R&D

Raising the standard of care through innovation

Coloplast Capital Markets Day 2020
September 29th 2020
Oliver Johansen, SVP Global R&D

Coloplast Group - Ostomy Care / Continence Care / Wound & Skin Care / Interventional Urology

Making life easier

Coloplast

During LEAD20 we have launched products across all business areas

16/17

SenSura Mio
Convex

SenSura Mio
Hospital Assortment

Biatain Silicone
Sizes & Shapes

3DFit® Technology

Brava extensions

17/18

SenSura Mio
Concave

SpeediCath
Flex Coudé Pro

18/19

SenSura Mio
Baby & Kids

Biatain Contact

SpeediCath
Navi

Biatain Fiber

HexaLock™ Technology

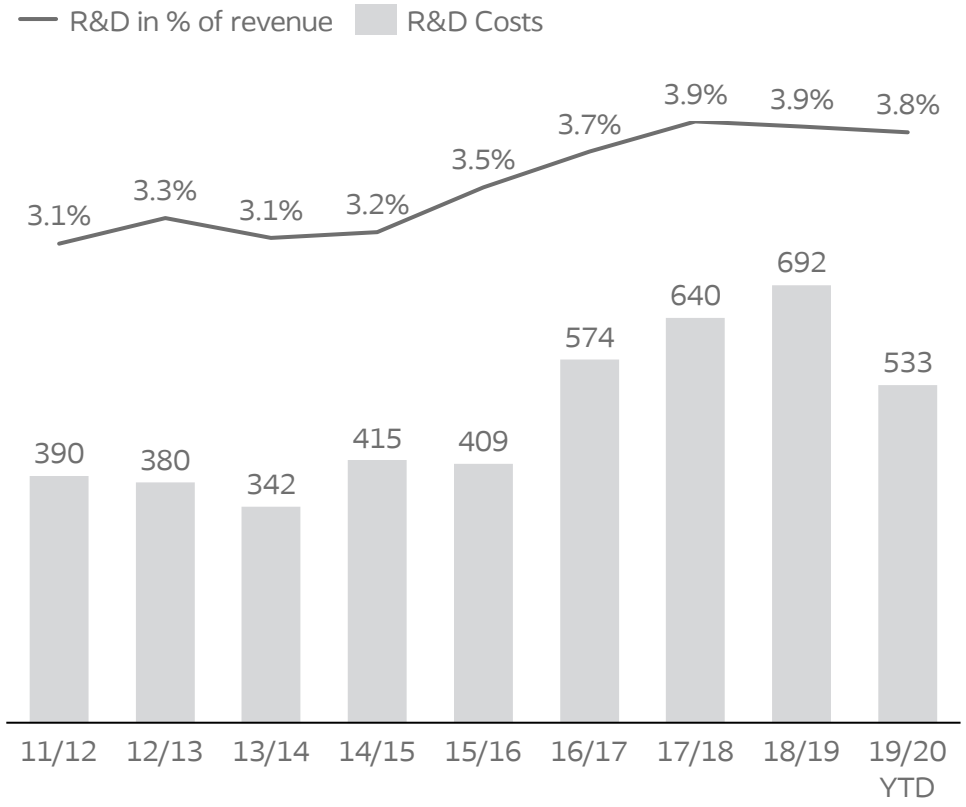
19/20

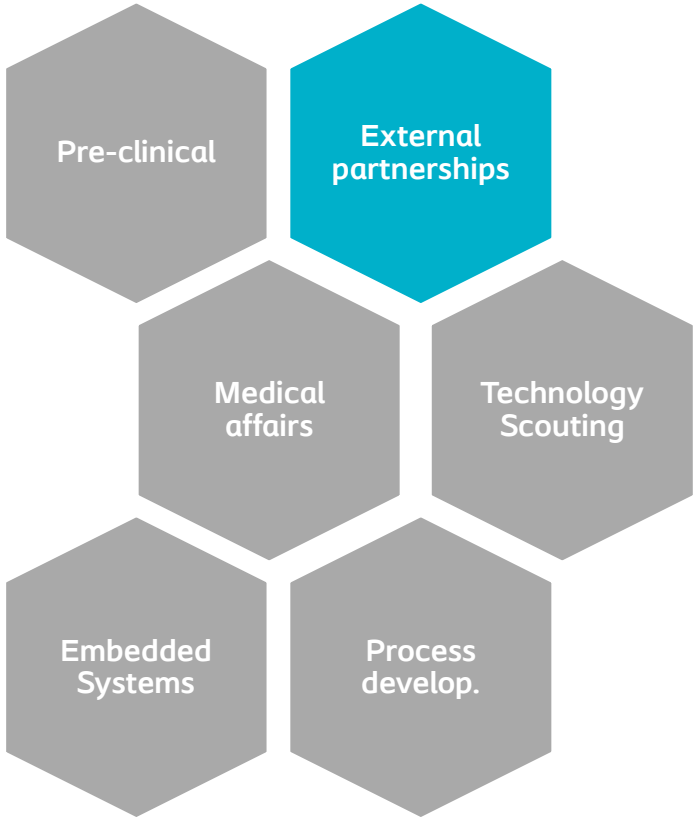
Peristeen Cone

SpeediCath
Soft

We have increased our R&D spend and strengthened key R&D capabilities

Higher absolute and relative R&D spend over the period

