



Protocol 5855-I

Assessment of

[REDACTED] [REDACTED] ET Tube Fastener

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Protocol Number: 5855-I

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Caution: Investigational device, limited by Federal (US) and Canadian law to investigational use. (if applicable)

1.0 STUDY SYNOPSIS

Name and address of Sponsor: Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048
USA

Hollister Study Lead: [REDACTED]

Investigator(s)/Study Center(s): United States [REDACTED]

Objective(s):

The objective of this study is to assess the acceptability and usability of the study product during use.

Study Design:

This is a multiple site prospective assessment of the study product in the ICU setting.

Study Period:

The study is comprised of each subject wearing one study product until the study product either needs to be changed or is no longer required by the subject.

Target Number of Subjects:

The sample size for this study is at least thirty (30) subjects.

Eligibility Criteria:

Study subjects who meet the inclusion and exclusion criteria are recruited by the Investigator or designee from the patient population requiring endotracheal tube care with subglottic suctioning. Subjects or their authorized representative must be willing to sign an informed consent document and comply with study parameters.

Study Product:

The [REDACTED] is designed to hold a standard or subglottic ET tube and help reduce the potential for occlusion (blockage) of the tube. In this study, the study product holds only ET tubes with subglottic suctioning capability sizes 6.0-8.0mm.

Statistics Methods:

Study data will be presented in their entirety or summarized using descriptive statistics. No hypothesis tests or other statistical analyses are planned.

Sample Size and Power:

A sample size of 30 subjects was chosen based on a literature review of two comparable sample size studies.

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2.0 ABBREVIATIONS AND TERMS

- **AE – Adverse Event**
- [REDACTED] – a medical device that holds a standard endotracheal tube during oral intubation
- [REDACTED] – a medical device that holds a standard endotracheal tube or one with integrated subglottic suction capability during oral intubation
- **CRF – Case Report Form**
- **CRO – Contract Research Organization**
- **EC – Ethics Committee**
- **eCRF – Electronic Case Report Form**
- **EDC – Electronic Data Capture**; a method used for electronic documentation of study procedures and data.
- **ET Tube – Endotracheal Tube** including the subglottic lumen and pilot line
- **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.
- **ICH – International Conference on Harmonization**
- **ICU – Intensive Care Unit**
- **IFU – Instructions for Use**
- **IRB – Institutional Review Board**
- **LAR – Legally Authorized Representative** – individual(s) who are legally authorized under state and federal law to consent to research participation on behalf of a designated person
- **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.

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.

4.0 INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

This is a multiple site prospective assessment of the study product in ICU settings. The study is comprised of each subject wearing one study product until the device either needs to be changed or is no longer required by the subject.

5.0 BACKGROUND/RATIONALE

Endotracheal intubation is the placement of a flexible tube into the trachea via the nose or mouth, primarily the mouth. The primary purpose of intubation is to establish and maintain

an open airway for the patient. ET tube securement with a fastener is critical for management of a patient with an ET tube in the ICU settings.

The current commercially available [REDACTED] provides a convenient way to hold an oral ET tube securely in place with an integrated tube protection sleeve. The [REDACTED] protection sleeve is designed to accommodate the standard ET tube sized 5.0-10.0mm. Multiple ET tubes with subglottic suction capabilities are on the market and the current AnchorFast products do not easily accommodate these tubes. With the advent and usage of these ET types in the ICUs, [REDACTED] device with tube protection sleeve has been designed to hold both the standard ET tube sized 5.0-9.0mm and ET tube with integrated subglottic suction capability sized 6.0-8.0mm.

This study is designed to assess the acceptability and usability of the study product by clinicians caring for an orally intubated patient using an ET tube with integrated subglottic suction capability.

6.0 STUDY OBJECTIVE

6.1 Objective

The objective of this study is to assess the acceptability and usability of the study product during use.

