Clinical Investigation Plan

CP348

A randomized, open-labelled, crossover study confirming performance of a new single-use compact intermittent catheter in a population of adult female intermittent catheter users.

June – December 2023

Master

NCT identifier: NCT05814211

Document date: 2023-02-14

CHANGE LOG

VERSION NUMBER	ISSUED BY *(INITIALS)*	COMMENTS (MAJOR CHANGES SINCE LAST REVISION)
1.0	[redacted]	First approved version
2.0		5.5 Assessments and 5.8 Blinding has been added. 6.4 Screening Failures and Drop-Outs has been changed
3.0		18.7 has been changed to 18.6.1 and 18.8 to 18.6.2

SYNOPSIS OF THE CLINICAL INVESTIGATION

Title:

A randomized, open-labelled, crossover study confirming performance of a new single-use compact intermittent catheter in a population of adult female intermittent catheter users.

Investigational device and comparators:

The investigational device is a new single-use compact intermittent catheter, which will be tested in two different sizes - size CH12 and CH14 - for female catheter users. The investigational device is a catheter for single use only and is intended to be used for drainage of the bladder through the urethra.

The investigational devices are not CE-marked, and they will be provided by Coloplast A/S, Denmark.

The comparators are CE-marked SpeediCath Eve and SpeediCath Compact Plus Female in the sizes CH12 or CH14 and will be provided by Coloplast A/S.

Intended use:

The investigational device is a urinary catheter for intermittent use, available in the sizes CH12 and CH14.

The catheter is intended for transient (less than 60 minutes) intermittent drainage of the bladder.

Objective(s):

Primary objective:

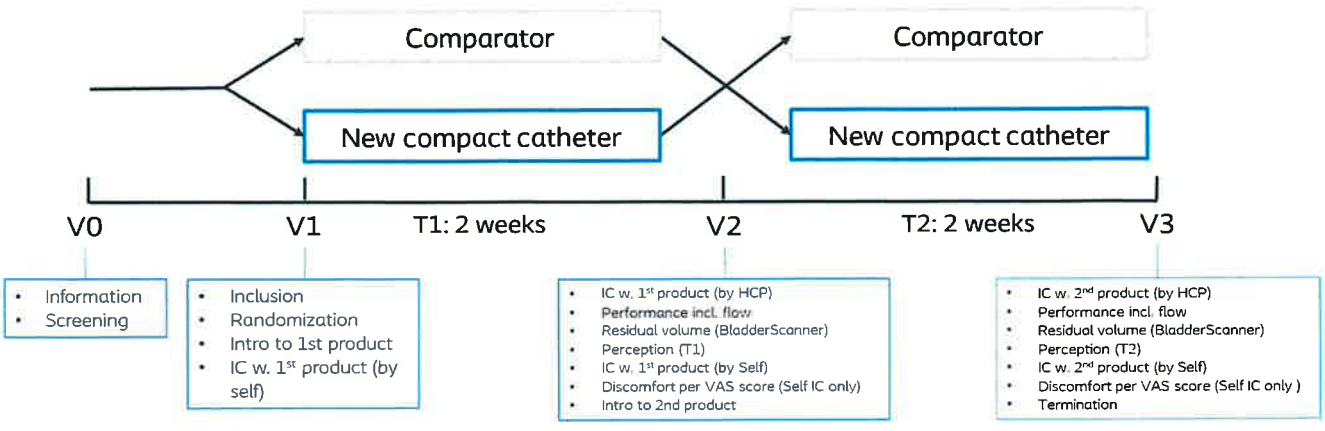
To demonstrate superiority of the new compact catheter in terms of improved bladder emptying, with the catheterisation performed by a health care professional.

Secondary objectives:

To assess safety and catheter perception of the new compact catheter.

Design of the investigation:

The investigation is a multi-centre, randomised, controlled crossover study including 72 female IC users. The total study duration for the individual subject will be approximately 4 weeks, consisting of four site visits and two 2-week test periods (T) at home (+/- 3 days). Visits 0 and 1 can be performed on the same day. One self-catheterisation will be done at visit 1. For visit 2 and 3, two catheterisations, (one HCP and one self-catheterisation) will be performed in a hospital setting for bladder emptying assessment at each visit. Test periods (at home) take place directly following visit 1 and 2. Visit 3 will terminate the study.



Expected duration of the clinical investigation:

The dates below are approximate, and no subjects will be enrolled before all required approvals have been obtained. If changes are required, applicable EC and regulatory authorities will be notified.

First patient in (FPI)	June-August 2023
Last patient in (LPI)	November 2023
Last patient out (LPO)	December 2023
Database lock (DBL)	January 2024

Endpoint(s):

Primary endpoint

- Residual volume at 1st flow-stop i.e., post catheterisation volume minus volume at 1st flow-stop, both derived from a catheterisation profile (catheterisation performed by a healthcare professional), [g].

Secondary endpoints

- Number of flow-stop episodes derived from a catheterisation profile (catheterisation performed by a healthcare professional), [number].
- Number of flow-stop episodes derived from a catheterisation profile (self-catheterisation), [number]
- Residual volume at first flow-stop i.e., post catheterisation volume minus volume at 1st flow stop, both derived from a catheterisation profile (self-catheterisation), [mL]
- Average residual volume post catheterisation measured with the Bladder Scanner (triplicate measurements) (HCP and self-catheterisation), [mL], (V2, V3)
- Number of Adverse events, [number]

Exploratory endpoints

- Perception questions evaluated on a 5-point scale assessed on V2 and V3 (perception questionnaire)

Population/subjects:

The clinical investigation will be conducted in 72 subjects enrolled at approximately 10-12 clinical investigation sites in Denmark, UK and France. The enrolment is competitive.

To be included in the investigation, the subjects must comply with the selection criteria described below:

Inclusion criteria	Exclusion criteria
1. Is Female	1. Is participating in any other clinical study during this investigation
2. Is at least 18 years of age and has full legal capacity	2. Has previously participated in this study
3. Has signed an informed consent form	3. Has symptoms of urinary tract infection at the time of inclusion, as judged by the investigator (if the patient recovers within the recruitment period, a second inclusion is allowed, under a different subject id)
4. Has used clean intermittent self-catheterisation (CH12 or CH14) for at least one month up to inclusion	4. Is an individual with a history of – suspected to be - or showing signs of producing an excessive amount of mucus or large/clustered sediments or debris
5. Is using intermittent self-catheterisation for a minimum of 3 times per day for bladder emptying	5. Has any known allergies towards ingredients in the investigational device
6. Has used a compact catheter 50% of the times (or more) for the last two weeks prior to entering the study	6. Is pregnant
7. Has the ability (assessed by investigator) and willingness to follow study procedures	7. Is breastfeeding

LIST OF ABBREBIATIONS

ABBREVIATION	WRITTEN OUT	EXPLANATION (IF APPLICABLE)
ADE	Adverse Device Effect	See section 18.2
AE	Adverse Event	See section 18.1
ASADE	Anticipated Serious Adverse Device Effect	See section 18.4.2
CIP	Clinical Investigation Plan	
CH12 CH14	Refers to Catheter Diameter	Se section 7.1.1
CRF	Case Report Form (paper or electronic)	Questionnaire to be used for data collection
CM	Clinical Manager	
DQF	Data Query Forms	A DQF is a query specifically used in clinical research. The DQF is the primary data query tool from the sponsor to clarify discrepancies and ask the investigator for clarification. The DQF is part of the data validation process in a clinical investigation.
DD	Device deficiency	See section 18.3
EC	Ethics Committee	
eCRF	Electronic Case Report Form	
IB	Investigator's Brochure	Compilation of the current clinical and non-clinical information on the investigational medical device(s,) relevant to the clinical investigation.
IC	Intermittent Catheterisation	
IFU	Instruction For Use	
IRB	Institutional Review Board	
ITT	Intention to Treat	
PI	Principal Investigator	Qualified person responsible for conducting the clinical investigation at an investigation site. If the clinical investigation is conducted by a team of individuals at an investigation site, the PI is the responsible leader of the team. Whether this is the responsibility of an individual or an institution can depend on national regulations.
PP	Per Protocol	
RV	Residual volume	See section 5
SADE	Serious Adverse Device Effect	See section 18.4.1
SAE	Serious Adverse Event	See section 18.4
SCCPE	SpeediCath Compact Plus Female	See Section 5.9
SCCE	SpeediCath Compact Eve	See Section 5.9
USADE	Unanticipated Serious Adverse Device Effect	See section 19.4.3
UTI	Urinary Tract Infection	
VAS	Visuel Analogue Scale	See section 5.5

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1 List of personnel involved in the investigation

COORDINATING CLINICAL MANAGER	CLINICAL MANAGER
[redacted]	[redacted]
HEAD OF CLINICAL TRIAL MANAGEMENT	**MEDICAL AFFAIRS PROJECT MANAGER**
[redacted]	[redacted]
PRINCIPAL BIOSTATISTICIAN	**DATA MANAGEMENT SPECIALIST**
[redacted]	[redacted]

In case of emergency, please contact the Clinical Managers from the above list of sponsor representatives.

2 Rational/justification for conducting the clinical investigation

Urinary tract infections (UTIs) are a common sequela in individuals with lower urinary tract diseases who are dependent on urinary catheters for bladder emptying (Averbeck et al., 2018; De Ridder et al., 2005; Feneley, Hopley, & Wells, 2015; Kennelly et al., 2019; Wyndaele, 2002). Although clean intermittent catheterisation (IC) is considered one of the safest drainage methods, the incidence of catheter associated UTIs is still high with rates between 0.8-3.5 per year (Kennelly et al., 2019). Common risk factors from IC include urethral- and bladder trauma, incomplete bladder emptying and bacterial insertion supporting an environment for infection (Averbeck et al., 2018; Fisher et al., 2018; Kennelly et al., 2019).

Therefore, Coloplast A/S has developed a new intermittent compact catheter for females, to ensure thorough bladder emptying without the need for repositioning and with minimal urethral- and bladder trauma.

The aim of this investigation is to assess performance of this new compact catheter compared to a conventional 2-eyelet catheter.

3 Objective(s) and hypotheses of the clinical investigation

3.1 Objectives

Primary objective:
To demonstrate superiority of the new compact catheter in terms of improved bladder emptying, with the catheterisation performed by a health care professional.

Secondary objectives:
To assess safety and catheter perception of the new compact catheter.

3.2 Hypothesis

The aim is to assert the hypothesis of superior performance of the compact catheter compared to conventional compact 2-eyelet catheters.

4 Investigational device and comparator(s)

4.1 Description of investigational device

The investigational device is a ready-to-use, sterile, hydrophilic-coated female compact catheter for intermittent catheterisation, available in the sizes CH12 and CH14. The device is for single use only and is intended to be used for drainage of the bladder through the urethra by people with missing or reduced bladder control.

