Evaluation Plan

CP284

Evaluation of the ability of newly developed adhesives to absorb moisture

May 2018 – July 2024

ClinicalTrials.gov ID: NCT03619226

Approval date of version 6.0: 2023/08/23

CHANGE LOG

VERSION NUMBER	ISSUED BY *(INITIALS)*	COMMENTS (MAJOR CHANGES SINCE LAST REVISION)
1.0	[redacted]	This Evaluation Plan is based on current version of Clinical Investigational Plan master version 5.
2.0		[redacted] p27: Reference 3 and 4 added.
3.0		Minor editorial changes [redacted] p19: Electronic CRF added [redacted]
4.0		[redacted]
5.0		[redacted]

		[redacted]
6.0	[redacted]	[redacted]

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> SYNOPSIS OF THE EVALUATION

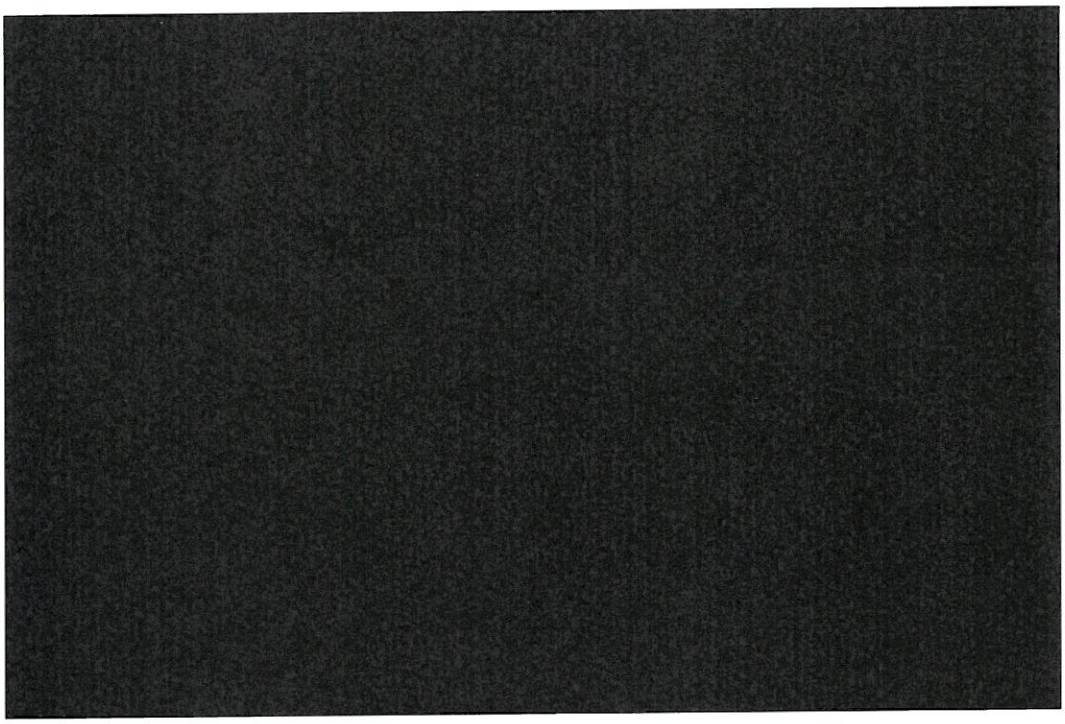
Objective

The aim of this evaluation is to investigate the ability of newly developed adhesive patches to absorb moisture.
The primary objective is:

- To investigate the ability of different adhesives to absorb moisture in the adhesive layer closest to skin and within the adhesive layer, using an electronic sensor system.

Primary endpoint:

Resistance assessed by a sensors system including time for passing pre-defined resistance thresholds for individual sensors.



Pass/fail criteria

No formal success criteria are applied in this pilot evaluation. The study will provide valuable insight into the performance of adhesives when exposed to output and/or sweat.

Design of the investigation

Overall:

- Single arm. Open-labelled, not randomized
- Controlled

[redacted]

Completion/Termination visit (can be done by phone). At the test visits, the subjects will be exposed up to 2 adhesive patches [redacted]

Population

The population consists of subjects who comply with the following inclusion criteria and do not comply with the following exclusion criteria:

[redacted]

[redacted]

Inclusion criteria for [redacted] Healthy volunteers:

1. Have given written informed consent
2. Be at least 18 years of age and have full legal capacity
3. Have intact skin on the area used in the evaluation
4. Have an abdominal area accessible for application of test product (assessed by investigator)
5. Negative pregnancy test for fertile women
6. Signed document claiming use of safe contraceptives for fertile women

1. Currently receiving or have within the past 2 month received radio- and/or chemotherapy
2. Currently receiving or have within the past month received topical steroid treatment in the peristomal skin area or systemic steroid (tablet/injection) treatment.
3. Are pregnant or breastfeeding
4. Having dermatological problems in the peristomal- or abdominal area (assessed by investigator)
5. Participating in interventional clinical investigations or have previously participated in this evaluation. Exception: Participation in other Coloplast sponsored clinical investigations or evaluations is accepted under the circumstances that the subject has paused the activities in the investigation/evaluation and are otherwise complying with the inclusion and exclusion criteria of this (CP284) Evaluation

Test products

A range of different newly developed adhesive patches embedded with sensors will be tested in this evaluation to assess the moisture absorption capabilities of the adhesive. [redacted]

Test products can be applied in combination with CE-marked accessories

[redacted]

The test product is not considered a medical device.