7.0 STUDY PRODUCT

7.1 INVESTIGATIONAL DEVICES

The United States Food and Drug Administration (FDA) classify endotracheal tube holders under regulation 21 CFR 868.5770. As such, AFGS is categorized as a Class I device. Health Canada classifies AFGS as a Class I device with the Preferred Name Code (PNC) of 73CBH. Class I devices: (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 the study devices are non-significant risk devices.

This non-significant risk clinical study, including the Informed Consent, will be reviewed by the institution's EC or IRB in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56 and/or conformance to Health Canada Subsection 80(3) and Section 81 of the Medical Devices Regulations. EC or IRB approval will be obtained prior to study initiation at all study sites, as applicable.

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

The study materials are oral endotracheal tube fasteners with adhesive skin barriers, adjustable neckband, and an updated tube protection sleeve. The devices are manufactured by Hollister Incorporated under protocol number [REDACTED], and released under standard manufacturing controls. [REDACTED]

All study materials are assessed by Biomaterials Safety and found to be safe for their intended use as documented in [REDACTED]

Study product will be labeled:

Manufactured by Hollister Incorporated
Libertyville, IL 60048 USA
Protocol 5855-I
Rx Only

[REDACTED]

1 Unit



CAUTION – Investigational Device

Limited by Federal Law for Investigational Use Only

Not for Sale

Instrument de recherché

Réservé uniquement à l'usage de chercheurs compétents

Expiration date and Lot numbers are displayed on the package of the study product and are based on manufacturing date of study product.

The devices are supplied non-sterile and individually packaged. All study materials are stored in a secure location at room temperature. Extreme hot or cold temperatures should be avoided.

7.3 RESPONSIBILITY FOR PRODUCT CONTROL, RETURN AND DISPOSAL

A [REDACTED] is maintained at the site. Used study product is disposed of as normal sanitary waste. If a study product fails, the Investigator or designee returns the study product that failed to the Sponsor within [REDACTED] unless otherwise notified. Unused study product is either returned to the Sponsor or destroyed by the site according to Sponsor's instructions.

7.4 INSTRUCTIONS FOR USE OF INVESTIGATIONAL PRODUCT

Study product is applied by the Investigator or designee according to the [REDACTED]
[REDACTED]

8.0 STUDY DESIGN

8.1 STUDY PERIOD

This is a multiple site prospective assessment of the study product in ICU settings. The study is comprised of each subject wearing one study product until the study product either needs to be changed or is no longer required by the subject, per [REDACTED]
[REDACTED]. Subjects who meet the inclusion and exclusion criteria may enroll into the study.

9.0 STUDY SUBJECTS

9.1 INCLUSION CRITERIA

- a) Is 18 years of age or older and require oral tracheal intubation with subglottic ET tube size 6.0-8.0mm.
- b) Requires the use of a bite block (ex. [REDACTED], B&B Medical, etc.) per the hospital's standard of care
- c) Has intact skin on and around application site, including cheeks and lips
- d) Oral cavity is free of open sores, ulcers, wounds, and lesions
- e) Subject or LAR able to provide informed consent for the study
- f) Is qualified to participate in the opinion of the Investigator, or designee

9.2 EXCLUSION CRITERIA

- a) Has actual or perceived loose teeth, is without teeth, or is unable to wear upper dentures.
- b) Has facial hair that interferes with the adhesion of the skin barrier pads
- c) Has a clinically significant skin disease or condition, or damaged skin on the application site, such as psoriasis, eczema, atopic dermatitis, active cancer, sores, sunburns, scars, moles
- d) Has a medical condition, surgery or a procedure that prevents the proper application of the device, including placement of the neck strap.
- e) Has a known or stated allergy to adhesives
- f) Currently is participating in any clinical study which may affect the performance of the device

9.3 SUBJECT TREATMENT AND CARE

All subject care is consistent with standard health care practices. No treatment is withheld or altered during the course of the study.

9.4 STUDY STOPPING RULES

If [REDACTED] of enrolled subjects are discontinued due to reasons related to the study product, the Sponsor will assess if the study should be continued.

