Myoelectric Activity Following Colorectal Surgery and Return of Bowel Function

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PRINCIPAL INVESTIGATOR:

Name Ira Leeds, MD
Department. Surgery – Division of Colon & Rectal Surgery
Telephone Number. 475-224-8745
Email Address ira.leeds@yale.edu

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Synopsis

Primary Objective To measure myoelectric signals with the G-Tech WPS and determine if a correlation exists between signal strength and the rate of gastrointestinal recovery following colorectal surgery. Determine the relationship between gastrointestinal myoelectrical signal strength and clinical markers of recovery such as passage of flatus/bowel movement, oral tolerance of diet, and discharge readiness.
Secondary Objective (if applicable) To measure myoelectric signals with the G-Tech WPS and determine if there are differences in signal patterns for right colon resections, left colon resections, and rectal resections.
Study Duration 12 months for data collection followed by 12 months of data analysis
Study Design This is a single-arm, prospective, non-randomized, feasibility study.
Number of Study Sites 1 (Yale New Haven Hospital)
Study Population Patients undergoing elective colorectal surgery
Number of Participants 200
Primary Outcome Variables GI functional recovery after surgery as measured by first flatus
Secondary and Exploratory Outcome Variables (if applicable) Rate of inpatient postoperative ileus; rate of readmission for post-discharge ileus; GI functional recovery as measured by first bowel movement

APPROVED BY THE YALE UNIVERSITY IRB 4/22/2022

Abbreviations

Abbreviation	Explanation
AE	Anticipated adverse event
CRF	Case report form
GI	gastrointestinal
SAE	Serious adverse event
WPS	Wireless Patch System

Glossary of Terms

Glossary	Explanation
Erythema	Reddening of the skin that is a non-specific sign of skin irritation, inflammation, or injury. It is caused by dilatation of superficial blood vessels in the skin
Myoelectric	The electric property of a muscle
Rash	A reddened inflamed skin usually temporary
Transcutaneous	Transdermal; performed through the skin

Table of Contents

Preface ..... **Error! Bookmark not defined.**

Synopsis 3

Primary Objective 3

Secondary Objective (if applicable) 3

Study Duration 3

Study Design 3

Number of Study Sites 3

Study Population 3

Number of Participants 3

Primary Outcome Variables 3

Secondary and Exploratory Outcome Variables (if applicable) 3

Abbreviations 5

Glossary of Terms 6

1 Introduction 10

1.1 Introductory Statement 10

2 Background 11

2.1.1 Device Preclinical Experience 11

2.1.2 Device Clinical Experience 11

2.2 Background/prevalence of research topic 11

3 Rationale/Significance 13

3.1 Problem Statement 13

3.2 Purpose of Study/Potential Impact 13

3.2.1 Potential Risks 13

3.2.2 Potential Benefits 14

4 Study Objectives 15

4.1 Hypothesis 15

4.2 Primary Objective 15

4.3 Secondary Objectives (if applicable) 15

5 Study Design 16

5.1 General Design Description 16
5.1.1 Study Date Range and Duration 16
5.1.2 Number of Study Sites 16
5.2 Outcome Variables 16
5.2.1 Primary Outcome Variables 16
5.2.2 Secondary and Exploratory Outcome Variables (if applicable) 16
5.3 Study Population 16
5.3.1 Number of Participants 16
5.3.2 Eligibility Criteria/Vulnerable Populations 16
6 Methods 18
6.1 Treatment – Device 18
6.1.1 Intended Use for Device (provide the following information for each device being investigated in the study) 18
6.1.2 Device Administration and Schedule 19
6.1.3 Method of Assignment/Randomization (if applicable) 19
6.1.4 Device Calibration 21
6.1.5 Storage Conditions 21
6.1.6 Concomitant therapy 21
6.1.7 Restrictions 21
6.2 Assessments 21
6.2.1 Efficacy 21
6.2.2 Safety 22
6.2.3 Adverse Events Definition and Reporting 22
6.2.4 Pharmacokinetics (if applicable) 24
6.2.5 Biomarkers (if applicable) 24
6.3 Study Procedures 24
6.3.1 Study Schedule 25
6.3.2 Informed Consent 25
6.3.3 Screening 25
6.3.4 Enrollment 25
6.3.5 On Study Visits 25

6.3.6 End of Study and Follow-up 26
6.3.7 Removal of subjects 26
6.4 Statistical Method 26
6.4.1 Statistical Design 26
6.4.2 Sample Size Considerations 26
6.4.3 Planned Analysis 27
6.4.4 Subsets and Covariates 28
6.4.5 Handling of Missing Data 28
7 Trial Administration 29
7.1 Ethical Considerations: Informed Consent/Assent and HIPAA Authorization 29
7.2 Institutional Review Board (IRB) Review 29
7.3 Subject Confidentiality 29
7.4 Deviations/Unanticipated Problems 30
7.5 Data Collection 30
7.6 Data Quality Assurance 30
7.7 Study Records 30
7.8 Access to Source 31
7.9 Data or Specimen Storage/Security 31
7.10 Retention of Records 31
7.11 Study Monitoring 31
7.12 Data Safety Monitoring Plan 31
7.13 Study Modification 31
7.14 Study Discontinuation 31
7.15 Study Completion 31
7.16 Conflict of Interest Policy 31
7.17 Funding Source 32
7.18 Publication Plan 32
8 Appendices 33
9 List of Tables 34

1 Introduction

1.1 Introductory Statement

This document is a protocol for a human research study. The purpose of this protocol is to ensure that this study is to be conducted according to ICH GCP guidelines, and according to CFR 21 Part 812, other applicable government regulations, and Institutional research policies and procedures.

2 Background

2.1.1 Device Preclinical Experience

G-Tech Medical has developed a noninvasive wireless patch system that measures electrical activity from the gastrointestinal smooth muscles on the abdominal surface.

