



## CLINICAL EVALUATION STUDY



**NUASURGICAL**  
Innovating in Women's Health



**NUA Surgical** is a Galway based, start-up company dedicated to innovating in women's health. The company, which is a spin-out from the University of Galway and BioInnovate Ireland, was founded in 2019 by Barry McCann (CEO), Marie-Therese Maher (COO) and Padraig Maher (CTO). They have developed the patented SteriCISION™ C-section retractor, which aims to improve access and visualisation during caesarean surgery and provide multiple benefits to clinicians, patients and healthcare systems.

The Enterprise Ireland backed high potential start-up has been recognised nationally and internationally with multiple awards for its innovative approach to improving maternal health outcomes. These include overall winner of Intertradelreland Seedcorn Competition (2020), EIT Health Headstart winner (2020), Parkview Health Global Maternal Health Innovation winner (2021), and overall winner at the National Start-Up Awards (2022).

## About FemTech @ HIHI

FemTech focuses on women's health from birth to death and includes areas such as adolescent health, fertility, menstruation, menopause, gynaecological health, pregnancy, cancer, mental health, female wellness and health conditions that affect women disproportionately. Health Innovation Hub Ireland's FemTech initiative, **FemTech @ HIHI**, will stimulate and support the development of **high potential new products, services and start-ups**. This will impact the health and wellbeing of 50% of the Irish population, create a geographical FemTech focus and build an ecosystem of experts and entrepreneurs supporting, driving and innovating. There will be a unique pathway of access to clinical, research and business expertise. FemTech entrepreneurs will have access to critical **research expertise** through University College Cork Innovation and business and enterprise support will be provided through our **FemTech Advisors**. Clinical expertise through a partnership with the Ireland South Women and Infants Directorate will provide invaluable access to **discipline specific clinical teams**.

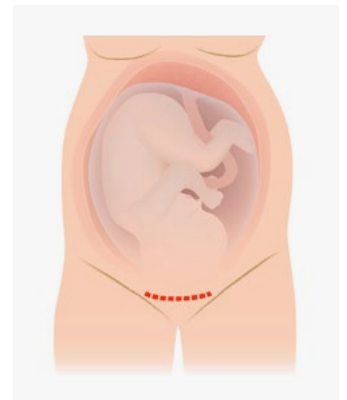
## The Healthcare Challenge

There are approximately 29 million C-Sections performed globally every year, making it the most common major surgery in the world. Although it can be a lifesaving procedure for both mother and infant, C-Sections bring higher risk of haemorrhage, infection and even death as opposed to a vaginal birth, and the risk of complication is magnified in patients with a higher body mass index (BMI).

Every incision must be retracted to provide a surgical field of view and access to the uterus, and this task is more challenging as BMI increases. A lack of innovation in obstetrics means that current methods of retraction are suboptimal, especially given that today

over half of all C-Sections in Europe and two-thirds of those in the US are performed on overweight or obese patients. This presents a significant challenge to the clinical team, requires extra staff, adds cost to hospitals and results in higher complication rates for patients including Surgical Site Infections (SSIs).

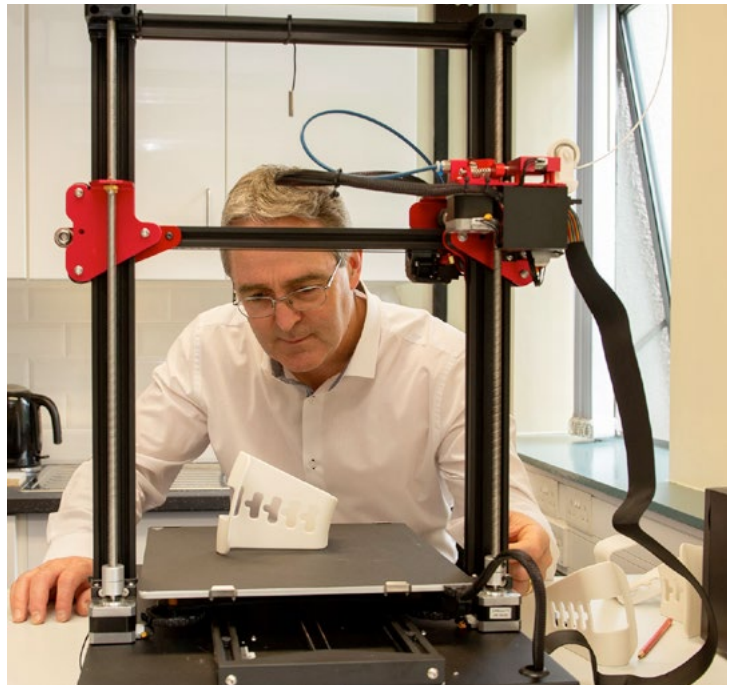
SSIs impact a mother's ability to care for her newborn, requires longer hospitalisation, sometimes readmission and is associated with maternal mortality. Obesity not only significantly increases the likelihood of caesarean section being required but also the likelihood of developing an SSI.



# The Healthcare Solution

NUA Surgical's SteriCISION™ retractor has been designed alongside obstetricians to answer their unmet needs when performing a caesarean delivery. It will provide superior access to the uterus, enabling hands free management of the surgical incision space and therefore reducing the opportunity for bacteria transfer into the wound. The self-retaining retractor will be provided as a sterile, single use disposable device which is also important to reduce the risk of infection.

Its ergonomic design enables easy, safe and fast retraction, mimicking the natural hand movements of the obstetrician and the soft-touch adjustable paddles cater for their visualization needs on each patient's anatomy. Ultimately, SteriCISION™ will provide suitable access and visualization for clinicians to safely deliver the baby, identify any bleeds and repair the uterus in a time-sensitive surgery.



## HIHI Role

Feedback from clinical experts was required in the early stages of the design development. HIHI recruited a targeted number of 10 key opinion leaders (KOLs) from the discipline of Obstetrics and Gynaecology and facilitated one-to-one feedback sessions with human factor testing. Relevant feedback and information on the device, device design, usability and functionality

was gathered through interviews and questionnaires. A prototype of the device was available for participants to review and test on a simulation model. This allowed for human factor testing and design insights. The feedback gathered from the interactions was analysed and included in a final report for NUA Surgical.

## Outcome Report

Feedback obtained from KOLs during simulation highlighted that the SteriCISION™ C-Section retractor was easy to use, increased the field of visibility, and was easy to insert, adjust, and remove from the simulation model. NUA Surgical gathered relevant feedback that has informed their iterative design process to date and can be used to inform future iterations of the device. A device such as the SteriCISION™ retractor has the potential to reduce challenges associated with caesarian deliveries and provide some necessary innovation in obstetric surgery. The team will continue to work with the KOLs in designing the clinical studies which will generate the clinical evidence required to drive future clinical adoption and for regulatory purposes.



## Testimonial

*"The insights are invaluable! We are grateful for the support of the HIHI team and are excited to be involved with their FemTech programme moving forward."*

Barry McCann  
CEO of NUA Surgical



info@hih.ie  
www.hih.ie

HIHI (UCC)  
Western Gateway Building  
University College Cork  
Cork, Ireland  
+353 (0)21 420 5560

HIHI (TCD)  
H&H Building  
St James' Hospital  
Dublin 8, Ireland  
+353 (0)1 896 2573

HIHI (University of Galway)  
Lambe Institute  
National University of Ireland  
Galway, Ireland  
+353 (0)91 492 072

HIHI (MTU)  
CREATE Building  
Munster Technological University  
Cork, Ireland  
+353 (0)21 432 6758