

Ostomy Life Study^{2015/16}

Insights contributing to raise the standards of ostomy care:

This edition of the Ostomy Life Study presents a new perspective on quality of life measurements, and shares new data on the relation between body shape, convexity solutions and leakage concerns. Also: A **discussion** of how much we actually know about convexity – and how to best use that knowledge to provide the best treatment for people with an ostomy, hereby helping them to live a good life.

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Insights that matter

Welcome to the Ostomy Life Study 2015/16. The Ostomy Life Study aims to share interesting and inspiring knowledge about living with an ostomy and using ostomy appliances.

With the Ostomy Life Study Coloplast **commits** to conduct yearly life studies exploring clinically relevant themes. The Life Studies will provide insights on the everyday challenges people depending on medical devices face. The Life studies will be developed in close cooperation with the Global Coloplast Ostomy Forum (COF) represented by international experts within ostomy care¹. In this issue, the focus is on the guiding star in ostomy care: **Helping people with an ostomy live a good life.**

A new perspective on how to approach quality of life measurements is introduced, moving away from 'quality of life' as a general and abstract term, and towards a much greater awareness of the actual, small everyday situations that can make or break a good life.

Coloplast Ostomy Forums (COF) have for years contributed to providing a better understanding of **the needs** of people with challenging peristomal areas including poor positioning of the ostomy opening, and it is getting increasingly clear that there is a huge potential for improving the quality of life for this specific group of people.

Could the world of ostomy care become better at recognising a need for a convex solution early, avoiding a trial and error phase that negatively impacts the quality of life of the patient? Are there ingrained practices or beliefs that are hard to overcome and therefore preventing health care professionals from bringing in new evidence-based treatment solutions?

In researching the cross-section of convexity and quality of life, many ideas and concepts were illuminating and inspiring. In this publication, some of these insights are shared, and hopefully you will agree that this is a fascinating area in need of much more exploration in the future, as convexity research and products improve.



Lena Ehmsen Lachenmeier
Director of Medical Marketing at Coloplast A/S

Sources: ¹COF (Coloplast Ostomy Forum) was established in 1995 and is today involving more than 500 stoma care nurses. There are national COF boards in more than 20 countries around the globe. The Global COF group consists of 15 stoma care nurses from 11 different countries with many years of experience and high level of expertise within stoma care.

There is more to quality of life than just a score

What is quality of life?

In health sciences, quality of life is often associated with health-related aspects such as; being able to get out of bed, walk around and not feeling pain. However, for people depending on medical devices, there may be much more to quality of life than just the basic human functions.

- Are you able to shampoo your hair?
- Are you able to bend down and pick up things from the floor?
- Are you able to open car doors?
- Are you able to do daily activities such as gardening, shopping, exercising etc.?

All of the above are simple activities that may affect how a person perceives his quality of life based on his experiences and daily challenges. Hence, it is important to understand, that quality of life is a term covering much more than just a generic score.

Quality of life for people living with an ostomy

Having an ostomy and adjusting to a new life situation with altered bodily function can be physically and mentally overwhelming. The loss of control and the sudden dependence on an ostomy appliance just add to the challenges, a person with an ostomy has to deal with. A wide variety of ostomy appliances and accessories exists and finding the right appliances that fit and fulfill the needs for the individual may feel like finding a needle in a haystack.

An ostomy appliance with less than optimal fit may increase the risk of leakage and peristomal skin complications. The fear and worries of leakage may lead to e.g. interruption of sleep and avoidance of social and physical activities². Needless to say, that the ostomy appliance can have a great impact on the health-related quality of life for people living with an ostomy.

Understanding the underlying factors of quality of life when using an ostomy appliance – a new assessment tool

Based on input from ostomy care experts and users of ostomy appliances a new assessment tool has been developed to get a better understanding of how ostomy appliances affect everyday life, and how it impacts the health-related quality of life. The new assessment tool consists of four key quality of life categories each including a number of questions related to the use of an ostomy appliance.