Investigation approval

The Evaluation will be approved by the Ethics Committee in Denmark before initiation.

> LIST OF ABBREBIATIONS

ABBREVIATION	WRITTEN OUT	EXPLANATION
AE	Adverse Event	See section 13.1
CRF	Case Report Form	
CM	Clinical Manager	Coloplast study operational responsible and author of this Evaluation
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.
EC	Ethics Committee	
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.
SAE	Serious Adverse Event	See section 13.2

> SIGNATURE PAGE

All parties declare by their signature on the electronic signature page that they will follow the Evaluation Plan CP284 in accordance with the Declaration of Helsinki, and as far as possible in compliance with the ISO 14155 considering the nature of the evaluation not investigating a medical device.

SPONSOR

Coloplast A/S

[redacted]

1. List of personnel involved in the Investigation

1.1. Investigator

PRINCIPLE INVESTIGATOR (PI)
[redacted]

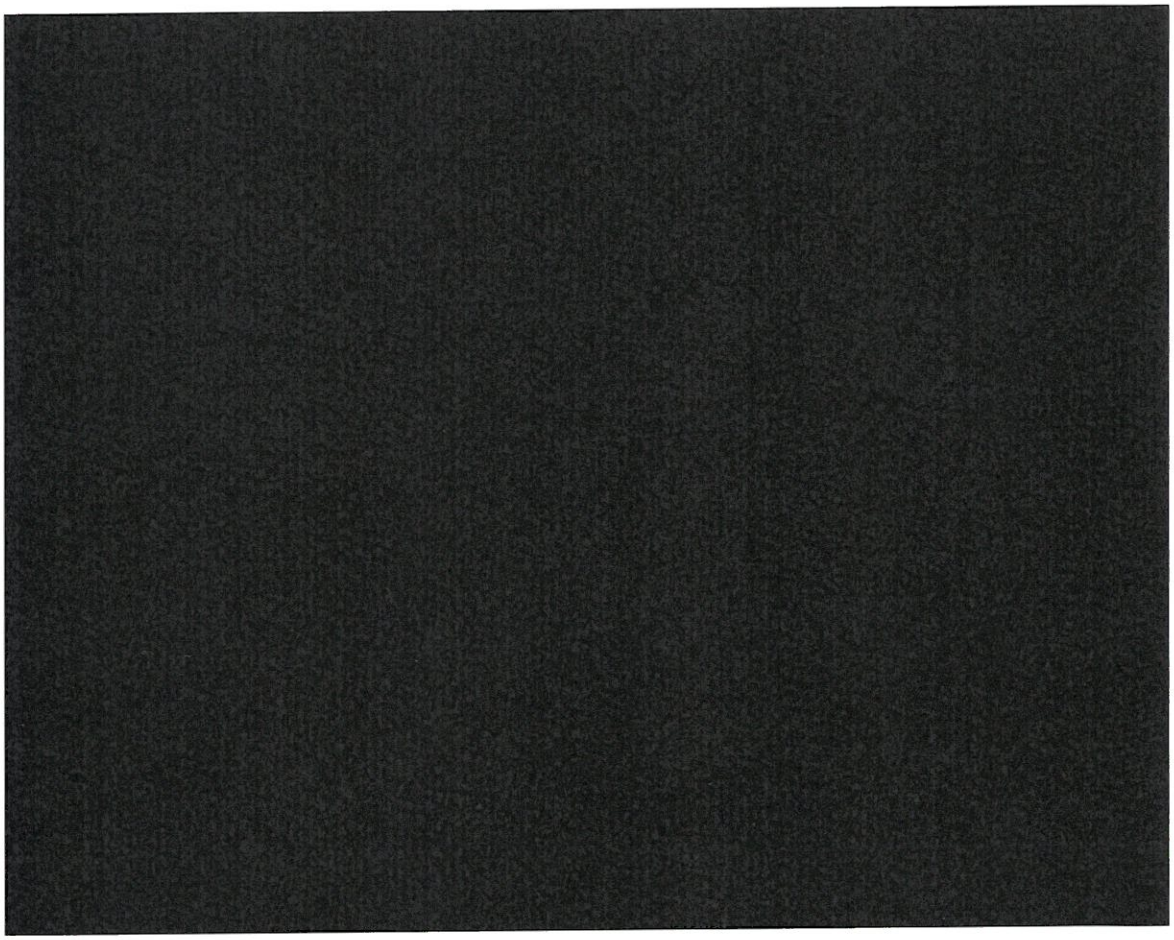
1.2. Sponsor representatives

SENIOR STATISTICIAN	HEAD OF CLINICAL OPERATIONS
[redacted]	
SENIOR MEDICAL AFFAIRS PROJECT MANAGER	SCIENTIFIC MANAGER
[redacted]	
CLINICAL MANAGER	MEDICAL ADVISOR
[redacted]	

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

2. Identification and description of the material

The test product (see Figure 2 and 3) is not considered a medical device, but a range of different, newly developed adhesive strips [redacted]



[redacted]

3. Justification for the conduct of the Evaluation

[redacted]

The present evaluation investigates the ability of different adhesives to absorb moisture in the adhesive layer closest to skin and within the adhesive layer, using an electronic sensor system.

