OSTOFORM

The Ostoform Seal with FLOWASSIST Protection

Product Overview

www.ostoform.com

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COMPANY OVERVIEW

Ostoform Limited 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.

Ostoform is a multi-award-winning company recognised *"as a business with major potential for innovation and market impact."* The company is supported by Enterprise Ireland and the European Commission.

THE OSTOFORM APPROACH

At Ostoform, we are a small team of people working towards the common goal of solving problems experienced by those living with an ostomy.

From the very beginning, Ostoform has been guided by process and procedure, grounded in science and reason. From new product development to customer interactions, we adopt the same pragmatic, measured and solution-focused approach. Adopting this mindset has allowed us to rethink what is possible, to innovate and to create a product that offers a new solution to an age-old problem.

DEFINING THE PROBLEM

Peristomal Skin Complications

93% of people with a stoma worry about leakage[1] and approximately 60% suffer from peristomal skin complications[2]. These skin complications account for one-third of visits to stoma care nurses[3], placing additional pressure on already overburdened healthcare systems. Furthermore, approximately one-third of people with a stoma experience a skin complication within 90 days of stoma surgery, resulting in significantly higher costs of postsurgical care[4]. Peristomal skin complications are expensive and difficult to manage[5], and there is a clear need to find new and alternative solutions to address this well-established problem.

Peristomal Moisture-Associated Skin Damage

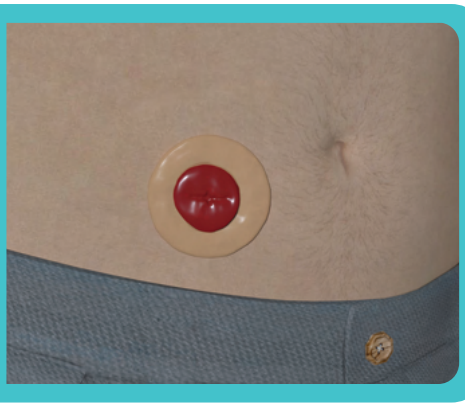
The most common form of peristomal skin damage is Peristomal Moisture-Associated Skin Damage (MASD)[6]. This occurs when exposure to stoma output leads to inflammation of the skin, with or without erosion or secondary cutaneous infection[7]. Individuals with fluidic and high-output stomas are at higher risk of experiencing this challenge because of the irritant nature of their output.

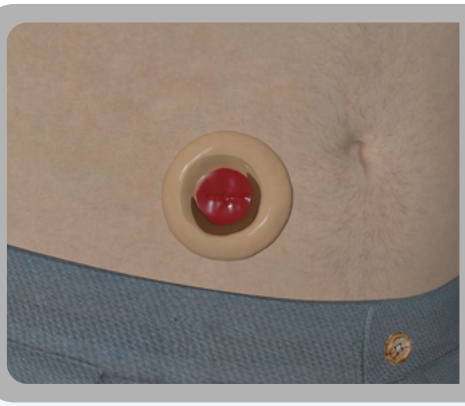
Hydrocolloid Breakdown

Even with the use of barrier rings and seals, there is still a high incidence of skin complications among people with a stoma. One of the reasons why a standard barrier ring does not offer comprehensive skin protection is due to the absorbency of the hydrocolloid material used in these products[8]. When the absorbent hydrocolloid material used in most protective barrier rings absorbs the ostomy output and swells, the barrier loses its structural integrity and subsequently disintegrates. Compromised protective hydrocolloid material, compounded by the absorption of corrosive stoma output towards the skin can result in an increased likelihood that the wearer will experience skin irritation and peristomal MASD[8,9]. Hydrocolloid breakdown also results in reduced appliance wear-time, leading to a recurring cycle of leakage and worsening skin condition. While standard barrier rings can delay the peristomal MASD issues experienced by people with a stoma, they cannot prevent output from contacting the skin over an extended period of time.

1. Coloplast Ostomy Life Study Review 2016/2017
2. Martins L, et al. (2011) Maintaining healthy skin around an ostomy: peristomal skin disorders and self-assessment. Gastrointestinal Nurs, 9 (Suppl 2):9–13.
3. Jemec G, Nybaek H. (2008) Peristomal skin problems account for more than one in three visits to ostomy nurses. B J Derm, 159
4. Taneja C et al. (2017) Clinical and economic burden of peristomal skin complications. J Wound Ost Cont Nurs, 44(4).
5. Meisner S et al. (2012) Peristomal Skin Complications Are Common, Expensive, and Difficult to Manage: A Population Based Cost Modeling Study. PLoS ONE, 7(5)
6. Gray M, et al. (2013) Peristomal moisture-associated skin damage in adults with fecal ostomies: a comprehensive review and consensus. J Wound Ostomy Continence Nurs, 40(4):389-399.
7. Colwell JC, et al. (2011) MASD part 3: peristomal moisture-associated dermatitis and periwound moisture-associated dermatitis: a consensus. J Wound Ostomy Continence Nurs, 38(5):541-555.
8. 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
9. 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

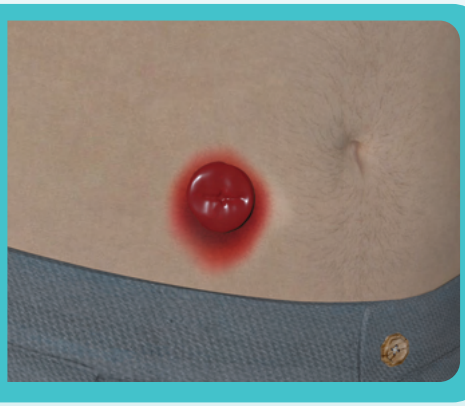
Standard barrier rings do not offer comprehensive skin protection due to the absorbency of the hydrocolloid material used in these products.





When the hydrocolloid absorbs the ostomy output and swells, the barrier erodes and disintegrates.

The corrosive stoma output then contacts the skin, resulting in an increased likelihood of skin irritation and peristomal moisture-associated skin damage.



