Medtronic

Clinical Investigation Plan

Clinical Investigation Plan/Study Title	AFFIX: Evaluation of the performAnce and saFety of the MaxTack™ Motorized FIXation Device in subjects undergoing repair of ventral hernia by minimally invasive surgery
Clinical Investigation Plan/Study Identifier	MDT23014
Study Product Name	MaxTack™ Motorized Fixation Device (MAXTACK30)
Sponsor/Local Sponsor	Medtronic-Covidien Surgical Operating Unit 15 Hampshire St Mansfield, MA, 02048 USA
Document Version	3.0
Version Date	09 Oct 2024

Confidentiality Statement

1. Investigator Agreement and Signature Page

Study Product Name	MaxTack™ Motorized Fixation Device
Sponsor	Medtronic-Covidien Surgical Operating Unit 15 Hampshire St Mansfield, MA, 02048 USA
Clinical Investigation Plan Identifier	MDT23014
Version Number/Date	Version 3.0 / 09 Oct 2024
I have read the protocol, including all appendices, and I agree that it contains all necessary details for me and my staff to conduct this study as described. I will conduct this study as outlined herein and will make a reasonable effort to complete the study within the time designated. I agree to comply with the Declaration of Helsinki, the Clinical Investigation Plan, and Good Clinical Practice, as well as local laws, regulations, and standards. I agree to ensure that the confidential information contained in this document will not be used for any purpose other than the evaluation and conduct of the clinical investigation without the prior written consent of Medtronic. I will provide all study personnel under my supervision copies of the protocol and access to all information provided by Medtronic. I will discuss this material with them to ensure that they are fully informed about the products and the study.	
Investigator's Signature:	
Investigator's Name:	
Institution:	
Date:	

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2. Glossary

2.1 Terms

Acronym	Term
ADE	Adverse Device Effect
AE	Adverse Event
ASA	American Society of Anesthesiologists
CA	Competent Authority
CDC	Centers for Disease Control and Prevention
CIP	Clinical Investigation Plan
CRF	Case Report Form
CT	Computerized Tomography
CTA	Clinical Trial Agreement
CV	Curriculum Vitae
DD	Device Deficiency
DOA	Delegation of Authority
DoH	Declaration of Helsinki
DTL	Delegated Task List
eCRF	Electronic Case Report Form
EC	Ethics Committee
FAL	Foreseeable Adverse Event List
FAS	Full Analysis Set (FAS)
FD	Financial Disclosure
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act

Acronym	Term
GCP	Good Clinical Practice
HerQLes	Hernia Quality of Life Survey
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
IEHS	International Enohernia Society
IFU	Instructions For Use
IRB	Institutional Review Board
ICMJE	International Committee of Medical Journal Editors
ISO	International Organization for Standardization
LED	Light-Emitting Diode
LTFU	Lost to Follow-Up
MaxTack™	MaxTack™ Motorized Fixation Device
MedDRA	Medical Dictionary for Regulatory Activities
MHLW	Ministry of Health, Labor, and Welfare
MM	Medical Monitor
NRS	Numerical Rating Scale
OR	Operating Room
PCBA	Printed Circuit Board Assembly
PG	Performance Goal
PGLA	Poly (Glycolide-co-L-lActide)
PHI	Protected Health Information
PI	Principal Investigator
PMCF	Post-Market Clinical Follow-Up

Acronym	Term
PPAS	Per Protocol Analysis Set
Q1	First Quartile
Q3	Third Quartile
QoL	Quality of Life
RA	Regulatory Authority
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SHT	Seriously Health Threat
SOC	Standard of Care
SSI	Surgical Site Infection
SSO	Surgical Site Occurrence
SSOPI	Surgical Site Occurrence Requiring Procedural Intervention
TSE	Touch Surgery™ Ecosystem
UAE	Unavoidable Adverse Event
USADE	Unanticipated Serious Adverse Device Effect
US	United States

2.2 Definitions

Term	Definition
Body Mass Index (BMI)	Calculated as per kg/m2 (kg is person's weight in kg and m is the height in meters)
Early Termination	Closure of a study that occurs prior to meeting defined endpoints. This is possible for the whole study or a single study site.

Enrollment	A subject is considered enrolled in the study when: • it is confirmed that the ICF is properly signed and dated, • they meet all preoperative inclusion criteria, • they meet no preoperative exclusion criteria, • they meet no intraoperative exclusion criteria, and • MaxTack™ tacks are utilized for fixation
Evaluable Subject	An enrolled subject that completes the specific protocol assessment and timing requirements to be included in the data analysis for the specified endpoint
Hernia Recurrence	A palpable fascial defect and/or a clinically manifested bulge, exacerbated by a Valsalva maneuver evaluated during physical examination by the investigator and confirmed per site standard of care medical imaging, if necessary, at the respective clinical site
Intraoperative Screen Failure	Subjects who were determined to be eligible prior to procedure, but who met any intraoperative exclusion criteria
Maximum	Largest value in the data set
Median	The sum of the value of each observation in a dataset divided by the number of observations
Mesh	Medical device used to provide additional support to weakened or damaged tissue
Minimum	Smallest value in the data set
Preoperative Screen Failure	Subjects who do not meet eligibility criteria prior to procedure (skin incision)
Quartiles	Values that divide a distribution into quarters when the values are arranged in ascending order. The first quartile has a quarter of the values below that value, and the third quartile has three-quarters of the values below that value
Standard Deviation (SD)	A measure of how dispersed the data is in relation to the mean. The square root of the variance
Study Closure	The closure of a study that occurs when Medtronic and/or regulatory requirements have been satisfied per the CIP and/or by a decision by Medtronic or RA, whichever occurs first
Study Completion Date	The date on which the last study subject had their last visit to collect data for a primary or secondary endpoint or adverse event data; however, the study closure process will continue until all required steps are complete

Surgical Site Occurrence (SSO)	Adverse events related to the study device, mesh, and/or study procedure including: seroma, hematoma, surgical site infection, and bleeding at tack implantation site
Suspension	A temporary postponement of study activities related to enrollment and distribution of the product

3. Synopsis

Title	**AFFIX**: Evaluation of the perform**A**nce and sa**F**ety of the MaxTack™ Motorized **FIX**ation Device in subjects undergoing repair of ventral hernia by minimally invasive surgery
Clinical Investigation Plan Identifier	MDT23014
Clinical Study Type	Prospective, post-market, multicenter, nonrandomized, single-arm, interventional
Product Name	MaxTack™ Motorized Fixation Device (MAXTACK30)
Sponsor/Local Sponsor	Medtronic-Covidien Surgical Operating Unit 15 Hampshire St Mansfield, MA, 02048 USA
External Organizations	If any external organizations become involved in the clinical study, this will be included under separate cover.
Indication under Investigation	MaxTack™ Motorized Fixation Device is indicated for use in the fixation of prosthetic material to soft tissue in minimally invasive ventral hernia repair procedures.
Investigation Purpose	The purpose of this study is to evaluate the performance and safety of the MaxTack™ Motorized Fixation Device when used for fixation of prosthetic material to soft tissue in minimally invasive ventral hernia repair procedures. Data from this study may be used for regulatory and publication purposes.
Product Status	MaxTack™ Motorized Fixation Device was 510(k) cleared by the Food and Drug Administration (FDA) in September 2023.
Primary Objective	The primary objective is to evaluate the performance (hernia recurrence rate) within 3 months following the use of the MaxTack™ Motorized Fixation Device for fixation in minimally invasive ventral hernia repair procedures.
Secondary Objective	The secondary objectives of this study are to evaluate the safety and performance of the MaxTack™ Motorized Fixation Device when used for fixation in minimally invasive ventral hernia repair procedures within 12 months postoperatively.
Primary Endpoint	The primary endpoint is the **incidence of hernia recurrence within 3 months** following the MaxTack™ Motorized Fixation Device used for fixation in minimally invasive ventral hernia repair procedures. The

	evaluation of clinical hernia recurrence will be performed via a Valsalva maneuver during a physical examination and confirmed per site standard of care medical imaging, if necessary.
Secondary Endpoint	Secondary endpoints are as follows: • **Incidence of Surgical Site Occurrence (SSO)** which are the following AEs related to the study device, mesh, and / or study procedure and defined as seroma, hematoma, surgical site infection, bleeding at tack implantation site following the MaxTack™ Motorized Fixation Device used for fixation in minimally invasive ventral hernia repair procedures at the following timepoints: o by Discharge o within 1 month o within 3 months o within 12 months • **Incidence of SSO requiring Procedural Intervention (SSOPI)** which are the following AEs related to the study device, mesh, and / or study procedure (seroma, hematoma, surgical site infection, bleeding at tack implantation site) following the MaxTack™ Motorized Fixation Device used for fixation in minimally invasive ventral hernia repair procedures at the following timepoints: o by Discharge o within 1 month o within 3 months o within 12 months • **Incidence of hernia recurrence** following the MaxTack™ Motorized Fixation Device used for fixation in minimally invasive ventral hernia repair procedures. The evaluation of clinical hernia recurrence will be performed via a Valsalva maneuver during a physical examination and confirmed per site standard of care medical imaging, if necessary, at the following timepoints: o within 1 month o within 12 months • Incidence of **hernia recurrences resulting in reoperation**, defined as an operative procedure performed with the specific goal of repairing the recurrent hernia, at the following timepoints: o within 1 month

	○ within 3 months ○ within 12 months • Incidence of a MaxTack™ Motorized Fixation **device deficiency (DD)** (e.g., insufficient tack penetration, loose tacks, tack(s) migration, tacker battery issue, etc.) on the day of the index procedure. • **Operative time for mesh fixation,** defined as the time elapsed from the initiation of the mesh fixation process with MaxTack™ to its completion. • **Surgeon satisfaction** as assessed by Surgeon Satisfaction Questionnaire postoperatively. • **Length of hospital stay** after minimally invasive ventral hernia repair procedure where the MaxTack™ Motorized Fixation Device was used for fixation. • Change in subject-reported pain at the hernia site evaluated with **Numeric Rating Scale (NRS) score** from 0 to 10 at screening and compared to the following timepoints: ○ at Month 1 ○ at Month 3 ○ at Month 12 • Change in **subject Quality of life (QoL)**, as measured through the administration of the Hernia Quality of Life (**HerQLes) questionnaire**, evaluated at screening and compared to the following timepoints: ○ at Month 1 ○ at Month 3 ○ at Month 12
Study Design	This study is a prospective, post-market, multicenter, nonrandomized, single-arm, interventional clinical study aimed at evaluating the performance and safety of the MaxTack™ Motorized Fixation Device used for fixation in minimally invasive ventral hernia repair procedures. The study will be conducted at approximately 10 sites within the United States. However, additional sites in other regions may be added as needed to meet study objectives. Upon obtaining IRB/EC approvals, subjects who have signed an informed consent form and who meet eligibility criteria will be enrolled in the study. Subjects will undergo elective minimally invasive ventral hernia repair

	surgery using mesh for reinforcement. The procedure will utilize the MaxTack™ Motorized Fixation Device for mesh fixation and evaluations will be conducted at various time points, including Screening, Operative, Discharge, and postoperative visits at Month 1, Month 3, and Month 12. The study duration is estimated to be approximately 13 months of recruitment followed by a 12-month postoperative follow-up period (+ 45 Days). The primary analysis will be conducted when all subjects have completed their Month 3 follow-up visits (or exited the study) and may be used for regulatory and publication purposes. The final analysis, intended for comprehensive assessment, will be conducted when all subjects have completed their Month 12 follow-up visit and / or exited the study.
Sample Size	Approximately 110 subjects will be enrolled at approximately 10 sites located in the United States (US) who are undergoing elective minimally invasive ventral hernia repair. However, additional sites in other regions may be added as needed to meet study objectives.
Inclusion/Exclusion Criteria	**Subjects are eligible to be enrolled in the study only if they meet all the following criteria:** <u>Preoperative Inclusion Criteria:</u> 1. Subject has provided informed consent (IC) 2. Subject is 18 years of age or older at the time of consent 3. Subject is able and willing to comply with the study requirements and follow-up schedule 4. Subject is undergoing an elective, single-stage, primary or incisional ventral hernia repair 5. Subject is undergoing minimally invasive ventral hernia repair procedure using the MaxTack™ Motorized Fixation Device 6. Subject is undergoing minimally invasive ventral hernia repair procedure using a Medtronic (including Covidien) mesh that is intended to be used in compliance with the mesh Instructions for Use (IFU) 7. Subject is expected to meet the criteria for a Class I wound (clean) as defined by the Centers for Disease Control and Prevention (CDC) classification **Subjects will be excluded from the study if they meet any of the following criteria:** <u>Preoperative Exclusion Criteria:</u>

	1. Subject is undergoing an emergency surgery (e.g., lifesaving procedures performed where subject is in imminent danger of death, strangulated hernia, etc.) 2. Subject has history of 3 or more hernia repair procedures 3. Subject has existing mesh in the space where the physician needs to apply the new mesh to be fixated with the MaxTack™ motorized fixation device 4. Subject is scheduled (or anticipated to be scheduled) for additional surgery, and subsequent surgery would jeopardize previous application of study treatment 5. Subject has history of allergic reactions to Poly (Glycolide-co-L-lActide) (PGLA) 6. Subject has history of allergic reactions to the components of the intended mesh 7. Subject has any systemic or local ongoing infection at the time of the surgery 8. Subject has a Body Mass Index (BMI) greater than 45 kg/m^2 9. Subject has life expectancy in the opinion of the investigator, of less than 3 years at the time of enrollment 10. Subject is pregnant (as determined by standard site practices) or is planning to become pregnant during study duration period 11. Subject has participated or will participate in an investigational drug or device research study that would interfere with the results of this study 12. Subject's participation in the study may jeopardize the safety or welfare of the subject, as determined by the investigator 13. Subject is already enrolled or was previously enrolled in this study <u>Intraoperative Exclusion Criteria</u> 1. Subject did not receive the MaxTack™ Motorized Fixation Device tacks to fixate the mesh 2. Subject did not receive a Medtronic (including Covidien) mesh 3. Inability to comply with the mesh IFU 4. Subject required more than a single piece of mesh 5. Subject has a surgical wound classified as Class II (clean-contaminated), Class III (contaminated) or Class IV (dirty/infected) as defined by the CDC classification 6. Subject with an American Society of Anesthesiologists (ASA) score of Class 4, 5, or 6 7. Inability to close the hernia defect

	8. Subject's procedure required a multi-stage repair 9. Subject's minimally invasive procedure required to convert to open

Study Procedures and Assessments	Subjects will be evaluated at Screening, Operative, Discharge, Month 1, Month 3, and Month 12 visits post-surgery. Assessments to be conducted/data collected include:
	Screening (-60 – 0 Days preoperative):
	• Verification of Subject Eligibility (preoperative criteria)
	• Obtain Subject Informed Consent
	• Obtain pain score (Numerical Rating Scale (NRS)) at Hernia Site
	• Obtain HerQLes Quality of Life Questionnaire – Preoperative Assessment
	• Conduct medical record review and physical exam:
	  ○ Obtain subject demographics (e.g., gender, age, ethnicity, race, weight and height)
	  ○ Obtain medical/surgical history, and relevant comorbidities
	  ○ Obtain American Society of Anesthesiologists (ASA) grade
	• Medication assessment (anticoagulants, antiplatelets, antithrombotic, and/or pain medication)
	Operative Data (Day 0):
	Note: Preoperative (Screening) Day and Operative Day can be combined
	• Verification of Subject Eligibility (including intraoperative criteria)
	• Medication assessment (prophylactic antibiotics, anticoagulants, antiplatelets, antithrombotic, and/or pain medication)
	• Obtain procedure information including:
	  ○ Operative times
	  ○ General anesthesia information (type)
	  ○ Hernia defect description, defect closure and surgical technique
	  ○ Tack, mesh, and other fixation data
	• Obtain Surgeon Satisfaction Questionnaire
	• Assess and report adverse events, device deficiencies and study deviations, if applicable
	Discharge:

	• Medication assessment (anticoagulants, antiplatelets, antithrombotic, and/or pain medication) • Obtain date discharged from hospital (length of hospital stay) • Assess and report adverse events, device deficiencies, and protocol deviations, if applicable **Month 1 (30-51 days), Month 3 (90-120 days), Month 12 (365-410 days) Follow-up:** • Obtain pain score (Numerical Rating Scale (NRS) at Hernia Site • Obtain HerQLes Quality of Life Questionnaire – Postoperative Assessment • Medication assessment (anticoagulants, antiplatelets, antithrombotic, and/or pain medication) • Conduct clinical assessment which includes: clinical physical examination for hernia recurrence (including a Valsalva maneuver), hernia recurrences resulting in reoperation, if applicable • Assess and report adverse events, device deficiencies, and protocol deviations, if applicable **Unscheduled Visits** • Visit reason • Medication assessment (anticoagulants, antiplatelets, antithrombotic, and/or pain medication) • Details of hernia recurrence/reoperation, if applicable • Assess and report adverse events, device deficiencies, and protocol deviations, if applicable
Safety Assessments	Safety will be assessed via adverse event (AE) data collected in this study. AEs related to the study device MaxTack™ Motorized Fixation Device, mesh, or study procedure; including any events that cause death, that occur from the time of skin incision through study exit; as well as any non-subject adverse events will be reported. Additionally, any device deficiency (DD) will be collected. AEs will be assessed by the investigator and the sponsor as well as an external independent Medical Monitor (MM) for events requiring adjudication. AEs and DDs will be documented in the electronic case report form (eCRF).
Statistics	This study is a prospective, post-market, multi-center, nonrandomized, single-arm, interventional clinical study with a predefined performance

	goal (PG). The primary outcome is hernia recurrence rate within 3 months by clinical exam and confirmed per site standard of care medical imaging, if necessary. Based on meta-analysis the estimated expected recurrence rate within 3 months is 1.0% (95% CI: 0.6% to 4.6%). The PG of 8.6% for the maximum upper confidence limit for the study is set at the highest expected recurrence rate at 3 months of 4.6% plus a 4% clinical margin to balance the number of subjects while maintaining proof of acceptable performance. The PG will be met if the upper confidence limit from the 95% two-sided Clopper-Pearson confidence interval on the primary outcome of hernia recurrence rate within three months is less than 8.6%. The null and alternative hypotheses are given below: H_0: three-month recurrence rate $\geqslant$ 8.6% versus H_1: three-month recurrence rate < 8.6%. A binomial test for proportion with a one-sided alpha of 0.025 will be used to test the hypothesis. A total of enrollment of approximately 110 leaves 100 evaluable subjects assuming a 9% attrition within 3 months. With 100 evaluable subjects the power to reject the null hypothesis is over 90% assuming an event rate of 1.0%. With 100 evaluable subjects if 3 or less recurrences (3 %) are observed, the PG will be met. Continuous variables will be summarized using means, standard deviations, quartiles, minimum, maximum values and 95% confidence intervals as appropriate. Categorical variables will be summarized using counts, percentages and 95% confidence intervals as appropriate.

4. Introduction

4.1 Background

A hernia is comprised of an abnormal protrusion of abdominal cavity contents or preperitoneal fat through a defect or weakness in the abdominal wall. A ventral hernia is a hernia of the abdominal wall, excluding the inguinal area, pelvic area, and diaphragm [(1)]. Hernias may occur spontaneously (primary hernia) or at the site of a previous surgical incision (incisional hernia).