4. Ethical Considerations, risks and benefits

The evaluation is conducted in accordance with current law and applicable standards see section 11.

The rights, safety and well-being of human subjects will prevail over interest of science and society.

[redacted] All adhesives will undergo risk assessment and biological safety evaluations before initiation of the evaluation and therefore, the risks are considered to be equal to the use of ostomy products already on the market. Risks associated with the use of ostomy products are skin irritation and mechanical trauma.

The evaluation is conducted in accordance with 'The Declaration of Helsinki', 1964, last amended at the 64th WMA General Assembly, Fortaleza, October 2013, and as far as possible in compliance with the ISO 14155 considering the nature of the investigation not investigating a medical device. The participating subjects will contribute with important information for developing new ostomy products that may reduce leakage and the risk and disadvantages for participating is estimated to be low.

5. Objectives of the evaluation

5.1. Objective

The primary objective is:

- To investigate the ability of different adhesives to absorb moisture in the adhesive layer closest to skin and within the adhesive layer, using an electronic sensor system.

[redacted]

5.2. Risks and anticipated adverse device effects to be assessed

Each type of adhesives will undergo risk assessment and biological safety evaluations before application and therefore, the risks are considered to be equal to the use of ostomy products already on the market. Risks associated with the use of ostomy products are skin irritation and mechanical trauma.

6. Design of the Evaluation

6.1. General

The pilot evaluation is based on an open explorative design evaluating the impact that moisture has on newly developed adhesives materials. [redacted]

Overall:

- Single arm. Open-labelled, not randomized
- Controlled

[redacted]

[redacted]

Baseline visit:
At the baseline visit, the subjects are included in the evaluation and baseline information is collected.

Test visits:
The test product will be applied by trained study personnel. Each subject can wear up to 6 test products at the time (Figure 1: Placement of test product)

[redacted]

During a test visit the adhesive patch may be deliberately exposed to moisture e.g. by subjects doing exercise on a spinning cycle or taking a shower.

[redacted]

6.1.1. Primary end points

Resistance assessed by a sensors system including time for passing pre-defined resistance thresholds for individual sensors.

[redacted]

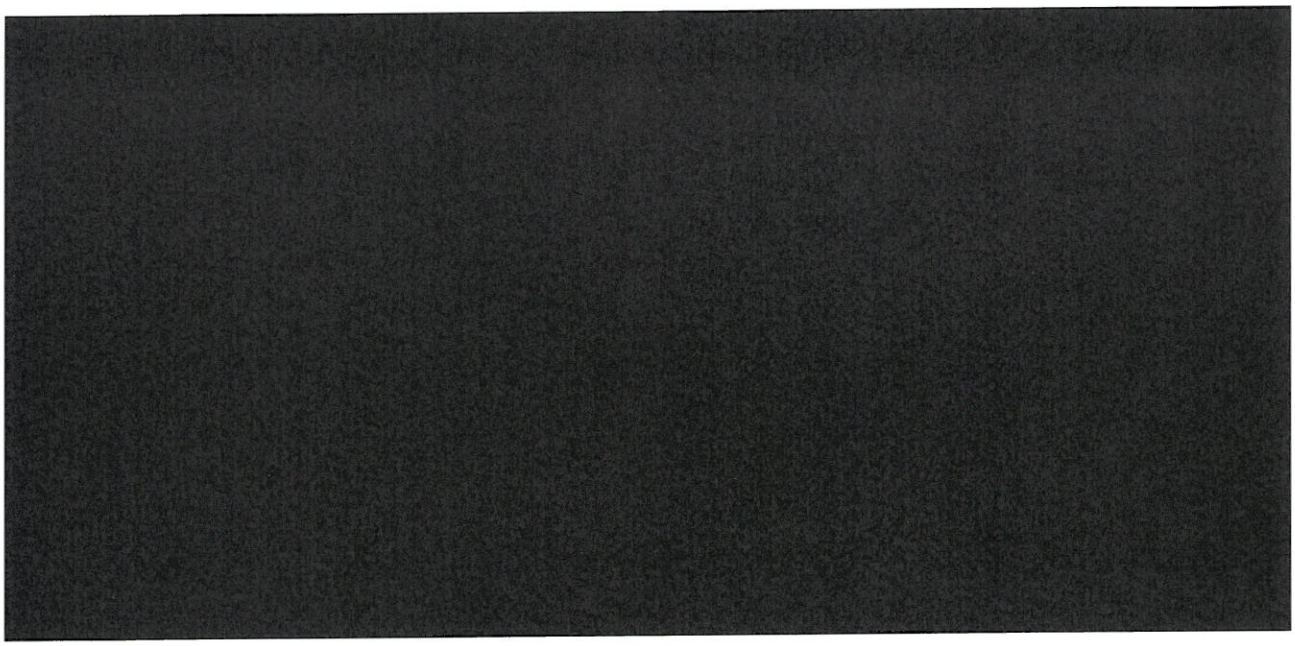
[redacted]

6.1.3. Rationale for selection and measurement of end points

[redacted]

Leakage is one of the greatest concerns for people with an ostomy. The frequency of leakage correlates to the degree of peristomal skin complications; therefore, ostomy appliances with better ability to reduce leakage have the potential of improving the peristomal skin condition and quality of life. Constant evaluation and development of new ostomy appliances is therefore of high importance and clinically relevant.

