Prospective, multi-center, single-arm, open label study designed to assess the safety and feasibility of the use of the Dual Robotic Arm Accessory with the Levita Magnetic Surgical System in laparoscopic procedures

Investigational Product:	**Dual Robotic Arm Accessory (DRAA)**
Protocol Name:	**MARS in GI**
Protocol Number:	**CP008**

1 ADMINISTRATIVE INFORMATION

1.1 Contacts

Medical, Clinical, and Operational Support

Sponsor Name:	Levita Magnetics
Sponsor Telephone Number:	+1 650-204-0529
Sponsor Email:	CP008@levita.com
Manufacturer and Sponsor Address:	Levita Magnetics Corp. 4055A Campbell Avenue Menlo Park, CA 94025 USA

1.2 Sponsor Protocol Approval

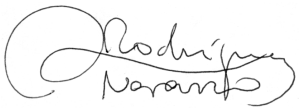
Representatives of Levita Magnetics

This study will be conducted with the highest respect for the individual participants in accordance with the requirements of this clinical study protocol and in accordance with the following:

The ethical principles that have their origin in the Declaration of Helsinki. International Conference on Harmonization Harmonized Tripartite Guideline for Good Clinical Practice E6 (ICH GCP E6).

All applicable laws and regulations, including, without limitation, data privacy laws and regulations.

SIGNATURES



13-Sep-2022

Dr. Alberto Rodríguez Navarro, CEO Levita Magnetics — Fecha

17-Sep-2022

Matthew Kroh MD, Medical Expert- Cleveland Clinic — Date

Investigator Agreement and Certification
Clinical Evaluation of the Dual Robotic Arm Accessory

I will provide copies of the clinical trial protocol and all pertinent information to all individuals responsible to me who assist in the conduct of the study. I will discuss this material with them to ensure they are fully informed regarding the investigational products and the conduct of the study.

I agree to ensure informed consent is appropriately obtained from all subjects prior to inclusion in this study in accordance with requirements as specified in ICH Guideline for Good Clinical Practice; Section 4.8 and I will fulfill all responsibilities for submitting pertinent information to the Ethics Committee (EC). I will use only the informed consent form approved by the Sponsor and the EC or its representative.

I understand that this study will not be initiated without approval of the appropriate EC and that all administrative requirements of the governing body of the institution will be complied with fully.

I also agree to report all information or data in accordance with the protocol and I agree to report without unjustified delay, all Adverse Events (AEs) and Serious Adverse Events (SAEs) that could have led to any Unanticipated Adverse Device Events (UADEs).

I understand that this investigation may be monitored by the Study Sponsor and/or a designee employed by Study Sponsor and agree that Levita Magnetics and/or designee will have access to any original source documents from which paper case report form (CRF) information may have been generated. This monitoring would involve periodic inspection of my investigational site and ongoing review of the data that is submitted by me to Study Sponsor. I am also aware that I may be inspected by a representative of the U.S. Food and Drug Administration (FDA) or other regulatory authorities.

I am aware that Study Sponsor reserves the right to discontinue this investigation at any time.

My current curriculum vitae is attached along with the curriculum vitae of those physicians at this institution who will be using this investigational device or participating in this study as co-Investigators under my supervision. These include the extent and type of our relevant experience with pertinent dates and locations.

I certify that I have not been involved in an investigation that was terminated for noncompliance at the insistence of Study Sponsor, this institution’s Ethics Committee (EC) or any regulatory authority.

I understand that this investigation, protocol, and trial results are confidential, and I agree not to disclose any such information to any person other than a representative of Study Sponsor or regulatory authority without the prior written consent of Study Sponsor.

I also agree to have control over all clinical supplies (including investigational products) provided by Levita Magnetics and/or designee and collect and handle all clinical specimens in accordance with the protocol. I further agree not to originate or use the name of Levita Magnetics and/or Dual Robotic Arm Accessory (DRAA), or any of its employees, in any publicity, news release or other public announcement, written or oral, whether to the public, press or otherwise, relating to this protocol, to any amendment hereto, or to the performance hereunder, without the prior written consent of Levita.

I will provide financial information by completing a Levita Financial Disclosure Form and update it as necessary.

I herewith declare that I agree with the protocol described in detail in this document and agree to conduct the study in accordance with the protocol and in compliance with Good Clinical Practice and all applicable regulatory requirements.

Accepted by

Principal Investigator Signature	Printed name	Date

Protocol Synopsis

Sponsor:	Levita Magnetics
Protocol Title:	Prospective, multi-center, single-arm, open label study designed to assess the safety and feasibility of the use of the Dual Robotic Arm Accessory with the Levita Magnetic Surgical System in laparoscopic procedures
Protocol Number:	CP008
Investigational Device:	Levita Dual Robotic Arm Accessory (DRAA)
Device Description:	The Dual Robotic Arm Accessory (DRAA) for the MSS comprises two collaborative robotic arms, which along with their controllers and control software, are intended for use in medical applications, and additional adaptors, for 1) attaching the Magnetic Controller of the commercially available Levita Magnetics MSS to one robotic arm and 2) attaching a commercially available camera and endoscope to the second robotic arm. The design of the robotic arms, referred to as the Scope Arm and the Magnet Arm, includes several redundant safety features that make them well suited for use with the MSS in the operating room environment, including hardware and software safety controls. When mounted on the Scope Arm, an endoscope can be pivoted and translated as controlled by the user, while maintaining minimal motion at the point where the endoscope enters the patient's body via a standard trocar. Similarly, when mounted on the Magnet Arm, the Magnetic Controller can be moved to different positions on or away from the abdominal wall.
Study Objective:	The purpose of this study is to evaluate the safety and feasibility of the Dual Robotic Arm Accessory (DRAA) used with the Levita Magnetic Surgical System (MSS).
Study Design:	Prospective, multi-center, single-arm, open label study.
Enrollment Size and Number of Sites:	Up to 50 subjects will be competitively enrolled in up to 3 clinical sites in Chile.