Ventral hernia repair remains one of the most common and challenging general surgical procedures due to variations in surgical techniques and patient characteristics/comorbidities. Approximately 250,000 ventral incisional hernia repairs are performed annually in the United States [(2-5)]. The repair of ventral hernias can be performed through either an open or a laparoscopic approach using a suture repair or a mesh repair technique.

Use of prosthetic mesh repair is considered as standard of care for ventral hernia treatment [(6)]. Depending on the surgical technique, the mesh may be implanted either in an intraperitoneal position or outside of the abdominal cavity, such as onlay, retrorectus, or preperitoneal techniques. Surgical meshes are medical devices used to provide additional support to weakened or damaged tissue. The majority of surgical mesh devices currently available for use are constructed from synthetic materials and/or animal tissue. The mode of action of the mesh primarily relies on the strength provided by the structural component of the implant, i.e., the textile/tissue structure. The surgical mesh is intended to be progressively colonized by the host tissue following the cascade of biological mechanisms inherent to wound healing and soft tissue remodeling so that the mesh will ensure a long-term reinforcement of soft tissues.

The International EndoHernia Society (IEHS) [(6)] recommends that hernia meshes are fixated using tacks, alone or in combination with sutures, for the laparoscopic repair of ventral and incisional hernias. The clinical benefit of fixating a mesh to soft tissue during ventral hernia repair contributes to reinforcing the weakened defect in the abdominal wall and minimizes the risk of recurrence and other complications [(7)].

The development of the MaxTack™ Motorized Fixation Device (MaxTack™) relies on the long-term knowledge acquired by Medtronic in the development of mesh fixation along with mesh fixation devices. The MaxTack™ Motorized Fixation Device was specifically developed as a motorized device with fully absorbable tacks as an alternative to similar devices currently available on the market.

The MaxTack™ Motorized Fixation Device is a sterile, single use, Medtronic fixation device. This device contains 30 absorbable tacks made of an absorbable synthetic polyester copolymer derived from lactic and glycolic acid. The tacks of MaxTack™ are 7mm in length [(8)].

Medtronic has tested the MaxTack™ Motorized Fixation Device for biocompatibility using standard EN ISO 10993-1 (2009), demonstrating its biological safety as noted in internal documentation. This testing covered both the implantable green tack and the delivery system (tube assembly), ensuring compliance

with relevant device categorization standards. The Poly (Glycolide-co-L-lActide) PGLA material, colored with D&C Violet #2, which is also used in the AbsorbaTack™ device (equivalent Medtronic device), has been previously evaluated for ISO 10993-1:2018 compliance. The tube assembly for both the MaxTack™ Motorized Fixation Device and AbsorbaTack™ is similar in device categorization and intended use, as well as materials and manufacturing processes. No new issues affecting the biocompatibility of AbsorbaTack™ Violet tacks were identified, eliminating the need for additional testing for MaxTack™ Violet tacks. D&C Green No. 6 dye, used in Maxon™ Monofilament Absorbable Sutures and V-LOC™ 180 Absorbable Wound Closure Device by Medtronic since 1999 and 2009, has a long history of safe use with no associated complaints. The green dye in MaxTack™ tacks has been thoroughly tested for biocompatibility and proven safe.

4.2 Purpose

Medtronic is sponsoring and funding the AFFIX study, a prospective, post-market, multicenter, nonrandomized, single-arm, interventional clinical study. The purpose of this study is to evaluate the performance and safety of the MaxTack™ Motorized Fixation Device when used for fixation of prosthetic material to soft tissue in minimally invasive ventral hernia repair procedures. Data from this study may be used for regulatory and publication purposes.

5. Objectives and Endpoints

5.1 Objectives

5.1.1 Primary Objective

The primary objective is to evaluate the performance (hernia recurrence rate) within 3 months following the use of the MaxTack™ Motorized Fixation Device for fixation in minimally invasive ventral hernia repair procedures.

5.1.2 Secondary Objectives

The secondary objectives of this study are to evaluate the safety and performance of the MaxTack™ Motorized Fixation Device when used for fixation in minimally invasive ventral hernia repair procedures within 12 months postoperatively.

5.2 Endpoints

5.2.1 Primary Endpoint

The primary performance endpoint is the incidence of hernia recurrence within 3 months following the use of MaxTack™ Motorized Fixation Device for fixation in minimally invasive ventral hernia repair procedures.

Hernia recurrence is defined as a palpable fascial defect and/or a clinically manifested bulge, exacerbated by a Valsalva maneuver evaluated during a physical examination by the investigator and confirmed per site standard of care medical imaging, if necessary, at the respective clinical site. If a Valsalva maneuver is not conducted during physical examination, this must be reported as a protocol deviation.

If standard of care imaging (Computerized Tomography Scan (CT scan), ultrasound, or Magnetic Resonance Imaging (MRI)) is done for hernia recurrence confirmation at the discretion of the study investigator, the final decision to report a hernia recurrence will be based on the study investigator's assessment. Standard of care imaging may be done by a non-study, standard of care assessor, such as a radiologist.

5.2.2 Secondary Endpoints

The secondary endpoints will include:

- Incidence of Surgical Site Occurrence (SSO) which are the following Adverse Events (AEs) related to the study device, mesh, and / or study procedure and defined as Seroma, Hematoma, Surgical Site Infection (SSI), bleeding at tack implantation site following the MaxTack™ Motorized Fixation Device used for fixation in minimally invasive ventral hernia repair procedures at the following timepoints:
    - by Discharge
    - within 1 month
    - within 3 months
    - within 12 months
- Incidence of SSO requiring Procedural Intervention (SSOPI), which are the following AEs related to the study device, mesh, and/or study procedure and defined as Seroma, Hematoma, Surgical Site Infection, bleeding at tack implantation site following the MaxTack™ Motorized Fixation Device used for fixation in minimally invasive ventral hernia repair procedures at the following timepoints:
    - by Discharge
    - within 1 month
    - within 3 months
    - within 12 months
- Incidence of hernia recurrence following the MaxTack™ Motorized Fixation Device used for fixation in minimally invasive ventral hernia repair procedures. The evaluation of hernia recurrence will be performed via a Valsalva maneuver during a physical examination and confirmed per site standard of care medical imaging, if necessary, at the following timepoints:
    - within 1 month
    - within 12 months
- Incidence of hernia recurrences resulting in reoperation, defined as an operative procedure performed with the specific goal of repairing the recurrent hernia, at the following timepoints:

  - within 1 month
  - within 3 months
  - within 12 months
- Incidence of MaxTack™ Motorized Fixation Device deficiencies (e.g., insufficient tack penetration, loose tacks, tack(s) migration, tacker issue battery etc.) on day of the index procedure.
- Operative time for mesh fixation, defined as the time elapsed from the initiation of the mesh fixation process with MaxTack™ to its completion
  - Surgeon satisfaction as assessed by Surgeon Satisfaction Questionnaire postoperatively.
  - Length of hospital stay after minimally invasive ventral hernia repair procedure where the MaxTack™ Motorized Fixation Device was used for fixation.
- Change in subject-reported pain at the hernia site evaluated with Numeric Rating Scale (NRS) score from 0 to 10 at screening and compared to the following timepoints:
  - at Month 1
  - at Month 3
  - at Month 12
  - Change in subject Quality of life (QoL), as measured through the administration of the Hernia Quality of Life Survey (HerQLes) questionnaire, evaluated at screening and compared to the following timepoints:
    - at Month 1
    - at Month 3
    - at Month 12

6. Study Design

This prospective, post-market, multicenter, nonrandomized, single-arm, interventional clinical study will evaluate the performance and safety of the MaxTack™ Motorized Fixation Device when used for fixation in minimally invasive ventral hernia repair procedures.

The study is expected to be conducted at approximately 10 study sites located in the United States (US). However, additional sites in other regions may be added as needed to meet study objectives. Approximately 110 subjects will be enrolled in the study using the MaxTack™ Motorized Fixation Device. Enrolled subjects will be subjects who have signed an informed consent form, who meet all eligibility criteria and at least one MaxTack™ tack is utilized for fixation. Study subjects will be evaluated at Screening (-60-0 days preoperative), Operative, Discharge, Month 1 (30-51 days postoperative), Month 3 (90-120 days postoperative), and Month 12 (365-410 days postoperative) visits.

Measures to control bias:

Enrollment parameters are included in the study to avoid introduction of bias to the study results due to disproportionate enrollment. Enrollment shall not exceed 25 subjects per site (this is 25% of the minimum

number of evaluable subjects needed [100]). Enrollment will be competitive across study sites. The per-study site enrollment cap may be increased upon sponsor approval. At any time, the study sponsor may place an enrollment hold on individual sites for reasons relating to data quality, overall performance, concerns with Principal Investigator (PI) oversight, or other reasons not specified within the Clinical Investigative Plan (CIP).

All investigators will be required to provide financial disclosure (FD). Physicians will not be able to participate if they have any significant conflict of interest that cannot be mitigated in this study.

Physicians performing procedures will be qualified surgeons experienced with hernia repair procedures.

A Medical Monitor (MM) will be utilized to conduct an independent review and adjudication of specified adverse events. The assessments from the MM will be used in the study endpoint analyses where applicable.

The expected total study duration from the first subject enrollment to the last subject visit is approximately 25 months, representing approximately 13 months of enrollment and 12 months (+ 45 days) of subject follow-up. Assessments will occur at Screening, Operative, Discharge, Month 1, Month 3, and Month 12. The expected duration of each subject's participation in the study from Screening visit to the Month 12 is up to 15.5 months (screening visit could occur 60 days prior to the Operative day, and with the Month 12 follow-up having an upper window of 45 days). Study subjects will be followed until the final study visit or official study closure, defined as when Medtronic requirements have been satisfied per the CIP and/or by a decision by Medtronic, Institutional Review Board (IRB), or Ethics Committee (EC), or Regulatory Authority (RA), whichever occurs first.

6.1 Rationale

MaxTack™ Motorized Fixation Device was 510(k) cleared by the Food and Drug Administration (FDA) (US) on September 8th, 2023.

The rationale and justification for the chosen design is based on the evaluation of clinical data from equivalent devices, similar studies [14-23], and the Instructions for Use (IFU).

Rationale for Prospective, Post-Market, Single Arm-Design

In designing the AFFIX clinical study, Medtronic considered currently available evidence for similar studies [14-23], feasibility of enrollment, relevant markets/regions, and efficiency of execution, among other factors. A comprehensive literature review was conducted to evaluate the existing body of evidence. Multiple published studies and reports provide substantial data demonstrating the similar devices efficacy and safety in various clinical scenarios [14-23]. These studies collectively establish a substantial foundation of evidence regarding device performance objectives. Additionally, Medtronic has tested the MaxTack™ Motorized Fixation Device for biocompatibility using standard EN ISO 10993-1 (2009), demonstrating its biological safety.

The AFFIX study is a US-based, prospective, post-market, multicenter, nonrandomized, single-arm, interventional study that is not mandated by the US FDA. The purpose of this study is to evaluate the performance and safety of the MaxTack™ Motorized Fixation Device when used for fixation in minimally invasive ventral hernia repair procedures. Due to the substantial evidence on similar devices, a single-arm study design was chosen [14-23]. This study was designed without concurrent treatment control, as a single-arm design was the most feasible and efficient method to achieve the study's objectives for subjects and sites participating in the study. As a single-arm design, the study's primary limitation is, therefore, the lack of a direct comparison to other products on the market.

Rationale for Number of Sites and Subjects

Approximately 10 sites may be selected to participate in the AFFIX study to ensure a multicenter evaluation and to achieve the enrollment goal in a timely manner. The rationale for the sample size of 110 is provided in Section 14.6, Sample Size Determination.

Rationale for Subject Population

The MaxTack™ Motorized Fixation Device is indicated for use in the fixation of hernia mesh to soft tissue during minimally invasive ventral hernia repair procedures. The subject population will include adult subjects 18 years or older who are undergoing ventral hernia repair by minimally invasive surgeries. Excluding subjects with high risk factors such as infection, American Society of Anesthesiologists (ASA) score of 4, 5, or 6, history of three or more hernia repair surgeries, history of allergic reaction to device components, or a Body Mass Index (BMI) more than 45, may mitigate procedure or device performance risks to the subjects. Restricting enrollment to subjects who have a life expectancy of 3 years or more may aid in ensuring the subjects can complete 12 months of follow-up.

Rationale for Chosen Endpoints and Timing of Endpoints

This post-market study will assess the performance and the safety of the MaxTack™ Motorized Fixation Device during minimally invasive ventral hernia repair procedures. Subjects will be evaluated at the screening, operative, discharge, Month 1, Month 3, and Month 12 visits.

The primary endpoint of the performance of MaxTack™ by measuring the incidence of hernia recurrence within 3 months postoperatively has been selected for this study. The absorbable tacks need to retain strength long enough to hold the mesh in place until sufficient ingrowth occurs. Wound healing and mesh integration processes occur up to 12 weeks. If the tacks fail in terms of strength or there is a deficiency, it should be observed within 3 months and may lead to a hernia recurrence during this period. For this reason, having a primary endpoint within the 3 months is appropriate.

The secondary endpoints further evaluate the performance and safety of MaxTack™. These include evaluations at Month 1, 3, and 12. Subject follow-up is until 12 months postoperative since the MaxTack™ tacks will be fully absorbed by 12 months. Based on similar clinical studies, the endpoints were chosen to

best characterize the performance and safety of MaxTack™, as well as to evaluate the compatibility and ease of use of MaxTack™.

Surgical Site Occurrences (SSO) has been defined in this study as the following AEs: Seroma, Hematoma, Surgical Site Infection, and bleeding at tack implantation site. These events were chosen based on previous clinical studies and tailored to the type of events that could occur due to fixation, including tacks [25]. Though other events may occur in a subject, these SSOs (beyond hernia recurrence) are the events of interest for this study.

The visit windows for the Month 1, 3, and 12 visits all open on the target date (e.g., Month 1 window begins at 30 days) rather than the allowance for windows to open early. The visit windows are designed to ensure accurate capture of what occurred within that timeframe rather than evaluating the endpoints too early (e.g., within 3 months).

Claims to be verified:

The AFFIX study will verify the following relevant claims related to MaxTack™:

- Positive clinical outcomes for fixation of prosthetic material to soft tissue in minimally invasive ventral hernia repair procedures compared to State Of The Art expressed by:
    - the hernia recurrence rate
    - the change in subject Quality of Life (QoL), as measured through the administration o the Hernia Quality of Life Survey (HerQLes) questionnaire (Section 18.4 Appendix D – HerQLes Quality of Life Questionnaire), evaluated at screening and compared to other timepoints
    - the change in subject-reported pain score at the hernia site evaluated with the Numeric Rating Scale (NRS) (Section 18.3 Appendix C – Pain Numerical Rating Scale) at screening compared to other timepoints
- Ability to accommodate physicians in their surgical techniques and clinical cases by enabling prosthetic material fixation to soft tissue: ease of use, compatibility with minimally invasive surgical approach(es) assessed using the Surgeon Satisfaction Questionnaire (Section 18.8 Appendix H – Surgeon Satisfaction Questionnaire).

7. Product Description

7.1 General

MaxTack™ Motorized Fixation Device is composed of three main subsystems: the tack and the delivery system, which includes the shaft and handle (Figure 1).

The tack is the fixation implant delivered by the device to secure the hernia mesh to the tissues. The tack is constructed of an absorbable synthetic polyester copolymer derived from lactic and glycolic acid. The

first 25 tacks are dyed with D&C Violet No. 2. The last 5 tacks are dyed with D&C Green No. 6 to serve as an indicator of low tack count to the user. The total tack length (including tack head) is 7 mm.

The distal portion of the shaft is inserted into the cannula and into the patient's body cavity. The shaft contains the tacks and the drive mechanism that deploys and advances the tacks. The distal end of the shaft has a mesh manipulation/grip feature that may be used to help facilitate the positioning of the mesh.

The handle is the interface that the user grips when using the device. The handle contains a single motor assembly, printed circuit board assembly (PCBA) with microprocessor, encoder, light-emitting diode (LED) indicator, speaker, tactile switch, and two 9V alkaline batteries in parallel. The motor within the handle provides the mechanical torque controlled by the PCBA for tack deployment. The LED and speaker provide device status information to the user through visual lights and audible tones. When the trigger push-button firing mechanism is depressed, tack deployment is initiated by the software stored in the microprocessor. The PCBA has an encoder to provide shaft position information. The software controls the motor speed and position using encoder pulses. As the motor rotates, tacks advance through the drive system of the shaft and a single tack is deployed into the desired tissue (Figures 2, 3 and 4).

Figure 1: MaxTack™ Motorized Fixation Device Overview

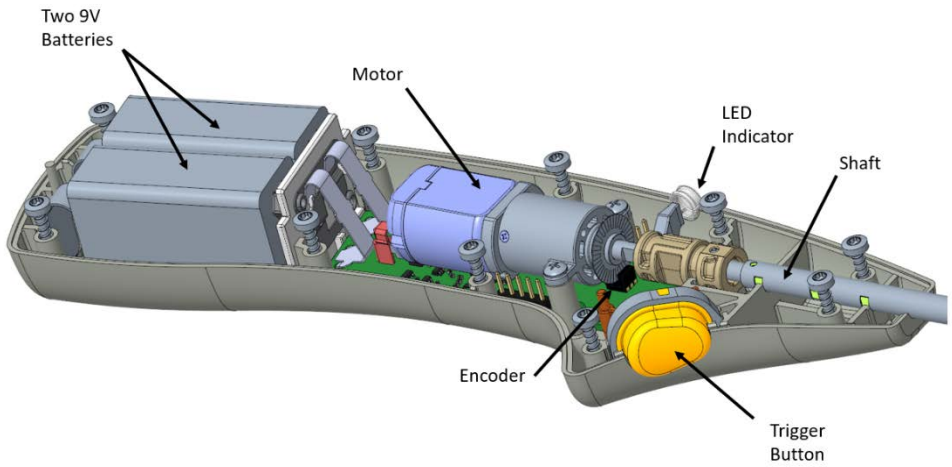


Figure 2: MaxTack™ Motorized Fixation Device Handle Internal Assembly – 1

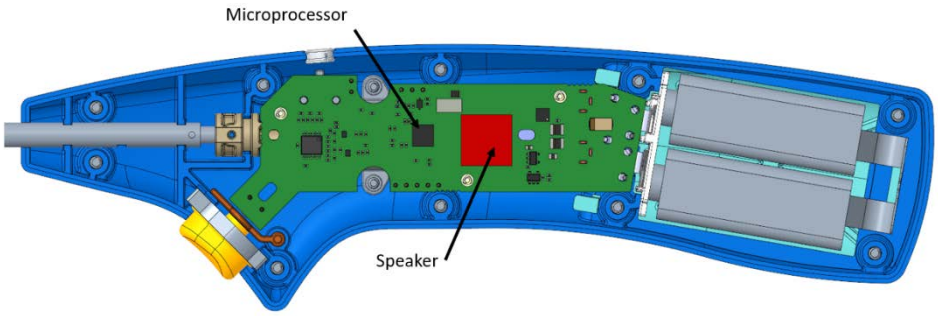


Figure 3: MaxTack™ Motorized Fixation Device Handle Internal Assembly – 2

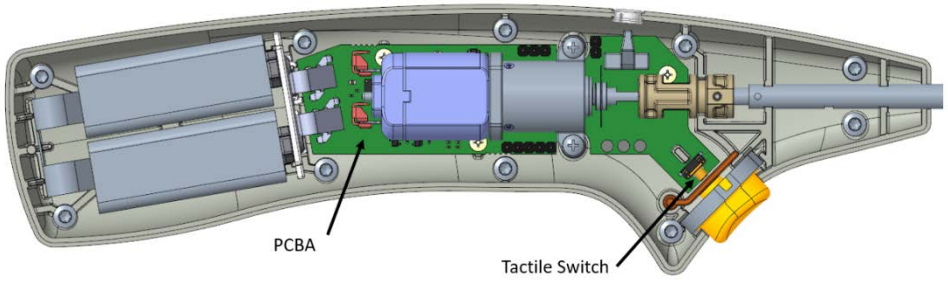


Figure 4: MaxTack™ Motorized Fixation Device Handle Internal Assembly

According to ISO 10993-1, the MaxTack™ Motorized Fixation Device is an implantable device (absorbable tacks) in long-term contact (> 30 days) with tissues. The absorbable tacks do not contain any medicinal substances, animal tissues, or blood components.

