



The New Standard.



Fewer Leaks



Healthier Skin



Reduced Cost of Care



Company Overview Ostoform is an Irish-based company that is certified to ISO 13485 for the design, manufacture and supply of ostomy products. The company was born out of a need to improve skin health and quality of life for people who have an ostomy.

Our mission is to set the new standard in stoma care through an unrelenting desire to deliver empowering, breakthrough solutions.

How **FLOWASSIST** Was Born



During his time in a Stanford-affiliated incubator program, Dr. Kevin Kelleher, CEO of Ostoform, had the opportunity to delve deep into clinical settings where he witnessed firsthand the challenges faced by ostomates. It was there that he discovered a critical issue – that absorbency and adhesive breakdown were significant contributors to peristomal skin complications. Drawing from his professional experience and Ph.D. in Biomedical Engineering, Dr. Kelleher embarked on a mission to address these issues.

This pursuit led to the creation of a revolutionary ostomy appliance component – FLOWASSIST. FLOWASSIST effectively channels stoma output away from the skin and into the ostomy appliance. The result? **Fewer leaks, healthier skin,** and a **reduced cost of care**. Backed by extensive research published in esteemed peer-reviewed journals, FLOWASSIST represents a significant leap forward in the field of ostomy care.

The Problem







Hydrocolloid breaks down because it absorbs corrosive stoma output.

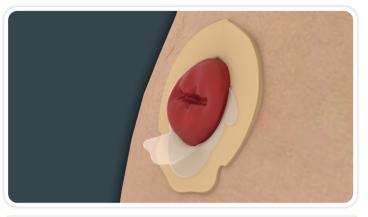
The corrosive output reaches the skin, causing peristomal moisture-associated skin damage.

cycle of leakage and worsening skin condition.

How **FLOWASSIST** Works



Shields the adhesive from excessive absorption and erosion.



Directs corrosive stoma output away from the skin and into the pouch.

Benefits of **FLOWASSIST**





Enhanced Leakage Protection



Hydrocolloid Protection For Extended Wear Time



Improved Skin Health



Premium Security & Comfort



Study 1



Read Clinical Study

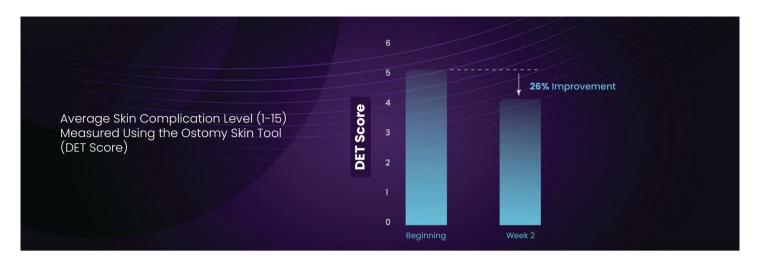
Kelleher K et al., 2019. A Single-arm Practical Application Assessment of User Experience and Peristomal Skin Condition Among Persons with an Ileostomy.

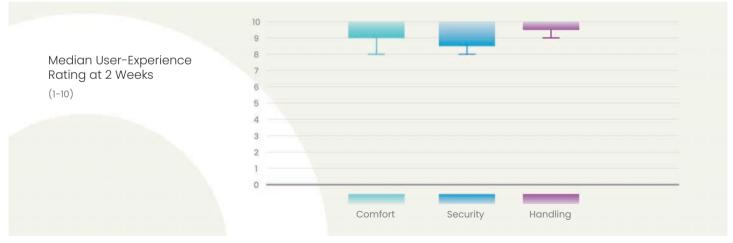
Wound Management & Prevention., 65(1) pp. 14-19

5 ileostomates wore the FLOWASSIST Seal for a period of 2 weeks. Skin condition was assessed by a research nurse at the beginning and end of the study. At 2 weeks, participants demonstrated, on average, a 26% improvement in skin condition while using the FLOWASSIST Seal. In addition, participants rated the FLOWASSIST Seal at a median of 10/10 (10 being the most positive result) for key metrics: Comfort, Security and Handling.

This study has been published in the Journal Wound Management & Prevention.

- Mean DET score decreased from 5.4 ± 2.2 at initial assessment to 4.0 ± 1.9 at 2 weeks.
- Participants demonstrated, on average, a 26% improvement in skin condition.
- Patients scored highly for all user-experience ratings.