[redacted]



6.2. Test products and comparator(s)

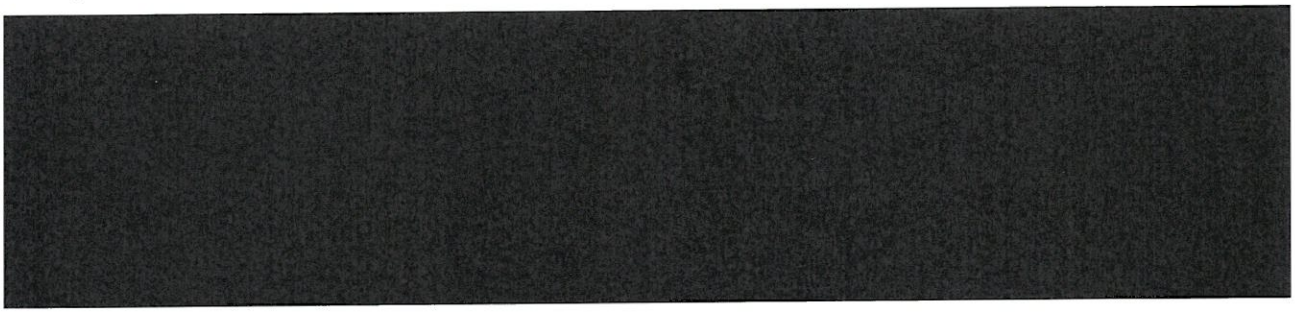
The test products will be newly developed adhesives. The evaluation does not include comparator devices.

6.3. Subjects

To be included in the evaluation, the subjects must comply with the selection criteria described in section 6.3.1 and must not comply with criteria described in 6.3.2.

6.3.1. Inclusion criteria for subject selection

Subjects interested in participating the evaluation must comply with the following criteria:



Inclusion criteria for healthy volunteers [redacted]

1. Have given written informed consent
2. Be at least 18 years of age and have full legal capacity
3. Have intact skin on the area used in the evaluation
4. Have an abdominal area accessible for application of test product (assessed by investigator)
5. Negative pregnancy test for fertile women
6. Signed document claiming use of safe contraceptives for fertile women

6.3.2. Exclusion criteria for subject selection

Subjects complying with the following criteria must be excluded from participation in the evaluation:

1. Currently receiving or have within the past 2 month received radio- and/or chemotherapy

2. Currently receiving or have within the past month received topical steroid treatment in the peristomal skin area or systemic steroid (tablet/injection) treatment.
3. Are pregnant or breastfeeding.
4. Having dermatological problems in the peristomal- or abdominal area (assessed by investigator)
5. Participating in interventional clinical investigations or have previously participated in this evaluation. Exception: Participation in other Coloplast sponsored clinical investigations/evaluations is accepted under the circumstances that the subject has paused the activities in the investigation/evaluation and are otherwise complying with the inclusion and exclusion criteria of this (CP284) Evaluation

Inclusion 5, 6, 7 and Exclusion 3: Women are considered fertile if they have had a least one period during the last 12 months. Besides a negative pregnancy test the women must also sign a document claiming that they will use safe contraceptives during the study period (i.e. contraceptive coil, hormone based contraceptives or surgical sterilization). However, in some cases when females older than 50 years but not yet post-menopausal, the investigator may evaluate that it is not reasonable to ask these females to start using safe contraceptives for the duration of the investigation (e.g. if the subject is abstinent, the partner is surgically sterilized, or either subject or partner is infertile). In these cases, the investigator can include the females, but has a responsibility of ensuring that he/she has done what he/she can to prevent these subjects from becoming pregnant. As a minimum, the investigator, must talk to the females about the risk of and how to avoid unwanted pregnancy at inclusion and at every visit hereafter.

6.3.3. Recruitment and enrolment

[redacted]

The recruitment of potential subjects will commence only once authorisation has been received from the Ethics Committee.

[redacted]

If healthy volunteer's responds to the advertisement material, written information about the evaluation (subject information) and the letter "Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt" will

be sent to them to ensure that potential subjects are given the opportunity to read about the evaluation before a possible informational visit, and so that they can prepare any possible questions they may have. The subject information provides information to potential subjects about how to contact the sponsor representative (name, telephone number and e-mail address), if they wish to learn more about the evaluation.

[redacted]

Information visit [redacted]

If the potential subject is interested in participating in the evaluation, a visit will be arranged in a room at Coloplast A/S reserved for the purpose of ensuring privacy and quiet surroundings. The subjects will receive both written and verbal information about the possibility of bringing a companion to the informational visit and to any possible subsequent visits. See section 12 for information to be given to the subjects, as well as the informed consent process. If a potential subject so desires, and it is certain that he/she has understood what the evaluation entails and has signed the informed consent, he/she can continue directly to screening and inclusion as a continuation of the informational visit.

6.3.4. Subject withdrawal criteria

[redacted]

The investigating scientist must withdraw a subject from the evaluation for the following reasons:

- Non-compliance with the Evaluation Plan impacting the scientific integrity of the evaluation.
- If a subject's safety and well-being is compromised by further participation.

A subject who is withdrawn from the evaluation, for any reason, will be encouraged to contact the investigating scientist if problems arise that the subject believes are related to the evaluation.

6.3.5. Point of enrolment

A subject is considered enrolled in the evaluation when written informed consent is obtained.