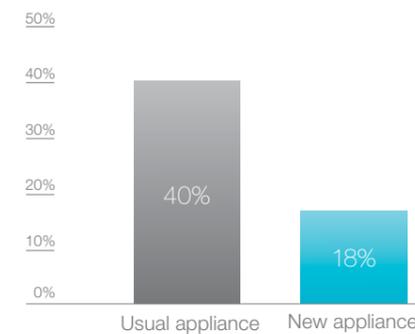
- Discreetness (e.g. visibility under clothing, being self-conscious about the appearance)
- Comfort (e.g. comfortable to wear, not noticing appliance, sleep through night)
- Confidence (e.g. confident not leaking, smell, being physically active)
- Social life and relationships (e.g. social life restrictions, avoiding close relationships)

The questions are rated on a five-point Likert scale from 'strongly agree' to 'strongly disagree'.

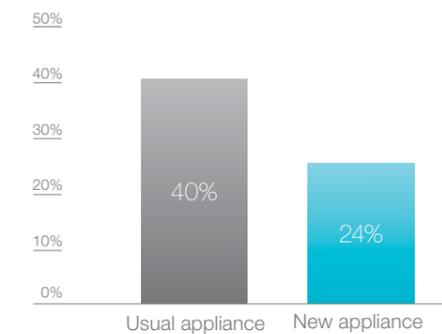
Results from a recent clinical study³

The new assessment tool has been successfully used in a recent clinical study investigating the performance of newly developed ostomy appliances compared with the participants usual appliance. Several aspects have been identified, including how the new ostomy appliances provide a significantly improved difference, for almost all the users, in quality of life-related issues. Presented in the figures below are examples of questions and results of the amounts of participants that chose 'strongly agree' and 'agree'. The four questions are among a series of questions under four domains related to Discreetness, Comfort, Confidence and Social life and relationships.

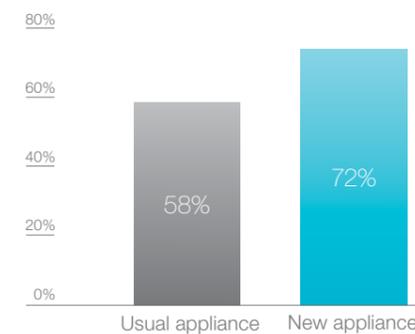
Discreetness The ostomy appliance limited the choice of clothes that I could wear



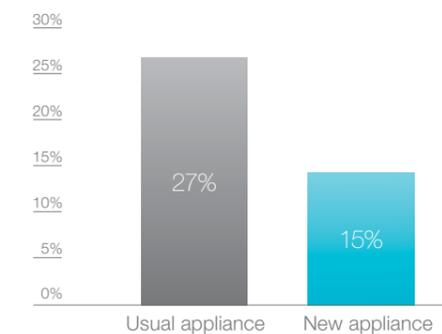
Comfort The ostomy appliance disrupted my sleep during night



Confidence I felt confident that I could spend the night away from home despite wearing the ostomy appliance



Social life and relationships I worried about whether the ostomy appliance would affect my sex life



Sources: ²Claessens et al. 2015. The Ostomy Life Study: The everyday challenges faced by people living with a stoma in a snapshot, *Gastrointestinal Nursing*, 13, 33-38. ³Walker et al. Raising the bar: New flexible convex stoma appliance - a randomized controlled trial. Accepted for publication WCET supplement 2016.

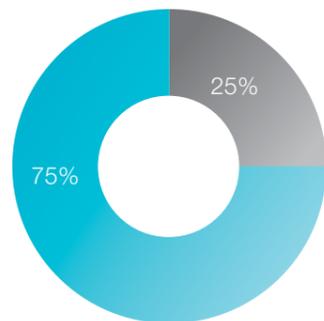
Convexity – the next frontier?

How much is actually known about convexity? While research is sparse, Coloplast data^{4,5} can cast some light on an area that looks to be the next frontier in Ostomy care.

From these data sets it appears that there is a large group of patients for whom convex solutions are potentially relevant. It is also clear that many in this group of patients are struggling with their existing solutions.

There is evidence of a high degree of worrying about leakage – and higher actual leakage experience than other ostomy patients. Data also show that these concerns greatly impact quality of life for the patients negatively.

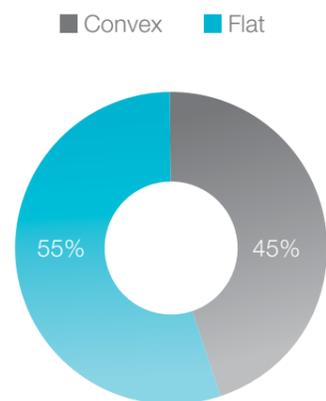
With these facts, it seems there is all the more reason to focus on giving people with a need for convexity the best possible solution and treatment in the future, through both scientific research and product innovation.



