SINGLE SITE, PROSPECTIVE, PHASE I STUDY, SAFETY AND EFFICACY OF ENTERAL FEEDING TUBE STOMA SITE ACCESSORY

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Funded by: Cleveland Clinic Innovations

Version Number: V3_11JAN2023

NCT 05288556

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Definitions

Aspiration: Inhalation of gastric contents into the lungs.

Body temperature norms: A temperature over 100.4°F (38°C) most often means you have a fever caused by an infection or illness. Normal body temperature varies by person, age, activity, and time of day. The average normal body temperature is generally accepted as 98.6°F (37°C). Some studies have shown that the "normal" body temperature can have a wide range, from 97°F (36.1°C) to 99°F (37.2°C).

Cellulitis: Skin infection
Dermatitis: Irritation of the skin.

Device Migration/Buried Bumper: Uncommon complication of PEG when the internal fixation device migrates alongside the stoma tract out of the stomach.

Erosion: An erosion is an eating away of a surface. For example, a skin erosion is a loss of part or all of the epidermis (the outer layer) leaving a raw, sensitive surface.

Gastrocolocutaneous fistula: A rare complication of PEG, which occurs when a PEG tube penetrates the interposed colon between the abdominal wall and the stomach during the initial insertion of PEG

Hemorrhage: A heavy discharge of blood from a blood vessel. A hemorrhage may be "external" and visible on the outside of the body or "internal," where there is no sign of bleeding outside the body.

MyChart: Electronic platform for secure patient access to electronic medical records

Necrosis: Irreversible injury to cells as a result of encounters with noxious stimuli invariably leads to cell death. Such noxious stimuli include infectious agents (bacteria, viruses, fungi, parasites,) oxygen deprivation or hypoxia, and extreme environmental conditions such as heat, radiation, or exposure to ultraviolet irradiation. The resulting death is known as necrosis, a term that is usually distinguished from the other major consequence of irreversible injury, known as cell death by apoptosis

Necrotizing fasciitis: A type of soft tissue infection. It can destroy the tissue in your skin and muscles as well as subcutaneous tissue, which is the tissue beneath your skin.
Necrotizing fasciitis is most commonly caused by an infection with group A *Streptococcus*, commonly known as “flesh-eating bacteria.” This is the fastest moving form of the infection. When this infection is caused by other types of bacteria, it typically doesn’t progress as quickly and isn’t quite as dangerous.

PEG: percutaneous endoscopic gastrostomy

Percutaneous: An approach or entry by puncture or minor incision, of instrumentation through the skin or mucous membrane and any other body layers necessary to reach and visualize the site of the procedure.

Peritonitis: Inflammation of the peritoneum, the membrane that lines the inner abdominal wall and covers the organs within the abdomen, usually due to a bacterial or fungal infection.

Stoma: An opening on the abdomen that can be connected to your digestive system. It may lie fairly flat to your body or protrude out.

Tissue Granulation: Also known as connective tissue or scar tissue that forms on the surface of a wound when the wound is healing. *If too much granulation tissue forms, leaving an excess of bumpy, shiny, red tissue, this can actually hinder the healing process and lead to a long-lasting wound.

Acronyms

AE: Adverse Event (See also SAE)

C5: Cleveland Clinic Coordinating Center for Clinical Research or C5: C5Research, Cleveland Clinic Coordinating Center for Clinical Research, is an associated research organization (ARO) that provides clinical trial services to the pharmaceutical, biotechnology, and medical device industries.

DPEJ: Direct percutaneous endoscopic jejunostomy

EN: Enteral Nutrition is nutrition therapy where liquid formula or food is delivered to the gastrointestinal (GI) tract to supplement or provide all caloric intake by a tube for patients with a functional GI tract.

FDA: Food and Drug Administration

HEN: Home enteral nutrition is EN delivered in the home setting

IRB: Institutional Review Board. An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. The Cleveland Clinic IRB has the authority to approve, require modifications to secure approval and disapprove all research activities overseen and conducted by the organization. CC employee may not conduct human based research if the CC IRB has not approved it.

PEG: Percutaneous endoscopic gastrostomy and PEGJ, with jejunal extension is an endoscopic medical procedure in which a tube (PEG tube) is passed into a patient's stomach through the abdominal wall, most commonly to provide a means of feeding when oral intake is not adequate.

PROMIS 10: A 10 question patient reported outcomes measurement of quality of life

QOL: Quality of Life

SAE: Serious Adverse Event

SOC: Standard of Care

WOCBP: Women of Childbearing Potential

Protocol Synopsis

Study Title	Single site, Prospective, Phase I Study, Safety and Efficacy of Enteral Feeding Tube Stoma Site Accessory
Investigational Accessory	Cleveland Clinic Innovations: Provisional Patent filed with drafted Claims: Serial No. 62/736,637 with U.S. Patent Office on SEP 26, 2018
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Study Purpose	The purpose of the study is to collect safety and efficacy data on the performance of the study stoma site accessory when used to prevent abdominal wall leakage for patients with a long term feeding tube. This accessory has been developed by the Cleveland Clinic and will be used for the first time in human subjects according to the labeled indication for clinical use in accordance with the Manufacturer's Instructions for Use based on other similar, FDA approved gastrostomy and jejunostomy enteral feeding tube accessory components. After providing informed consent, eligible patients will receive a study stoma site accessory during a feeding tube replacement procedure the patient is scheduled to have as a standard of care procedure.
Study Design	Single site, prospective, phase I, non-randomized safety and efficacy of feeding tube stoma site accessory for patients with enteral feeding tubes.
Primary Endpoints	Safety and efficacy of the study stoma site accessory as evidenced by successful study accessory placement at time of initial replacement procedure, post procedure adverse events including recurrence of any documented pre-procedure [abdominal surface] condition and repeat intervention up to 6 months after the initial replacement procedure.
Secondary Endpoints	Patient Quality of Life is hypothesized to improve significantly with leak reduction, therefore various Quality of Life questionnaires will be collected at baseline, 2 weeks and 6 months or early termination.
Patient Population	Inclusion Criteria: • Male or female, aged ≥22 and ≤85. Note: Because the study accessory is designed for adult use, participants <22 years of age are excluded but will be eligible for future trials, if applicable. • Ability to understand and the willingness to sign a written informed consent document.

	• Patients with existing gastrostomy and jejunostomy enteral feeding tubes, placed ≥ 3 months, undergoing replacement of feeding tube inpatient or outpatient. • Willing to adhere to placement of study stoma site accessory and ability to take oral temperature at specified times. • Stated willingness to comply with all study procedures and availability for the duration of the study. • Willing to adhere to removal of study stoma site accessory at mo. 6 <u>Exclusion Criteria</u> • Patient requires general anesthesia in an OR for tube changes • Current use of steroids (any dose) daily ≥ 3 months including, but not limited to: prednisone, prednisolone, methylprednisolone, cyclosporine • Current use of Immunosuppressants including, but not limited to: azathioprine, mycophenolate. • BMI ≥ 40 • Non-English speaking patients. • Pregnant Women. • Known allergic reactions to components of the study stoma site accessory: Medical Grade Silicone as described in Technical Data Prospectus from Dow Corning Corporation. • Treatment with another investigational drug or device within 6 months of screening/baseline. • Uncontrolled illness, recent open abdominal surgery or social situations that in the opinion of the investigative team would limit compliance with study requirements, including, but not limited to: o Ongoing or active infection o Psychiatric illness o Unable to self-report o Not ambulatory and incapable of carrying out all self-care • Unsuccessful study accessory placement at initial replacement procedure
Number of Subjects	The study will enroll until 10 patients have had successful study stoma site accessory placement and reached the 2 week research follow-up visit.
Number of Sites	1
Sample Size Justification	The sample size is 10 subjects. No formal sample size calculations were performed for pre-market safety and efficacy data.
Study Hypothesis	The study is a pilot trial to access feasibility and safety with the aim to improve patient quality of life using pre and post measures. Patient quality of life assessment will be collected at baseline and 6 months for comparison.

Duration of Study	Expected enrollment period is 12 months. Follow-up duration is 6 months from initial replacement procedure with follow-up research visit at week 2 and phone calls at weeks 4 and 6 and month 6 and research visits at months 3, 4 and 6. The study will conclude 6 months from the enrollment of the last subject.
Study Monitoring	Site monitoring will be performed internally by Cleveland Clinic Clinical Research Personnel.

Purpose

The purpose of the study is to collect safety and efficacy data on the performance of the study stoma site accessory when used to prevent abdominal wall leakage for patients with a long term, ≥ 3 months, enteral feeding tube including, gastrostomy or jejunostomy tubes. This study accessory has been developed by the Cleveland Clinic (CC) for clinical use in human subjects and will be used according to the labeled indication and in accordance with the Manufacturer's Instructions for Use based on other similar, Food and Drug Administration (FDA) approved enteral tube stoma site accessory components. Patients receiving the study accessory will also be asked pre-procedure and post-procedure quality of life questions to identify change in quality of life. After providing informed consent, eligible patients will receive a study stoma site accessory during an upcoming enteral tube replacement procedure the patient is scheduled to have as a standard of care procedure.