Study 2



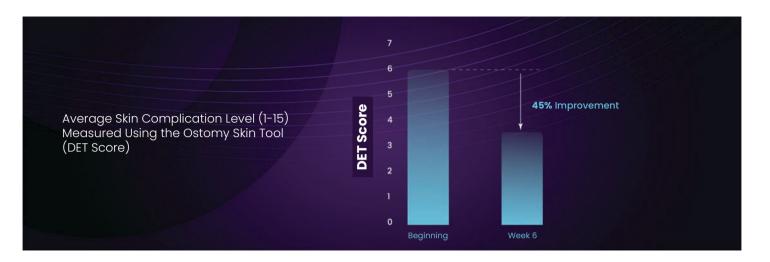
Read Clinical Study

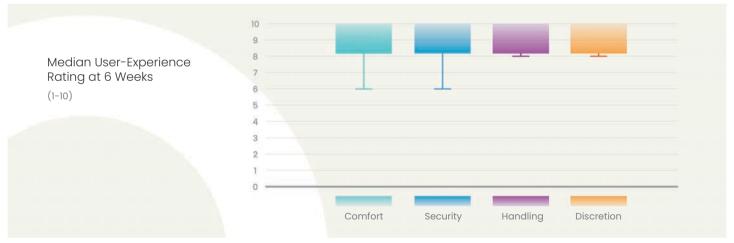
Hunt R et al., 2018. Changes in Peristomal Skin Condition and User Experience of a Novel Ostomy Barrier Ring with Assisted Flow. **J Wound Ostomy Continence Nurs., 45(5) pp. 444-448**

12 ileostomates wore the FLOWASSIST Seal for a period of 6 weeks. Skin condition was assessed by a research nurse at the beginning and the end of the study. At 6 weeks, participants demonstrated, on average a 45% improvement in skin condition while using the FLOWASSIST Seal. No participant experienced worsening in skin condition during the study. In addition, participants rated the device at a median of 10/10 (10 being the most positive result) for key metrics: Comfort, Security, Handling and Discretion.

This study has been published in the Journal of Wound Ostomy & Continence Nursing.

- Mean DET score decreased from 6.2 at baseline to 3.1 at 6 weeks, indicating a statistically significant reduction (95% CI; P<0.001).
- The peristomal skin condition of 9 participants improved, 3 experienced no change.
- Patients scored highly for all user-experience ratings.





Study 3



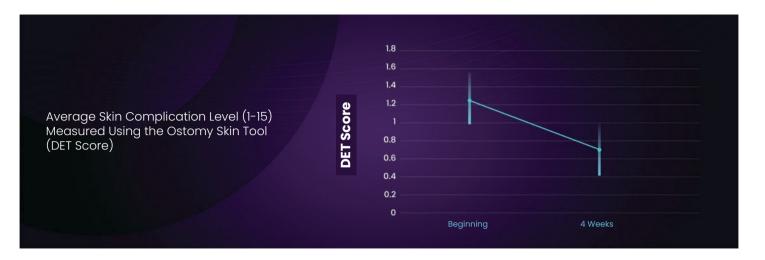
Read Clinical Study

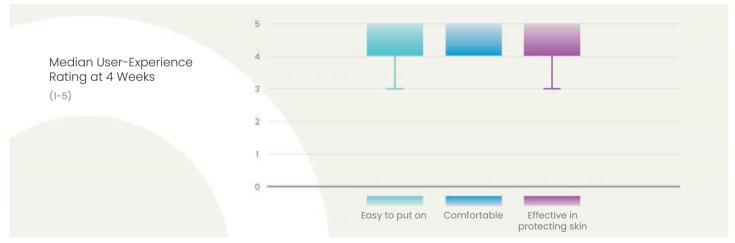
Quigley et al., 2021. Evaluation of a Novel Ostomy Barrier Ring with Assisted Flow for individuals with an ileostomy. **Advances in Skin & Wound Care, 34 pp. 1-5**

20 ileostomates wore the FLOWASSIST Seal for a period of 4 weeks. Data was collected across 3 clinical sites. At 4 weeks, the median participant peristomal skin complication score was 0, measured using the Ostomy Skin Tool (OST). 14 of the 20 participants who completed the study used a seal before the beginning of the study. An average improvement in skin condition of 62% was demonstrated for the 14 participants who wore a regular seal before commencing the study. 71% of participants stated that the FLOWASSIST Seal lasts longer that their current seal, and participants scored very highly on user experience ratings, with a median score of 5/5 (5 being the most positive experience).