The device is intended to be used by female catheter users in this clinical study.

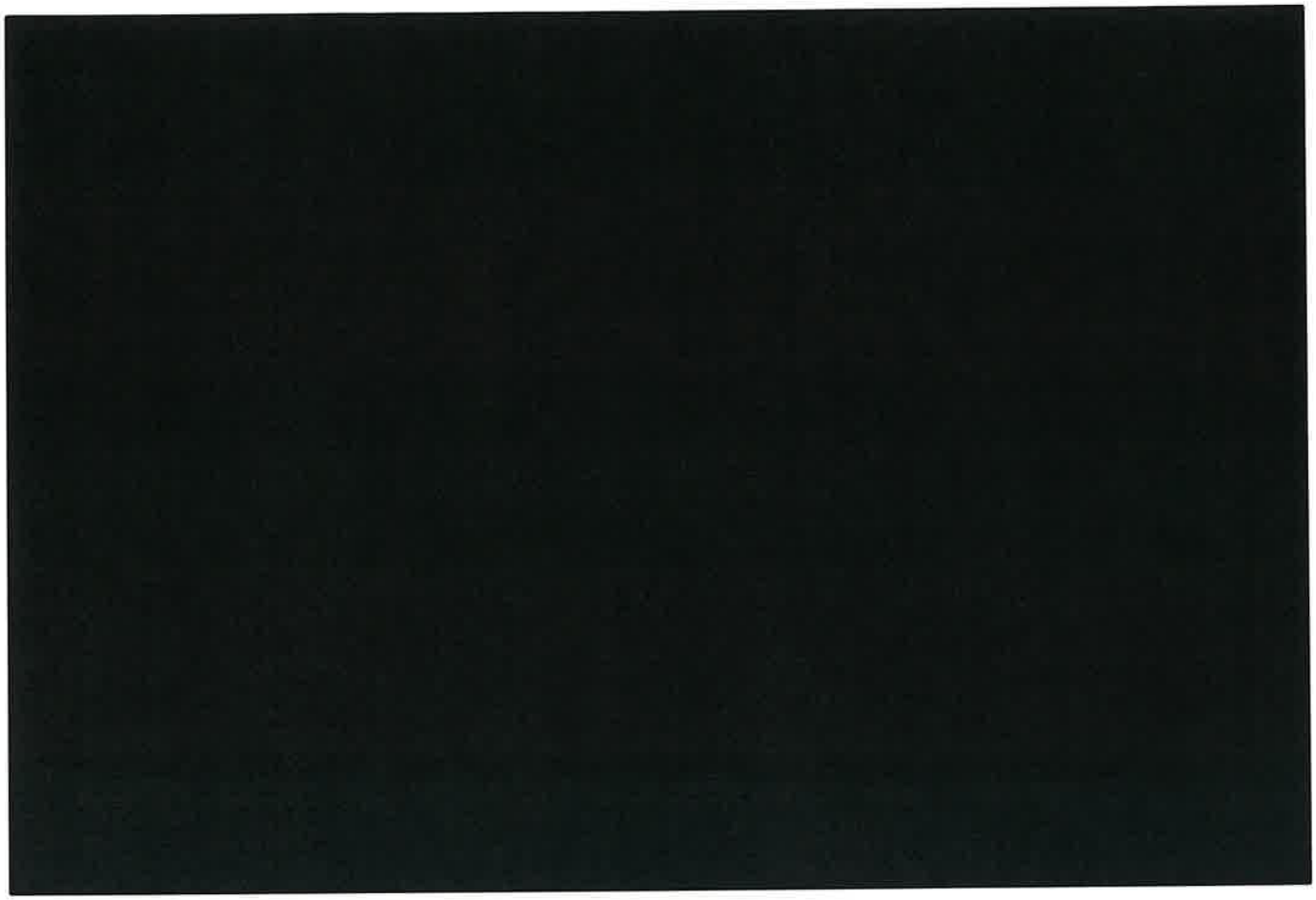


Figure 1. Illustrates the investigational device used in the study

4.1.1 Manufacturing

Responsible for manufacturing the investigational device:

Coloplast A/S
Holtedam 1
3050 Humlebæk
Denmark

4.2 Identification and traceability of the device

All investigational devices are labelled as per regulations and include "Exclusively for Clinical Investigational" on the label. The devices are also identified with study number, device name/code, and item/lot number and are accounted for through a sponsor accountability log.

Upon EC/CA approval, investigational devices will be shipped to the principal investigator or delegate. Additionally, all investigational devices will be accounted for and documented on a site accountability log. The receipt and disposition of all investigational devices will be verified through monitoring. All unused devices will be returned to Coloplast at the conclusion of the study.

4.3 Intended use of the device in the clinical investigation

The catheter is intended for transient (less than 60 minutes) intermittent drainage of the bladder.

4.4 Intended population for the device

The eligible population is female intermittent compact catheter (IC) users who are depending on IC for drainage of the bladder. This population will be eligible to use the newly developed device when it becomes commercially available.

There are no proposed contraindications.

4.5 Handling of the investigational device

The handling of the investigational device is described in detail in the Instruction for Use (IFU) accompanying the devices. It is stated in the IFU that the investigational devices are for single-use and must be stored away from direct sunlight. Reprocessing, washing, disinfection, and sterilisation may compromise device characteristics, causing additional risk of physical harm to, or infection of, the user.

All Principal Investigators and delegates will receive training by the sponsor and/or principal investigator in the handling and correct use of the investigational devices. All training will be documented.

For further details regarding the Investigational device, please refer to the Investigators Brochure VV-0518890.

4.6 Total number of devices intended for the clinical investigation

72 subjects will be included in the study. Subjects will be supplied with sufficient amount of test products to accommodate their usual catheterisation procedure for each test period. The investigational devices and comparators are packed in retail boxes with 30 products in each.

Example: The test period (home-use) is 2 weeks (14 days) and with an estimated usage of 6 catheters/day it equals 84 catheters, so subject will receive 3 retail boxes for home use (90 catheters) for each test period.

4.7 Description of the comparator products

Two comparators: SpeediCath Compact Eve and SpeediCath Compact Plus Female, sizes CH12 or CH14. Both comparators are CE-marked Coloplast products and will be provided by Coloplast A/S.

As the comparator devices are already on the market and will be used within the intended use in this investigation, it is not considered an investigational device according to ISO 14155:2020 and is thus not described into further details here.

5 Design of the clinical investigation

5.1 General

The investigation is a multi-centre, multi-national, randomised, controlled crossover study including 72 female IC users.

The total study duration for the individual subject will be approximately 4 weeks, consisting of four site visits and two 2-week test periods (T1 and T2) at home (+/- 3 days). Visits 0 and 1 can be performed on the same day. One self-catheterisation will be done at visit 1 with the first randomised product. For visit 2 and 3, two catheterisations (HCP and a self-catheterisation) will be performed in a hospital setting for bladder emptying assessment at each visit. At visit 2 the catheterisations will be done with the first randomised product, and at visit 3 the catheterisations will be done with the second randomised product. Test periods (at home) take place directly following visit 1 and 2. No data will be collected in the test periods at home. Visit 3 will terminate the study.

The study design and procedures are described below in figure 1.

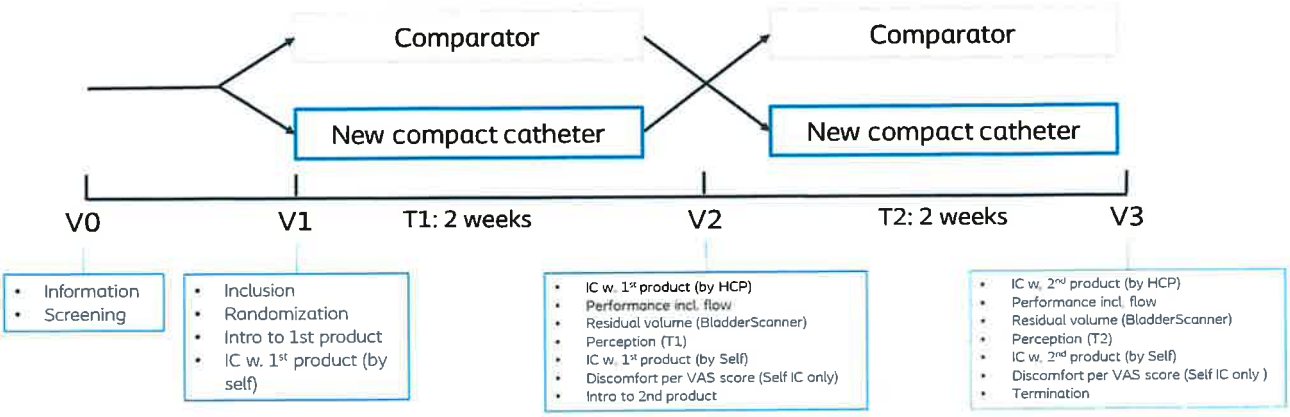


Figure 1. Study design

5.2 Primary endpoints

- Residual volume at 1st flow-stop i.e., post catheterisation volume minus volume at 1st flow-stop, both derived from a catheterisation profile (catheterisation performed by a healthcare professional), [mL]. (V2, V3)

5.3 Secondary Endpoints

- Number of flow-stop episodes derived from a catheterisation profile (catheterisation performed by a healthcare professional), (V2, V3) [number]
- Number of flow-stop episodes derived from a catheterisation profile (self-catheterisation), (V2, V3), [number]
- Residual volume at 1st flow-stop i.e., post catheterisation volume minus volume at 1st flow-stop, both derived from a catheterisation profile (self-catheterisation), (V2, V3), [mL]
- Average residual volume post catheterisation measured with the BladderScanner (triplicate measurements) (V2, V3) for both self-catheterisation and for HCP catheterisation, [mL]
- Number of Adverse events, [number]

5.4 Exploratory endpoints

- Perception questions evaluated on a 5-point scale assessed on V2 and V3 (perception questionnaire), see appendix A; Perception questionary based on perception of catheterisations in test period leading up to the visit

5.5 Assessments

Assessments collected in a hospital setting

(Catheterisation by HCP and self-catheterisation):

- Position of the subject when performing the catheterisation, [sitting/standing] (V1, V2, V3)
- Catheter used for catheterisation [investigational product/comparator, including product size (CH12/CH14)] (V1, V2, V3)
- Discomfort at insertion measured using the visual analogue scale (VAS) (only self-catheterisation), [cm], (V2, V3)
- Discomfort at withdrawal measured using the VAS (only self-catheterisation) (V2, V3)
- Discomfort during emptying of bladder measured using the VAS (only self-catheterisation) (V2, V3)
- Discomfort at end of emptying the bladder measured using the VAS (only self-catheterisation) (V2, V3)
- Urine volume at 2nd until 10th flow stop (derived from catheterisation profile), [mL] (V2, V3)
- Urine volume measured post catheterisation (derived from catheterisation profile), [mL] (V2, V3)
- Residual volume pre catheterisation measured with the Bladder Scanner (triplicate measurements that must be more than 150 ml to proceed) (V2, V3), [mL]

Other assessments

- Investigational device used in the test period (Test product/Comparator), including size (CH12/CH14))
- Device Deficiencies
- Data for complaint reporting (Vigilance) (for Adverse Device Effects, Device Deficiencies and Serious Adverse Device Effects reported in CE-marked Coloplast products in the investigation.
-

Backup (redundant) measurements by HCP in case of missing profile readout:

- Urine volume at 1st flow stop (scale), [g].
- Urine volume measured post catheterisation (scale), [g].
- Time for start of catheterization ([HH+:nn],[hours and minutes]
- Number of flow-stop episodes counted by HCP, [number]

5.6 Rationale for selection and measurement of endpoints

The endpoints have been selected based on the evaluation of performance of the new catheter features in terms of efficiency of catheter-associated bladder emptying and degree of catheter-associated microtrauma. Both inadequate bladder emptying and urethral/urothelial microtrauma, are important risk factors for UTI (Kennelly et al., 2019).

