



## Clinical Protocol

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# A Study Determining Variances In Ostomy Skin Conditions And The Economic Impact **(ADVOCATE)**

Protocol Number: 5787-O

Date: 09 August 2016

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## 1.0 STUDY SPONSOR

Hollister Incorporated  
2000 Hollister Drive  
Libertyville, IL 60048  
USA

[REDACTED]

[REDACTED]

[REDACTED]

## 2.0 ABBREVIATIONS AND TERMS

- AE – Adverse Event
- CRO – Contract Research Organization
- CTF – Cut-to-fit; a barrier hole opening that is cut to size.
- DET score; Validated Ostomy Skin Tool [1]. The DET score assesses Discoloration, Erosion, and Tissue Overgrowth of the peristomal skin.
- eCRF – Electronic Case Report Form
- EDC – Electronic Data Capture; a method used for electronic documentation of study procedures and data.
- EC – Ethics Committee
- HIPAA – Health Insurance Portability and Accountability Act; a US law designed to provide privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals and other health care providers.
- IRB – Institutional Review Board
- MEDDEV – Medical Device Directives (guidance documents) provided by the European Commission
- Peristomal Skin; the skin covered by the adhesive portion of the pouching system (barrier and tape).
- PSC – Peristomal Skin Complication; For the purposes of this study, a peristomal skin complication, is defined as a DET score of greater than 0 due to anything other than normal post-operative healing and/or scar tissue, or an increase in the subject's DET score as compared to the DET score at the prior visit as determined by a study investigator.
- PHI – Protected Health Information; any information about health status, provision of health care, or payment for health care that can be linked to a specific individual.

- **Stoma-related cost;** costs assigned to utilization data accrued through the duration of the study period (including both [REDACTED] and [REDACTED]). This includes treatments related to stoma and/or PSCs (topical medications, clinic visits, accessory use, etc.), social impact of stoma and/or PSCs (e.g. missed work/appointments), hospitalizations, ER visits, physician/clinic visits, ostomy-related medication use and therapies, and barrier utilization.

### 3.0 ETHICS

- 3.1 The study and any amendments will be reviewed by an EC or IRB.
- 3.2 The study will be conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki.
- 3.3 This non-significant risk clinical study, including the Informed Consent, will be reviewed by an EC in the EU in accordance with MEDDEV, the IRB in Canada, and the IRB in the US in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. EC/IRB approval will be obtained prior to study initiation at the study site.

### 4.0 BACKGROUND/RATIONALE

PSCs are common and have been reported to be the reason for over 30% of the visits to an outpatient stoma clinic [2]. Peristomal skin problems can cause pain and reduce life satisfaction, and in addition, contribute to higher ostomy product usage, which may raise healthcare costs [3], [4]. It is evident, that maintaining and restoring the integrity of the peristomal skin has important implications.

Hollister Incorporated is marketing a new ostomy product [REDACTED] skin barrier is designed to maintain adhesive properties [REDACTED]

The purpose of this study is to demonstrate how the use of [REDACTED] impacts stoma related cost of care and peristomal skin condition. It is hypothesized that the [REDACTED] barrier improves peristomal skin condition by reducing the incidence [REDACTED] of PSCs which would manifest itself as an overall reduction in the stoma related cost of care.

## 5.0 STUDY OBJECTIVES

### 5.1 PRIMARY OBJECTIVE

The primary objective of the study is to compare stoma related cost of care for subjects using [REDACTED] to subjects using the control barriers [REDACTED].

### 5.2 SECONDARY OBJECTIVE

The secondary objective of the study is to compare incidence of PSCs in subjects using [REDACTED] to subjects using the control barriers [REDACTED].

## 6.0 STUDY PRODUCTS

### 6.1 STATUS OF STUDY PRODUCTS

The study barriers used in this protocol are Class I ostomy medical devices. Ostomy barriers are medical devices that: (1) are not intended as implants and do not present a potential for serious risk to the health, safety, or welfare of a subject; (2) are not purported or represented to be for use in supporting or sustaining human life; (3) are not for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health; or (4) do not otherwise present a potential for serious risk to the health, safety or welfare of a subject. By this definition ostomy barriers are non-significant risk devices.