Coloplast estimates that three out of four people having ostomy surgery leave the hospital using a flat adhesive and this has been the case over the past years

■ Convex ■ Flat

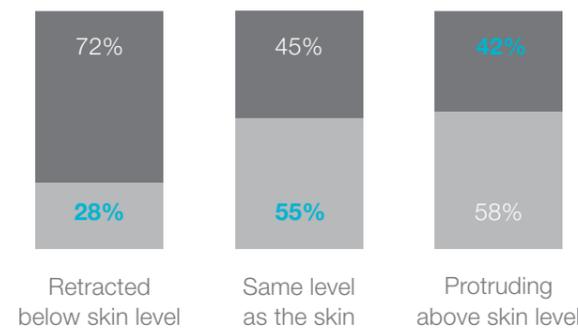
However, looking at Coloplast Community data⁴, almost half the users end up using a convex product



■ Convex ■ Flat

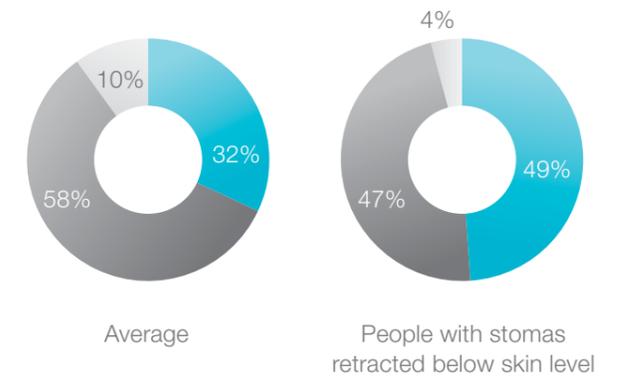
There is a clear relation⁴ between usage of convex products and the height of the ostomy (above or below skin level)

■ Convex ■ Flat



And there is also a link between the height of the ostomy and leakage issues: On average 32% experience leakage daily/weekly. However for people with stomas retracted below skin level this is the case for 49%⁴

■ Daily/weekly
■ Less than weekly
■ Never



93% of convex users worry about leakage and 81% have experienced leakage in the last 6 months⁵



Even worrying about leakage leads to change in behaviour for the patients: More use of accessories and more frequent visits to their nurse⁵

- 54% use accessories (e.g. tape, rings, paste)
- 43% change their product more often
- 32% seek advice from their ostomy care nurse
- 22% try another product (e.g. a new brand or adhesive type)
- 18% live with it/accept it
- 14% seek advice online
- 11% seek advice from the manufacturer
- 6% seek advice from peers/other ostomates

But worrying about leakage also impacts their everyday life negatively in many other ways⁵

- 45% limit their choice of clothing
- 45% wake up at night
- 35% limit their physical activities
- 35% limit how often/how far they travel
- 32% limit their social activities
- 28% limit their professional activities
- 22% adapt their diet
- 22% avoid intimate relations
- 21% don't believe it has any impact
- 20% avoid close physical contact
- 11% isolate themselves
- 11% are afraid of meeting new people
- 11% worry that their family feels awkward around them

Sources: ⁴Zeeberg 2015, Convexity data in the Coloplast CORE panel (Countries: UK, US, FR, DE). Data on file. ⁵Mason 2015, Leakage experience and worries among convex users in the Ostomy Life Study (Countries: FR, DE, UK, NL, IT, BE, SE, US, CA, AU, JP). Data on file.

