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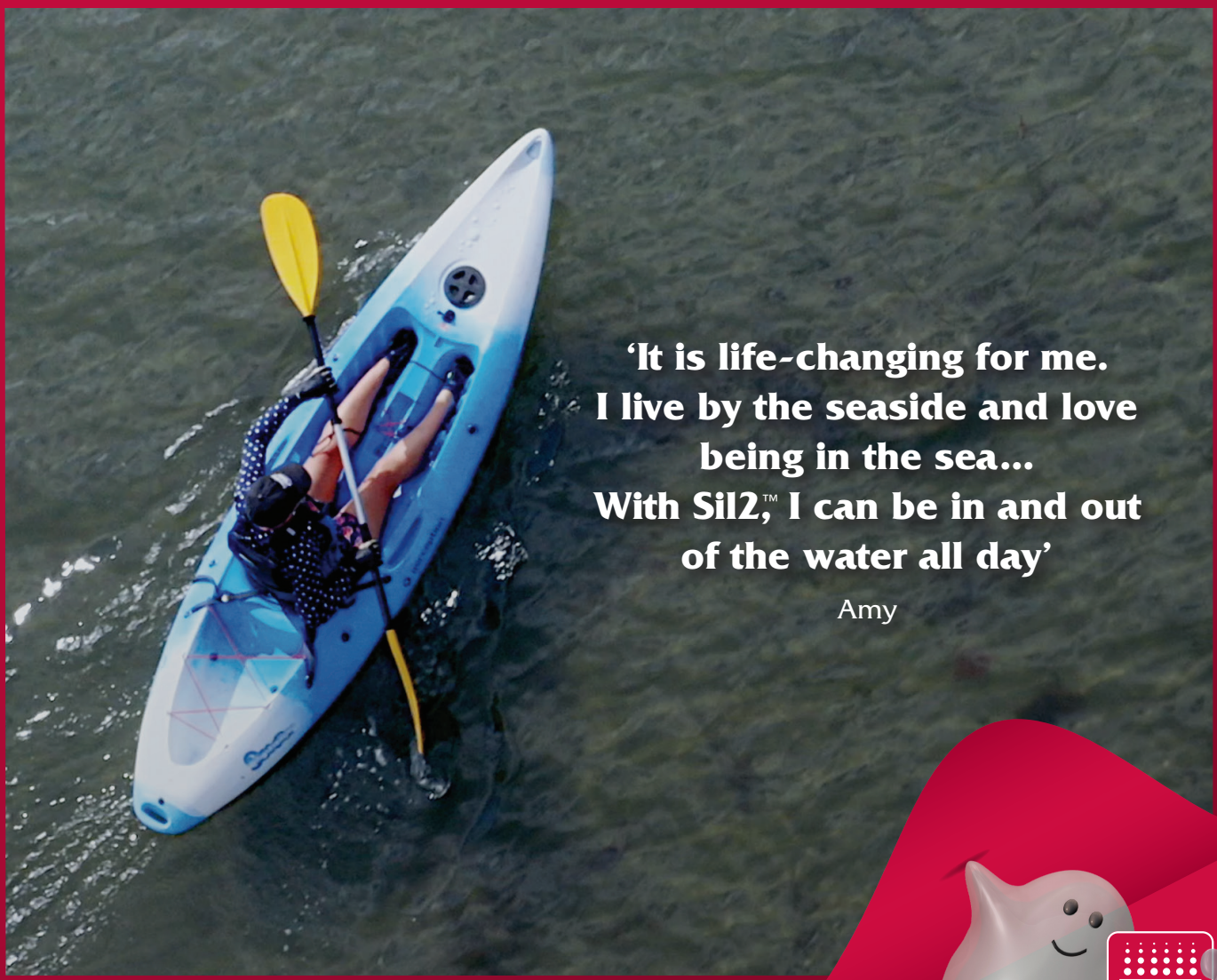
Transforming peristomal skin care with Sil2 Breathable Silicone Technology®: a preliminary clinical evaluation



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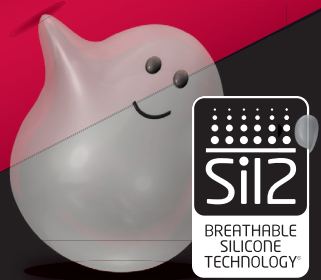

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Use of breathable silicone technology in an ostomy appliance flange

Peta Lager and Lisa Loxdale

A stoma (or ostomy) is a piece of bowel surgically diverted to the surface of the abdomen. This creates an opening for the expulsion of faeces or urine (output or effluent), depending on whether the stoma diverts from the ileum (ileostomy), colon (colostomy) or urinary tract (urostomy). Stomas are formed on a temporary or permanent basis, often as a result of colorectal cancer or severe inflammatory bowel disease (Burch and Black, 2017).

For people with a stoma (ostomates), the products that they use in their stoma care routine have a major impact on their quality of life (Nichols, 2018). An effective product is often the difference between a secure pouching system and recurrent leaks, as well as between healthy peristomal skin and painful complications. Many ostomates come to accept these, as demonstrated in a study of ostomates diagnosed with a complication, where only 38% accepted they had a PSC and only 20% sought professional care (Herlufsen et al, 2006). Even with the most advanced existing ostomy products, the risk of leaks and skin damage remains a fact of life for many ostomates, suggesting that there is room for improvement in technological solutions.

Stoma care nurses (SCNs) are in a positive position to work constructively with ostomy manufacturers to develop increasingly effective stoma products. This professional collaboration is in keeping with guidelines from the Nursing and Midwifery Council (2018) and the Association of Stoma Care Nurses UK (2016). Such involvement has the potential to improve patients' clinical outcomes, including their physical health and psychological wellbeing.