> *When I was studying, I had access to the gastroenterology department in a local clinic, observing various procedures. During this time, I heard many people speak about peristomal skin complications and how difficult they are to manage. As a biomedical engineer I was eager to explore potential solutions. This was the beginning of Ostoform's journey.*
>
> **- Dr. Kevin Kelleher, CEO**

HOW THE OSTOFORM SEAL WORKS

Split Ring

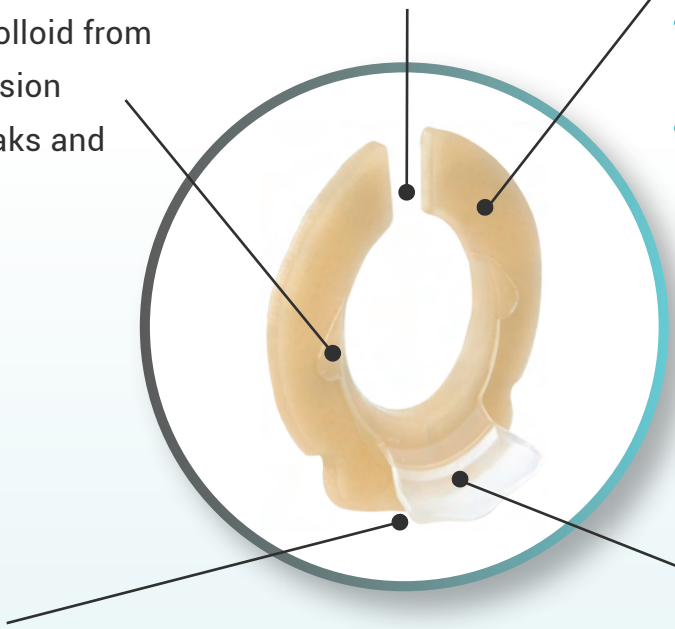
- Enables an accurate, secure fit

Non-Absorbent Polymer

- Shields the hydrocolloid from absorption and erosion
- Results in fewer leaks and longer wear-time

Moldable Hydrocolloid

- Next generation, skin-friendly, longer-lasting material
- Can mold and shape to fit all stoma types



Unique Pouch Positioning Slot

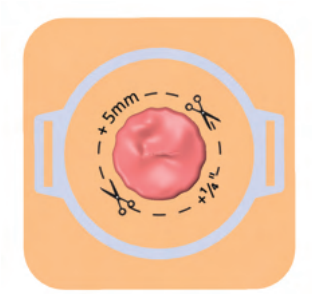
- Ensures an accurate, secure pouch attachment
- Compatible with one-piece and two-piece pouches
- Compatible with flat and convex pouches

Patented FLOWASSIST Technology

- Flexible spout directs the flow of output away from the skin and into the pouch
- Keeps skin safe, healthy and comfortable
- Spout acts as a non-tacky handling tab for easy application

> *High liquid volume is a big problem for me as this can have me changing even twice a day. When I experimented with the Ostoform Seal, I no longer had the fear of liquid making its way beneath the baseplate as FLOWASSIST helps to direct it away and does not let it puddle and leak in around the stoma… I am happy to have discovered this product as it provides me with much needed security for managing a stoma with a high liquid output.*
>
> **- Phoebe, Ostomate, USA**

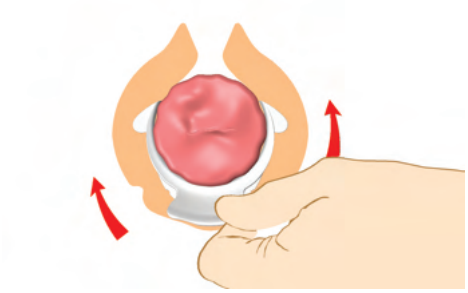
HOW TO USE THE OSTOFORM SEAL



Step 1

Cut the pouch or wafer opening to stoma size + ¼ " (5mm)

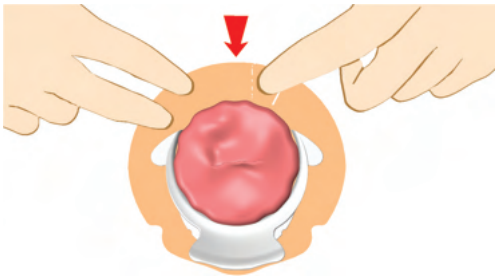
e.g. for a 1" stoma, cut the pouch opening to 1 ¼ ".



Step 2

Position the spout below the stoma

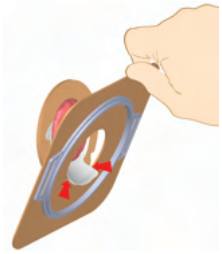
or rotate to align with the direction of output.



Step 3

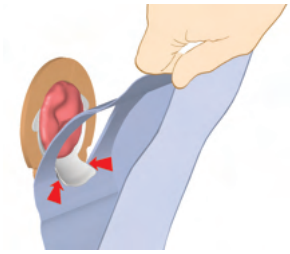
Wrap around the stoma and overlap the tabs

to ensure a complete seal.



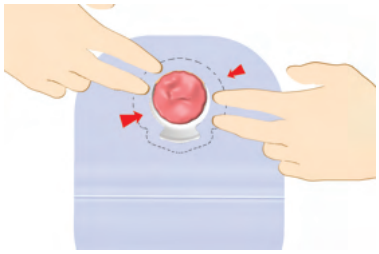
Step 4A

For secure 2-piece pouch attachment, position the baseplate over the Seal first, ensuring that the spout passes through the opening. Then, secure the pouch to the baseplate.



Step 4B

For secure 1-piece pouch attachment, ensure the spout is fully inside the pouch opening. Then, pull the pouch up into the slot underneath the spout.



Step 5

Press the pouch adhesive against the Seal

and skin to achieve secure adhesion.

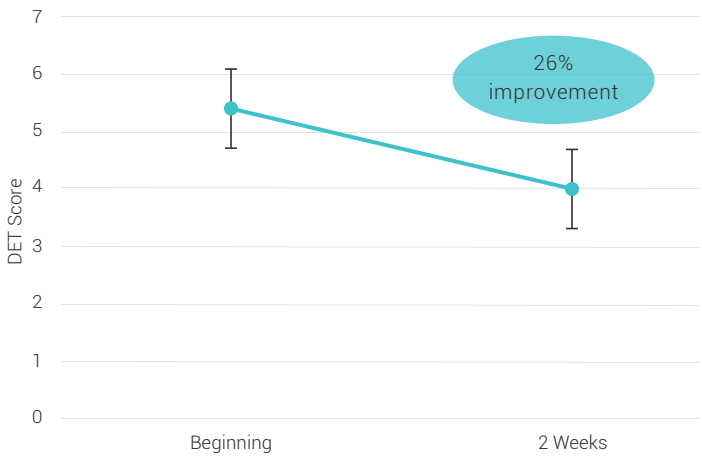
PROVEN IN CLINICAL STUDIES

CLINICAL OVERVIEW OSTOFORM SEAL STUDY 1

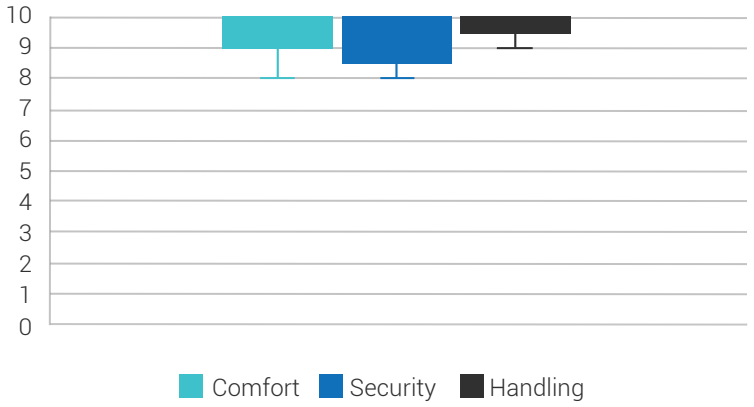
Kelleher K et al., 2019. A Single-arm Practical Application Assessment of User Experience and Peristomal Skin Condition Among Persons with an Ileostomy. **Wound Management & Prevention., 65(1) pp. 14-19**