Flow-stops: A common process of IC is the repositioning of the catheter towards the end of drainage to ensure thorough bladder emptying (Vahr S., 2013). The rationale behind this process is that as the bladder empties with a standard 2-eyelet catheter, the bladder wall deflates around the drainage holes, causing bladder mucosa to be sucked into the eyelets, withholding urine to exit. In 1965, mucosal suction and consequently mucosal microtrauma was first described with an indwelling Foley catheter (Milles, 1965) and later reproduced in several other settings (Glahn, 1988; Glahn, Braendstrup, & Olesen, 1988; Grocela & Jura, 2010). The event has been reproduced with intermittent catheters in a porcine bladder model in a pre-clinical setting at Coloplast (Tentor, 2022) and exploratory clinical activities involving healthy subjects and IC-users (both male and female) have demonstrated a significantly reduced number of flow-stops with the new micro-hole catheter compared to conventional 2-eyelet catheters (Coloplast A/S, 2021a).

Residual volume at 1st flow-stop: As a consequence of mucosal suction, urine flow may come to a halt prematurely, i.e. before the bladder is thoroughly emptied, hence the need to adjust the catheter (e.g. repositioning) to ensure that urine starts to flow again. The aim with the micro-hole drainage is to avoid mucosal suction, thereby securing a thorough bladder emptying at the first sensation of a flow-stop.

Therefore, residual urine volume at 1st flow-stop (RV1) represent the volume left in the bladder for those IC-users who perceive a flow-stop as an emptied bladder and therefore withdraws the catheter prematurely. RV1 is a technical/theoretical term and is thought to be a contributing factor to any other residual urine left in the bladder after catheterisation.

RV1 is measured *in* catheterisation by HCP and by self-catheterisation as it allows for comparison between catheters during an expectedly correctly applied catheterisation technique.

5.7 Equipment/methods and timing for assessing the variables.

Scales for measurement of total amount of urine, ultrasound scanner measuring residual urine [BladderScan i10, Verathon Inc.], databox, container, funnel for urine collection and pregnancy tests will be provided by Coloplast A/S.

5.8 Randomisation Procedure

All subjects that have given informed consent and meet the inclusion and exclusion criteria will be randomised.

This investigation involves two treatments, the investigational device, and the comparator devices

The Rave RTSM™ is a validated randomization solution, that will be used for the randomization in this investigation. A centralized randomization will be implemented, in which, participants are to be randomly assigned to two intervention sequences in block sizes of 8.

For technical reasons, to ensure correct randomization in an equal split between treatment arms, the two treatment arms are technically implemented as illustrated below.

Treatment A: Investigational Device × Comparator 1 (SpeediCath Compact Eve) (25%)

Treatment B: Investigational Device × Comparator 2 (SpeediCath Compact Plus Female) (25%)

Treatment C: Comparator 1 (SpeediCath Compact Eve) × Investigational Device (25%)

Treatment D: Comparator 2 (SpeediCath Compact Plus Female) × Investigational Device (25%)

Randomisation will be 2:1:1 (Investigational device: Comparator: SpeediCath Compact Eve: SpeediCath Compact Plus Female)

5.9 Blinding

Subjects will not be blinded in this investigation due to inclusion of self-catheterisation. Furthermore, personnel present at the catheterisation i.e. nurses and assisting Coloplast Clinical Managers, Data Management Specialists and CRAs are also not blinded. All other Coloplast personnel i.e. the Statistician, the specialists analysing the catheterisation profiles and Project Manager will be blinded until the data base lock.

5.10 Total expected duration of the clinical investigation

The dates below are approximate, and no subjects will be enrolled before all required approvals have been obtained. If changes are required, applicable IRB/EC and regulatory authorities will be notified.

First patient in (FPI)	June 2023
Last patient in (LPI)	November 2023
Last patient out (LPO)	December 2023
Database lock (DBL)	January 2024

6 Clinical Investigation population

The clinical investigation will be conducted in 72 subjects enrolled in 10 clinical investigation sites in Denmark, UK and France.
To be included in the investigation, the subjects must comply with the selection criteria described below.

6.1.1 Inclusion criteria

For a subject to be eligible, all inclusion criteria must be answered "yes":

Inclusion criteria	Justification for inclusion criteria
1. **Is Female**	Intended patient population of investigational and comparator devices.
2. **Is at least 18 years of age and has full legal capacity**	Intended patient population of investigational and comparator devices. To meet Helsinki Declaration.
3. **Has signed an informed consent form**	To ensure that the subject has been given written and oral information regarding the investigation and know enough about the investigation to decide on participation. To ensure voluntariness and that Helsinki Declaration is met.
4. **Has used clean intermittent self-catheterisation (CISC) (CH12 or CH14) for at least one month up to inclusion**	To ensure that the subject is used to catheterisation
5. **Is using intermittent self-catheterisation for a minimum of 3 times per day for bladder emptying**	To ensure that the subject is used to catheterisation.
6. **Has used a compact catheter 50% of the time (or more) for the last two weeks prior to entering the study**	To ensure that the subject is able to use compact catheters.
7. **Has the ability (assessed by investigator) and willingness to follow study procedures**	To ensure sufficient data for successful completion of the study.

6.1.2 Exclusion criteria

For an eligible subject, all exclusion criteria must be answered "no":

Exclusion criteria	Justification for exclusion criteria
1. **Is participating in any other clinical study during this investigation**	To eliminate uncertainty whether any Adverse Events (AE's) or Serious Adverse Events (SAE's) occurring during the investigation relate to the usage of the herein tested devices. Also, to eliminate unintentional effect from other devices/medicines on the investigation's data.
2. **Has previously participated in this study**	To ensure integrity of results.
3. **Has symptoms of urinary tract infection at time of inclusion, as judged by the investigator (if the**	To ensure subject safety and integrity of results.

	patient recovers within the recruitment period, a second inclusion is allowed, under a different subject id)	
4.	**Is an individual with a history of - suspected to be – or showing signs of producing an excessive amount of mucus or large/clustered sediments or debris**	To ensure subject safety and integrity of results.
5.	**Has any known allergies towards ingredients in the investigational device**	To ensure subject safety and integrity of results.
6.	**Is pregnant**	Even though the ingredients and the recipes have been approved for human beings, their effect on embryos, foetuses and infants are unknown
7.	**Is breastfeeding**	Even though the ingredients and the recipes have been approved for human beings, their effect on embryos, foetuses and infants are unknown

6.1.3 Pregnancy and breastfeeding

For female subjects with childbearing potential (they have had at least one period during the last 12 months), a urine pregnancy test will be performed at the inclusion visit, to ensure that the subject is not pregnant. The urine pregnancy test will be performed by dip-stick at the trial site. Furthermore, the female subjects should not be breastfeeding, when participating in the clinical investigation.

Example: As a minimum, Investigator must talk to the women about the risk of and how to avoid unwanted pregnancy at inclusion and at every test period the subject participates in hereafter.
If the subject is sexually active, she should be willing to practice appropriate contraceptive methods until the end of the investigation. Appropriate contraceptive methods are: sexual abstinence (in some cases when the women are older than 50 years, but are not yet post-menopausal, the investigator may evaluate that it is not reasonable to ask these women to start using safe contraceptives for the duration of the investigation); oral contraceptives, trans dermal patches or depot injection of a progestogen drug, double barrier method: condom or occlusive cap (diaphragm or cervical/vault caps) plus spermicidal agent; intrauterine device (IUD), intrauterine system (IUS), implant, or vaginal ring (placed at least 4 weeks before the first test period); or male partner sterilization before the female participant's entry into the investigation and is the sole sexual partner for that female participant. However, national requirements should always be followed.

If the subject becomes pregnant during the investigation, it is important, that the subject informs the Investigator/Investigator representative immediately. The medical adviser will then consider whether she should continue in the investigation.

6.2 Recruitment and enrolment

6.2.1 Recruitment process

The recruitment of potential subjects will commence only once authorisation has been received from the Regulatory Authorities (if applicable) and EC approval. The recruitment period from first subject enrolled to last subject enrolled is expected to be approximately 4 months. Recruitment will be competitive.