This study has been published in the Journal Advances in Skin & Wound Care.

- Average improvement in skin condition of 62% was demonstrated for the participants who wore a regular seal before commencing the study.
- 71% of participants stated that the FLOWASSIST Seal lasts longer than their regular seal.
- Patients scored highly for all user-experience ratings.





Study 4



Read Clinical Study

Quigley et al., 2022. Statistically significant improvement in peristomal skin condition due to adhesive breakdown prevention by novel barrier ring with assisted flow. **Gastrointestinal Nursing, Vol. 20, No. 8. pp. 34-41**

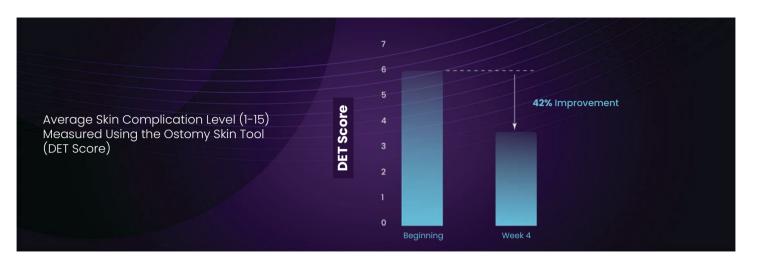
19 patients with an ileostomy for 3 months or more wore the FLOWASSIST Seal for a period of 4 weeks.

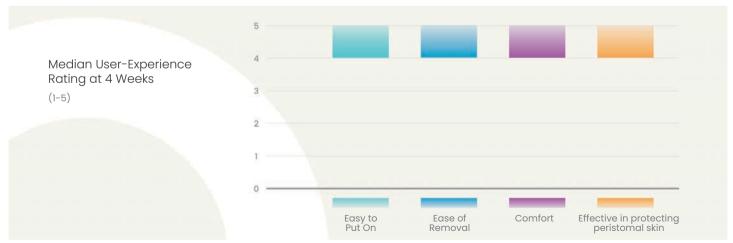
Among the participants, switching to the FLOWASSIST Seal resulted in statistically significant improvement in peristomal skin health. The average skin damage (DET) score started at 6.21 ± 3.63 at time T=0 and decreased to 3.63 ± 3.56 at time T=4 weeks (p<0.001; Cohen's D=1.09). The average scores for ease of application, ease of removal and comfort of the novel barrier ring were all greater than 4.5 out of 5 (5 being the most positive experience) and an average score of 4 out of 5 was given for its effectiveness at protecting the peristomal skin.

This study has been published in the Journal Gastrointestinal Nursing.

- Statistically significant improvement in skin condition

 average improvement of 42%.
- Rated highly by patients for effectiveness in protecting the skin.
- · Consistently positive user experience ratings.





Study 5



Read Clinical Study

Colwell, J, Pittman J et al., 2024. Evaluation of a Skin Barrier Ring with Assisted Flow: A Prospective Cohort Study. **J Wound Ostomy Continence Nurs., 51(1) pp 46-50.**

Both inpatients and outpatients with newly created (n=14) or established (n=1) ileostomies wore the FLOWASSIST Seal. Upon final assessment, 8 of the 14 (57%) participants with newly created ileostomies maintained a skin complication (DET) score of \leq 2, measured using the Ostomy Skin Tool. One participant with an established ileostomy had a DET score reduced from 10 at baseline to 0 on final assessment.

When comparing the incidence of PSCs in participants with an ileostomy in this study to incidence reported in literature, the clinical outcomes appear favorable and encouraging in using the FLOWASSIST Seal.

Of the 15 participants, 13 (86.7%) agreed that the FLOWASSIST Seal was easy to put on, and 14 (93.4%) agreed that it was both comfortable and easy to remove. All 15 (100%) participants agreed was it discreet under clothing.

This study has been published in the Journal of Wound Ostomy & Continence Nursing.