MaxTack™ involves an implantable component, which is absorbable. The tack is made up of a copolymer poly (glycolide-co-L-lactide) (PGLA). This copolymer degrades and is absorbed by hydrolysis to glycolic acid and lactic acid, which are then metabolized by the body. The absorption profile of PGLA in the first two weeks after initial implantation is minimal, with significant absorption from three to five months. Following this significant breakdown, the polymer absorption is essentially completed prior to one year.

In view of the detailed consideration of all the relevant data, the biological safety evaluation of MaxTack™ has been found compliant with the biological safety requirements of ISO 10993-1, Ministry of Health, Labor and Welfare (MHLW) and FDA guidance on the use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

All materials that may contact tissues and/or body fluids are presented in Table 1.

Table 1: Materials in Contact with Tissues and/or Body Fluids

MaxTack™ Motorized Fixation Device Component	Materials	Subject Contact
Shaft	304L Stainless Steel with laser etched logo	Limited subject contact (less than 24 hours)
Implant (Tack)	L1 Polymer: Absorbable Synthetic Polyester [poly (glycolide-co-L-lactide) (PGLA)]	Greater than 30 days

At the time of document approval, MaxTack™ is 510(k) cleared in the United States (US). There is no anticipated change in the product during the course of the study.

7.2 Manufacturer

The manufacturer contact details are as follows:

Medtronic-Covidien
Surgical Operating Unit
15 Hampshire St
Mansfield, MA, 02048
USA

7.3 Packaging

MaxTack™ devices used in this study will be packaged in accordance with released product standards as single-use sterile devices. Each device will be individually packaged within a PETG tray with a Glidex lid. A

desiccant is taped outside of the tray. The device and tray are placed and sealed in a foil pouch packaging system (TYVEK-UNCOATED 1073B PERFECFLEX 35678-G foil pouch with breather stamp). For secondary packaging, one primary package including Instruction for Use (IFU) is inserted into a CLAY COATED NEWSBACK straight tuck display box, which will be sealed with two round Pilfer labels on each end. The display box will also be labeled appropriately.

Device packaging will contain Instructions for Use as noted in Section 18.6, Appendix F – Instructions for Use. The device labeling will be provided in English and/or local language upon requirements in the countries participating in the study.

7.4 Intended Population

The MaxTack™ Motorized Fixation Device is indicated for use in the fixation of prosthetic material to soft tissue in minimally invasive ventral and minimally invasive groin hernia repair procedures. The intended purpose of the device is the fixation of prosthetic material. The study only includes the population of subjects undergoing minimally invasive ventral hernia repair procedures and those meeting the study eligibility criteria listed in Section 9.

Further information on contraindications can be found in the device instructions for use, Section 18.6, Appendix F – Instructions for Use.

7.5 Equipment

No equipment is required to assess the endpoints in the AFFIX study. However, at the physician's discretion, imaging (e.g., CT scan, ultrasound exam, MRI) may be used to confirm hernia recurrence if this is the site standard of care. Any equipment for assessing hernia recurrence will be used/maintained/calibrated according to the study site's standard protocol. The maintenance and calibration report should be made available to monitors upon request. Since the use of such equipment is not required per protocol and may differ by site, Medtronic will not monitor maintenance and calibration of equipment.

7.6 Product Training Materials

Investigator(s) and study staff participating in the clinical study and the associated clinical study staff will receive training on the clinical study protocol by the Medtronic study teams prior to performing study activities. Each Investigator performing a study procedure will receive training on using the MaxTack™ Motorized Fixation Device by an authorized Medtronic representative, in addition to device characteristics, shelf life, storage requirements, device use, warnings, precautions, and contraindications. As the device is commercially available and is very similar to other tackers on the market, this training may occur after the site's study activation and during the physician's first case.

7.7 Product Accountability

The study site is responsible for maintaining the MaxTack™ Motorized Fixation Device tracking during the study. Electronic Case Report Form (eCRF) device accountability logs must be kept at each study site and updated when the study device is received, opened, implanted, explanted, disposed of, or returned to Medtronic. If the delegated site study team member does not have direct access to the study database, a paper worksheet may be utilized to document device use prior to entering data into the database. In addition to tracking the date of events, the device accountability log tracks product information including, but not limited to, device lot number, date received and expiration date for the product, subject ID of the implanted subject, reason(s) for and method of destruction/disposal for explanted components not returned to Medtronic (if applicable), and name of the person responsible for return or destruction/disposal (if applicable).

Medtronic will perform periodic reconciliation of the study devices to ensure traceability.

7.7.1 Product Delivery

MaxTack™ Motorized Fixation Device is market released in the United States. Despite this, distribution of the study product to study sites during the study will be managed by Medtronic and can only be ordered by Medtronic personnel. Sites with purchasing agreements for MaxTack™ may not use commercially procured devices in place of study devices. Study products will be distributed to a study site only when Medtronic has received all required documentation and has notified the study site of study site activation or the site is nearly activated.

If there are additional local requirements related to the study device beyond what is collected by Medtronic, this is the Investigator's responsibility and should be recorded in the subject's medical records but may not be collected by Medtronic (e.g., national registration card number, identification code linked to names and contact information, log of all subjects enrolled in the study).

7.7.2 Product Receipt and Tracking

The MaxTack™ Motorized Fixation Device will be shipped to each site only when the sponsor has received all required documentation (not limited to) Ethics Committee (EC)/Institutional Review Board (IRB) Approval, a signed Clinical Trial Agreement (CTA) and documentation of training. MaxTack™ will have traceable lot numbers. Each site will document the quantity received, lot number(s), expiration date(s), and any additional details upon receipt in the Device Accountability Log.

Device traceability may be required per local laws and regulations.

7.7.3 Product Storage

Once MaxTack™ is received at the study site, it must be stored in a secure location. The investigator is responsible for correctly handling, storing, and tracking the study devices maintained at the study site.

Access must be limited to authorized personnel listed on the Delegation of Authority Log. Study devices will be used only in the clinical study according to the CIP and IFU (Section 18.6, Appendix F – Instructions for Use). According to the IFU, MaxTack™ should be stored at room temperature and not exceed 48°C (118°F). MaxTack™ does not require any additional special storage conditions.

7.7.4 Product Return

All explanted devices (not including any study device not fully implanted during the study procedure) should be returned to Medtronic for analysis in compliance with the site's policy on explanted devices and as permissible by local laws and regulations. If the products are explanted but not returned, a justification must be reported on the appropriate case report forms (eCRF) or disposition logs. The site is responsible for promptly informing the Medtronic study team when MaxTack™ tacks are explanted. The Medtronic study team will assist with the shipment of the product back to Medtronic.

At the conclusion of the study, any unused MaxTack™ will be returned to Medtronic and documented in the Device Accountability Log eCRF.

8. Study Site Requirements

8.1 Investigator/Investigation Site Selection

This study will be conducted by experienced surgeons in the field of hernia surgery who are board certified/board eligible, qualified by education and training in accordance with US and hospital guidelines, education, and relevant experience appropriate to the use of the product and associated procedures. Investigator(s)/sites must have adequate time and resources to conduct the study throughout the study and have access to an adequate number of eligible subjects.

Investigator(s)/sites must be able to comply with applicable Institutional Review Board (IRB) / Ethics Committee (EC) and regulatory requirements. Investigator(s) must not be debarred, disqualified, or working under sanctions in applicable regions. Qualifications are verified through valid curriculum vitae (CV) and current licensing and maintained with study documentation.

The role of the site principal investigator is to implement and manage the day-to-day conduct of the clinical study and ensure data integrity, as well as the rights, safety, and well-being of the subjects involved in the clinical investigation.

8.2 Study Site Activation

During the activation process (prior to subject enrollment), Medtronic will train study site personnel on the clinical investigation plan, relevant standards and regulations pertinent to study activities, informed consent, and data collection and reporting tools. If new members join the study site team, they will receive training on the applicable study requirements relevant to their role before contributing to the study. Medtronic trained investigators are allowed to train their study staff as needed during the study.

Before performing study-related activities, all regulatory requirements shall be fulfilled, including, but not limited to, the following:

- The IRB/EC approval (and voting list, as required by local law), the current version of the CIP, Informed Consent (IC), and other study-specific documents (if applicable),
- Fully executed CTA,
- Financial disclosure (FD) (if allowed by local regulations),
- Curriculum vitae (CV) of investigators and applicable site personnel listed on the Delegation of Authority Log. CV must be considered current and signed/dated if required per local regulation(s), as applicable,
- Documentation of delegated tasks,
- Documentation of study training,
- Additional requirements imposed by local regulations of the IRB/EC shall be followed if appropriate

In addition, all participating study site staff must be trained on the current version of the CIP and the applicable study requirements depending on their role, and the principal investigator must delegate them to perform study-related activities.

Medtronic will provide each study site with documentation of study site/principal investigator readiness; this letter must be received before performing study-related activities.

Medtronic contracts with participating institutions/investigators through a CTA that defines the scope, responsibilities, and compensation for carrying out the obligations under a clinical study sponsored by Medtronic.

9. Selection of Subjects

9.1 Study Population

The study population will consist of consented adults 18 or older who undergo elective minimally invasive ventral hernia repair surgery using mesh for reinforcement. The procedure will utilize the MaxTack™ Motorized Fixation Device for mesh fixation. Additional inclusion and exclusion criteria are listed below. Subjects will be enrolled at approximately 10 sites in the US. However, additional sites in other regions may be added to meet study objectives.

9.2 Inclusion Criteria)

Subjects are eligible to be enrolled in the study only if they meet all the following criteria:

Preoperative Inclusion Criteria:

1. Subject has provided informed consent (IC)
2. Subject is 18 years of age or older at the time of consent
3. Subject is able and willing to comply with the study requirements and follow-up schedule
4. Subject is undergoing an elective, single-stage, primary or incisional ventral hernia repair
5. Subject is undergoing minimally invasive ventral hernia repair procedure using the MaxTack™ Motorized Fixation Device
6. Subject is undergoing minimally invasive ventral hernia repair procedure using a Medtronic (including Covidien) mesh that is intended to be used in compliance with the mesh Instructions for Use (IFU)
7. Subject is expected to meet the criteria for a class I wound (clean) as defined by Centers for Disease Control and Prevention (CDC) classification

9.3 Exclusion Criteria

Subjects will be excluded from the study if they meet any of the following criteria:

Preoperative Exclusion Criteria:

1. Subject is undergoing an emergency surgery (e.g., lifesaving procedures performed where subject is in imminent danger of death, strangulated hernia, etc.)
2. Subject has history of 3 or more hernia repair procedures
3. Subject has existing mesh in the space where the physician needs to apply the new mesh to be fixated with the MaxTack™ Motorized Fixation Device
4. Subject is scheduled (or anticipated to be scheduled) for additional surgery, and subsequent surgery would jeopardize previous application of study treatment
5. Subject has history of allergic reactions to Poly (Glycolide-co-L-lActide) (PGLA)
6. Subject has history of allergic reactions to the components of the intended mesh
7. Subject has any systemic or local ongoing infection at the time of the surgery
8. Subject has a Body Mass Index (BMI) greater than 45 kg/m^2
9. Subject has life expectancy in the opinion of the investigator, of less than 3 years at the time of enrollment
10. Subject is pregnant (as determined by standard site practices) or is planning to become pregnant during study duration period.
11. Subject has participated or will participate in an investigational drug or device research study that would interfere with the results of this study
12. Subject's participation in the study may jeopardize the safety or welfare of the subject, as determined by the investigator
13. Subject is already enrolled or was previously enrolled in this study

Intraoperative Exclusion Criteria:

1. Subject did not receive the MaxTack™ Motorized Fixation Device tacks to fixate the mesh

2. Subject did not receive a Medtronic (including Covidien) mesh
3. Inability to comply with the mesh IFU
4. Subject required more than a single piece of mesh
5. Subject has a surgical wound classified as Class II (clean-contaminated), Class III (contaminated) or Class IV (dirty/infected) as defined by the CDC classification
6. Subject with an American Society of Anesthesiologists (ASA) score of Class 4, 5, or 6
7. Inability to close the hernia defect
8. Subject's procedure required a multi-stage repair
9. Subject's minimally invasive procedure required to convert to open

9.4 Subject Enrollment

Prior to enrollment, patients should be fully informed of the details of study participation as required by applicable regulations, the site's respective IRB/EC, and Medtronic. Informed consent must be obtained from each subject before conducting any study-specific non-standard of care, using the informed consent form (ICF) approved by the IRB/EC and Medtronic.

There are two analyses set as described in Section 14: the Full Analysis Set (FAS) and Per Protocol Analysis Set (PPAS). The table below defines the enrollment types that may occur in the study and where these subjects may be analyzed.

Table 2: Enrollment Type and Definitions

Enrollment Type	Definition	Analysis Set
Preoperative Screen Failure	Subjects who have signed consent but do not meet eligibility criteria prior to the procedure (skin incision).	None
Intraoperative Screen Failure	Subjects determined to be eligible prior to procedure, but who met any intraoperative exclusion criteria.	None
Enrolled	A subject is considered enrolled in the study when: • it is confirmed that the ICF is properly signed and dated, • they meet all preoperative inclusion criteria, • they meet no preoperative exclusion criteria, • they meet no intraoperative exclusion criteria, and • MaxTack™ tacks are utilized for fixation	FAS, PPAS

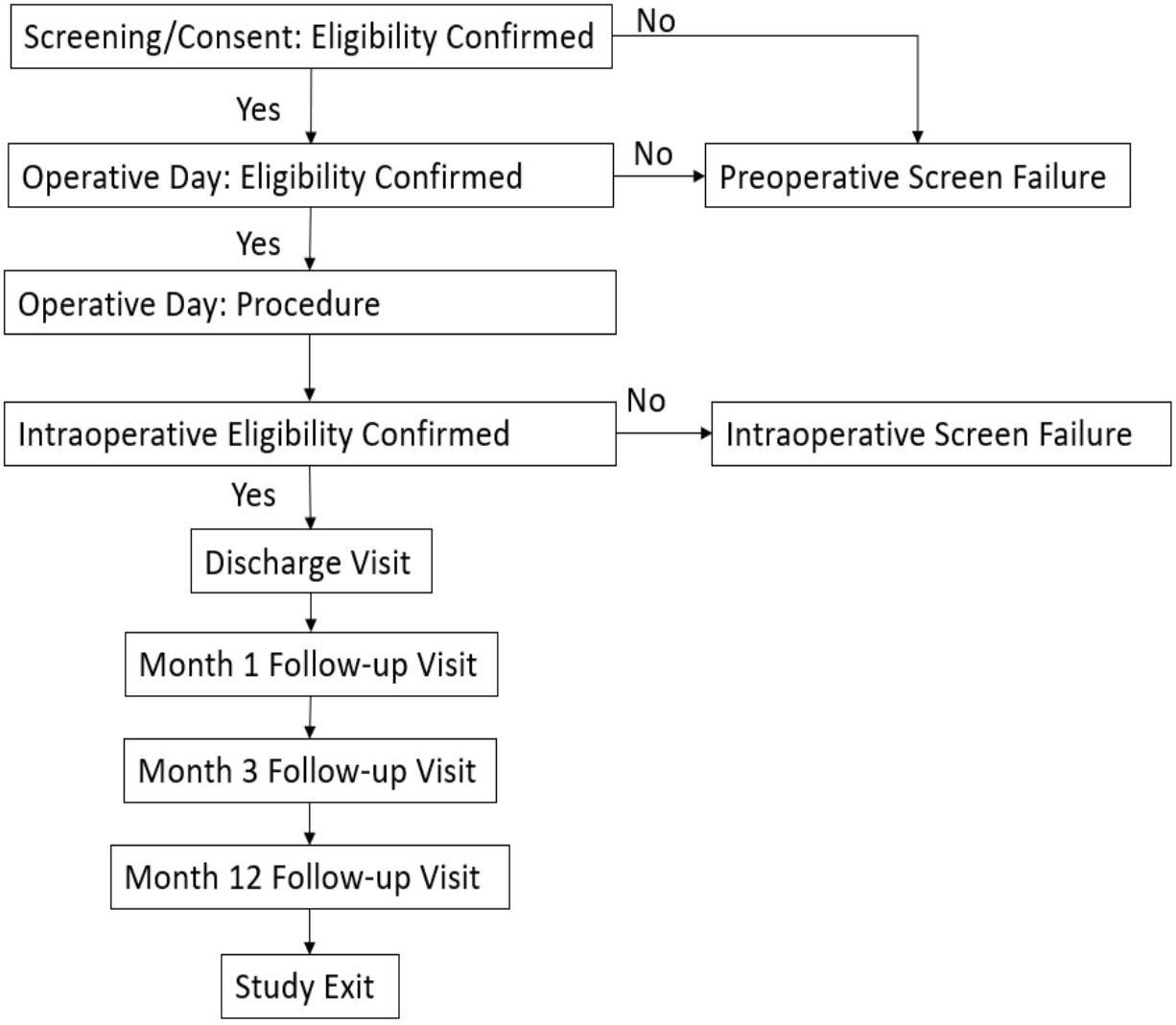
Refer to Figure 5 for an enrollment flowchart.

10. Study Procedures

10.1 Schedule of Events

Following confirmation of preoperative eligibility criteria, including collection of informed consent, subjects who require elective, minimally invasive ventral hernia repair will undergo the procedure using the MaxTack™ to fixate the mesh to the soft tissue. Refer to Figure 5 for a general summary of the study's schedule of events.

Figure 5: Study Flow Chart



10.2 Data Collection

Subjects will be evaluated at screening, operative day, discharge, and postoperatively at Month 1, 3, and 12.