Subject Population:	All patients at least 18 years of age presenting for elective laparoscopic surgery are potential candidates.
Rationale:	Levita has developed a Robotic Platform (DRAA) to assist in external management of the controlling magnet and the laparoscopic camera, which would give better control of surgical tools to the surgeon. The DRAA replaces the commercially available surgical support arm that is currently used with the MSS.
Safety Outcomes:	All adverse events will be captured and reported. Adverse events will be summarized by relatedness to the device and/or procedure, seriousness and level of severity. If device related, AEs will be further characterized as to relationship to the MSS the DRAA or both.
Feasibility Outcomes:	Ability to utilize the Levita MSS with the DRAA as intended in laparoscopic procedures. The following outcomes will be considered in this feasibility study: 1. The DRAA is able to engage, move, and decouple with the MSS as intended / controlled by the surgeon 2. The DRAA is able to provide adequate endoscopic visualization via a conventional endoscopic system as intended / controlled by the surgeon 3. The procedure is successfully performed with the MSS and DRAA. 4. The MSS or the DRAA cannot be successfully used and due to a MSS or DRAA performance issue the procedure must be converted to an open procedure.
Inclusion Criteria:	*Participants must meet <u>ALL</u> of the following inclusion criteria to be eligible for participation in the study:* At least 18 years of age Scheduled to undergo elective laparoscopic procedure Willing and able to provide a written Informed Consent Form (ICF) to participate in the study prior to any study required procedures
Exclusion Criteria:	*Individuals must be <u>EXCLUDED</u> from participation in this study if <u>ANY</u> of the following exclusion criteria are met:* Individuals with pacemakers, defibrillators, or other electromedical implants Individuals with ferromagnetic implants Significant comorbidities: cardiovascular, neuromuscular, chronic obstructive pulmonary disease, and urological disease (renal failure)

	Clinical history of impaired coagulation confirmed by abnormal blood tests Anatomical abnormality or disease of intended target tissue noted after initiation of index procedure that would prevent device use Pregnant or wishes to become pregnant during the length of study participation Individual is not likely to comply with the follow-up evaluation schedule Participating in a clinical trial of another investigational drug or device Prisoner or under incarceration
Study Duration / Follow-up Period	Subjects will be followed for 30 days post-procedure, with follow-up visits at hospital discharge, 7 days, and 30 days post-procedure.
Clinical Sites and Site Principal Investigators*:	Julio Jiménez, MD Hospital Luis Tisne Santiago, Chile Ignacio Robles, MD Hospital de la FACH Santiago, Chile Pablo Marín, MD Clínica Colonial Santiago, Chile
Medical Expert:	Matthew Kroh, MD Cleveland Clinic, OH, USA

*Additional Investigators and Clinical Sites will be listed in a study report or separate document.

Table of Contents

2 ABBREVIATIONS / ACRONYMS

Abbreviations	Definitions
AE	Adverse Event
CDC	Center for Disease Control and Prevention
CFR	Code of Federal Regulations
CRF	Case Report Form
CRO	Contract Research Organization
EC	Ethics Committee
EUA	Emergency Authorization Use
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GDP	Good Documentation Practice
HHS	United States Department of Health and Human Services
HIPPA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Council for Harmonization
IFU	Instructions for Use
IRB	Institutional Review Board
ISO	International Organization for Standardization
LAR	Legal Authorized Representative
LOS	Length of Stay
DRAA	Dual Robotic Arm Accessory
MC	Magnetic Controller
MIS	Minimally Invasive Surgery
MSS	Magnetic Surgical System
N/A	Not Applicable
N/D	Not Done
NSR	Non-significant Risk
OR	Operating Room
PACU	Post Anesthesia Care Unit
PD	Protocol Deviation
PHI	Protected Health Information
PI	Principal Investigator
PP	Per Protocol
RA	Robotic Arm
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SD	Standard Deviation
SDV	Source Document Verification
SOC	Standard of Care
SOP	Standard Operating Procedures
SID	Subject Identification Number
UADE	Unanticipated Adverse Device Effect

3 INTRODUCTION

3.1 Background and Rationale

Since the introduction of minimally invasive surgery (MIS) in the 1980's, laparoscopy has become the preferred approach for intra-abdominal procedures. With limited access to the surgical field, one of the key requirements of laparoscopic surgery is the ability to achieve and maintain adequate visualization of the surgical target throughout the procedure. During certain MIS procedures, the patient's internal organs can block or obscure the surgical view. A number of surgical instruments (graspers or retractors) have been developed to help mobilize abdominal organs to obtain an adequate surgical view during MIS procedures. Most of these instruments require an additional abdominal wall puncture/incision, leading to potentially increased complications. These complications include risk of postoperative pain, additional scars, injury to major blood vessels and bowel, infection, incision-related hernias, and chronic incisional pain, among others.

To maximize the benefits of MIS, robotic surgery was developed more than 30 years ago. However, the use of the robotic technology has not resulted in demonstrated clinical benefit and the same number of incisions are typically required in robotic procedures (Tan et al; Leal and Campos). Nevertheless, one of the advantages of a robotic platform is that the surgeon has full control of all instruments during the surgery.