- The use of the FLOWASSIST Seal with newly created stomas yielded very positive outcomes.
- Comparative analysis indicated favorable clinical outcomes in peristomal skin complications when using the FLOWASSIST Seal.
- Consistently high user experience ratings.



I was sick in bed with some virus and when I finally changed my bag after lying flat for three days, the skin was perfect, not a mark! Another time I was in hospital very sick and unable to move. I got bed baths but the bag was left in place for five days and when it was eventually removed, my skin was fine, **no burns or leaks after lying flat for five days.** I am more than happy to recommend FLOWASSIST to anyone with a liquid output, as it's the best Seal I've used.



FLOWASSIST has been a **game-changer** for every patient I have tried it on. I keep it in stock at the hospital now. I have shared this product with our local WOC community because I have been so impressed with the outcomes!

HEALTHCARE PROFESSIONAL · Lisa, USA



I have an ileostomy with large output. I had been changing my appliance every two days with lots of skin breakdown. Now with the creation of the FLOWASSIST Seal I am getting 4–5 days of wear time and my skin looks better than it has looked in years. I want to thank all those involved in the creation of the FLOWASSIST. It has **really changed my life**.

OSTOMATE · Mary, USA

Choose **FLOWASSIST** FIRST: The best defense for all stoma types.

FLOWASSIST: A Catalyst for Healthcare Savings – Independent Validation and Case Studies

FLOWASSIST technology has garnered support for its costsaving potential in healthcare systems. An independent analysis¹ by Fraunhofer IMW, a reputable German health economics research institute, summarizes findings from existing studies, clinician interviews, and market data. The report concludes that FLOWASSIST has the potential to save £10.79 million (\$13.72 million USD) annually in the UK.

Additionally, four UK-based case studies conducted at Aintree Hospital, Liverpool, highlight FLOWASSIST's efficacy in improving clinical outcomes and extending ostomy appliance wear-time. Cost savings, calculated by UK Health Economist Grahame Wilkinson, MSc Health Econ, demonstrate substantial cost saving potential for each patient, extrapolated over a year.



Annual Savings

The Fraunhofer analysis reinforces FLOWASSIST's cost-saving capabilities, revealing that "On average, a tripling in the use of ostomy products is to be expected with leakage. Thus, by using FLOWASSIST with the appropriate target group, an extension of the wear time can be achieved, which goes hand in hand with lower material consumption."

Repeated demonstrations underscore FLOWASSIST's ability to prolong the lifespan of ostomy appliances by protecting adhesive integrity. By preventing excessive stoma output absorption, FLOWASSIST ensures the adhesive remains intact, leading to longer wear-time for stoma appliances and potential cost savings for healthcare systems.

Case Study 1

£2,598.80 (\$3,303 USD) annual savings

Case Study 3

£2,395.13 (\$3,044 USD) annual savings

Case Study 2

£4,123 (\$5,241 USD) annual savings

Case Study 4

£1,863.79 (\$2,369 USD) annual savings

This is such an **innovative barrier ring**. The directional flow makes a tremendous difference in draining liquid effluent in the pouch rather than undermine the barrier. Brilliant!



HEALTHCARE PROFESSIONAL Paula, USA

Every day, more and more people are realizing the benefits of using **FLOWASSIST**.

I recently had ileostomy surgery. After the surgery, I could not seem to stop the leaking and my skin breakdown was getting worse. After finding the FLOWASSIST Seal my skin has had a chance to heal. I was having leakage multiple times a day, sometimes every 15 minutes. I can now get **5-7 days wear time** using the FLOWASSIST Seal. My skin is now healing, and I am able to use bags longer without leaks!!!



I have to say that the samples you sent have been used by a few patients with **great results!** We have one patient in particular who had an ostomy revision and due to scar tissue, the stoma sits flush to her skin causing constant leaking. Very rarely could she go 12 hours or more without a leak. With the FLOWASSIST Seal, she had a better result and less skin breakdown.



HEALTHCARE PROFESSIONAL · Trish, USA

Male with hemicolectomy with diverting loop ileostomy

Patient History

- Patient had several weeks of extreme leakage from his high-output fluidic stoma.
- · Downward and slanted OS.

Introduced the FLOWASSIST Seal

• Used with 1-piece convex pouch.

Feedback

- This case demonstrates how convexity alone was inadequate to prevent leakage.
- Pouch wear time increased to 6 days with no further leaks.