Background

Nutrition therapy where liquid formula or food is delivered to the gastrointestinal tract to supplement or provide all caloric intake by a tube for patients with a functional GI tract is known as enteral nutrition (EN). Since the first use of endoscopic gastrostomy tube for EN was documented in late 1970 by Gauderer et al.[1] use of several additional types of feeding tubes have been widely reported. Tubes, such as, percutaneous endoscopic gastrostomy (PEG,) PEG with jejunal extension (PEGJ) and direct percutaneous endoscopic jejunostomy (DPEJ) have been reported to offer long term solutions for nutrient and medication delivery to patients with intact and functional GI tracts [2] who have a variety of underlying diseases. Design modifications allowing the placement procedure to be technically easier and safer have been made over the years but very few modifications have been made to the kit component parts throughout this same period of time. [2]

The study stoma site accessory, for regulatory purposes, can be considered an accessory to a newly replaced feeding tube. The accessory materials and method of use are substantially similar to commercially available feeding tubes used with PEG, PEGJ and DPEJ. We believe that, since the study stoma site accessory attaches to the external portion of a newly replaced feeding tube at a previously established stoma site and inserts 1 cm into the stoma, which is not as deep as the actual feeding tube, it poses no significant risk to its users. By potentially decreasing the leakage from the edges of the tube and the friction of the tube against the skin, it does not pose a risk of local infection. It is made of commercially available, FDA cleared materials commonly used for enteral feeding tubes and tube components that the patient already has in place. The study accessory will be sterilized and packaged at the Cleveland Clinic through a validated process and provided specific numerical identification for documented tracking.

This study will evaluate the safety and efficacy of the study stoma site accessory used in place of a commercially available feeding tube accessory, i.e., button or flange, at the time of a standard of care replacement procedure the patient is scheduled to have at Cleveland Clinic's Main Campus. Patients enrolled in the study will participate for a period of 6 months with outcomes assessed using our protocol patient questionnaires. The length of the study will be approximately 12-18 months to allow for recruitment, and 6 months of ongoing follow-up after the last patient is enrolled.

KNOWN POTENTIAL RISKS

The literature supports that the number of patients with enteral feeding tubes is increasing. [3] [4] Although enteral feeding tubes are considered to be a safe intervention that can be placed in an outpatient setting or, at the patient's hospital bedside, procedure-related complications are common. [5] The type and frequency vary depending on the specific access route of the enteral feeding tube but all complications fall into four major categories: mechanical, gastrointestinal, infectious, and metabolic. [6] Overall, complications associated with percutaneous endoscopic gastrostomy vary from 16% to 70%, though the majority of these are minor. [7]

Complications, such as maceration from leakage of gastric contents around the tube [7] resulting from a mechanical problem, e.g., secondary displacement of the feeding tube, is a problem described as a minor complication, however, it is a common complaint and a major symptom that causes the patient, family or caregiver to request a gastrostomy feeding tube change. Upwards of 78% of patients with long-term gastrostomy tube placement report leakage and 12%-39% of these patients consider it problematic.[5] Leakage frequently occurs within a few days of a gastrostomy tube placement but may occur at any time in patients with a mature gastrostomy tract. Management of co-morbidities and measures to address skin breakdown are cited as common treatment. [6]

Participating study patients are anticipated to include a broad range of disease processes for which they will be receiving EN or home enteral nutrition (HEN). Significant patient co-morbidities and their underlying challenges, which contribute to the 1%-3% of reported major complications [5] will be taken into consideration for study patients and their continuing medical care and reporting of adverse events. However, major complications requiring repeat intervention compromising the study stoma site accessory will result in early termination of patient participation. The study will focus on the known minor risks of tube leakage [5] associated with feeding tube components.

<u>Minor</u>

- Tube leakage
    - Stoma site abdominal surface complications
        - Contact irritation/dermatitis
        - Cellulitis
        - Tissue granulation
        - Redness/tenderness
        - Pain at stoma site
        - Local infection
        - Bleeding
        - Necrosis

- Tube blockage
- Pain at the PEG site

Major Risks

- Aspiration
- Peritonitis
- Hemorrhage
- Device Migration/Buried Bumper Syndrome
- Gastrocolocutaneous fistula
- Wound Infection
- Necrotizing fasciitis
- Inadvertent removal of PEG tube

Unknown Risk

- Allergic Reaction
- Long term risks

KNOWN POTENTIAL BENEFITS

Enteral access placement and replacement is possible without requiring patient hospital admission. [9] Nutrition therapy administered to outpatients is known as home enteral nutrition (HEN). Studies reveal significant clinical benefits with EN and HEN support, including improved wound healing, reduction in complications and overall improvement in clinical outcomes and mortality.[8] Due to these benefits, the prevalence of HEN continues to increase worldwide.[8] In the United States, it has been more difficult to ascertain the prevalence of HEN given our healthcare insurance model of Medicare and commercial providers, but as recently as 2013, was reported to have increased from 463 per million population in 1995 to 1385 per million.[8][9]

Review of literature includes considerably less on patient's perspectives concerning the role of enteral tube feeding and how the associated complications effect quality of life (QOL). A 2019 systematic literature review examining the role of enteral tube feeding on patients' QOL [10] supports the notion that even though patient's medical conditions greatly influence their outcomes, enteral feeding tubes are effective in improving patients' QOL. [10]

Our study aims to reduce the complication of tube leakage through modified component design allowing better adherence, flexibility and management of the enteral feeding tube device. The adjustment of study stoma site accessory management is expected to improve clinical outcomes by reducing stoma site abdominal surface complications, reducing frequency of emergency room visits, unplanned physician visits and hospital admission and improving the patient and caregiver experience and quality of life.

- Reduction of stoma site abdominal surface complications
    - Blanching cellulitis
    - Bleeding

  - Contact irritation/dermatitis
  - Erosion/Skin breakdown
  - Local infection
  - Necrosis
  - Pain at stoma site
  - Redness/tenderness
  - Tissue granulation
- Consistent nutritional support
- Fewer emergency room visits or hospital admissions
- Improved quality of life
  - Fewer dressing changes
  - Less discomfort and pain
  - Improved social opportunities
  - Improved psychological outlook

ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Factors believed to influence risks and benefits impacting patient outcomes for the identified categories of complications, e.g., mechanical, gastrointestinal, infectious and metabolic, are influenced by differences in types of gastrostomy tubes and enteral feeding methods as well as by individual patient medical conditions. [10]

Our study will include patients with these varying influences, anticipating adverse events (AEs) will vary widely. Consequently, AEs will potentially impact study participation following the initial feeding tube replacement procedure with the use of the study stoma site accessory.

Adverse Events and Serious Adverse Events Reporting

The study will collect and document Adverse Events (AEs) and Serious Adverse Events (SAEs) for the 4 major groups associated with EN feeding tubes , mechanical, gastrointestinal, infectious, and metabolic, during the entire study period for relationship to the study stoma site accessory and for reporting to the Institutional Review Board (IRB) according to the IRB guidelines. AEs that are determined by the Principal Investigator, or his/her designee to be related or possibly related to the study accessory will be documented with focus on the safety and efficacy of the accessory. If the Principal Investigator, or his/her designee concludes the study accessory is malfunctioning, inadvertently removed or compromised or, for any reason, determined to be a greater risk than benefit, e.g., the patient has an allergic reaction, and is replaced by a commercially available accessory, the patient will be exited from the study by early termination. All AEs will be treated or referred to a medical specialist for standard of care treatment the same as if the patient was the recipient of a commercially approved accessory.

There may be no direct benefit to the patient. The study accessory materials and method of use is intended to reduce stoma site leakage that causes abdominal surface complications, thus improving functional outcomes with less complications and improved quality of life when used with replacement of commercially available PEG, PEGJ and DPEJ tubes. Potential for outcomes improvement extends to patient safety, patient and caregiver quality of life [6] and financial improvement since loss of enteral access functionality diminishes patient safety and results in financial losses to healthcare systems with additional visits to emergency rooms or hospital admissions [6] [11.]