Five ileostomates wore the Ostoform Seal with FLOWASSIST Protection for a period of two weeks. Skin condition was assessed by a research nurse at the beginning and end of the study. At two weeks, participants demonstrated, on average, a 26% improvement in skin condition while using the Ostoform Seal. In addition, participants rated the Ostoform 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.

Average Skin Complication Level (1 - 15)
Measured using the Ostomy Skin Tool (DET Score)



Median User-Experience Rating at 2 Weeks
(1 - 10)

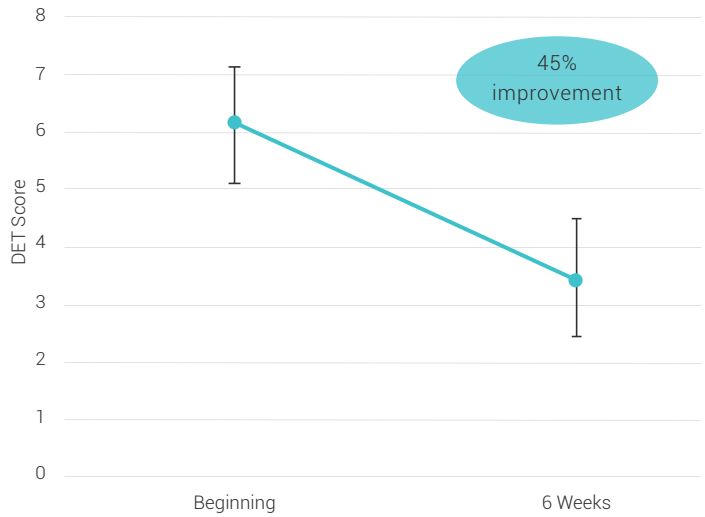


CLINICAL OVERVIEW OSTOFORM SEAL STUDY 2

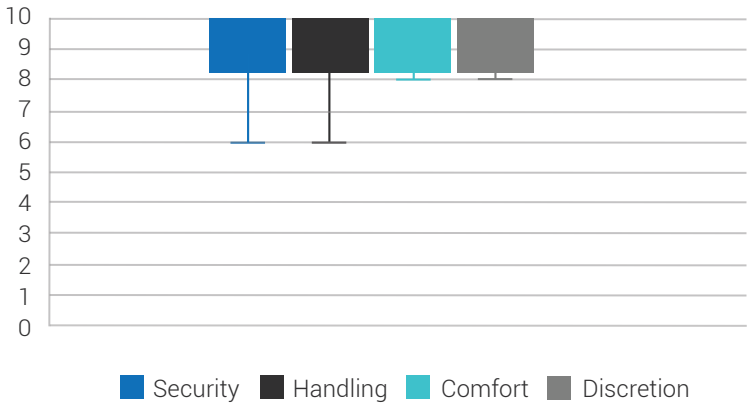
Hunt R et al., 2018. Changes in Peristomal Skin Condition and User Experience of a Novel Ostomy Barrier Ring with Assisted Flow. **J Wound Ostomy Continence Nurse., 45(5) pp. 444-448**

Twelve ileostomates wore the Ostoform Seal with FLOWASSIST Protection for a period of six weeks. Skin condition was assessed by a research nurse at the beginning and the end of the study. At six weeks, participants demonstrated, on average, a 45% improvement in skin condition while using the Ostoform Seal. No participant experienced a 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.

Average Skin Complication Level (1 - 15)
Measured using the Ostomy Skin Tool (DET Score)



Median User-Experience Rating at 6 Weeks
(1 - 10)

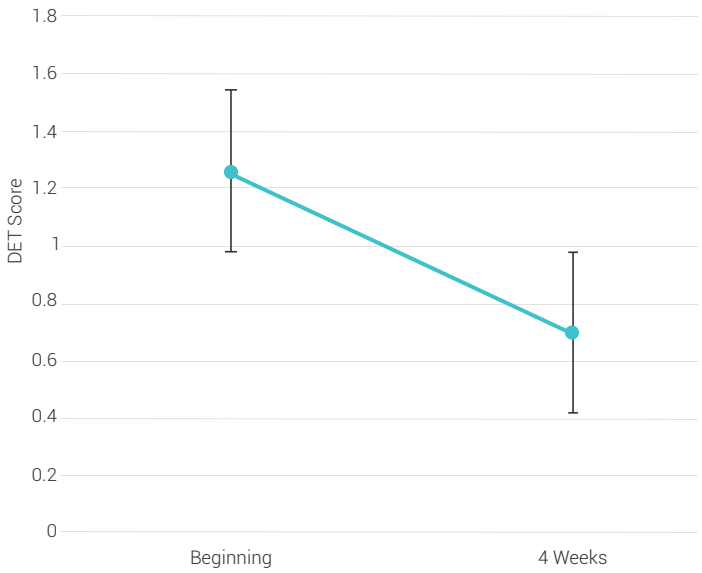


CLINICAL OVERVIEW OSTOFORM SEAL STUDY 3

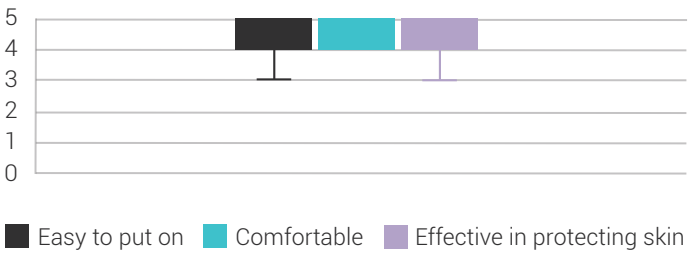
Quigley et al., 2021. Evaluation of a Novel Ostomy Barrier Ring with Assisted Flow for Individuals with an Ileostomy. **Advances in Skin & Wound Care, 34 pp. 1-5**

Twenty ileostomates wore the Ostoform Seal with FLOWASSIST Protection for a period of four weeks. Data was collected across three clinical sites. At four weeks, the median participant peristomal skin complication score was 0, measured using the Ostomy Skin Tool. Fourteen of the twenty participants who completed the study used a seal before beginning the study. An average improvement in skin condition of 62% was demonstrated for the fourteen participants who wore a regular seal before commencing the study. 71% of participants stated that the Ostoform Seal lasts longer than their current seal, and participants scored very highly on user experience ratings, with a score of 5/5 being the most positive experience. This study has been published in the Journal Advances in Skin & Wound Care.