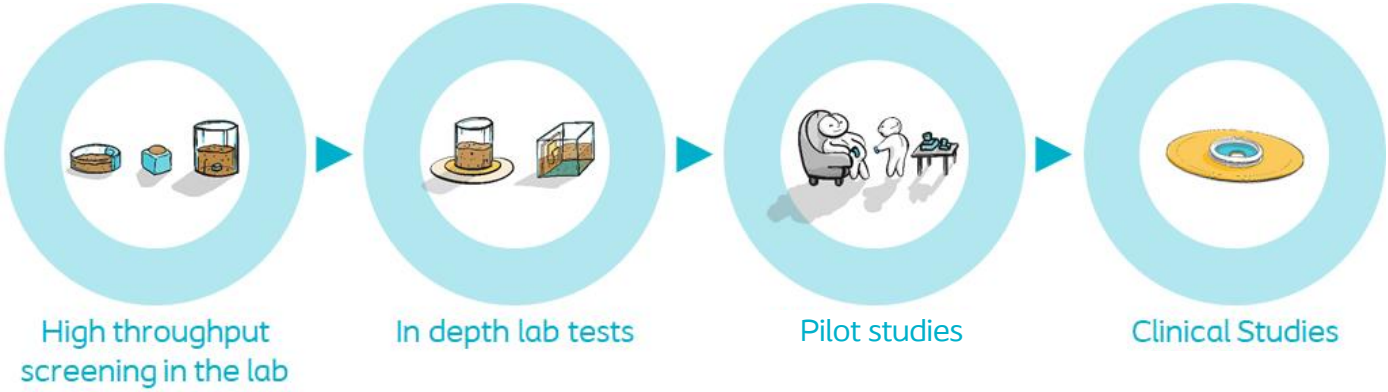




Source: Coloplast

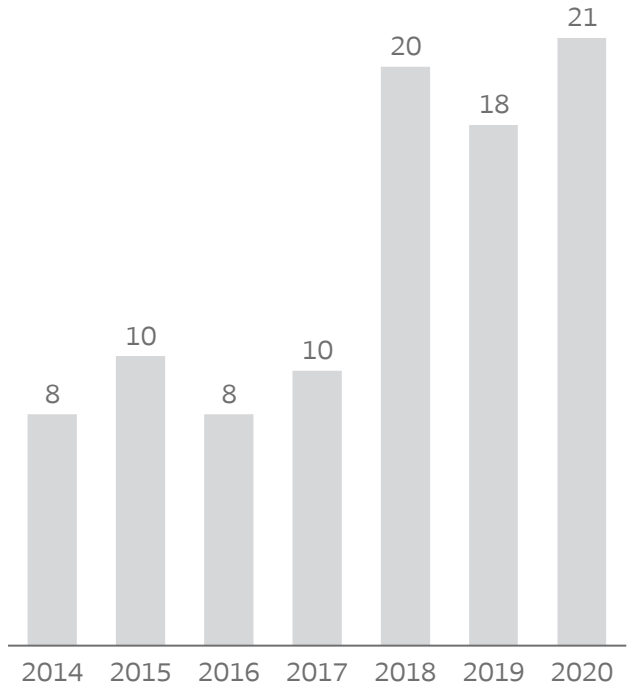
Our pre-clinical and clinical efforts have more than doubled

Phase of clinical studies: Test new technologies and accelerating development



1 Pre-clinical | 2 Pilot | 3 Pivotal

Number of clinical studies pr. year



Source: clinicaltrials.gov

We want to raise the standard of care through clinically superior products and innovation

Focus in this CMD meeting

Deliver on the Clinical Performance Program
- Execute on the clinical performance programs to strengthen Coloplast's position as leading provider and to avoid commoditisation

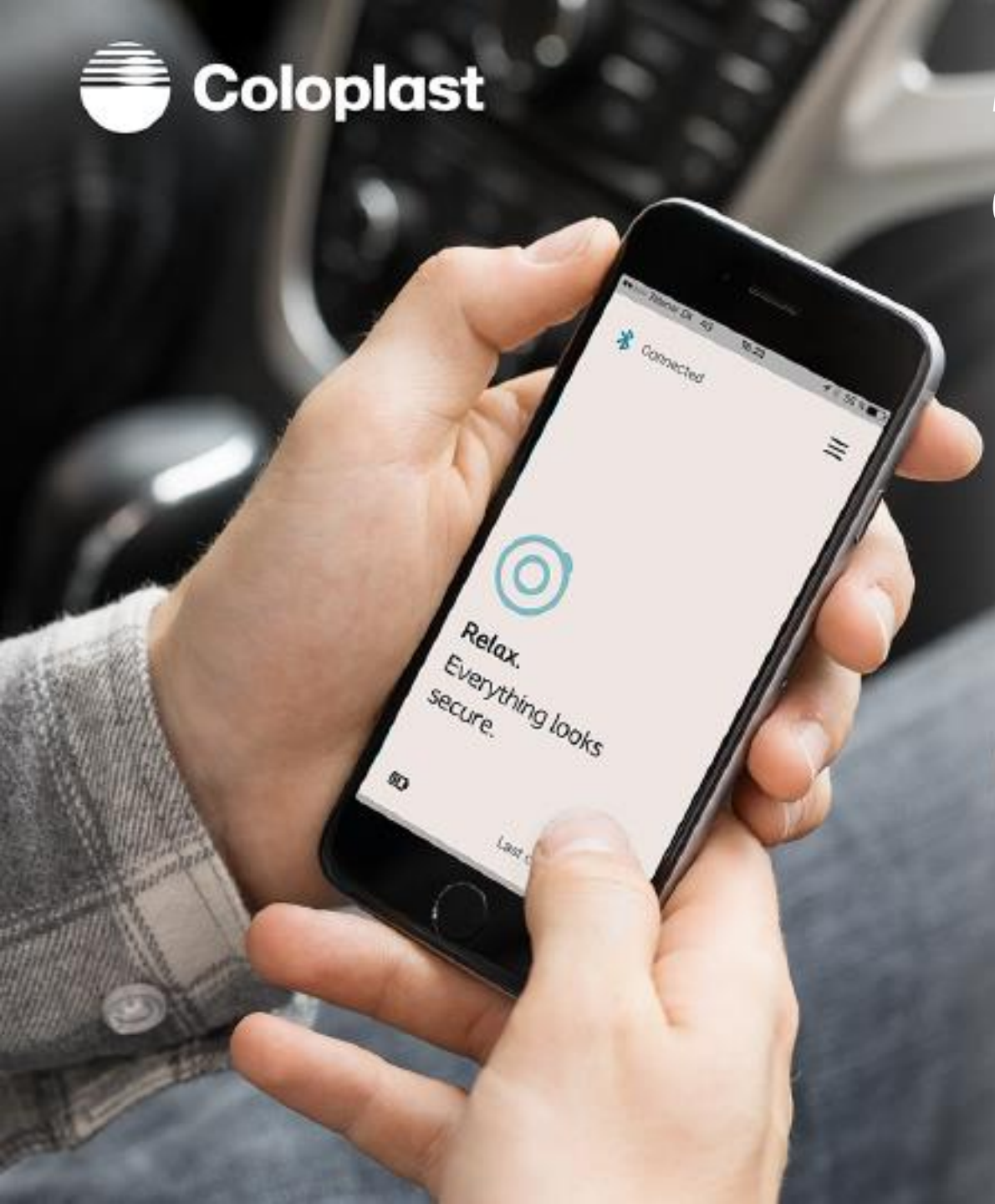
Continue launch cadence and build more options into the pipeline
- Continue launch cadence in existing categories
- Identify new growth drivers and disruptive technologies to secure future growth