2.1.2 Device Clinical Experience

This technology has been studied as part of several non-significant risk IRB approved studies in both adults and pediatric populations to evaluate the patterns of gastrointestinal myoelectrical signals following surgery.[20–22] The studies demonstrate that signals measured by the G-Tech Wireless patches correlate with clinical markers of postoperative recovery such as time to feeding and time to flatus following pancreaticoduodenectomy and general abdominal surgeries respectively. The study in patients undergoing pancreaticoduodenectomy procedures was conducted in collaboration with researchers at Stanford University.[20] The study demonstrated that measurement of gastric activity beginning immediately after pancreaticoduodenectomy with the G-Tech Wireless Patch System, based on the measured spectral peak near 3 cpm, could distinguish patients with shorter or longer times to diet readiness. The study demonstrated the potential utility of the G-Tech Patch System in providing objective data to identify patients who are progressing as well as, or better than expected, and those who are at risk for delayed gastric emptying. In another open, prospective study, researchers examined the use of the G-Tech Wireless Patch System in predicting time to first flatus by looking at colonic myoelectrical activity following general abdominal surgeries.[21] Patients with early flatus had stronger early colonic activity than patients with late flatus. At 36 h post-surgery, a linear fit of time to flatus vs cumulative colonic myoelectrical activity predicted first flatus as much as 5 days (± 22 h) before occurrence.

2.2 Background/prevalence of research topic

Gastrointestinal recovery after any visceral surgery is a complex dynamic process with multiple factors ranging from complexity of the surgery, degree of bowel handling and preoperative comorbidities affecting whether the recovery happens over few days, or is a slow prolonged affair lasting weeks.[1] Delays in the gastrointestinal recovery process or ileus is accompanied by distention of the abdomen, pain, nausea, vomiting and the inability to tolerate oral feeding.[2,3] Interventions to alleviate the ileus/distention include insertion or reinsertion of a nasogastric tube, instating *nil per os* and, if necessitated, parenteral

nutrition.[4] All of these factors contribute not only to patient discomfort, but extend length of stay (LOS), increase hospital resource utilization and thereby add to overall costs.[5–7]

Clinically, the markers of gastrointestinal recovery are noted by passage of flatus, defecation and the ability to tolerate solid food without significant nausea and vomiting.[8] Passage of stool or flatus - considered a surrogate for intestinal and anastomotic continuity - is often used as the trigger to start stepwise dietary orders with the patient's ability to tolerate each step marking their readiness for the subsequent meal. Fast-track and Enhanced Recovery After Surgery (ERAS) programs that promote early feeding in advance of these clinical markers, along with opioid sparing techniques and use of minimally invasive procedures have been shown to be safe and beneficial for many patients by demonstrating earlier recovery and shorter length of stay.[9–11] However, it has also been shown that, for as many as 25% of cases, the strategy does not work as noted earlier, with the need for reinsertion of the nasogastric tube and reinstating nil per os status. In a recent study of 513 consecutive colorectal patients who were on an ERAS protocol, 128 patients (24.7%) needed postoperative reinsertion of nasogastric tube at the 3.9±2.9 postoperative day.[9] This suggests that, while early postoperative feeding is beneficial to patients in whom recovery is on track, it does not work in cases where patients are not ready for it.

At present, there is no reliable measurement that can predict gastrointestinal recovery/diet readiness for patients in advance of these clinical markers that may allow for interventions or fast-track programs to facilitate timely recovery. Auscultation for return of bowel sounds, long part of the standard of care, is controversial in its usefulness to indicate recovery. Bowel sounds have shown to have poor correlation with flatus/defecation and have proved unsuccessful in guiding diet interventions.[12,13]

Smooth muscle electrical activity on the other hand is directly related to gastrointestinal function and motility. Researchers have previously shown a 1:1 correlation between electrical and mechanical (contractile) events in the colon with internally placed electrode-strain gauge force transducers.[14–16] Electrical activity in the colon has been reported across a wide range of frequencies ranging from 0 to 40 cycles per min (cpm)).[17] Condon et. al have documented the progressive return of colonic electrical related to resolution of postoperative ileus and clinical recovery following surgery.[18,19] These measurements have been performed using electrodes placed internally during surgery, a major impediment towards broader use of such technology.

3 Rationale/Significance

3.1 Problem Statement

GI functional recovery after surgery is unpredictable and contributes to increased length of stay and postoperative readmissions for ileus.

3.2 Purpose of Study/Potential Impact

The purpose of the Phase 1 study is to determine if the myoelectrical measurements made by the G-Tech Wireless Patch System correlate with clinical markers of postoperative recovery such as passage of flatus/bowel movement, oral tolerance of diet and discharge readiness. Subsequently the data will be studied to establish which information in the signals is important in determining when to feed patients and possibly discharge them.

These pilot prospective, open clinical studies suggests that myoelectrical activity, measured on the abdominal surface with a noninvasive wireless patch system, carries predictive value in determining time to feeding and time to flatus following open abdominal surgery. Having such information in advance of clinical measures could facilitate timely interventions, be it early feeding or delaying feeding as dictated by the patient's unique recovery profile. The G-Tech Wireless Patch System would provide a unique insight into the process allowing for a tailored protocol that could improve patient satisfaction and optimize recovery. The system could also enable feedback on the impact to the overall gastrointestinal myoelectrical activity of medications, particularly opioids, used for pain management that are known to inhibit gastrointestinal function by disrupting the normal recovery patterns of colonic motility.[23–25] While it remains to be seen, in addition to predicting time to flatus/bowel movement early on, the ability to continue monitoring the patient may allow one to predict onset of secondary complications, such as wound infections or anastomotic leaks, that are associated with ileus. Although not part of this protocol, given the wireless noninvasive nature of the system the patients could be discharged home with the patches, whereby they would serve as a remote monitoring tool. This could be particularly useful in cases where the patients may have been discharged early and may be at a high risk for readmission. The system would then send updates/alerts to the care team for management and potentially avoid preventable readmissions.

3.2.1 Potential Risks

The risks associated with the G-Tech Patch System are related with the use of the G-Tech Patch (electrical risks, skin allergy or chemical) and the export of the data (anonymized data sent to G tech).