Table 3: Data Collection

Assessment	Visit (Days from Procedure)						
	Screening[1] (-60-0 Days)	Operative Day	Discharge	Month 1 (30-51 Days)	Month 3 (90-120 Days)	Month 12 (365-410 Days)	Unscheduled Visit
Informed Consent[1]	X[1]						
Subject Eligibility	X[2]	X[2]					
Medical Record Review and Physical Exam[4]	X						
Medication Assessment[5]	X	X	X	X	X	X	X
HerQLes Quality of Life Questionnaire	X			X	X	X	
Pain (Numerical Rating Scale (NRS)) at Hernia Site	X			X	X	X	
Hernia Repair Procedure[6]		X					
Surgeon Satisfaction Questionnaire		X					
Length of Hospital Stay			X				
Clinical Assessment[7]				X	X	X	X
Exit Subject						X[3]	
Adverse Event Evaluation[8]		X	X	X	X	X	X
Device Deficiency Evaluation[8]		X	X	X	X	X	X
Protocol Deviation Evaluation	X	X	X	X	X	X	X

1) Written Informed Consent must be obtained prior to any non-standard of care study assessments.
2) Screening may occur on the same day as Operative Day. If the Screening and Operative visits occur on different days, study eligibility assessments that occur at Screening must be reconfirmed on the Operative day.
3) Exit is to occur at the Month 12 visit unless the subject exits early (refer to Section 10.14.5 regarding details and procedures related to subjects considered Lost to Follow-up (LTFU)).
4) Medical Record Review and Physical Exam includes demography, medical history, surgical history, and weight/height
5) Medication Assessment includes prophylactic antibiotics, anticoagulants, antiplatelets, antithrombotic, and/or pain medication; where applicable
6) Hernia Repair Procedure includes operative times, general anesthesia information, hernia defect description, defect closure and surgical technique, tack, mesh and other fixation data
7) Clinical Assessment includes a Valsalva Maneuver during a physical examination for hernia recurrence, details of hernia recurrences / reoperation if applicable
8) See Section 12 for AE and DD reporting requirements

10.3 Scheduled Follow-up Visit Windows

Data analyses for follow-up visit data will be conducted regardless of whether the visit occurs within the window. A late visit is preferred over an early or missed visit. Should a subject miss a visit or the visit falls outside the prespecified window, a study deviation must be reported, and the original follow-up schedule must be maintained for subsequent visits.

Follow-up visit windows are listed in Table 4 below and are based on the Operative day.

Table 4: Subject Follow-up Visit Windows

Study Follow-up Visit	Window (days from Operative Day)	
	Window Start / Target	Window End
Screening	-60	0
Operative	0	0
Discharge	0	n/a
Month 1	30	51
Month 3	90	120
Month 12	365	410

10.4 Subject Screening (-60-0 Days)

A screening visit will be used to confirm preoperative eligibility and consent subjects. Subjects will be consented prior to the start of any non-standard of care study-specific assessments. Data collected as part as standard of care may be utilized to establish eligibility. The screening visit may occur on the same day as the operative visit. If the screening and operative visits occur on different days, study eligibility assessments that occur at screening must be reconfirmed on the operative day.

The following assessments will be performed at screening, and the results will be recorded:

- Verification of Subject Eligibility (preoperative criteria)
- Obtain Subject Informed Consent
- Conduct medical record review and physical exam:
  - Obtain subject demographics (e.g., gender, age, ethnicity, race, weight and height)
  - Obtain medical history, surgical history, and relevant comorbidities
  - Obtain American Society of Anesthesiologists (ASA) grade
- Medication assessment (anticoagulants, antiplatelets, antithrombotic, and/or pain medication)
- Obtain HerQLes Quality of Life Questionnaire – Preoperative Assessment
- Obtain pain score (Numerical Rating Scale (NRS)) at Hernia Site

10.5 Prior and Concomitant Medications

There are no required medications or medication protocols that subjects are required to follow for this study. All prior and concomitant medications should be managed according to the standard of care. Only limited, specific medication data will be collected in this study. These include prophylactic antibiotics, anticoagulants, antiplatelets, antithrombotic, and/or pain medication. Data collection of these specific medications will begin 30 days prior to Operative Day and follow through until study exit, as applicable. Medications the subject was taking and ended more than 30 days prior to the Operative Day do not need to be documented.

10.6 Subject Consent

Informed consent (IC) is defined as a legally effective documented confirmation of a subject's agreement to participate in a particular study after the information has been given and explained to the subject on all aspects of the study that are relevant to the subject's decision to participate. This process includes obtaining an IC form approved by the study site's IRB or EC and signed and dated by the subject. A subject may only consent after information has been given and explained to the subject on all aspects of the clinical investigation that are relevant to the subject's decision to participate.

The template ICF will be provided under a separate cover. Prior to enrolling subjects, the clinical study (including the patient-facing documents and site ICF) must be approved by the IRB or EC. The document(s) must be controlled (i.e., versioned and dated) to ensure it is clear which version(s) were approved by the IRB or EC. Any adaptation of the sample IC must be reviewed and approved by Medtronic and the IRB or EC reviewing the application prior to enrolling subjects.

The investigator must notify the subject of any significant new findings related to the study that become available during the study that are pertinent to the safety and well-being of the subject, as this could impact a subject's willingness to participate in the study. If relevant, subjects may be re-consented to confirm their continued participation.

Before initiating any study-specific procedures, IC must be obtained from the subject. Likewise, privacy or health information protection regulations may require subjects to sign additional forms to authorize study sites to submit subject information to the study sponsor.

The IC process must be conducted by the principal investigator or an authorized designee, and the IC form must be given to the subject in a language the subject is able to read and understand. The process of IC must be conducted without coercion or undue improper influence on or inducement of the subject to participate by the investigator or other study site personnel. The subject must have ample time and opportunity to read and understand the ICF, inquire about the details of the study, and decide whether to participate. All questions about the study should be answered to the satisfaction of the subject.

When the subject decides to participate in the study, the ICF must be signed and personally dated by the subject and the investigator (or authorized designee).

A copy of the ICF signed and dated must be provided to the subject, as required by law. The original of the signed IC must be filed in the hospital/clinical chart and/or with the subject's study documents.

If the IC is obtained the same day the subject begins participating in study-related procedures, it must be documented in the subject's case history that consent was obtained prior to participation in any study-related procedures. The IC process shall be documented in the subject's case history, regardless of circumstance. The ICF and any required privacy forms must be available for monitoring and auditing.

In the event the subject cannot read and/or write, the IC process shall be obtained through a supervised oral process, and an independent and impartial witness must be present during this process, provided detailed documentation of the process is recorded in the subject's case history and the witness signs and dates the ICF. The ICF and any other information must be read aloud to the prospective subject. Even in these situations, the subject shall sign and personally date the informed consent form. The witness shall also sign and personally date the ICF, attesting that the information was accurately explained, and that informed consent was freely given. Consistent with the Declaration of Helsinki (DoH), vulnerable adults (i.e., those subjects mentally incapable of giving consent) are excluded from this study. This protocol defines vulnerable adults as those subjects mentally incapable of giving consent, in the investigator's opinion.

10.6.1 Enrollment

A subject is considered enrolled (refer to Section 9.2) when the consent process has been finalized, the subject has met all eligibility criteria and no preoperative or intraoperative exclusion criteria, the Medtronic mesh has been placed and MaxTack™ has been utilized for fixation. See Figure 5 for the Study Flowchart. A log of all subjects enrolled in the study should be maintained.

10.7 Operation Requirements

Screening and operative days may be combined if necessary.

The study investigator(s) should perform the elective surgical ventral hernia repair procedure according to the institution's standard of care, the IFUs for both MaxTack™ and the mesh, and the additional requirements noted here. The procedure must be conducted via a minimally invasive approach (conventional laparoscopic or robotic techniques). If the subject met any intraoperative exclusion criteria, the subject will be considered an intraoperative screen failure and will not count toward the total enrollment. The hernia must be repaired with a Medtronic (including Covidien) permanent synthetic mesh that is intended to be used in compliance with the mesh instructions for use, and that is fixated with MaxTack™. Other criteria for the mesh fixation exclude:

- the use of barbed and conventional sutures applied on the edge of the mesh with a running (simple continuous) suture pattern and/or
- the use of tissue adhesives (glue) in addition to MaxTack fixation.

The compatibility of Medtronic (including Covidien) meshes with sutured edge fixation and/or tissue adhesives has not been established.

The study procedure includes the necessity to close the hernia defect; in all cases, a minimum of 5 cm overlap over the edges of the initial defect should be achieved superiorly and inferiorly. When possible, a minimum of 5 cm over the edges of the initial defect should be achieved laterally, or at least a mesh coverage of the entire width of the retrorectus/retromuscular compartment is required when applicable. Only a single piece of mesh should be used. The subject should not require a multi-stage repair, and the procedure should not be changed to open. If the procedure cannot be completed with the necessary criteria, the subject will be considered an intraoperative screen failure. If all eligibility criteria are met, the subject will be considered enrolled.

The following procedures and assessments are required to be performed:

- Verification of Subject Eligibility (including intraoperative criteria)
- Medication assessment (prophylactic antibiotics, anticoagulants, antiplatelets, antithrombotic, and/or pain medication)
- Obtain procedure information, including:
    - Operative times
    - General anesthesia information (type)
    - Hernia defect description, defect closure, and surgical technique
    - Tack, mesh, and other fixation data
- Obtain surgeon satisfaction questionnaire
- Assess and report adverse events, device deficiencies, and study deviations, if applicable

As mentioned, if a subject no longer meets eligibility criteria during the procedure, the patient will be considered an intraoperative screen failure, and no AEs will be reported. For enrolled patients, adverse event and device deficiency collection begins at the time the skin incision is made. Only the specific medications need to be reported, and only for those specific medications that were taken within 30 days of the procedure.

10.8 Discharge Visit

The following assessments are required to be performed prior to subject discharge:

- Medication assessment (anticoagulants, antiplatelets, antithrombotic, and/or pain medications)
- Obtain date discharged from hospital (length of hospital stay)
- Assess and report adverse events, device deficiencies, and protocol deviations, if applicable

10.9 Month 1 (+21 Days), 3 (+30 Days), and 12 Follow-up Visits (+45 Days)

The following assessments are required at the Month 1, 3, and 12 follow-up visits:

- Obtain pain score (Numerical Rating Scale (NRS)) at Hernia Site
- Obtain HerQLes Quality of Life Questionnaire – Postoperative Assessment
- Medication assessment (anticoagulants, antiplatelets, antithrombotic, and/or pain medication)
- Clinical assessment, which includes a Valsalva maneuver during clinical physical examination for hernia recurrence, hernia recurrences resulting in reoperation, if applicable
- Assess and report adverse events, device deficiencies, and protocol deviations, if applicable

All visits are to be completed in person. If subjects are unable or unwilling to be seen in person, unforeseen beyond the investigator's control, upon approval by Medtronic, subjects may be given the option to complete the HerQLes Quality of Life questionnaire, provide their pain score, and conduct an AE and medication assessment as well as assess the status any potential hernia recurrence and/or reoperation remotely. In these cases, a study deviation will need to be completed for not being able to perform the required assessments in person.

If a hernia or hernia recurrence is suspected, the subject will be instructed to return to the clinic or hospital for diagnosis by the surgeon through clinical assessment. This should be done at the discretion of the investigator.

10.10 Unscheduled Follow-up Visits

If a subject must be seen by a physician for a study-related adverse event or concern outside of the study follow-up visit schedule, an unscheduled visit form within the database must be completed. The assessments below should be performed at unscheduled follow-up visits. Should the subject see a physician who is not delegated to the study, the information should be obtained from the medical records.

- Visit reason
- Medication assessment (anticoagulants, antiplatelets, antithrombotic, and/or pain medication)
- Details of hernia recurrence/reoperation, if applicable
- Assess and report adverse events, device deficiencies, and protocol deviations, if applicable

10.11 Questionnaires

HerQLes Quality of Life Questionnaire

The HerQLes quality of life questionnaire (QoL) is a hernia-specific survey tool with a focus on abdominal wall function [10-11], which will be used throughout the study. Subjects will complete the preoperative assessment at screening and the postoperative assessments at Months 1, 3, and 12. See Section 18.4: Appendix D – HerQLes Quality of Life Questionnaire. Prior to site activation, the applicable site personnel will be trained on the requirements for properly administering the QoL questionnaires to subjects.

Subjects should complete QoL questionnaires in the language of their understanding. Generally, the language version of a subject's QoL questionnaire should be the same as the subject's informed consent. If the language version of the subject's QoL questionnaire differs from the subject's informed consent, it is recommended that an explanation be documented (e.g., the subject consented via a translator).

Subjects should complete their own QoL questionnaires. If the subject needs assistance completing their own QoL questionnaire (e.g., physical limitations), an appropriately authorized person may assist (e.g., reading questions to the subjects and completing the QoL questionnaire on their behalf). Any assistance should be recorded on the QoL questionnaire or applicable source documentation.

The completed QoL questionnaire should include the subject identifier, the associated visit (e.g., 6-month visit), and the visit date.

Surgeon Satisfaction Questionnaire

After each procedure, the operating physician must complete the Surgeon Satisfaction Questionnaire. The Surgeon Satisfaction Questionnaire is a short survey to evaluate the surgeon's use and satisfaction of MaxTack™ (Section 18.8: Appendix H – Surgeon Satisfaction Questionnaire).

Pain Numerical Rating Scale (NRS)

Subject Pain Numerical Rating Scale (NRS) (Appendix C – Pain Numerical Rating Scale (NRS)) will be collected at follow-up visits per Section 10.1. The Pain NRS requires the patient to choose a number on a defined scale between 0–10, where 0 is no pain, and 10 is the worst possible pain.

An appropriately authorized person will assist with data collection (e.g., verbally reading questions to the subjects and completing the source document on their behalf).

Completed subject NRSs should include the subject identifier, the associated visit (e.g., 3-month visit, 6-month visit), and the visit date.

10.12 Recording Data

This study will utilize an electronic database and eCRFs. Study visits or assessments not collected or recorded will be considered deviations unless otherwise specified. The Principal Investigator or authorized designee(s) must ensure the accuracy and completeness of the recorded data. Once completed, investigators will sign off on (approve) their study data via electronic approval of the eCRFs.

Data entered must be traceable to source documents. Source documentation is defined as all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical investigation necessary for the reconstruction and evaluation of the clinical investigation (e.g., hospital records, clinical and office charts, procedure reports, laboratory notes, subject files, subject questionnaires, device data, and copies, or transcriptions certified after verification as being accurate copies).

In general, eCRFs may not serve as source documents. Depending on the study site, the exceptions may be as follows: Surgeon Satisfaction Questionnaire, adverse event seriousness and relationship, device deficiency classifications, and protocol deviation assessments. The study site may use source document worksheets if they are identified as source documents.

The investigator must ensure the availability of source documents from which the information on the eCRFs was derived. The type and location of source documents should be documented. Where printouts of electronic medical records are provided as source documents or copies of source documents are retained as source documents, those should be certified as indicated by a dated signature by a member of the investigation site team unless generated through a validated process.

The source documents must be made available for monitoring or auditing by Medtronic's representative or representatives of applicable regulatory agencies.

10.13 Deviation Handling

A study deviation is defined as an event within a study that did not occur according to the CIP or the Clinical Trial Agreement (CTA).

Planned deviations to the CIP will not be permitted. The investigator is not allowed to deviate from the CIP except under emergency circumstances to protect human subjects' rights, safety, and well-being or in unforeseen circumstances beyond the investigator's control. The investigator(s) must notify Medtronic and the reviewing IRB/EC of any deviation from the CIP when specific to the protection of the life or physical well-being of a subject in an emergency per local IRB/EC regulations.

All study deviations must be reported on the eCRF regardless of whether they were medically justifiable, inadvertent, or occurred to protect the subject in an emergency. Multiple deviations of the same type at the same visit (i.e., multiple, but not all, study assessment missed or completed outside of window) may be reported on one case report form. If the deviation involves a failure to obtain a subject's consent or is made to protect the life or physical well-being of a subject in an emergency, the deviation must be reported to the IRB/EC as well as Medtronic within five (5) working days. Reporting of all other study deviations should comply with IRB or EC policies, local laws, and/or Regulatory Authority requirements. Upon the study site becoming aware of the deviation, these must be reported to Medtronic as soon as possible. Refer to Table 9: Investigator Reports for deviation reporting requirements and timeframes.

Medtronic is responsible for analyzing deviations, assessing their significance, and identifying any additional corrective or preventive actions (e.g., amend the CIP, conduct additional training, terminate the investigation). Severe or repetitive investigator compliance issues may result in initiating a corrective action plan with the investigator and study site. In some cases, it may necessitate suspending enrollment until the problem is resolved or ultimately terminating the investigator's participation in the study. Medtronic will provide study site-specific reports to investigators, periodically summarizing information on deviations that occur at the study site.

Examples of study deviations include but are not limited to:

- Failure to obtain proper IC or failure to document IC process
- Failure to collect required study data (e.g., required questionnaires)

- Late reported adverse event
- Missed study visit
- Study visits occurring outside of the visit window
- Valsalva maneuver not done for physical examination
- Subjects for which informed consent is not collected
- Inclusion/exclusion criteria not met
- Subjects who become pregnant during study follow-up, as pregnancy may impact performance outcome measurements
- Missing hernia recurrence assessment at each time point for performance outcome measurements

If a subject becomes unexpectedly pregnant during the study, they will remain in the study, and pregnancy status will be assessed during follow-up visits. Pregnancies during the study will be considered protocol deviations.

10.14 Subject Exit, Withdrawal or Discontinuation

10.14.1 Preoperative Screen Failure

Subjects who provide study consent but are determined to be ineligible prior to the procedure due to preoperative inclusion or exclusion criteria will be considered a “preoperative screen failure” and will not require additional study follow-up visits. The reason for the screening failure will be clearly recorded on the applicable eCRFs, and subjects who are considered a preoperative screen failure will not count towards enrollment. Subjects who screen fail prior to surgery will not have AEs reported (Table : Subject Status Adverse Event Reporting). For preoperative screen failures, a limited amount of data must be recorded in the study database (e.g., consent date, reason(s) for not meeting eligibility, etc.).

10.14.2 Intraoperative Screen Failure

Subjects who provide study consent, experience the skin incision but then are determined to be ineligible during the procedure due to intraoperative exclusion criteria will be considered an “intraoperative screen failure” and will not require additional follow-up visits. For intraoperative screen failures, a limited amount of data will need to be recorded on any applicable eCRFs (e.g., consent information, reason(s) for not meeting eligibility etc.). Subjects who are considered screen failed during surgery will not have AEs and DDs reported.

10.14.3 Enrolled Subjects who Complete the Study

At the completion of the Month 12 follow-up visit, subjects will be exited from the study. The Month 12 follow-up visit, and study exit should be combined, and both Month 12 follow-up eCRF and a study exit eCRF need to be completed.

10.14.4 Withdrawal

A subject can withdraw from the study at any time. If the subject wishes to withdraw from the study (i.e., the subject revokes consent), the study site is required to document the reason for exit and the date on the Exit eCRF. In addition, study sites shall follow the regulations set forth by the IRB or EC. Before the subject withdraws consent, an option for follow-up, which does not include direct contact with the subject, should be offered. This may include medical record review or follow-up with Primary Care Provider or referring physician.

If the study investigator voluntarily removes a subject from further study participation, supporting documentation must be in place for the rationale and date of removal. No subjects should be withdrawn by investigator(s) unless compelling medical justification is present. It is recommended investigators discuss with the Medtronic study team prior to withdrawing subjects. Non-study/routine follow-up of withdrawn subjects will be determined by the investigator according to the standard of care at the respective site. Withdrawn subjects will not be replaced.