Continue to develop an innovative organisation and culture
- Strengthen our innovation culture and mindset through a well defined set of initiatives

Simplify to grow
- Simplify our innovation process to free up resources and shorten time to market
- Increase focus on Design for Manufacturing to enable profitable volume production going forward

Coloplast

Introducing a new digital ostomy solution

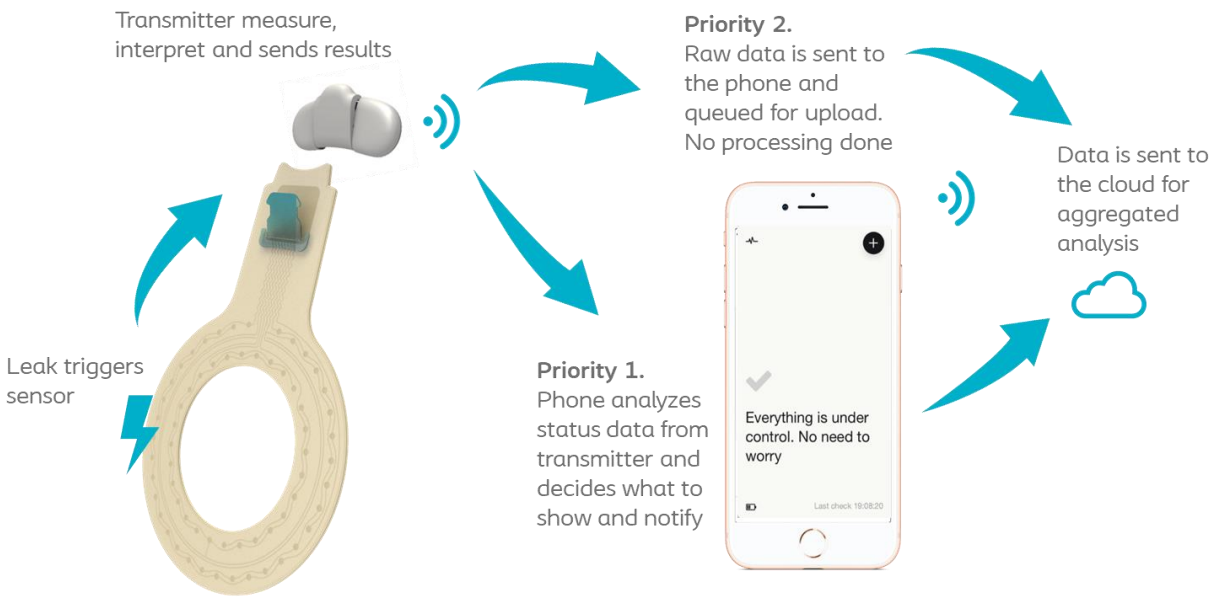


The *digital leakage notification system* presented is an investigational device currently in development.
It is not available for sale and its safety and effectiveness have not been established.
It is not been cleared or approved in the U.S., EU, or any other market.
Features and technology of the future *digital leakage notification system* may vary.
Access to the system is contingent upon regulatory approval or clearance.
Approval or clearance timelines are subject to the regulatory process of individual countries and regions and are not guaranteed.

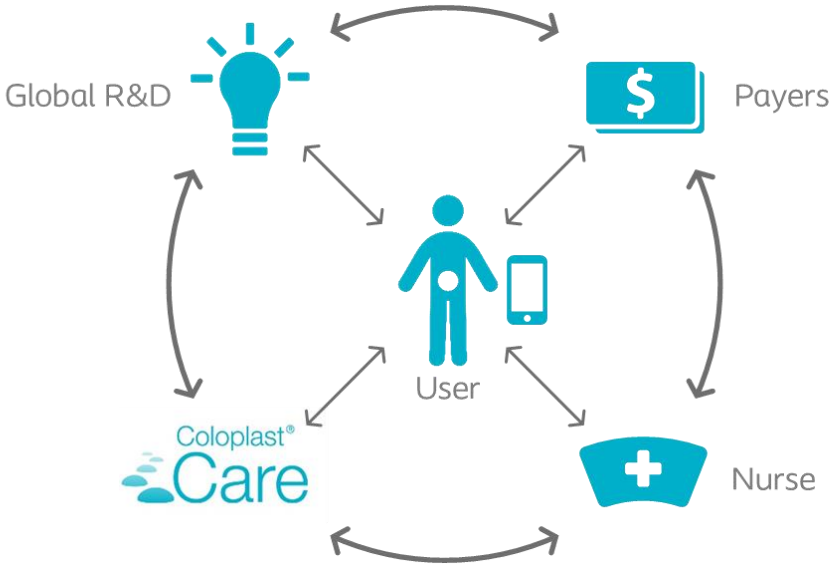
Supporting reference: Data from clinical trial CP308 and OLS16 review. Coloplast data on file.

