PRODUCT PILOT

Health Innovation Hub Ireland

OSTOFORM

Ostoform is an Irish based company specialising in improving quality of life for ostomy patients. As part of their product development process, Ostoform required additional studies prior to device commercialisation. Company founder, Kevin Kelleher was advised to contact HIHI. Ostoform requested HIHI support to design and deliver a study that would address the criteria for application to the Primary Care Reimbursement Scheme (PCRS).

About Health Innovation Hub Ireland

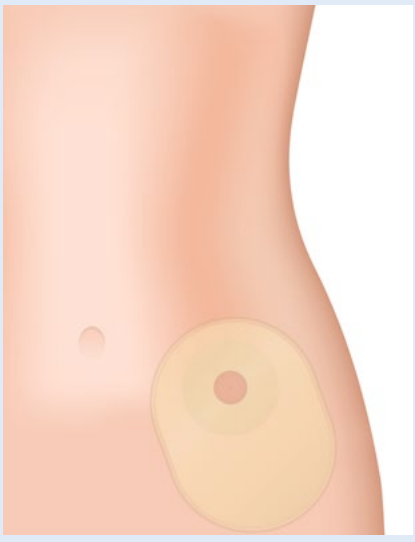
Health Innovation Hub Ireland (HIHI) was established by the Department of Business, Enterprise and Innovation and the Department of Health, supported by Enterprise Ireland (EI) and the Health Service Executive (HSE) to drive collaboration between the health service and enterprise.

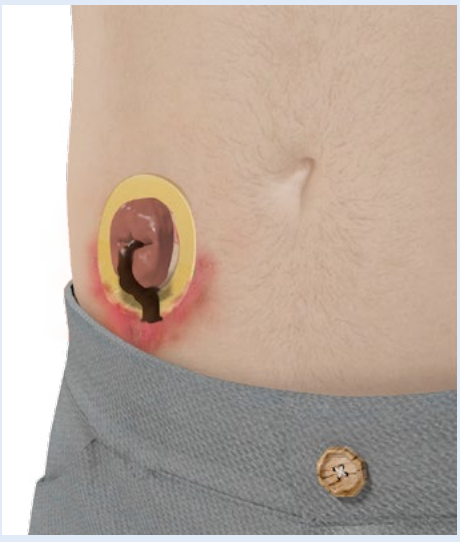
We offer companies the opportunity for pilot and clinical validation studies and the health service access to innovative products, services and devices that they may not otherwise be exposed to.

HIHI is built on the recognition that collaboration with enterprise can benefit patient care, patient pathways and outcomes.

The Healthcare Challenge

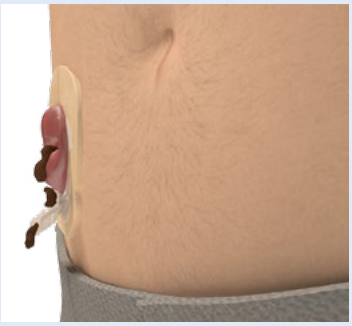
People who have had a surgically created stoma, particularly an ileostomy, are at risk of developing peristomal skin complications, with incidence rates of up to 63% reported in literature. Currently, treatments of peristomal skin complications are limited. Pastes are available, but they can often impede ostomy bags from sticking to the skin. Furthermore, the bags themselves can contribute to peristomal skin complications, by allowing waste to contact the peristomal skin, causing chemical irritation and standard seals are often broken down by stoma output, which then contacts your skin resulting in irritation and discomfort.

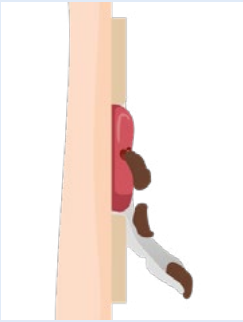




The Healthcare Solution

The Ostoform Class I medical device aims to prevent the development of peristomal skin complications. With all ileostomies, there is a risk of stoma output contacting the peristomal skin and causing irritation. Ostoform was designed to minimise this risk. The Ostoform Seal is a device designed to prevent the development of peristomal skin complications and ensures that stoma output flows away from the skin, keeping it safe, healthy and comfortable.





HIHI Role

HIHI designed and project managed 2 separate multisite clinical studies to assess the impact and efficacy of their FLOWASSIST novel ostomy device. The initial study included Tallaght University Hospital St James's Hospital and University Hospital Galway, engaging two CRFs in Dublin and Galway. The second study was conducted at Cork University Hospital, Mercy University Hospital Cork and University Hospital Galway. Patients with an ileostomy were screened from the stoma nurse's outpatients list, those who met the inclusion criteria were invited to participate. There was no control group in this study as currently there is no accepted 'standard care' device for the management of peristomal skin complications so patients use a range of different devices. Ethics approval was obtained for both studies.

Outcome Report

The purpose of this practical application study was to evaluate the effectiveness of the Ostoform® Mouldable Seal with FLOWASSIST® Protection in protecting the skin of people with an ileostomy, as well as to gather user feedback on the perception of the device. 60% of the participants remained at a very low DET score throughout the study, and 35% of participants demonstrated an improvement in DET score provides an indication that the novel barrier ring can be effective in protecting the skin. User feedback was positive with respect to comfort, device handling and the perception of the device's ability to protect the skin. Furthermore, the majority of participants who already used a barrier ring, indicated that the FLOWASSIST device would result in a longer wear time.

In 2021, the clinical study with Ostoform and HIHI concluded and results were accepted for publication. An application for inclusion of this product on HSE Primary Care Reimbursement Scheme for public patients was submitted to the HSE and approved in September 2022. As a result, the Ostoform FLOWASSIST product is now available to Irish patients.

Testimonial

The HIHI supported Ostoform by preparing and conducting two separate clinical studies, both of which demonstrated very encouraging results. Our FLOWASSIST technology demonstrated a statistically significant reduction in peristomal skin complications, along with additional user benefits. As a result, the product has been awarded premium reimbursement by the HSE. The HIHI played a central role in getting the Ostoform Seal to market in Ireland, and this will result in improved quality of life for ostomy patients across the country.

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