Day 1







Week 4

Poster "Game Changer: Use of an Innovative Spouted Hydrocolloid Ostomy Barrier Seal to Manage High Output Ileostomy" presented at the Mid-Atlantic WOCN Conference 2023, by Keisha McElveen-Edmonds MS, BSN, RN, CWON, Baltimore VA Medical Center Baltimore, Maryland, USA.

Colostomy patient with peristomal skin complications

Patient History

- History of left lower quadrant diverting colostomy and partial colectomy for ruptured diverticulum 6 weeks prior to evaluation.
- Patient also developed a midline abdominal wound infection.
- Home Health requested assistance for Deteriorating peristomal skin and frequent pouch changes due to leakage.

Introduced the FLOWASSIST Seal

• Used with a convex skin barrier.

Feedback

- By day 14, skin condition had improved.
 Home Health reported a reduced need for unscheduled calls for pouch changes within 1 week and no unscheduled visits by day 14.
- By day 21, the peristomal skin was intact with post-inflammatory hyperpigmentation.
- The patient was learning self-care for stoma with new regimen.







Day 14



Day 21

Poster "An Innovative Combination Ostomy Barrier Seal and Spout to Reduce Peri-Stomal Skin Complications" presented at WOCNext 2022 by Catherine T. Milne MSN,APRN, ANP/ACNS-BC, CWOCN-AP, Connecticut Clinical Nursing Associates, Bristol, Connecticut, USA.

Colostomy patient with large peristomal hernia

Patient History

- 4-year history of pruritus and "burning" at the edge of a diverting colostomy.
- Flush stoma with lateral retraction and altered abdominal topography.
- Changed pouch every 2 days due to leakage and resulting pruritus.
- During the initial evaluation, stitch granulomas were noted, and the suture was removed.

Introduced the FLOWASSIST Seal

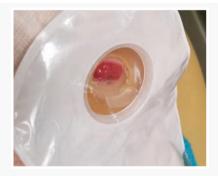
• Used with 1-piece convex pouch.

Feedback

- By day 7, early flattening of the granulomas was observed, and the patient no longer experienced pruritus/burning symptoms.
- By day 28, the patient had reduced pouch changes from every 2 to every 5 days.







Poster "An Innovative Combination Ostomy Barrier Seal and Spout to Reduce Peri-Stomal Skin Complications" presented at WOCNext 2022 by Catherine T. Milne MSN,APRN, ANP/ACNS-BC, CWOCN-AP, Connecticut Clinical Nursing Associates, Bristol, Connecticut, USA.

Colostomy patient with growth near stoma

Patient History

- 35 year history of left lower quadrant diverting colostomy for rectal cancer.
- Significant other reported skin changes or "growths" that appeared near the stoma 2 years prior to an initial consultation.
- Patient wanted no intervention and was sent by colorectal surgeon for peristomal skin management.
- · Large parastomal hernia was noted.
- 5-year history of poor pouch adherence with pouch changes 2 times per day.
- Resistant to change current pouching system.

Introduced the FLOWASSIST Seal

- Used with hydrocolloid strips for extra dressing.
- Collogen was applied over ulceration and other open areas prior to the Seal.

Feedback

- By day 14, patient reported minimal leakage under the Seal.
- Patient reported improved quality of life.
- By day 28, the peristomal skin had improved.
- The patient was referred to colorectal surgery for follow-up.











Day 1

Day 14

Day 28

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lleostomy patient with pressure ulcers from firm convex baseplate

Patient History

- Loop ileostomy with parastomal hernia.
- Used a firm convex baseplate for 2 years.
- Developed pressure ulcers from the rigid baseplate.

Introduced the FLOWASSIST Seal

• Used with 2-piece flat pouch.

Feedback

 In the space of a week, there was a visible improvement, healing was taking place, he had no leaks, and he was able to manage his own appliance change himself.









Day 7

Poster "A Practical Look at the Novel FLOWASSIST Barrier Ring and Its Indications For Use in the Stoma Care Setting" presented at ASCN UK 2023 by Mary W Quigley, Clinical Nurse Specialist in Stoma Care / Colorectal, Galway University Hospital, Galway, Ireland.

Urostomy patient in need of convexity

Patient History

- Soft convex pouch was not giving the required seal.
- Tried convex seal but found it too uncomfortable.
- Conventional flat seal was showing evidence of MASD.