We want to provide users with an intelligent solution that helps avoid leakage accidents and gives peace of mind

Giving users control and peace of mind



Our digital aspiration



We have conducted a pilot study to test our new digital ostomy solution end-to-end for the first time

End-to-end pilot study

We tested the end-to-end solution in a **9 weeks** pilot study to determine technical feasibility of the entire solution

18 patients completed the pilot study

Key outcome areas

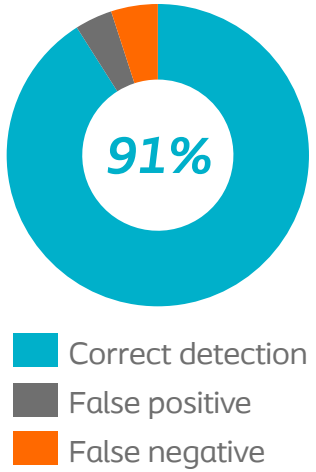
1. **Leakage notification** (as evaluated by users)
2. **Leakage detection accuracy** (live data vs. pictures)
3. **Skin redness & Leakage area** (picture analysis)
4. **User Experience** (possible to use, System Usability Scale score)
5. **Mental health** (Quality of life, feeling of security, worry of leakage)

CP308 study execution and comparative outcome plan

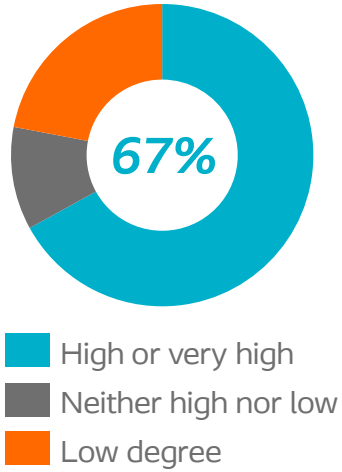
Pilot study[1] shows high accuracy in detecting leakage, preference and peace of mind with regards to leakage

Preliminary results (n=18)

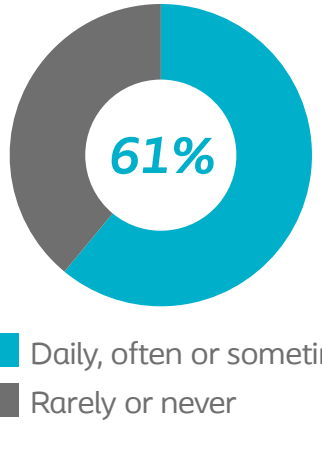
91% Accuracy
(correct status detected)



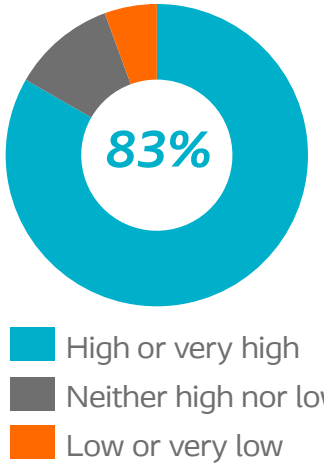
67% of patients reported **high or very high trust & reliability** in system



61% of patients would use system frequently



83% reported **high or very high** information from system to avoid full **leakage onto clothes**

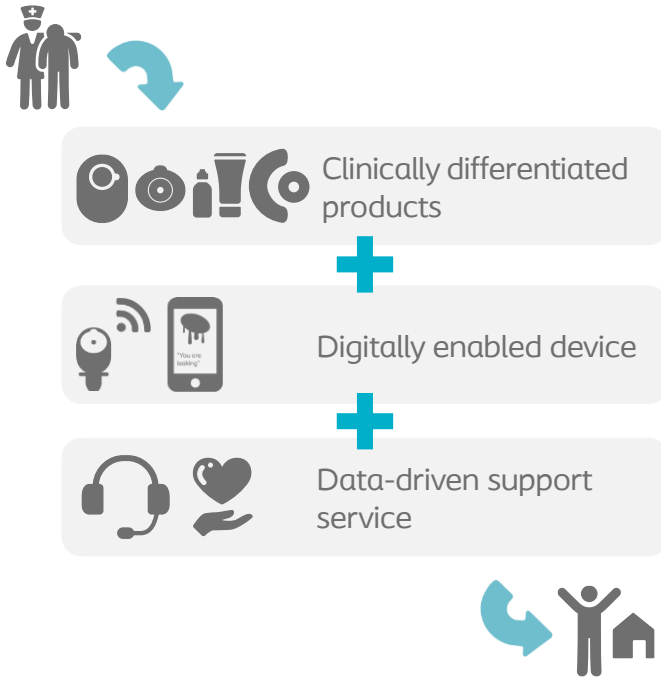


1. Clinicaltrials.gov : Identifier: NCT04374890

Our solution empowers users to take control of their life with a stoma. Here, we are taking a true pilot approach

The Solution

Offers a powerful, innovative and effective way to proactively improve the overall health and wellbeing of ostomy patients



Value Creation Model

Through our Burden of Illness studies and the Ostomy Life Study we have identified value drivers that provides user and payer value

- Reduced leakage
- Optimal healthcare resource utilisation (readmissions, A&E, GP and HCP visits)
- Improved quality of life (QoL)
- Improved mental wellbeing
- Improved self management (incl. establishing routine), physical mobility, sociability and activity levels
- Appropriate product consumption
- Reduction in peristomal skin complications (PSCs)

Payer Pilot Process

The pilots will be set up according to the commercial needs for each market, in collaboration with local payer organisations

- UK & DE selected
  Value model developed
  Pilots to be conducted
- Payer partners identified
  UK – NHS bodies
  DE – Health Insurance companies
- Publication plan defined and clinical endpoints and plan agreed
- National launches to be planned

Introducing our new ostomy care platform

Coloplast

Peristomal skin complications are common and a burden for many users and costly to payers and society