3.2.2 Potential Benefits

There are no direct benefits to participants. The information gained from their experience with the device may decrease healthcare utilization needs of future patients.

4 Study Objectives

4.1 Hypothesis

Myoelectric signaling patterns of the abdominal cavity after surgery will correlate with first flatus.

4.2 Primary Objective

To measure myoelectric signals with the G-Tech WPS and determine if a correlation exists between signal strength and the rate of gastrointestinal recovery following colorectal surgery. Determine the relationship between gastrointestinal myoelectrical signal strength and clinical markers of recovery such as passage of flatus/bowel movement, oral tolerance of diet, and discharge readiness.

4.3 Secondary Objectives (if applicable)

To measure myoelectric signals with the G-Tech WPS and determine if there are differences in signal patterns for right colon resections, left colon resections, and rectal resections.

5 Study Design

5.1 General Design Description

Single-arm, nonrandomized feasibility study to evaluate the ability to correlate myoelectric signals of the abdomen after surgery to GI functional recovery.

5.1.1 Study Date Range and Duration

Data Collection: June 1, 2022 to May 30, 2023

Data Analysis: June 1, 2022 to May 30, 2024 (data analysis intentionally overlaps with collection as it is done algorithmically in near real-time)

5.1.2 Number of Study Sites

Single site. Yale New Haven Hospital

5.2 Outcome Variables

5.2.1 Primary Outcome Variables

GI functional recovery after surgery as measured by first flatus

5.2.2 Secondary and Exploratory Outcome Variables (if applicable)

- Rate of inpatient postoperative ileus
- Rate of readmission for post-discharge ileus
- GI functional recovery as measured by first bowel movement

5.3 Study Population

Patients undergoing resection of portions of the colon and rectum with anastomosis.

5.3.1 Number of Participants

200

5.3.2 Eligibility Criteria/Vulnerable Populations

Any subject who undergoes an open or laparoscopic colon or rectum resection surgery

Inclusion Criteria:

1. Willing and able to provide informed consent
2. Eighteen (18) years of age or older
3. Subject is willing and able to follow all study requirements
4. Subject has undergone or will undergo a laparoscopic or open colorectal surgery with resection and anastomosis

Exclusion Criteria:

1. Subject is pregnant or suspects pregnancy.
2. Known allergy to medical grade adhesive.

6 Methods

6.1 Treatment – Device

6.1.1 Intended Use for Device (provide the following information for each device being investigated in the study)

The G-Tech WIRELESS Patch System is a non-invasive wireless gastrointestinal monitoring system. The platform has received approval via the 510(k) process supervised by the U.S. Food and Drug Administration. The system consists of G-Tech Patches, the G-Tech Patch Monitor, an iOS application, and data analysis algorithms.

The G-Tech Patch acquires and transmits electrical signals from the gastrointestinal tract via Bluetooth to the G-Tech Patch Monitor. The G-Tech Patch Monitor receives the raw data and periodically uploads it to a secure cloud server. Additionally, the Patch Monitor has a patient interface to allow the patient to manual enter events such as meals, bowel movements, pain or the taking of medications.

Figure 1 The G-Tech Wireless Patch System (WPS)

Data analysis algorithms process the uploaded data to measure and report myoelectrical motor activity levels for the stomach and intestines. These measurements will be made available to the study investigators to identify correlations between return and patterns of myoelectrical activity with time to feeding and discharge. Patients do not have

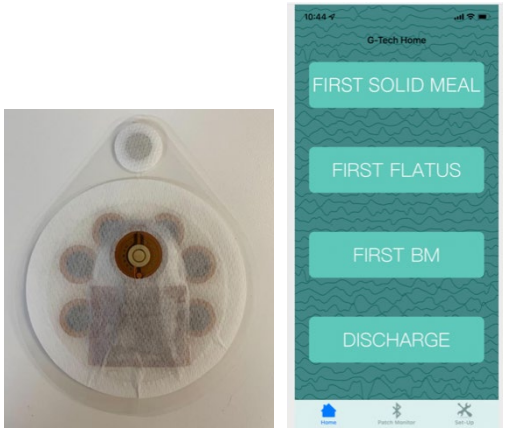

Figure 2 The G-Tech Patch and G-Tech Patch Monitor App

independent access to either the raw data or calculated results except as shared with them by their physician.

6.1.2 Device Administration and Schedule

The G-Tech patches will be placed on patient post-operatively following surgery either in the Post Anesthesia Care Unit (PACU) or in their hospital room, within 4 hours of being transported out of the operating room. Research staff will activate three (3) G-Tech patches and pair them with the G-Tech App on an iPhone 7 (provided). The patches will be periodically sending the data to the paired iPhone 7, which will remain by the patient's bedside until discharge. The G-Tech Patches are intended to run continuously for up to 6 days and have been shown to run continuously for up to 14 days in pilot testing. The patient, caregiver or staff member shall record activities such as first solid meal, first flatus, first bowel movement on the easy-to-use iPhone app during the patients stay. The inpatient physician-led team will also remind the patient to enter information into the app daily. The recorded events and gut myoelectrical activity are transferred wirelessly via the paired iPhone to the cloud. The Patches shall be replaced as needed. All patches are removed before patient is discharged.

Skin Preparation

Locate the approximate patch locations on the abdomen according to Figure 2. Patch locations can be varied depending upon the surgery incisions. Patches are not sterile and should be placed at least an inch distance from any incision. Clip abdominal hair as needed in the patch location if not clipped prior to surgery. Clean the skin thoroughly using alcohol pads and let dry before applying the patches.

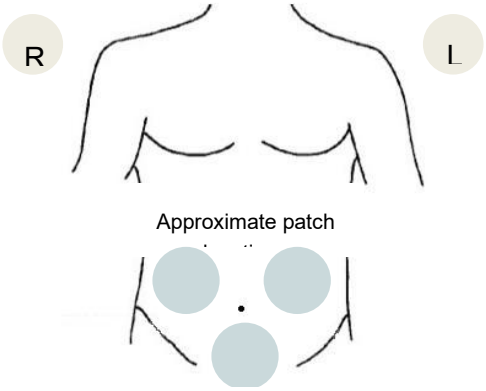

Figure 3 G-Tech Patch abdominal locations

G-Tech Patch Placement Procedure

Patches should be placed on the patient as soon as possible and in no case later than **4** hours after surgery. Staff member shall activate and apply G-Tech Patches (recommended number of patches is 3) to the patient in the locations shown in Figure 3. The G-Tech Patches are intended to run continuously for up to 6 days. Patches shall be replaced as needed. Patches are removed before patient is discharged.