Study Accessory and Technique Description

OVERALL DESIGN

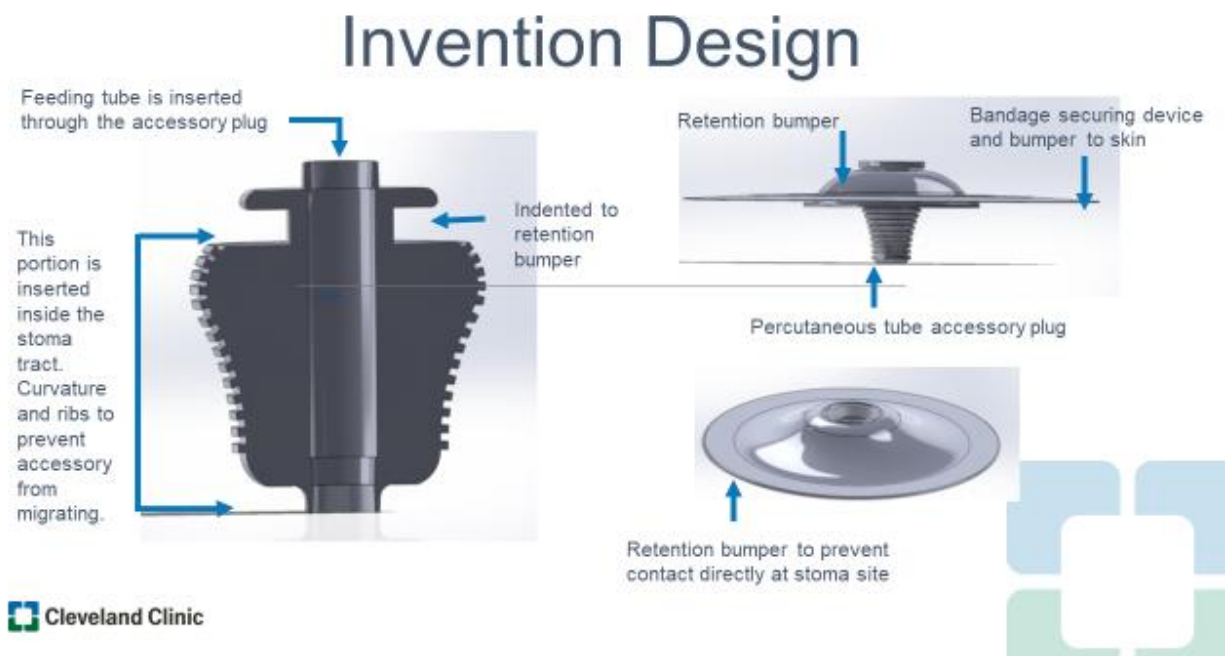


Fig 1. From Left; ribbed accessory plug, retention bumper side view and view from top

This is a single site, prospective, phase 1 pilot study designed to evaluate the safety and efficacy of the study stoma site accessory when used to prevent abdominal wall leakage for patients with a long term, ≥ 3 months, enteral feeding tube, including gastrostomy or jejunostomy tubes. Outcomes of these patients will be evaluated based on collected measures of successful study accessory placement, incidence of reported adverse events and quality of life measures. Patients enrolled in the study will participate for a period of 6 months with outcomes assessed using our protocol patient questionnaires. The length of the study will be approximately 12-18 months to allow for recruitment, and 6 months of ongoing follow-up after the last patient is enrolled.

Proof of concept testing on the study stoma site accessory showed the accessory is effective at preventing leakage. Prototypes for the test were constructed by Cleveland Clinic Medical Device Solutions. A bench model of an artificial bladder with a balloon inside was used to simulate a stomach (Fig 2).

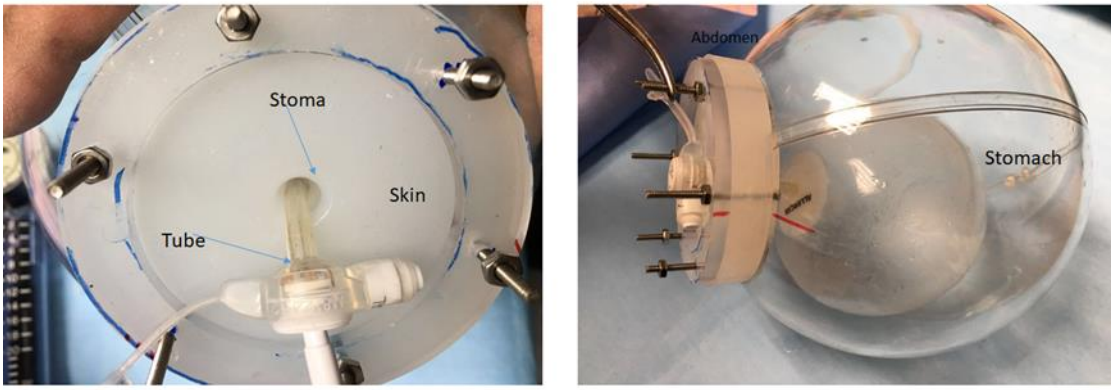


Fig 2. Control test without study accessory

For the control, a low profile feeding tube was placed in the stoma site without the study accessory. The bladder was filled with yellow dyed water and the balloon was inflated to increase pressure to the point of leakage.

In the control test without the study accessory, there was no pressure change nor build up because leakage occurred immediately through the space between "stoma" and the tube (Fig 2). For the bench test, the low profile feeding tube end was inserted into the study stoma site accessory and the assembly was placed in the bench model. With the study stoma site accessory, the bench model was pressurized up to 100mmHg. No leakage formed at the "Stoma Site." Leakage was seen from other parts of the model, such as the screws (Fig 3).

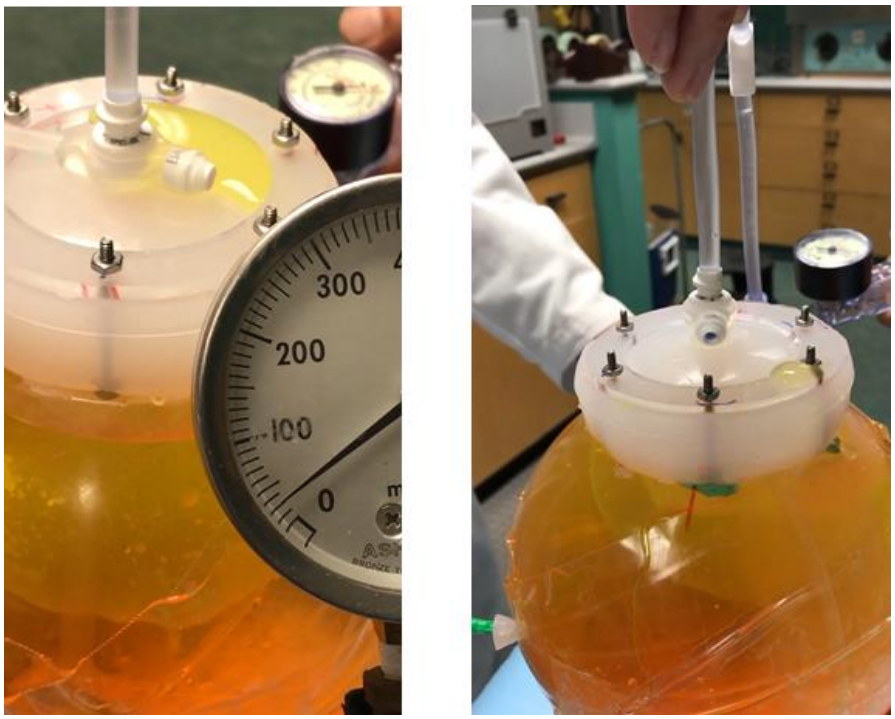


Fig 3. Test setup with study accessory

PRODUCT INFORMATION

- **Custom components:** Accessory retention bumper and plug with introducer
- **Material:** Dow Corning® QP1-250 Liquid Silicone Rubber
- **Manufacturing:** Injection molded in soft, medical-grade silicone. Two-part, platinum catalyzed.
- **Quality:** Raw materials are lot traced by ISO 9001-certified manufacturer, Proto Labs
- **Biocompatibility:** Raw material has been tested by the manufacturer to USP Class VI biocompatibility standards including:
    - Cytotoxicity
    - Skin Sensitization
    - 7-Day Implantation (systemic toxicity)
- **Sterilization:** Liquid silicone rubbers are regularly used in implanted medical devices subject to ethylene oxide sterilization. ETO has been demonstrated to have no adverse effects on the material. [12] [13]

STUDY INTERVENTION ADMINISTRATION

The study stoma site accessory consists of two components made of silicone elastomers specifically designed for the fabrication of medical devices and device components. The study stoma site accessory is compatible with commercially available enteral nutrition feeding tubes ranging from 16F to 20F and is intended for use during EN feeding tube standard practice replacement procedures. A rigid introducer, also made of silicone elastomers is included with each study accessory retention bumper and plug. The accessory components are supplied by Proto Labs and intended for one-time use. All three components will follow the ETO sterilization process and will be packaged and labeled as individual kits for accountability.