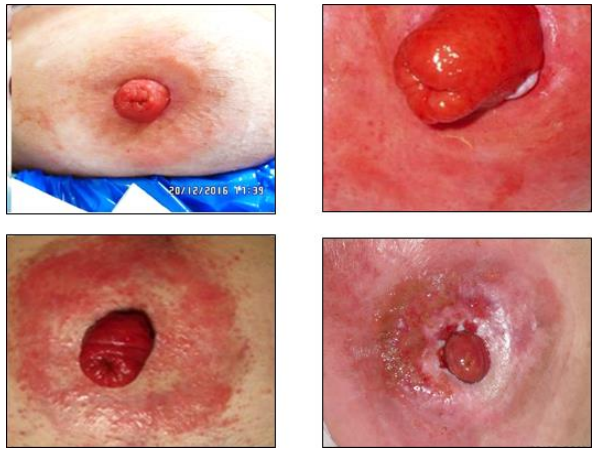
Peristomal skin complications are a burden for many users …

73%

*Of all users have experienced skin issues within the past 6 months**

52%

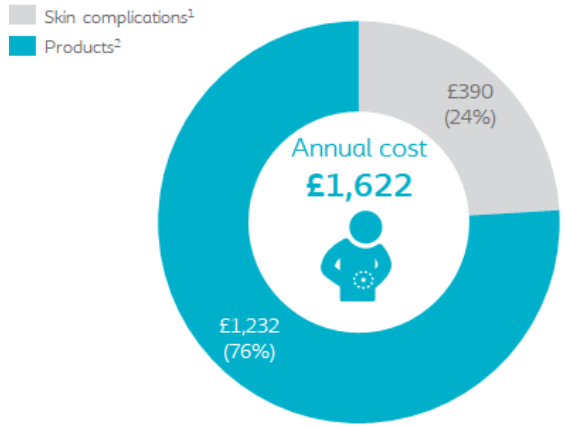
*Reports skin issues as one of the main reasons to see a nurse**



… and is a real cost driver

An ileostomist in UK

(vs. SenSura Mio, Flat, 1pc user)



With a prevalence of **Peristomal Skin Complications of 49%**[1]

We see direct **potential savings of 1/3 of product costs** for the payers by reducing the need for:

- Stoma Care Nurse Interventions
- GP visits
- Specialist visits
- Medication

* The Ostomy Life Study: the everyday challenges faced by people living with a stoma in a snapshot. Claessens, et al., Gastrointestinal Nursing, Vol. 13, No. 5. doi.org/10.12968/gasn.2015.13.5.18

1) Martins et al. 2012 (adjusted for inflation) - British Journal of Nursing
2) One product per day, Drug Tariff 2019

Coloplast

We have tested our new skin protecting technology against the standard of care in an international RCT

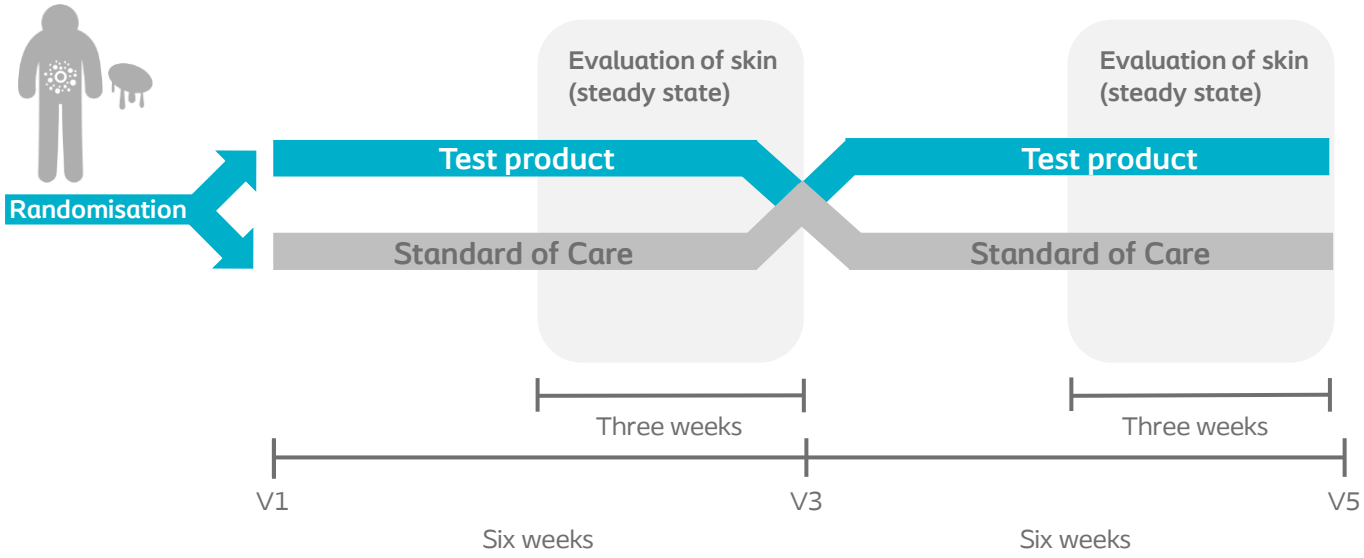
Countries:

First patient in: Feb. 2020
Last patient out: July 2020
Data presentation: Sept 2020

79 patients recruited
64 patients completed

Endpoints:

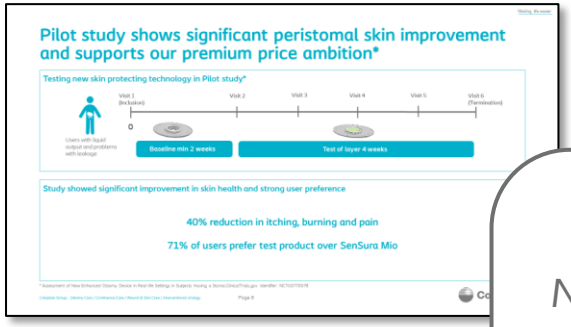
- Skin (itching)
- Skin affected area
- DET score[1]
- Quality of Life (QoL)
- Other relevant endpoints



1. DET Score: Ostomy Skin Tool is a standardized measuring instrument for assessing the extent and severity of peristomal skin change in terms of discolouration (D), erosion (E), and tissue overgrowth (T).