Study subject instructions for reporting events such as diet and physical symptoms

The patient, caregiver or staff member shall record activities such as first solid meal, first flatus, first bowel movement on an easy-to-use iPhone app during the patient's stay. The recorded events and gut myoelectrical activity are transferred wirelessly via the paired iPhone to the cloud. If they forget to log an event, they may change the time to backlog.

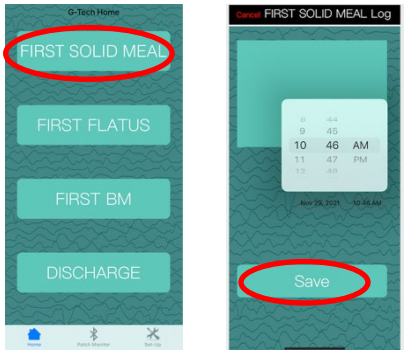

Figure 4 Logging events in the G-Tech App

6.1.3 Method of Assignment/Randomization (if applicable)

n/a

6.1.4 Device Calibration

n/a

6.1.5 Storage Conditions

Each device comes sealed from the manufacturer and is designed to be used and re-processed. Sealed patches will be kept in a temperature-controlled (10-40 degrees Celsius), locked research cabinet in the PI's divisional offices. Used patches will be placed in a sealed plastic bag and returned to the manufacturer per their re-processing instructions. The re-processing itself has been reviewed and approved by the U.S. FDA under the manufacturer's 510(k) approval. The investigator and research team have no role in re-processing other than returning opened and activated patches back to the manufacturer through regular U.S. mail.

6.1.6 Concomitant therapy

No restrictions

6.1.7 Restrictions

No tub bathing while device is in use (showers ok).

The G-Tech Patch has an IP23 rating which means it is protected from touch by fingers and objects greater than 12 millimeters. The rating also indicates that it is protected from water spray less than 60 degrees from vertical. It is advised to take short 5-minute showers with back facing shower head. Tub bathing or any type of bathing where the device could be submersed in water or exposed to moisture or water or soaked with water (sponge bath or bed bath) during washing is not permitted.

6.2 Assessments

6.2.1 Efficacy

n/a

6.2.2 Safety

The investigator will collect data and report the treatment or device related events that occur during the Study. Anticipated adverse events in this study are adverse events that are not considered serious and have previously been identified in the nature, severity, or the degree of incidence. An anticipated adverse event is synonymous with adverse event. These are not serious, and they are possibly, probably, or definitely related to the device.

Assessment for unanticipated adverse device effects and serious adverse events will take place at each treatment visit prior to, during, and after each treatment, and at each follow-up visit.

6.2.3 Adverse Events Definition and Reporting

Adverse Event Reporting Requirements

Adverse event data will be collected on the adverse event case report form for the study. Adverse events are not required to be reported immediately to G-Tech Medical. Adverse events are to be collected, and data is to be provided on the case report form.

Assessing for Adverse Events

Assessment for adverse events will take place during the wearing of the G-Tech Patch device. List of Anticipated adverse events related to the G-Tech Patch:

- Erythema
- Pruritis (itching)
- Ecchymosis (bruising)
- Rash
- Discomfort

Unanticipated Adverse Device Effect

Unanticipated Adverse Device Effect Definition (UADEs)

An unanticipated adverse device effect (UADE) is defined as “any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in the nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects”.

UADE Reporting Requirements (21 CFR 812.46 & 812.150)

UADEs must be reported by the clinical investigator to the reviewing IRB and G-Tech Medical, as described below:[1]

- An investigator shall notify G-Tech Medical immediately but no later than within 24 hours first notification of a UADE.
- G-Tech Medical, with the assistance of the study site, must immediately conduct an evaluation of a UADE.
- G-Tech Medical must report the results of the evaluation to the reviewing IRB, and participating investigator within 10 working days after G-Tech Medical first receives notice of the effect (§§ 812.46(b), 812.150(b)(1)).
- Investigators are required to submit a report of a UADE to the reviewing IRB and G-Tech Medical as soon as possible, but in no event later than 10 working days after the investigator first learns of the event (§ 812.150(a)(1)).

Assessing for UADEs

Assessment for UADEs will take place at each treatment visit prior to, during, and after each treatment, and at each follow-up visit.

Serious Adverse Events (SAEs)

Serious Adverse Event Definition

Serious adverse events are anticipated and serious in nature. Serious adverse event is defined as follows:

- Results in death,
- Is life threatening,
- Requires inpatient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/incapacity, or
- Is a congenital anomaly / birth defect

SAE Reporting Requirements

An investigator shall notify G-Tech Medical immediately but no later than within 24 hours of a SAE. G-Tech Medical shall conduct an immediate investigation of any SAE. An investigator shall submit to G-Tech Medical and to the reviewing IRB a report of any SAE occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator learns of the effect.

Assessing for SAEs

Assessment for SAEs will take place at each treatment visit prior to, during, and after each treatment, and at each follow-up visit.

Categories of Device Relationship

The following categories will be used to document adverse events and serious adverse events relatedness to the investigational device or treatment, and what is reportable to G-Tech Medical.