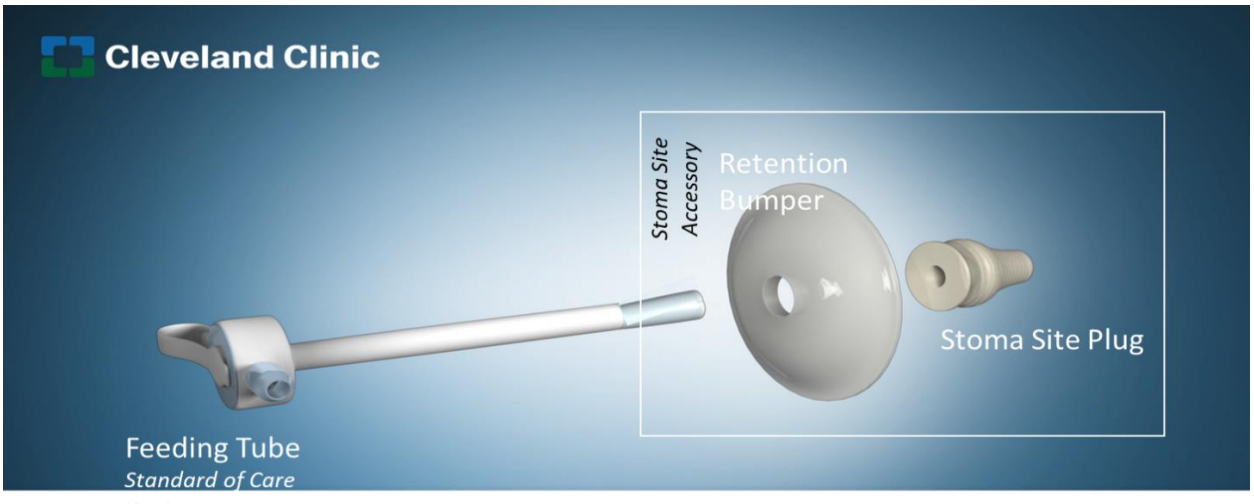


Fig.4 Stoma site accessory retention bumper and plug shown with SOC feeding tube

Instructions for use:

It is recommended that the tube French size selected be similar in size to the tube being removed, unless otherwise indicated by the physician. For questions or information about the tube's Instructions for Use (IFU) and a list of complete complications, please refer to the specific manufacturer's Instructions for Use. The following steps (1 through 5) are generalizable and not specific to any single manufacturer's IFU:

1. Select the appropriate size tube, remove from the package and inspect for any visible defects.

2. Using the manufacturer's specific type syringe, inflate the balloon through the balloon port using the specified mL units of sterile or distilled water for a standard balloon.

3. Remove the syringe and verify balloon integrity by gently squeezing the balloon to check for leaks. Visually inspect the balloon to verify symmetry. Symmetry may be achieved by gently rolling the balloon between the fingers. Reinsert the syringe and remove all the water from the balloon.

4. Using the syringe, flush water through balloon port to verify patency.

5. Lubricate the distal end of the tube with water-soluble lubricant. Do not use mineral oil or petroleum jelly.

The following steps (6 through 14) are specific to incorporating the accessory placement subsequent to the standard Instructions for Use for tube placement. It is recommended that the accessory plug size selected be compatible in size to the tubing French size being placed, e.g., 16 Fr. The accessory plug component will be in a separate package, labeled by size compatibility. One retention bumper and one introducer will share one package since they are identical respectively in size.

6. Remove the selected accessory components from sterile packaging and inspect for any visible defects. If defects are observed, do not use. Obtain another package.

7. Place retention bumper over proximal end of plug.

8. Slide the retention bumper so it is seated within the indentation at the proximal end of the accessory (see figure 5 below.)

9. Lubricate the Introducer with water-soluble lubricant. Do not use mineral oil or petroleum jelly.

10. Insert the proximal end of the Introducer (which is the slimmer end) into the distal end of the tube until the flared end of the Introducer is abutted to the end of the tube (see figure 6.)

11. With the Introducer in place, orient the plug so the proximal end is inserted first over the tapered Introducer.

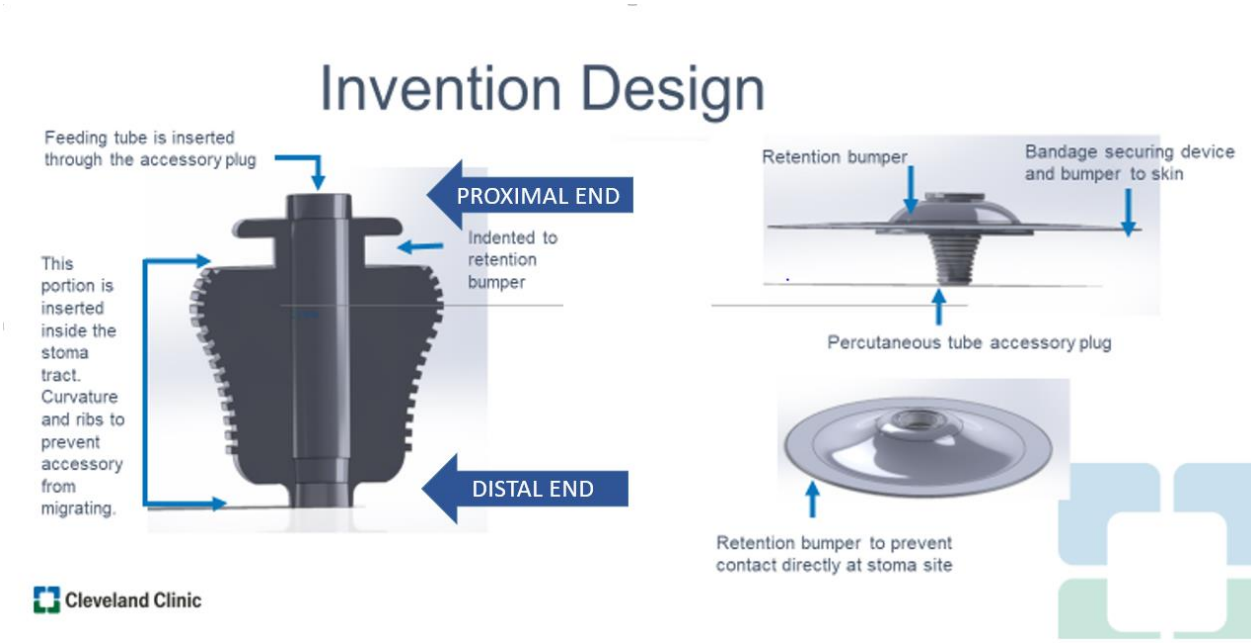
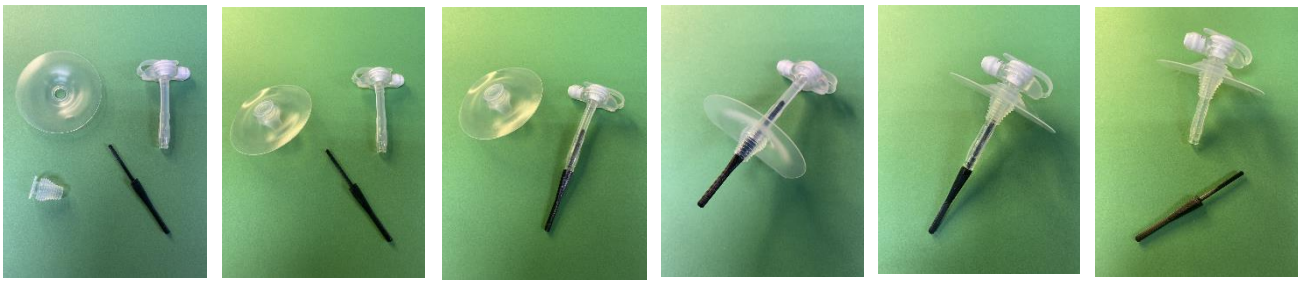


Fig 5



Figs.6
From left, Introducer used to pull through SOC feeding tube to finished assembly with Introducer removed and the stoma site accessory plug in place at the right position.

12. Continue sliding the plug through the Introducer's body until it reaches the shaft of the tube and is at least an inch away from the Introducer.

13. Remove the Introducer from the lumen of the tube.

14. Refer to the specific manufacturers IFU to insert the tube in the stoma track and to inflate the balloon of the tube.

15. Once tube has been placed and the balloon inflated to recommended capacity, place the accessory plug and position the bumper so that it is in contact with the skin to ensure secure placement.

16. Check around the stoma for gastric leakage. If the stoma leaks, follow the manufacturer's recommended instructions to adjust balloon fill volume.

17. Follow the standard procedural guidelines for cleansing the skin around the stoma site.

    For tube care instructions, nutrition and medication administration, refer to the specific tube manufacturer's Instructions for Use.

Description of each component:

- Stoma site accessory plug
  - Surrounds the feeding tube
  - Curvature and ribs to prevent accessory component from migrating
  - Indented to retention bumper

- Retention accessory bumper
  - Cupped, to allow greater mobility of flexible tubing

- Introducer
  - A double tapered plastic rod to assist the stoma site accessory plug onto the feeding tube. One end will insert into the distal end of the feeding tube. The accessory plug will be put onto the opposite end of the introducer and slide toward feeding tube.