6.3.6. Total expected duration of the Evaluation

The dates below are approximate and no subjects will be enrolled before approval from Ethics Committee is obtained. The relevant Ethics Committee will be notified of significant changes.

[redacted]

6.4. Procedures

6.4.1. Evaluation-related procedures

Before initiation of the evaluation, **sponsor must be provided with key personnel's 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 evaluation. Also, the sponsor will ensure that all site personnel are trained in the evaluation 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 [redacted]

Information visit:

At the information visit, oral and written information about the evaluation is given by the PI or his/her representative and the subjects are given the opportunity to ask questions about the evaluation (Informed consent process section 12). Subjects can continue to Baseline visit the same day - If practical possible.

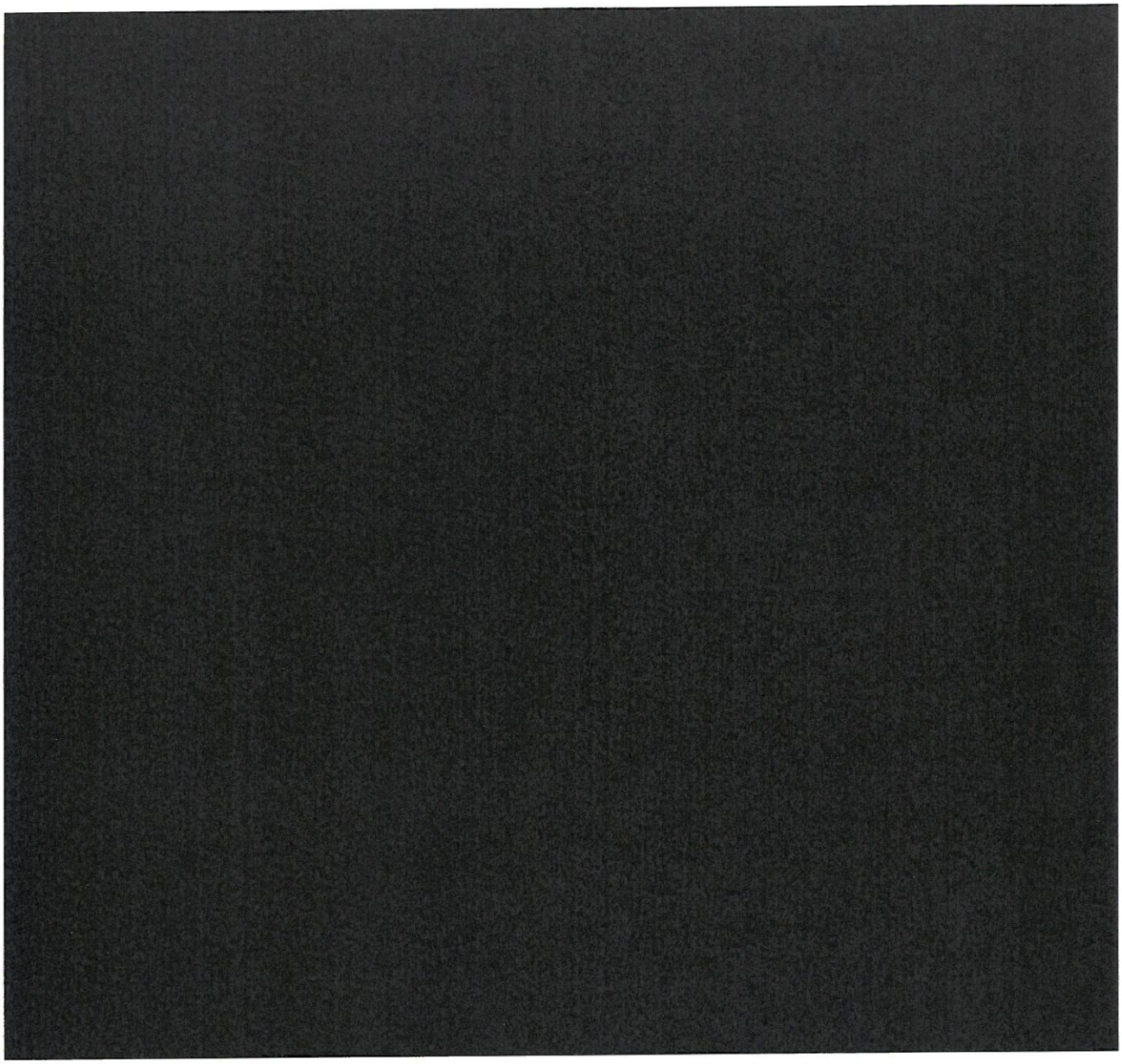
In case pre-stripping of the abdominal skin (not peristomal skin) is required, subjects will be instructed how to do this. Pre-stripping is done to remove dead skin cells and grease in the outer skin layer and must be done 3 days prior to test visit. If pre-stripping is requested, it will be done with a CE-marked adhesive material.

Baseline visit:

At the Baseline visit, following documents will be collected:

1. Signed Informed Consent Form
2. Signed Informed Consent Form - Interview
3. Signed Secrecy consent
4. Pregnancy test for fertile women and document claiming use safe contraceptives

[redacted]



Completion/Termination visit:

- Subject will visit site for study completion and termination (visit can also be done by phone)
- Subjects that can/will not complete the test period will proceed to the termination visit.
- If the subject experiences skin complications during the test period, the investigator/study nurse will evaluate the skin condition to decide whether subject can complete the test.