Average Skin Complication Level (1 - 15)
Measured using the Ostomy Skin Tool (DET Score)



Median User-Experience Rating at 4 Weeks
(1 - 5)



MATERIAL SPECIFICATIONS

Biocompatability

Using an external ISO 17025 and GLP accredited laboratory, the Ostoform Seal has successfully completed external Biocompatibility testing based on ISO 10933 and FDA Guidelines. The device is approved for use on skin, based on cytotoxicity, skin irritation and skin sensitization testing. Relevant standards used in testing include:

- *ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.*
- *ISO 10993-10:2013 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization.*

Raw Materials

The raw materials used in the manufacturing process of the Ostoform Seal do not contain any of the following substances:

- *Animal derivatives*
- *Antibiotics*
- *Lanolin*
- *Latex*
- *Silver*
- *Triclosan*
- *Pectin*

> *This is such an innovative barrier ring. The directional flow makes a tremendous difference in draining liquid effluent into the pouch, rather than undermine the barrier. Brilliant!*
>
> **- Paula, Healthcare Professional, USA**

BENCH TESTING

Introduction

Ostoform has developed functional and performance test methods as part of design validation and conformity to ISO 13485:2016 – Medical Devices. The test methods and protocols used are derived from the International Organization for Standardisation ISO 12505 Skin barrier for ostomy aids — Test Methods. There are 2 parts to the ISO 12505 Skin barrier standard:

Part 1 details a test method called "Water Absorbency", defined as the "possibility which allows water in the skin barrier." This test is intended to assess "the fluid absorption capacity of skin barriers through the skin contact surface."

Part 2 details a method called "Wet Integrity", defined as the "ability of a skin barrier to maintain its physical form when exposed to fluid." Because skin barriers absorb water, deform and collapse over time, the test is used to measure swelling and/or erosion in simulated use.

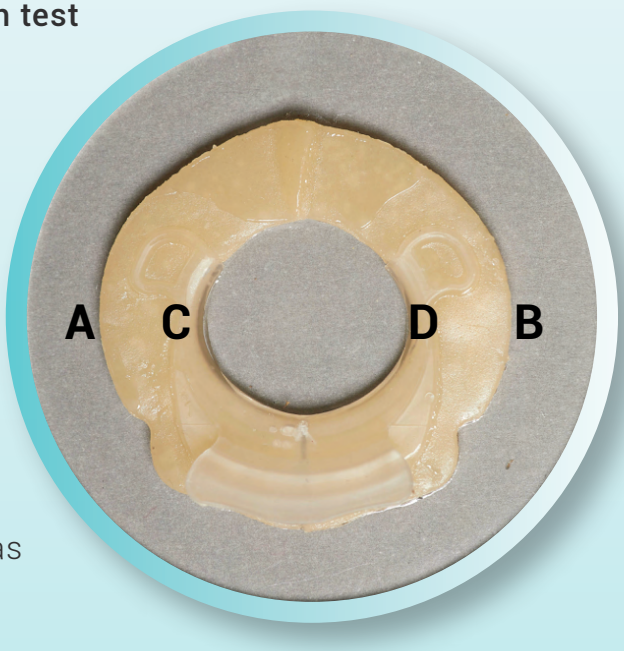
Measurements

Test Specimens

The Ostoform Seal was tested against two of the most popular brands of ostomy seals, considered to be the market standard. These comparator seals will be labelled "Market Standard 1" and "Market Standard 2".

Measurements taken at the beginning and end of each test

- Outer diameter: Distance measured from A to B.
- Inner diameter: Distance measured from C to D.
- Weight of the product.
- Height: Distance measured from base to top of hydrocolloid.



Reporting

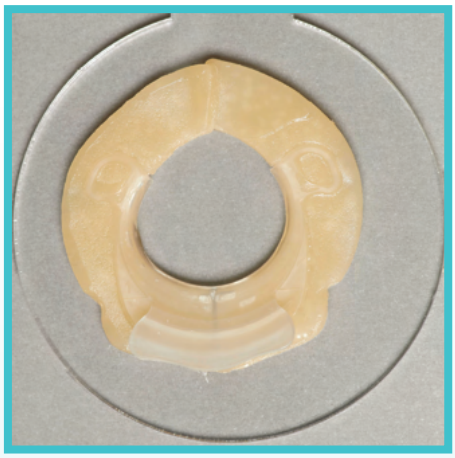
- In all cases, the change in each of these measurements from the beginning to the end of the tests was recorded. Results are reported as a percentage change.

Test 1: Water Absorbency (ISO 12505 – part 1)

Background

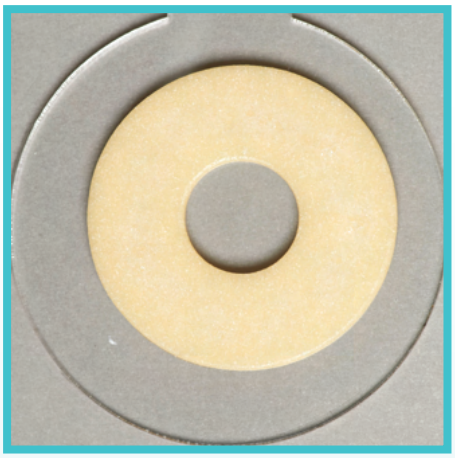
Saline solution is placed in the centre of each seal over a 24-hour time period.