Duration of implant or exposure

The average life span of PEG tubes is reported to be three months with tube degradation being the primary reason for replacement.[5] The study stoma site accessory is anticipated to be compatible with this duration based on similar SOC flange and button accessories. Maximum duration is unknown but could be significantly longer. Many commercial insurers will cover up to four tube replacements per calendar or rolling year. For study purposes the maximum length of time during which data will be collected for tubing change, as ordered by the treating physician, will be 6 months from initial study accessory placement.

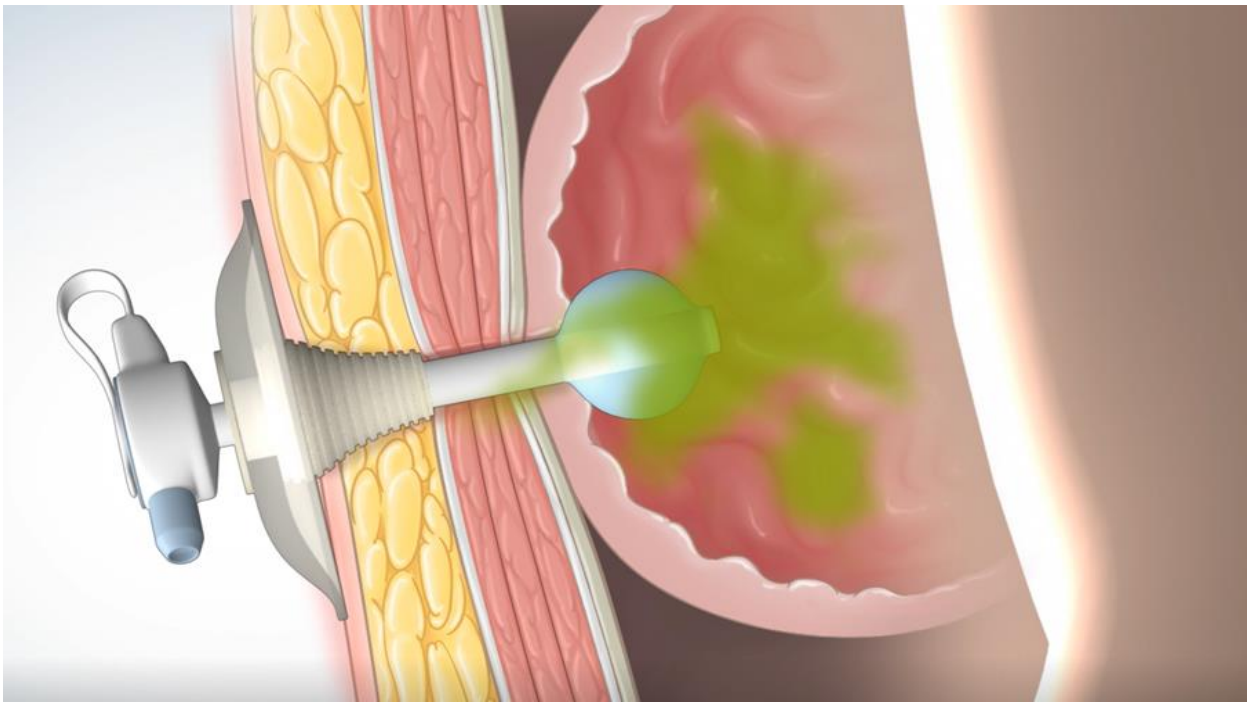


Fig7. The study stoma site accessory depicting prevention of stomach acid from leaking on the abdominal wall.

Labeling/Accessory Tracking

The study stoma site accessory components will be sterilized by Cleveland Clinic's OR Surgical Processing Department. One retention bumper and one introducer will share one package since they are identical respectively in size. The accessory plug component will be in a separate package, labeled by size compatibility, e.g., "16 Fr, 20 Fr". All components will be double wrapped, barcoded and assembled as kits. Kits will be delivered for accountability and storage at room temperature in the Internal Medicine Research Unit (IMRU) located on the Cleveland Clinic (CC) Main Campus study site. Kits will be secured in a locked cabinet, accessible only to study personnel. Study personnel will maintain and monitor usage on a Case Report Form. IMRU study personnel can readily provide the study stoma site accessory kits to any procedure area on the Main Campus at short notice.

Manufacturing Information

Dow Corning® QP1-250

Silicone

Dow Corning Corporation

PROSPECTOR®
www.ulprospector.com

Technical Data

Product Description

Liquid Silicone Rubber materials for device and component fabrication in the healthcare industry.

APPLICATIONS

Dow Corning® QP1-2XX Liquid Silicone Rubbers (LSRs) are platinum-catalyzed, heat-cured materials designed for the fabrication of medical devices and device components and for short term applications.

DESCRIPTION

Dow Corning QP1-2XX LSRs are a series of two-part platinum-catalyzed silicone elastomers specifically designed for liquid injection molding. Each elastomer is supplied in a two-part kit (Part A and Part B), equal portions (by weight) of which must be thoroughly blended together prior to use. The elastomer is thermally cured via an addition-cure (platinum-catalyzed) reaction. When blended and cured as indicated, the resulting elastomer consists of cross-linked dimethyl and methyl-vinyl siloxane copolymers and reinforcing silica.

The Dow Corning QP1-2XX LSRs are available in a range of nominal hardness from 30 to 70, Durometer-Shore A. The elastomers can be used without any post cure; although, if necessary, this may be employed to stabilize the final properties.Furthermore, the cured elastomers are heat stable up to 204°C (400°F), can be autoclaved, and exhibit high gas permeability compared with most thermoset elastomers and thermoplastics.

General

Material Status	• Commercial: Active		
Literature [1]	• Technical Datasheet (English)		
Search for UL Yellow Card	• Dow Corning Corporation • Dow Corning®		
Availability	• Africa & Middle East • Asia Pacific	• Europe • Latin America	• North America
Features	• Autoclavable • Fast Cure • Fast Molding Cycle	• Food Contact Acceptable • Good Colorability • Good Processability	• High Gas Permeability • Low Viscosity • Non-Blooming
Uses	• Medical/Healthcare Applications		
Agency Ratings	• USP Class VI		
Processing Method	• Injection Molding		

Physical	Nominal Value (English)	Nominal Value (SI)	Test Method
Density / Specific Gravity	1.12	1.12 g/cm³	ASTM D792
Viscosity [3]			
Part A	167 Pa·s	167 Pa·s	
Part B	152 Pa·s	152 Pa·s	
Elastomers	**Nominal Value (English)**	**Nominal Value (SI)**	**Test Method**
Tensile Stress (100% Strain)	305 psi	2.10 MPa	ASTM D412
Tensile Strength	1200 psi	8.30 MPa	ASTM D412
Tensile Elongation (Break)	500 %	500 %	ASTM D412
Tear Strength [4]	271 lbf/in	47.4 kN/m	ASTM D624
Hardness	**Nominal Value (English)**	**Nominal Value (SI)**	**Test Method**
Durometer Hardness (Shore A)	51	51	ASTM D2240

Notes

[1] These links provide you with access to supplier literature. We work hard to keep them up to date; however you may find the most current literature from the supplier.

[2] Typical properties: these are not to be construed as specifications.

[3] 10/s

[4] Die B

Form No. TDS-297761-en

Document Created: Tuesday, May 1, 2018
Added to Prospector: March 2016
Last Updated: 3/29/2016

TABLE 1: SCHEDULE OF EVENTS

Evaluation	Screening / Baseline	Day 1	Week 2 Follow-Up[8, 9] (+/- 3 days)	Phone Call Follow-up Weeks 4, 6 (+/- 3 days) unscheduled	Months 3 & 4 Follow-Up(+/- 3 days)[8, 9]	Early Termination [1, 7, 8, 10]	Month 6 Follow-Up [8,9] (+/- 7 days)
Informed Consent	X						
Assess Eligibility Inclusion/Exclusion	X						
Enrollment	X						
General Assessment of the Abdomen with stoma site inspection. Vital signs (Ht, Wt, BMI, temp, BP if avail) [1,7]	X		X		X	X	X
Quality Of Life Questionnaire PROMIS 10[2]	X					X	X
Tobacco use questionnaire	X					X	X
Characteristics of pain and leakage questionnaire[2]	X		X	X	X	X	X
Abdominal Pictures[3,7]	X		X		X		
Medications of Interest[4]	X		X	X	X	X	X
Accessory Placement [5]		X					
Dispense Oral Temperature Thermometer and Temperature Log[6]	X						
Review Oral Temperature Log[6,7]			X		X		
Adverse Events			X	X	X	X	X
Study completion telephone follow-up						X	X
Accessory Removal						X	X