One of the goals of MIS is a reduction in the number of abdominal incisions, resulting in less postoperative pain, reducing the risk of incision-related complications, improving the cosmetic results, and increasing overall patient satisfaction after surgery (Nguyen et al). Levita Magnetics developed the Levita® Magnetic Surgical System (MSS) for tissue/organ mobilization. The MSS allows the surgeon to move tissue/organs out of the visual field without requiring a dedicated incision/port for the tool.

Laparoscopic procedures often require several clinical team members to manage the instruments and camera. Ideally only one clinician, who would provide direct control of all the internal surgical tools, would be required. This would both improve the operating environment and reduce the cost of the procedure by decreasing the number of required personnel.

Recently, Levita has developed a Robotic Platform (DRAA) to assist in external management of the controlling magnet which would reduce required personnel and give control of all surgical tools to the same surgeon. The DRAA replaces the commercially available surgical support arm that is currently used with the MSS.

The safety and effectiveness of the MSS has been demonstrated for the retraction of the gallbladder during cholecystectomy (Rivas et al.). This pivotal study, published in the Annals of Surgery and conducted in Chile, supported the marketing clearance of the MSS in the United States in 2016. Initial US experience (Haskins et al.), performed at the Cleveland Clinic, confirmed the results described in the Rivas publication. The MSS has also been used successfully for liver mobilization in bariatric procedures at Duke Regional Medical Center in a series of 40 patients (Davis et al.) As use of the MSS for laparoscopic procedures expands additional data collection is ongoing to detail clinician's experiences with this system in various other laparoscopic procedures.

This current study is intended to evaluate the safety and feasibility of the Dual Robotic Arm Accessory when used with the Magnetic Surgical System for laparoscopic procedures.

4 SURGICAL SYSTEM DEVICE DESCRIPTION

The Dual Robotic Arm Accessory (DRAA) for the MSS, pictured below in **Figure 1**, comprises two collaborative robotic arms, which along with their controllers and control software, are intended for use in medical applications, and additional adaptors, for 1) attaching the Magnetic Controller of the commercially available Levita Magnetics MSS to one robotic arm and 2) attaching a commercially available camera and endoscope to the second robotic arm.

The design of the robotic arms, referred to as the Scope Arm and the Magnet Arm, includes several redundant safety features that make them well suited for use with the MSS in the operating room environment, including hardware and software safety controls.

When mounted on the Scope Arm, an endoscope can be pivoted and translated as controlled by the user, while maintaining minimal motion at the point where the endoscope enters the patient's body via a standard trocar. Similarly, when mounted on the Magnet Arm, the Magnetic Controller can be moved to different positions on or away from the abdominal wall.

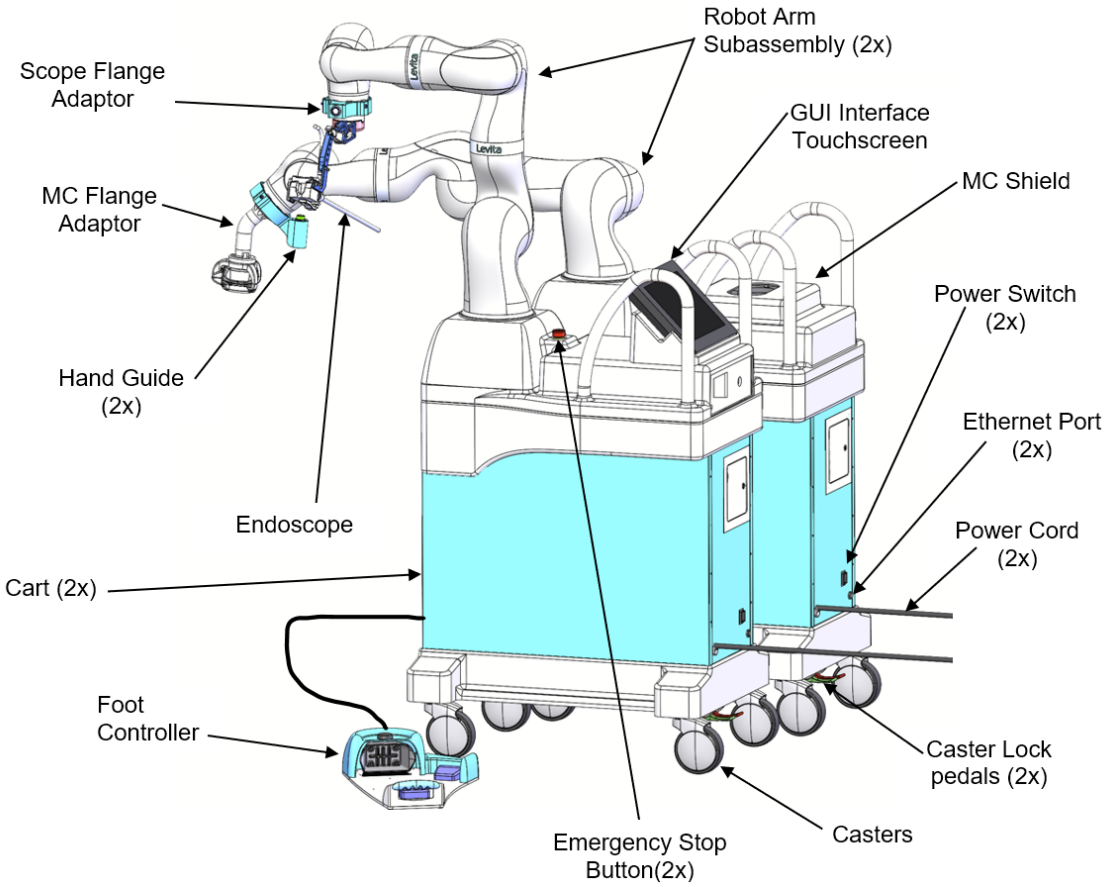


Figure 1. Diagram of Dual Robotic Arm Accessory: the Magnet RA (on far cart) is holding the Magnetic Controller (MC) of the Magnetic Surgical System; the Scope RA (on near cart) is holding a commercially available endoscope

The MSS is composed of three components: the Detachable Grasper, the Delivery/Retrieval Shaft (together, the “Magnetic Grasper Device”), and an external Magnetic Controller mounted on a Robotic Platform.

