

Study shows significant improvement in bladder emptying with Coloplast's Luja™ compared to competitor catheter

Study results show that Coloplast's new intermittent male catheter with 80+ micro-holes, Luja, achieved complete bladder emptying in one free flow* in 90% of catheterisations, while Hollister's 2-eyelet catheter, VaPro™, achieved this in 52% of catheterisations.

Coloplast has finalised its first pivotal clinical study on Luja, a new intermittent male catheter, designed to reduce the risk of urinary tract infections by minimising residual urine and reducing bladder microtrauma¹.

The study's primary endpoints were urinary flow-stop episodes and residual volume at first flow-stop. A flow-stop occurs when bladder mucosa is sucked into the catheter eyelets, thereby blocking the urine flow. A blockage requires repositioning of the catheter in order to resume the urine flow to empty the bladder². Additionally, hematuria was assessed by dipstick, and post-catheterisation volume of residual urine was measured with an ultrasound bladder scanner.

Statistically significant results

A selection of the data from the study, which showed statistically significant results, was presented at the United Kingdom Continence Society (UKCS) Annual Scientific Meeting in Sheffield, UK, on 30 March³:

- Catheterisation with Luja resulted in close to zero flow-stops compared to one flow-stop on average with VaPro*.
- Luja achieved complete bladder emptying* in 90% of catheterisations, while VaPro achieved this in 52% of catheterisations.
- Catheterisation with Luja resulted in a 74% less likelihood of hematuria post-catheterisation, compared to VaPro.

"I am very pleased with the results of the Luja CP353 study. All primary and secondary endpoints have been successfully met, and the study clearly demonstrates that Luja significantly improves bladder emptying. I am excited by what Luja can do for people who use intermittent catheters to empty their bladder, and I look forward to following the launch in the coming months," says Nicolai Buhl, Executive Vice President of Innovation at Coloplast.

The CP353 study

Urinary tract infections represent a significant challenge for people who use intermittent catheters to empty their bladder, and on average users experience 2-3 urinary tract infections per year^{1,4}. Almost half of intermittent catheter users are unsure whether their bladder has been fully emptied after catheterisation⁴.

Coloplast was founded on passion, ambition, and commitment. We were born from a nurse's wish to help her sister and the skills of an engineer. Guided by empathy, our mission is to make life easier for people with intimate healthcare needs. Over decades, we have helped millions of people to live a more independent life and we continue to do so through innovative products and services. Globally, our business areas include Ostomy Care, Continence Care, Wound and Skin Care, Interventional Urology and Voice and Respiratory Care.

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When emptying the bladder with conventional eyelet catheters, the flow of urine can be interrupted because the bladder mucosa surrounding the eyelets is sucked into the catheter**. These flow-stops can give users the false impression that their bladder is empty³, potentially leading to premature removal of the catheter and residual urine left behind in the bladder. To release the mucosa from the eyelets, and resume flow, users are required to reposition the catheter which can result in microtrauma**. Residual urine and microtrauma are both important risk factors for urinary tract infections^{1,5-6}. Consequently, users of conventional eyelet catheters are exposed to both these risk factors¹ when they perform their catheterisation.

The CP353 study investigated the performance of Coloplast's new intermittent male catheter, Luja, with 80+ micro-holes designed to reduce urinary flow-stops and minimise residual urine. The investigation was a single-centre, crossover, randomized and controlled study, which consisted of one inclusion visit and two single test visits. A total of 42 subjects enrolled were catheterized by a healthcare professional with a Luja catheter and a VaPro catheter³.

You can find the data set presented at the UKCS Annual Scientific Meeting via [this link](#).

The Luja launch

The launch of CE-marked Luja is progressing well. Denmark and Finland were the first launch markets initiated as of February, to be followed by launch in Italy and the Netherlands in April. The product is expected to be available across Coloplast's key markets over the next 12 months. Coloplast has finalised the second pivotal clinical study on Luja, the results of which are expected to be publicly available within the next few months.

CONTACTS

Peter Mønster
Sr. Media Relations Manager, Corporate Communications
+45 4911 2623
dkpete@coloplast.com

Aleksandra Dimovska
Director, Investor Relations
+45 4911 2458
dkadim@coloplast.com

Luja is a medical device for which CE-mark has been affixed. Product availability is subject to regulatory process of individual countries and is not guaranteed.

* Luja has close to zero flow stops. Complete bladder emptying is defined as <10 mL (CP353, NCT05485922). After catheterisation, both catheters emptied the bladder to low and comparable residual volume post-catheterization levels (meaning values for both Luja and VaPro were <8 mL).

**Tested in a pre-clinical setting (ex vivo)

REFERENCES

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1. Kennelly M, et al. Adult Neurogenic Lower Urinary Tract Dysfunction and Intermittent Catheterisation in a Community Setting: Risk Factors Model for Urinary Tract Infections. *Advances in urology*. 2019;2757862
2. Vahr et al. Catheterisation Urethral Intermittent in Adults. Arnhem, Netherlands: European Association of Urology Nurses (EAUN); 2013.
3. M.H. Landauro, et al. Micro-hole zone technology shows superior ability to empty the bladder: a crossover randomised controlled trial in users of intermittent catheters. UKCS Annual Scientific Meeting; Sheffield, United Kingdom 2023.
4. Islamoska et al. Nov 2022. Patient-reported risk factors for urinary tract infections are associated with lower quality of life among users of clean intermittent catheterisation. Poster at BAUN (Coloplast user survey 2022 (n=3464)
5. Grabe et al. Guidelines on urological infections. EAU Guidelines presented at the 26th EAU Annual Congress, Vienna. 2013:78-93.
6. Vasudeva and Madersbacher. Factors implicated in pathogenesis of urinary tract infections in neurogenic bladders: some revered, few forgotten, other ignored. *Neurourol Urodyn*. 2014;33(1):95-100.

Link to clinical trial:

<https://clinicaltrials.gov/ct2/show/NCT05485922?term=NCT05485922&draw=2&rank=1>

Link to Kennelly article: <https://www.hindawi.com/journals/au/2019/2757862/>

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