Pre - Testing Photos



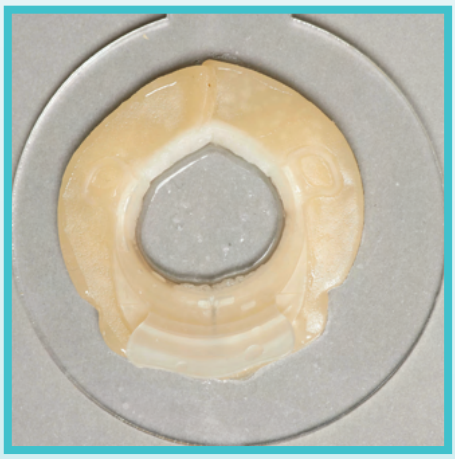
Ostoform OFA-M

Market Standard 1

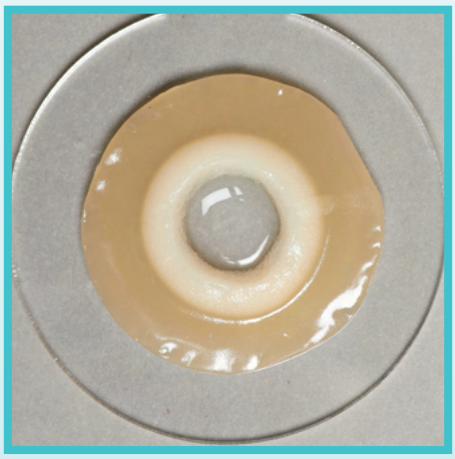


Market Standard 2

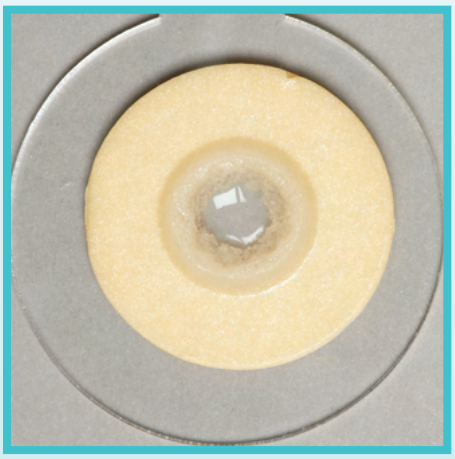
Completion (24 Hours)



Ostoform OFA-M

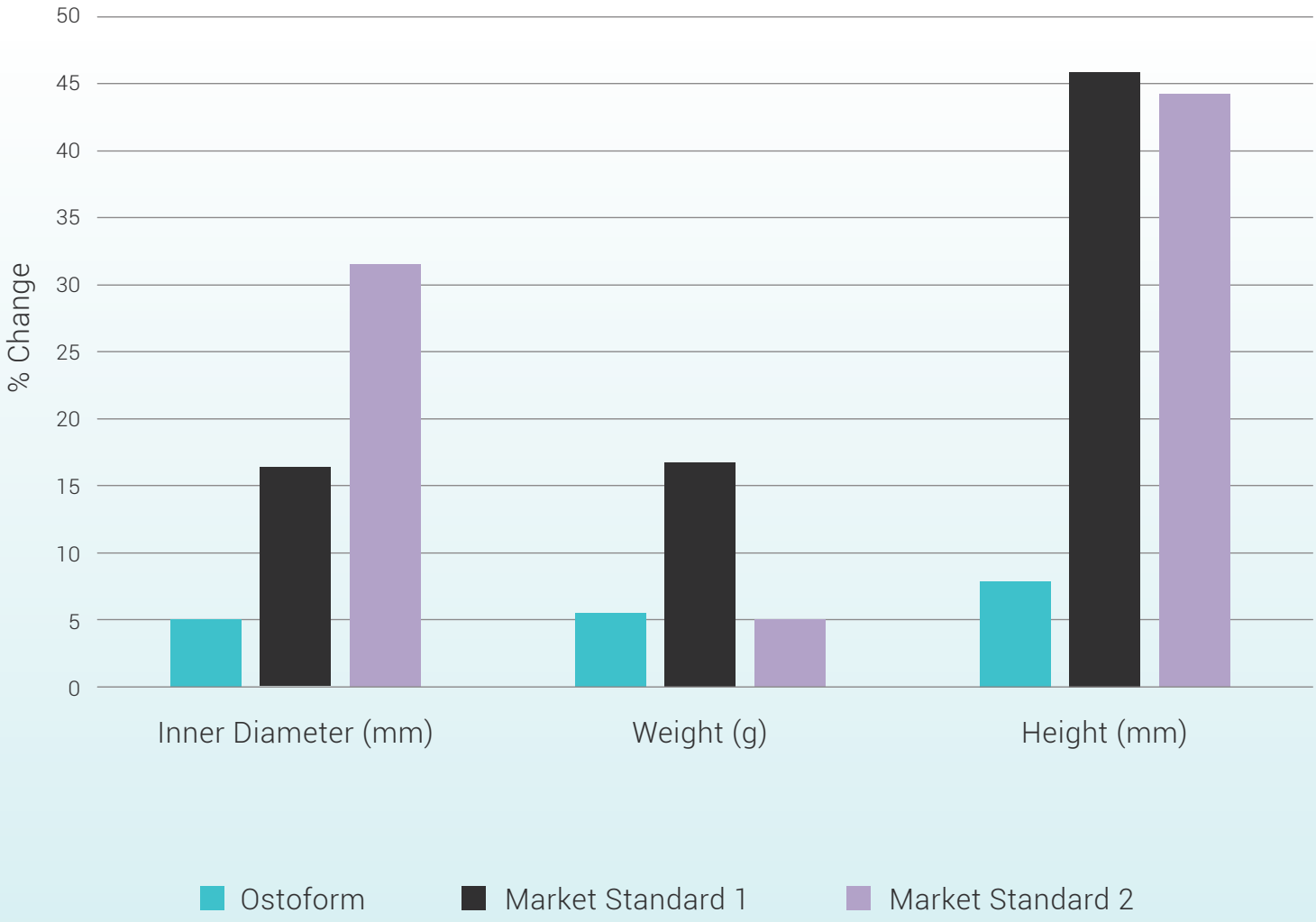


Market Standard 1



Market Standard 2

% Change in measurements from the beginning to the end of a 24-hour Water Absorbency Test

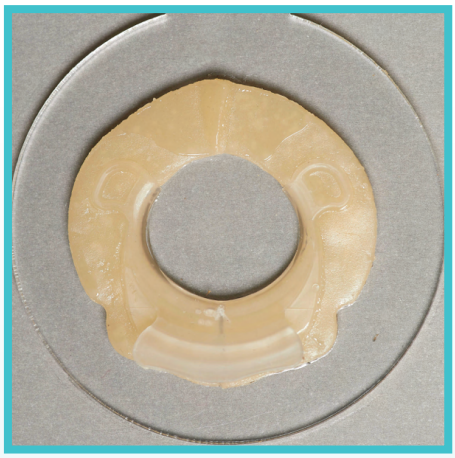


Test 2: Wet Integrity (ISO 12505 – part 2)

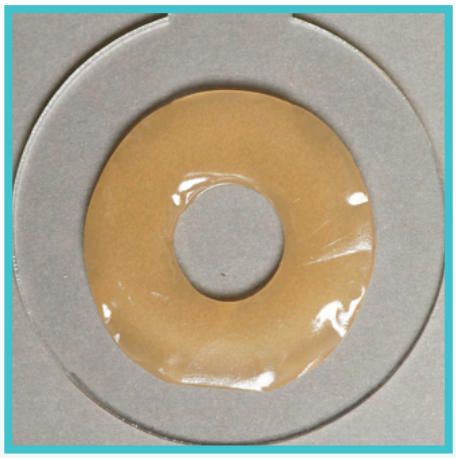
Background

Each seal is fully immersed in saline solution for 7 hours.