10.14.5 Lost to Follow-up (LTFU)

Subject lost to follow-up (LTFU) should be avoided as much as possible, and investigators are urged to do their best to maintain subject follow-up compliance. The site will make every attempt to contact subjects that are noncompliant with study follow-up visits. A subject is considered to be lost to follow-up if the following attempts to contact the subject are unsuccessful:

- Three (3) phone calls should be made to the subject at various times and at least one day apart. Each attempt should be clearly documented in the source documents and the response or lack thereof should be captured.
- If there is no response to the phone calls, then an official, certified letter should be written and sent to the subject. A copy of the letter and return or delivery receipts should be retained in the subject's source document.

In case a subject can no longer be found, the monitor shall check the appropriateness of the site's attempts to contact the subject.

The sponsor must be notified, and the study exit eCRF must be completed. The monitor shall check the appropriateness of the site's attempts to contact the subject.

The subject will not be considered lost to follow-up until the end of the study (Month 12 follow-up visit). When subjects are considered lost to follow-up the investigator will make efforts to confirm the vital status/health status of the subject, as described in the informed consent. Lost to Follow-up subjects will not be replaced. At the end of the study, the study exit eCRF will be completed with a status of Lost to Follow-up.

10.14.6 Study Exit

A study exit eCRF is required for all subjects. Following study exit, subjects will continue to receive standard medical care. Upon exiting the study, no further study data will be collected, or study visits will occur. All data available through the time of the subject's exit will be used for analysis.

Subjects are urged to remain in the study as long as possible but may be exited from the study for any of the following situations:

- Subject completed study (through Month 12 Follow-up Visit)
- Subject lost to follow-up
- Subject death
- Subject deemed a preoperative screen failure
- Subject deemed an intraoperative screen failure
- Subject did not provide consent or data use protection authorization
- Subject chooses to withdraw (e.g., consent withdrawal)
- Investigator deems withdrawal necessary (e.g., medically justified, failure of subject to maintain adequate study compliance)
- Sponsor request (e.g., study terminated early)

The following information is required to be collected at study exit:

- Reason for exit
- Date of Exit

11. Risks and Benefits

11.1 Potential Risks

Medtronic follows rigorous Quality Assurance and Control procedures throughout the life of a product, from the business analysis phase through development, market release, and post-market surveillance. The risk analysis process for the AFFIX Study, MaxTack™ Motorized Fixation Device is being performed in accordance with ISO 14971. Overall, the residual risk for the MaxTack™ Motorized Fixation Device was deemed acceptable.

The potential risks of the MaxTack™ Motorized Fixation Device have been described in the Instructions for Use (IFU) and are summarized below. As with any device, there is always a risk of a rare or previously unknown side effect developing from the treatment or use of the device. The IFU will be updated should a new risk become identified.

Risks associated with the use of any Tack Fixation devices may include improper tack placement, deployed tacks having insufficient holding force (resulting in tack/mesh migration, adhesions, erosion, recurrence and damaged mesh), excessive tack penetration, tack penetration through great vessels or cardiac

structures, tack impinging on nerves, and foreign body reaction (resulting in ‘‘meshoma’’ formation, tack hernias, chronic pain, and infection). Risks associated with the MaxTack™ Motorized Fixation Device include but are not limited to: seroma, fistula, perforation, hernia recurrence, bowel entrapment, strangulated bowel, tissue damage/trauma, cardiac tamponade and/or damage to pericardium, bleeding/hematoma, acute/chronic pain, nerve damage, infection, allergic reactions to the components of the product, burns, environmental contamination, inflammatory reaction, visceral adhesions, vascular injury, visceral injuries, and injuries to operator. Investigators participating in this study are experienced with the known risks related to standard of care for ventral hernia repair procedures. Due to the nature of the procedure and use of multiple products (tacks and mesh), it may be hard to differentiate between risk associated with the tack vs. those associated with the mesh, and / or the procedure. There are no known risks associated with an interaction of the tacks with any concomitant medication.

11.2 Risk Minimization

Medtronic has further minimized the possibility of risks by performing required laboratory and preclinical testing prior to the AFFIX study, implementing quality control measures into production, processes, providing guidelines for subject selection and evaluation, and providing adequate instructions and labeling. Risks are first and foremost mitigated by device design. Additionally, the potential risks associated with the MaxTack™ Motorized Fixation Device were identified and are mitigated with warnings and cautions described in the IFU. The CIP includes subject eligibility criteria that excludes patients with higher risk such as those that may have a history of an allergic reaction to the components of the device, or those with an infection. Any potential risks associated with this study are further minimized by selecting qualified investigators and training study personnel on the CIP. The IFU and study training will guide investigators on the proper use of the device. Additionally, physicians performing these procedures will likely have experience of using tackers for mesh fixation.

Investigators will be actively involved in the hernia repair procedure involving MaxTack™ and follow-up of the subjects. Any complications that occur with the use of the study device (either during the procedure or postoperatively) will be assessed by the investigator and reported per the CIP. Risks will be minimized by careful assessment of each subject prior to, during, and after implant of the study device.

11.3 Potential Benefits

The MaxTack™ Motorized Fixation Device may offer no benefit. The purpose of the MaxTack™ Motorized Fixation Device is to fixate mesh. The benefit of surgical prosthetic material fixation to soft tissue in hernia repair is to strengthen/reinforce the weakened defect in the abdominal wall. This type of surgical repair minimizes the risk of complications and reduces the risk of recurrence. The mechanical fixation of prosthetic material during hernia repair with device in combination with the prosthetic material may therefore provide the clinical benefit of a low hernia recurrence rate. Additionally, information collected

from this study may assist in the design of new product(s), therapy(ies), and/or updates to the MaxTack™ Motorized Fixation Device IFU.

11.4 Risk-Benefit Rationale

As described in the IFU for the MaxTack™ Motorized Fixation Device, a ventral hernia repair procedure involving a tacker involves risk. These complications are associated with both the procedure itself as well as the devices being used. For patients who are candidates for the study, the benefits of using the MaxTack™ Motorized Fixation Device during their hernia repair procedure may outweigh these risks.

In conclusion, the MaxTack™ Motorized Fixation Device has been shown to have a favorable benefit-risk profile based on the criteria of the target population and the risks and benefits potentials of the device.

12. Adverse Events and Device Deficiencies

For enrolled subjects, adverse events (AE) and device deficiencies (DD) will be collected from the time of skin incision until the subject exits. If an AE is considered unresolvable by the investigator, it will be documented within the eCRF that the AE remains unresolved or unrecovered at the time of study exit. Initial reporting of AEs or DDs may be done by phone, email, or by completing as much information as possible on the appropriate eCRF. The completed AE or DD eCRF must be submitted to Medtronic as soon as possible.

12.1 Adverse Events

The following AEs are required to be reported in the study after the point of skin incision until the subject exists:

- All AEs related to the MaxTack™ Motorized Fixation Device, mesh, or study procedure
- All events that lead to death, regardless of relatedness
- Any non-subject adverse event

Reporting of these events to Medtronic will occur on the applicable AE eCRF. Each event must be reported separately. Documented pre-existing conditions are not considered AEs unless the nature or severity of the condition has worsened. Subject deaths are required to be reported. Refer to Section 12.7 for Subject Death collection and reporting requirements.

12.2 Device Deficiency

The device deficiency (DD) definition is provided in Table 5: Adverse Event and Device Deficiency Definitions. DD information will be collected throughout the study and reported to Medtronic. Note that a DD that resulted in an AE to the subject should be captured as an AE only.

In the event of a DD, the device should be returned to Medtronic for analysis, if possible. Instructions for returning the study device will be provided. Device deficiencies should also be documented in the subject's medical record.

12.3 Definitions/Classifications

Where the definition indicates "device", it refers to any device used in the study. This includes the MaxTack™ Motorized Fixation Device and the mesh used during the procedure. All definitions and classifications are provided in Table 5: Adverse Event and Device Deficiency Definitions.

Table 5: Adverse Event and Device Deficiency Definitions

General	
Adverse Event (AE) **(ISO14155:2020, 3.2)**	Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated. NOTE 1: This definition includes events related to the investigational medical device or the comparator. NOTE 2: This definition includes events related to the procedures involved. NOTE 3: for users or other persons, this definition is restricted to events related to the use of investigational medical devices or comparators.
Serious Adverse Event (SAE) **(ISO 14155:2020, 3.45)**	Adverse event that led to any of the following: a) Death. b) Serious deterioration in the health of the subject, users or other persons as defined by one or more of the following: 1) a life-threatening illness or injury, or 2) a permanent impairment of a body structure or a body function including chronic diseases, or 3) in-patient or prolonged hospitalization, or 4) medical or surgical intervention to prevent life-threatening illness or injury, or permanent impairment to a body structure or a body function, or 5) foetal distress, foetal death, a congenital abnormality, or birth defect including physical or mental impairment. NOTE: Planned hospitalization for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a serious adverse event.
Adverse Device Effect (ADE) **(ISO14155:2020, 3.1)**	Adverse event related to the use of an investigational medical device. NOTE 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation or any malfunction of the investigational medical device.

	NOTE 2: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device. NOTE 3: This includes 'comparator' if the comparator is a medical device.
Serious Adverse Device Effect (SADE) (ISO14155:2020, 3.44)	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
Device Deficiency (DD) (ISO14155:2020, 3.19)	Inadequacy of a medical device with respect to its identity, quality, durability, reliability, usability, safety, or performance. NOTE 1: Device deficiencies include malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labeling. NOTE 2: This definition includes device deficiencies related to the investigational medical device or the comparator.
Serious Health Threat (SHT) (ISO14155:2020, 3.46)	A signal from any adverse event or device deficiency that indicates an imminent risk of death or a serious deterioration in the health in subjects, users or other persons, and that requires prompt remedial action for other subjects, users or other persons. NOTE 1: This would include events that are of significant and unexpected nature such that they become alarming as a potential serious health hazard or possibility of multiple deaths occurring at short intervals.
Relatedness Each AE will be classified according to four different levels of causality. The sponsor and the investigators will use the following definitions to assess the relationship of the AE to the MaxTack™ motorized fixation device, mesh, or study procedure. For purposes of analysis categories considered "related" will include Possible, Probable and Causal.	
Not Related	Relationship can be excluded when: ▪ the event has no temporal relationship with the use of the device or procedure ▪ the event does not follow a known response pattern to the device (if the response pattern is previously known) and is biologically implausible ▪ the discontinuation of device application or the reduction of the level of activation/exposure - when clinically feasible – and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the event ▪ the event involves a body-site or an organ not expected to be affected by the device or procedure ▪ the event can be attributed to another cause (e.g., an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors)

	▪ the event does not depend on a false result given by the device used for diagnosis, when applicable In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the event.
Possible	The relationship is weak but cannot be ruled out completely. Alternative causes are also possible (e.g., an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed or no information has been obtained should also be classified as possible.
Probable	The relationship seems relevant and/or the event cannot reasonably be explained by another cause.
Causal Relationship	The event is associated beyond reasonable doubt when: ▪ the event is a known side effect of the product category the device belongs to or of similar devices and procedures ▪ the event has a temporal relationship with device use/application or procedures ▪ the event involves a body-site or organ that ○ the device or procedures are applied to ○ the device or procedures have an effect on ▪ the event follows a known response pattern to the device (if the response pattern is previously known) ▪ the discontinuation of device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the event (when clinically feasible) ▪ other possible causes (e.g., an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out ▪ harm to the subject is due to error in use ▪ the event depends on a false result given by the device used for diagnosis, when applicable In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the event.
Unavoidable Adverse Events (UAE)	For study purposes, the following unavoidable adverse event (UAE) occurrences are considered to be expected observations following surgical procedures (primarily associated with anesthesia) and will not be considered reportable AEs, as long as the event is not associated with significant sequelae, does not prolong hospitalization, and responds to standard medical therapy:

	▪ Postoperative transient nausea determined to be procedure related within the first 24 postoperative hours. ▪ Postoperative transient emesis determined to be procedure related within the first 24 postoperative hours. ▪ Postoperative constipation determined to be procedure and/or medication related for the duration of medication administration for management of pain. ▪ Postoperative pain that the Investigator considers common and within normal limits for the procedure and is well-managed with medication.
Device/Procedure Relatedness	
Study Device Related	An AE that results from the presence or performance (intended or otherwise) of the MaxTack™ Motorized Fixation Device.
Mesh Related	An AE that results from the presence or performance (intended or otherwise) of the mesh.
Study Procedure Related	An AE that occurs due to any procedure (e.g., anesthesia, incision, other fixation methods, skin closure, etc.) related to the implantation or surgical modification of the MaxTack™ Motorized Fixation Device, or the mesh.

12.3.1 Reporting Requirements and Timelines for Adverse Events and Device Deficiencies

All AEs and DDs need to be reported in a timely manner to the sponsor and to the IRB/EC per the IRB/EC reporting requirements. It is the responsibility of the investigator and the sponsor to abide by the AE and DD reporting requirements as stipulated by local law and the study site's IRB/EC.

Table 6: Reporting Requirements Timeframe for Investigators

Type:	Report to:	Reporting Timeframe (from time of learning of event):
DD	Sponsor	Recommended within 10 working days
	IRB/EC	Per IRB/EC reporting requirements
AE	Sponsor	Recommended within 10 working days
	IRB/EC	Per IRB/EC reporting requirements
SAE	Sponsor	Recommended within 10 working days
	IRB/EC	Per IRB/EC reporting requirements
ADE	Sponsor	Recommended within 10 working days
	IRB/EC	Per IRB/EC reporting requirements
SADE	Sponsor	Recommended within 10 working days
	IRB/EC	Per IRB/EC reporting requirements

12.4 Reporting of Adverse Events and Device Deficiencies

Investigators should assess and report the appropriate information on the AE eCRF for the following events, starting from the point of skin incision until the subject exits the study:

- All AEs related to the MaxTack™ Motorized Fixation Device, mesh, or study procedure
- All events that lead to death, regardless of relatedness
- Any non-subject adverse event

Reporting requirements are noted in Section 12.3.1. Assessment of events will include date of event, relationship to study device, relationship to mesh, relationship to study procedure, description, seriousness, action(s) taken, date of resolution and outcome. Additionally, any medication/treatment administered to resolve an AE must also be reported.

Table 7: Subject Status Adverse Event Reporting

Subject Status	AE Reporting Required	AEs to Report Timeframe
Preoperative Screen failure	No	N/A
Intraoperative Screen failure	No	N/A
Enrolled	Yes	From skin incision through Study Exit (e.g., study completion, withdrawal or LTFU)

12.4.1 Adverse Event and Device Deficiency Classification

All AEs and DDs will be reviewed by a Medtronic representative. AEs and DDs will be classified according to the definitions provided.

Upon receipt of an AE, a Medtronic representative will review the AE/DD for completeness and accuracy and when necessary, will request clarification and/or additional information from the Investigator. Medtronic will utilize Medical Dictionary for Regulatory Activities (MedDRA) for Regulatory Activities, to assign a MedDRA term for each AE based on the information provided by the investigator.

Regulatory reporting of AEs and DDs will be completed according to local regulatory requirements. Refer to Table 6 for a list of site reporting requirement timeframes. It is the responsibility of site and Medtronic to abide by any additional AE reporting requirements stipulated by the IRB/EC responsible for oversight of the study.

Table 8: Adverse Event and Device Deficiency Classification Responsibilities

What is classified?	Who classifies?	Classification Parameters
Relatedness	Investigator	MaxTack™ Device, mesh, study procedure
	Sponsor	MaxTack™ Device, mesh, study procedure
Seriousness	Investigator	SAE, DD with SADE potential
	Sponsor	SAE, DD with SADE potential
Diagnosis	Investigator	Based on presenting signs and symptoms and other supporting data
	Sponsor	MedDRA term assigned based on the data provided by Investigator

Appendix I contains the Foreseeable Adverse Event List (FAL), which is a list of AEs related to the device or procedure that have been observed in previous studies and may be experienced by subjects.

12.5 Processing Updates and Resolution

For any changes in status of a previously reported AE or DD (i.e., change in actions taken, change in outcome, change in relatedness), information needs to be updated, or added to the original AE or DD eCRF. All AEs must be followed until the AE has been resolved, is unresolved with no further actions planned, the subject dies or exits the study, or until study closure, whichever occurs first.

In the event that a subject is exited from the study, all efforts should be made to continue following the subject until all unresolved device or study procedure related AEs, as a classified by the investigator, are 'resolved', 'unresolved with no further actions planned', or the subject has been followed for 30 days, whichever occurs first after which the subject should be exited. If AEs are still ongoing 30 days post study completion, the subject will be exited and the AE eCRF updated to indicate the AE is unresolved.

At the time of study exit, all collected AEs that are 'unresolved' must be reviewed and an update to the original AE eCRF must be reported. Any AEs with outcomes classified as 'recovering/resolving', and where no update can be provided at the time of study exit, will be updated to 'not recovered/not resolved'.

12.6 Product Complaint Reporting

A product complaint is any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a medical device that has been placed on the market. It is the responsibility of the investigator to report all product complaint(s) associated with a medical device distributed by Medtronic, regardless of whether they are related to intended use, misuse, or abuse of the product. Reporting must be done immediately and via the regular channels for market-released products. The reporting of product complaints by the clinical team must be

done according to the local Standard Operating Procedures and Medtronic will notify the RAs as applicable or the following incidents immediately upon learning of them:

- Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or instructions for use which led or might have led to the death or serious deterioration in the state of health of a patient, user, or other person.
- Any serious deterioration in the state of health related to the device or procedure, including:
  - Life-threatening illness or injury
  - Permanent impairment of a body function or permanent damage to a body structure
  - A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

12.7 Subject Death

All subject deaths after the point of skin incision must be reported by the investigator to Medtronic on an AE eCRF (AE with outcome of fatal) as soon as possible after the investigator or delegated member of the study team first learns of the death. In case of death, there should be one AE with the outcome of fatal.

A redacted copy of the death certificate, if available and allowed by state/local law, should be sent to the Medtronic clinical study team. When a death occurs in a hospital, a copy of the death summary report and all relevant hospital records, if available, should be sent to the Medtronic clinical study team. If an autopsy is conducted, a copy of the autopsy report should also be sent to the Medtronic clinical study team if available and allowed by state/local law. When a death occurs at a remote study site, it is the investigative study site's responsibility to attempt retrieval of information about the death. Additionally, device disposition information should be updated.

In summary, the following data will be collected (all documents should have Protected Health Information (PHI) redacted):

- Date of death
- Detailed description of death
- Relatedness to device and procedure
- Device disposition information
- Death summary/hospital records (if available and allowed by state/local law)
- Autopsy report (if available and allowed by state/local law)
- Death certificate (if available and allowed by state/local law)
- Any other relevant details as requested by Medtronic

13. External Committees

13.1 Independent Medical Monitor

At regular intervals, an independent Medical Monitor (MM) will conduct an independent adjudication of specified adverse events for subjects participating in the study. Source documents to support adjudication may be requested.

The MM will be a board-certified/board-eligible physician with expertise in hernia surgery and experience in the use of similar tacking devices. This physician will not be employed by Medtronic, will not be a participating investigator in the study, and will possess the necessary qualifications through education, training, and relevant experience to oversee the product's use and associated procedures.

Most adjudications will be conducted independently by the MM via entry of their assessments into the database. Medtronic personnel may facilitate adjudication meetings if needed, but the final adjudication decision will be solely from the MM.

