

Coloplast Meet the Management
31 August 2022

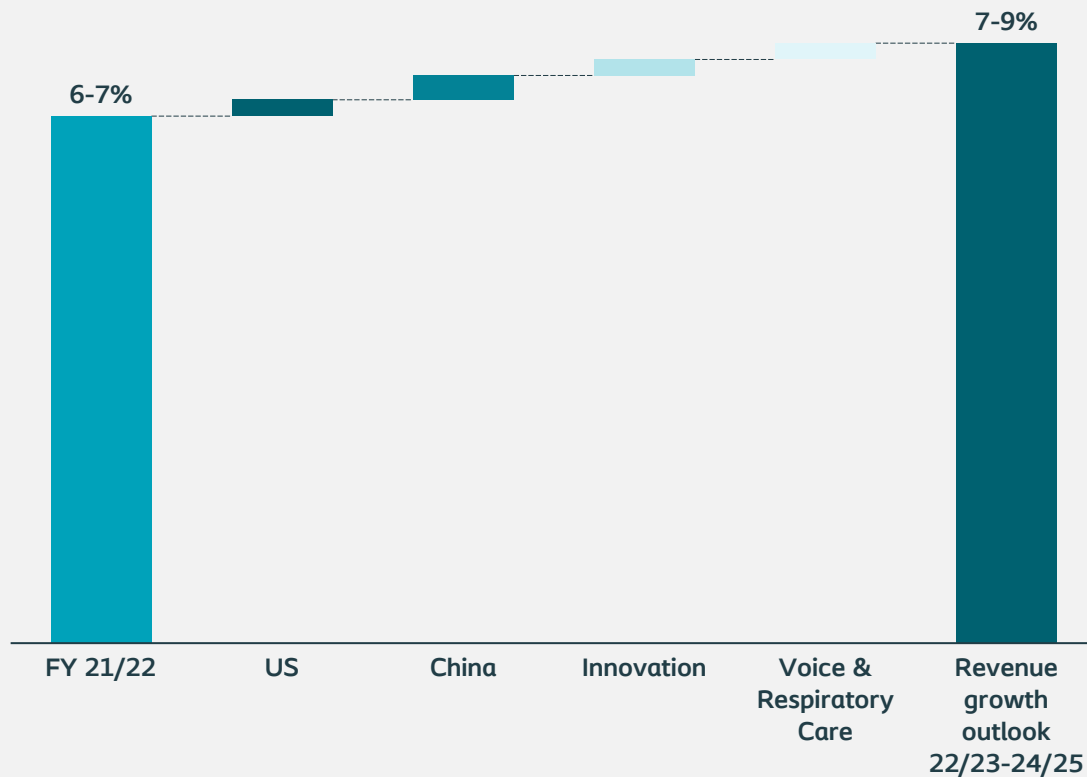
Clinical Performance Program

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UK



Innovation will contribute to organic growth in the upper end of the 7-9% range in the outer part of Strive25



Strive25 Innovation Agenda Define, develop & deliver our commercial offerings



Focusing on our clinical performance programs

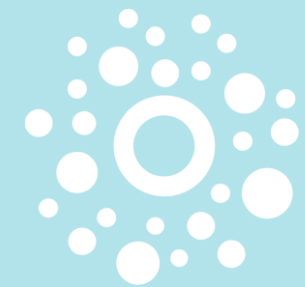
LujaTM



HeyloTM



New OC technology platform



Preventing UTIs remains one of the biggest unmet needs we need to solve for in IC