Table 1. Overview of the recruitment process

Recruitment method	Outpatient clinic/hospital	Advertising	Coloplast Database
Potential subjects	Recruitment will go through the outpatient clinic/ hospital site. Potential subjects are qualified by the inclusion criteria described in section 6.1.1	Recruitment will go through advertising in relevant channels of online and offline media (e.g., posters, social media, online paid media etc.). For the online channels, potential subjects will be directed to a landing page with a self-screener that qualifies the subjects in accordance with the inclusion criteria described in section 6.1.1 For the offline channels, study duration and screening criteria will be listed, and subjects are encouraged to contact the PI for further information.	Recruitment will go through the Coloplast database, where potential subjects are contacted by email. Subjects are selected according to the inclusion criteria described in section 6.1.1 and include: age, gender, product usage, type, size, and permission status. If the subjects are interested, they will be directed to a landing page, where eligibility is confirmed through a self-screener that qualifies subjects in accordance with the inclusion criteria.
First contact	Potential subjects will be contacted by email, phone call or contacted during a planned visit in the outpatient clinic at the hospital. If a subject is eligible and interested in participating in the investigation upon a short introduction, then written information about the investigation (Subject Information Form/Informed Consent Form) will be distributed to the subject. The Principal Investigator or delegate will invite the subject to a Screening Visit (V0).	Potential subjects will be directed via the advertisement to a landing page with a self-screener. If a subject qualifies for the study, telehealth nurses will call the subject to verify eligibility. A list of all eligible subjects is sent to site, where a final screening call is conducted to reconfirm eligibility. If subjects qualify and are interested in participating, a date for V0 is agreed and written information about the investigation (Subject Information Form/Informed Consent Form) is sent to the subject.	Potential subjects from the database will be contacted by email. Potential subjects will via the emails be directed to a landing page with a self-screener, and if a subject qualifies for the study, telehealth nurses will call the subject to verify eligibility. A list of all eligible subjects is sent to site, where a final screening call is conducted to reconfirm eligibility. If subjects qualify and are interested in participating, a date for V0 is agreed and written information about the investigation (Subject Information Form/Informed Consent Form) is sent to the subject.
Screening visit (V0)	At the scheduled Screening Visit (V0) the Principal Investigator or delegate will introduce the investigation and review the inclusion and exclusion criteria. If the subject wishes to reconsider her participation at V0, the subject has the right to wait a minimum of 24 hours before deciding on participation. If the subject hereafter decides to participate in the clinical		

Recruitment method	Outpatient clinic/hospital	Advertising	Coloplast Database
	investigation a Baseline Visit (V1) will be scheduled unless performed the same day as the Screening Visit. The Screening Visit can be performed at the site or as a phone call. If the subject does not meet the inclusion criteria or meets the exclusion criteria, this will be registered at the Subject Pre-Screening Log.		
Baseline visit (V1)	If the subject decides to participate and it is certain that it is understood what the investigation entails, the subject will be asked to sign the SIF/ICF. When the SIF/ICF is signed, the subject is considered included in the investigation.		

6.3 Subject withdrawal criteria

The subject is allowed to withdraw from the investigation at any time for whatever reason without any consequences for their future treatment outside the clinical investigation. The principal investigator may withdraw a subject from the investigation at any time if they judge it to be the subject's interest.

The principal investigator must withdraw a subject from the investigation due to:

- Noncompliance with the CIP impacting the scientific integrity of the investigation.
- If a subject's safety and wellbeing is compromised by further participation.
- Subjects lost to follow-up. At least three documented attempts will be made to verify subjects lost to follow-up.

Randomized subjects that for some reason withdraw from the clinical investigation can be replaced. Replacements should be discussed with Sponsor. Please also refer to section 10.7 Sample size for further information.

6.4 Screening Failures and Drop-Outs

Subjects that have signed the informed consent form but fail to comply with inclusion or exclusion criteria are considered "screening failures" up until randomisation. After randomisation subjects who fail to comply with inclusion or exclusion criteria will be withdrawn from the study and considered "drop-outs"

6.5 Subject Identification and Confidentiality

Subjects will be identified in the electronic CRF (eCRF) and any other document transmitted to the sponsor by the principal investigator or clinical site staff, by a unique identification number.

Data entered in the eCRF are confidential and will only be available to the sponsor (including sponsor delegates), members of data management teams, the statistician, members of the EC or IRB and if requested to regulatory authorities.

The principal investigator, for each clinical investigation site, will maintain as part of the investigational file a list identifying all subjects entered into the clinical investigation.

7 Procedures

7.1 Catheterisation set-up

Subjects are not allowed to lay down during catheterisation. Only sitting at minimum 45 degrees angle or standing is optional (V1, V2 and V3).

At V2 and V3 it is important to ensure free urine flow from catheter outlet into urine collection container placed on scale. Urine collection container must remain untouched during catheterisation. The scale is connected to the databox, which will record catheterisation profile during catheterisation. If the scale is moved, it must be calibrated. See separate manual for use of the databox.

7.2 Clinical investigation-related procedures

Visit 0 (V0) – Screening:

- Information about investigation, screening and review of Informed Consent Form/Subject Information Form
- Scheduling Baseline Visit (V1) unless performed the same day as Screening Visit (V0)
- Register the potential subject on the Pre-screening Log if not already registered

Visit 1 (V1) – Inclusion, Baseline and introduction to T1:

NB! The subject should not have changed their medication the last 24 hours before V1.
If subjects show symptoms of UTI (assessed by investigator), they must be rescheduled.

- Introduction to the investigation reviewed and confirmed
- Informed Consent signed
- Enrolment in the investigation and allocation of subject number
- Check of in- and exclusion criteria
- For female subjects of childbearing potential: urine pregnancy dipstick
- Collect Baseline information:
  - Age [years]
  - Height [cm]
  - Weight [kg]
  - When did you start using a catheter (YEAR + MONTH (if known))
  - Average number of catheters used per day [number]
  - Current primary product
    - Coloplast: SpeediCath Compact Female, SpeediCath Compact Female Plus, SpeediCath Compact Eve
    - Wellspect: Lofric Sense, Lofric Elle
    - Hollister: Infyna Chic, Vapro Pocket
    - B. Braun:, Actreen Mini
    - Bard: Hydrosil Rose, Hydrosil GO, Magic3Go
    - Convatec: GentleCath Air Female
    - Curan: Curan Lady, Curan Twist
    - Other (text)
  - Current product size
    - CH12
    - CH14
  - Position most frequently used in catheterisation
    - Sitting
    - Laying
    - Standing
    - Other (text)
  - Urethral sensation
    - Normal
    - Impaired
    - None

    - Hypersensitive
- Reason for using intermittent catheterisation
    - Spinal cord injury
    - Multiple sclerosis
    - Spina Bifida
    - Others (as text)
- Neurogenic/Non-neurogenic
- Body mobility / ambulation
    - Walking
    - Walking with difficulty/aids
    - Using a wheelchair
    - Confined to bed
- How is your dominant hand?
    - Right-handed
    - Left-handed
    - Mixed or cross-dominant (i.e., changes according to task)
    - Ambidextrous (i.e., equal ability in both hands)
- How would you describe the level of dexterity of your hands?
    - Left hand
        - Normal dexterity
        - Reduced dexterity
        - Greatly reduced dexterity
        - Don't know
    - Right hand
        - Normal dexterity
        - Reduced dexterity
        - Greatly reduced dexterity
        - Don't know

- Concomitant medication related to urinary function (assessed by principal investigator) and pain management
- Relevant medical history (assessed by the investigator)

- Randomization
- Introduction to 1st randomly assigned product, including IFU.
- Self-catheterisation (with 1st randomly assigned product)
- Catheterisation position noted [Sitting/standing]
- Catheter used for catheterisation noted [investigational product/comparator, including product size (CH12/CH14)]
- Catheter handed out for the first test period is noted [investigational product/comparator, including product size (CH12/CH14)]
- Scheduling Visit (V2), 14 days (+/-3 days) days after Baseline Visit (V1)
- Complete eCRF

Test Period 1 (T1):
The two weeks of home-use with the first randomly assigned product according to an individual usage regime. No data will be collected during the home period.

Visit 2 (V2) – Catheterisation, follow-up and introduction to T2
The subject should not have changed their medication the last 24 hours before V2 or show symptoms of UTI (assessed by investigator). If signs of UTI, they must be rescheduled and registration of AE.

- Ask for change in relevant medical history since last visit.
- Review of Adverse events/Serious adverse events/Adverse device events, Device deficiencies and Protocol Deviations
- Review of changes in concomitant medication
- Assessment on user perception for Test Period 1.

HCP-Catheterisation:

- Pre-catheterisation volume [mL] measured in triplicate with a bladder scanner. All three measurements must be above 150 ml to proceed. If not subject is asked to intake fluid and wait until bladder volume is ≥150 ml.
- Catheterisation with the 1st randomly assigned product used in T1 will be performed by HCP. NB! HCP should wait for 3 sec. when suspicion of flow-stop before rotating catheter to make it more clear on the profile from the databox.
- Catheter used for catheterisation [investigational product/comparator, including product size (CH12/CH14)], position [Sitting/standing], and time for start of catheterisation is noted.
- Urine volume at 1st flow stop [g] and post catheterisation [g] is noted.
- Number of flow stops is noted.
- All assessments pertaining to performance, including catheterisation profile, will be recorded at the catheterisation.
- Residual volume [mL] will be measured in triplicate with bladder scanner after catheterisation is completed.
- After first catheterisation subjects will be asked to intake fluid and wait in the waiting room to ensure there is urine in the bladder before the second catheterisation.

Self-Catheterisation:

- Pre-catheterisation volume [mL] measured in triplicate with a bladder scanner. All three measurements must be above 150 ml to proceed. If not subject is asked to intake fluid and wait until bladder volume is ≥150 ml.
- Catheterisation with the 1st randomly assigned product used in T1 will be performed by subject. Subject should wait for 3 sec. when suspicion of flow-stop before rotating catheter to make it more clear on the profile from the databox.
- Catheter used for catheterisation [investigational product/comparator, including product size (CH12/CH14)], position [Sitting/standing], and time for start of catheterisation is noted.
- Urine volume at 1st flow stop [g] and post catheterisation [g] is noted.
- Number of flow stops is noted.
- All assessments pertaining to performance, including catheterisation profile, will be recorded at the catheterisation
- Residual volume [mL] will be measured in triplicate with bladder scanner after catheterisation is completed.

- After completed self-catheterisation, subjects are asked to assess any level of discomfort during catheter insertion, during emptying of bladder, at the end of emptying and at withdrawal of catheter (evaluated on the visual analogue scale (VAS) [cm],). VAS scores are asked to be rated immediately after withdrawal of catheter.
- Introduction to 2nd randomly assigned product, including IFU.
- Schedule V3 within 28 days (+/- 3 days) after V1
- Complete eCFR

Test period 2 (T2)
The two weeks of home-use with the second randomly assigned product according to an individual usage regime.

Visit 3 (V3) – Catheterisation, follow-up, and termination
The subject should not have changed their medication the last 24 hours before V2 or show symptoms of UTI (assessed by investigator). If signs of UTI, they must be rescheduled and registration of AE.

- Ask for change in relevant medical history since last visit.
- Review of Adverse events/Serious adverse events/Adverse device events, Device deficiencies and Protocol Deviations
- Review of changes in concomitant medication
- Assessment on user perception for Test Period 2.

HCP-Catheterisation:
- Pre-catheterisation volume [mL] measured in triplicate with a bladder scanner. All three measurements must be above 150 ml to proceed. If not subject is asked to intake fluid and wait until bladder volume is ≥150 ml.
- Catheterisation with the 2nd randomly assigned product used in T2 will be performed by HCP. NB! HCP should wait for 3 sec. when suspicion of flow-stop before rotating catheter to make it more clear on the profile from the databox. NB! Position for the catheterisation must be the same as the position for the HCP catheterisation at V2.
- Catheter used for catheterisation [investigational product/comparator, including product size (CH12/CH14)], position [Sitting/standing], and time for start of catheterisation is noted.
- Urine volume at 1st flow stop [g] and post catheterisation [g] is noted
- Number of flow stops is noted
- All assessments pertaining to performance, including catheterisation profile, will be recorded at the catheterisation.
- Residual volume will be measured in triplicate with bladder scanner after catheterisation is completed.