If the MM disagrees with the investigator's classification of the event, the MM assessment will be provided to the investigator. If the investigator agrees with the MM's adjudication, the investigator is responsible for updating the AE CRF accordingly.

If the investigator does not agree with the MM's adjudication classification, both determinations will be provided within the final report; however, the MM's adjudication will be used for data analysis. If required, both determinations will be included in reporting to IRB/ECs and regulatory authorities.

14. Statistical Design and Methods

This section presents statistical considerations and justification for the study design and provides a high-level description of planned analysis and reporting. More details will be given in a separate Statistical Analysis Plan (SAP) that will be finalized and approved before first data freeze or lock. Any deviation to the prespecified statistical analyses including justification, will be noted in the clinical study report(s).

14.1 General Aspects of Analysis

Data analysis will be performed by Medtronic or its designee.

The primary analysis will be based on all evaluable subjects, which will utilize a performance goal (PG), as outlined in Section 14.4. The Clopper-Pearson exact method, along with a 95% confidence interval, will be used for statistical evaluation. A two-sided p-value less than 0.05 (one-sided less than 0.025) is considered statistically significant. Subject disposition will be illustrated in a CONSORT diagram.

The study will be considered successful if the upper 95% two-sided confidence limit for the proportion of hernia recurrence within 3-months is less than the performance goal of 8.6%. With an evaluable sample

size of 100 or more, a rate of 3% (3 or less) hernia recurrence within 3-months will be required to meet the PG.

Descriptive statistics will be used to summarize study outcomes. Continuous variables will be summarized using means, standard deviations, quartiles, minimum, maximum values and 95% confidence intervals, as appropriate. Categorical variables will be summarized using counts, percentages and 95% confidence intervals, as appropriate.

Subject visits will be tabulated and compliance to visit schedule / visit windows will be summarized. The main analysis will include data from all study sites.

All statistical analyses will be performed using SAS for Windows (Version 9.4 or higher, SAS Institute Inc. Cary, NC), R Statistical Software (Version 4.2.1 or higher; R Core Team 2022), or other widely accepted statistical or graphical software.

14.2 Analysis Population

Statistical analysis for device performance (including primary and secondary endpoints) will be performed on the Full Analysis Set (FAS) as the primary analysis and on the Per Protocol Analysis Set (PPAS) as supportive analysis, as described in the Statistical Analysis Plan (SAP).

- **Full Analysis Set (FAS):** Including any subject enrolled and received study device (representing the primary analysis population)
- **Per Protocol Analysis Set (PPAS)**: Subset of Full Analysis Set excluding subjects in the following situation. Subject's data will be part of the PPAS until the following is reached:
    - Tack removal
    - Mesh removal or alteration (Mesh cut or partially excised during the procedure)
    - Subject with protocol deviations that may impact performance outcome measurements

14.3 Analysis Execution

The primary analysis will be conducted when all subjects have completed their Month 3 follow-up visits (or exited the study) and may be used for regulatory and publication purposes. The final analysis for the study will occur when all study subjects have completed the Month 12 follow-up visit and/or exited the study, and a final report will be prepared. The analysis will include both primary and secondary endpoints. The primary objective is based on the hernia clinical recurrence rate within the 3-month follow-up and may be assessed prior to study completion for regulatory and communication needs. The study will continue through 12 months post-procedure to evaluate performance and safety.

14.4 Primary Objective(s)

14.4.1 Primary Objective (Performance)

The primary objective of this study is to assess the performance of the MaxTack™ Motorized Fixation Device in minimally invasive ventral hernia repair procedures by evaluating the hernia recurrence rate within 3 months. The primary outcome is hernia recurrence rate within 3 months by a Valsalva maneuver at a clinical exam and confirmed per site standard of care medical imaging, if necessary.

14.4.2 Rationale for Performance Criteria

The primary endpoint is defined in Section 5.2.1. The primary endpoint will be assessed in comparison to a performance goal (PG) based on meta-analysis of available literature [13-22] (Figure 6) . The estimated expected hernia recurrence rate within 3 months is 1.0% (95% CI: 0.6% to 4.6%). The PG for the study is set at 8.6% (Figure 6), which is based on the upper bound of the CI from the meta-analysis at 4.6% plus a 4% clinical margin to balance the number of subjects, account for variability of subjects treated in a real-world setting and maintain proof of acceptable performance.

The meta-analysis was done using R Version 4.2.1 [12]. A random intercept logistic regression model was used to accommodate variations across studies and the bootstrap method was used to estimate the confidence interval for the average proportion [23, 24].

14.4.3 Hypothesis and Performance Requirements

The null and alternative hypotheses are as follows:

H_0: three-month recurrence rate $\geqslant$8.6% versus

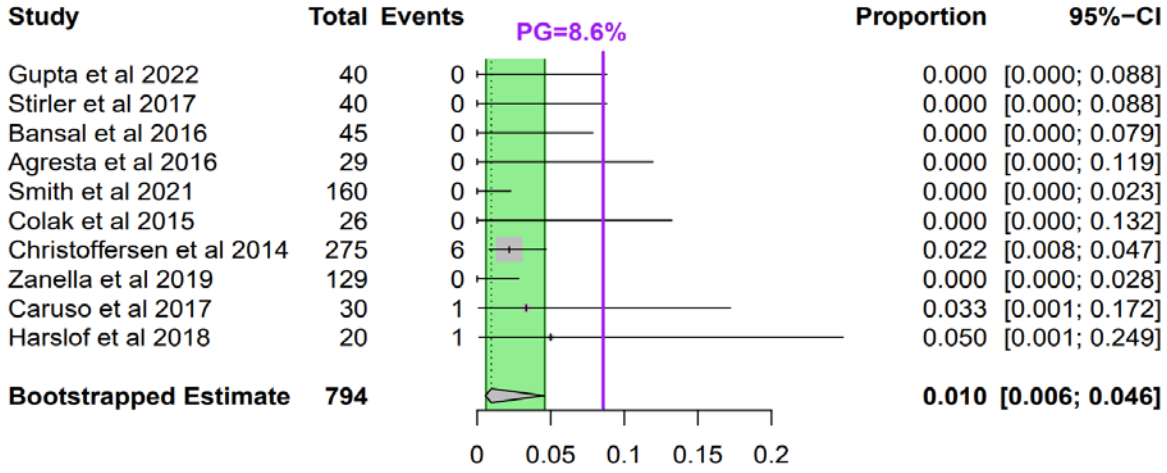
H_1: three-month recurrence rate <8.6%

The primary objective will be met if the upper 95% two-sided confidence limit for the hernia recurrence rate within 3-months is less than the performance goal of 8.6%.

14.4.4 Analysis Method

A binomial test for proportion with a one-sided alpha of 0.025 will be used on the FAS to test the hypothesis, and 95% two-sided Clopper-Pearson confidence intervals will be calculated. A sample size of approximately 110 is planned (100 evaluable, assuming 9% attrition). If three or less recurrences (3%) are observed out of 100, the performance goal will be met.

Figure 6: Forest Plot for Meta-analysis of 3-Month Recurrence Rate for Ventral Hernia Surgeries done with Absorbable Tacks[1]



14.5 Secondary Objective(s)

The secondary objective of this study is to evaluate the performance and safety of the MaxTack™ Motorized Fixation Device when used for fixation in minimally invasive ventral hernia repair procedures within 12 months post procedure.

See Section 5.2.2 for a full list of secondary endpoints.

Where applicable, descriptive statistics and 95% confidence intervals will be used to summarize secondary study endpoints. Continuous variables are presented as means, standard deviations (SD), medians, first and third quartiles, and minimum/maximum and categorical variables as counts and percentages. A statistical summary of secondary endpoints will be based on data from the full analysis set for subjects, with non-missing data for each secondary endpoint. Recurrence endpoints will be based on a previous recurrence or evaluable data at the time point.

14.6 Sample Size Determination

The sample size was determined using PASS 2024 v24.0.2. A total of 100 evaluable subjects is estimated to provide over 90% of power, with a one-sided alpha of 0.025, assuming a 3-month hernial clinical recurrence rate of 1.0%, to meet the performance goal of 8.6% (i.e. the upper 95% confidence limit lower

[1] Notes: References 13-22. For Colak et. al. 2015, Zanella et. al. 2019, and Caruso et. al. 2017 an exponentially distributed survival curve was assumed and the interpolated number of events at 3 months was calculated and rounded to the nearest whole number. For Christoffersen. et. al. 2014, the rate at 3 months was estimated using Kaplan-Meier curve. For Harslof et. al. 2018 0% (1M) and 5% (6M and 12M) used 6 month rate of 1 out of 20.

than 8.6%). By accounting for a projected attrition rate of 9%, a total of approximately 110 subjects will be enrolled.

14.7 Handling of Missing Data

The primary analysis will be based on observed data from all subjects enrolled and receiving study devices (full analysis set) with no imputation for missing data. A sensitivity analysis with all possible outcome values for any missing data will be run on the primary endpoint analysis to assess the robustness of the study results. All practical monitoring and follow-up steps will be taken to ensure complete and accurate data collection.

14.8 Multiplicity Adjustment

Only one hypothesis test is planned. All secondary endpoints will be summarized using descriptive statistics, and no multiplicity adjustment will be considered.

14.9 Study Site Pooling

The study will be conducted at approximately 10 study sites in the United States (US). However, additional sites in other regions may be added to meet study objectives. There is no a priori provision to exclude any study sites from the analysis. The data from all study sites will be pooled for analysis. To reduce the possibility of atypical results from a study site overly influencing the combined results, enrollment shall not exceed 25 subjects per site (25% of the minimum number of evaluable subjects needed [100]).

14.10 Minimization of Bias

Selection of subjects, treatment of subjects, and evaluation of study data are potential sources of bias. Methods incorporated in the study design to minimize potential bias are noted in Section 6. In summary, potential sources of bias that may be encountered in this study have been considered and minimized by careful study design.

15. Ethics

15.1 Statement(s) of Compliance

This study will comply with international ethical and scientific quality standards, known as good clinical practice (GCP). GCP includes review and approval by an IRB/EC before initiating a study, continuing review of an ongoing study by an IRB/EC and obtaining and documenting a subject's freely informed consent before initiating any study procedures.

The AFFIX study was designed to reflect the GCP principles outlined in ISO 14155:2020 and other clinical requirements outlined below. These include the protection of the rights, safety, and well-being of human subjects, controls to ensure the scientific conduct and credibility of the clinical investigation and the

definition of responsibilities of the sponsor and investigators. In accordance with ISO 14155:2020, the sponsor shall avoid improper influence on, or inducement of, the subject, monitor, any investigator(s), or other parties participating in or contributing to the clinical investigation. Investigators will disclose financial conflicts of interest prior to the initiation of the clinical study at the site or during the clinical study for all new investigators added to the site team and investigators who have a change in previously disclosed financial information. All investigators shall avoid improper influence on or inducement of the subject, sponsor, monitor, other investigator(s), or other parties participating in or contributing to the clinical investigation.

The principles of the Declaration of Helsinki (DoH) have been implemented through the Informed Consent (IC) process, IRB/EC approval, study training, clinical trial registration, preclinical testing, risk-benefit assessment, and publication policy. The clinical study shall not begin until the required approval from the IRB/EC and regulatory authorities, if applicable, has been obtained. Any additional requirements imposed by the IRB/EC or regulatory authority shall be followed as appropriate.

Ultimately, all study sites will follow and comply with*:*

- Principles of DoH (2013)
- 21 CFR Parts:
  - 11 (Electronic Records, Electronic Signatures)
  - 50: (Protection of Human Subjects)
  - 54 (Financial Disclosure by Clinical Investigators)
  - 56 (IRBs)
- The CTA
- The procedures described within this CIP
- Local IRB/EC Requirements
- ISO 14155:2020

All participating sites will make study data available to the regulatory body if the regulatory body deems an onsite inspection necessary. The regulatory body will be able to inspect records at clinical study sites to resolve any uncertainties about whether the study was conducted in accordance with good clinical practice.

The study will be publicly registered prior to in accordance with the 2007 Food and Drug Administration Amendments ACT (FDAAA) and DoH on http://clinicaltrials.gov (PL 110-85, Section 810(a)).

Approval of the CIP and CIP amendments is required from the following groups prior to any study procedures / revised study procedures at a study site:

- Medtronic
- IRB/EC

<u>This study contains the following from ISO 14155:2020:</u>

- **Point of Enrollment:** Per ISO 14155:2020, the point of enrollment is the time at which, following recruitment and before any clinical investigation-related procedures are undertaken, a subject signs and dates the informed consent form. In this study, a subject is considered enrolled when it is confirmed: the ICF is obtained, they meet all preoperative inclusion criteria, and they do not meet any preoperative or intraoperative exclusion criteria, and at least one MaxTack™ tack is used. (See Section 10.6 for Enrollment details). Those subjects who sign the ICF but fail all screening criteria, will not be included in the study. Those subjects who sign the ICF and are considered intraoperative screen failures will not count as an enrollment.
- **Adverse Event Collection:** Per ISO 14155:2020, all AEs shall be documented. In this study, only AEs related to the MaxTack™ motorized fixation device, mesh, or study procedure, all events that lead to death, and any non-subject adverse event will be collected. Additionally, adverse events will be collected starting at the time of skin incision. Enrolled subjects will have adverse events collected from skin incision through study exit.
- **Unanticipated Serious Adverse Device Effect (USADE):** Per ISO 14155:2020, USADEs are defined as, a SADE, which by its nature, incidence, severity, or outcome has not been identified in the current risk assessment. Due to this being a post-market study, USADEs are not applicable, therefore classification of AEs as such is not required.
- **Device Labelling:** Per ISO 14155:2020, the investigational device, the instructions for use and packaging shall indicate the investigational device is exclusively for use in a clinical investigation. However, since this is a post-market study and the devices are already commercially available, additional investigational labeling is not necessary. All devices will be securely stored within research offices and will not be stored in the operating room with other similar commercially available devices. This controlled storage process ensures that the devices are not mistaken for standard-of-care devices by clinical staff. Furthermore, since the devices are not being utilized outside of the defined study parameters, the risk of misidentification is significantly mitigated, thus justifying the decision to forgo standard investigational labeling.

16. Study Administration

16.1 Monitoring

It is the responsibility of Medtronic to ensure proper monitoring of this study. Authorized Medtronic representatives will perform study monitoring activities in accordance with Medtronic SOPs and the study Monitoring Plan, to ensure the study is conducted in accordance with this CIP, the CTA, and the applicable regulatory and local requirements. These Medtronic representatives must therefore be allowed direct access to subjects' medical and study records (clinic and hospital records, and other source data /

documentation) upon request. The principal investigator should make every attempt to be available during monitoring visits.

16.1.1 Monitoring Visits

Monitoring for the study includes site initiation visits, interim monitoring visits, and closeout visits, and may be performed via in person visits or remotely, when applicable.

Site initiation visits will be completed prior to enrollment of the first subject to ensure appropriate site staff are trained and delegated where applicable, and all required study documents are completed and collected.

Frequency of interim monitoring visits may be based upon subject enrollment, study compliance, number of adverse events, number of deviations, observations from previous monitoring visits and any suspected inconsistency in data that requires investigation. Monitoring visits may be conducted periodically to assess study site progress, the investigator's adherence to the CIP, regulatory compliance, maintenance of records and reports, and review of source documents against subject CRFs in accordance with the study-specific monitoring plan. To ensure the rights, safety, and welfare of study subjects are being maintained, the monitor will maintain assurance that all study staff are trained on the CIP and use of the study devices.

Monitors review study site regulatory and study compliance by identifying observations of non-compliance and communicating those observations along with recommendations for preventative/corrective actions to study site personnel. Monitors may work with study personnel to determine appropriate corrective action recommendations and to identify trends within the study or at a particular study site. If the monitor discovers that an investigator is not complying with the signed Investigator Statement, the CIP, applicable laws, or any conditions of approval imposed by the reviewing IRB/EC, the monitor will report to the Sponsor and take such steps necessary to promptly secure compliance. If compliance cannot be secured, the investigator's participation in the investigation may be terminated.

A closeout visit will occur once a site has fulfilled (or mostly fulfilled) all requirements for the clinical study and/or the study is terminated. The visit will include a review of any outstanding items and final steps and/or obligations in the study.

16.2 Data Management

Data will be collected using an electronic data management system for studies. CRF data will be stored in a secure, password-protected database, backed up nightly. Data will be reviewed using programmed and manual data checks. Data queries will be made available to study sites for resolution. Study management reports may be generated to monitor data quality and study progress. At the end of the study, Medtronic will lock and retain the data per applicable regulations.

All records and other information about subjects participating in this study will be treated as confidential. Data will be transferred and processed by Medtronic, or a third party designated by Medtronic, in a key coded form unless it's impossible to pseudonymize, for instance, where the subject's name cannot be removed from the data carrier, such as CT images.

Procedures in the CIP require source documentation. Source documentation will be maintained at the study site. The study site team must create and maintain source documents, which may include worksheets and subject medical records.

The investigator will clearly mark clinical records to indicate that the subject is enrolled in this clinical investigation.
The data reported on the eCRFs shall be derived from source documents and be consistent with these source documents, and any discrepancies shall be explained in writing. See Section 10.12 for CRFs and data collection elements that may be considered as source.

16.3 Direct Access to Source Data/Documents

Medtronic may conduct audits at participating study sites. The purpose of an audit is to verify the performance of the monitoring process and the study conduct independently of the personnel directly involved in the study. Regulatory Authorities, such as the FDA, may also perform inspections at participating study sites. The investigator and/or institution shall permit Medtronic, IRB/ECs and RAs direct access to source data and documents during monitoring, audits, and regulatory inspections.

16.4 Confidentiality

All information and data sent to parties involved in study conduct concerning subjects or their participation in this study will be considered confidential. Study subjects will be assigned a unique subject ID (SID). Records of the subject/SID relationship will be maintained by the study site. The SID number is to be recorded on all study documents to link them to the subject's medical records at the study site. Confidentiality of data will be observed by all parties involved at all times throughout the clinical investigation. All data shall be secured against unauthorized access. The privacy of each subject and confidentiality of his/her information shall be preserved in reports and when publishing any data.

Protected Health Information (PHI) will be maintained in compliance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996. To maintain confidentiality, the subject's name or any other PHI should not be recorded on any study document other than the IC. This scenario will be covered in the IC. In the event a subject's name/PHI is included for any reason, it will be blinded as applicable. In the event of inability to blind the identification (e.g., digital media), it will be handled in a confidential manner by the authorized personnel. Data relating to the study might be made available to third parties (for example in case of an audit performed by RA), provided the data are treated as confidential and that the subject's privacy is guaranteed. No identifiable subject information will be published.

16.5 Liability

Medtronic maintains appropriate clinical study liability insurance coverage as required under applicable laws and regulations and will comply with applicable local law and custom concerning specific insurance coverage. If required, a clinical study insurance statement/certificate will be provided to the IRB/EC.

16.6 CIP Amendments

Any revisions or amendments to the CIP or IC document, along with a statement of justification for the changes, will be submitted to all affected RAs (if applicable) and governing IRB/ECs, according to applicable regulations. Approval by RAs (where applicable) and IRB/ECs must be obtained prior to implementing a CIP revision at the study site. All principal investigators shall agree upon amendments to the CIP before executing the CIP amendment. Version history of the CIP can be found in Section 19.

