentable medical device with freedom-to-operate issues!

What is the innovation?

Regional Anaesthetic Delivery System – a device that allows single-handed administration of peripheral regional anaesthesia negating the need for an assistant.

Who came up with the innovation?



Consultant Anaesthetist from Leeds Teaching Hospitals came up with the idea 2011.

What problem does it solve?

During delivery of peripheral regional anaesthesia, an anaesthetist needs to hold an ultrasound probe with one hand and fine-position a needle to sub-mm accuracy with the other hand. This is often required to be repositioned throughout the procedure. At the same time, around 30-50ml of anaesthetic needs to be administered and so a second (usually untrained) person is asked to aspirate (to check that the needle is not in a blood vessel) and inject set amounts of anaesthetic as well as to give a subjective opinion as to whether it is difficult to inject or not (which may indicate that the needle is too close to, or within, a nerve). A survey of UK anaesthetists showed that they would prefer to be in control of the whole procedure.

What was the inspiration for the idea?

Nerve damage from anaesthesia can be caused by a number of factors, for example: by injecting at too high a pressure, or injecting the anaesthetic too close to, or actually into a nerve. This can result in symptoms (temporary or permanent) for patients and potentially litigation for the hospital. The anaesthetist inventor wanted a device that would limit the pressure of injection as well as allow him to be able to control the whole procedure himself to prevent communication errors with other practitioners that are currently involved.

How did the innovation journey start?

The consultant that had the idea for the invention approached a local university medical engineering team, who put him in touch with an experienced professor of design engineering. Four Masters' students were enlisted to undertake the design and engineering aspect of the work, first attending the hospital and observing the procedure to completely understand the needs of the user.

In conjunction with the clinician, various designs and mechanisms of action were evaluated over a few months until a final design was accepted and a 3D printed prototype produced. Laboratory testing was carried out on the mechanical aspects, to ensure that the pressure limiting aspect would work.

Medipex were informed about the invention because there had been Trust involvement and the University wanted to ensure that any potential reward would be shared equally between the two organisations.

Was there any IP? How was it protected? Were there any complications?

The device has patentable features, although an application has not yet been filed. The reason is that there were complications! After the design and mechanics had been finalised, a patent application from another organisation was published that describes part of the device that we had invented. This caused "Freedom to Operate" issues, meaning that even if we could get protection for some of the patentable features of our device, we would not be free to sell it into two of the biggest markets – the EU and US. We tackled this by approaching the organisation in question, and having confidential discussions using non-disclosure agreements. They liked our solution to the problem, and expressed an interest in licensing the IP from us in order to take our device to market as well as their own – fortunately we could see different potential uses for the two different designs. In the future, we aim to have patent and design right protection on the device.

Where is the innovation now (stage of development)?

Regarding technical development, we have not got any further than the original 3D printed prototype, but regarding commercial development we are in the process of licensing the technology to a third party who can take it to market once they have secured the investment to do so.

Future plans for the innovation?

Future plans are to finalise the license agreement and work with the licensee to ensure that the device gets to market. This should generate royalties for the Trust, University and inventors involved.

Has this idea sparked more innovations/other colleagues to come forward – other impact?

The clinical inventor is very keen to promote innovation in the Trust and we are planning to hold a drop-in session where his colleagues can come to discuss their ideas.

Any lessons learned?

It is vital to maintain vigilance on the IP landscape as it can change overnight! Always have a back-up plan and prepare to compromise. The inventor has stated "Being an anaesthetist, I'm used to near-instant medicine. What I was wholly unprepared for was the time scales involved in developing a new medical device. I could not have done it without the help of Medipex."