ATTRIBUTION	DEFINITION	DATA COLLECTED
Unrelated	The adverse event is clearly not related to the device or procedure(s). This is NOT collected.	NO
Possibly Related	The adverse event may be related to the device or treatment(s). This will be collected according to the reporting requirements in this protocol.	YES
Probably Related	The adverse event is likely related to the device or treatment (s). This will be collected according to the reporting requirements in this protocol.	YES
Definitely Related	The adverse event is clearly related to the device or treatment (s). This will be collected according to the reporting requirements in this protocol.	YES
Unknown	The investigator cannot determine the relatedness of the adverse event to the device. This will be collected according to the reporting requirements in this protocol.	YES

6.2.4 Pharmacokinetics (if applicable)

n/a

6.2.5 Biomarkers (if applicable)

n/a

6.3 Study Procedures

If a patient is unreachable by telephone, an alternative recruitment strategy will be used where they are approached in person in the preoperative readiness area prior to proceeding to the OR. The same scripted paragraph will be read, and they will be offered the opportunity to e-consent using the REDCap form provided on a study-supplied, secured iPad.

6.3.1 Study Schedule

Preoperative period – Study Consent

Within 4 hours of existing operating room – Patches placed by study staff

Daily postoperative visit – reminder to enter information to the supplied iPhone

Day of discharge – Removal of patches by study staff

6.3.2 Informed Consent

Informed consent will be obtained using the documents reviewed and approved by the Yale IRB of the participant or their legally authorized representative. The process will be managed with the patient by a non-clinician member of the study team to avoid undue influence or coercion. The patient will be able to review the electronic informed consent document in the place and time of their own choosing.

6.3.3 Screening

Patients will be treated according to standard of care. The study team will perform a daily review of postings by colorectal surgeons included on this proposal (Longo, Reddy, Pantel, Mongiu, and Leeds). Eligibility criteria used to review these postings will be accessible in the patient's electronic medical record.

6.3.4 Enrollment

Patients will be recruited by a non-clinician member of the study team by telephone. This device study represents low-risk. Informed consent will be obtained preoperatively by telephone. Patients will verbally hear a scripted consent by a member of the study team and be asked for their assent. If they agree, they will be electronically emailed a unique single-use REDCap link to complete the e-consent which will include the scripted paragraph heard earlier as well as all necessary consent components.

6.3.5 On Study Visits

Electronic informed consent – Average read time 10 minutes. Patients will be consented in electronic form and have up to 3 weeks to review document if desired and consent.

Postoperative patch placement – 5 minutes

Daily visit – 5 minutes

Day of discharge patch removal – 5 minutes

6.3.6 End of Study and Follow-up

End of study will be discharge of the patient and removal of patches, or early withdrawal by patient or clinician request.

30-days after discharge each patient's electronic medical record will be reviewed for documentation of primary and secondary end points and entered into a REDCap database.

6.3.7 Removal of subjects

During the study, it is possible that study subjects may be withdrawn from the study. If a withdrawal is related to the study procedure causing an adverse event, a Study Termination Form will be completed for each subject withdrawal. Factors that may lead to a withdrawal from the study may include, but are not limited to the following:

Subject Withdrawal

At any time, a study subject may voluntarily withdraw from the study. This withdrawal will not affect their future medical treatment or benefits.

Physician Decision/Medical Decision

Should a physician decide that the requirements of the protocol are detrimental to the health and welfare of the study subject, the study subject may be withdrawn from this study. The reason for the decision will be documented in the case report form. If the subject is found to not be wearing the device in its proscribed fashion and the data cannot be interpreted in its intended form, a member of the study team will complete a Study Termination Form and review with the prinicipal investigator upon withdrawal.

6.4 Statistical Method

6.4.1 Statistical Design

6.4.2 Sample Size Considerations

This study aims to enroll 200 subjects. In a similar study[1] where subjects were enrolled and monitored after pancreaticoduodenectomy surgery, it was observed that 75 subjects

[1] Dua, M.M., Navalgund, A., Axelrod, S., Axelrod, L., Worth, P.J., Norton, J.A., Poultsides, G.A., Triadafilopoulos, G. and Visser, B.C., 2018. Monitoring gastric myoelectric activity after

provided the required power to detect significant difference between early and late oral tolerance diet groups. The increase sample size shown here is to observe myoelectric differences between right colon, left colon, and rectum resections.

6.4.3 Planned Analysis

6.4.3.1 Primary Analyses

The primary endpoint is to determine if there is a correlation between the measured motor activity metrics of the various GI organs with measures of recovery, and to mathematically characterize the correlation in a manner that leads to predictive ability. The study is retrospective without intention to treat. Data analysis is performed by the staff of G-Tech Medical located in Mountain View, CA using proprietary software developed specifically for this purpose. Data is accessed on a secure cloud server to which it was uploaded by the mobile app connected to the patches.

Data analysis consists of extracting the myoelectric motor activity measured by the patches in ten-minute time segments and assigning them to an organ or organs. The motor activity at any one time (instantaneous) and the cumulative activity up to that point in time will be examined for correlation to parameters associated with recovery rate such as time to first flatus, time to first solid meal, time to discharge, etc. This will be done across all time points to find the earliest time that offers predictive value. The specific final analysis approach taken will depend on the findings of this pilot study.

In the study[2] with colonic myoelectric activity measurements after open abdominal surgery an inverse correlation was found between cumulative colon signal strength and time to first flatus which was approximately linear and was best characterized by the root mean square (RMS) deviation of the residuals from a linear fit, in units of hours. The optimal time for this analysis was found to be at 36 hours after surgery.

Similarly in the study[1] with patients undergoing pancreaticoduodenectomy procedure, a correlation was found between cumulative signal strength of the stomach and time to first full meal that was also inverse but not well represented by a linear or other fit. In this case the analysis involved assigning patients to one of two groups, early and late feeders. The stomach activity data were then tested for predictive value against these groups. Patients with stronger signals were more likely to be in the early feeding group and vice versa. A statistical analysis was performed using a receiver-operator characteristic approach that led

pancreaticoduodenectomy for diet “readiness”. American Journal of Physiology-Gastrointestinal and Liver Physiology, 315(5), pp.G743-G751.

[2] Navalgund, A., Axelrod, S., Axelrod, L., Singhal, S., Tran, K., Legha, P. and Triadafilopoulos, G., 2019. Colon myoelectric activity measured after open abdominal surgery with a noninvasive wireless patch system predicts time to first flatus. Journal of Gastrointestinal Surgery, 23(5), pp.982-989.

to specificity and sensitivity values as a function of time after surgery, which allowed determination of the optimal time, which was again at approximately 36 hours.