### 6.2 IDENTITY OF PRODUCT(S), PACKAGING AND STORAGE, TEST METHODS, PROCEDURES FOR RELEASE

Study barriers will be labeled with either of the following two labels, depending on if [REDACTED] is sold in that country and available in the

country's language, as necessary [REDACTED]

Hollister Incorporated  
Libertyville, IL 60048 USA  
Protocol 5787-O



EC REP

Hollister ULC  
Ballina Ireland

LOT \_\_\_\_\_



*CAUTION: For study use only*

Hollister Incorporated  
Libertyville, IL 60048 USA  
Protocol 5787-O



EC REP

Hollister ULC  
Ballina Ireland

LOT \_\_\_\_\_



*CAUTION: For study use only*

[REDACTED]

Study materials are supplied non-sterile. Subjects are provided up to a twelve (12) week supply of ostomy barriers in a flat or convex design [REDACTED]

[REDACTED] Subjects are also instructed to bring any unused study barriers and pouches with them to in-person study visits.

The control barrier material is [REDACTED], depending on the Investigator's standard of care and the subject's needs, and the test barrier

material is [REDACTED]. Subjects are instructed to wear the study barriers consecutively and according to their clinician recommended changing habit throughout the study period. The Investigators are to rely on clinical judgment to determine whether a subject requires a flat or convex barrier and [REDACTED] barrier material. If deemed necessary, Investigators may switch subjects between the flat and convex barriers of the same barrier material at any point during the study as well as adjust the stoma opening size or barrier flange size.

Currently marketed Hollister pouches are provided by the manufacturer. Accessories, [REDACTED], can be used as needed but are not provided as study products. If a site or subject does not have access to a barrier ring other than the [REDACTED], an alternative barrier ring can be provided by the Sponsor.

#### 6.3 RESPONSIBILITY FOR PRODUCT CONTROL, RETURN AND DISPOSAL

Used study barriers are discarded according to the subjects' normal practice. Any unused study barriers are returned to the Investigator at each visit. The Investigator is to maintain product accountability for dispensed and returned study barriers [REDACTED]. Unused study barriers are then either returned to the Sponsor or destroyed according to Sponsor's directions at the end of the study.

#### 6.4 INSTRUCTIONS FOR USE OF STUDY PRODUCT

The study barrier is self-applied by subjects and used according to the [REDACTED] provided in each box. It is the responsibility of the Investigator to make sure that the subject fully understands the Instructions for Use and the [REDACTED].

## 7.0 STUDY DESIGN

The study is multi-center, randomized, controlled, double-blinded, and utilizes an adaptive design.

Subjects who meet the Eligibility Criteria (listed in Sections 8.1 and 8.2) are enrolled and randomized to Arm 1 or Arm 2 during the Initial [REDACTED] Visit. The assigned Arm and the study barrier are double blinded. All subjects receive standard clinical management of stoma needs as per the Investigator's usual practices. Subjects are initially enrolled into the [REDACTED] which consists of two study visits after enrollment [REDACTED]. If the subject develops a PSC, as defined as a DET score greater than 0 due to anything other than normal post-operative healing and/or scar tissue, or an increase in the subject's DET score as compared to the DET score at the previous visit, prior to the end of the [REDACTED], the subject will be immediately moved to the four (4) week [REDACTED].

which consists of two study visits [REDACTED]. Thus, the total possible time of participation in the study is up to 12 weeks and up to 5 scheduled study visits.

Subjects in Arm 1 are assigned to the [REDACTED] barrier (Test) and subjects in Arm 2 are assigned to either the [REDACTED] barrier (Control).

Study visits consist of a physical evaluation and photography of the stoma area with the pouching system removed [REDACTED], a structured interview by the investigator or designee [REDACTED], and subject completion of a paper or online Quality of Life questionnaire [REDACTED] provided in the subject's local language. The duration of each study visit is approximately 30 minutes.