The Detachable Grasper and Delivery/Retrieval Shaft make up the Magnetic Grasper Device (**Figure 2**). Once the Magnetic Grasper Device is inserted through an access port and the Grasper is attached to the desired tissue, the Detachable Grasper can be detached from the Delivery/Retrieval Shaft and controlled externally using the Magnetic Controller. Traction of the tissue is maintained through the magnetic field attraction between the Detachable Grasper and the Magnetic Controller. The Magnetic Grasper Device is operated by hand and is inserted into the abdominal cavity through a ≥ 10 mm laparoscopic trocar port. The Magnetic Grasper Device is single-use, disposable, and provided sterile to the user.

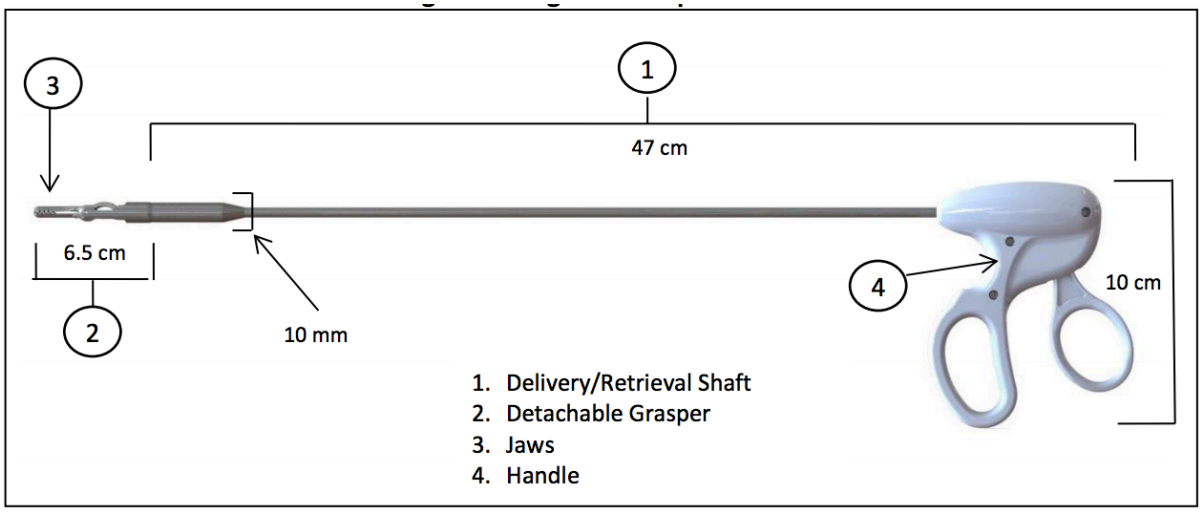


Figure 2. Magnetic Grasper Device

The Magnetic Controller mounted on the robotic arm (**Figure 3**) emits a magnetic field that attracts the Detachable Grasper. Once the Detachable Grasper is attached to the desired tissue/organ and detached from the Delivery/Retrieval Shaft, the robot arm brings the Magnetic Controller to the external surface of the abdominal wall so that it can magnetically couple to the internal Detachable Grasper under control of the surgeon, the DRAA moves the Magnetic Controller along the surface of the abdomen. When the Magnetic Controller moves, the Detachable Grasper follows, thus retracting the internal tissue/organ to a location of the surgeon's choice. The external Magnetic Controller and the DRAA is re-usable, provided non-sterile to the user, and must be placed in an off-the-shelf sterile bag prior to use.

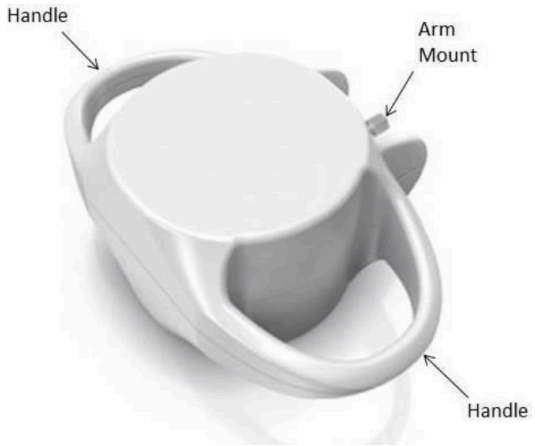


Figure 3. Magnetic Controller

The Dual Robotic Arm Accessory (**Figure 4**) includes two robotic arms, control unit(s), and control software. A handheld and/or foot-operated control pad allow

for DRAA control by the surgeon or surgical assistant. One arm of the DRAA attaches the Magnetic Controller using the arm mount of the Magnetic Controller and the second robotic arm attaches a conventional laparoscopic camera.