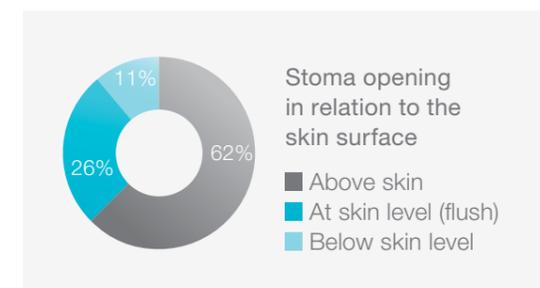
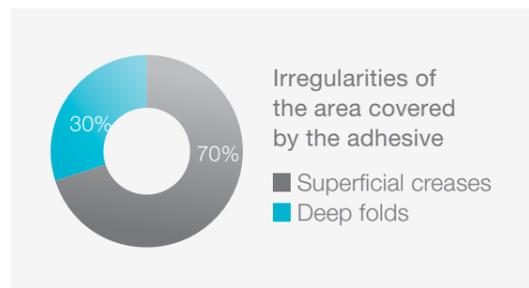
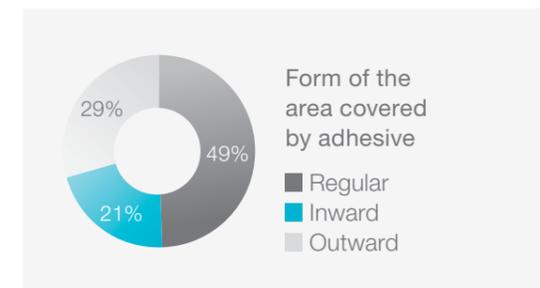
Making the right choice

In light of the data in this publication, it is important to be able to recognise a need for a convex solution – and avoid a trial and error approach. With this in mind, the Global Coloplast Ostomy Forum (COF) and numerous national COF sessions have contributed to develop a simple tool that takes the complexity out of convexity: The Convexity Wheel – a guide that helps all nurses make the best choice when it comes to convexity.

The guide is based on the Body Profile Terminology, characterising individual body shapes, leading to more uniform treatment and processes – as in the BodyCheck tool to be found here:

www.bodycheck.coloplast.com

Data from 8041 self-assessments⁶ show that 21% have an “inward area”, 30% have “deep folds” and 37% have the “opening of the ostomy at or below skin level”. These situations are all indicators for considering the use of a convex product.



It should be noted that data represents only online users and non-professional assessments.

Sources: ⁶Zeeberg 2015. Coloplast Self-Assessment Body Check Tool. Data on file. ⁷Area is defined as the peristomal skin area that is covered by the adhesive.

The Convexity Wheel - the right fit in two steps



Step 1: Identify the body profile⁶



Regular: The area⁷ is more or less level with the abdomen

Inward: The area⁷ sinks into the abdomen

Outward: The area⁷ rises from the abdomen creating a peak

Step 2: Identify the position of the ostomy opening



Above skin surface

In level with skin surface

Below skin surface

Myths & facts about convexity

What is a myth? A myth can be defined as a widely held belief or idea that must be considered untrue based on the available evidence. In many cases myths are stories that allow a culture to continue to hold on to a particular belief, even if this belief is contradicted by evidence.

Myths influence us in subtle ways. If a myth is strong enough, it can even influence how personal experiences are interpreted. In a way, myths can change the way reality is perceived, in what is known as “confirmation bias”.

If, for instance, a certain treatment is believed to be the most effective, any supporting experience is likely to be considered as definite proof, ‘confirming’ the belief as true – even if the experience was really just an exception.

On the other hand, if an experience contradicts popular belief, it will often simply be dismissed as being “the exception that proves the rule”.

Of course, this doesn’t mean that nurses should not trust their experiences – quite the contrary. But the experience-based knowledge should be considered together with all the evidence-based knowledge, where such scientific evidence exists.

Why is this important for nurses? Because even with a high level of personal experience it will still be a subset of the total evidence for or against a given treatment or practice.

Together with the experts of the Coloplast Global COF board, some common questions about convexity were discussed. Is there enough scientific clinical evidence to determine what beliefs are facts and which are myths? Where is there a need for more research?

Question #1 How much do we really know about convexity?

Despite the many convexity products, leakage is still a critical issue and research on convexity is in its infancy. With the variety of convexity solutions available, the knowledge base on how and when to use convex solutions should be convincing. But reality shows that there is very little solid research and evidence-based findings⁸ available, stressing that it is important to be observant and aware of the few scientific articles that are available. It is clear that there is a need to learn a lot more about convexity to make the best possible decisions.

Question #2 Does convex cause more pressure complications?

This seems to make intuitive sense, and traditional convex solutions are often associated with risk of pressure ulcers when discussed in the circles of ostomy care experts. But the reality is that evidence is insufficient to document if and how convexity and pressure complications are related⁹. More than three out of four of the COF experts agreed that in their professional experience, they had no proof of a direct relation. At least, it is an area where more evidence is needed.