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ABSTRACT

Leaks and peristomal skin complications are highly prevalent among people with a stoma, reported by over 80% of ostomates within 2 years of surgery. This suggests that there is room for improvement in ostomy appliances, particularly in their hydrocolloid-based adhesive flanges. Hydrocolloid has an absorptive method of moisture management that, over time, risks maceration and skin stripping, potentially leading to moisture-associated skin damage (MASD) and medical adhesive-related skin injury (MARSI). The newly developed Genii ostomy appliances (Trio Healthcare) use novel Sil2 Breathable Silicone Technology to provide secure, effective adhesion and manage moisture levels by replicating natural transepidermal water loss (TEWL). This has the potential to increase appliance wear time, reduce incidence of MASD and permit atraumatic removal without adhesive remover, reducing the risks of MARSI, as well as time burdens on the user and economic burdens on the healthcare system. Meanwhile, the silicone flanges and water-resistant sports fabric pouches are lightweight, flexible and unobtrusive, and they are the first appliances to be available in colours to match different skin tones, all of which provides security, comfort, confidence and discretion. This article explores the features of Sil2 and Genii ostomy appliances, with reference to preliminary data from a user evaluation.

Key words: Medical adhesive-related skin injury ■ Moisture management ■ Moisture-associated skin damage ■ Peristomal skin complications ■ Stoma care

ROOM FOR IMPROVEMENT

Ostomates need to continually wear a disposable ostomy appliance. This appliance consists of a pouch and an adhesive flange (also known as a baseplate or skin barrier), which can be combined (one-piece) or separable (two-piece). The pouch collects the stomal output (also known as effluent). Meanwhile, the flange serves the dual purposes of holding the pouch in place over the stoma and protecting the peristomal skin from contact with the

corrosive output. The flange must also maintain normal moisture levels on the skin, as well as allow for atraumatic removal (*Box 1*) (LeBlanc et al, 2019;Voegeli et al, 2020).

The efficacy of the appliance flange is of the utmost importance. Poor performance leads to leakage and the development of peristomal skin complications (PSCs). PSCs typically manifest as redness, discomfort and/or pain, and they often impede flange adhesion (Burch et al, 2021). Repeated leaks and PSCs can make adhesion of the flange harder to achieve, which can result in a viscous cycle of issues for ostomates. This is likely to harm body image and confidence, which can cause long-term anxiety, depression and self-imposed social isolation (Brown, 2017). All of this means that the efficacy of a flange has a direct and significant impact on patient outcomes and quality of life.

The occurrence of leaks and PSCs among people with a stoma remains common (Gray et al, 2013). This has resulted in ostomy appliance manufacturers evolving the technology used in an attempt to improve user experience. Prevalence statistics vary, but are typically high, with 80% of ostomates reporting a PSC within 2 years of surgery (LeBlanc et al, 2019) and 73% reporting a PSC in the previous 6 months (Voegeli et al, 2020). Patients with PSCs have been shown to have higher care costs and a significantly greater likelihood of being readmitted to hospital (Taneja et al, 2019).

SIL2 BREATHABLE SILICONE TECHNOLOGY

Improvements in material technology could allow for more effective appliances that are better able to hold the pouch in place, protect the skin and manage moisture, while allowing for a longer wear time and atraumatic removal at any time. At present, ostomy flanges are largely manufactured from hydrocolloid, an occlusive, moisture-retentive substance with flexible, protective and adhesive qualities (ScienceDirect, 2021). In recent decades, a number of occlusive and adhesive devices in wound and continence care, as well as some stoma care accessories, have made use of silicone technology (Swift et al, 2020). Established soft silicone polymers are suited to these uses because they are flexible enough to conform to the shapes and contours of the body, and they have a naturally tacky quality and a low surface energy that allow instant adhesion to dry surfaces. These silicones are comfortable, hygienic, non-odorous and hypo-allergenic (Meuleneire and Rücknagel, 2013). They are also non-toxic, impermeable to bacteria and incapable of being absorbed into the body (Meuleneire and Rücknagel, 2013). All of these advantages could make silicone an ideal material for an ostomy appliance flange. However, established silicone formulations, such as those used in wound care, have not provided the effective adhesion and moisture management necessary for this use.

Therefore, Trio Healthcare has developed Sil2 Breathable Silicone Technology, a patented silicone polymer specifically engineered to provide effective adhesion and moisture management, properties that are essential to meet the needs of an ostomy appliance flange (Swift et al, 2020). In late 2020, Trio Healthcare undertook a user evaluation of prototype Sil2 flanges, involving 30 established ileostomates and colostomates who met the inclusion criteria, 29 of whom returned completed evaluations. The study was limited to those with healthy peristomal skin or mild skin irritation. Preliminary results from evaluation are referenced in this article (*Figures 1* and *2*), and the full results will be published at a later date.

The success of this evaluation supported the development of a complete ostomy appliance system under the brand name Genii (Trio Healthcare). Genii appliances are available in closed and drainable one-piece systems (*Figure* 3), and two-piece systems have been developed for launch in the near future (*Box* 2). This article details the features of the Genii system and the results of this preliminary user evaluation.

Box 1. Key functions of an appliance flange

- Holds the pouch in place over the stoma
- Protects the skin from contact with stomal output
- Maintains normal moisture levels on the skin
- Allows for atraumatic appliance removal

NATURAL MOISTURE MANAGEMENT

Sustained contact between output and skin will often result in moisture-associated skin damage (MASD), which is defined as any PSC that is primarily caused by chemical irritation from corrosive output (contact dermatitis) and/or maceration from increased moisture levels (Voegeli, 2019). MASD can be exacerbated if the flange does not adequately manage moisture levels and instead allows moisture to build up on the skin.