- After first catheterisation subjects will be asked to intake fluid and wait in the waiting room to ensure there is urine in the bladder before the second catheterisation.

Self-Catheterisation:
- Pre-catheterisation volume [mL] measured in triplicate with a bladder scanner. All three measurements must be above 150 ml to proceed. If not subject is asked to intake fluid and wait until bladder volume is ≥150 ml.
- Catheterisation with the 2nd randomly assigned product used in T2 will be performed by subject. Subject should wait for 3 sec. when suspicion of flow-stop before rotating catheter to make it more clear on the profile from the databox. NB! The position must be the same as the position for the self-catheterisation at V2.
- Catheter used for catheterisation [investigational product/comparator, including product size (CH12/CH14)], position [Sitting/standing], and time for start of catheterisation is noted.
- Urine volume at 1st flow stop [g] and post catheterisation [g] is noted
- Number of flow stops is noted
- All assessments pertaining to performance, including catheterisation profile, will be recorded at the catheterisation.

- Residual volume [mL] will be measured in triplicate with bladder scanner after catheterisation is completed.
- After completed self-catheterisation, subjects are asked to assess any level of discomfort during catheter insertion, during emptying of bladder, at the end of emptying and at withdrawal of catheter (evaluated on the visual analogue scale (VAS) [cm],). VAS scores are asked to be rated immediately after withdrawal of catheter.
- Terminate subject
- Complete eCRF

Unscheduled visit/call

If an unscheduled call/visit is needed the unscheduled form in the eCRF must be completed.

7.3 Flow-chart

Table 2. Chart showing the connection between visits and assessments.

Visit(V)	V0	V1	V2	V3 (EoT)
Timing of visit (Days)	0	0	14 (±3)	28 (±3)
Activity				
Introduction to investigation and review of Subject Information Form/Informed Consent Form	X			
Signed Informed Consent		X		
Allocation of subject number in eCRF		X		
Check of in- and exclusion criteria		X		
Pregnancy test (urine dipstick) – for subjects of childbearing potential only		X		
Baseline information		X		
Concomitant medication related to urinary function and pain management assessed by PI		X	X	X
Relevant medical history assessed by PI		X	X	X
Randomisation		X		
Training in use of investigational device		X	X	
Hand out investigational devices and supplementary supplies		X	X	
Perform device accountability		X	X	X
Subject to complete perception questionnaire based on home period			X	X
HCP catheterisation			X	X
Bladder scan before and after catheterisation			X	X
Recording of catheterisation profile (data box)			X	X
Position, catheterisation start time and catheter registered			X	X
Urine volume at 1st flow-stop (scale)			X	X
Urine volume measured post catheterisation (Scale)			X	X
Number of flow-stop episodes counted by HCP			X	X
Self-Catheterisation		X	X	X
Bladder scan before and after catheterisation			X	X
Recording of catheterisation profile (data box)			X	X
Position, catheterisation start time and catheter registered			X	X
Position and catheter registered		X		
Urine volume at 1st flow-stop (scale)			X	X
Urine volume measured post catheterisation (Scale)			X	X
Number of flow-stop episodes counted by HCP			X	X
Subject to complete discomfort on VAS (only self-catheterisation)			X	X
Subject to complete perception questionnaire based on home period			X	X
AEs/ADEs/SAEs/SADEs		X	X	X
Device deficiencies		X	X	X
Protocol deviations		X	X	X
Complaint handling (Vigilance form)		X	X	X
Complete eCRF		X	X	X
Termination form				X

7.4 Case Report Forms

All assessments and observations throughout the investigation for each subject must be carefully recorded in an electronic CRF (eCRF).

CRFs will be filled in by the principal investigator and/or delegated site personal, who have signed the Site Personnel Signature and Delegation List and Clinical Investigation Training Log. The delegated site personal will be required to complete e-learning prior to system access. Delegated personal will receive credentials.

It is the responsibility of the principal investigator that all data is entered promptly and correctly.

7.5 Concomitant treatment

Concomitant medication, related to urinary function (assessed by principal investigator) and pain management, taken from the time of consent through the study, until termination will be registered in the eCRF in the concomitant medication section.

To the extent possible – the subjects should not have changed their medication the last 24 hours before visit 1, 2 and 3. Any changes in medicine related to urinary function (assessed by principal investigator) and pain management, should be recorded under concomitant medication.

8 Risk – benefit analysis and ethical considerations

8.1 Risk-benefit analysis of the investigational device

A risk management process has been performed in accordance with the requirements stated in ISO 14971:2019 and in accordance with internal Coloplast procedures, including design verification, validated test methods, risk analysis and completion of a biological evaluation report for the investigational device.

Risks have been proven minimized or eliminated through appropriate risk control measures, confirmed by pre-clinical bench, laboratory, and biological safety evaluations.

The following risks will be mitigated by actions during the clinical investigation.

- Urinary tract infection. The subject is instructed to contact the principal investigator or delegate in case the subject is in doubt if they have a UTI or have symptoms of UTIs, mild pain or bleeding. If seen, this will be discussed with the principal investigator or delegate.

To mitigate and reduce the risks, the principal investigator/designees will be trained, according to the IFU, in use of the device.

8.2 Risk-benefit for subjects participating in the clinical investigation

The investigation is conducted in accordance with current law and applicable standards, see section 15. Statement of Compliance. The rights, safety and well-being of human subjects shall prevail over the interest of science of society.

The catheterisation of subjects, with both investigational device and the comparator will be performed by experienced urology nurses at sites with many years of experience in conducting IC and with previous experience in working with clinical investigations.

Risks associated with the investigation may be discomfort or stinging in the urethra during the catheterisation and additional risk of micro-trauma after catheterisation, which is expected to heal within 1-3 days. Hence, the risks are considered equal to the use of intermittent catheters already on the market.

To mitigate and reduce these risks, principal investigator or delegate will be trained, according to the IFU, in correct handling and catheterisation of the principal investigator and comparator device. The investigational setting is not expected to result in increased frequency or severity of the known risks associated with urethral catheterisation.

There are no direct benefits for the subjects involved; but, by participating in this investigation, the subjects will contribute with important information for developing improved solutions for urinary IC that in turn may benefit individuals who are dependent on catheters for emptying their bladder. The subjects will be compensated for the time spent (see section 17.2).

For further information on Adverse Events for this study please refer to section 18.

8.3 Risk Analysis for the conduct of the clinical investigation

A risk assessment of the clinical investigation will be conducted prior to the first subject enrolment and periodically re-assessed based on any new risks identified through the process. This assessment will be completed throughout the duration of the investigation, as defined by the study team.

8.4 Delegation of responsibility

Before initiation of the clinical investigation, sponsor must be provided with key personnel signed and dated curriculum vitae (not more than 2 years old) to verify their qualifications. Key site personnel are those, who treat or evaluate subject data in the clinical investigation. Also, the sponsor will ensure that all site personnel are trained in the investigation procedures, how to complete the CRFs, procedure for reporting an adverse event or serious adverse event (how, when, to whom), and who to contact in case of emergency related to the investigational device.

9 Monitoring Plan

The sponsor is responsible for ensuring appropriate monitoring of the clinical investigation activities.

The monitors will be the primary contact for the principal investigator and clinical investigation site personnel.

The monitoring of this Clinical Investigation can be delegated by the sponsor to a Clinical Research Organisation (CRO). The monitors will be the primary contact for the Principal Investigator and clinical investigation site personnel.

Monitoring activities are mandatory as per good clinical practice, however the extend and depth of these activities depend on the criticality of the clinical investigation, speed of enrolment, the experience of the clinical investigation site personnel in carrying out clinical investigations and specific study designs.

The data collected throughout the investigation and the conduct of the investigation, will be monitored according to the Monitoring Plan to ensure and verify, that the rights and well-being of the subjects are protected, that the data are accurate, complete and verifiable from source documents and that conduct of the investigation complies with the approved CIP, subsequent amendments (if any), ISO14155:2020 and the applicable regulatory requirements.

The monitoring will be conducted periodically at all sites by qualified personnel.

The principal investigator must be available for and agrees to cooperate with Coloplast Clinical Managers (CM) and/or the Clinical Research Associates (CRA) during their visits and ensure, that they have direct access to all documents required, including direct access to subjects' files, to ensure thorough monitoring.

The investigation can be subject to internal audits, if relevant. All monitoring visits and possible audits will be followed by internal reports and corrective actions, if needed. Follow-up letters will be forwarded to sites after all visits and any findings should be addressed by the principal investigator or delegate.

To ensure proper conduct of the investigation the following on-site or remote visits will be performed during the investigation:

- Site selection visit
- Site initiation visit
- Periodic monitoring visits
- Close out visit

9.1.1 Site selection visit

Depending on the prospective clinical investigation sites experience with the specific investigational device, an on-site qualification or site selection visit shall be performed, during which the feasibility of the clinical investigation requirements will be discussed and common agreement between sponsor and principal investigator shall be reached. This visit may also be replaced by one or more phone calls, if the principal investigator is known to the sponsor.

9.1.2 Site initiation visit

Before initiation of the clinical investigation, sponsor must be provided with key personnel signed and dated curriculum vitae, less than two years old and documentation of current qualifying training in the ISO14155 to verify their qualifications as research staff.

All clinical investigation sites will complete an initiation visit during which, full training on all aspects of the clinical investigation will be provided.

Training in use of the equipment used for measuring endpoints will be performed at sites.

9.1.3 Monitoring visit(s)

The sponsor shall determine the extent and nature of monitoring appropriately for the clinical investigation based on the risk assessment. The sponsor shall ensure, through oversight of the clinical investigation and timely adverse event reporting, that unanticipated adverse device effects are identified and investigated rapidly so that, where necessary, additional risk control measures can be implemented.

The site dedicated monitor is to ensure adherence to the clinical investigation plan, the safety of the subjects, accurate data recording on the e-CRFs and to monitor recruitment rates and adherence to follow-up schedules. During the clinical investigation, monitors shall check that appropriate written informed consents have been obtained. The principal investigator shall permit and assist the monitor to carry out verification of completed e-CRFs against data in the source documents.

The principal investigator can delegate tasks to his/her collaborators, however the roles and responsibilities as time period of involvement for each clinical site personnel must be documented on the Site Personnel signature and Delegation list as well as training received before getting involved with the clinical investigation, must be documented in the Clinical Investigation Training Log.

The monitor shall inform the sponsor about any problems relating to facilities, technical equipment or medical staff at the clinical investigation site. The monitor shall also be responsible for notifying such deficiencies in writing to the principal investigator and convene with the clinical investigation site personnel appropriate and timely corrective actions.