6.4.2. Activities performed by sponsor representatives

The Investigation will be conducted at Sponsor's site and all activities described in section 6.4.1, will be conducted by Sponsor personnel.

6.4.3. Flow-chart

Table 1 chart showing the connection between visits and assessments.

	PERFORMED BY	INFOR-MATION VISIT	BASE-LINE VISIT	[redacted]	TERMINATION VISIT
General					
Oral information	Investigator*	X			
Written informed consent	Investigator*		X		
Written informed consent – interview	Investigator*		X		
Signed Secrecy consent	Investigator*				
Documentation for pregnancy test	Investigator*		X		
Check of in- and exclusion criteria	Investigator*		X		
Insurance of subjects well being and compliance with the Evaluation Plan	Investigator*		X		
Registration of baseline data					
Date of birth	Investigator*		X		
Gender	Investigator*		X		
[redacted]	Investigator*		X		
	Investigator*		X		
	Investigator*		X		
	Investigator*		X		
	Investigator*		X		
	Investigator *		X		
	Investigator*		X		
	Investigator*		X		
Registration/measurement of end points					
State primary end point	Investigator*				X
[redacted]					
Registration of termination					
AEs/ADEs/SAEs/SADEs	Investigator*				X
Termination form	Investigator				X

*Performed by investigator or a trained representative hereof

6.4.4. Case Report Forms

All assessments and observations throughout the investigation for each subject will be carefully recorded in the CRF. In this investigation, a paper CRF or an electronic CRF will be used.

The CRFs are supplied by sponsor. A CRF is provided for each subject and it is the responsibility of the Investigator that all data are entered promptly and correctly.

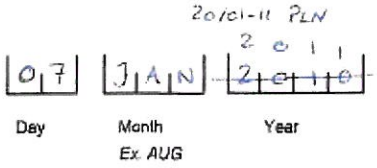
Each CRF have printed instructions for completion.

The CRF will be filled out by the investigator/relevant staff, who have signed the Site Personnel Signature and Delegation List and Evaluation Training Log. It will be the responsibility of investigator that all measurements and observations are correctly noted, **for paper CRF's** with a pen (permanent writing utensil).

The CRF and Photos are source data and corrections cannot be made except for unambiguous corrections that can be reconstructed from other source documents.

Any correction in the paper CRF must be clearly signed and dated by authorised site personnel (see Figure 3). The entry corrected must be crossed out so that the entry is still legible.

Example 1:



Example 2:

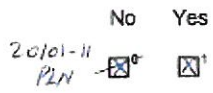


Figure 4: Two examples of how to make corrections in the CRF

The investigator will keep in a locked room a separate list with the subject ID numbers, names and addresses. Only data referred to in this Evaluation Plan will be recorded in the CRFs.

6.4.5. Concomitant treatment

[redacted]

6.5. Monitoring

During the period of the investigation monitoring is carried out by the CM or a delegated sponsor representative. To minimise systematic errors the first monitoring of CRFs should be performed as soon as reasonably possible after the first subject has completed the first test period of the evaluation.

The CM shall have close contact to the investigator or representative hereof to ensure that any concerns, problems or recruitment challenges are solved in a timely manner.

The CM is responsible for planning the monitoring of the CRFs and all monitoring visits will be documented in a monitoring report.

There will be ongoing data cleaning during the study, i.e. queries will be sent by Coloplast representative to the PI on an on-going basis.

6.5.1. Source data verification

In this study the following is considered source data:

- Informed Consent Form
- Informed Consent Form – Interview
- Electronic resistance/time curve
- CRF

[redacted]

All data will be collected using an CRF. The investigator is responsible for entering all data and only data referred to in this evaluation plan will be recorded in the CRF.

Data points for data verification:

- Informed Consent Forms
- In- / Exclusion criteria
- Pregnancy test
- Concomitant medication(s)
- Concomitant disease(s)
- AE/ADE

The informed consent forms will be 100% verified for timely completeness.

All CRF will be 100% verified for completeness.

Only the investigator, delegated site personnel and the sponsor representatives will have access to all the CRFs. The subject will have access to his/her own CRF.

7. Statistical considerations

7.1. Statistical design, method and analytical procedures

[redacted]

7.2. Sample size

This is a pilot evaluation of adhesives under development. [redacted]

7.3. Level of significance and power

The data will primarily be evaluated based on summary statistics and listings of data from cohort. If explorative statistical analyses are performed a significance level of 5% will be applied.

7.4. Pass/fail criteria

No formal pass/fail criteria are applied in this explorative pilot evaluation.

[redacted]

7.6. Statistical reason for termination of investigation

There will be no statistical reasons for termination of the investigation.

7.7. Deviation(s) from statistical plan

Deviations from the statistical analysis plan will be described in the Evaluation report.

8. Data management

8.1. Data review, database cleaning, and issuing and resolving data queries

Data management and statistical analyses are carried out by [redacted]

Data is entered in database by investigator or his/her representative. Data management is responsible for control of data consistency and for completeness of data from each subject.

Discrepancies are listed in Data Query Forms (DQF) and the Investigator is responsible for solving these promptly. When all DQFs are solved the database is locked and the statistical analyses are performed.

8.2. Verification, validation and securing of electronic clinical data systems

[redacted] 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. This system also generates electronic CRF's

8.3. Data retention

The sponsor and investigator file, all evaluation files and the evaluation database, will be archived for a minimum period of 5 years after the final evaluation report has been signed.