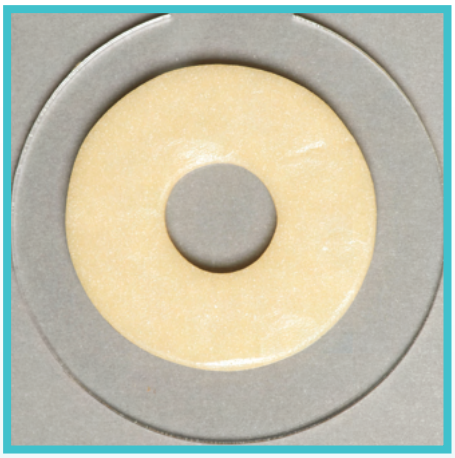
Pre - Testing Photos



Ostoform OFA-M

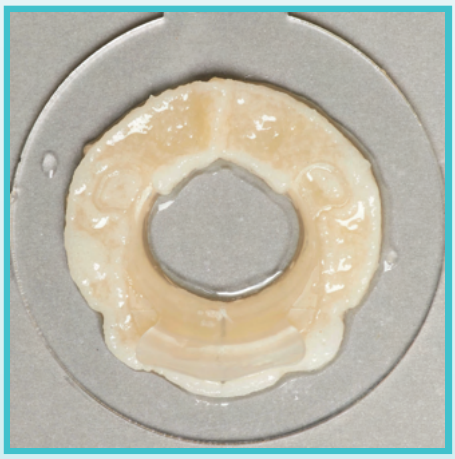


Market Standard 1



Market Standard 2

Completion (7 Hours)

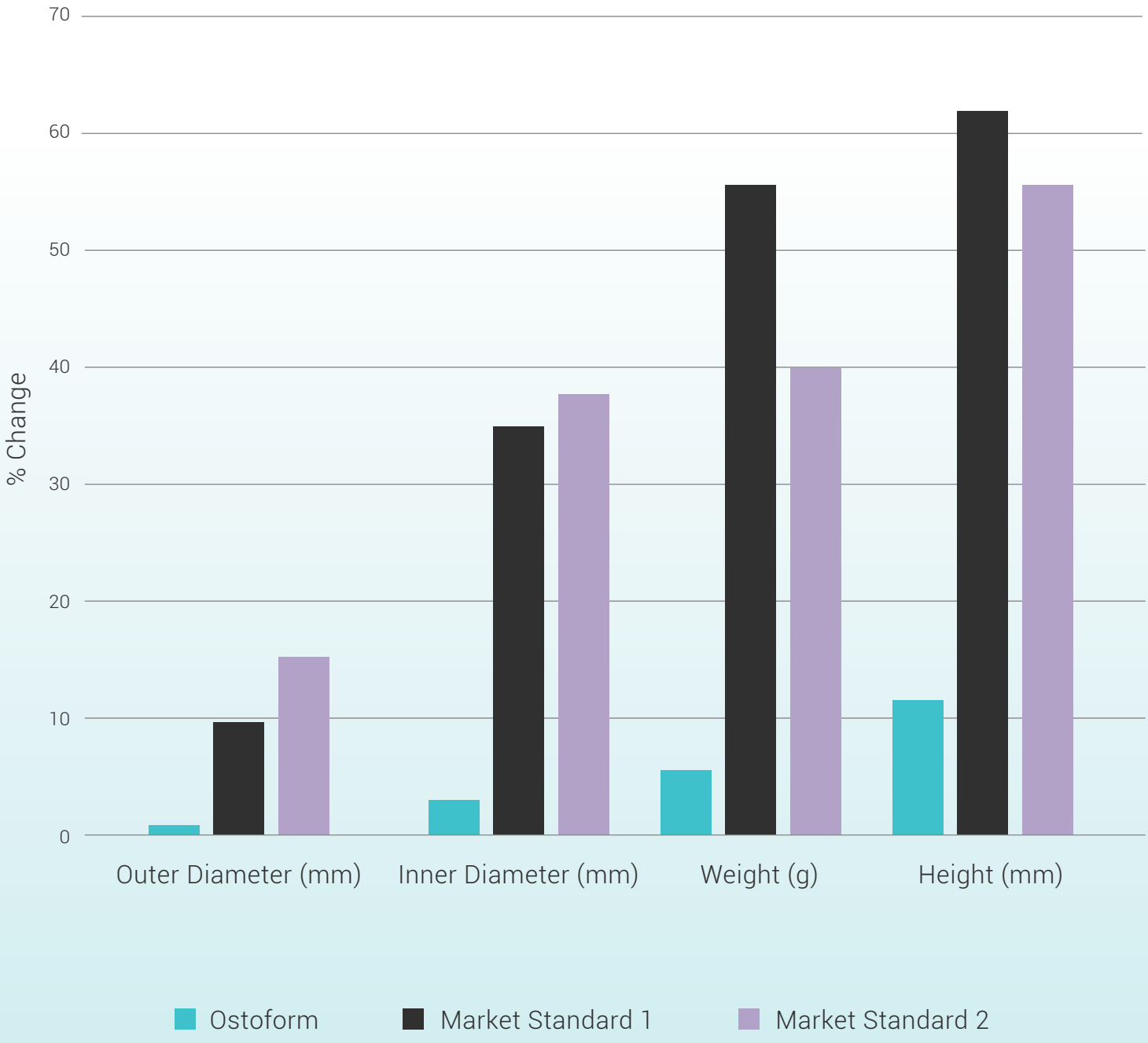


Ostoform OFA-M

Market Standard 1

Market Standard 2

% Change in measurements from the beginning to the end of a 7-hour Wet Integrity Test

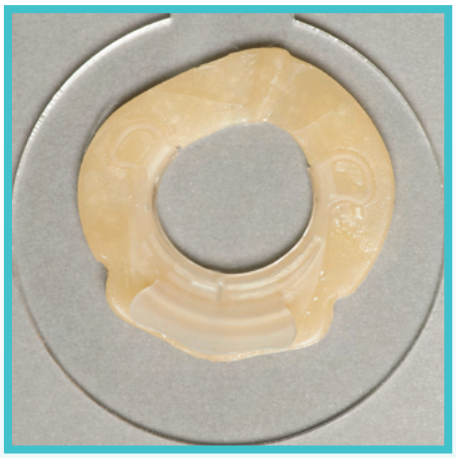


Test 3: Partial Immersion

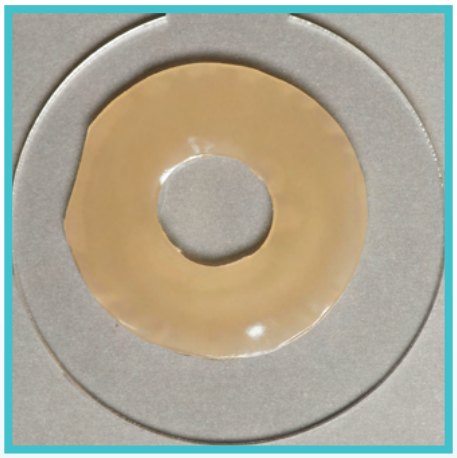
Background

Each seal is partially immersed in saline solution for 6 hours.