16.7 Record Retention

All study-related documents must be retained for at least 2 years after study closure (or longer if required by local law or regulations).

For sites, no study document or image will be destroyed without prior written agreement between Medtronic and the investigator. The investigator should take measures to prevent accidental or premature destruction of documents. Should the investigator wish to assign the study records to another party or move them to another location, advance written notice must be given to Medtronic.

Medtronic will retain the study records according to Medtronic corporate policy and record retention schedule.

16.7.1 Investigator Records

The investigator is responsible for the preparation and/or retention of the study documents such as study correspondences, subject case histories, site personnel CVs, training documents, IRB/EC approvals, etc. All the study records, except for case history records and case report forms, should be kept in the Investigator Site File and/or Subject Study Binder. CRFs must be maintained and signed electronically within the electronic data capture system during the study.

16.7.2 Sponsor Records

Medtronic shall maintain accurate, complete, and current records such as correspondence, investigator, site, and staff qualifications and training documents, signed agreements, approved study plans, IRB/EC approval documents, visit reports, records of AEs/SAEs reported to sponsor, clinical study reports etc.

After closure of the study Medtronic will archive records and reports according to Medtronic corporate policy and record retention schedule.

16.8 Reporting Requirements

16.8.1 Investigator Reports

The investigator is responsible for the completion and submission to the sponsor of all case report forms, including adverse events, device deficiencies, deaths, and any deviations from the clinical investigation plan. If any action is taken by an IRB/EC with respect to this study, copies of all pertinent documentation must be forwarded to Medtronic in a timely manner. Reports are subject to inspection and to the retention requirements as described above for investigator records.

Investigator safety reporting requirements are listed in Section 12.

The investigator shall prepare and submit in a complete, accurate and timely manner the reports listed in this section.

Table 8: Investigator Reports

Report	Submit to	Description/Constraints
Withdrawal of IRB/EC approval (either suspension or termination)	Sponsor and relevant authorities	The investigator must report a withdrawal of approval by the reviewing IRB/EC of the investigator's part of the investigation within 5 working days.
Study deviations	Sponsor and IRB/EC	Any deviation from the clinical investigational plan shall be recorded together with the explanation of the deviation. Notice of deviations from the CIP to protect the life or physical well-being of a subject in an emergency shall be given as soon as possible but no later than 5 working days after the emergency occurred.
Final report	IRB/ECs and relevant authorities	This report must be submitted within 3 months (or timing per IRB/EC requirements) of study completion or termination of the investigation or completion or termination of the investigator's part of the study.

16.8.2 Sponsor Reports

Medtronic shall prepare and submit the following complete, accurate, and timely reports listed in the table below. In addition to the reports listed below, Medtronic shall, upon request of the reviewing IRB(s)/EC or RA, provide accurate, complete, and current information about any aspect of the investigation.

Table 9: Sponsor Reports

Report	Submit to	Description/Constraints
Withdrawal of IRB/EC approval	Investigators, IRB, and relevant authorities	Notification within 5 working days.
Recall and device disposition	Investigators, IRB/EC, and relevant authorities	Notification within 30 working days and will include the reasons for any request that an investigator return, repair, or otherwise dispose of any devices.
Clinical Study Reports	Investigators, IRB/EC, RAs upon request	Clinical study reports will be submitted to investigators and IRB/ECs following the completion or termination of this clinical study (where applicable).
Premature termination or suspension of clinical study	IRB/EC, Investigators, and regulatory authorities, where applicable	Medtronic will provide prompt notification of termination or suspension and reason(s) to the investigator and, where required, to IRB/EC and RAs.

16.9 Publication and Use of Information

Publications from the AFFIX study will be handled according to Standard Operating Procedures and as indicated in the CTA. A publication may occur from primary analysis and/or final analysis.

16.9.1 Publication Committee

Medtronic may form the AFFIX study Publication Committee from study investigators and/or National Principal Investigators. Medtronic personnel may also serve as members of the committee. This committee will manage study publications with the goal of publishing findings from the data. The Publication Committee will develop the strategy for publication which will be maintained as separate documentation.

The Publication Committee's role is to 1) manage elements addressed in the publication strategy as outlined in this section, 2) develop the publication strategy under separate cover, 3) execute the publication strategy, 4) oversee the publication of primary, secondary and ancillary study results, 5) review and prioritize publication proposals, 6) provide input on publication content, and 7) determine authorship. In addition, the committee will apply and reinforce authorship guidelines set forth in the publication strategy.

Membership in the Publication Committee does not guarantee authorship. The committee will meet at regular intervals as needed.

16.9.2 Management of Primary, Secondary, and Ancillary Publications

The Publication Committee reviews, prioritizes, and manages all publications, including primary, secondary, and ancillary publications. Primary and secondary publications are those that address analyses of any or all primary objectives or secondary objectives, respectively, as specified in the CIP.

An ancillary publication is any publication that does not address the study objectives identified in the CIP. They include publications proposed and developed by other Medtronic departments or entities, clinicians participating in this study, and clinicians not participating in this study. Medtronic, or the publication committee, if established, will ensure that requests do not present conflicts with other proposals and are not duplicative and determine which ancillary publication proposals, if any, will be supported.

It may be decided that no publications, including abstracts, will be published prior to the end of the study or with individual study site data. Requests for publications on study objectives utilizing subset data (e.g., regional) will be evaluated for scientific validity and Medtronic's ability to provide resources.

16.9.3 Criteria for Determining Authorship

Publications will adhere to authorship criteria defined by the International Committee of Medical Journal Editors (ICMJE), Uniform requirements for manuscripts submitted to biomedical journals, www.icmje.org). Individual authorship criteria defined by the target journal or conference will be followed when it differs from ICMJE criteria.

Authors, including Medtronic personnel, must at a minimum, meet all of the conditions below:

- Substantial contributions to the conception and design of the work or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Medtronic and/or a publication committee will make decisions regarding authorship and contributor-ship. The selected authors will be responsible for drafting the publication. All selected authors must fulfill the authorship conditions stated above to be listed as authors, and all contributors who fulfill the conditions must be listed as authors.

All investigators not listed as co-authors will be acknowledged as the "Medtronic AFFIX Study Investigators" and individually listed according to the guidelines of the applicable scientific journal when possible and affiliation. Any other contributors will be acknowledged by name with their specific contribution indicated.

16.9.4 Transparency

Transparency of clinical study results will be maintained by the following means:

- A final report describing the results of all objectives and analyses will be distributed to all investigators and IRB/ECs when required by local law.
- Register and post the study results on a publicly accessible database, e.g., ClinicalTrials.gov, based on the posting rules stipulated.
- Disclosing conflicts of interest (e.g., financial) of the co-authors of publications according to the policies set forth by the corresponding journals and conferences.
- Making an individual study site's study data accessible to the corresponding investigator after the completion of the study, if requested.

16.10 Suspension or Early Termination

16.10.1 Planned Study Closure

The study completion date is defined as the date on which the last study subject had their last visit to collect data for a primary or secondary endpoint or adverse event data; however, the study closure process will continue until all required steps are complete. Study Closure is a process initiated by the distribution of a study closure letter. Study closure is defined as closure of a study that occurs when Medtronic and/or regulatory requirements have been satisfied per the CIP and/or by a decision by Medtronic or RA, whichever occurs first. The study closure process is completed upon distribution of the final report or after final payments, whichever occurs last. Ongoing IRB/EC oversight is required until the overall study closure process is complete.

16.10.2 Early Termination or Suspension

Early Termination is the closure of a study that occurs prior to meeting defined endpoints. This is possible for the whole study or a single study site. Suspension is a temporary postponement of study activities related to enrollment and distribution of the product. This is possible for the whole study or a single study site.

16.10.2.1 Study-Wide Termination or Suspension

Possible reasons for considering study-wide suspension or termination of the study include but are not limited to:

- AEs associated with the study device which might endanger the safety or welfare of the subject
- Observed/suspected performance different from the study device's design intent
- Decision by Medtronic or RA
- Technical issues during the manufacturing process

16.10.2.2 Investigator/Study Site Termination or Suspension

Possible reasons for investigator or study site termination or suspension include but are not limited to:

- Failure to obtain initial IRB approval or annual renewal of the study
- Persistent non-compliance to the clinical investigation (e.g., failure to adhere to inclusion/exclusion criteria, failure to follow subjects per scheduled follow-ups)
- Lack of enrollment
- Non-compliance to regulations and the terms of the CTA (e.g., failure to submit data in a timely manner, failure to follow-up on data queries and monitoring observations in a timely manner, etc.)
- IRB/EC suspension of the study site
- Fraud or fraudulent misconduct is discovered (as defined by local law and regulations)
- Investigator request (e.g., no longer able to support the study)

16.10.3 Procedures for Termination or Suspension

16.10.3.1 Medtronic-Initiated and Regulatory Authority-Initiated

- Medtronic will promptly inform the clinical investigators of the termination or suspension and the reasons and inform the RAs where required
- In the case of study termination or suspension for reasons other than a temporary IRB/EC approval lapse, the investigator will promptly inform the IRB/EC
- In the case of study termination, the investigator must inform the subjects and may inform the personal physician of the subjects to ensure appropriate care and follow-up is provided
- In the case of a study suspension, subject enrollment must stop until the suspension is lifted by Medtronic
- In the case of a study suspension, enrolled subjects should continue to be followed out of consideration of their safety, rights, and welfare

16.10.3.2 Investigator-Initiated

- The investigator will inform Medtronic and provide a detailed written explanation of the termination or suspension

- The investigator will promptly inform the institution (where required per regulatory requirements)
- The investigator will promptly inform the IRB/EC
- The investigator will promptly inform the RAs, as applicable
- The investigator will promptly inform the subjects and/or the personal physician of the subjects to ensure appropriate care and follow-up is provided
- In the case of a study suspension, subjects enrolled should continue to be followed out of consideration of their safety, rights, and welfare

16.10.3.3 IRB/Ethics Committee-Initiated

- The investigator will inform Medtronic and provide a detailed written explanation of the termination or suspension within 5 business days
- Subject enrollment must stop until the suspension is lifted
- Subjects already enrolled should continue to be followed in accordance with IRB/EC policy or its determination that an overriding safety concern or ethical issue is involved
- The investigator will inform his/her institution (where required per local requirements)
- The investigator will promptly inform the subjects, and/or the personal physician of the subjects, with the rationale for the study termination or suspension
- The investigator will promptly inform the RAs, as applicable

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18. Appendices

18.1 Appendix A – ASA Physical Status Classification System

Approved by the ASA House of Delegates on October 15, 2014, and last amended on December 13, 2020).

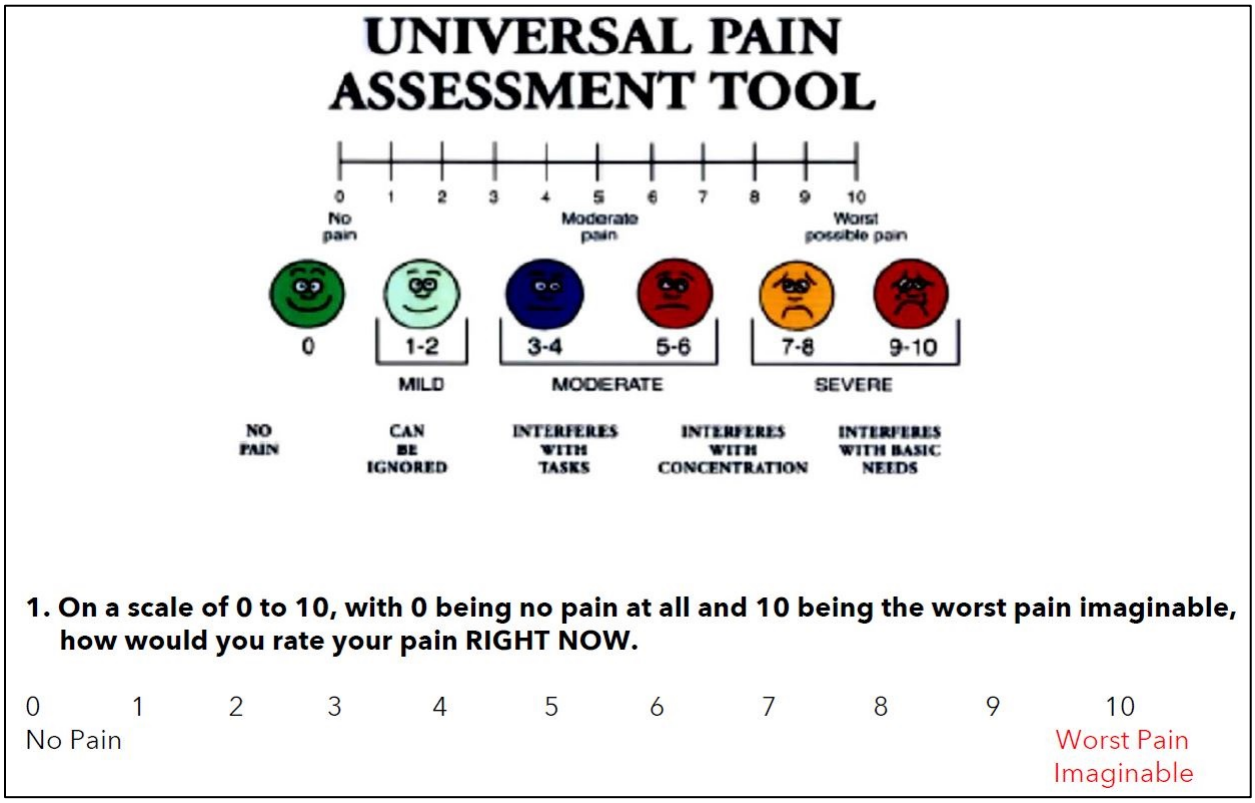
ASA PS Classification	Definition	Adult Examples, Including, but not Limited to:
ASA I	A normal, healthy patient	Healthy, nonsmoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ⩾40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Recent (<3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, shock, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared braindead patient whose organs are being removed for donor purposes	

18.2 Appendix B – CDC Surgical Wound Classification Grades

Grade	Definition
Class I/Clean:	An uninfected operative wound in which no inflammation is encountered, and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow no penetrating (blunt) trauma should be included in this category if they meet the criteria.
Class II/Clean-Contaminated:	An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in a sterile technique is encountered.
Class III/Contaminated:	Open, fresh, accidental wounds. In addition, operations with major breaks in a sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute or no purulent inflammation is encountered are included in this category.
Class IV/Dirty-Infected:	Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

18.3 Appendix C – Pain Numerical Rating Scale (NRS)

The Pain NRS numerical rating scale (NRS) requires the subject to circle a number on a defined scale between 0–10 where 0 is no pain and 10 is the worst pain imaginable.



18.4 Appendix D – HerQLes Quality of Life Questionnaire

The HerQLes Quality of Life Questionnaire requires the subject to circle a number on a defined scale between 1–6 assessing abdominal wall function.

For the following statements, please circle the number that is most appropriate for you.	Strongly Disagree	Moderately Disagree	Slightly Disagree	Slightly Agree	Moderately Agree	Strongly Agree
1. My **abdominal wall** has a huge impact on my health	1	2	3	4	5	6
2. My **abdominal wall** causes me physical pain	1	2	3	4	5	6
3. My **abdominal wall** interferes when I perform strenuous activities, e.g. heavy lifting	1	2	3	4	5	6
4. My **abdominal wall** interferes when I perform moderate activities, e.g. bowling, bending over	1	2	3	4	5	6
5. My **abdominal wall** interferes when I walk or climb stairs	1	2	3	4	5	6
6. My **abdominal wall** interferes when I dress myself, take showers and cook	1	2	3	4	5	6
7. My **abdominal wall** interferes with my sexual activity	1	2	3	4	5	6
8. I often stay at home because of my **abdominal wall**	1	2	3	4	5	6
9. I accomplish less at home because of my **abdominal wall**	1	2	3	4	5	6
10. I accomplish less at work because of my **abdominal wall**	1	2	3	4	5	6
11. My **abdominal wall** affects how I feel every day	1	2	3	4	5	6
12. I often feel blue because of my **abdominal wall**	1	2	3	4	5	6

18.5 Appendix E – List of Investigators, Sites and Institutional Review Boards

Site information, including addresses, contact information, Principal Investigators, and their respective Institutional Review Boards, will be retained in a separate document from the body of the clinical investigation plan document. This will be provided to study sites when requested and updated as necessary.

18.6 Appendix F – Instructions for Use (IFU)

Instructions for use will be retained in a separate document from the body of the clinical investigation plan document. This will be provided to study sites and updated as necessary.

18.7 Appendix G – Consent Forms

Consent forms and informational materials used to consent subjects will be retained in a separate document from the body of the clinical investigation plan document. These will be provided to study sites and updated as necessary.

18.8 Appendix H – Surgeon Satisfaction Questionnaire

The Surgeon Satisfaction Questionnaire is a short survey that will be completed after each procedure to evaluate the surgeon's use and satisfaction with MaxTack™.

AFFIX Study | MaxTack | Surgeon Satisfaction Questionnaire

Surgeon to complete questionnaire immediately after procedure.

To aid in evaluation of performance of the MaxTack™ Motorized Fixation Device (MaxTack™), the study requires that the surgeon performing the ventral hernia repair with MaxTack™ completes a satisfaction questionnaire immediately after each study procedure.

Subject #: _____

For this subject's procedure:	***Please circle the number that best fits your answer***					
	Very Difficult	Difficult	Neutral	Easy	Very Easy	N/A
Rate the ease of use of MaxTack™ **to fixate the mesh**	1	2	3	4	5	N/A
Rate the ease of **maneuverability** of MaxTack™	1	2	3	4	5	N/A
Rate the ease of using the MaxTack™ **grip / mesh manipulation feature**	1	2	3	4	5	N/A

For this subject's procedure:	***Please circle the number that best fits your answer***					
	Totally Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied	N/A
Rate your satisfaction with the **force required to fire** MaxTack™	1	2	3	4	5	N/A
Rate your satisfaction with the performance of MaxTack™ when **fired at different angles** (30-60 degrees)	1	2	3	4	5	N/A
Rate your satisfaction with **procedure time saving** using MaxTack™ vs. other tackers used for mesh fixation	1	2	3	4	5	N/A
Rate your satisfaction with the **overall experience** using MaxTack™	1	2	3	4	5	N/A

Printed name of Performing Surgeon: _____

Signature: _____ **Date:** _____

18.9 Appendix I – Foreseeable Adverse Events List

The information provided in this section pertains to foreseeable adverse events that may be observed in the AFFIX study and may collectively assist in identifying those events for a given device or therapy that are unexpected in nature.

An evaluation of potentially anticipated events, adverse device effects observed in previous clinical studies, and reported events in literature may be used in combination with device labeling, current event reporting information, and other published data to assess for an unexpected occurrence.

The MaxTack™ Motorized Fixation Device involves surgery when used to fix prosthetic material to soft tissue in minimally invasive ventral hernia repair procedures. Therefore, standard adverse events associated with a surgical procedure may be experienced (e.g., anesthesia complications, infections, bleeding, etc.). However, the focus of this section is to address in more detail the foreseeable events due to the use, performance, and/or presence of the MaxTack™ Motorized Fixation Device under investigation.