In support of the primary objective, the following utilization information is collected to support cost of care calculations: utilization of treatments related to stoma and/or PSCs (topical medications, clinic visits and accessory use), social impact of stoma and/or PSCs (missed work/appointments), stoma and/or PSC related hospitalizations, ER visits, physician/clinic visits, medication use and therapies, and barrier utilization (not including pouch utilization). This data is collected at each study visit through the use of [REDACTED] and may include documentation on [REDACTED].

In support of the secondary objective, the following clinical information is collected: the Investigators evaluation of the subject's peristomal skin at all in-person visits, including the [REDACTED] Visits, [REDACTED] Visits and any extra visits, if necessary. Each clinical evaluation consists of a visual assessment of the stoma and peristomal skin, rating on the DET scale [1], and photographs. This data is collected using [REDACTED].

[REDACTED]

## 8.0 STUDY SUBJECTS

### 8.1 INCLUSION CRITERIA

1. At least 18 years of age
2. Have a colostomy, ileostomy, or urostomy
3. Less than or equal to 12 weeks post-op from stoma creation or stoma relocation



4. Have normal peristomal skin (as defined by a DET score = 0 or a DET score > 0 due to normal post-operative healing and/or scar tissue) at study enrollment  
Note: Subjects with suture granulomas or any other peristomal skin complication are not eligible for enrollment.
5. Able to provide an informed consent for study participation
6. Willing to follow protocol procedures, including attending in-person visits, as demonstrated by signing the informed consent

## 8.2 EXCLUSION CRITERIA

1. Have a fistula, wound (e.g. mucocutaneous separation), lesion or suspected infection in the peristomal area
  2. Have known tape allergies
  3. Pregnant, planning to become pregnant, or lactating (as determined by interview only)
  4. Unwilling to discontinue use of [REDACTED] for the duration of the study.
  5. Uses topical steroids on peristomal skin at study enrollment
  6. Unable to wear a standard size 2-piece ostomy barrier
  7. Unable to read and understand local language
  8. Current living situation is long term care facility.
  9. Unable to discontinue use of [REDACTED] for the duration of the study.
- [REDACTED]

## 8.3 SUBJECT TREATMENT AND CARE

Subjects wear the study barrier and perform their peristomal skin care according to their normal daily routines and Investigator recommendations. All subject care is consistent with standard health care practices. No treatment is withheld during the course of the study (therapies, peristomal skin treatments, etc.).

## 8.4 DISCONTINUATION OF SUBJECTS FROM THE STUDY

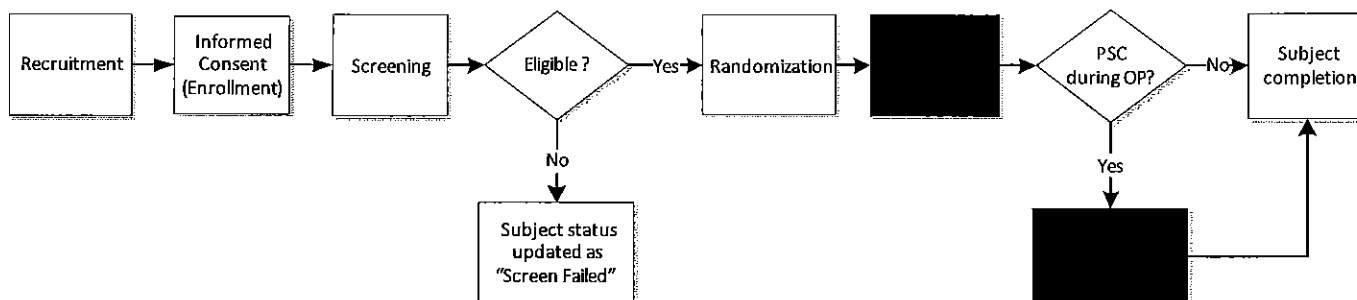
Subjects must be informed of their right to discontinue from participation in the study at any time without prejudice. The Investigator may choose to discontinue a subject from the study. Reasons for a subject discontinuation may include the occurrence of an adverse event, significant protocol deviation, non-compliance, development of a concurrent illness or change of medication that would put the subject at increased risk or invalidate the results of the study. [REDACTED]

In addition Sponsor may end the study at any time.