Pivotal study results are unsatisfactory – however we remain confident in the technology

Positive pilot study results presented in 2019



RCA

No statistically significant difference in skin condition measured by Pain, Itching and Burning sensations

Latest pivotal study shows unsatisfactory results

Slight tendency for lower fraction of Moderate/Severe skin complications, but not statistically different.

Statistically significant improvement of QoL (Quality of Life) compared with SoC (Standard of Care)

Root Cause Analysis (RCA) process completed, indicating need to optimize product device design 12 months delay


Introducing our new intermittent catheter platform
Tabitha
Coloplast

Our new IC platform addresses some of the key UTI risk factors in the recently published Risk Factor Model

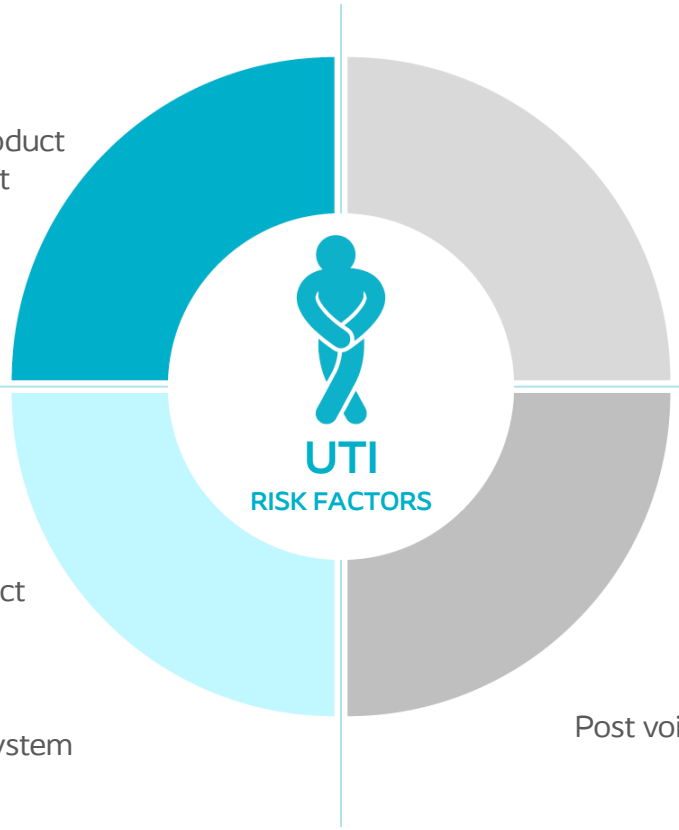
Intermittent catheterisation

- ✓ Bacteria inserted by product
- ✓ Urethral and bladder trauma from product
- ✓ Post void residual urine due to product design

No urethral rinsing

General conditions

High Intravesical pressure
Impaired bladder compliance
Host deficiencies
Bowel dysfunction
Diabetes
Age and Gender



User compliance/adherence

- ✓ Non-hygienic procedure
- ✓ Insufficient education
- ✓ Post void residual urine due to incorrect handling

Voiding frequency
Fluid intake (with hydration indicator)
Residence country & social support system

Local urinary tract conditions

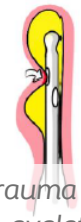
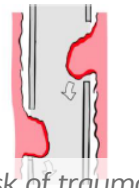
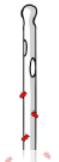
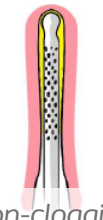
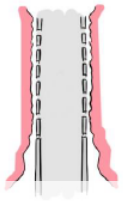
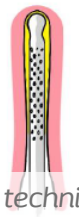
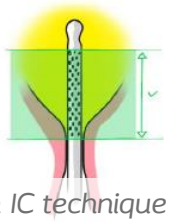
Bacterial virulence
Previous UTI
Botulinum Toxin A injections
Urodynamic investigations
Bladder and kidney stones
Post void residual urine caused by bladder shape

Source: Kennelly et al 2019: Adult Neurogenic Lower Urinary Tract Dysfunction and Intermittent Catheterisation in a Community Setting: Risk Factors Model for Urinary Tract Infections

The new IC platform addresses key UTI risk factors

Reducing mechanical trauma, residual urine and insertion of bacteria

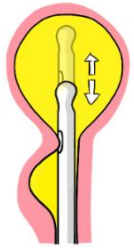
Benefits of the new IC platform v. standard catheters

	Reduced bladder and urethral trauma		Reduced residual urine and simpler use		Reduce bacteria
Standard catheter	 *Risk of trauma in bladder wall, i.e. eyelet clogging*	 *Risk of trauma in urethra*	 *IC technique needed Re-positioning catheter*	 *IC technique needed Finding the right position*	 *Bacteria insertion*
New IC platform	 *Non-clogging drainage zone*	 *Trauma-free*	 *Minimum IC technique needed Complete voiding*	 *Minimum IC technique needed Complete voiding*	 *Minimal bacteria insertion (Bacteria Barrier Technology)*

Tests in live pig bladders demonstrate elimination of blockage of catheter eyelets occurring with conventional catheters