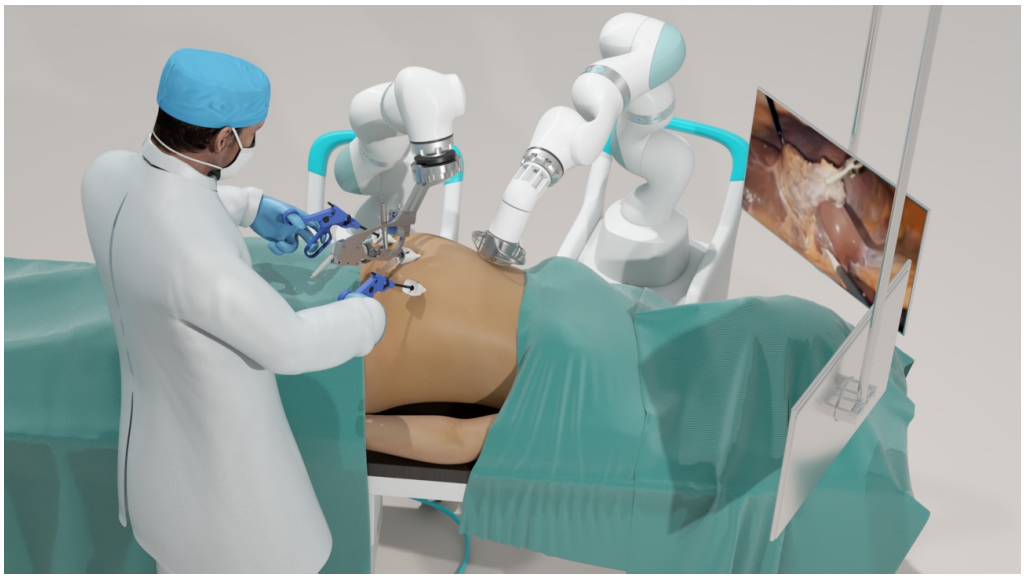


Figure 4. DRAA. One arm is mobilizing the External Magnetic Controller (external magnet) and the second arm is mobilizing a conventional laparoscopic camera.

The DRAA is certified to international electrical safety and software standards for use in medical products. The design of the DRAA includes several redundant safety features which make it well suited for use with the MSS in the operating room environment. These features include hardware and software safety controls including requirement for an enabling switch, an emergency stop, and controls for the workspace, velocity and axis torque of the robot. As noted, the DRAA is provided non-sterile to the user. While no portions of the DRAA are in direct patient contact, the Robot Arms are in the sterile field. Therefore, prior to use, the Robot Arms must be draped in off the shelf sterile bags (such as the Mayo Stand Cover CFI-708).

5 INDICATION FOR USE AND INTENDED USE

The Magnetic Surgical System is already commercial approved as a class II device, is designed to grasp, hold, retract, mobilize, or manipulate soft tissue and organs in minimally invasive procedures. The Robotic Platform is an accessory designed to facilitate use of the Magnetic Surgical System and an Endoscopic Camera in a hands-free manner.

The Dual Robotic Arm Accessory (DRAA) is intended to assist in accurate control of the Magnetic Surgical System and a commercially available endoscope. It is intended for use by trained and qualified surgeons, who are familiar with this device prior to surgery, in an operating room environment in accordance with the representative specific procedures set forth in the Instructions for Use.

6 STUDY PURPOSE AND OBJECTIVE

The purpose of this study is to evaluate the safety and feasibility of the Robotic Platform used with the Levita Magnetic Surgical System in laparoscopic procedures.

7 STUDY ENDPOINTS

The following endpoints will be evaluated in all subjects who undergo laparoscopic procedures using the Robotic Platform and Magnetic Surgical System.

7.1 Safety Outcomes

All adverse events will be captured and reported. Adverse events will be summarized by relatedness to the device and/or procedure, seriousness and level of severity. If device related, AEs will be further characterized as to relationship to the MSS the DRAA or both.

7.2 Feasibility Outcomes

Ability to utilize the Levita MSS with the DRAA as intended in laparoscopic procedures. The following outcomes will be considered in this feasibility study:

- The DRAA is able to engage, move, and decouple with the MSS as intended / controlled by the surgeon
- The DRAA is able to provide adequate endoscopic visualization via a conventional endoscopic system as intended / controlled by the surgeon
- The procedure is successfully performed with the MSS and DRAA.
- The MSS or the DRAA cannot be successfully used and due to a MSS or DRAA performance issue the procedure must be converted to an open procedure.

7.3 Other Assessments

- Operative time
- Time spent in the Post Anesthesia Care Unit (PACU)
- Length of stay (LOS) (time from admittance to post-anesthesia care unit until hospital discharge)

- Conversion rate (conversion to an open procedure due to inadequate MSS performance)
- Number of required surgeons
- Estimated blood loss
- MSS and Robotic Platform malfunctions
- Patient and Surgeon satisfaction with the system

8 STUDY DESIGN

8.1 Overview

This feasibility study is a prospective, multi-center, single-arm, open label study designed to assess the safety and feasibility of the use of the Dual Robotic Arm Accessory with the Levita Magnetic Surgical System in laparoscopic procedures.

8.2 Sample Size and Number of Centers

The study will be conducted at up to three (3) clinical sites with a target maximum of 50 subjects in which the Robotic Platform and Levita Magnetic Surgical System is used for laparoscopic procedures.

8.3 Study Duration

Enrollment of subjects in this study is anticipated to take up to 12 months. Clinical follow-up evaluations will be conducted at discharge, 7 days, and 30 days following surgery. The total study duration is expected to be approximately 13 months.

9 STUDY PROCEDURES

9.1 Subject Eligibility, Pre-Screening, and Exclusions

All individuals presenting for elective laparoscopic procedures are potential candidates and will be screened for eligibility. Study clinicians will select subjects based on knowledge/experience. A Screening/Enrollment Log will be provided to the study sites to maintain a cumulative tracking of all screened subjects.

Subjects must meet all study entrance criteria for enrollment in the clinical study. Reasons for screening failure(s) will be documented.