10.0 STUDY PROCEDURES

10.1 RECRUITMENT/SUBJECT IDENTIFICATION PROCEDURE

Subjects who meet the stated inclusion and exclusion criteria are recruited by the Investigator or designee. At least thirty (30) subjects are enrolled.

Subjects are assigned an identification code by study personnel. [REDACTED]

[REDACTED] All data forms identify the subject by this identification only. All study data is confidential and kept in a secure location. The Subject ID is documented on [REDACTED]

10.2 ENROLLMENT

Enrollment follows Informed Consent (see Section 10.3) but both may occur during the same visit. The Investigator, or designee confirms Inclusion and Exclusion Criteria (listed in Sections 9.1 and 9.2) prior to enrolling the subject.

10.3 INFORMED CONSENT

Written informed consent is obtained from all qualified subjects or the subject's LAR prior to enrolling in the study. Subjects or the subject's LAR have the study explained to them by the Investigator or designee, read the Informed Consent form, have the opportunity to ask questions, and sign the approved Informed Consent form prior to any protocol procedures. The subject (or their LAR) is given a signed copy of the Informed Consent form. Written consent to use Personal Health Information (PHI) under HIPAA (USA) or according to Canadian regional Healthcare Privacy Laws is obtained.

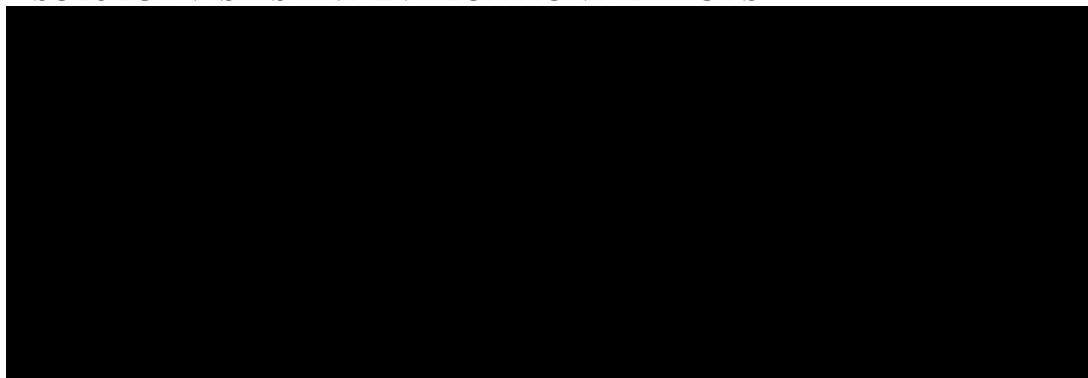
10.4 BLINDING

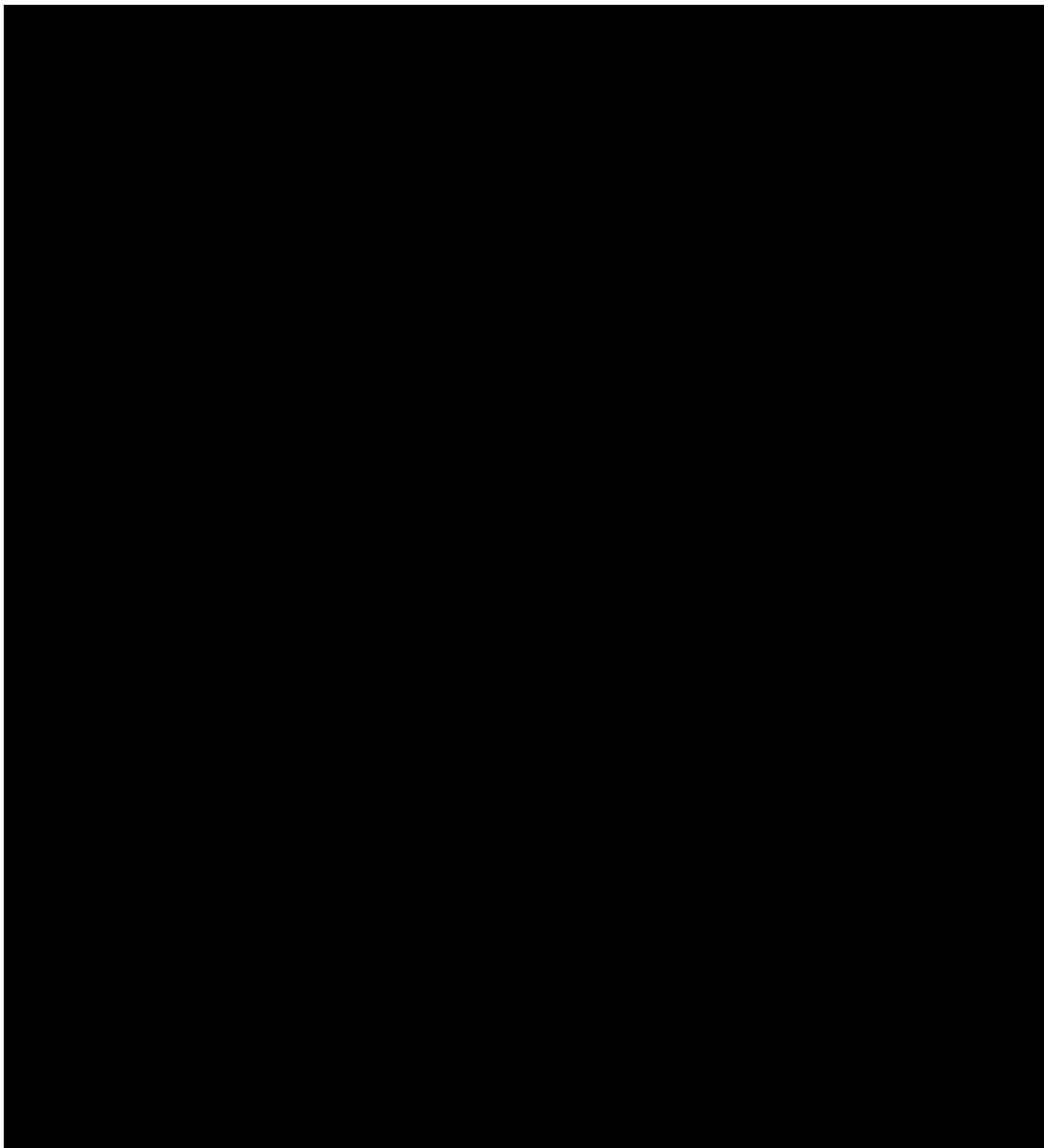
This is an open label study and there is no blinding.

10.5 PRIOR AND CONCOMITANT THERAPY

Concomitant therapy is not relevant to this study and is not collected.

10.6 SUBJECT VISITS AND EVALUATION METHODS





10.7 SUBJECT / CAREGIVER INSTRUCTIONS

All subject care is consistent with standard health care practices. No treatment is withheld or altered during the course of the study. The Investigator or designee uses the study product's instructions for use [REDACTED]

10.8 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.

10.9 PROCEDURES FOR SUBJECT WITHDRAWAL

Subjects or their LAR must be informed of their right to withdraw from participation in the study at any time without prejudice. The Investigator or designee may choose to discontinue a subject from the study. Reasons for subject discontinuation include, but are not limited to, the occurrence of an adverse event (see Section 11). If the subject withdraws from the study or is discontinued by the Investigator, [REDACTED] is completed.

While being orally intubated, there is a possibility that the tongue could become swollen and/or displaced from its normal resting place and result in contact with the study product or prevent the study product from moving/shuttling properly. If in the clinician's assessment of the subject, the study product should be removed, complete a [REDACTED]. The occurrence of tongue displacement is also captured on [REDACTED].