The sponsor, or delegate, will provide clinical monitoring, including review of eCRF with verification to the source documentation.

The monitor shall make written reports to the sponsor, including documentation of any deviations after each visit and provide written follow up action items if any, to the principal investigator and/or clinical investigation site personnel.

Periodic monitoring visits (remote or on-site) will be performed as soon as reasonable possible, after the site has enrolled the firs subject in the investigation. A final monitoring visit will be performed after all subjects on site have completed the investigation.

9.2 Remote monitoring

Remote (source data verification) and/or centralized (data review) monitoring is carried out by sponsor personnel or representatives (e.g., data management personnel, statisticians, or clinical monitors) at a

location other than the site(s) at which the clinical investigation is being conducted (evaluation without visiting the investigation site). Remote monitoring processes can provide many of the capabilities of on-site monitoring as well as additional capabilities.

In addition to onsite monitoring visits, remote monitoring of the data entered in the eCRF system could be used to achieve the following:

- Conduct activities such as: standard checks of range, consistency, and completeness of data and checks for unusual distribution of data, such as too little variance
- Special attention will be given in case of frequent data anomalies or errors, protocol deviations or excessive dropouts.
- Augment on-site monitoring by performing monitoring activities that can only be accomplished using centralized processes (e.g., statistical analyses to identify data trends not easily detected by on-site monitoring)
- Monitor data quality through routine review of submitted data in real-time to identify missing data, inconsistent data, data outliers, and potential protocol deviations that may be indicative of systemic and/or significant errors in data collection and reporting at the site
- Verify source data remotely, provided that both source data and CRFs can be accessed remotely
- Conduct aggregate statistical analyses of study data to identify subject data that are outliers relative to others and to evaluate individual subject data for plausibility and completeness
- Conduct analyses of site characteristics, performance metrics (e.g., high screen failure rates, high frequency of eligibility deviations, and delays in reporting data), and clinical data to identify early on corrective actions needed for characteristics correlated with poor performance or noncompliance

9.3 Source data verification

Source data is all information in original records, certified copies of original records of clinical findings, observations, or other activities in the clinical investigation, necessary for the reconstruction and evaluation of the clinical investigation. This includes source data initially recorded in an electronic format.

All documents and data related to the clinical investigation handled by site personnel, shall be produced and maintained in a way that assures reliability, integrity, control and traceability, and shall be appropriately stored to provide a complete history.

The Principal Investigator shall assure the accuracy, attribution, completeness, legibility and timeliness of the data reported to the sponsor in the eCRFs and in all required reports. All printed copies of electronic source documents shall be certified, as indicated by a dated signature by the investigational site personnel at the time the document is printed. Special requirements should be applied to the capture, review and retention of electronic source data, to ensure reliability, quality, integrity and traceability.

The data reported in the eCRFs shall be derived from source documents and be consistent with these source documents, and any discrepancies shall be explained in writing. The eCRF can serve as the source document and this must be documented on the Source Data Specification Form. The Source Data Specification Form must be completed at the initiation visit detailing the location of the source data for each data point agreed upon by the principal investigator.

10 Statistical considerations

10.1 Statistical design, method, and analytical procedures

The primary objective will be evaluated by analysing the primary endpoint.

Baseline assessments and endpoints will be reported by descriptive statistics and/or listed.

Summaries will be presented by device i.e., investigational or comparator device and if relevant, by other grouping variables.

Descriptive statistics for continuous variables are presented with N, Mean, SD (standard deviation), Median, Min and Max, where N denotes the number of subjects contributing with non-missing data. For discrete variables, descriptive statistics are presented with N and percentage, where percentage is based on the total number of subjects/observations with non-missing data.

All statistical analysis will be performed with SAS version 9.4/Enterprise Guide version 7.1.

10.2 Definition of analysis populations

Screening Failures (SF), Intention to Treat (ITT), Full Analysis Set (FAS), Safety and Per Protocol (PP) analysis set will be defined at a formal data review meeting prior to database lock. As a minimum, the data manager, the clinical manager, and the statistician will be involved in the classification of subjects.

Subjects not adhering to inclusion and/or exclusion criteria are considered screening failures (SF) and are not included and randomised.

- The Safety population will constitute all subjects included i.e. subjects who have given informed consent and fulfils the in- and/or exclusion criteria.
- The ITT population will constitute all randomised subjects.
- The full analysis set is a modified ITT population i.e., a sub-population of the ITT population, and will constitute all randomised subjects, who have been exposed to at least one device, with at least one endpoint recorded (data non-missing).
- The PP is a sub-population of the full analysis set where all subjects have received treatment as per protocol.

Individual endpoints/data points may be excluded from the analysis, even though the corresponding subject belongs to any of the pre-defined populations. Exclusion of subjects or data points must be documented.

All statistical analysis and test of hypothesis will be based on the full analysis set, and in addition, primary endpoint will also be analysed in the PP population, whereas adverse events and device deficiencies will be assessed in the safety population.

10.3 Analysis of the primary endpoint

Residual volume at first flow-stop, will be analysed in a linear mixed model (LMM) with subjects included as a random component. Evidence of superior effect will be concluded, if the 95% confidence interval of the difference between comparator and investigational device, does not include zero.

The model will include following fixed effects.

- Visit (visit 2 and 3 of catheterisation)
- Device (comparator and investigational device)

The primary endpoint will be evaluated with the null hypothesis being rejected at a 5% significance level (alpha 0.05).

Analysis of sensitivity

- The primary analysis will furthermore be analysed in the PP population, where subjects have received treatment as per protocol.

- Also, a Wilcoxon signed rank test will be applied the primary analysis, under the assumption of data not being normally distributed.

10.4 Analysis of secondary endpoints

- Number of flow-stop episodes will be analysed, in a generalized linier mixed model (GLMM), with subjects included as a random component. Evidence of effect will be concluded, if the lower 95% confidence limit of the risk ratio between comparator and investigational device, is greater than 1.
- Average residual volume post catheterisation will be presented with Descriptive statistics for a continuous variable (N, Mean, SD (standard deviation), Median, Min and Max.)
- Adverse events will be listed and/or summarized.

10.5 Analysis of exploratory endpoints

- Questions in the perception questionnaire will be summarised and listed.

10.6 Analysis of safety data

Adverse events will be listed and/or summarized. Device deficiencies and concomitant medications will be listed.

10.7 Sample size

Input for the sample size calculations i.e., means and standard deviations are based on three exploratory studies CP322, CP323 and CP324. The studies investigated earlier prototypes of the micro-hole catheter with identical or similar endpoints in populations of both IC users and healthy volunteers.

A sample size for the primary endpoint of residual urine at 1st flow-stop (RV1) is judged to be accommodated by 60 subjects with a power of ~ 90%, assuming a difference of 15 mL, a $sd_{comparator}$ of 50 mL and a sd_{active} of 15 mL (please see Table 3).

Table 3. Sample size calculation of Residual urine at 1st flow-stop in a cross-over design, solving for varying power and number of subjects, assuming no within subject correlation as a worst-case approach, using proc Power in SAS.

μ (sd) comparator	μ (sd) active	Alpha	Power	Sample size
25 (50)	10 (15)	0.05	71.9 %	40
25 (50)	10 (15)	0.05	81.2 %	50
25 (50)	10 (15)	0.05	87.7 %	60
25 (50)	10 (15)	0.05	92.2 %	70

Taken into consideration a discontinuation of 20%, the endpoint of RV1 is sufficiently supported by randomising at least 72 subjects.

If the number of subjects contributing to the primary analysis is less than 60 subjects, it must be carefully considered to include additional subjects (subjects replaced), to maintain sufficient power in the primary analysis.

10.8 Level of significance and power

A significance level of alpha 0.05 (2-sided) will be applied.

The power for concluding superiority of the investigational device is at least 90% or higher.

10.9 Pass/fail criteria

To demonstrate superiority of the investigational device, the null hypothesis of the primary endpoint must be rejected, at a 5% significance (alpha 0.05).

11 Data management

Data management and the final statistical analyses of all measurements described in this protocol are carried out by the Clinical Strategies team, Coloplast A/S.

Data will be collected through an electronic data capturing (EDC) system on electronic Case Report Form (eCRF), a secure, internet-based case report form. This system will be used to record all subject information collected in the investigation for secure data tracking and centralised data monitoring ("remote monitoring") done by monitors, as defined in the monitoring section.

The EDC system used is Rave EDC, version 2022.3.0, delivered by Medidata Solutions Inc. The system is designed to be compliant with the FDA requirements of 21 CFR part 11. It is a validated data management system allowing only qualified and trained personnel to enter the system. The system has full audit trail and electronic signature.

The data management system has restricted role-based access control. The principal investigator or delegate an CRA must be trained in the system prior to getting access. The sponsor will be responsible for training the principal investigator or delegate, in completion of the eCRF. The training is web-based and must be completed before access to the investigation is granted. Training will be documented in the data management system. The data manager will also demonstrate the system on a virtual meeting. Only the principal investigator, or delegate, will be authorised to enter data in the eCRF.

The monitor, using his/her personal login information shall verify all critical data points against the source documents and issue electronic queries for the authorised clinical site personnel to respond, as defined in the monitoring section.

A critical quality control will be performed by the sponsor's data management team and queries issued where needed. Such queries must be resolved by the site personnel.

The principal investigator, using his/her personal login information, shall sign each eCRF before the database can be locked. This must be done after acceptance from the data management team.

Automated, real-time access to the data enable control on study compliance and safety assessments.

A full audit trail ensures, that each user's (site personnel, monitor, sponsor, data manager) access to and actions in the system is tracked.

The Data Validation Plan describes which edit checks, range checks, and other consistence checks that will be done on the clinical data during conduct of the investigation. The Data Validation Plan will be developed in collaboration with the Clinical Manager and the Statistician and will be aligned with the monitoring section.

Principal Investigator, or delegate, at the clinical site will perform primary data collection directly into the eCRF or drawn from source-document (i.e., medical records or notes) reviews. The eCRF will be completed on a continuous basis starting from the point of enrolling the subject to final follow up.

The eCRF will be completed by the principal investigator or delegate, who have signed the Site Personnel Signature and Delegation List and Clinical Investigation Training Log. It will be the responsibility of the principal investigator to ensure that all measurements and observations are correctly noted in the eCRF.

All assessments and observations throughout the investigation for each subject must be carefully recorded in an eCRF during the visit or immediately after. The eCRF makes it possible to enter data right away when they are obtained. This is the preferred way of collecting data. In case this is not possible the data should be entered no later than 7 days after the visit / procedure. This deadline will be shorter after LPO at the site and will be agreed with the monitor.