9.1.1 Inclusion Criteria

Participants must meet ALL of the following inclusion criteria to be eligible for participation in the study:

1. At least 18 years of age
2. Scheduled to undergo elective laparoscopic procedure

3. Willing and able to provide a written Informed Consent Form (ICF) to participate in the study prior to any study required procedures

9.1.2 Exclusion Criteria

Individuals must be EXCLUDED from participation in this study if ANY of the following exclusion criteria are met:

1. Individuals with pacemakers, defibrillators, or other electromedical implants
2. Individuals with ferromagnetic implants
3. Individuals with significant comorbidities: cardiovascular, neuromuscular, chronic obstructive pulmonary disease, and urological disease (renal failure)
4. Individuals with clinical history of impaired coagulation confirmed by abnormal blood tests
5. Anatomical abnormality or disease of intended target tissue noted after initiation of index procedure that would prevent device use
6. The individual is pregnant or wishes to become pregnant during the length of study participation
7. Individual is not likely to comply with the follow-up evaluation schedule
8. Is participating in a clinical trial of another investigational drug or device
9. Is a prisoner or under incarceration

9.2 Screening/Baseline Evaluation

Patients will be prescreened for eligibility and if qualified will be approached with the study information and asked if they are willing to participate. The Screening visit will occur within 30 days prior to the laparoscopic procedure.

Informed consent will be obtained per Section 13.3. All patients who sign a consent form are considered study subjects. A study participant is considered enrolled after they have signed an informed consent form and after the inclusion/exclusion criteria have been met.

The following evaluations are required at the time of subject screening /baseline:

- Demographic Information: gender, race, age, weight, and height, and smoking status
- Medical / Surgical History
- Pre-operative blood draw for determination of coagulation disorders if warranted
- Urine pregnancy test for women of childbearing potential. Note that if the screening test is more than 1 week prior to the index

procedure, a second urine pregnancy test is required within 7 days of the index procedure.

9.3 Procedure

The Investigator will perform the surgical procedure in accordance with the methods detailed in the Instructions for Use (IFU).

The following intra-operative data will be collected:

- General anesthesia time
- Operative time (from the first incision to the last suture's placement)
- Device and procedure observations
- Number of required surgeons
- Conversion to open surgical procedure
- The need for an additional surgical tool to mobilize the intended organ or tissue
- Estimated blood loss
- Video recording of the overall procedure
- Adverse events

9.4 Post-Procedure / Hospital Discharge

Before hospital discharge the following data will be collected:

- Length of hospital stay (time from admittance to post-anesthesia care unit until hospital discharge)
- Length of time spent in Post Anesthesia Care Unit (PACU)
- Adverse events, if any

9.5 Follow-up

All subjects will be asked to return to the investigational site at 7 days and again at 30 days post-procedure according to the study schedule described in Table 1: Schedule of Assessments**.** Subjects will be queried about adverse events at these study visits. Study visits should be scheduled as closely as possible to the earlier part of the time period to allow for rescheduling if needed due to last minute schedule changes. Visits not completed within the specified time period will be regarded as deviations.

9.6 Unplanned Follow-up Visits

Subjects returning for unscheduled visits will be reported on the Unscheduled Visit case report form.

9.7 Early Discontinuation / Withdrawal

All subjects will be informed of their right to withdraw from the clinical study at any time without penalty or loss of benefits to which the subject is otherwise entitled. Additionally, the Investigator may prematurely discontinue any

subject's participation in the study if the Investigator feels that the subject can no longer fully comply with the requirements of the study or if any of the study procedures are deemed potentially harmful to the subject. The reason for early discontinuation will be documented in the source documents and the Study Termination case report form.

9.8 Lost to Follow-up Subjects

Every attempt will be made to have all subjects complete the follow-up visit schedule. A subject will not be considered lost to follow-up unless efforts to obtain compliance are unsuccessful. At a minimum, the effort to obtain follow-up information will include three attempts to make contact via telephone or email and if unsuccessful, then a certified letter from the Investigator will be sent to the subject's last known address. In general, the study Site Coordinator should attempt to contact the subject as soon as possible after each missed visit to reschedule the visit.

9.9 Study Exit

Subjects will be considered to have completed and exited the study after the 30 day follow up visit has been completed.

9.10 Study Schedule of Assessments

Table 1: Schedule of Assessments

Assessment	Time Frame			
	Pre-op	Index Procedure & Discharge	7-day follow-up	30-day follow-up
Visit Window	- 30 days	NA	(± 3 days)	(± 7 days)
Informed Consent	√			
Medical History	√			
Demographics	√			
Blood Tests	√			
Pregnancy Test *	√	√		
Intra-operative assessments		√		
Adverse events		√	√	√

* Urine pregnancy test for all women of childbearing potential at pre-op visit and repeated within 7 days of index procedure unless pre-op visit/prior urine pregnancy test was within 7 days of index procedure.

10 RISK / BENEFIT ANALYSIS

10.1 Benefits

Possible benefits of the use of the Levita Magnetic Surgical System and Robotic Platform are a reduction in the number of surgical incisions needed to perform the surgery, with associated reduction in post-operative pain and scaring, a shorter length of stay in the hospital, faster recovery, and reduced intraoperative labor required.

10.2 Risks

There are risks associated with use of the Levita Magnetic Surgical System and Robotic Platform including:

- Electromagnetic field incompatibility or interference
- Malfunctioning of the device
- Breakage of the device
- Allergic reaction related to the device
- Abdominal wall/cavity/tissue and/or organ injury or damage (e.g., inflammation, redness)
- Infection
- Tissue damage, including hematoma, bleeding or petechiae
- Vascular injury
- Gastro-intestinal injury
- Organ perforation
- Need for extended surgery
- Additional surgical intervention due to any of the above factors (includes reoperation)

These adverse events do not include all adverse events, which occur with surgery in general, but are important considerations particular to laparoscopic instrumentation.