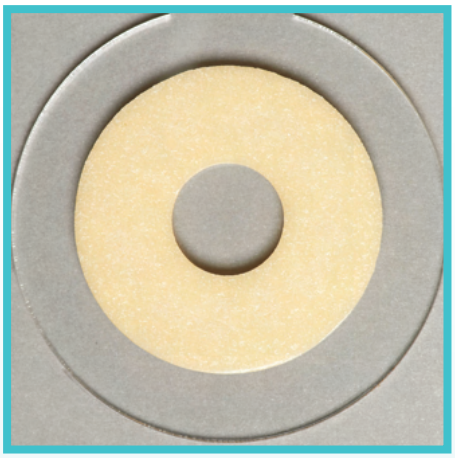
Pre - Testing Photos



Ostoform OFA-M



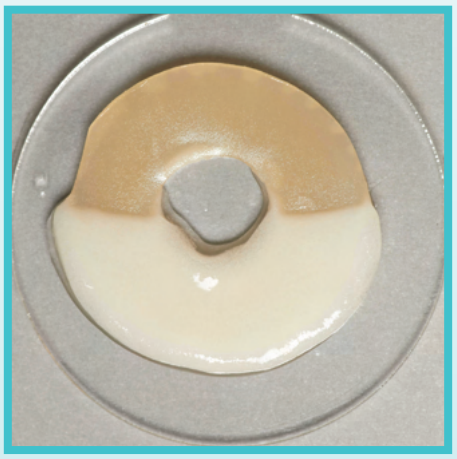
Market Standard 1



Market Standard 2

Completion (6 Hours)

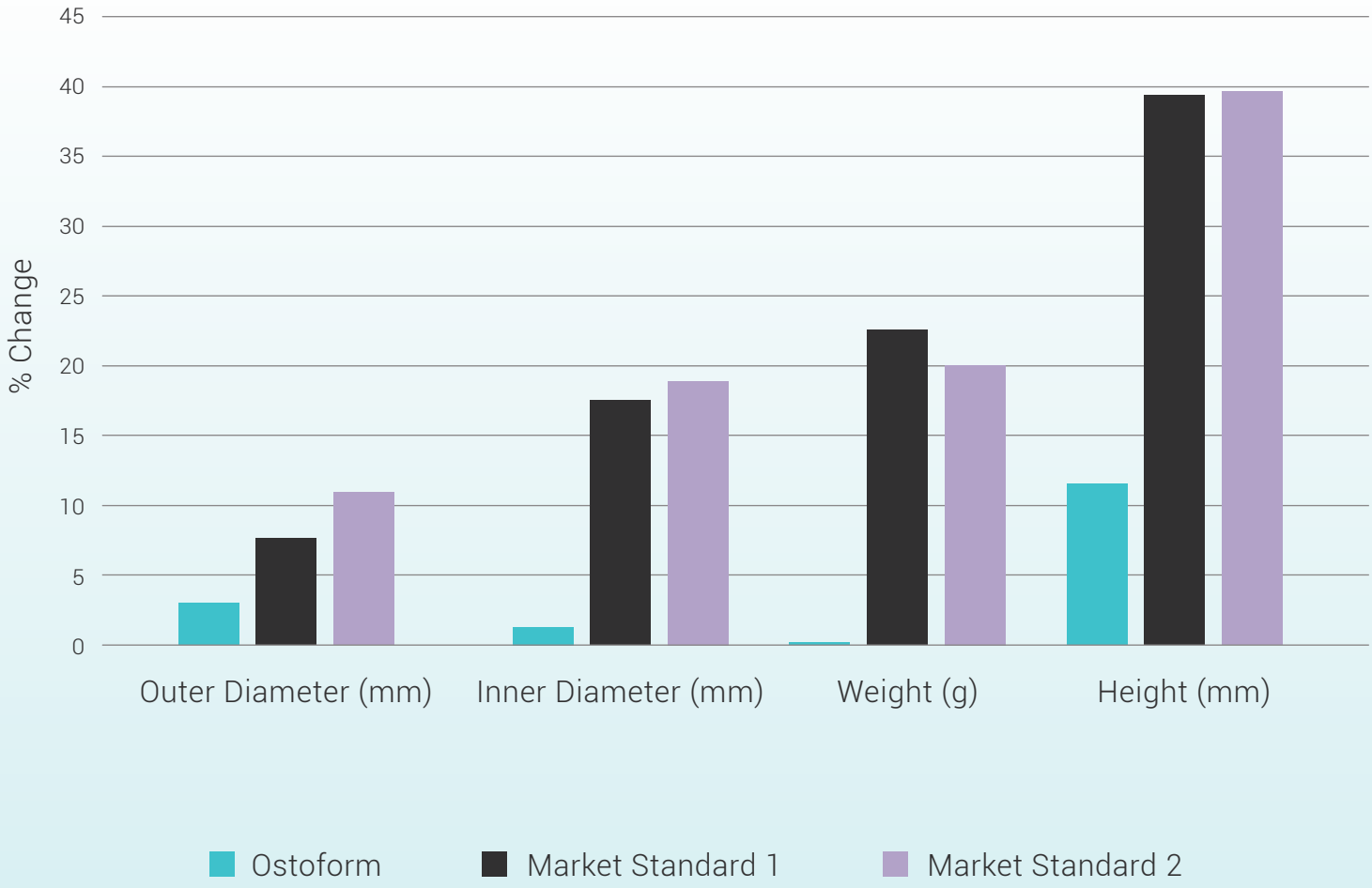
Ostoform OFA-M



Market Standard 1

Market Standard 2

% Change in measurements from the beginning to the end of a 6-hour Vertical Test



CONCLUSION

Summary

The percentage change in measurements was lower for the Ostoform Seal in all cases, relative to market standards. This was as a result of the Ostoform Seal's ability to minimise and control moisture absorption.