Despite many positive developments, the traditional hydrocolloid technology used in stoma appliance flanges has a number of drawbacks. Perhaps the most notable of these is hydrocolloid's method of moisture management. Hydrocolloid is hydrophilic, which means that it absorbs moisture from its surroundings. This allows flanges made from this material to temporarily maintain normal moisture levels on the skin and avoid maceration. However, hydrocolloid has a saturation point beyond which it cannot absorb more moisture, especially at the hydrocolloid–skin interface. Once this point is reached, the material breaks down and becomes gelatinous, and the skin is left

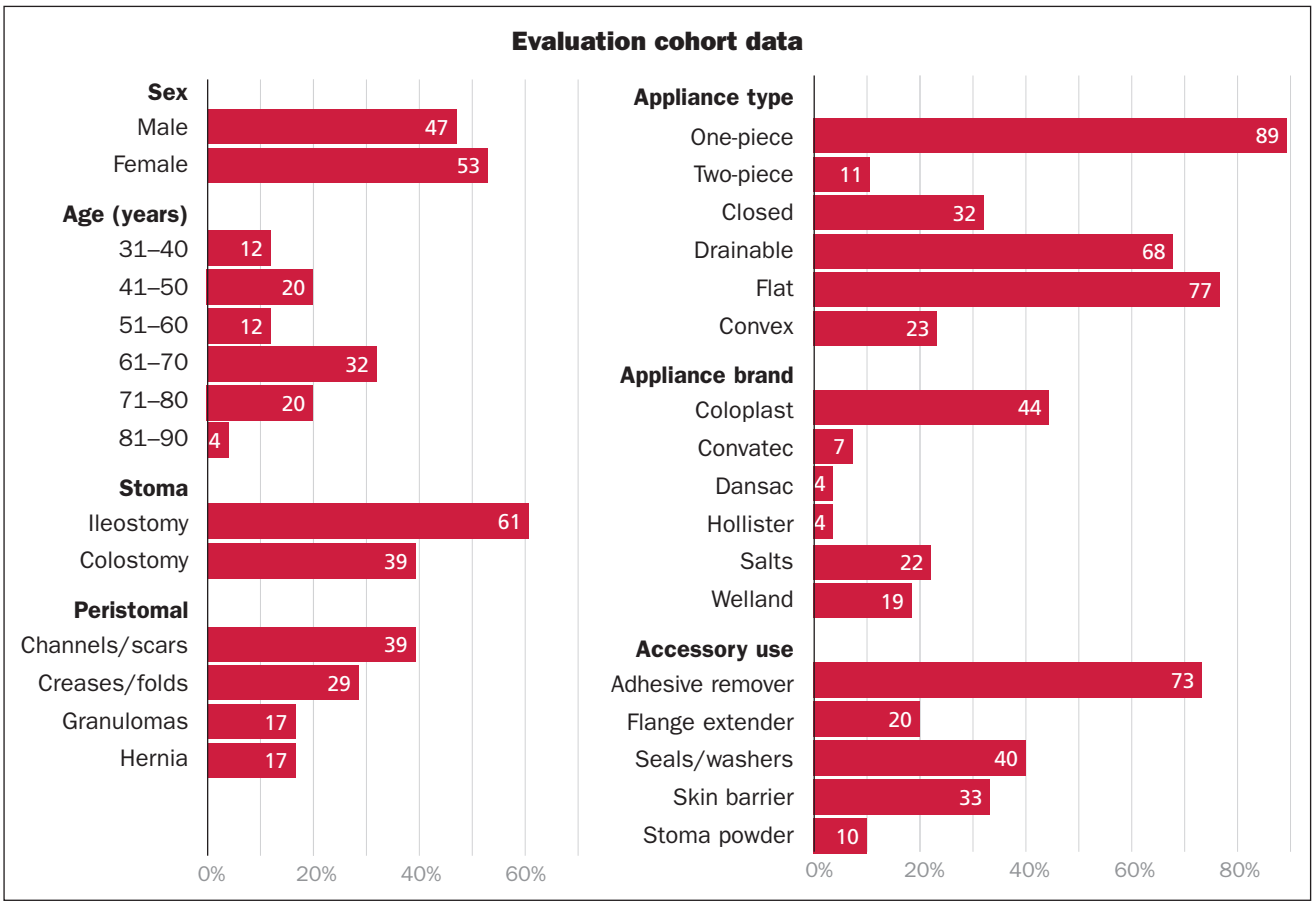

Figure 1. Preliminary data on participant profiles in clinical user evaluation, % (n=30)

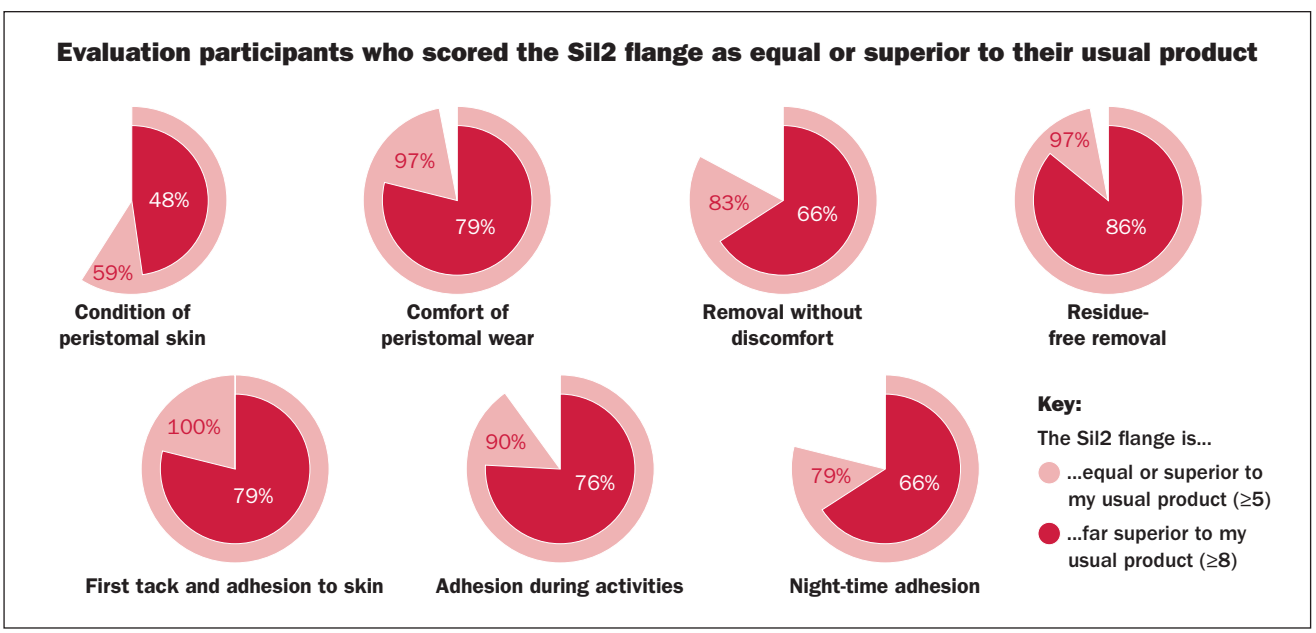

Figure 2. Preliminary results of participant responses at end of trial, comparing Sil2 flanges with their usual product (n=29)