Sources: ⁸Elaine Cronin, Senior Stoma Care Nurse, St Mary's Hospital, London, Gastrointestinal nursing no 6 no 2 March 2008 ⁹Use of Convexity in Pouching A Comprehensive Review Jo Hoefl ok Julia Kittscha Paris Purnell J Wound Ostomy Continence Nurs. 012;40(5):506-512. Published by Lippincott Williams & Wilkins ¹⁰British Journal of Nursing, 2001, Vol 10, No 15 ¹¹McKenzie and Ingram ¹¹Coloplast for Security, Marketing material, Coloplast – guidelines based on literature review & experience based knowledge.



Question #3 Is convex a poor choice for newly performed ostomies because of the risk of mucocutaneous separation?

As discussed on page 6 there is data to suggest that convex solutions are perhaps underrepresented among new ostomy patients. Perhaps some nurses are cautious in recommending a convex solution right after surgery even though their professional judgment tells them that it would be the optimal solution? Could the perception of increased risk of mucocutaneous separation be one of the reasons? Again, there is not a lot of evidence, but the available evidence does not confirm this concern nor has it been proven through research¹⁰. This is supported by the COF experts, where 11 of 12 consider this a myth based on their practical experience.

Question #4 Can convex in combination with a ring cause pressure complications?

While there is no evidence that convex solutions are problematic as such, there is indeed some scientific literature suggesting that the addition of a ring to a traditional convex solution could cause ‘intense pressure’⁸. Is this a fact, then? The quoted study stresses that this effect is observed for ‘some’ patients, but not all. This matches with the feedback from the Global COF experts, where about half of the group had observed this phenomenon.



Question #5 Does deep convex cause more pressure complications than light convex?

When looking at the traditional deep convex appliances, it does feel like the hard shells could cause more pressure. Yet, the evidence shows that a light convexity solution can actually place the same or more pressure on the skin¹¹, perhaps suggesting that it's more about finding a good fit for the individual patient, rather than about the depth of convexity. Three out of four of the COF experts agreed that deep convex doesn't necessarily cause more pressure complications than light convex.



For the good of the patient?

Could a more proactive decision on flat versus convex save patients from unnecessary leakage experiences?

In the research for this publication, two important facts quickly surfaced:

- 1 Convex solutions are less represented among new ostomy patients than later in life
- 2 For many of the presumed complications associated with convexity, the contribution of convexity has not been proven, as the relation to convex solutions is not supported by strong evidence. There are indications that other factors, such as a belt or a ring, may be contributing to the complications observed.

So, if data demonstrate that almost half of all patients will eventually end up with a convex solution, why are so many of them starting with a flat solution?

The Global COF experts highlighted a number of interesting points when meeting in September 2015. The overall consensus was clear: "Professional clinical judgement should always overrule 'what we usually do'".

The Global COF experts described the choice of convex as sometimes following a very conservative approach. It was also discussed that less experienced nurses may only explore the choice of convex following a trial and error process with flat appliances. Why is that?

It may be because most less experienced nurses have only little experience with convex ostomy appliances, so recommending convex can be perceived to be more risky, requiring more expertise and follow-up with the patient.

When also considering variables in the peristomal area and the positioning of the ostomy opening (e.g. choosing between deep/soft/light-convex shells), the decision becomes even more complex.

So on one hand, being more proactive in recommending convex solutions when appropriate, can be a less comfortable choice for the less experienced

nurse. On the other hand, it may save some patients from a trial and error period where they experience leakage issues. Based on the discussion around myths and facts and current available evidence, this inconvenience for the patient seems unnecessary. It might be a matter of sufficient training of less experienced nurses – maybe initiated already at nursing schools.

According to the Global COF experts, knowledge of the Body Profile Terminology, illustrations and methodology can help make the right decision even for less experienced nurses. The Convexity Tool is a good example of this (see page 9), a simple tool that can serve as a 'first-choice' guideline, helping nurses to make the right appliance recommendation as early and quickly as possible.

Knowing, that a large percentage will need a convex solution at some point, that there is a lack of evidence that convex solutions lead to additional complications, and that choosing the optimal ostomy appliance may have a huge impact on quality of life, it is clear that it is of great importance to correctly identify when to recommend a convex solution¹². But it is also clear that there is a need for a lot more knowledge, both evidence-based and documentation from personal experience, to consistently be able to make the right choice - for the good of the patient.