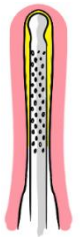
Standard catheter

Eyelets block completely and the flow stops

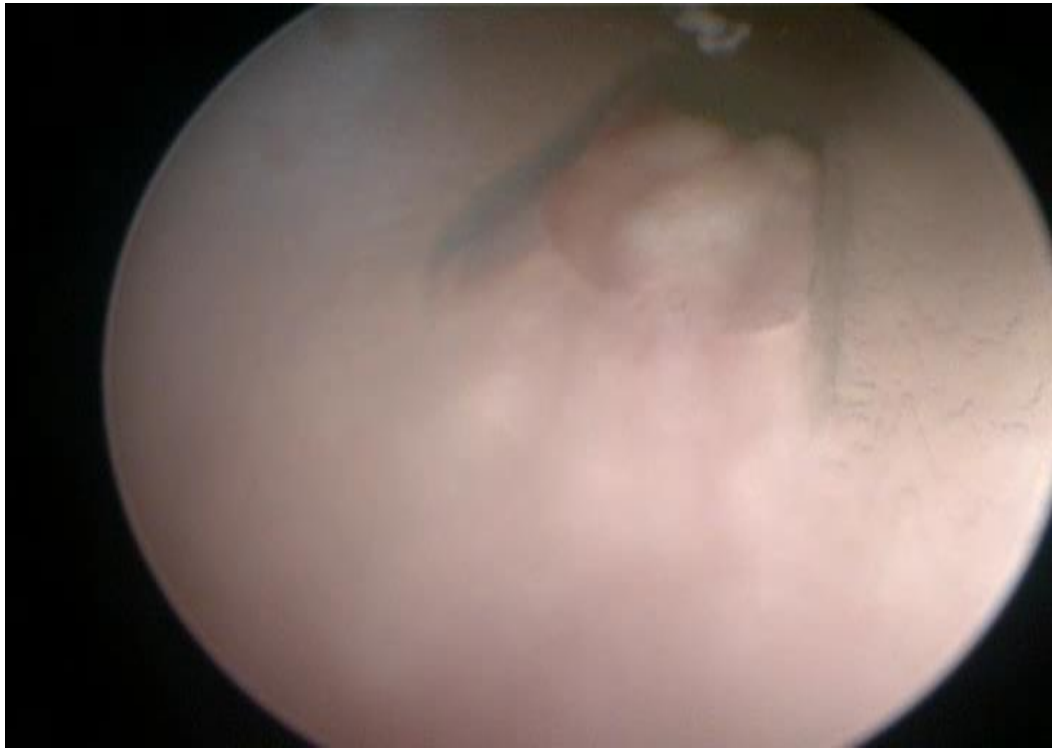


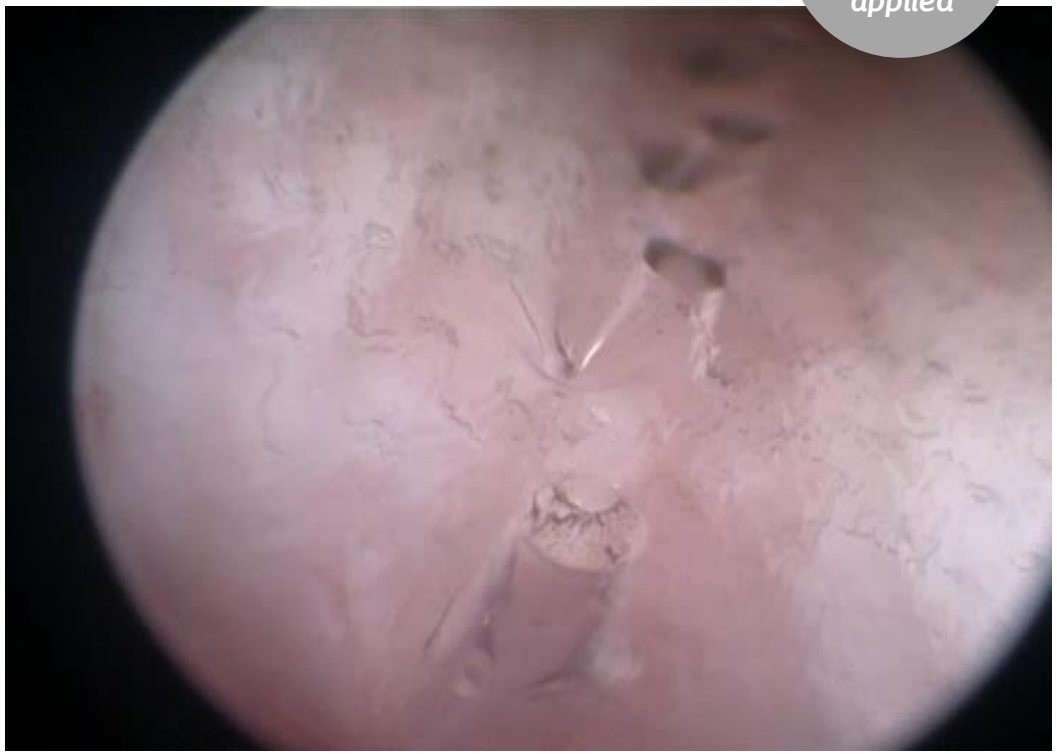
New IC platform with micro-eyelets

Complete emptying with elimination of catheter blockage



Strong patent protection applied





Source: Research done in collaboration with Research Unit of Clinical Microbiology, Odense University hospital. Video recorded during catheterization of anesthetized female pig in supine position.