Trio Healthcare

Figure 3. Closed (left) and drainable (right) options for Trio Genii ostomy appliances, in colours that match different skin tones

Box 2. One-piece and two-piece appliances

Closed ostomy appliances are available as one-piece systems, which are single-use, or two-piece systems, which have a removable pouch that can be detached from the flange and renewed a number of times before replacing the entire system. One-piece systems can be more convenient and physically flexible, whereas two-piece systems can provide a longer wear time, which can be more economical and kinder to the peristomal skin. The choice should be guided by the individual needs and preferences of the user, with regard to the consistency of their stomal output (Black, 2013). These appliances have a cut-to-fit flange of 15–60 mm and come with three sizes of pouch (mini, midi and maxi).

Notably, all prototype Sil2 appliances used in the evaluation were one-piece, which added a level of unfamiliarity for those used to two-piece systems

vulnerable to maceration and MASD. Moreover, should the absorbed moisture include any stomal output, the hydrocolloid holds the corrosive chemicals, enzymes and moisture contained in the output against the skin, where it can further exacerbate MASD.

Sil2 Breathable Silicone Technology is distinct from established silicone compounds in that it has a novel mechanism of moisture management capable of maintaining normal moisture levels on covered and protected peristomal skin (Swift et al, 2020). Sil2's mechanism is designed to replicate the skin's natural ability to regulate moisture and body temperature via transepidermal water loss (TEWL) (Gioia and Celleno, 2002). The presence of an occlusive device, such as an ostomy flange, usually prevents TEWL, because it traps the moisture accruing on the epidermis and stops it from evaporating into the air (Machado et al, 2010). Where a hydrocolloid flange would absorb this trapped moisture, silicone is hydrophobic and so does not absorb moisture. Instead, Sil2 uses a compound of hydrophobic silicone and hydrophilic additives to form a matrix that allows water molecules to pass through from the skin into the air as vapour, while still repelling entry of water from the outside (*Figure* 4). The Sil2's breathable matrix has also been designed to react and adapt to changes in skin moisture levels resulting from activity or warmer weather, which helps prevent circumstantial build-up of moisture under the flange (Swift et al, 2020).

Because the water vapour is not retained in the matrix, Sil2 manages moisture levels in a way that avoids the risks of saturation, deformation, maceration and increased adhesion that are associated with hydrocolloid's absorptive method of moisture management. This means that water and stomal output are not held against the skin, where they could contribute to MASD (Swift et al, 2020).

The ability of Sil2's method of moisture management to minimise the causes of MASD could have contributed to reported improvements in the condition and appearance of peristomal skin following use of this product (*Figure* 5). Visible improvement over a 7-day evaluation would be particularly notable, because the skin typically renews over a 28-day cycle (Galderma, 2021). When participants compared the condition of their peristomal skin before and after the evaluation, nearly two-thirds found it was least as good and around half that it was considerably better after using the Sil2 flange. Five evaluation participants opted into providing further information on their experiences and formed a focus group. After switching to the Sil2 flange, members of group noted that:

'My skin can be quite sensitive, but there was no redness or any soreness using the Trio flange. This is a huge bonus, as I know my stoma is with me for life, so whatever I use needs to be skin-friendly. The skin around my stoma looked the same as the rest of my tummy, rather than red and itchy.' Amy

'My skin was slightly rashy before, but, after trialling Sil2, my skin was most definitely better and cleared up completely … I cannot wait to use it full time. I am back to my original pouch, and my skin is slightly irritated again. Sally

EFFECTIVE ADHESION

Adhesion to the peristomal skin is essential. If a flange fails to adhere, the stomal output will leak out of the pouch,