Any new information gained during the study that might affect the subject's desire to continue participation will be conveyed to them in a timely manner.

## 9.0 STUDY PROCEDURES

### 9.1 STUDY FLOW CHART



### 9.2 RECRUITMENT/SUBJECT IDENTIFICATION PROCEDURE

Subjects are assigned an identification code by study personnel. The identification code is a single letter (A, B, C, etc.) indicating the study site, followed by a double digit number starting with (01) and proceeding consecutively with each subsequent subject. All data forms identify the subject by this number only. All study data is confidential and kept in a secure location. The Subject ID is documented on [REDACTED].

### 9.3 INFORMED CONSENT

The Investigator or designated personnel obtains written Informed Consent from all qualified subjects prior to their enrollment in the study. The Investigator or designated staff explains the nature and purpose of the study to the subjects. Subjects read the EC or IRB approved Informed Consent, have the opportunity to ask questions, and then sign and date the approved Informed Consent. One copy is given to the subject, and the original is retained by the

Investigator in a secure location with the study files. If applicable for HIPAA requirements, the Investigator obtains the subject's authorization to use PHI under HIPAA guidelines by obtaining their signature on an additional authorization form. The subject is provided with one copy of this authorization form and the investigator retains the original.

#### 9.4 ENROLLMENT

Enrollment follows Informed Consent (see Section 9.3) but both may occur during the same visit. The Investigator confirms Inclusion and Exclusion Criteria (listed in Sections 8.1 and 8.2) and, if the subject fulfills the criteria, the Investigator completes the [REDACTED]. The clinician will be blinded to whether the subject is randomized to the test barrier or control barrier.

#### 9.5 METHOD OF ASSIGNING PATIENTS TO STUDY ARMS

Subjects are randomized to Arm 1 (test barrier) or Arm 2 (control barrier) and assigned either study barriers [REDACTED] via a randomized block design stratified by study site and arm. The control barrier material is [REDACTED], depending on the Investigator's standard of care and the subject's needs, and the test barrier material is [REDACTED].

Central randomization is performed within the EDC system [REDACTED]

#### 9.6 BLINDING

Site personnel and subjects are blinded to the assigned study barrier; test or control. Thus, when randomized, the investigator is directed to study barriers which are labeled [REDACTED].

#### 9.7 CONCOMITANT THERAPY

Pertinent concomitant therapy is documented on [REDACTED] and [REDACTED].

#### 9.8 SUBJECT VISITS AND EVALUATION METHODS

The subject is enrolled into the eight (8) week [REDACTED] comprised of the Initial [REDACTED] Visit, the Mid-[REDACTED] Visit, and the Final [REDACTED] Visit. If during the [REDACTED] the subject experiences a PSC, they are immediately moved into the four (4) week [REDACTED] which is comprised of a Mid-[REDACTED] Visit, and a Final [REDACTED] Visit. An extra visit at any point during the study may also be necessary. Procedures for each visit are [REDACTED] listed in [REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

#### 9.9 SUBJECT / CAREGIVER INSTRUCTIONS

Subjects receive [REDACTED] in each box of study barriers. The subject also receives [REDACTED] including a phone number in order to reach the Investigator or designee. Subject is instructed to call the Investigator if peristomal skin condition changes. The subject may need to attend an extra in-person visit. [REDACTED] [REDACTED] also points out the importance of noting anything that has changed about the peristomal skin, and use of barrier, accessories, or other treatments.

#### 9.10 COMPLIANCE

Site personnel and study subjects are expected to fully comply with the protocol and study procedures. If the site personnel or subjects deviate from the protocol at any point, [REDACTED] is completed. Sites are monitored for compliance. If a site is found to have multiple deviations, corrective action or re-training may be necessary.