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

10.10 INVESTIGATOR RESPONSIBILITIES

It is the responsibility of the Investigator to follow applicable ICH Good Clinical Practice Guidelines and regulations including compliance with the protocol, recruiting and enrolling of appropriate subjects, properly storing and accounting for study product, 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.

10.11 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. (ICH GCP 5.2.1)

11.0 ADVERSE EVENTS

Anticipated Adverse Events

There is a small possibility that the subject may experience mild skin irritation. This may occur with the repeated application and removal of any adhesive material currently available on the market and while noted in the study file is not considered an adverse event.

Unanticipated Adverse 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 product 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, or that result in injury or death to a fetus. There are no serious adverse related to the study product anticipated in this study.

Handling of Adverse Events

The Investigator or designee will determine if an adverse event has occurred and if it was related to the study product. Adverse events are documented on [REDACTED] within the EDC system. The Investigator or designee indicates if the adverse event is related to the study product by marking “possibly”, “probably”, or “definitely” on the Adverse Event Form.

All Adverse Events are followed to determine resolution as prescribed by the hospital’s standard of care and the Adverse Event form is updated to indicate date of resolution. If at any point, the Investigator or designee determines the subject should no longer use the study product, the subject should be discontinued from the study.

Reporting of Adverse Events

Unanticipated and serious adverse events related to the study product must be reported by the Investigator or designee through the EDC system within 24 hours by documenting on [REDACTED].

Unanticipated or serious adverse events related to the study product must be promptly reported to the EC or IRB, per their reporting procedures.

12.0 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 into the EDC system. 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 or designee within [REDACTED] hours of study product application and within [REDACTED] hours of study product removal.

The Investigator or designee enters the data into the EDC system and retains the original source documents in the study binder for the monitor to perform source document verification as needed. The Investigator agrees to maintain all study files in a secure location for a minimum of two years.

13.0 STATISTICAL ANALYSIS

13.1 DATA ANALYSIS OF OBJECTIVE

Study data will be presented in their entirety or summarized using simple descriptive statistics; any open comments obtained will be provided without analysis or interpretation. No hypothesis tests, inferences to any population or any other statistical analyses are planned. [REDACTED]

The objective will be assessed via questionnaire items relating to product application, [REDACTED] and product removal. Overall acceptability relating to general experience with the study product will also be ascertained.

13.2 SAMPLE SIZE AND POWER

The sample size of 30 was chosen based on a literature review of two comparable sample size studies. Both studies aimed at comparing effectiveness of ET tube securement techniques. In the first study, a power analysis was performed before patient enrollment that determined 17 patients would need to be enrolled to show a difference of one standard deviation from the mean between the two fixation techniques at 80% power and 5% type 1 error. The sample size of 30 patients was chosen to increase the power of results and include a larger variety of patients undergoing different surgical procedures¹. The second study, a randomized controlled study, included a sample of 90 patients with 30 in each arm to

compare the effectiveness of three ET tube securement techniques (Twill, Adhesive, and Simple Bow) with respect to ET tube slippage, external jugular pressure measurement, oral mucosa and facial integrity and patient satisfaction after the fixation method². Details regarding the power, type 1 error, and effect size sought were not provided.

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 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

[REDACTED]

18.0 CITATIONS

1. Buckley, J., Brown, A., Shin, J., Rodgers, K. & Hoftman, N. (2016) A Comparison of the Haider Tube-Guard® Endotracheal Tube Holder Versus Adhesive Tape to Determine if This Novel Device Can reduce Endotracheal tube Movement and Prevent Unplanned Extubation. *Anesthesia and Analgesia* 122(5):1439-1443.
2. Mohammed, H & Hassan, M. (2015). Endotracheal tube securements: Effectiveness of three techniques among orally intubated patients. *Egyptian Journal of Chest Diseases and Tuberculosis* 64:183-196

19.0 INVESTIGATOR SIGNATURE

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

Investigator's Signature _____ Date: _____

Acknowledgement Signature
for Hollister Incorporated _____ Date: _____