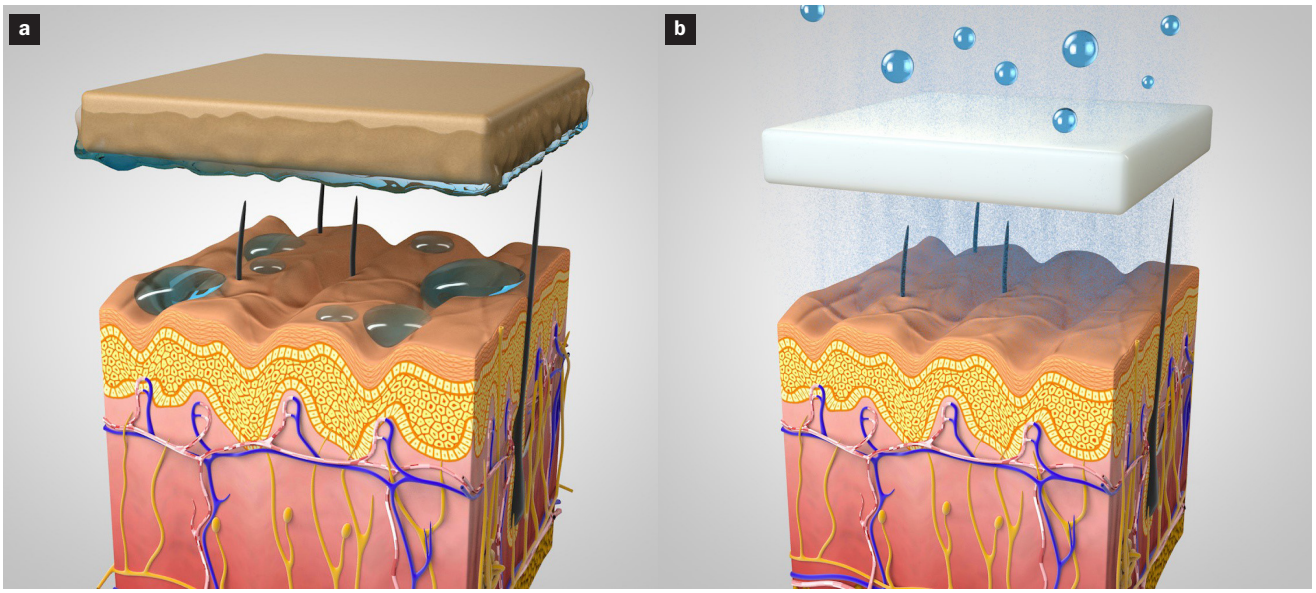

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Figure 4. Moisture management in stoma appliances made from (a) hydrocolloid, where water is absorbed into the material and retained against the skin, and (b) Sil2 technology, where water vapour passes through the material into the air

resulting in soiled clothes, unpleasant odour and intense psychological distress (Brown, 2017).

Genii's Sil2 flange is designed to adhere to and create an effective seal with the peristomal skin (Swift et al, 2020). This is supported by the preliminary results from the user evaluation, in which 100% of the participants reported that the Sil2 flange successfully adhered to their skin.

Three further questions asked participants to rate—out of 10, where 1 was poor and 10 excellent—the adhesion of Sil2 in different circumstances. Nearly 80% of participants scored 8 or more for first tack and adhesion to skin, for adhesion during activities and for adhesion at night. These last two situations are of particular importance. Physical activity can put extra strain on a flange, which increases the risk of leaks, the fear associated with that risk and the consequent avoidance of activities. At night, the occurrence, risk and fear of leaks can be highly disruptive, leading to broken sleep and waking up multiple times. Therefore, these results suggest that users might have found Genii flanges to be beneficial in these key aspects of ostomates' quality of life.

The focus group compared the adhesion and tack of Sil2 favourably with that of hydrocolloids:

'There was instant tack, unlike hydrocolloids, where you need to let the adhesive warm before the adhesive gains its full tack.' Hannah

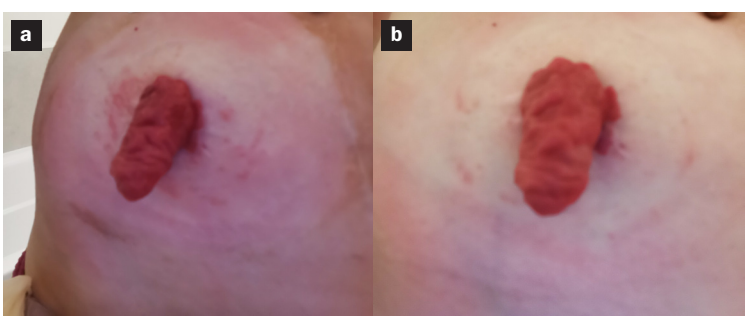

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Figure 5. Peristomal skin at days 5 (a) and 9 (b) of using a Sil2 flange, showing pre-existing skin irritation that significantly improved throughout the evaluation (very active female ileostomate in her 30s)

The absence of leaks was remarked upon:

'I had no leaks or even "near misses" when using the new product.' Kieran

One member of this group also noted how this adhesion remained consistent, even after the appliance was repositioned:

'This new development is incredible, a real game changer as far as I'm concerned, no crinkles in my skin (apart from age wrinkles), adhesive that not only sticks like a second skin but, if I've put it on the wrong place, I can adjust it without compromising the adhesive quality, and it doesn't leave a mark.' Amy

Members detailed how switching to a Sil2 flange had improved their confidence and/or sense of security. They noted a positive impact on their lifestyle, both during physical activity and at rest:

> **'Without a doubt, as a gym goer, I had a lot more confidence. The comfort while stretching and exercising was so much better; it almost didn't even feel like I had a pouch.' Sally**

'81% of participants gave a rating of 5 or more, indicating that Sil2 was as comfortable as or more comfortable to remove, with equal or less pain' [without using adhesive remover]

> **'The Sil2 flange was very good, comfortable, very confident while it was on, day and night' Ken**

ATRAUMATIC AND UNAIDED REMOVAL

A flange not only needs to stay adhered to the skin; it also needs to be easy to remove. If the adhesive bond is too strong, removing the flange will pull away the outer layer of skin cells (skin stripping) (Williams et al, 2010). Repeated traumatic removal can result in medical adhesive-related skin injury (MARSI), defined as any PSC primarily caused by traumatic and/or excessively frequent appliance removal (Fumarola et al, 2020). MARSI is implicated in increased morbidity, readmission and care costs, was well as reduced, psychosocial status and quality of life (LeBlanc et al, 2019). Evidence on the prevalence of MARSI suggests that it is present in anywhere from 3.4% to 25% of ostomates (Farris et al, 2015).

One of the drawbacks of hydrocolloid stoma flanges is that, as they become more saturated, they swell, changing in shape, increasing in size and breaking down on a chemical level. This presents a number of issues, the most significant of which is a considerable increase in adhesive strength. The more moisture a hydrocolloid flange has absorbed, the more difficult it is to remove and the greater the risk of skin stripping and MARSI (Swift et al, 2020).

In contrast, Sil2 was designed to permit atraumatic removal and reduction of MARSI without use of an adhesive remover. The absence of swelling and increased adhesion also means that the adhesive strength of a Sil2 flange remains consistent over time, distributing peel force evenly and allowing for comfortable, safe and easy appliance removal. This makes removal more comfortable and reduces the risk of MARSI (*Figure 6*) (Swift et al, 2020).