10.3 Minimization of Risk and Monitoring Procedures

Levita Magnetics has attempted to mitigate risks as much as possible through product design and development of the MSS which included *in vivo* performance testing, human factors testing, non-clinical performance testing, clinical testing of the MSS in other surgical procedures, biocompatibility testing, sterilization validation, reprocessing validation and shelf-life validation. Additionally, careful labeling, IFU and training are provided as detailed below for the MSS and DRAA.

Risks will be further mitigated through selection of qualified physicians with competence in minimally invasive surgery, appropriate training, and study monitoring.

Investigators who participate in the study will be experienced and skilled in laparoscopic surgical techniques. Additionally, Investigators, in conjunction with the investigational site, will have adequate resources for participation in a clinical study.

The study has been designed to ensure treatment and follow-up of subjects are consistent with current medical practice.

Each Investigator will ensure oversight and approval of the study by the Ethics Committee (EC) prior to initiation of the clinical study at his/her investigational site.

The Investigator and study personnel will be trained on the clinical protocol. All Investigators who have not previously used the Levita MSS will undergo training with MSS prior to first use during the clinical study.

All Investigators and operating room support personnel will be provided with a detailed IFU during training and as a reference for review as needed.

The IFU details appropriate safety zones for use of the Magnetic Controller in an OR setting and considerations for users of a product with a strong magnet.

Study personnel are also trained with and receive a “Magnetic Surgery Screening Checklist” and Operating Room (OR) signage to ensure safe use of the system for subjects and users.

Subjects will be carefully evaluated against the inclusion/exclusion criteria prior to entering the clinical study to ensure that their diagnosis and medical status are appropriate for participation in the clinical study.

Subjects will be monitored up to the 30-day follow-up visit as defined in the study protocol. The follow-up visit will be with an Investigator to monitor the subjects’ status.

A study Investigator will evaluate the subject for any adverse events potentially related to the device.

Levita Magnetics or its designee may conduct monitoring visits at the investigative sites at the initiation of the study and periodically throughout the study to evaluate protocol compliance and to determine if there are any issues that may affect the safety or welfare of the subjects.

11 STATISTICAL ANALYSIS

11.1 Statistical Methods

This study is not planned to provide statistical data but to provide initial outcomes for safety and feasibility of the DRAA used with the MSS.

Descriptive tables may be produced for baseline characteristics including demographics and medical history and for study outcomes.

11.2 Sample Size Justification

This is a single-arm, multi-center, investigational study to understand the safety and feasibility of the use of the DRAA with the MSS. A sample size of 50 subjects was planned to allow use of the system in a number surgeons and a number of different types of laparoscopic procedures. It is expected that enrollment of 50 subjects will provide appropriate information regarding the safety and feasibility of the DRAA and MSS in laparoscopic procedures.

11.3 Safety Variables

Safety will be monitored via the reported Adverse Events, in this study. All adverse events will be captured and reported. Adverse events will be summarized by relatedness to the device and/or procedure, seriousness, and level of severity. If device related, AEs will be further characterized as to relationship to the MSS the DRAA or both.

11.4 Safety

All adverse events for participants in the safety population will be reported.

- Serious Adverse Events
- Non-serious Adverse Events Device Related Adverse Event
- Device Related Serious Adverse Events

Results will include the number of participants experiencing each type of event as well as the number of events.

11.5 Demographics

Subject demographics will be summarized using descriptive statistics (mean, median, Standard Deviation (SD), minimum, maximum), number of subjects for continuous variables (e.g., age), and frequency distributions (number and percentage of subjects) for categorical variables (e.g., sex at birth, race, and ethnicity).

11.6 Handling Missing Data

Only subjects with non-missing data for safety will be used.

11.7 Interim Analysis

Interim analysis will not be conducted for this study.

12 DATA MANAGEMENT

12.1 Data Collection

Data will be collected on paper case report forms (CRF) supplied by the Sponsor. A CRF will be completed for every subject who signs a written Informed Consent Form and is enrolled in the study. The Site Principal Investigator is responsible for the accuracy and completeness of all study documentation.

Corrections to the CRF must be made by drawing a single line through the incorrect data, entering the correct data beside the incorrect entry, then initialing and dating the correction. Incorrect data must not be obscured. The use of pencil, erasable ink, or correction fluid on CRFs is prohibited. All fields must be completed, e.g., if the item was not done, mark “N/D”. If the item is not applicable to an individual case, mark the field “N/A”.

CRFs will be printed on 3-part No Carbon Required paper (or equivalent) so that both the site and monitor/Sponsor will have copies of the CRFs. One of the three copies may be sent to the Sponsor for remote monitoring. Any other subject information sent to the Sponsor must be redacted of personal identification information.

A unique study number will be assigned to each subject. All information recorded on the CRF about the subject will be recorded with the study number on it. The main database will contain only the study number to identify the subject. The code with subject name and study number will be maintained in a secured designated location at the site and will be inspected by study monitors and auditors. Any computerized data will be password protected.

Levita Magnetics or its designee will be responsible for database design and management for this study.

12.2 Data Processing

Prior to data entry, monitoring, as detailed below, may be completed. In association with data entry, the data will be reviewed for further inconsistencies or incongruities. All data will be collected on source documents and source document verification (SDV) will be conducted to ensure data collected are reliable and allow reconstruction and evaluation of the study. In the SDV process, information reported by the Investigator is compared with the original records to ensure that it is complete, accurate, and valid.