ISO 12505 defines a skin barrier / seal as follows:
"Skin barriers are made to seal the ostomy bag to the skin and stay on, **protecting the peristomal skin from stoma effluent** and keeping the skin physiology intact by absorbing or permeating sweat."

"The skin barrier is an important part of an ostomy product. It protects the peristomal skin and holds the ostomy bag in place. Skin barriers are flexible, **erosion-resistant**, skin-friendly and have adhesion properties that allow the bag to stay in place during use and be removed following use."

Changes in seal inner and outer diameters, weight and height are all associated with saline absorption. When an ostomy seal absorbs saline, it erodes. ISO 12505 specifies that an ostomy seal should be **"erosion-resistant"**. Ostomy seals need to be erosion resistant so that they can protect the peristomal skin over an extended time period, while maintaining their adhesion properties. If ostomy seals do not maintain their structural and adhesive integrity due to excessive absorption and erosion, they will no longer perform as desired. This, in turn, will result in compromised skin protection and compromised skin adhesion.

Conclusion

Because the Ostoform Seal can minimise and control absorption, it can last for longer than market standard seals. This, in turn, provides enhanced skin protection and secure skin adhesion over an extended time period.

> *I used the Ostoform Seal on vacation this past week .... I had no irritation and had five-day wear-time which is one day more than usual. Great new product.*
>
> **- Kevin, Ostomate, USA**

INDICATIONS FOR USE

Peristomal Skin Complications:

Peristomal moisture-associated skin damage is the most common form of peristomal skin damage. It occurs when exposure to faecal or urinary effluent leads to inflammation of the skin, with or without erosion or secondary cutaneous infection. Standard skin adhesives do not offer comprehensive skin protection due to their absorbent nature. When hydrocolloid absorbs the corrosive stoma output, it begins to erode and break down, resulting in reduced skin protection and compromised appliance adhesion. This, in turn, results in leaks and ultimately, peristomal moisture-associated skin damage.

Unlike conventional seals, the Ostoform Seal introduces a non-absorbent component, designed to protect the hydrocolloid from excessive absorption and erosion, while effectively assisting the flow of output away from the skin and into the pouch. Consequently, peristomal skin is better protected and if already damaged, heals quicker and more effectively.

Flush, Shallow or Retracted Stomas:

A flush, shallow or retracted stoma sits level with or below the skin covering the abdomen. These stomas are, by their nature, more difficult to manage. Due to their low profile, it is difficult for stoma output to flow directly into the pouch. Instead, it often empties onto the appliance hydrocolloid, resulting in absorption and erosion. This, in turn, can cause leakage and ultimately lead to peristomal moisture-associated skin damage and compromised appliance adhesion.

At skin level, the flexible, non-absorbent component protects the Ostoform Seal from excessive absorption and erosion, while the non-absorbent spout assists the flow of stoma output into the pouch.

Collecting output at skin level and directing it into the pouch provides a welcome solution for many people with flush or retracted stomas, because the output is no longer in frequent contact with the absorbent hydrocolloid, and therefore hydrocolloid erosion is prevented, resulting in a safer, more secure, system.

High-Output, Fluidic Stomas:

High-output, fluidic stomas can be challenging to manage and may include ileostomies, urostomies, transverse colostomies and jejunostomies. The flow from high-output stomas is often of a liquid consistency, and therefore more prone to leaks, resulting in peristomal moisture-associated skin damage.

The non-absorbent spout on the Ostoform Seal ensures that the fluidic, corrosive output is not absorbed by the skin adhesive. In fact, the non-absorbent spout channels the output away from the adhesive and away from the skin, safely into the pouch. Consequently, the adhesive remains intact for longer and the skin remains protected for longer, providing extended pouch wear-time.

Pancaking:

"Pancaking" is a well-documented issue, particularly for those people who have a colostomy. It may occur when the two sides of the pouch stick together, impeding stoma output from flowing down into the pouch. This, in turn, can also lead to leakage.

The Ostoform Seal can help in alleviating this issue as the physical nature of the spout prevents the two sides of the pouch from sticking together. By keeping the two sides of the pouch separated, the stoma output can more easily flow down into the pouch and away from the peristomal area.

Alternative to Hard Convex Pouches:

For several reasons, the use of a convex appliance may not be recommended by a healthcare professional.

The Ostoform Seal can be used as an alternative to a hard convex appliance as it assists the flow of stoma output into the pouch, without applying any unnecessary additional pressure around the stoma. Those people who begin to use the Ostoform Seal may be able to change from a hard convex pouch to a soft convex pouch, or even a flat pouch.

Extended Pouch Wear-Time:

Many people who have a stoma try to minimise how often they must change their accessories and their pouch.

If achieving a longer pouch wear-time is desired, then using the Ostoform Seal may provide a solution. The non-absorbent feature on the Ostoform Seal means that the stoma output is not absorbed, and excessive hydrocolloid erosion and breakdown is prevented, resulting in longer appliance wear-time. The Ostoform Seal is also manufactured using a next generation, skin-friendly hydrocolloid which is known to last longer than regular hydrocolloids.

Fistula Management:

Managing fistula output can be one of the more challenging areas in stoma care, and frequent appliance changes are often required, adding to the burden on the healthcare professional. This is, in part, because corrosive fistula output empties onto the skin and comes into direct contact with hydrocolloid material. In turn, the hydrocolloid absorbs fistula output, leading to erosion and compromised appliance adhesion.

The Ostoform Seal has been successfully used in fistula management, demonstrating improved clinical outcomes and longer appliance wear-time. Because the non-absorbent FLOWASSIST component protects the hydrocolloid at skin-level, fistula output is not absorbed, reducing the risk of hydrocolloid erosion and breakdown. This, in turn, results in fewer appliance changes, improved appliance adhesion, and improved skin protection over a longer period.

> *My background is in product design, and I have always taken a user-focused approach to product development. The usability challenges posed by handling sticky hydrocolloid material are plain to see. The really exciting part of the Ostoform Seal, from my perspective, is that it actually has a non-sticky handling tab - the FLOWASSIST spout. We are also working on some other exciting new developments that will improve product usability. Stay tuned!*
>
> **- Eoghan Spain, COO**

SIZE GUIDE

Ostoform Seal Size	Stoma Size
	**Small** ½" – 1" (15-23 mm)
	**Medium** 1" – 1 ¼" (23-30 mm)
	**Large** 1 ¼" – 1 ½" (30-40 mm)

> *Absolutely the best product I have used in 22 years of having an ileostomy. It is the first time I have experienced total comfort and complete confidence; no leaking or excoriated skin around my stoma.*
>
> **- Aideen, Ostomate, Ireland**

Contact Us

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