#### 9.11 PROCEDURES FOR SUBJECT DISCONTINUATION

Subjects electing to discontinue from the study for personal or other reasons are required to return all study materials and may be requested to schedule a final evaluation visit. The discontinuation of any subject following the Initial [REDACTED] Visit is documented using [REDACTED].

#### 9.12 INVESTIGATOR RESPONSIBILITIES

It is the responsibility of the Investigator to follow applicable Good Clinical Practice Guidelines and regulations including compliance with the protocol, recruiting and enrolling of appropriate subjects, properly storing and accounting for study barriers, ensuring adequate medical care is provided to subjects, properly obtaining Informed Consent, properly reporting Adverse Events, and maintaining all study related documents for a minimum of 2 years once informed from the Sponsor that the study is officially closed. The Investigator is responsible for providing source documentation that verifies the inclusion/exclusion criteria has been sufficiently met.

#### 9.13 SPONSOR RESPONSIBILITIES

It is the responsibility of Hollister to oversee the overall conduct of the trial and verify study procedures are adhered to by the Investigator. Hollister may transfer any or all trial-related duties and functions to a CRO, but the ultimate

responsibility for the quality and integrity of the study data resides with the sponsor.

## 10.0 ADVERSE EVENTS

### Anticipated Adverse Events

There is a small possibility that the subject may experience low level irritation of the peristomal skin. [REDACTED]

[REDACTED] Moderate or severe irritation is an anticipated Adverse Event.

### Unanticipated Events

An unanticipated adverse event occurs when the nature, severity or frequency of the event is not consistent with the known or foreseeable risk of the anticipated adverse events associated with the study barrier or procedures involved with this research.

### Serious Adverse Events

A serious adverse event is one that results in death, results in life-threatening illness or injury, requires in-patient hospitalization or prolongation of hospitalization, results in medical intervention to prevent permanent impairment, or results in permanent impairment of body structure or function. There are no serious adverse device events anticipated in this study.

### Handling of Adverse Events

Upon study enrollment, all subjects are informed to notify the Investigator immediately if they experience any study-related problems. The Investigator will determine if an adverse event has occurred and if it was related to the study barrier and the stoma and/or skin around the stoma. Adverse events are documented on [REDACTED] within the EDC system. The Investigator indicates if the adverse event is related to the study barrier by marking "possibly", "probably", or "definitely" on the Adverse Event Form. The Investigator also indicates if the Adverse Event is related to the stoma and/or peristomal skin. Subjects who report health problems may be directed to seek care from their healthcare provider or emergency room as appropriate.

All Adverse Events are followed to determine resolution [REDACTED] by the Investigator and the Adverse Event form is updated to indicate date of resolution. If at any point, the Investigator determines the subject should no longer remain on the study barrier, the subject should be discontinued from the study.

### Reporting of Adverse Events

Unanticipated device events and serious adverse events must be reported by the Investigator through the EDC system [REDACTED] by documenting on [REDACTED].



Serious adverse events must be reported to the Ethics Committee or Institutional Review Board, if appropriate, [REDACTED] or according to the Investigative site's Standard Operating Procedures.

## 11.0 DATA MANAGEMENT

It is the responsibility of the Investigator to ensure the completeness and accuracy of the Case Report Forms. It is the responsibility of the Investigator and the monitor to resolve any data queries recorded in the CRFs. All attachments are collected by the Sponsor except [REDACTED]

The Sponsor implements edit checks on the eCRF to enforce data entry guidelines, data consistency, and compliance to the protocol and regulatory requirements. The Investigator or designee is responsible for entering study data on the eCRFs, including data from the Quality of Life Questionnaire paper form completed by the subject during the visit. The Sponsor tracks eCRFs and reviews them for completeness, the presence of mandatory values, consistency, and dated electronic signatures. The Sponsor generates data clarification queries during the review process to ensure data quality. Once the Investigator or designee have provided acceptable responses to the queries and implemented the changes on the eCRFs, the Sponsor closes the queries with the appropriate resolution status. At the end of the study, the database is locked and the data is released for reporting and statistical analysis.