45%

of users consider UTIs to be their greatest challenge¹



48%

of users are worried whether they have emptied their bladder⁴



IC users have

2-3

 UTIs on average per year...²

...over a lifetime users will have up to

70-105

 UTIs³

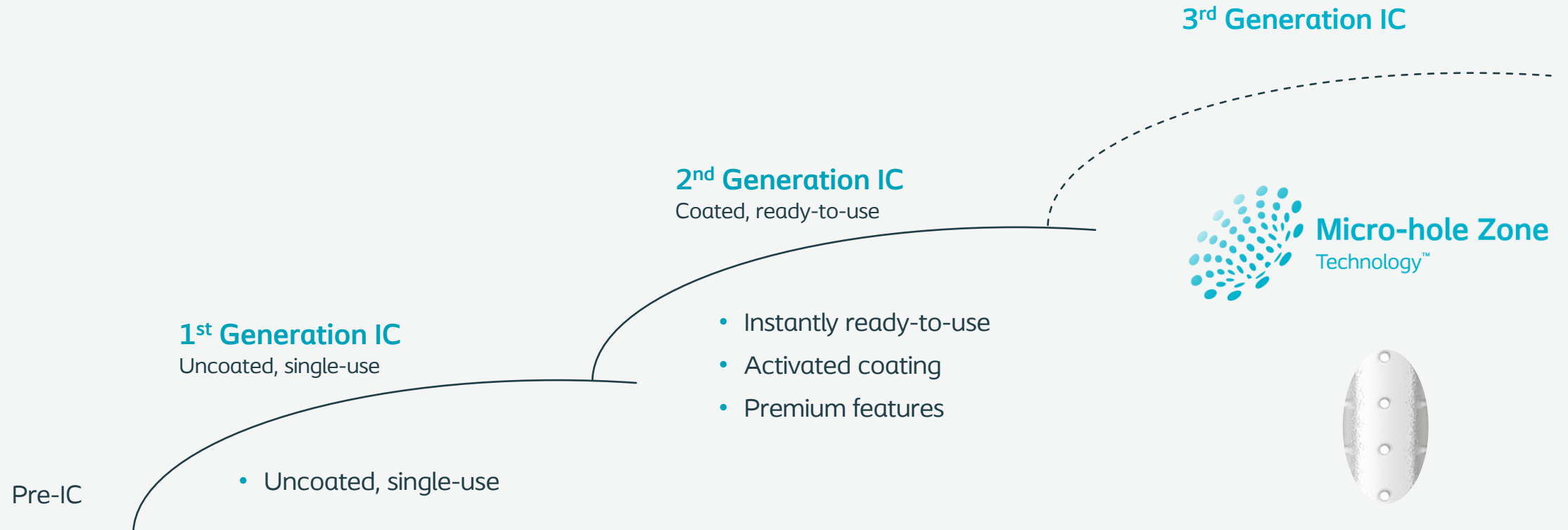
¹ IC Value Proposition user questionnaire (n=2,942). Data-on-file. 2016

² Kennelly et al. 2019, Fischer 2018, Vahr et al. EAUN guidelines 2013

³ Middleton et al. 2012

⁴ Extended CORE survey 2022. Data on file

We want to set a new standard in IC with Luja™ and the Micro-hole Zone technology™



Luja™ with Micro-hole Zone Technology™ addresses the key UTI risk factors

UTI Risk Factor Model¹

Intermittent catheterisation

General patient conditions



User compliance

Local urinary conditions

UTI risk factors addressed by Luja™



UTI risk factor:
Non-hygienic technique

UTI risk factor:
Urethral trauma

UTI risk factor:
Residual urine

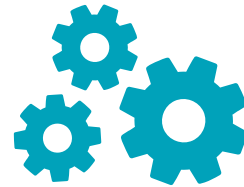
UTI risk factor:
Bladder micro trauma

Adapted from ¹Kennelly et al 2019: Adult Neurogenic Lower Urinary Tract Dysfunction and Intermittent Catheterisation in a Community Setting: Risk Factors Model for Urinary Tract Infections.

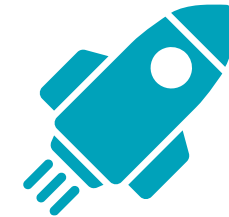
Luja™ has gone through an extensive research & development program and is now in its final preparation for launch



- Identify UTI risk factors with KOLs and publish UTI Risk Factor Model
- Develop concepts, processes and pre-clinical models
- Initial performance testing



- Develop and mature product
- Develop production processes
- Conduct pilot studies



- Establish production capacity
- Confirm clinical results in a large trial setting
- Launch readiness
- Establish market access

Comprehensive clinical program behind Luja™ to demonstrate the clinical relevance and difference

✓ Pre-clinical studies

In-vivo and *in-vitro* animal models used to optimize technology features and document the effect.

✓ Pilot studies

8 studies comparing Luja vs. conventional catheters¹ involving 160+ users, demonstrating

number of flow-stops and residual volumes at first flow stop significantly lower with micro-hole zone catheters as compared to conventional catheters

● Pivotal studies

3 multinational pivotal studies² involving 150+ users demonstrating the impact on the key risk factors of UTI.

Multicenter, randomised cross over trial comparing Luja™ vs standard of care.