In the unforeseen situation, where site cannot establish connection to the EDC system, a paper CRF (pCRF) has been printed and supplied by sponsor.

11.1 Data collection procedure

During catheterisations at visit 2 and 3 a catheterisation profile is created using a scale connected to a data box. The catheterisation profile shows a scale curve of accumulated urine (urine volume/time). The catheterisation profiles are analysed by two Coloplast specialists, independently, and results then compared to derive the relevant endpoints. The data for the catheterisation profile relevant endpoints are then uploaded to the database by the data management specialist.

Discomfort will be assessed using the visual analogue scale (VAS). The subject will be asked to indicate the level of discomfort (from 'No discomfort' and 'Worst possible discomfort') in a 10 cm line on paper. Hereafter, the site personnel must measure the length (cm) from the start of the line to the subject's mark and add to the paper form. In addition, the site personnel must register the number in the eCRF.

Perception questionnaires will be completed by the subject at site using an electronic patient-reported outcome (ePRO) app that collects subject responses to questionnaires and transfers data to the Medidata Clinical Cloud. The ePRO used is Rave electronic clinical outcome assessment (eCOA), current version. All data will be transferred automatically into RAVE EDC. At sites where the ePRO is not available the subject must complete the questionnaire on the paper CRF, and the data must be entered into the eCRF by site personnel.

The remaining endpoints, assessments, backup measurements and baseline information can be entered directly into the eCRF.

At the end of the study a formal data review meeting will be performed before the database will be locked.

The Data Management procedures are further described in the Data Management instructions.

The principal investigator will keep a separate list of the subjects' ID numbers, names, and addresses in a locked room/cabinet. Only data referred to in this clinical investigation plan will be recorded in the CRFs.

Adverse events should be registered following the timelines described in the Adverse Event section.

11.2 Data retention

The Investigator file must be archived for a minimum period of 10 years after the final clinical investigation report has been signed.

12 Amendments to the Clinical Investigation Plan

No changes in the clinical investigation procedures shall be affected without mutual agreement between the principal investigator and the sponsor. The agreement of the changes must be documented by signing the corresponding clinical investigation plan amendments and registered in the Change Log.

All significant changes require notification to the EC/IRB and applicable regulatory authority. Substantial changes may require approval from the EC/IRB and applicable regulatory authority prior to implementation.

13 Deviations from the Clinical Investigation Plan

Deviations to the Clinical Investigation Plan occurs when the activities during the clinical investigation do not comply with the EC/IRB and regulatory authority approved investigation plan.

A minor deviation is defined as those that doesn't increase risk or decrease benefit or don't have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. If a deviation increases risk or decreases benefit and/or; has a significant effect on the subject's rights, safety or welfare and/or has a significant effect on the integrity of the data it is defined as a major deviation and the principal Investigator must inform the monitor immediately, and the Monitor will report and inform the Clinical Manager or designee immediately.

The principal investigator is not allowed to deviate from the Clinical Investigation Plan unless, under emergency circumstances or to protect the rights, safety and welfare of the subject(s).

For the purposes of this investigation, any variance from the protocol is considered a deviation and is to be reported.

The site will complete a deviation eCRF form for all data-related deviations and all deviations that are not related to the data (for example, an untrained nurse performing study procedures) are reported by the monitor in the Site Report – Periodic Monitoring and actions are addressed to the principal Investigator for completion.

If any deviations to the investigation plan are detected during the monitoring visit, the Monitor shall ensure the site reports all deviations in the eCRF or on the Deviation log in the Investigator File. Additionally, the monitor must report any deviation noted during the visit in the Periodic Monitoring Report.

Monitor will align with data management in each investigation, how data management will be informed about all deviations.

The following information about the deviation will be collected:

- Site ID
- Subject ID
- Date the deviation took place
- What the deviation is related to
- If the deviation affects data integrity
- If the deviation affects subject safety
- Supplementary description of the deviation
- Actions taken with regards to the deviation

14 Device Accountability

All access to the investigational devices (including comparators) used in the clinical investigation is controlled by storage procedures and device accountability logs as described below. The investigational devices must only be used in this clinical investigation and only according to the CIP.

Sponsor keeps a device accountability log that states the physical location of all investigational devices from shipment of investigations devices to the investigational sites until return of or disposal.

The PI or an authorized designee keeps records documenting the receipt, use and return and disposal of the investigational devices, which includes:

- Date of receipt.
- Identification of each investigational device (batch no./serial no./unique code).
- The expiry date,
- Subject identification.
- The date on which the investigational device was returned/explanted from the subject

The date of return unused, expired or malfunctioning investigational devices

15 Statement of compliance

The clinical investigation is conducted in accordance with:

- Ethical principles that have their origin in the Declaration of Helsinki, 1964, Last amended at the 59th WMA General Assembly, Brazil, October 2013.
- MDR (EU) 2017/745
- ISO 14155:2020 "Clinical Investigation of medical devices for human subjects – Good clinical practices".
- Any applicable regional or national regulations will be specified in the country specific CIP.

15.1 Ethics committee and regulatory authorities

The CIP and/or other relevant documents are submitted to the appropriate EC and regulatory authorities. This clinical investigation will not begin until the required approval from the EC and regulatory authorities have been obtained. Any amendment to the protocol will be submitted to the same EC and regulatory authority.

Sponsor will notify the relevant regulatory authority and EC concerned of the end of the clinical investigation.

15.2 Data protection

As part of the investigation Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark ("Coloplast") will collect and process the personal information the subject provides for the investigation ("subject personal data"). This includes identification and contact information (which may be anonymised depending on the nature of the investigation) as well as information about product usage experience and your health. Coloplast will comply with the EU General Data Protection Regulation (GDPR) and the Danish act on data protection ("databeskyttelsesloven"), including in connection with transfer of data to third countries, cf. chapter V of GDPR, Coloplast will only process the subjects' personal data:

1. To conduct the investigation and carry out related research based on subject consent (primary use), cf. articles 6(1)(a) and 9(2)(a) of GDPR,
2. To comply with applicable legal obligations to e.g. ensure reliability and safety, cf. article 6(1)(c) in conjunction with article 9(1)(i) of GDPR, and
3. If separate consent is given for secondary use of subject personal data, cf. articles 6(1)(a) and 9(2)(a) of GDPR – carry out research outside the clinical protocol to improve Coloplast's products and services, and for use in education.

Part of Coloplast's processing is carried out on third-party platforms (clinical trial databases) and certain third parties are assisting Coloplast in the processing (e.g. the principal investigator). Such cases will imply a transfer of your personal data to the third parties, but solely for the specified purposes and with the third parties acting on instruction from Coloplast. Data may be collected and processed across the Coloplast network, which may entail processing of personal data outside the European Economic Area. In such cases, an adequate

level of protection will be ensured by the third parties being subject to the standard contractual clauses on data protection adopted by the EU or to an EU-approved certification mechanism on data protection. For further information about this please the subject can always consult Coloplast's data protection officer (details below).

Subject personal data will be kept as long as required under applicable laws and regulations. The EU Medical Device Regulation obligates Coloplast to keep the data for a period of at least ten years after the investigation is completed, or, in the event that the device is subsequently placed on the market, at least ten years after the last device has been placed on the market. Subject personal data will be deleted at the end of the mandatory retention period.

If the subject has questions or queries regarding Coloplast's handling of personal information, the subject can always contact Coloplast's Data Protection Officer at [redacted] Complaints related to Coloplast's handling of subject personal information may similarly be sent to the Data Protection Officer, and the subject is also entitled to file a complaint with the relevant supervisory authority, which in the case of Denmark is the Danish Data Protection Agency (www.datatilsynet.dk).

The subject can write to [redacted] at any time to request:

- Access to personal data
- Correction of errors in personal data or to erase personal data
- Limit what can be done with personal data
- To receive personal data in machine-readable format (data portability).
- Withdrawal of consents the subject has given Coloplast to process personal data

15.3 Indemnity

All subjects are fully covered by Coloplast A/S insurance throughout the investigation:

[redacted]

15.4 Financial conditions

Coloplast A/S will compensate all investigators involved in the clinical investigation for their time and resources spent on the investigation. All financial agreements with the investigation sites involved in the clinical investigation will be specified in a sponsor investigator agreement.

16 Informed consent process

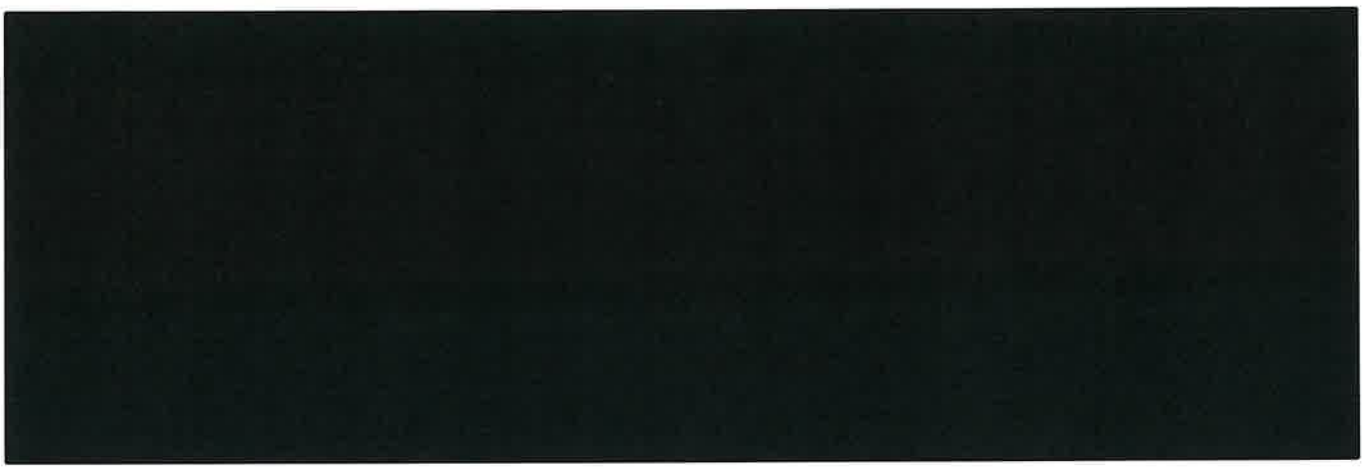
Written informed consent is obtained from all subjects participating in the investigation after thorough written and verbal information. The information is given by the principal investigator or delegate in the subjects' native non-technical language. Each subject will be fully informed about the aim of the investigation, procedures, potential risks or inconveniences and/or expected benefits, all anticipated adverse device effects and then have a minimum of 24h (ensure ample time) before deciding on participation. The subjects will be informed that their participation is voluntary and that they may leave the investigation at any time, without this having any influence on their further treatment.