6.4.3.2 Secondary Objectives Analyses

In addition to the analysis above, electronic medical record review will allow for the rate of ileus, readmission, and first bowel movement to be further correlated with the processed myoelectric signal.

6.4.3.3 Safety

Anticipated and unanticipated adverse device events will be monitor through hospitalization and 30-days after surgery based on the definitions above. Descriptive statistics will be reviewed with the study team and the manufacturer.

6.4.3.4 Analysis of Subject Characteristics

Descriptive statistics will be reported for age, sex, race, indication for surgery, type of anatomic resection, ostomy present preoperatively, ostomy present postoperatively, duration of operation, operative approach (open, laparoscopic, robotic).

6.4.3.5 Interim Analysis (if applicable)

n/a

6.4.3.6 Health economic evaluation

n/a

6.4.3.7 Other

n/a

6.4.4 Subsets and Covariates

See subject characteristics above 6.4.3.4.

6.4.5 Handling of Missing Data

Missing data will be first attempted to be mitigated by soliciting patient recall through an additional telephone encounter. If information remains missing, this patient will be dropped from further analysis if the missing data is necessary.

7 Trial Administration

7.1 Ethical Considerations: Informed Consent/Assent and HIPAA Authorization

Declaration of Helsinki

Compliance with the Declaration of Helsinki provides public assurance that the rights, safety, and well-being of trial subjects are protected, and that the clinical trial data are credible.

7.2 Institutional Review Board (IRB) Review

The protocol will be submitted to the IRB for review and approval. Approval of the protocol must be obtained before initiating any research activity. Any change to the protocol or study team will require an approved IRB amendment before implementation. The IRB will determine whether informed consent and HIPAA authorization are required.

The IRB will conduct continuing review at intervals appropriate to the degree of risk, but not less than once per year.

A study closure report will be submitted to the IRB after all research activities have been completed.

Other study events (e.g. data breaches, protocol deviations) will be submitted per Yale's institution's IRB's policies.

7.3 Subject Confidentiality

Subject confidentiality is held in strict trust by the research team. Subject medical record review will be limited to the just the elements needed to complete the study. Only authorized HIPAA and GCP trained study team members will be allowed to extract research data from medical records and enter it into REDCap. No direct subject identifiers will be entered into the data provided to the manufacturer.

Each subject will be assigned a unique study number. A master list linking the unique study number to the human subject will be maintained in a secured Yale Box.com file held by the PI. Each subject will be assigned an alphanumeric character consisting of 4 alpha characters, followed by 3 decimal digits. The 4 alpha characters shall represent the site/institution name. The 3 decimal digits shall start with the number (001) followed by consecutive numbering of all consented study subjects. For example, Yale's third subject consented and enrolled will be numbered:

Y A L E – 0 0 3.

All subjects enrolled will be numbered consecutively even if they are a screen failure. The subjects will be identified as consented, enrolled, and receiving the investigational device in the screening and device accountability log on Yale's REDCap,

7.4 Deviations/Unanticipated Problems

Protocol deviations are not permitted in this study. A protocol deviation is only acceptable if it is to protect the welfare and safety of a subject. A Protocol Deviation Case Report Form will be required to be completed if a protocol deviation occurs.

7.5 Data Collection

Screening, Demographics, and Eligibility Case Report REDCap Form

The Principal Investigator will ensure collection of screening and eligibility data that allows for documentation to show the study subject meets all eligibility criteria and has been properly selected to participate in the study. This can be achieved through a case report form submitted via REDCap. Additionally, demographics and clinical history shall be used to further document the subject's appropriateness for this study and collect the characteristics of the subject that contribute to the analysis of the statistical characteristics of the study population.

Recording Procedure and Clinical Markers Case Report Form

The Principal Investigator will ensure collection of the time of device placement, and the device serial number. The information shall be updated if a new device is used. The Principal Investigator will ensure collection of clinical markers of recovery which at a minimum include time of first flatus, time of first bowel movement, time of first solid meal and time of discharge. These minimum set of inputs should be entered in the G-Tech Patch Monitor App.

7.6 Data Quality Assurance

Data will be stored and collected into two centrally cloud-based locations. Myoelectric signal data and clinical markers of recovery will be fed into G-Tech's centrally managed, deidentified cloud server via the G-Tech Patch Monitor App. Eligibilty criteria, clinical history, and 30-day recovery will be abstracted by a member of the study team, input into REDCap with a study tablet, and stored locally at the Yale REDCap instance.

7.7 Study Records

Screening, Eligibility, and Clinical Case Report Form (REDCap)

Informed e-Consent Log (REDCap)

Recording Procedure and Clinical Marker Case Report Form (REDCap)

Protocol Deviation Form (REDCap)

Study Exit Form (REDCap)

Subject ID Log (PI Yale Box.com)

7.8 Access to Source

Myoelectric signal analysis and G-Tech App clinical marker information will be provided back to the PI courtesy of G-Tech. The PI will use the unique identifier to re-link these results to the demographic and clinical characteristic data collected locally and held within REDCap.

7.9 Data or Specimen Storage/Security

All data will be collected in REDCap. Archival logs and analytic datasets derived from the REDCap data will be maintained on a HIPAA-compliant partition of Yale Box.com in a file owned by the PI.

7.10 Retention of Records

Records will be retained up to 3 years to allow for subanalysis as needed.

7.11 Study Monitoring

Study monitoring will be performed by the internal study team with triggers for manufacturer notification and IRB notification as described above in study safety sections.

7.12 Data Safety Monitoring Plan

The risk level of this study is deemed to be low. The device has already received US FDA 510(k) approval and the information collected from patients is not provided back to the treating clinical team.

7.13 Study Modification

Protocol deviations are not permitted. All changes to the study protocol will be submitted as an amendment for review to the Yale IRB.

7.14 Study Discontinuation

Study will be discontinued when meeting its enrollment goal or deemed to be unsafe to proceed after any IRB- or manufacturer-reviewed patient safety event.