We have completed the first phase of the exploratory pilot study evaluating the micro-eyelets

Timeline:

- First patient in: June 2020
- Final data presentation: H1 2021

Study population

Phase 1

- 15 healthy males ✓
- 14 healthy females ✓

Phase 2

- 15 male IC users
- 15 female IC users

Key endpoints:

- Catheter blockage/flow stops
- Volume at 1st flow stop
- Discomfort
- Haematuria
- Handling evaluation

The pilot study evaluates the micro-eyelets in SpeediCath (SC) catheters

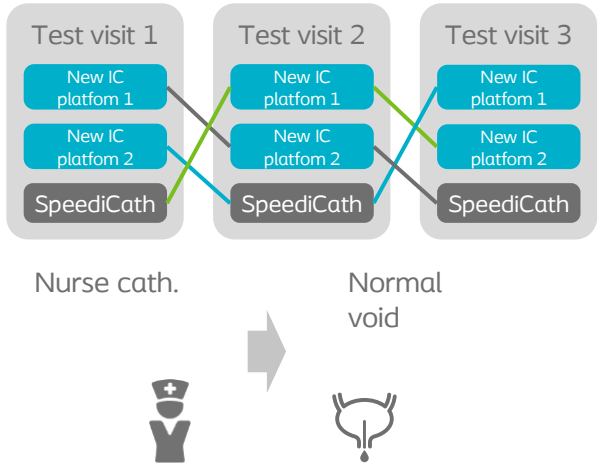
Male

- Multiple micro-eyelets ver. 1
- Multiple micro-eyelets ver. 2
- Standard hydrophilic catheter

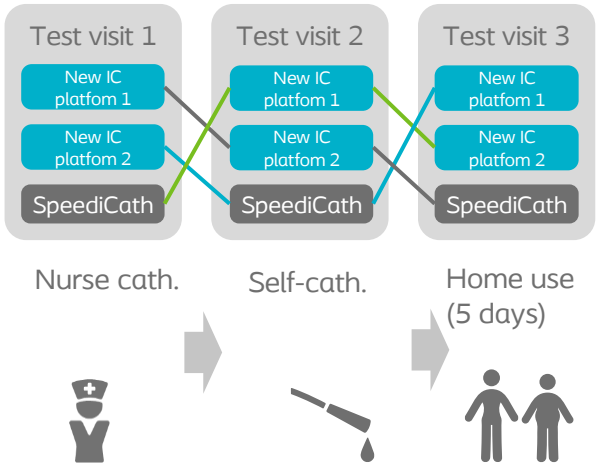
Female

- Multiple micro-eyelets ver. 1
- Multiple micro-eyelets ver. 2
- Standard hydrophilic catheter

Phase 1: Healthy volunteers ✓

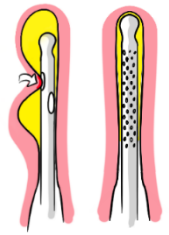


Phase 2: IC users



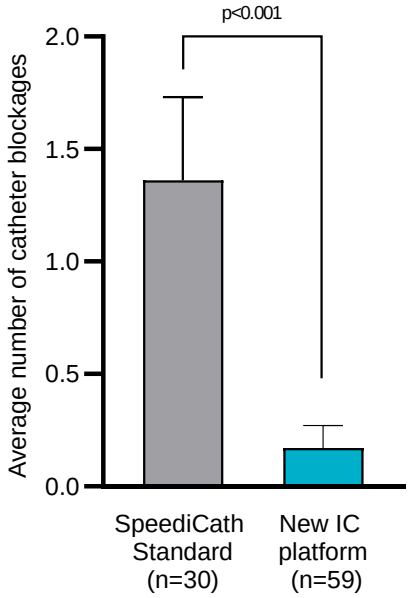
Results indicate improved performance with micro-eyelet catheters in healthy volunteers

- a reduced number of catheter blockage events leading to reduced residual volume at first blockage and reduced blood in urine after catheterisation

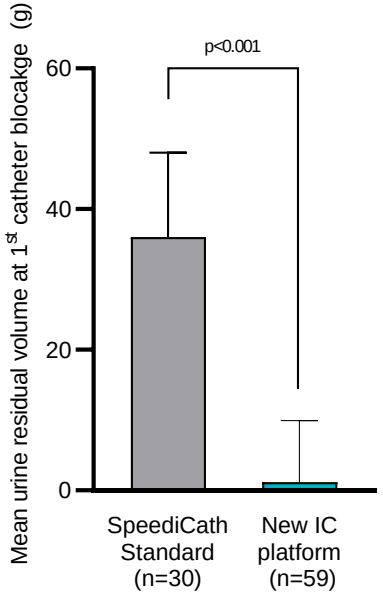


Preliminary results[1]

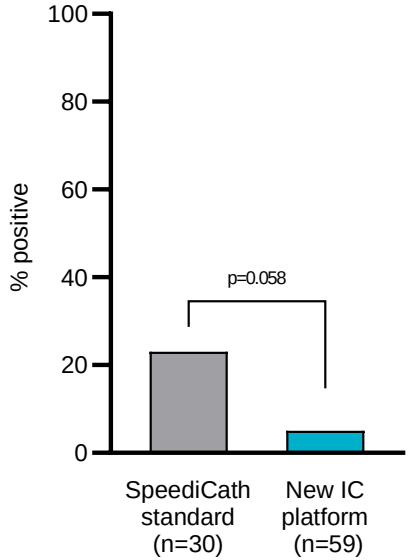
New IC platform reduces catheter blockage



New IC platform reduces residual volume at first catheter blockage



New IC platform reduces blood in urine following catheterisation



1) Final conclusions to be reached after completion of CP323-24 in IC users

We have made significant progress across the Clinical Performance Program

	Progress as of today	*Strive25 strategy period ends in 2025*	
Digital ostomy solution	***Pilot studies conducted with successful results*** ✓	Additional pilot study to further test the technology in broader setup Payer pilots to be conducted for reimbursement processes in key markets	Product launch expected **in first half** of strategy period
New ostomy platform	***Initial pilot studies indicated positive outcomes*** ✓ ***Pivotal study showed non-significant results*** ✗	Product device design to be optimised New pilot study to be completed Pivotal study to be completed	Product launch expected **in first half** of strategy period
New catheter platform	***Pilot studies conducted with successful results*** ✓	Further pilot studies in progress Pivotal study to be completed	Product launch expected **in second half** of strategy period

Simultaneously, continue our launch cadence into existing categories within ostomy care and continence care

Our mission

Making life easier for people
with intimate healthcare needs

Our values

Closeness... to better understand
Passion... to make a difference
Respect and responsibility... to guide us

Our vision

Setting the global standard
for listening and responding

Coloplast