Sources: ¹²Claessens et al. 2015. The Ostomy Life Study: The everyday challenges faced by people living with a stoma in a snapshot, *Gastrointestinal Nursing*, 13, 33-38.

A snapshot of the ostomy market

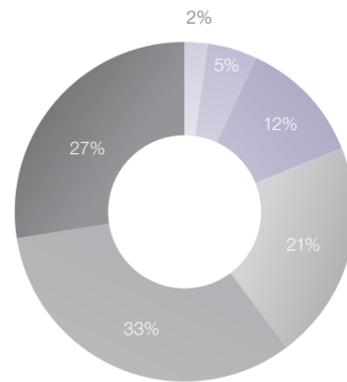
Demographic data from the global Ostomy Life Study^{13,14}

n = 4138

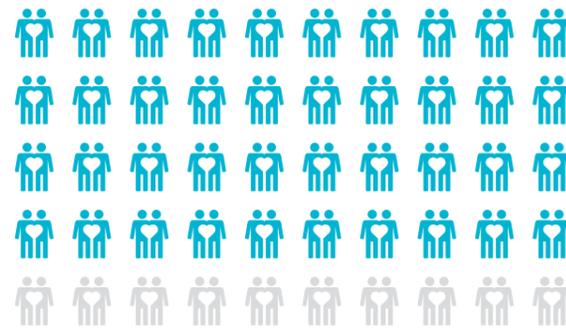


Age of users

- 18-29 years
- 30-39 years
- 40-49 years
- 50-59 years
- 60-69 years
- 70+ years



80% are living with a partner



Type of ostomy by age

- 18-29 years
- 30-39 years
- 40-49 years
- 50-59 years
- 60-69 years
- 70+ years

Colostomy



Ileostomy



Urostomy



When did you have your first ostomy surgery?

- Less than 1 year ago
- 1-2 years ago
- 3-12 years ago
- +12 years ago



Which type of ostomy do you have?^{14,15}

- Colostomy
- Ileostomy
- Urostomy



48%

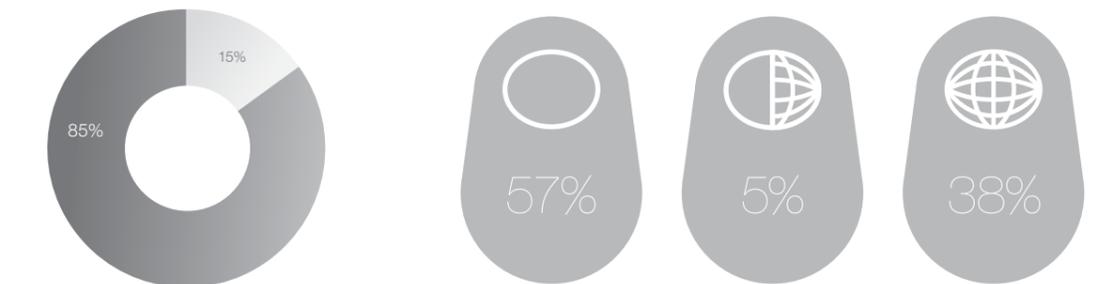
Is the appliance you are using a 1 piece or a 2 piece?

52%



How does your ostomy pouch attach to the base plate on the product you use?

Is the shape of your base plate (the part that sticks to the skin) flat or convex?



- Adhesive
- Mechanical
- Flat
- Alternate between flat and convex
- Convex

Which type of appliance do you use?

- Urostomy appliance
- Closed appliance
- Open appliance



Sources: ¹³Global includes following countries: FR, DE, UK, NL, IT, BE, SE, US, CA, AU, JP ¹⁴Claessens et al. 2015. The Ostomy Life Study: The everyday challenges faced by people living with a stoma in a snapshot, Gastrointestinal Nursing, 13, 33-38. ¹⁵Zeeberg 2015, Coloplast CRM data on Stoma Type in Italy. Data on file.

Coloplast develops products and services that make life easier for people with very personal and private medical conditions.

Working closely with the people who use our products, we create solutions that are sensitive to their special needs. We call this intimate healthcare.

Our business includes ostomy care, urology and continence care and wound and skin care. We operate globally and employ more than 10,000 people.

Ostomy Care
Urology & Continence Care
Wound & Skin Care