7.15 Study Completion

The study is intended to be completed by May 30, 2024. Study completion will be officially recognized with termination documents submitted to the Yale IRB.

7.16 Conflict of Interest Policy

No member of the internal study team maintains a conflicted relationship with the device manufacturer. Any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The study leadership in conjunction with the appropriate conflict of interest review committee has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

All investigators will follow the applicable conflict of interest policies.

7.17 Funding Source

All expenses are supported by internal departmental research startup funds. There is no external source of funding

7.18 Publication Plan

Results of this study will be disseminated via peer-reviewed conference abstracts and scientific journals.

8 Appendices

Appendix #	Title
1	Informed e-Consent
2	Screening, Eligibility, and Demographics Form
3	Recording Procedure and Clinical Markers Case Report Form
4	Protocol Deviation Form
5	Exit Form
6	Adverse Event Form

9 List of Tables

10 References

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Appendix 1

10.1.1 COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE

YALE-NEW HAVEN HOSPITAL

Study Title: Myoelectric Activity Following Colorectal Surgery and Return of Bowel Function

Principal Investigator (the person who is responsible for this research): Ira Leeds, MD

Phone Number: 203-785-2616

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to evaluate electrical signals made by your intestines that tell us how you are recovering after surgery.
- Study procedures will include: small medical-grade patches placed on your skin that monitor your intestines and send the information to a smartphone.
- No additional visits are required.
- There are some risks from participating in this study. You may experience a skin reaction to the patch if you already have had reactions to other skin adhesives. Data about your recovery is shared in a non-identifiable way with the device manufacturer.
- The study may have no benefits to you, but the data collected may help others with a similar surgery in the future.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits. How we care for you will not change based on your decision to participate.
- If you are interested in learning more about the study, please continue reading, or have someone read to you the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate. If you agree, this form will need to be signed to participate.

Why is this study being offered to me?

We are asking you to take part in a research study because you have a planned surgery involving your intestines, colon, or rectum. We are looking for 200 participants 18 years old or older to be part of this research study.

Who is paying for the study?

This study has no external funding and is being supported by internal funds.

Who is providing other support for the study?

The medical device is being provided free of charge by the manufacturer.

What is the study about?

The purpose of this study is to record the electrical signals that naturally occur in your digestive tract and motility patterns in individuals who undergo surgery. Patients who have surgery have the potential to experience delayed recovery of their bowel movements or passing gas. Delayed recovery, or ileus, causes the intestinal contents to back up because the bowels do not move in a rhythmic way that is needed. The symptoms resulting from this include painful distended abdomen, nausea, vomiting, and dehydration. A device, the G-Tech Wireless Patch System (WPS) has been developed by a company, G-Tech Medical, Inc., which measures the electrical activity from your intestines. The device uses adhesive to adhere to your skin and it is placed on your stomach or abdomen to measure the natural electrical activity. The purpose of the study is to determine if the measurements made by the G-Tech Wireless Patch System correlate with clinical markers of gastrointestinal recovery such as passage of flatus or your first bowel movement, oral tolerance of diet, and discharge readiness.

This study is solely for obtaining patterns in various individuals to determine if the myoelectric signals measured by the G-Tech Wireless Patch System correlate with rate of gastrointestinal recovery following surgery.

What are you asking me to do and how long will it take?

The device will be placed post-operatively within 4 hours of your surgery. The patches will typically remain on until discharge. You will be asked to return the patches prior to discharge. While you are an inpatient, you may shower with the patches in place if the surgical team has approved of showering after surgery.

What are the risks and discomforts of participating?

A potential risk in this study is the adhesive on the patch may cause mild irritation and leave temporary red or pink areas or possibly glue marks on your skin, which should go away on their own a few days after the patch is removed.

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about taking part in this study.

What if there are unexpected findings from the study related to my participation?

We do not anticipate findings that would directly relate to your care as the meaning of the data is not yet fully understood and the primary purpose of this study. If the results suggest a long-term relevance of the data to your current or future health status, we will communicate these findings to you.

How can the study possibly benefit me?

There are no direct benefits to you for participating in this study.

How can the study possibly benefit other people?

The results of this study will help the future development of technology and to potentially help future patients by optimizing their post-operative care and decrease their length of stay in the hospital.

Are there any costs to participation?

You will not have to pay for taking part in this study. There will be a few minutes of time each day for the first 6 days of your inpatient recovery that require your attention with study staff.

Will I be paid for participation?

This study is conducted without compensation for participants.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission separately from this consent.

We will also share data with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- The entire research record and any medical records held by Yale New Haven Hospital from the month of your booking for surgery to the month after your discharge for surgery.
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - HIV / AIDS test results
    - Hepatitis infection
    - Sexually transmitted diseases
    - Other reportable infectious diseases
    - Physical exams
    - Laboratory, x-ray, and other test results
    - Diaries and questionnaires
    - The diagnosis and treatment of a mental health condition
    - Use of illegal drugs or the study of illegal behavior
    - Records about any study drug you received
    - Records about the study device

How will you use and share my information?

We will use your information to conduct the study described in this consent form.

We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.

- The U.S. Food and Drug Administration (FDA) This is done so that the FDA can review information about the device involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- The study sponsor or manufacturer of study drug/device
- Drug regulatory agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to **Ira Leeds, MD** (789 Howard Ave, Tompkins 202, New Haven, CT 06519) at Yale University, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

Because this study only involves recording your electrical activity in your abdomen, it is unlikely that you will experience injury related to this study. Should you experience injury, you should see your physician. You and your insurance company may be billed for medical care.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

If you develop side effects, the researchers may withdraw you from participating in the research study. If you are unable to tolerate wearing the device in its proscribed fashion, you may be withdrawn from the study by the research team.

What will happen with my data if I stop participating?

Data already transmitted to the device manufacturer will not be able to censored.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at 203-785-2616

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the participant in _____ (state language) by an individual proficient in English and _____ (state language).