1. Documentation of general assessment with stoma site inspection and vitals at baseline as standard of care for ambulatory services will be collected from the patient's electronic chart. Vitals at week 2 and months 3, 4 will be collected from the patients chart or as reported by the patient for virtual visits. Month 6 vitals will be collected from the patient's electronic chart. Documentation of general assessment with stoma site inspection and vitals for hospital bedside or ambulatory services at early termination between Day 1 and Month 6 follow-up will be collected from the patient's electronic chart.
2. Month 6 questionnaires can be completed over the phone. If the patient leaves the study prior to month 6, study members will attempt to collect QOL questionnaires PROMIS 10 and characteristics of pain and leakage for outcomes reporting.
3. Abdominal Pictures will be taken using Haiku software on CC issued cellphones and uploaded securely to the patient electronic chart. Pictures can be sent by the patient in MyChart for virtual visits scheduled through MyChart. Virtual visit abdominal pictures and screen captures are optional if not feasible to obtain at any study time points. Pictures are optional for study participation.
4. Medications of interest are primarily antibiotics.
5. Intervention at the study site occurs within 30 days of Informed Consent.
6. Daily temperature log to be completed by patient on days 3 through 10 and reported at week 2 and at months 3 and 4. Temperatures are self-recorded for all virtual visits; collection of temperature log is not required. The patient will be asked to call their treating physician if the patient is reporting a temperature over 100.4°F .
7. General assessment of the abdomen with stoma site inspection occurs at baseline evaluation, week 2 and months 3, 4 and 6 research visits and early termination. The week 2 and months 3 and 4 research visit may be scheduled in person or virtually. When the exam is virtual, the patient will be asked to report body temperature and vitals and allow/provide a visual of the abdomen for assessment and pictures when applicable. Pictures are optional for study participation.
8. Additional labs, radiology or other medically necessary procedures at week 2, months 3, 4 and 6 or early study termination as determined by the attending physician are considered standard of care. Patients will be asked to contact the study coordinator within 48 hours of a qualifying event, e.g., removal of study stoma site accessory that occurs at an external medical facility leading to participant early study termination.
9. Study personnel will schedule a research visit for months 3, 4 and 6 Study visits week 2 and at months 3 and 4 can be conducted virtually or in person. The month 6 study visit will be conducted in person for purposes of accessory removal.
10. Patients will be asked to contact study personnel to schedule in-person study accessory removal when removal is voluntary.

Number of patients

Ten patients to be recruited at one site, the Cleveland Clinic Main Campus. Patients who are prematurely withdrawn prior to week 2 follow-up will be replaced until the total number of patients exceeding week 2 equals 10.

Study Duration

Expected enrollment period is 6 months, follow-up duration is 6 months from initial replacement procedure with follow-up visit at week 2 +/- 3 days and phone calls at weeks 4, 6 and early termination and months 3, 4 and 6 study visits. The study will conclude at 6 months from the last enrolled patient.

Patients undergoing intervention, surgical or repeat EN feeding tube replacement, after the initial replacement procedure that compromises the study stoma site accessory integrity will no longer be followed but will be included in the analysis of the endpoints until the time of intervention.

Stoma site study accessory removal with standard of care enteral feeding tube replacement and patient QOLs will be completed at month 6. The Investigator also must provide follow-up medical care for all patients who are prematurely withdrawn from the study or, must refer them for appropriate ongoing care.

Patient Characteristics

Inclusion criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

- Male or female, aged ≥22 and ≤85 Note: Because the study accessory is designed for adult use participants <22 years of age are excluded but will be eligible for future trials, if applicable
- Ability to understand and the willingness to sign a written informed consent document
- Patients with existing gastrostomy and jejunostomy enteral feeding tubes, placed ≥ 3 months, undergoing replacement of feeding tube inpatient or outpatient
- Willing to adhere to placement of study stoma site accessory and ability to take oral temperature at specified times
- Stated willingness to comply with all study procedures and availability for the duration of the study
- Willing to adhere to removal of study stoma site accessory at month 6

Exclusion criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

- Patient requires general anesthesia in an OR for tube changes
- Current use of steroids (any dose) daily ≥ 3 months including, but not limited to: prednisone, prednisolone, methylprednisolone, cyclosporine
- Current use of Immunosuppressants including, but not limited to: azathioprine, mycophenolate.
- BMI ≥ 40
- Non-English speaking patients
- Pregnant Women
- Known allergic reactions to components of the study stoma site accessory: Medical Grade Silicone as described in Appendix A: Technical Data Prospectus from Dow Corning Corporation
- Treatment with another investigational drug or device within 6 months of screening/baseline
- Uncontrolled illness, recent open abdominal surgery or social situations that in the opinion of the investigative team would limit compliance with study requirements, including, but not limited to:
    - Ongoing or active infection
    - Psychiatric illness
    - Unable to self-report
    - Not ambulatory and incapable of carrying out all self-care
    - Unsuccessful stoma site study accessory placement at time of initial replacement procedure

CONCOMITANT THERAPY

For this protocol, a prescription medication is defined as a medication that can be prescribed only by a properly authorized/licensed clinician. Medications will be reported in the Case Report Form (CRF) including concomitant prescription medications. Concomitant prescription medication will be reviewed on an initial basis to confirm eligibility and at weeks 2, 4, 6 and months 3, 4 and 6 or at early termination. The independent effects of concomitant therapies will be compared with the study intervention, clinical outcomes and patient reported outcomes, pre and post procedure, to ascertain if there are direct effects on the study primary and secondary endpoints.
Patient electronic charts or outside records will be collected for review.
Use of steroids (any dose) daily ≥ 3 months or Immunosuppressant(s) will be considered an exclusion. Following enrollment and successful placement of study stoma site accessory during initial feeding tube replacement procedure, medications prescribed will be reported and collected for steroids or immunosuppressants including, but not limited to:

- Prednisone
- Prednisolone
- Methylprednisolone
- Cyclosporine
- Azathioprine
- Mycophenolate

STRATEGIES FOR RECRUITMENT AND RETENTION

Patients at a single site will be recruited over a period of 12 months until recruitment reaches 10 patients who have completed the week 2 research visit. Participation based on referrals will be made by the study team investigators and site staff associate physicians who would otherwise refer a patient for a replacement enteral feeding tube. Referring physicians are primarily Gastroenterology physicians who have expertise in some of the underlying diseases for which patients are on enteral nutrition therapy and may include patients with history of gastroparesis, bariatric bypass procedures or abdominal cancers. Study team investigators are represented by internal medicine, geriatrics and general surgery specialties who are knowledgeable of these diseases and are knowledgeable of the inclusion/exclusion criteria, patient history of illness and medical needs. General surgery study team members are experienced with enteral nutrition feeding tube replacement procedure for the various types of tubes; percutaneous endoscopic gastrostomy (PEG,) PEG with jejunal extension (PEGJ) and direct percutaneous endoscopic jejunostomy (DPEJ.) Internal medicine and gastroenterology staff have a solid understanding of the complications, needs and management of the patient study population. The eligible patient population will be approached by study personnel both in-patient and outpatient to discuss the Informed Consent process in a manner that assures privacy and confidentiality to ascertain and document that the patient acknowledges understanding and agrees to the study requirements. The procedure will take place within 30 days of the consent.

Patients will include male or female, aged ≥22 and ≤85 with ability to understand and the willingness to sign a written informed consent document. Because the accessory is designed for adult use, participants <22 years of age are excluded but will be eligible for future trials, if applicable. Patients requiring sedation for a feeding tube replacement are identified as an exclusion for this phase I, 10 patient, feasibility study.

Women of Childbearing Potential (WOCBP) will be asked at the time of consent if they are known to be pregnant. Known pregnancy is an exclusion due to the inherent physiologic changes of the female anatomy during pregnancy and the decreased ability to discern differences between study accessory

complications and pregnancy complications for analysis. WOCBP not known to be pregnant will be eligible for the replacement study stoma site accessory using standard of care (SOC) precautions and electronic chart documentation and will be asked to use an effective method of contraception for the duration of study participation = 6 months +/-7 days from study intervention. Pregnancy testing is not required as SOC prior to the accessory replacement procedure or for the study. Eligible women who are scheduled for EN feeding tube replacement while in the hospital or on an outpatient basis may have a pregnancy test at the time of admission or prior to procedure as SOC. Available results will be collected from the electronic chart and if positive for pregnancy, will be considered an exclusion. Pregnancy after accessory placement will not exclude a female patient. Should a woman become pregnant or suspect she is pregnant while participating in this study, she should inform her study physician immediately. Male or female patients who have BMI ≥ 40 who present additional risks specifically related to morbid obesity will be excluded from the study due to decreased ability to discern differences in confounding risk factors.

All study team members will be trained to perform and document the Informed Consent process as well as administer the pre-procedure questionnaires Study personnel will be trained to notify the entire team at the earliest opportunity of an Informed Consent and the location and timing of the procedure so that the study accessory and oral thermometer can be delivered by trained study personnel to the appropriate location, e.g., hospital floor at bedside or endoscopy suite. Study personnel delivering study stoma site accessory and oral thermometer will confirm completion of pre-procedure questionnaires and patient understanding of the oral temperature log prior to intervention. The study accessories will be stored for use in a locked cabinet, at room temperature, in the 4C Research office located on site. From there, it can readily be provided to any area on the Main Campus at short notice. Appropriate documentation of use, including identification labels will be maintained by the site coordinator(s) in the 4C Research office on the applicable Case Report Form.