All required signatures on the eCRF are provided electronically by the Investigator or designee. Access to the eCRF for data entry and signature is controlled by user identification and password, which are provided by the Sponsor or designee. Investigators and their personnel are trained, by Sponsor and/or a designated CRO, in the use of eCRFs and application of electronic signatures before the start of the study.

Because it is extremely important to have proper data collection in a timely manner, the Investigator or designee and subjects complete the eCRFs on an ongoing basis. It is expected that the eCRFs for a particular subject are reviewed and completed by the Investigator within [REDACTED] of the subject's completion of the visit.

A limited supply of paper CRFs are provided to the site and can be used to collect data in the event of a loss of power or internet connection. Once power or internet connection is restored, the Investigator or designee enters the data into the EDC system and retains the original source documents in the study binder for monitoring.

## 12.0 STATISTICAL METHODS

### 12.1 ANALYSIS PRINCIPLES

All tests of the effect of treatment on outcome will be conducted for [REDACTED] the intent-to-treat population [REDACTED]. The analyses datasets will include data from randomized subjects only; subjects who are not randomized (i.e. screen failed) will be excluded from analysis.

### 12.2 ANALYSIS POPULATIONS

#### Intent-to-treat (ITT)

The ITT population will consist of all enrolled subjects who have been randomized to a study arm. Subjects will be analyzed in the arm to which they were randomized regardless of whether they received the assigned treatment and irrespective of any protocol deviations or violations.

[REDACTED]

[REDACTED]

### 12.3 INCOMPLETE FOLLOW-UP AND MISSING DATA

In the event that a subject does not complete the full eight weeks of the [REDACTED], or in the event of a PSC the full four weeks of the [REDACTED], the complete set of data available for that subject prior to loss-to-follow-up will be used for analysis. If there is missing data, there will be no imputation performed.

### 12.4 COVARIATE ADJUSTMENT

The primary statistical analysis of total cost of care will be adjusted for, obesity (defined via BMI), ostomy type, stomal age (defined as weeks after surgery), and presence of a hernia. This is to account for the potential variability in the data induced by these covariates. All other analyses will be unadjusted.

### 12.5 MULTI-CENTER ADJUSTMENT

Multiple centers/sites will contribute data to this study. Given the variance in standard of care between sites, the primary analysis will be adjusted for site variability. This will be done by including a categorical site covariate in the primary analysis model. The secondary [REDACTED] objectives will not be adjusted for site.

## 12.6 MULTIPLE COMPARISONS AND MULTIPLICITY

[REDACTED]),  
Dunnnett's test, [REDACTED] will be used to assess whether there is any significant difference between [REDACTED] as they relate to the primary objective. A Bonferroni correction will be used to adjust the secondary endpoint. All other analytical results, unless explicitly stated, will be assessed against an unadjusted alpha of 0.05.

## 13.0 STATISTICAL ANALYSIS

### 13.1 ANALYSIS OF PRIMARY OBJECTIVE

Total cost of care is defined as all stoma related costs accrued through the duration of the study period. Health care resource utilization data collected to support this objective includes treatments related to stoma and/or PSCs (topical medications, clinic visits, accessory use, etc.), social impact of stoma and/or PSCs (e.g. missed work/appointments), hospitalizations, ER visits, physician/clinic visits, ostomy-related medication use and therapies, and barrier utilization (not including pouch utilization). [REDACTED]

[REDACTED] A corresponding country specific unit cost or reasonable estimate (when data is not available) will be assigned to each of the health care resource units listed above. Total cost of care will be calculated by multiplying the units of health care resources by the corresponding country specific resource unit cost and then summing costs across the study period.

The primary objective will be analyzed via an analysis of covariance (ANCOVA) model comparing the mean daily total cost of care between the treatment ([REDACTED]) and control ([REDACTED]) arms. The model will be adjusted for the covariates listed in Section 12.4, site location, and relevant demographic variables. Formally, the null and alternative hypotheses being evaluated are:

- a) Null: No difference in the mean total cost of care for 12 weeks between [REDACTED] and control i.e.  $H_0: \mu_{Test} = \mu_{Control}$  vs.
- b) Alternative: The mean total cost of care for 12 weeks for [REDACTED] is not equal to that of the control i.e.  $H_A: \mu_{Test} \neq \mu_{Control}$ .

