



CLINICAL EVALUATION STUDY



AltaScience

AltaScience, a winner of the Health Innovation Hub Ireland Femtech Call 2023, is an Irish medical device company. AltaScience has developed AltaSeal®, a hysteroscopic permanent contraceptive device, a non-surgical alternative to tubal ligation.

AltaScience consists of a team of highly experienced biomedical engineers, scientists, quality and regulatory professionals and medtech industry veterans. At their facility in Dublin, they have a laboratory and R&D facilities allowing rapid prototyping and device assembly.



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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.



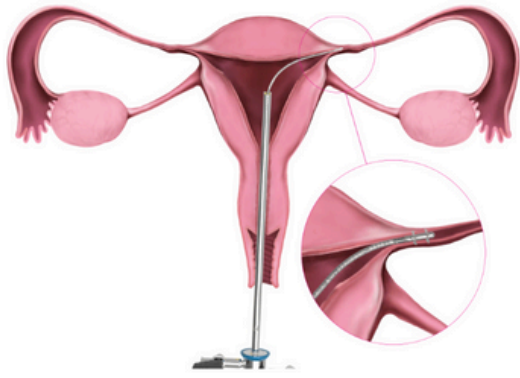
The Healthcare Challenge

Female contraception can be categorised into temporary and permanent. A number of temporary options are available to women. However the only method of permanent contraception available remains tubal ligation, a surgical procedure where the fallopian tubes are surgically cut, tied or blocked to permanently prevent pregnancy. Around the world, circa 220 million women are currently relying on permanent contraception via surgical tubal ligation to avoid pregnancy.

Surgical solutions like tubal ligation which has been the leading permanent birth control method have limitations such as scarring, safety concerns and recovery time. A significant unmet need exists to provide an option for women seeking accessible, minimally invasive, non-surgical, pain-free, permanent contraception.



The Healthcare Solution

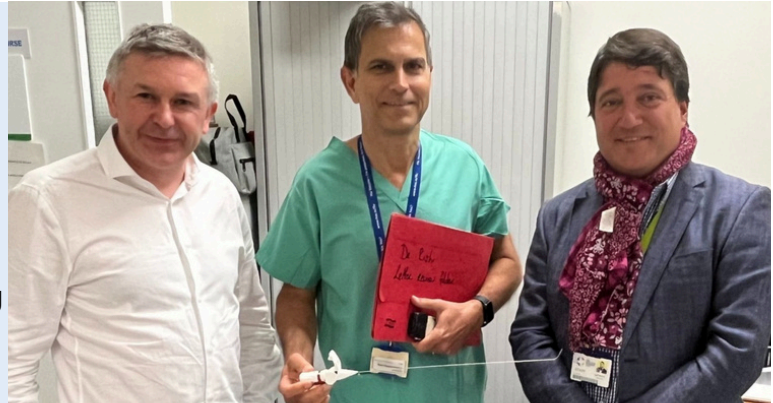


AltaScience has developed AltaSeal®, a stainless steel medical grade micro-insert, which is placed in the fallopian tubes using a hysteroscope. This micro-insert mechanically blocks the fallopian tube and is then encapsulated in the anatomy, thus preventing pregnancy. The AltaSeal® micro-insert and delivery system is based on a similar platform technology to the Celt ACD®, an FDA approved arterial closure device which is now implanted in >300,000 patients worldwide.

AltaSeal® can be performed in a gynaecologist's office, rather than in an operating theatre with the procedure taking about 15 minutes. Because there's no anaesthesia or surgery, AltaSeal® eliminates the risks and discomforts associated with surgery, general anesthesia and recovery. A woman can expect to resume normal activities on the same or next day.

HIHI Role

Health Innovation Hub Ireland recruited five clinicians with expertise in obstetrics and gynaecology in the Rotunda Hospitals and organised two feedback sessions on the AltaSeal® ambulatory hysteroscopic contraception technology. HIHI chaired these sessions which included discussion based on prepared strategic questions and a practical hands-on session of delivering the device using training models. HIHI prepared an independent final project report capturing this feedback.



Outcome Report

The clinical feedback from obstetrics and gynaecologists was hugely positive with only small adjustments recommended to further improve the product. The positive feedback received focused on AltaSeal®'s ease of use, flexibility and new tip designs. In addition, all consultants demonstrated speed and efficiency with implanting the device, demonstrating its user-friendly features. It was reported that the AltaSeal® product could be used in future clinical practice when commercially available.

The clinical experts were of the opinion that AltaScience is addressing a clear gap in women's health with the AltaSeal® product. With the gap between temporary (e.g. the contraception pill) and permanent contraception (tubal ligation) representing a large difference in required healthcare resources, AltaSeal® provides a product that is easy to administer and with less significant requirements on healthcare staff and women (i.e. no need for anaesthesia and recovery room).

Testimonials

"HIHI has provided us with fantastic support in our product development though their Clinical / End-User Evaluation Project. One thing I immediately liked was the enthusiasm of HIHI and the up-front collaborative session to understand our needs before engaging the "right" users. The user sessions they organised were truly excellent. We were provided unrestricted access to expert clinical users and opinion leaders in a clinically representative setting where they were hands-on using the device in training models. This allowed them to provide extremely valuable insights to product development, including clinical considerations and different patient groups, ergonomic of use, compatibility with other device, critical aspects of user training and general logistics of use. The feedback is invaluable in ensuring we are developing the "Right Choice" for women seeking permanent contraception.

I want to especially thank the Team at the Rotunda Hospital for their instrumental insights and collaboration throughout the user sessions, and also HIHI Project Manager, Jonathan Moran, for coordinating and then organising these sessions, maintaining focus on the aims of the project. In my opinion, is not really possible to develop innovative solutions to unmet clinical needs without the support of a strong clinical user group ensuring the user experience is succinctly translated to the development team. The fact this can be seamlessly facilitated by HIHI through their programs may provide healthcare innovators in Ireland with a distinct competitive advantage over peers in other jurisdictions."

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