Informed Consent Process

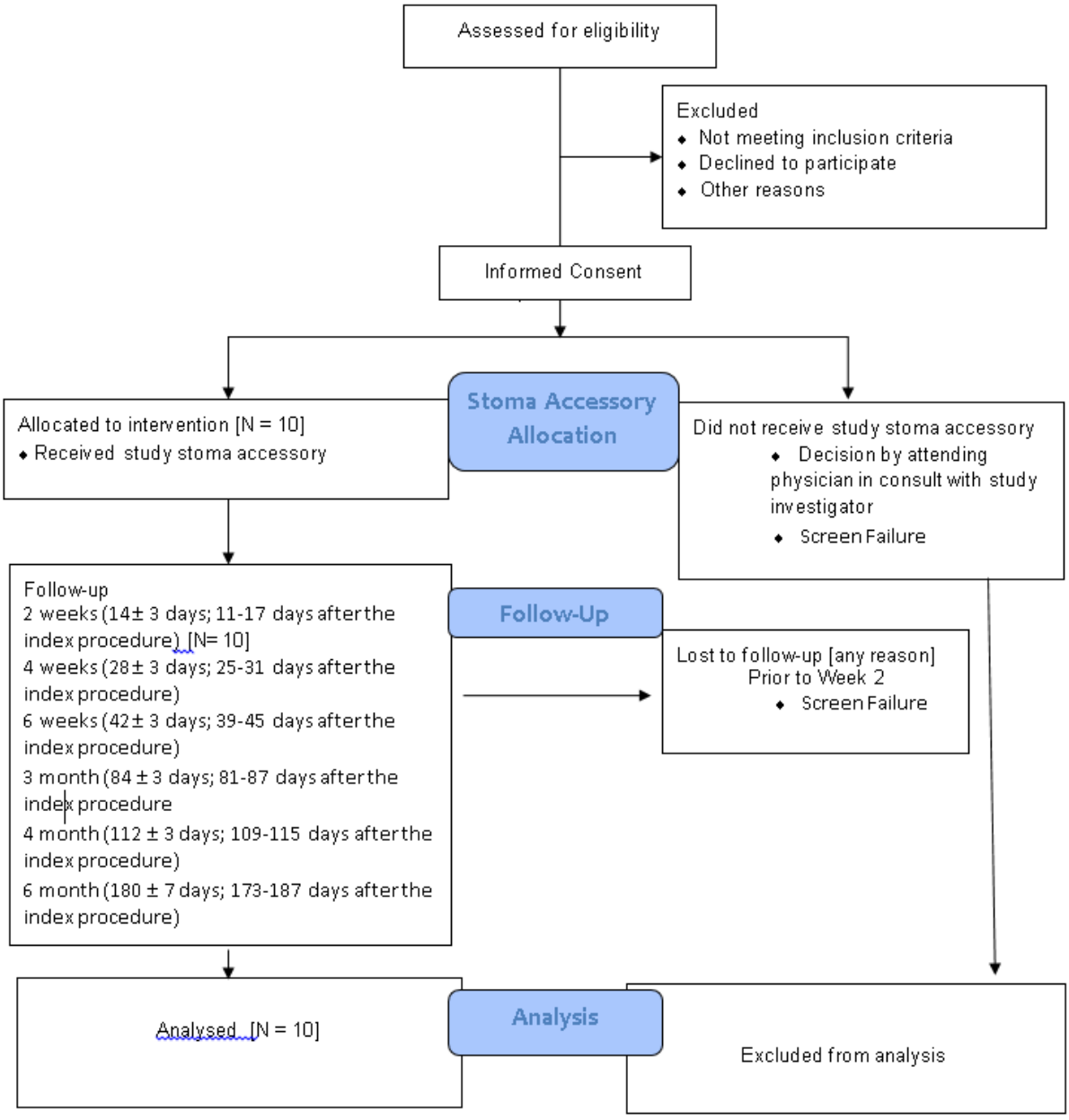
Patients meeting all of the inclusion criteria and none of the exclusion criteria may be invited to participate in the study. . The study plan, potential risks and benefits of participation in the study and authorization for optional abdominal photos at the time of consent, week 2, and months 3 and 4, seen in Table 1, page 22, will be explained to all patients eligible for entry into the study. Patients can be consented up to 30 days in advance of their scheduled replacement procedure, using the IRB approved consent. Patients who require sedation for the procedure will not be eligible for the study stoma site accessory. All patients should be familiar with the Informed Consent and its content, and have been given opportunity to have their questions answered about the study prior to signing the Informed Consent as well as given the choice to decline consent. Each patient who decides to participate will be required to sign an Informed Consent document prior to any study-related procedures, including additional authorization or opt-out for abdominal photos. Patients can sign the Informed Consent in advance and be declined participation on the day of procedure if the attending physician determines them unfit for replacement with the study stoma site accessory.

If new information is obtained after a patient receives treatment with the device, patients who have not exited the study will be informed about the new information and will be re-consented at the discretion of the site's IRB.

Patients will undergo a baseline evaluation including the following:

- General assessment of the Abdomen with stoma site inspection
- Clinical assessments for confirmation of inclusion / exclusion criteria

ENROLLMENT SCHEMA



An overview of the study activities is presented in Table 1 Schedule of Events

Follow-Up

Patients are expected to participate in this study for up to 6 months after the index procedure. The follow-up visits and phone calls should occur within the following time frames when possible. Follow-up time frames are intended as guidelines only. They are not absolute and are not intended to limit data collection due to scheduling conflicts.

2 week (14 ± 3 days; 11-17 days after the index procedure)
4 week (28 ± 3 days; 25-31 days after the index procedure)
6 weeks(42 ± 3 days; 39-45 days after the index procedure)
3 month (84 ± 3 days; 81-87 days after the index procedure)
4 month (112 ± 3 days; 109-115 days after the index procedure)
6 month (180 ± 7 days; 173-187 days after the index procedure)

The follow-up visit at 2 weeks can be scheduled as in-person or a virtual visit and will include:

- General Assessment of the abdomen with stoma site inspection
- Characteristics of pain and leakage questionnaire
- Abdominal Pictures
- Medications of Interest
- Oral Temperature Log Review
- Oral Temperature
- Adverse events

The follow-up phone calls at weeks 4, 6 and after an unscheduled visit will include the following:

- Characteristics of pain and leakage questionnaire
- Medications of Interest
- Adverse events

The follow-up visit at months 3 and 4 will be virtual or in-person and include:

- General Assessment of the abdomen with stoma site inspection
- Characteristics of pain and leakage questionnaire
- Abdominal Pictures
- Medications of Interest
- Oral Temperature
- Adverse events

The follow-up visit at month 6 will be in-person and include:

- General Assessment of the abdomen with stoma site inspection
- Feeding tube change with removal of study device and replacement with SOC tubing
- PROMIS 10
- Tobacco use questionnaire
- Characteristics of pain and leakage questionnaire
- Medications of interest
- Adverse events

If early termination occurs, study personnel will attempt to collect the following:

- General Assessment of the Abdomen with stoma site inspection
- PROMIS 10
- Tobacco use questionnaire
- Characteristics of pain and leakage questionnaire
- Medications of Interest
- Vitals

Any unscheduled visits discovered during follow-up phone calls or patient reported will be recorded on the appropriate case report form (CRF); The reason for the visit, adverse events of interest, treatments, interventions, hospitalizations and those resulting in early termination will be captured.

A Study Completion CRF should be completed at Month 6. The Investigator also must provide follow-up medical care for all patients who are prematurely withdrawn from the study, or must refer them for appropriate ongoing care.

SCREEN FAILURES

Participants who are consented to participate in the clinical trial, who are scheduled for enteral feeding tube replacement with the study stoma site accessory and who are determined by the attending clinician investigator at the time of intervention to be inappropriate candidates for anatomical or medical reason, e.g., requiring sedation, not previously ascertained during the screening procedures, are considered screen failures.

Informed consent language will include description of allowance for the study investigator to determine that the patient is not a good candidate after consent and prior to, or at the time of intervention. Determination of inappropriateness will be made in the best interest of the patient. If such determination is made, the investigator will identify the decision directly with the patient. The patient will have acknowledged and agreed to this decision as part of the Informed Consent process. The patient will understand and agree that no additional financial compensation will be provided if they are considered ineligible. The patient will have acknowledged and agreed to an alternative, standard of care replacement or other procedure to be performed in their best interest.

- Individuals who do not meet the criteria for inclusion in this trial because of a previously undetermined condition of anatomical or medical origin may be rescreened at a later date if, a) the study is still recruiting patients b) the previous condition has been resolved. Rescreened participants should be assigned the same participant number as for the initial screening.