The informed consent signature form includes personally dated signatures of the subject and the PI or delegate responsible for conducting the informed consent process. A copy will be provided to the subject.

If new information is to be given during the investigation, sponsor will inform the principal investigators, and the new information is given to the subjects by the principal investigator. If new information becomes available that can significantly affect a subject's future health and medical care that information will be provided to the subject in written form. CM is responsible for writing the information and providing the approved Subject Information and Consent Form to principal, investigators that will further provide it to the subjects. If applicable, all affected subjects shall be asked to confirm their continuing informed consent in writing.

This procedure also applies to informed consent obtained from a subject's legal representative. The procedure cannot waive the subjects' legal rights.

17 Subject compensation



18 Adverse events, adverse device effects and device deficiencies

18.1 Adverse events

An adverse event is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, whether or not related to the investigational medical device(s) or the comparator(s), or the procedures involved. The adverse event shall be marked with the intensity mild, moderate or severe. This could include events such as headache or dizziness.

18.2 Adverse device effect

An adverse event, which is related to the use of the investigational medical device or comparator, is an adverse device effect, and should be marked as unlikely related, possible related, probable related or with causal relationship on the adverse event form.

The definition of an adverse device effect includes any event resulting from insufficiencies or inadequacies in the instruction for use, deployment, or any malfunction of the medical device, as well as any event resulting from use error or from intentional misuse of the device.

Table 4. Anticipated adverse device effects and their likely incidence rates

ANTICIPATED ADE	INCIDENCE RATE
Irritation of mucosa	Likely
Stinging and pain in urethra during catheterisation	Likely
Macroscopic haematuria	Unlikely
Macroscopic leukocytes	Unlikely
Urinary tract infection	Very unlikely

18.3 Device deficiency

A device deficiency is the inadequacy of the investigational medical device or comparator with respect to its identity, quality, durability, reliability, usability, safety, or performance. This includes malfunctions, use errors and inadequacy in the information supplied by the manufacturer including labelling.

List of examples: no coating, no micro-holes, hole in the packaging, broken catheter etc.

If any Device Deficiencies occur for CE-marked Coloplast products the incident shall be stated in the Vigilance Form in the eCRF.

18.4 Serious adverse events (SAE)

A serious adverse event is an adverse event that:

- Led to death,
- Led to a serious deterioration in the health of the subject, users or other persons as defined by one or more of the following:
  1) a life-threatening illness or injury, or
  2) a permanent impairment of a body structure or a body function including chronic diseases, or
  3) in-patient or prolonged hospitalization, or
  4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function.

- Led to foetal distress, foetal death, a congenital abnormality, or birth defect including physical or mental impairment.

This includes device deficiencies that might have led to a serious adverse event if:

1) Suitable action had not been taken, or
2) Intervention had not been made, or
3) Circumstances had been less fortunate.

These are handled under the serious adverse event reporting.

Planned hospitalization for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a serious adverse event.

18.4.1 Serious adverse device effect (SADE)

A serious adverse device effect is an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

If any serious adverse device effects occur for CE-marked Coloplast products the incident shall be stated in the Vigilance Form in the eCRF.

18.4.2 Anticipated serious adverse device effect (ASADE)

There are no anticipated SADEs.

18.4.3 Unanticipated serious adverse device effect (USADE)

An unanticipated serious adverse device effect is a serious adverse device effect which by its nature, incidence, severity, or outcome has not been identified in the current version of the risk analysis report.

18.5 Medical care of subjects

Principal investigator shall ensure that adequate medical care is provided, during and after participation in the clinical investigation, to a subject experiencing an adverse event. All ongoing ADEs, SAEs, SADEs and DDs

that could have led to a SAE at subject termination will be followed according to the Risk Benefit analysis (see 8.2). An ongoing adverse event at subject termination visit is documented as the current status for the adverse event and will not be followed up.

The subjects shall be informed of any significant new findings occurring during the clinical investigation, including the need for additional medical care that can be required, and of the nature and possible cause of any adverse events experienced.

18.6 Reporting and timelines

18.6.1 Investigator's reporting responsibilities

- PI at each site must assess all (S)AE`s that occur at his/her site.

- All serious adverse events and serious adverse device effects must be reported to sponsor within 24 hours of the site becoming aware of the event.
- A device deficiency that could have led to a serious adverse event but did not because suitable action was taken, intervention had been made or because of fortunate circumstances should be reported to sponsor within 24 hours of the site becoming aware of the event.
- New findings and/or updates in relation to already reported serious events should also be reported to sponsor within 24 hours of the site becoming aware of the event.
- Device deficiencies and all adverse device effects related to Investigational Product and/or comparator must be reported to sponsor within 24 hours of becoming aware of the event.

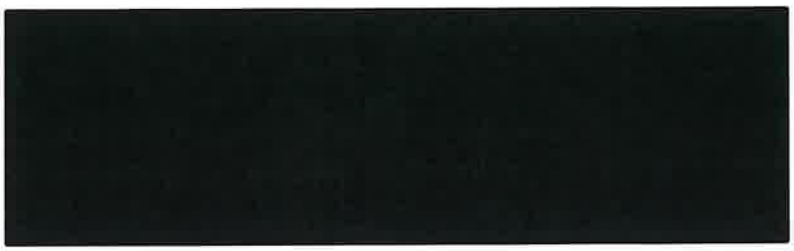
When reporting the SAE, the relationship to the test material shall be described whether the event is considered

- **Not related**, the event has no temporal relationship with the use of the test material or the procedures.
- **Unlikely related,** the relationship with the use of the test material seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained.
- **Possible related,** the relationship with the use of the test material is weak but cannot be ruled out completely. Alternative causes are also possible (e.g., an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug, or treatment). Cases where relatedness cannot be assessed, or no information has been obtained should also be classified as possible.
- **Probable related,** the relationship with the use of the test material seems relevant and/or the event cannot reasonably be explained by another cause, but additional information may be obtained.
- **Definitely related/Causal relationship,** the event has a temporal relationship with the test material use/application or procedures.

and the intensity of the event should be considered, as such:

- **Mild,** the intensity of the event is mild with no further action or intervention
- **Moderate,** the intensity of the event will lead to an action or intervention to solve the event
- **Severe,** the intensity of the event will lead to follow up on the action or intervention, as the effect of the action or intervention may not decrease the symptoms.

All above events must be reported to the sponsor representatives from below list by use of the relevant adverse event/serious adverse event/device deficiency form.



18.6.2 Sponsors reporting responsibilities

It is the responsibility of sponsor to ensure that the following are reported to national regulatory authorities immediately, but no later than 7 calendar days following the date of awareness by sponsor.

All serious adverse events.

All serious device effects.

All device deficiencies that could have led to serious adverse events but did not because suitable action was taken, intervention had been made or because of fortunate circumstances.

New findings and/or updates in relation to already reported events.

If the serious adverse event results in imminent risk of death, serious injury, or serious illness that requires prompt remedial action for other subjects, users or other persons or a new finding to such a serious adverse event, sponsor must immediately, but no later than 2 calendar days after awareness by sponsor, report the event to national regulatory authorities.

It is the responsibility of sponsor to inform all investigators in writing within 10 working days if device deficiencies, adverse events, adverse device effects, near-incidents, serious adverse events, serious adverse device effects or unanticipated serious adverse device effects lead to corrective actions (e.g. change of IFU).

19 Suspension or premature termination of the clinical investigation

Sponsor may suspend or prematurely terminate an investigation site or the entire clinical investigation for documented significant reasons.

If a suspicion of an unacceptable risk to subjects develops during the clinical investigation, sponsor will suspend the investigation while the risk is assessed. Sponsor will terminate the investigation if an unacceptable risk is confirmed. Sponsor will ensure that the premature termination will be justified in writing and will promptly inform the regulatory authorities and relevant EC. If monitoring or auditing of the clinical investigation identifies serious or repeated deviations at one of the participating investigation sites, sponsor will suspend or terminate the particular investigational site. The sponsor or investigator will inform the regulatory authority as appropriate and notify the EC about the termination of the site.

20 Clinical investigation report

At completion of the investigation sponsor is responsible for writing the clinical investigation report. The report is retained on file. The report contains a critical evaluation of all data, which have been collected during the investigation. The report describes the methodology and design and a data analysis, including statistical preparation and conclusion.

Sponsor and national coordinating investigators must sign the final version of the clinical investigation report or an affidavit, indicating their agreement with the contents. If no coordinating investigators are appointed, then the signatures of the principal investigators should be obtained.

The clinical investigation report must be submitted to EC and regulatory authorities.

21 Publication policy

Coloplast, sponsor, is referring to the internal document 'Clinical Publication Policy' that will be available for internal and external persons involved in the publication process.

The investigation will be registered in a publicly accessible database before recruitment of the first subject. The results of the investigation, positive as well as inconclusive and negative will be published in the same publicly accessible database. The subjects' identity will remain confidential. Publication of results in the database will be conducted per the law of personal data protection and will be initiated as soon as scientifically acceptable, however, within one year after the last subject has completed the investigation. Data from the investigation is considered confidential until it is published per the conditions of this Clinical Investigation Plan and the 'Clinical Publication Policy'. Sponsor may publish anonymous single subject case stories (or public, if the subject consents) at any time during and after the investigation. The identification of the participant must not be possible. Sponsor reserves the right to use the data (published and unpublished) for reimbursement or regulatory purposes.

22 Suspension/termination of the clinical investigation

Sponsor will withdraw from sponsorship of the clinical investigation if

- major non-adherence to the clinical investigation plan is occurring
- it is anticipated that the subject recruitment will not be adequate to meet the investigation objectives (at least 75% of the subjects should be entered within the recruitment time).

In case sponsor withdraws, sponsorship for the subjects already recruited into the clinical investigation will continue.

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24 Appendix A:

Perception questionnaire (Please only tick one box per question)

Handling	Very difficult	Difficult	Neither Difficult nor Easy	Easy	Very easy	Don't know
How is it to use the catheter?						
How is it to open the catheter?						
How is it to insert the catheter?						
How is it to empty the bladder?						
How is it to handle the catheter during insertion?						
How is it to re-close the catheter?						

Confidence and in control	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree	Don't know
The catheter is discreet						
The catheter is hygienic to use						
It is fast to empty my bladder completely using this catheter						
I feel the catheter has a sufficient length to empty my bladder completely						
I feel confident the catheter empties my bladder completely						
I don't worry about urine left in my bladder using this catheter						
I feel confident using the catheter						

Sensation	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree	Not applicable (Lack of sensation)
It is gentle to insert the catheter						
It is gentle to empty the bladder						

It is gentle to withdraw the catheter						
I feel pinching/stinging during catheterization using this catheter						
Satisfaction	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree	Don't know
I am satisfied with the catheter						
I would like to use the catheter in the future						
I would recommend the catheter to others						