Print name of impartial witness: _____

Signature of impartial witness: _____Date: _____

See the attached short form for documentation.

Appendix 2

Screening, Eligibility, and Demographics Form

SCREENING

Patient ID #_____

Planned Surgery (pick one)

Enterectomy Only

Right-sided Colectomy

Left-sided Colectomy

Proctectomy

Date of Planned Surgery __/__/___

ELIGIBILITY

1. Inclusion Criteria (All responses must be "YES" below)		**YES**	**NO**
a.	Subject is willing and able to provide informed consent;	☐	☐
b.	Subject is ≥ 18 years of age;	☐	☐
c.	Subject is willing and able to follow all study requirements;	☐	☐
d.	Subject who will undergo or has undergone open or laparoscopic colorectal surgery	☐	☐
2. Exclusion Criteria (All responses must be "NO" below)		**YES**	**NO**
a.	Subject has a known allergy to skin adhesives;	☐	☐
b.	Subject is pregnant or suspects pregnancy;	☐	☐

2. Informed Consent Obtained

a. Informed Consent Obtained Y N

b. Date of Informed Consent ___/___/__

1. Demographics

1. Date of Birth ____ ____ / ____ ____ / ____ ____ ____ ____
   MM DD YYYY
2. Gender ☐ Male ☐ Female
3. Stated Height ____ Feet ____ Inches
4. Stated Weight ____ ____ ____ lbs.
5. Ethnicity ☐Caucasian ☐Black ☐Hispanic ☐ Asian ☐Other: _____

Appendix 3

Recording Procedure and Clinical Markers Case Report Form

Patient ID #_____

Date of Surgery ____/_____/_____

Procedure Performed (pick one)

Enterectomy Only

Right-sided Colectomy

Left-sided Colectomy

Proctectomy

Ostomy Preop? Y N

Ostomy post? Y N

POSTOPERATIVE MARKERS

First Flatus Date ____/_____/_____

First BM Date _____/_____/_____

First Solid Food _____/_____/_____

Clinical Ileus (emesis after POD 2, no flatus, reversal of diet order, +/- NGT placed)

Y N

Readmission Y N

Reason for Readmission (choose any)

[ ] Ileus

[ ] Dehydration

[ ] Infection / Anastomotic Leak

[ ] VTE

[ ] Unknown

[ ] Other:

Readmission likely related to surgery? Y N

Appendix 4

Protocol Deviation Form

Date(s) Deviation Occurred:

_____

(If this deviation occurred over multiple days, please indicate entire deviation period)

Associated Study Visit (if applicable):

_____

Type of Deviation

☐ Informed consent not properly obtained

☐ Study procedure performed prior to consent

☐ Subject enrolled outside inclusion/exclusion criteria

☐ Required evaluation not performed

☐ Follow up visit missed (specify visit in 2 above)

☐ Follow up visit out of window (specify visit in 2 above)

☐ Device used outside protocol requirements

☐ Other deviations (specify in deviation description)

Describe Deviation in Detail:

Date Manufacturer Notified (if applicable): _____

Name of Individual Notified (if applicable):

_____

Was an Exemption Granted? ☐ **Yes, date:** _____ ☐ **No**

Did Deviation Meet IRB/EC Reporting Requirements? ☐ **Yes, date reported:** _____ ☐ **No**

Corrective Actions Taken (if required, otherwise, state N/A):

Appendix 5

Study Exit Form

1.1. Patient ID #_____

1.2. Date of Study Exit: _____

1.3. Associated Study Visit (if applicable):

_____

1.4. Reason for Study Exit

☐ Completed study visits as planned: if checked, skip to Principal Investigators' signature

☐ Screen Failure: if yes State reason for screen failure

_____

☐ Voluntary subject withdrawal, e.g., no longer wanted to participate

☐ Investigator decision to withdraw subject from the study

_____

☐ Other

Appendix 6

Adverse Event Form

A. DATE OF ADVERSE EVENT - ADVERSE EVENT # _____ OF _____			
1.	Date of Adverse Event: *(1 event per form)*	___ ___ / ___ ___ / ___ ___ ___ ___ Month Day Year	
2.	Post-op Day:	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ _____	
B. ADVERSE EVENT NOTED BY SITE			
COMPLETE THIS FORM FOR ALL ANTICIPATED, NOT SERIOUS, ADVERSE EVENTS			
1.	Date of Adverse Event Onset	___ ___ / ___ ___ / ___ ___ ___ ___ Month Day Year	
2.	Date Adverse Event Reported to the Site	___ ___ / ___ ___ / ___ ___ ___ ___ Month Day Year	
3.	Date Adverse Event Reported to the IRB ☐ N/A	___ ___ / ___ ___ / ___ ___ ___ ___ Month Day Year	
C. ANTICIPATED ADVERSE EVENT (Check One per Form)			
#	**ADVERSE EVENT TYPE**	**YES**	**ADVERSE EVENT #** (Chronologically # by 1st event to last event)
1.	Erythema	☐	
2.	Itching (pruritis)	☐	
3.	Ecchymosis	☐	
4.	Rash	☐	
5.	Discomfort	☐	
6.	Allergy to adhesive	☐	
7.	Other: _____ _____	☐	

D. ANTICIPATED ADVERSE EVENT OUTCOME / ATTRIBUTION / TREATMENT		
OUTCOME (COMPLETE AT EACH VISIT UNTIL EVENT RESOLVED)		
1.	☐ Event resolved/ patient recovered – Enter date resolved below: ____ ____ / ____ ____ / ____ ____ ____ ____ Month Day Year ☐ Event ongoing / no current treatment ☐ Event ongoing / still under treatment ☐ Uncertain – subject lost to follow-up ☐ Ongoing at end of study at time subject was terminated from study and MD is aware of this event at study closure.	
ATTRIBUTION		
2.	**Relatedness**	**Definition**
	☐ Unrelated	Clearly not related to the study device
	☐ Possibly related	May be related to the study device
	☐ Probably related	Likely related to the study device
	☐ Definitely related	Clearly related to the study device
	☐ Unknown	Not known if the adverse event was related to the study device