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

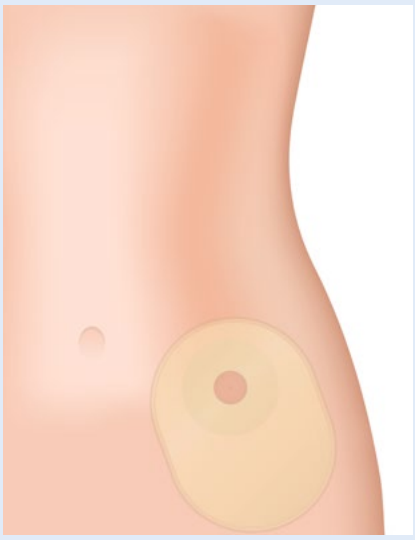
Health Innovation Hub Ireland (HIHI) was established by the Department of Business, Enterprise and Innovation and the Department of Health, supported by Enterprise Ireland (EI) and the Health Service Executive (HSE) to drive collaboration between the health service and enterprise.

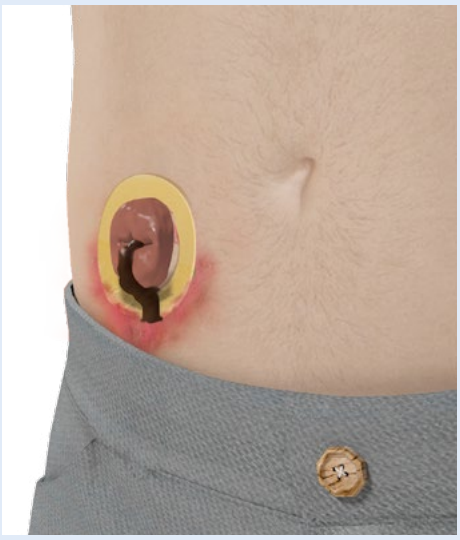
We offer companies the opportunity for pilot and clinical validation studies and the health service access to innovative products, services and devices that they may not otherwise be exposed to.

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

The Healthcare Challenge

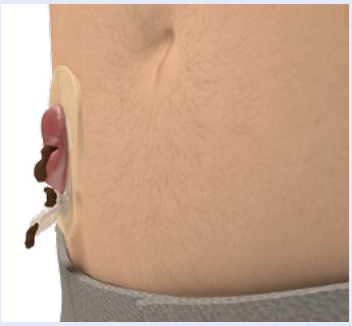
People who have had a surgically created stoma, particularly an ileostomy, are at risk of developing peristomal skin complications, with incidence rates of up to 63% reported in literature. Currently, treatments of peristomal skin complications are limited. Pastes are available, but they can often impede 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.

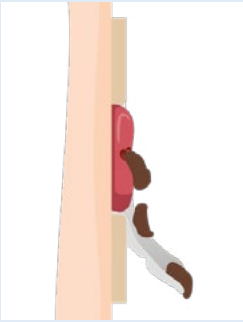




The Healthcare Solution

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 a clinical single arm investigation study, including ethics and protocol submission support. The study ran across three sites – TUH, St James' and UHG, engaging two CRFs in Dublin and 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.

There were two parts to the study - 1: assess the efficacy of Ostoform in managing peristomal skin complications in patients with ileostomies over a four-week period. Part 2: Assess patient satisfaction and experience with the use of Ostoform over a four-week period. There were 21 participants in total across the three sites.

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 Ostoform Seal would result in a longer wear time.

Follow-up studies, assessing the ability of the novel barrier ring to reduce skin complications among participants with a higher baseline DET score were recommended.

Testimonial

HIHI gave us access to the Irish clinical network and support in achieving ethics approval and study setup. The support in study management was an efficient framework to conduct an independent study across multiple sites.

Kevin Kelleher,
Founder/CEO Ostoform

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