The procedure (ventral hernia repair) and the devices (mesh + tack) are closely interrelated, so it may be difficult to identify the origin of the complications (i.e., procedure-related versus device-related). The most common complications that may occur after a ventral hernia repair procedure, regardless of the type of mesh or tack used, include hernia recurrence, pain, and seroma. Treatment required for procedure and/or device-related adverse events may include medication, device surgical removal, or other surgical and medical remedies.

Potential risks associated with the implantation of the MaxTack™ Motorized Fixation Device and risk minimization are discussed in Section 11. The risk management process for MaxTack™ is performed in accordance with ISO 14971:2019 and ensures that the level of risk is acceptable prior to starting the study.

The foreseeable adverse events information presented in this section consists of three parts:

1) Observed adverse device effects in similar Medtronic studies,

2) Adverse events reported in published literature, and

3) Additional foreseeable adverse events.

Observed Adverse Device Effects (ADEs) in similar Medtronic Clinical Studies

MaxTack™ just launched in the USA; at the moment of the CIP revision, there is no history of adverse events with this specific device and no indication that can be reported.

MaxTack™ is made of the same polymer material as the AbsorbaTack™ Fixation Device and ReliaTack™ Fixation Device, and all indicated for fixation of prosthetic material to soft tissue. AbsorbaTack™ and ReliaTack™ have been commercialized since 2009 and 2015, respectively. Published results from Medtronic sponsored studies are available as follows:

Medtronic Sponsored Clinical Study for AbsorbaTack™ Fixation Device

Study title: Evaluation of Postoperative Pain Following Laparoscopic Hernia Repair: A Prospective, Randomized Comparison to Evaluate the Incidence of Postoperative Pain Associated with Absorbable Fixation (AbsorbaTack™) vs. Conventional Fixation (ProTack™) Following Laparoscopic Hernia Repair

Results: One hundred-six (106) subjects were enrolled in the study under the ventral hernia repair arm and 54 patients were randomized to the AbsorbaTack™ group. There were five (5) reported adverse events classified as possibly or definitely related to AbsorbaTack™ were reported in the study and are highlighted in the table below:

Preferred Term	N	%
Gastrointestinal disorders		
Abdominal distension	1	2%
Abdominal pain	1	2%
Injury, poisoning and procedural complications		
Incision site pain	2	4%
Seroma	1	2%

Thirty-nine (39) reported adverse events were classified as possibly or definitely related to the study procedure (ventral hernia repair), as determined by the investigator and are highlighted in the table below:

Preferred Term	N	%
Blood and lymphatic system disorders		
Anaemia	1	2%
Gastrointestinal disorders		
Abdominal distension	1	2%
Abdominal pain	4	7%
General disorders and administration site conditions		
Pain	1	2%
Suture related complication	1	2%
Swelling	1	2%
Infections and infestations		
Incision site infection	1	2%
Infusion site cellulitis	1	2%
Postoperative wound infection	1	2%
Urinary tract infection	1	2%
Injury, poisoning and procedural complications		

Incision site pain	3	5%
Seroma	12	22%
Traumatic liver injury	1	2%
Wound complication	2	4%
Nervous system disorders		
Hypoaesthesia	1	2%
Renal and urinary disorders		
Urinary retention	2	4%
Respiratory, thoracic and mediastinal disorders		
Hypoxia	1	2%
Skin and subcutaneous tissue disorders		
Dermatitis allergic	1	2%
Skin Irritation	1	2%
Vascular disorders		
Haematoma	1	2%
Hypotension	1	2%

No unexpected AE were reported. The study concluded that AbsorbaTack™ is safe and effective for use in the repair of primary ventral and incisional ventral repair procedures.

Medtronic Sponsored Clinical Study on ReliaTack™ Fixation Device (MDT17047RAF)

Study title: Post Market Clinical Follow Up Study for ReliaTack™ Articulating Reloadable Fixation Device with Deep Purchase Tacks (RAFDT)

Results: Forty (40) patients were enrolled in the ventral hernia repair arm study and received the ReliaTack™ Fixation Device. Six (6) AE related to the study procedure were reported in 4 subjects (10%).

Preferred Term	**N**	**%**
General disorders and administration site conditions		
Incision site Swelling	1	2.5%
Injury, poisoning and procedural complications		
Seroma	3	7.5%
Vascular disorders		
Haematoma	1	2.5%
Ecchymosis	1	25%

Additionally, no reportable AE related to fixation or the tack device, device deficiencies, deaths, or serious adverse events were observed during the study. This study concluded that the ReliaTack™

Articulating Reloadable Fixation Device with Deep Purchase Tacks is safe and effective for primary ventral and incisional ventral repair procedures.

Adverse Events (AEs) Reported in Published Literature:

As MaxTack™ has just been launched in the US , at the moment of the CIP version there is no history of adverse events with this specific device and no indication that can be reported. Nevertheless, it is appropriate to consider prior reportable AE and ADE from similar studies on competitor devices as anticipated ADE that may be observed in the AFFIX study.

The anticipated risks of participation in the study and the possible ADEs associated with the use of MaxTack™ for ventral hernia repair are those typically associated with surgically implantable tacks as described in the IFU: Seroma, Fistula, Perforation, Hernia recurrence, Bowel entrapment, Strangulated bowel, Tissue damage/trauma, Cardiac tamponade and/or damage to pericardium, Bleeding/hematoma, Acute/chronic pain, damage, Infection, Allergic reactions to the components of the product, Burns, Environmental contamination, Inflammatory reaction, Visceral adhesions, Vascular injury, Visceral injuries, Injuries to operator.

The identified competitor devices described in this section are similar devices to MaxTack™. Per MDCG-2020-6, similar devices belong to the same generic device group. The MDR defines a generic device group as "a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics [(11)]." Hence, the competitor landscape of MaxTack™ is defined as those absorbable tacks that are similar in design, have the same intended purpose (indicated for ventral hernia repair), and are the main contributors to the European market in terms of sales.

The competitors identified for MaxTack™ Motorized Fixation Device are:

- Absorbable Tack Fixation devices

Clinical data retrieved from evidence generated through published scientific literature have been summarized below for competitor devices of MaxTack™ for ventral hernia repair and encompasses over 1000 patients published in 49 studies.

The key parameters for performance are hernia recurrence following ventral hernia repair, and the key safety metrics are pain and seroma.

In the tables below, the key safety and performance outcomes of competitor devices of MaxTack™ from clinical literature are compared to those of the alternative therapeutics [i.e., all tacks (absorbable and permanent)] reported in the State Of The Art (SOTA) for Tack Fixation Devices.

The SOTA document for Tack Fixation Devices is an internal sponsor document revised on an annual basis that provides a comprehensive review of the current knowledge and evidence collected from the applicable standards, guidelines, and literature to establish the state of art for the use of Medtronic tack

fixation devices for securing prosthetic material during surgical procedures. Data and rates from the SOTA reported in the table below are from the time of the CIP development.

Safety and Performance Metrics for Fixation Devices with Absorbable Tacks during VHR

Fixation Method	Recurrence	Seroma
	Events / Patient n (%)	
Absorbable Tacks	111 / 1054 (10.53)	53 / 785 (6.75)
All Tacks	252 / 2527 (9.97)	153 / 1640 (9.33)

Regarding pain, the subjective nature of this measure and the lack of standardization and consensus on which specific pain assessment tool should be used limit a comprehensive comparison of pain/discomfort in the literature. In conclusion, these aggregated safety/performance metrics for Absorbable Tack Fixation devices include results from over 1000 patients demonstrating that the devices routinely used in hernia repair procedures have acceptable safety/performance outcomes.

Rates of key safety metrics from competitor devices compare similarly to the range of rates reported from the SOTA for alternative therapeutics (all tacks).

Additional risks related to this study may not yet be known. The Sponsor's risk management file will be updated periodically for impact on the product's overall residual risk for issues identified during the clinical study and following market release, per EN ISO 14971:2019.

Additional Foreseeable Adverse Events

Potential adverse events related to MaxTack™, as well as any other tack fixation devices, have been identified through Medtronic's risk assessment processes and listed as possible complications in the IFU of MaxTack™ and in the SOTA for Tack Fixation Devices are presented respectively below.

Some of these AE have not been reported in the published literature on similar and competitor devices and / or in the SOTA and consequently do not have associated expected rates.

Risks associated with the use of MaxTack™ Motorized Fixation Device:

- Seroma
- Fistula
- Perforation
- Hernia recurrence
- Bowel entrapment
- Strangulated bowel
- Tissue damage/trauma

- Cardiac tamponade and/or damage to pericardium
- Bleeding/hematoma
- Acute/chronic pain
- Nerve damage
- Infection
- Allergic reactions to the components of the product
- Burns
- Environmental contamination
- Inflammatory reaction
- Visceral adhesions
- Vascular injury
- Visceral injuries
- Injuries to operator

Risks associated with the use of any Tack Fixation devices may include:

- Improper tack placement
- Deployed tacks having insufficient holding force (resulting in tack/mesh migration, adhesions, erosion, recurrence, and damaged mesh)
- Excessive tack penetration
- Tack penetration through great vessels or cardiac structures
- Tack impinging on nerves
- Foreign body reaction (resulting in ‘‘meshoma’’ formation, tack hernias, chronic pain, and infection)

18.10 Appendix J - Optional Touch Surgery™ Ecosystem (TSE) Sub Study

18.10.1 Introduction

Touch Surgery™ ecosystem (TSE) is a comprehensive operating room (OR) computing and cloud-based solution designed to manage and analyze surgical videos for training and education purposes. The DS1 Computer, part of the TSE solution, is a computing device placed in the OR and records surgical video data and other non-patient metadata from the video imaging system in robotic and laparoscopic procedures. Powered by artificial intelligence (AI), the DS1 Computer automatically captures, redacts, and uploads surgical videos directly from the OR. Videos are then stored on a secure mobile and web platform - Touch Surgery™ ecosystem, allowing seamless access and review by the surgical team.

An optional sub-study was added to the AFFIX study, which will utilize TSE to capture surgical videos. This sub-study involves placing the (DS1) Computer, a non-medical device, in the OR to record, redact, and upload surgical videos. This sub-study aims to support product development and scientific research into digital technologies, such as artificial intelligence. Importantly, the recording process is designed to occur without interfering with patient care, the surgical procedure, or other trial activity.

18.10.1.1 Background

Artificial Intelligence (AI) has been used in medical technology and health care for some years, primarily in image and pattern recognition for diagnostic efforts. For example, in oncology, pathologists have used AI to reduce error rates in the detection of cancer-positive lymph nodes, and surgeons and radiologists have reduced lumpectomy rates in instances of benign breast lesions. However, due to the recent rapid growth in computing power, in addition to the development and access to large digital data sets, the proliferation of the integration of AI-powered technology in hospitals is emerging, particularly in the operating room.

Medtronic hopes to provide surgeons with advanced technology by providing additional information in real-time when performing laparoscopic or robotic surgeries. For certain minimally invasive procedures, TSE provides postoperative surgical analytics powered by machine learning on surgical processes such as surgical phases, anatomy, and instruments in view. TSE has been used for pre-operative rehearsal and post-operative review. The platform serves as an analytics and learning platform for surgeons and their teams. To continue to develop high-quality intra- and postoperative AI solutions, surgical procedure videos from a broad range of patients and geographies are required for analysis and scientific research.

18.10.2 Objective

The primary objective of this sub-study is to obtain the redacted surgical video of procedures from subjects enrolled in the AFFIX study for product development and scientific research of advanced digital technologies such as artificial intelligence algorithms.

18.10.3 Product Description

Touch Surgery™ ecosystem is a combined software and hardware solution for securely recording, storing, and analyzing surgical videos. It consists of the following components:

- A secure cloud platform supported by Amazon Web Services (AWS), where surgical videos and other non-patient metadata are stored. The platform is accessible through web browsers or a mobile app (upon successful login through multifactor authentication) OBJ
- The DS1 computer (Medtronic equipment) is a computing device that records and processes video data and other metadata from surgical video systems. It is accompanied by a paired device that acts as its wireless controller.
- Third party equipment: smartphone and cable/s.

Surgical videos will be recorded via an encrypted hard drive and Touch Surgery™ ecosystem. Touch Surgery™ ecosystem (including the DS1 computer) is commercialized as a non-medical device.

The DS1 computer is connected to the operating room's video imaging system with an HDMI cable (or other compatible wired connectivity). The DS1 features end-to-end encryption. A member of the operating room staff uses the DS1 wireless controller to select the procedure and surgeon's name. Throughout the case, and while the recording is in process, the video passes through the Medtronic AI-powered safeguard, RedactOR™, before it is saved to the Touch Surgery™ app and/or the DS1 computer. RedactOR™ works on the video in real time to determine when the scope has exited the patient. The algorithm then pixelates the video frames and will continue to do so until the scope re-enters the patient.

All videos will be uploaded to TSE and, therefore, be processed through RedactOR™. This redaction is irreversible, giving additional confidence that visual information that could identify a patient is not transmitted, processed, or stored. Upon direction by the authorized user, the video is uploaded from the DS1 computer to our secure cloud provided by Amazon Web Services (AWS). AWS complies with ISO 9001, ISO 27001, ISO 27017, and ISO 27018 and is audited against HDS (France).

Touch Surgery™ ecosystem will record, process, and provide analytics on video recordings of minimal-access surgical procedures. These are recorded through the standard operating stack and require no additional steps or changes to standard care. Currently, procedures are often routinely recorded in the operating room for training purposes to allow review and debriefing after a procedure or to evaluate where improvements could be made.

The DS1 computer complies with the following regulations and directives standards:

Regulations and Directives

- Safety
  - US OSHA regulation (29 CFR 1910.399)

- EU LVD (Directive 2014/35/EU)

- EMC
  - EU EMC (Directive 2014/30/EU)
- Radio
  - EU Radio Equipment Directive (Regulation 2014/53/EU)
  - US FCC (Regulation 47 CFR, subparts B, C, E; §2.1091)
- Environmental
  - EU REACH (Regulation EC 1907/2006)
  - EU RoHS (Directive 2011/65/EU, including amendment EU 2017/2102)
  - EU WEEE (Directive 2002/96/EC)
  - Packaging Waste (Directive 94/62/EC)
- Country of Origin
  - US 19 CFR Parts 102 and 134
- Other
  - Regulatory plans for privacy rules of EU and US
  - EU GDPR Regulation (EU 2016/679)
  - US HIPAA
  - Regulatory plans for IT cloud networking and cybersecurity in the EU and US

Touch Surgery ™ ecosystem is commercialized as a non-medical device and is not an investigational component of the AFFIX study.

Medtronic will loan, track, install, and train sites to use Touch Surgery ™. Following the study, all Medtronic equipment should be returned to Medtronic.

18.10.4 Eligibility Criteria

All subjects who have consented and are enrolled in the AFFIX study will be eligible to participate in the sub-study using the Touch Surgery™ ecosystem (TSE). No additional eligibility criteria will apply. Participation in the sub-study is optional, and subjects who choose to participate will provide separate informed consent specifically for this sub-study.

18.10.5 Informed Consent Process

All standard informed consent procedures outlined in the main body of this document apply to participants of the sub-study as well. The only additional requirement for participants is the completion of a separate informed consent form specifically for video collection. This video collection consent is entirely optional, and participants who choose not to sign the video consent form can still fully participate in the main AFFIX study without any impact on their involvement in the AFFIX study or their treatment.

18.10.6 Data Collection

Following the finalization of the consent process, the surgical video will be recorded on the day of the participant's surgery, following the institution's standard of care. A unique 7-digit identifier will be assigned to the video recording and collected from the DS1 controller. The unique identifier will be inputted into the case report form for the Operative Visit. In addition, surgeons are advised to title the surgical video with the patient study ID only. This will enable the necessary Medtronic times to link and process the collected data accurately.

18.10.7 Benefits and Risks

Touch Surgery ™ ecosystem is classified as a non-medical device; it does not change standard care or interact with the patient. We do not anticipate any added risk from recording the patient's procedure, which is routine in many operating rooms. No part of TSE will contact tissues and/or bodily fluids or interfere with the patient's procedure. TSE is not an investigational component of the AFFIX study.

The primary benefit of video collection is to support scientific advances in how operations are managed and improved. A secondary benefit to the site and surgical team is being able to utilize the technology. Surgical video analysis has been shown to benefit postoperative briefing, surgical education, coaching, and skill improvement (1-9). Users (Surgeons) will have the opportunity to use TSE for the duration of the study to record, store, and analyse their surgical video. All users will benefit from the real-time deployment of the commercialized RedactOR ™ Algorithm, which de-identifies the video frames in the operating room.

18.10.8 Analysis

Medtronic employees from Digital Technologies will analyse the video data and case report forms collected from participants for the purposes described in sub-study objectives: internal product development and scientific research. Aggregate patient metadata can be used to train and validate a future AI algorithm, which will be submitted for regulatory approval. No identifiable patient data or unredacted videos will be published externally.

18.10.9 References

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6. Hu Y, Peyre S, Arriaga A, et al. Postgame analysis: using video-based coaching for continuous professional development. J Am Coll Surgeons. 2012;214(1):115-124.
7. Based on a mixed-method analysis evaluating one-on-one coaching of ten resident physicians. Hu Y, Mazer L, Yule S, et al. Complementing operating room teaching with video-based coaching. JAMA Surg. 2017;152(4):318.
8. Based on a randomized controlled trial in porcine models. Singh P, Aggarwal R, Tahir M, Pucher P, Darzi A. A randomized controlled study to evaluate the role of video-based coaching in training laparoscopic skills. Ann Surg. 2015;261(5):862-869.

19. Version History

Version	Summary of changes	Justification of changes	Potential impact of the change on performance, effectiveness, or safety or other endpoints	Identification of the affected study documents	Author(s)/Title
1.0	'Not Applicable, New Document	Not Applicable, New Document	Not Applicable, New Document	Not Applicable, New Document	Alyssa Sutch / Senior Clinical Research Specialist, Clinical Study Manager

2.0	▪ Added Operative Time for mesh fixation as endpoint ▪ Added clarity that Valsalva Maneuver is required during physical exams ▪ Removed collection of prophylactic antibiotics at screening ▪ Clarified emergent surgery exclusion criteria by adding strangulated hernia as an example ▪ Added Surgeon Satisfaction Questionnaire to appendix ▪ Added FAL to appendix ▪ Minor administrative changes throughout	Operative time was already a data point collected in AFFIX. Due to its significance for this device, it was added as an endpoint. Clarifications were made where warranted, such as the requirement of the Valsalva maneuver to assess hernia recurrence.	Added an endpoint: Operative Time for mesh fixation	▪ CRFs ▪ Surgeon Satisfaction Questionnaire ▪ FAL	Alyssa Sutch / Senior Clinical Research Specialist, Clinical Study Manager

3.0	▪ Product accountability ▪ Touch Surgery video collection ▪ Included option of other geographies included in the study ▪ Intraoperative Screen failure definition change ▪ Removed intraoperative exclusion criteria and clarified surgical requirements ▪ Minor administrative changes throughout	▪ Study device will be provided to sites at no cost, therefore device accountability is required. ▪ Video collection included as an optional sub-study to support product and research development ▪ Flexibility to expand study participation beyond the US ▪ Clarified surgical requirements for investigators	▪ Not applicable	▪ CIP ▪ ICF ▪ CRFs ▪ Various study documents	Alyssa Sutch / Senior Clinical Research Specialist, Clinical Study Manager