9. Amendments to the Evaluation Plan

Any significant changes to the Evaluation Plan must be:

- Justified in a statement included in the amended section. The version number and date of amendment must be documented
- Registered in the Change Log
- Notified to or approved by the Ethics Committee before implementation (if applicable)

Examples of significant changes include: changes to inclusion criteria, endpoints or assessment methods.

10. Evaluation Plan deviations/violations

The investigator is not allowed to deviate from the Evaluation Plan unless under emergency circumstances and to protect the rights, safety and well-being of the subject(s). Deviations affecting the scientific aspect of the evaluation or the safety of the subject are reported to the Ethics Committee by the sponsor if required by national regulations.

Deviations to the Evaluation Plan

Deviations to the Evaluation Plan occurs when the activities during the evaluation diverge from the EC approved Evaluation plan.

Examples of deviations:

- Vital signs obtained prior to informed consent
- Weighing participant with shoes on
- Urine dipstick is completed, but not sent for formal urine analysis
- Partly completing required tests

A deviation does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data.

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

If any deviation to the investigation plan are detected, the Monitor shall complete a Deviation Form and report all deviations detected during the monitoring visit in the Periodic Monitoring Report.

Violations to the Evaluation Plan

Violations to the Evaluation Plan occurs when there is divergence from the EC approved investigation plan (a deviation) *that also:*

- Reduces the quality or completeness of the data
- **Impacts a subject's safety, rights or wellbeing**
- Affects the scientific integrity

Examples of violations:

- Inadequate informed consent
- Enrolment of subjects not meeting the inclusion / exclusion criteria
- Initiation of study procedure prior to completion of informed consent
- **Unreported SAE's**
- Improper breaking of the blinding of the study
- Multiple visits missed or outside permissible windows
- Intentional deviation from the protocol, ISO 14155 or regulations by study personnel in a non-emergency setting
- Repeated deviations of the same nature
- Falsification

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

If any violations to the investigation plan are detected, the Monitor will complete a study specific Violation Form [redacted] and inform the Clinical Manager via email within 5 days of knowledge.

The Monitor must report all violations detected during a monitoring visit in the Periodic Monitoring Report.

11. Statement of compliance

The evaluation is conducted in accordance with: The ethical principles that have their origin in the Declaration of Helsinki, 1964, Last amended at the 64th WMA General Assembly, Fortaleza, October 2013, and as far as possible in compliance with the ISO 14155 considering the nature of the evaluation not investigating a medical device.

11.1. Ethics committee

The Evaluation Plan and/or other relevant documents are submitted to the appropriate Ethics Committee. This evaluation will not begin until the required approval from the Ethics Committee has been obtained. Any substantial amendment to the Evaluation Plan will be submitted to the same Ethics Committee.

The sponsor will notify the relevant Ethics Committee concerned regarding the end of the evaluation (no later than 90 days after the last subject has ended his/her participation.)

11.2. Other relevant authorities

As the test products evaluated in the present study are not medical devices only Ethics Committee approval is requested and the Evaluation Plan is not submitted to other authorities.

11.3. Data protection

Coloplast follows Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 and General Data Protection Regulation (EU) 2016/679 from 27th of April 2016 on the protection of individuals regarding the processing of personal data and on the free movement of such data.

All information collected during the course of this evaluation is kept strictly confidential. Subjects are identified by a subject number. Any information which could identify a subject remains with the investigating scientist where it is archived with investigation documents. Subjects remain anonymous for the purposes of data analysis. If payment to a subject's bank account is required (e.g. reimbursement of travel costs) it may be necessary to collect the subject's social security number, which will then be handled confidentially. Should the evaluation require future review, relevant regulatory authorities and Ethics Committee will be allowed access to all relevant information for audit and inspection purposes.

11.4. Indemnity

All subjects are fully covered by Coloplast A/S insurance throughout the evaluation [redacted]

11.5. Financial conditions

The evaluation is initiated and sponsored by Coloplast A/S.

[redacted]