In the preliminary results of the evaluation, participants rated the level of discomfort or pain that they experienced during removal (without using an adhesive remover) of the Sil2 flange compared with their usual hydrocolloid appliance. On a scale of 1–10, where 1 was more and 10 less discomfort/pain, 79% of participants gave a rating of 5 or more, indicating that Sil2 was as comfortable as or more comfortable to remove, with equal or less pain. This includes the participants whose previous product was already providing comfortable and painless removal, for whom parity represents a successful result.

REDUCED PRODUCT USAGE

Leaks and PSCs often result in more frequent appliance changes and increased use of stoma care accessories, which are time-consuming for the patient and place a major financial burden on healthcare resources (Bird, 2017). In addition, the tendency of hydrocolloid

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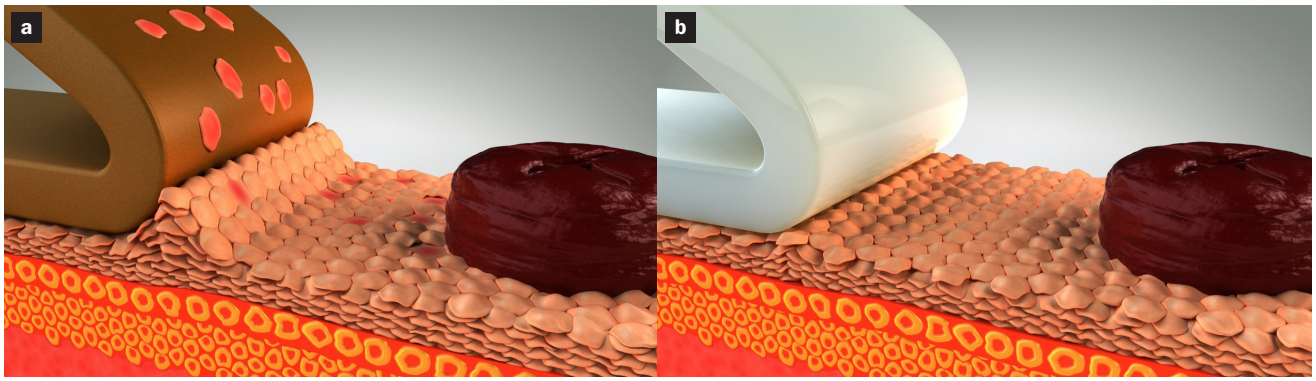

Figure 6. Removal of adhesive from peristomal skin in stoma appliances made from (a) hydrocolloid, with increasing adhesive strength that risks skin injury, and (b) Sil2 technology, with consistent adhesive strength that allows atraumatic removal

flanges to increase in adhesive strength over time can limit appliance wear time (Swift et al, 2020). This both increases the frequency of removals, which is time-consuming and compounds the risk of MARSI, and increases the rate of ostomy appliance use, which is uneconomical. This increase in adhesive strength can also necessitate the use of an adhesive remover wipe or spray to avoid uncomfortable removal and/or MARSI. All of this presents consequent burdens on patient time and healthcare resources (White, 2014).

The non-absorptive nature of Sil2 provides Genii appliances with a greater potential wear time than hydrocolloid appliances (Swift et al, 2020). These longer wear times can be convenient for the user and help reduce risk of MARSI, as well as appliance usage and costs. In the evaluation, participants were asked to describe how switching to the Sil2 flange affected their accessory use. Some reported that it removed the need for accessories entirely:

'I was able to go out without all the products to replace a pouch (spray and remover). It took less than 5 minutes to change against 20 minutes with my old pouches.'

'I did not use any accessories, only the flange and warm water.'

'I didn't use or need to use any extra accessories.'

More specifically, others singled out that that the Sil2 flange reduced or eliminated their need for adhesive removers, which are expensive for the health system and time-consuming for the user (Bird, 2020). Backing up the result that 83% of users experienced the same or less discomfort and pain, participants stated:

'I used less barrier spray and only a little adhesive remover.'

'I've always used adhesive remover with all my previous products, but not with the silicone flange.'

'I removed [it] without adhesive remover.'

'I had no need for either the adhesive remover or skin protector.'

The Sil2 flange used in Genii appliances was designed to allow atraumatic removal without the need to use adhesive remover (Swift et al, 2020). Members of the focus group noted this as a major benefit:

'The product was easy to apply with good adhesion, yet was easy to remove without an adhesive remover, which I have always used with my normal stoma pouch.' Kieran

'…easy to remove; very confident with the product; it also saves time on changing, with no messing with adhesive removal sprays and wipes.' Ken

Hydrocolloid can leave a residue on the peristomal skin following removal, the cleaning up of which can take time and resources and, in some circumstances, contribute to skin damage (Hess, 2003). By contrast, when evaluation participants rated the level of residue left out of 10, where 1 was a lot and 10 was none, Sil2 flanges received an average rating of 8.8, with 86% giving a score of 8 or above. This was reflected in user comments, comparing Sil2 with their usual hydrocolloid flange:

'Not needing to use my fingernails or adhesive remover was a huge plus.'

Adhesive remover was not the only accessory to be specified by participants as no longer necessary after switching to a Sil2 flange:

'My current skin barrier ripples around the edge, as it's trying to mould over a rounded area of my abdomen, and I use tape to hold it flat. I didn't need to do this with the Trio skin barrier.' Hannah

'I still needed to use my seal but had no use for the tape, which I used to add extra adhesion to the side that lifted at night.'

It should be noted that accessory seals may require adhesive remover, even when the flange itself does not.

FLEXIBILITY AND COMFORT

People with a stoma need to wear an ostomy appliance against their skin at all times, and therefore the comfort of that appliance is a major priority (Burch and Black, 2017).

Both of the distinct materials used in Genii appliances are designed to help provide greater, longer-lasting comfort than established ostomy appliances. Both the silicone compound used in the flange and the sports fabric used in the pouch are designed to be lightweight, flexible and soft against the skin. This is reflected in the evaluation, where participants were asked to rate the comfort of wearing a

Sil2 flange against their skin, compared with their usual product. They gave an average comfort score of 8.5 out of 10, with 79% giving a relative comfort score of 8 or above.