Endpoints: Residual volume, Flow stops, Blood in urine, QoL

¹ Clinicaltrials.gov references: NCT03337048, NCT04633291, NCT04231149, NCT04250987, NCT04445051, NCT04543136, NCT04557787, NCT05224544.

² Clinicaltrials.gov references: NCT05485935, NCT05485922. One study not yet registered.

Focusing on our clinical performance programs

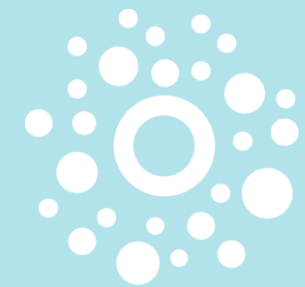
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Leakage remains the biggest challenge for our users

91% of people with a stoma worry about leakage¹

40% of users experience leakage onto their clothes every month²

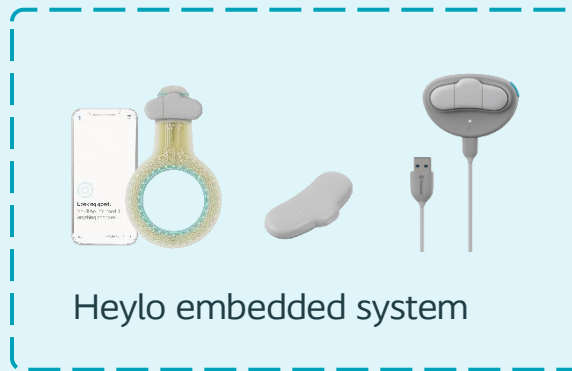
Heylo addresses the mental burden caused by fear of leakage

Control and peace of mind

1. Claessenes et. al. Gastrointestinal Nursing 2015
2. Usage pattern Study 2015, N=652 patients (US, UK, FR, DE)

Heylo™ is an extended OC solution with integrated service offerings

Enablers



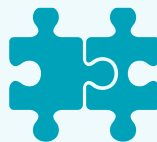
Benefits



Fewer leakages



Peace of mind



Seamless user experience



Payer relevant outcomes

Data is promising. Pre-pilot study with Heylo™ shows high product performance and user preference

Product performance & user experience¹

reduction in worry of leakage

92%*



less leakage episodes

85%**

would recommend to others

87%



Quality of life and future use¹

+9%

significant improvement to emotional impact of leakage

96%

report higher feeling of security

35%

report improved sleep

¹ CP321 study, 3W use of full system by n=25

* Reduction from 48% to 4% with high/very high worry of leakage (p-value<0.001)

** Reduction from 2.7 to 0.4 episodes of leakage onto clothes per 3 weeks (p-value=0.009)

The clinical program supports national launches, reimbursement applications and generates user insights

Single-arm confirmatory study, n=100

Show benefit to support Drug Tariff application:

- Leakage onto clothes
- Quality of Life
- Healthcare utilisation



Cross-over RCT confirmatory study, n=145

Document quality of life improvements:

- Emotional leakage impact
- Leakage onto clothes
- User behaviour and use patterns



User insights data collection, n=~150

Insights into user behaviour and product performance:

- Confirm unmet need
- User behavior and use patterns
- Willingness-to-pay



- Support reimbursement in DE & UK
- Document Heylo™ performance
- Understand user behaviour and use patterns
- Document value to payers

Focusing on our clinical performance programs

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Peristomal skin complications is a significant challenge and it is primarily the enzymes that damage the skin

88%

of all users have experienced skin issues since their last change



54%

report skin issues as one of the primary reasons to see a nurse¹



Underlying causes for skin issues are primarily irritant contact dermatitis caused by leakage



Digestive enzymes damage the skin

¹Fellows et al. 2021. Multinational survey on living with an ostomy: prevalence and impact of peristomal skin complication. BJN, 2021

²Voegeli et al. Gastrointestinal Nursing, 2020

Performance of technology confirmed in clinical trial and project now re-initiated to conclude on development and initiate launch preparation

Core technology is unchanged

Randomized control trial

Significant reduction of peristomal skin complications compared to standard of care
17% reduction on non-visible symptoms



Device has been redesigned

10 weeks period
82 experienced users
12 years since surgery

Significant improvement of QoL compared to standard of care



Mission

Making life easier for people with intimate healthcare needs

Values

Closeness... to better understand

Passion... to make a difference

Respect and responsibility... to guide us

Vision

Setting the global standard for listening and responding