Minimal information including demography, eligibility criteria, screen failure details and any adverse event or serious adverse event (SAE) from the time of consent up to the intervention will be collected for Consolidated Standards of Reporting Trials publishing requirements and to respond to queries from regulatory authorities.

EARLY PATIENT WITHDRAWAL/STUDY TREATMENT DISCONTINUATION

A patient may voluntarily withdraw from the study at any time either before or after undergoing the initial replacement procedure without prejudice or loss of care. The patient should notify the investigator of his/her desire to withdraw. The Principal Investigator, or his/her designee, or in consultation with multiple study team personnel, may also decide to withdraw the patient from the study at any time based on medical judgment.

A patient should be withdrawn from the study if the Principal Investigator believes, or agrees in consultation with the study team and/ or Safety Officer recommendation that continuation would be detrimental to the patient's well-being. Reasons for Study Treatment Discontinuation/Early Patient Withdrawal are:

- Withdrawal of Informed Consent, (subject's decision to withdraw for any reason).
- Any clinically significant AE/SAE(s), laboratory abnormality, and/or concurrent illness which, in the opinion of the investigator, indicates that continued treatment with study accessory and/or further participation in the study, is not in the best interest of the subject.
- Significant protocol violation.
- Protocol deviation resulting in significant patient safety risk.
- Subjects who for any reason cannot be followed and/or are unable to meet the requirements of the protocol.
- Death after consent

Patients who leave the study prior to month 6 voluntarily will be asked to schedule an in person, early termination visit for the study stoma site accessory removal and a standard of care tube replacement.

In all instances of withdrawal, the appropriate study visit and study termination data should be recorded in the electronic chart and should include the reason why the patient has been withdrawn from the study. Any data collected on the patient up to the point of withdrawal may be used in the analysis. Subjects who are prematurely withdrawn from the study prior to week 2 research follow-up will be replaced until 10 patients have been successfully recruited.

In the event a patient cannot be contacted for follow-up assessments, at least three attempts should be made to locate the patient, and these efforts will be documented. If the patient cannot be located, a lost to follow-up entry will be submitted for regulatory purposes.

COSTS AND COMPENSATION

The study stoma site accessory, week 2 interval assessments and months 3, 4 and 6 follow-up visits will be covered by the study, which will not be billed to the patient or their health insurance plan. These "research only" services that are paid for by the Clinic include: abdominal assessment not done for conventional standard care, removal of the study accessory at month 6 with replacement of standard, conventional tubing components and administration of study specific questionnaires. If additional medical services are performed during this research study that are considered to be conventional, routine clinical services that would have been performed even if the patient were not participating in the research study, these will be billed to the health insurance plan or the patient. Examples of these routine services include but are not limited to: CT scans, conventional care, drug and labs not required by the study and additional

feeding tube changes. The patient will be responsible for paying any deductibles, co-payments or co-insurance that are a normal part of their health insurance plan.

The patient may incur some expenses as a result of being in the study, such as hotel, food, bus/taxi fare and parking fees when attending scheduled or unscheduled visits. To assist with the cost of time and travel associated with study participation at CC, subjects will be paid $50.00 for the completed week 2 interval assessment and again at early study termination and months 3, 4 for completed research visits and month 6 following removal of the study accessory and completion of patient questionnaires. Patients will be provided a parking voucher for the week 2 and months 3, 4 and 6 study visits attended in-person and compensated for their time and effort toward participation at the rate of $50.[Table2] If, at any time prior to month 6, the patient experiences a repeat intervention scheduled at the Clinic with either a feeding tube change that requires removal of the study accessory and results in early termination the patient will be compensated at the rate of $50 for their time and effort toward participation and provided a parking voucher. The Clinic is paying the study doctors and the study team for their work in this study.
Subjects will be paid per the schedule below in the form of a check mailed to the patient's confirmed residence.

Study Calendar Visits	Compensation Amount
Screening/Baseline visit with Consent	
Day 1 (Accessory Placement)	
Week 2 (Research Visit Assessment)	$50.00
Week 4 (Phone Call)	
Week 6 (Phone Call)	
Month 3 (Research Visit Assessment)	$50.00
Month 4 (Research Visit Assessment)	$50.00
Unscheduled or Early Termination	$50.00
Month 6 (Research Visit with Accessory Removal and Completed Patient Questionnaires)	$50.00

Table 2 Overview of participant compensation

In the event of physical injury or illness resulting during participation in the study, medical care is available at the Cleveland Clinic, however, the Cleveland Clinic has no plans to provide free care or compensation for a patient's lost wages. The study participant and/or their insurance carrier will be responsible for all expenses related to the injury or illness.

Primary Outcome Measures

STUDY OBJECTIVES AND ENDPOINTS		
OBJECTIVES	**ENDPOINTS**	**JUSTIFICATION FOR ENDPOINTS**
Primary		
Safety and efficacy of the study accessory as evidenced by rate of successful device placement and related post procedure adverse events.	Rate of procedural success will be defined as placement of the device at the intended location, including securing of the device in place and its effectiveness at the week two [2] exam.	Demonstrate study accessory viability; its safety and efficacy for use in a general population of patients

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
The study will focus on the known minor risks of tube leakage associated with feeding tube components including recurrence of any documented pre-procedure [abdominal surface] condition, new condition or repeat intervention up to 6 months after the initial replacement procedure.	Patients will be followed up to 6 months after the index procedure. However, any patient who requires re-intervention that compromises the study stoma site accessory integrity (e.g., study accessory is removed and replaced with standard of care components or otherwise damaged) subsequent to the initial replacement procedure will no longer be followed but will be included in the analysis of the endpoints until the time of re-intervention. Rate of post-procedure adverse events to be collected from initial replacement procedure through month 6, including but not limited to: • Dermatitis • Cellulitis • Erosion • Accessory migration over 1 cm • An adverse event determined as related or possibly related • Allergic reaction to the accessory material	displaying a broad range of disease processes for which they will be receiving EN or HEN for ≥ 3 months.
Secondary		
Change in patient quality of life after intervention as self-reported by participants. Outcomes will be collected at various intervals.	Various participant reported outcomes will be collected at baseline, week 2 and month 6: • PROMIS 10, nationally validated quality of life survey tool • Alcohol/ tobacco use • Study accessory management questions • Characteristics of pain and leakage at site of study accessory placement	Demonstrated ability to predict clinical benefit to patients with enteral feeding tubes.

Table 3

Hypothesis Testing

This is not a hypothesis driven study. The study is a pilot trial to determine safety and efficacy of a feeding tube accessory and feasibility of determining improvement of patient quality of life using pre and post measures. Patient quality of life assessment will be collected at baseline and 6 months for comparison.

Data Collection and Analysis

Study related data, including patient reported outcomes and data collected from the patient electronic medical record will be entered in a password protected database by study personnel, with oversight by Cleveland Clinic Coordinating Center for Clinical Research (C5 Research). C5 Research is an Academic Research Organization (ARO.) An ARO, associated with a university and/or hospital, combines clinical and academic expertise to independently conduct clinical trials and/or to provide services to trial sponsors in the coordination of clinical trials. To protect the patient privacy, all records will be stored by a patient identifier code assigned to the patient at the time of enrollment. The database will be password protected. Only approved research team members associated with this study will have access to these records. The accumulated data will be analyzed and used for reporting purposes. Fees associated with the data capture and analysis will be paid for by the study with no cost to the patient.

Patient characteristics will be summarized as appropriate descriptive statistics. The primary and secondary endpoints will be summarized as frequencies and percentages. Ninety-five % confidence intervals will be also computed. We will also compute the lost to follow-up proportions. All analyses will be conducted with SAS 9.3 (Cary, NC).

Safety and Monitoring

A data Safety Officer (SO) will be assigned to monitor the study data collection, minimally, on a quarterly basis. The Safety Officer will be a CC staff physician, independent of the study team, who will review the accumulating data with regard to recruitment, safety and efficacy. The SO will not be involved in the conduct of this study. The data manager will summarize and report data to the SO at least quarterly, who will review the report and make recommendations to the investigators.

FDA approved, commercially available enteral feeding tube accessories have not been shown to affect mortality. The study stoma site accessory is intended for use with commercially available enteral tubes during a standard of care replacement procedure and is not believed to pose significant risk to its users. EN feeding tube device replacement is performed at CC in both ambulatory and in-hospital settings for patients with varying underlying diseases so, there are expected to be AEs and possible SAEs not related to the study stoma site accessory.

The SO will be asked to perform assessment of serious events in aggregate on a quarterly basis but may request an unscheduled review at any time for evaluation of causal link between the study stoma site accessory and any serious complications, including death. Serious events that appear to be potentially related to the study intervention will be reported to the SO within 24 hours of an investigator becoming aware of the event. The SO will be consulted regarding whether or not accrual should be suspended to allow for investigation in the occurrence of serious adverse events, particularly for those that are related or possibly related to the study accessory.

The primary study coordinator will disseminate the event and results of the SO review with the entire study team.

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