[REDACTED]

[REDACTED]



3. Given assumptions 1 and 2, this results in a difference in mean total cost of care for the [REDACTED] and control arms of [REDACTED].
4. Using Meisner's costs of PSC according to level of severity [REDACTED] for 50% of the population, the estimate of the standard deviation for total cost of care is [REDACTED]

Using the estimates above the sample size required for to achieve 80% power with a 2.5% type 1 ( $\alpha$ ) error would be 72 per arm completed for the primary endpoint and 93 completed per arm for the secondary endpoint. In order to cover both primary and secondary endpoints, an initial sample size of 93 completed per arm was chosen. Based on the findings of the first interim analysis with 92 subjects [REDACTED] the sample size has been increased to 105 subjects per arm.

### 13.5 INTERIM ANALYSIS

Given the uncertainty in the effect size estimates used to create the initial sample size requirement, this study employs an adaptive design. While the initial sample size was estimated based on available published data, the impact [REDACTED] will have in this population is not well known. Due to this limited knowledge, the data was analyzed once 92 subjects [REDACTED] were completed in each arm. Based on the interim findings it was determined that [REDACTED] and the sample size requires an increase to 105 subjects per arm to maintain 80% conditional power. [REDACTED]

[REDACTED] To allow for early stopping and a re-evaluation of sample size an additional interim analysis will be performed once 76( $\pm$ 5) subjects per arm have completed. The general approach of the adaptive design has been derived from Mehta and Pocock [6]. [REDACTED]

## 14.0 FINAL REPORT

The Sponsor is responsible for issuing a final report to the study sites. It is the responsibility of the Investigator to provide a final report to the IRB/EC, as required.

### **15.0 MONITORING**

A qualified Hollister Incorporated monitor or designee(s) monitor(s) the study.

### **16.0 AMENDMENT PROCEDURES**

The sponsor is responsible for initiating any protocol amendments. Approval of the amendment must be obtained by the EC or IRB prior to implementation. Investigator(s) are notified of the changes, and a copy of the amendment is kept in the study file.

### **17.0 ATTACHMENTS**



## 18.0 REFERENCES

1. Jemec GB, Martins L, Claessens I, et al. (2011) Assessing peristomal skin changes in ostomy patients: validation of the Ostomy Skin Tool. *British Journal of Dermatology*. Volume 164, Issue 2, pages 330–335. doi: 10.1111/j.1365-2133.2010.10093.x
2. Jemec, G.B., & Nybaek, H. (2008). Peristomal skin problems account for more than one in three visits to ostomy nurses. *Br J Dermatol*, 159, 1211-1211
3. Pittman, J., Rawl, S.M., Schmidt, C.M., Grant, M., Ko, C.Y., Wendel, C., & Krouse, R.S. (2008). Demographic and clinical factors related to ostomy complications and quality of life in veterans with an ostomy. *J Wound Ostomy Continence Nurs*, 35, 493-503
4. Meisner S, Lehur P-A, Moran B, et al. (2012) Peristomal Skin Complications Are Common, Expensive, and Difficult to Manage: A Population Based Cost Modeling Study. *PLoS ONE*. Volume 7, Issue 5, e37813. doi:10.1371/journal.pone.0037813
5. [REDACTED]
6. Mehta CR and Pocock SJ. (2011) Adaptive increase in sample size when interim results are promising: a practical guide with examples. *Statistics in Medicine*. Volume 30, Issue 28, pages 3267-84. doi: 10.1002/sim.4102.

## 19.0 INVESTIGATOR SIGNATURE

I have read the foregoing protocol and agree to conduct the study as outlined herein.

Investigator's Signature \_\_\_\_\_ Date: \_\_\_\_\_