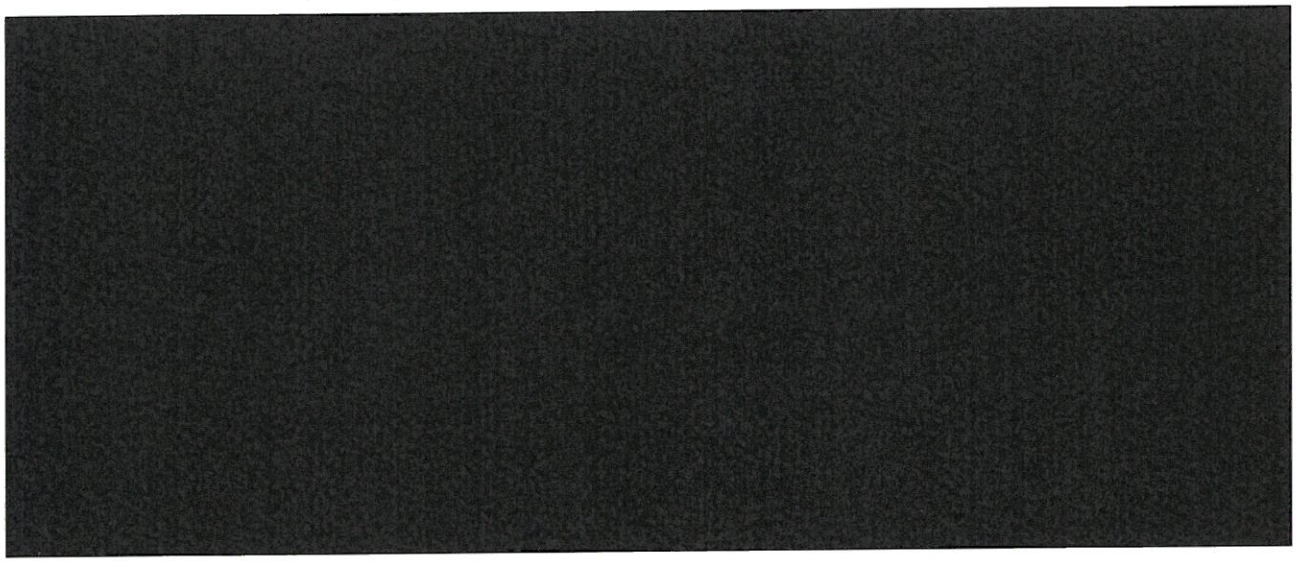
12. Informed consent process

Written informed consent is obtained from all subjects participating in the investigation after thorough written and verbal information. The information is given by the investigator or his/her representative 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 and have a minimum of 24h 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 his/hers representative responsible for conducting the informed consent process. A copy will be provided to the subject.

If new information becomes available during the evaluation, the new information will be provided to the subjects by the investigating scientist. If new information becomes available that can significantly affect a subject's future health and medical care, the information will be provided to the subjects in written form. The PI is responsible for producing the written information and provides it to the subjects. If applicable, all affected subjects will be asked to confirm their continued, 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.



13. Adverse events and serious adverse events

13.1. Adverse events

13.1.1. Adverse event

An adverse event is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other parties, whether or not related to the medical device(s), or the procedures involved. This could include events such as headache or dizziness.

13.2. Serious adverse events

13.2.1. Serious adverse event

A serious adverse event is an adverse event that:

- Led to death
- Led to a serious deterioration in health of the subject that either resulted in:
  1) a life-threatening illness or injury, or
  2) a permanent impairment of a body structure or a body function, or
  3) required in-patient hospitalization or prolongation of existing 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 fetal distress, fetal death or a congenital abnormality or birth defect

Planned hospitalization for a pre-existing condition, without serious deterioration in health, is not considered a serious adverse event.

13.3. Medical care of subjects

The medical advisor will ensure that adequate medical care is provided to any subjects experiencing an adverse event during or after participation in the evaluation. All serious adverse events will be followed until a resolution is addressed.

The current status of all ongoing adverse events is documented during site close-out.

13.4. Reporting and timelines

13.4.1. Investigators reporting responsibilities

- The PI must assess all (S)AEs that occur.
- The monitor must report AEs to the clinical manager in the periodic site monitoring reports
- SAEs must be reported to sponsor immediately, but no later than 3 calendar days after investigational site study personnel's awareness of the event.
- New findings and/or updates in relation to already reported serious events should be reported to sponsor within 3 calendar days.

13.4.2. Sponsors reporting responsibilities

It is the responsibility of the sponsor to ensure that the following are reported to the Ethics Committee immediately, but no later than 7 calendar days, following the date the sponsor is made aware:

- All serious adverse events.
- 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 related to such a serious adverse event, the sponsor must immediately, but no later than 2 calendar days after they are made aware of the event, report it to the Ethics Committee.

14. Suspension or premature termination of the Evaluation

The sponsor may suspend or prematurely terminate the entire evaluation for significant and documented reasons.

If a suspicion relating to an unacceptable risk to subjects arises during the evaluation, the sponsor will suspend the evaluation if the risk cannot be assessed immediately. The sponsor will terminate the evaluation if an unacceptable risk is confirmed. The sponsor will ensure that the premature termination will be justified in writing and will promptly inform the Ethics Committee.

If suspension or termination of the evaluation occurs, the investigator will promptly inform the enrolled subjects. The sponsor will provide resources to fulfil its obligations from the Evaluation Plan for subject follow-up as necessary.

15. Evaluation report

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

The sponsor and investigator must sign the final version of the evaluation report or an affidavit, indicating their agreement with the contents.

The evaluation report must be submitted to the Ethics Committee within 1 year after LPO.

16. Publication policy

The results of the evaluation, positive as well as inconclusive and negative, will be published. The subjects' identity will remain confidential. Publication of results will be initiated as soon as scientifically acceptable and according to the law of personal data protection.

17. Bibliography

[1] Porret T et al. DialogueStudy: An international real-life study of stoma care nursing using a new ostomy appliance. Gastrointestinal Nursing. 2011 Mar 9(2) (Supplement): 1-24.

[2] Nybaek H, Knudsen DB, Laursen TN, Karlsmark T, and Jemec GB. Quality of life assessment among patients with peristomal skin disease. Eur J Gastroenterol Hepatol. 2010 Feb; 22(2): 139-43.

[3] Fumio T, Yumi Y, Takeyasu H, Hiroshi N. Regional differences in adhesive tape stripping of human skin, Skin Research and Technology 2006; 12: 178–182

[4] Karwoski AC, Plaut RH. Experiments on peeling adhesive tapes from human forearms, Skin Research and Technology 2004; 10: 271–277