Improved Obstetric Forceps (Pro-Nata)

What is the innovation?
The improved obstetric forceps device is single use, has built in safety features to prevent too much traction force being applied to the head of the baby and risk of trauma to the perineum of the mother due to use of excessive traction force.

Who came up with the innovation?
The idea was disclosed to Medipex in 2008 and originated from a consultant obstetrician at Hull and East Yorkshire Hospitals NHS Trust, Dr Alexander Oboh. He wanted to re-develop the obstetric forceps into an improved, patient friendly and safer device.

What problem does it solve?
Giving birth is one of the most natural of processes having evolved over millions of years to allow the safe delivery of an offspring. However, assistance is sometimes required to affect a delivery. The use of obstetric forceps was first reported in 1792 and it has proved highly effective over the years. Today it is still seen as the best of the tools available for carrying out an assisted vaginal delivery (AVD). In 2009 there were 298,000 forceps assisted deliveries in the UK, Europe & US. However, the last recorded improvements to the obstetric forceps were made about 150 years ago! The modern obstetrician when presented with a situation where an AVD is required is therefore using a device designed in Victorian times.

The new obstetric forceps have been designed with an in-built safety device to regulate the amount of traction force that can be applied to achieve AVD. The operator is simultaneously able to see the amount of force being applied and get additional auditory and tactile feedback once the maximum traction force is exceeded. This removes individual variations in the maximum amount of force used and the risk of use excessive traction force. The new device is intended to be single use and is made of lightweight, recyclable, non-steel materials. This has environmental benefits and in low-resourced countries reduces the risk of cross-infection and the cost of sterilisation.

What was the inspiration for the idea?
Globally 10-15% of births are AVD using either the forceps or vacuum devices. The forceps have a higher success rate for AVD but also major drawbacks: the risk of trauma to the perineum of the mother and baby due to use of excessive traction force; steel construction; success dependent on the operator’s skill and
experience. Whilst the vacuum device has been improved over time, there have been no innovative improvements to the forceps devices on the market.

**How did the innovation journey start?**

Dr Oboh was a Yorkshire Enterprise Fellow supported by Medipex and a winner at the Medipex Innovation 2010 Awards for his improved design for obstetric forceps. Having determined that there were gaps in both the intellectual property (IP) landscape and the market, Medipex helped him apply for a grant so that a working prototype based on his idea could be developed. A Europe-wide market research study was carried out with 150 clinicians to gather views on the use of obstetric forceps and to determine what features they would like to see improved about the device. The data gathered supported the need for the suggested device and was used to help prepare a design brief. A local design and prototyping company was engaged to turn the concept and information into a product which would be capable of manufacture at scale and to produce a series of initial prototypes. These were tested on a birthing simulator to effect a successful delivery using a consistent level of traction force at a level lower than that used by standard forceps (used as a comparison), thus showing proof of concept. Feedback from other clinicians was then garnered which helped to further refine the device. A further piece of work was carried out to confirm that the product could be made and sold for the target price.

A collaboration with a specialist surgical instrument development & manufacturing company was necessary to develop and commercialise the forceps. A number of companies were considered by Medipex before NuSurgix Limited (Now Surgical Dynamics Limited) located in Consett was selected. Surgical Dynamics entered into a licence agreement with the NHS to develop and take the device to market. With the assistance of Medipex, Surgical Dynamics won an Innovate UK SMART award to develop the instrument through the advanced prototyping stages to a point where a CE Mark was obtained.

**Was there any IP? How was it protected? Were there any complications (infringement/FtO)?**

The device is protected by a Community registered design, providing monopoly protection for a maximum of 25 years, renewable in five-year blocks. A UK patent application was filed on behalf of the Trust and then prosecuted in the following countries: Australia, Brazil, Canada, China, Europe, Hong Kong, Japan, Korea, India, New Zealand, South Africa and USA. Some alternative devices were cited as prior art which could present freedom to operate or patent novelty issues but these have been successfully argued against during patent prosecution and patent claims have been granted in several of the countries.

**Where is the innovation now (stage of development)?**

The device has been CE marked and was presented in June 2016 at the Royal College of Obstetricians and Gynaecologists World Congress in Birmingham. The device will now be used in some small clinical studies, the data published and the device then placed on the market under the name Pro-Nata.
Future plans for the innovation?
The size of the obstetric forceps blade has been based on equivalent metal blades in common use. During the human studies and also once the product is on the market alterations to the blades blade size and shape will be explored.

Has this idea sparked more innovations/other colleagues to come forward – other impact?
The inventor has informed Medipex of other ideas in the field of obstetrics and these are being assessed to determine how best to take them forward.

Any lessons learned?
The main lesson is that it takes longer and is always costlier than you initially think to get a product to market!