'with 79% giving a relative comfort score of 8 or above' [compared with their usual product]

The focus group described the feeling of wearing the silicone flange against their skin, comparing it with how they felt when wearing a traditional hydrocolloid flange. Some noted the absence of hard plastic edges as a major benefit:

'Very comfortable, no hard plastic edges' Ken

'The silicone barrier feels more comfortable; there's no pulling as the pouch fills, and it's a lot more comfortable around the stoma itself. There's no stiffness or hard edges… The comfort of Sil2 is on a whole other level and most definitely a game-changer for the ostomy world.' Sally

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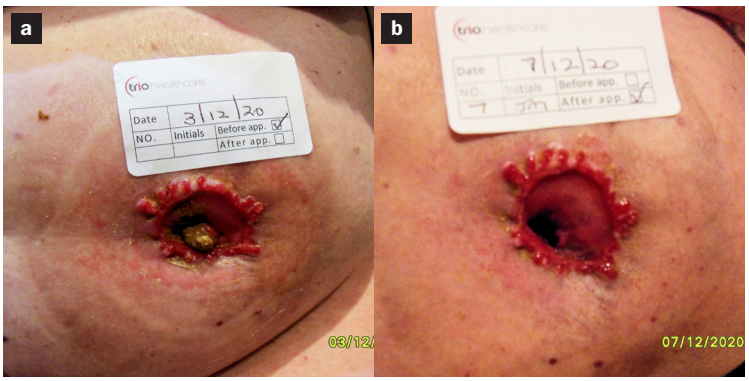


Figure 7. Peristomal skin at days 1 (a) and 5 (b) of using a Sil2 flange, showing improvement around where the skin was initially raised due to irritation, as well as effective management of irregular contours around the stoma (female colostomate)

Box 3. Multisensory discretion

Genii ostomy appliances are designed with a variety of features to maintain a discreet profile:

Sight	Colours that match different skin tones
Smell	Carbon filter that reduces flatus odour
Sound	Fabric pouch that reduces rustling
Touch	Flexible silicone flange and soft, lightweight fabric

It was also noted that the flange did not crease or fold, which can provide channels for output escape and leakage:

There was no folding or bunching up of the flange, unlike what happens when underwear rubs against my usual product.' Amy

'Easy to fit, movement very good, no creases in the flanges.' Ken

Sil2 is an extremely flexible material, allowing for flanges that can be moulded to conform completely to the uneven surface of the peristomal skin (*Figure* 7). This creates a larger contact area, which improves adhesion, reduces the risk of leaks and allows complete freedom of movement (Swift et al, 2020). Silicone also allows for a widespread and consistent contact with the skin that give the material a low surface tension (Swift et al, 2020). Members of the focus group emphasised Sil2's flexibility and consequent ability to conform to the skin, including to uneven body profiles:

'It seems to conform to the body shape more readily, especially as I have a hernia around the stoma.' Kieran

'I found the silicone barrier incredibly conformable to the skin … It was incredibly flexible, a little larger than my current skin barrier, but this greater coverage made me feel more secure.' Hannah

DISCRETION

The low surface tension of Sil2 minimises the noticeable sensation of wearing the Genii appliance on the skin (Le Ber, 2020). One user comment suggested that the comfort of the silicone flange was such that it felt invisible:

'I couldn't feel it!' Amy

This sense of invisibility encapsulates how discretion is often a major priority for many people with a stoma (Brown, 2017). To meet this underserved need, Genii appliances have been designed to be unobtrusive (*Box* 3). This means both that the ostomate should not be continually reminded of its presence and that they should be able to keep their ostomy discreet from people they come into contact with.

The lightweight fabric of the Genii pouch is not only discreet to the touch, it is also designed to minimise audible rustling. These pouches are also equipped with a high-performance carbon filter, designed to minimise the unwelcome sound and smell of flatus, as well as to manage airflow and reduce ballooning and pancaking.

Genii is the only range of ostomy appliances on the market that is available in a variety of colours to match different skin tones (Stoma Care Handbook, 2020). Other appliances are often available in colours, such as white or beige, that visually stand out from human skin, when users would rather that they blend in. Those that do attempt to blend in with the skin have previously only matched certain pale skin tones, which has been a disservice to people with a stoma who have darker skin. Genii goes some way to addressing this health inequality by being available in three different colours (light, medium and dark), providing camouflage and discretion for people of various complexions. A clear drainable option is under development (*Box* 4).

Genii drainable appliances are designed to allow for discrete emptying, which can be particularly useful in shared and/or public toilet facilities. The outlet has a pull tab that is easy to clean and makes draining quick and simple.

SUITABILITY FOR ACTIVE LIFESTYLES

In the user evaluation, participants were asked how well the Sil2 flanges stayed adhered during physical activity, and 90% found it to be at least as good and 76% significantly better than their usual product.

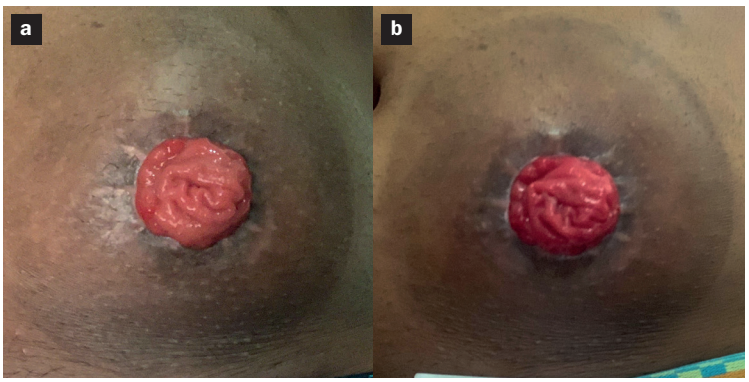
Genii appliances have a cover made of fabric, as opposed to the non-woven comfort backing used in most older appliances. This lightweight sports fabric is soft, water-resistant and designed for active wear, which makes it more comfortable during increased perspiration, such as during physical exercise (*Figure* 8). Like the breathable silicone flange, the fabric pouch has a breathable design that allows moisture to escape and is dry to the touch after showering.