Introduced the FLOWASSIST Seal

• Used with 2-piece flat pouch.

Feedback

- Introducing the FLOWASSIST Seal allowed the urine to flow into the pouch away from the skin.
- This small change has made a huge difference to this lady's life.







"I can now trust that when I change my appliance, it will give me 48 hours of comfort, I now have a routine and I'm in control."

QUOTE FROM PATIENT

Poster "A Practical Look at the Novel FLOWASSIST Barrier Ring and Its Indications For Use in the Stoma Care Setting" presented at ASCN UK 2023 by Mary W Quigley, Clinical Nurse Specialist in Stoma Care / Colorectal, Galway University Hospital, Galway, Ireland.

Female experiencing unexplained leakage

Patient History

- Long-term IBD patient.
- · New end ileostomy.
- Experienced leakage.
- Used a flat pouching system with a flat barrier ring.
- Found convexity to be too uncomfortable.

Introduced the FLOWASSIST Seal

• Used with flat pouching system.

Feedback

- Patient finds the FLOWASSIST Seal comfortable and easy to fit.
- Since using FLOWASSIST, the patient has not experienced a single leak.
- Stoma nurses say FLOWASSIST prevented her from becoming a 'problem patient'.



Conclusion

The FLOWASSIST Seal has meant that this patient was able to happily adapt to life with a stoma. She was able to go on her first vacation since surgery without the worry of leakage.

Urostomy patient experiencing severe leakage

Patient History

- Urostomy patient with a retracted stoma.
- Used convex seal with a convex pouching system.
- Experiencing leakage up to 5 times per day.
- Frequent leakage lead to flare-ups in sore skin.

Introduced the FLOWASSIST Seal

• Used with convex pouching system.

Feedback

- 'This product has been a raging success'.
- Now changing his baseplate once every 4 days.
- No leaks since using FLOWASSIST which has given his skin time to recover.
- Skin is now healthy.



Conclusion

The FLOWASSIST Seal has changed this patient's life. He has gone from not knowing what each day will bring (1 pouch change or 5) to now reliably being able to change his pouch once every 4 days.

Before trying FLOWASSIST, the patient explained he sometimes did not want to leave the house, now he is going out dancing.

lleostomy patient with extreme leakage from pancaking

Patient History

- · Post-op ileostomy.
- · Retracted stoma.
- Experienced extreme pancaking, which lead to frequent leakage (up to 10 times per day).
- Peristomal skin was irritated and sore to touch.
- On average, was changing their pouching system 8 times per day.

Introduced the FLOWASSIST Seal.

• Used with 1-piece flat drainable pouching system.

Feedback

- · Now rarely experiences pancaking.
- · Leakage is now under control.
- Skin breakdown is beginning to heal.







"This product really has saved my life."

QUOTE FROM PATIENT

Day 1

Day 28

lleostomy patient requiring extended pouch wear time

Patient History

- · Ileostomy.
- Oval stoma that tilts downwards, but OS is central.
- Patient has a parastomal hernia.
- Has a history of leakage.
- Tried a traditional hydrocolloid seal but it failed.
- Experienced sore skin.

Introduced the FLOWASSIST Seal

• Used with 1-piece flat drainable pouching system.

Feedback

- Patient's skin condition has improved.
- Patient has continued to use the same pouching system and is no longer experiencing leakage.
- Patient reported no leaks since FLOWASSIST Seal was introduced.



Conclusion

Introducing FLOWASSIST has improved this patient's quality of life. She is able to resume daily activities without the worry of leakage.

lleostomy patient experiencing leakage

Patient History

- Post-op with new end ileostomy with prior loop stoma.
- Stoma OS points to the right.
- Found convexity to be too uncomfortable.
- Experienced leakage 2-3 times per day.
- Experienced skin breakdown with sore and inflamed skin.
- Leakage had impact on quality of life and daily activities.

Introduced the FLOWASSIST Seal

• Used with flat pouching system.

Feedback

- Before using the FLOWASSIST Seal, surgical intervention was being explored for stoma revision - it is now thought this will not be needed.
- Patient has now been using FLOWASSIST for 6 months with no leakage.
- Patient has an improved quality of life and describes the FLOWASSIST Seal as "lifechanging".