In the user evaluation, different members of the focus group emphasised how the Sil2 flange was better suited to use in water than hydrocolloid products:

> **'The silicone flange doesn't go gooey when subjected to water, so this will enable me to enjoy longer periods swimming on holiday—or, if I enjoy a spa day, I'll feel more confident and not have the need to change the pouch straight after getting out the pool and jacuzzi. The ability to not necessarily *have* to change the pouch after the adhesive gets wet is a bonus. Currently, all pouch changes are coordinated with baths and showers, so this could be a big thing for me … I feel that it ticks the boxes for everything that I would be looking for.' Hannah**

Box 4. Postoperative option

In the near future, the opaque Genii appliances are set to be joined by a drainable option with a clear cover. Clear appliances are designed for postoperative hospital use, as they allow stoma care nurses and other health professionals to view the stoma and output without having to remove the appliance. Peristomal skin can be particularly sensitive in the postoperative period, and frequent removal can disrupt the surgical site, damage the skin and cause emotional trauma for the patient. Sil2's protective, atraumatic properties could give it particular advantages over hydrocolloid in this setting, and there is evidence from wound care linking silicone dressings with improved healing (Matsumura et al, 2014).



Used with consent of participant

Figure 8. Peristomal skin at days 1 (a) and 7 (b) of using a Sil2 flange, showing healthy skin and effective management of skin ridges (very physically active male ileostomate in his 40s)

This represents an additional benefit for Genii's non-absorptive method of moisture management (Swift et al, 2020), which could be particularly significant for certain patients, depending on their lifestyle. One user emphasised how its water resistance also saved on product use—and consequently on time and healthcare resources:

> **'It is life-changing for me. I live by the seaside and love being in the sea. With other products, every time they get wet the adhesive becomes "gloopy", and taking that off is no fun. With the silicone flange, I can be in and out of the water all day with my grandchildren without any worries about having to use my nails or a chemical product to get rid of the adhesive left on my skin. I can shower with the flange, which extends the wear time of my appliance.' Amy**

NURSE EVALUATION

On launch of the Genii ostomy appliances, a sample was sent to two clinical nurse specialists in stoma care working

at Basildon Hospital. Both having been in post for over 20 years and having seen many changes in stoma appliances and accessories, they were interested in an early trial of the first silicone-based appliances.

The nurses' first impression of the silicone adhesive was that it was very soft, supple and flexible, and they found the fabric to be quiet and very soft. They also noted that the available range of colours was a better match with true skin tones than other products on the market.

The nurses had a brief opportunity to trial the appliances on three of their patients. All were male colostomates with intact healthy skin at the time of trying the product. Two of the colostomates were long-established with their stoma and the other had only had their stoma formed in the past 6 weeks.

In terms of security, the two established ostomates found the silicone adhesive to be very secure, even during showering. However, the newer colostomate reported finding it difficult to adhere securely, which may have been a consequence of limited experience, confidence and instruction from a nurse in the correct use of the product. The established ostomates were both particularly impressed that no adhesive remover was required when replacing the appliance. One ostomate noted an odour at night, despite no signs of leakage, and so questioned the efficacy of the filter. Both established ostomates felt that the pouch was aesthetically was very pleasing, and one reported that:

> **'The material is nice and feels fine on the skin. The silicone adhesive seal is so much smoother and comfortable. It secures snug and collects waste fine, and it is surprisingly easy to remove without spray.'**

CONCLUSION

Overall, the qualitative responses given by evaluation participants were positive about the experience of changing a Sil2 flange, describing it as 'Excellent … seriously impressed', 'Very good' and 'Much better, a lot easier to change' and saying that it went 'Very well—I had no issues'.

Genii ostomy appliances are the first to use Sil2 Breathable Silicone Technology, giving them a unique ability to manage moisture by facilitating natural TEWL, as well as to avoid skin stripping and MARSI on removal. Coupled with a comfortable and discreet pouch design, the Genii range has the potential to improve ostomates' quality of life, as well as reduce PSC occurrence and associated burdens on healthcare resources. **BJN**

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Genii ostomy appliances: product information

Light

Pip Codes	Code	Size	Flange	Bag size	Filter	Pack Size
Closed bags						
416-5304	TR321N	15-60mm	cut to fit	Mini	✓	30
416-5270	TR322N	15-60mm	cut to fit	Midi	✓	30
416-5247	TR323N	15-60mm	cut to fit	Maxi	✓	30
Drainable bags						
416-5395	TR324N	15-60mm	cut to fit	Mini	✓	30
416-5361	TR325N	15-60mm	cut to fit	Midi	✓	30
416-5338	TR336N	15-60mm	cut to fit	Maxi	✓	30

Medium

Pip Codes	Code	Size	Flange	Bag size	Filter	Pack Size
Closed bags						
416-5296	TR321T	15-60mm	cut to fit	Mini	✓	30
416-5262	TR322T	15-60mm	cut to fit	Midi	✓	30
416-5239	TR323T	15-60mm	cut to fit	Maxi	✓	30
Drainable bags						
416-5387	TR324T	15-60mm	cut to fit	Mini	✓	30
416-5353	TR325T	15-60mm	cut to fit	Midi	✓	30
416-5320	TR336T	15-60mm	cut to fit	Maxi	✓	30

Dark

Pip Codes	Code	Size	Flange	Bag size	Filter	Pack Size
Closed bags						
416-5288	TR321C	15-60mm	cut to fit	Mini	✓	30
416-5254	TR322C	15-60mm	cut to fit	Midi	✓	30
416-5221	TR323C	15-60mm	cut to fit	Maxi	✓	30
Drainable bags						
416-5379	TR324C	15-60mm	cut to fit	Mini	✓	30
416-5346	TR325C	15-60mm	cut to fit	Midi	✓	30
416-5312	TR336C	15-60mm	cut to fit	Maxi	✓	30

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