"After trying several products to help with the positioning of my stoma, this Seal has succeeded. The Seal fits snug around the stoma and is comfortable. The spout is soft, flexible and discreet under clothing. I feel safe and secure with this product, and I am not as anxious as I was."

QUOTE FROM PATIENT

lleostomy patient with complex fistula

Before FLOWASSIST

- New end ileostomy after jejunostomy reversal.
- Developed complex fistula post-op, which outputs more than 1 litre daily.
- Uses a high output system with flow collector and daily TPN
- Position of the fistula points downwards and has a tracking at 1 o'clock.

After 48 hours of using FLOWASSIST

- 2 large FLOWASSIST Seals are used to manage this fistula due to the positioning.
- Changing appliance 2-3 times per day.
- Patient was able to go home for the first time in months.

After 4 Days of using FLOWASSIST

• Skin is no longer painful to touch, appliances are now comfortable and manageable.

After 11 Days of using FLOWASSIST

· Skin condition significantly improved. *

*Subsequent to this case study, the patient had surgery to refashion her ileostomy and surgical intervention on the fistula. The patient is now using the FLOWASSIST Seal on her ileostomy with positive results.









FLOWASSIST
Innovation for
Every Stoma Type.

Colostomy patient with abdominal fistula

Patient History

- Catheter inserted into retracted transverse colostomy that was adjacent to an abdominal incision that had dehisced.
- Required VAC dressing that was causing the pouch to leak.

Introduced the FLOWASSIST Seal

 Used 2 FLOWASSIST Seals to separate and direct the output with a large moldable skin protector.

Feedback

- We were able to divert the liquid output and thereby isolate the abdominal wound.
- As time progressed, we were able to manage a seal without the catheter.





Poster "A Practical Look at the Novel FLOWASSIST Barrier Ring and Its Indications For Use in the Stoma Care Setting" presented at ASCN UK 2023 by Mary W Quigley, Clinical Nurse Specialist in Stoma Care / Colorectal, Galway University Hospital, Galway, Ireland.

Female with enterocutaneous fistula and colostomy

Patient History

- Colostomy for > 10 years.
- Developed fistula in wound area after parastomal hernia repair.
- Used a 1-piece moldable flat collection pouch.
- Experienced leakage more than 5 times per day.

Introduced the FLOWASSIST Seal

- Substituted moldable collection pouch for the FLOWASSIST Seal and a flat 1-piece drainable pouch.
- Initially a small of stoma paste is used to build up a deep surgical incision scar.

Feedback

- The FLOWASSIST Seal and pouch remain in place for at least 4 days.
- · Stoma paste is no longer required.
- This resulted in substantial reduction in labor and material costs and a significant improvement in the patient's quality of life.







This case study was carried out by stoma care professionals in collaboration with Wellform, Ostoform's distribution partner in the Netherlands

Male with enterocutaneous fistula

Patient History

- High-output enterocutaneous fistula.
- Patient being treated with chemotherapy experienced leakage 4-5 times per day.
- Used a conventional seal with a 1-piece convex ileostomy pouch.

Introduced the FLOWASSIST Seal

• Used with 1-piece convex ileostomy pouch.

Feedback

- After 3 days, no leaks were noted.
- Patient's skin is healing well.







This case study was carried out by stoma care professionals in collaboration with Wellform, Ostoform's ditstribution partner in the Netherlands.

lleostomy patient experiencing pancaking

Patient History

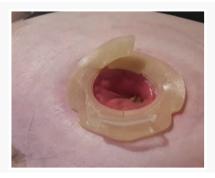
- Oval-shaped ileostomy.
- Wears 1-piece convex closed pouch.
- Developed problems with pancaking a few weeks post-op.
- · Pancaking resulted in frequent leakages.
- Changed pouch at least 3 times per day due to leakages.
- Followed nurse's advice on how to prevent pancaking but nothing worked.

Introduced the FLOWASSIST Seal

• Used with 1-piece convex closed pouch.

Feedback

- Patient only needs to change his pouch when it is full, which is usually once per day.
- Skin condition has improved.
- Now rarely experiences pancaking and resultant leakages.
- Patient is much more confident to go out and live his life.







Read Full Clinical Studies and Case Studies

https://ostoform.com/healthcare-professionals/clinical-studies/



Begin with Confidence. Start with **FLOWASSIST**.