The Monitor shall generate queries for data errors and discrepancies discovered in their review of source documents. When queries are necessary, the Monitor will a data clarification form. Upon notification, the Investigator or designee will respond with a reason for the discrepancy and document that data is correct as documented or will provide a corrected resolution to the data field. The Monitor shall review the resolution and close the query, if appropriate. If additional information is required, the Monitor will continue the process until all data requirements are satisfied.

12.3 Final Clinical Study Report

A final report will be completed, even if the study is prematurely terminated.

12.4 Publication Policy

Information concerning the study device, patent applications, processes, unpublished scientific data, the Protocol and other pertinent information is confidential and remains the property of the Sponsor.

The clinical investigation will be registered in a publicly accessible database. At the conclusion of the trial, the results may be prepared and used in support of a regulatory submission and provided at major meeting(s). The publication of results from any center experience within the trial is not allowed unless there is written consent from the Sponsor.

A publication strategy plan will be developed as a collaboration between the Principal Investigators and the Sponsor, Levita Magnetics.

13 MONITORING AND QUALITY CONTROL PROCEDURES

13.1 Control of Systemic Error/ Bias

Clinical monitors may verify subject data and ensure compliance with Good Clinical Practices (GCPs), clinical protocol and other study requirements.

13.2 Monitoring and Auditing

Monitoring visits to the clinical sites may be made periodically during the study, to ensure that it is conducted in accordance with the protocol and the following guidelines and standards: ISO 14155, The Code of Federal Regulations 21 CFR Part 812 and country specific regulations. Levita Magnetics intends to monitor the investigational site at an interval consistent with the screening rate.

Prior to the enrollment of any subject in this study, site study personnel will be trained to the protocol and the device including the IFU. Additionally, the procedure for obtaining informed consent and the procedure for reporting adverse events will be reviewed.

The Monitor will ensure through personal contact with the Investigator and site personnel that the members of the clinical staff clearly understand and accept the obligations incurred in this investigation, and that these obligations are being fulfilled throughout the study. Specifically, the Monitor will interact with the site via telephone contact and potentially periodic on-site visits to ensure that:

- Qualified subjects are appropriately consented
- Regulatory and study documents are complete and current
- The protocol is appropriately followed
- Protocol amendments have been approved by the EC, the hospital director (as applicable), and the Sponsor has received the approval in writing
- Accurate, complete, and current records are maintained for all subjects
- Source data verification may be undertaken to ensure the information recorded and submitted to the Sponsor is representative of the subject record and other supporting documentation
- Inconsistent and incomplete data are addressed and resolved
- Accurate, complete, and timely adverse event reports are being made to the Sponsor
- Investigational devices are properly stored, and accounted for

The Investigator or designee must, upon request, provide to the Monitor or regulatory authority the necessary study records for a thorough review of the study's progress. These records include, but are not limited to, case report forms, original documents, records such as hospital and clinic charts, consent forms, laboratory records, and any other study related documents.

The Monitor will provide a written report to the Sponsor after each on-site visit. The report will identify the personnel participating in the visit, the activities performed, any protocol deviations, and any action items/corrective actions identified.

If compliance problems or protocol deviations are noted, the Sponsor will recommend corrective action. If the response from the Investigator is not adequate, the Sponsor will terminate the site's participation in the study and notify EC and the regulatory authorities (if applicable).

The study may also be subject to a quality assurance audit by the Sponsor or its designees, as well as inspection by appropriate regulatory authorities.

It is important that the Investigator and relevant study personnel are available during the monitoring visits and possible audits and that sufficient time is devoted to the process.

13.3 Device Accountability

The device is investigational and not approved for commercial use. Access to investigational devices shall be controlled and used only in the clinical investigation and according to the protocol.

The Sponsor shall keep records to document the physical location of all investigational devices from shipment (or hand-carried) to the sites until return or disposal.

The site Principal Investigator or an authorized designee shall keep records documenting the receipt, use, return, and disposal of the investigational device, which shall include:

- The date of receipt
- Identification of each investigational device (lot number)
- The date of use
- Subject study identification number
- Date of return of unused or malfunctioning investigational devices, if applicable
- Date of disposal, if applicable

The Investigator must explain in writing the reasons for any discrepancy noted in device accountability.

14 ADVERSE EVENTS

14.1 Definitions

14.1.1 Adverse Event (AE)

AEs are any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in which subjects, users, or other persons, whether or not related to the investigational medical device. This definition includes events related to the procedures involved. For users or other persons, this definition is restricted to events related to investigational medical devices.

All adverse events, regardless of relationship to the device, must be recorded on the case report forms provided. Adverse events that occur during this study should be treated by established standards of care.

Adverse events shall be assessed by the Investigator as to its relationship and level of relatedness to the investigational device, assessment, and/or procedure, and documented at the time of the procedure and at all study follow-up visits.

Each Investigator shall provide source documentation as requested by the Sponsor to facilitate reporting and adjudication of these events.

14.1.2 Serious Adverse Event (SAE)

An adverse event is considered "serious" if, in the view of either the Investigator or Sponsor, it results in any of the following outcomes:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or permanent change
- Congenital Anomaly/Birth Defect
- Required Intervention to Prevent Permanent Impairment or Damage
- Other Serious (Important Medical Events)

Planned hospitalization for a pre-existing condition, without serious deterioration in health, is not considered a serious adverse event.

14.1.3 Serious Adverse Device Effect (SADE)

A serious adverse device effect is defined as an adverse event related to the use of an investigational medical device that has resulted in any of the consequences characteristic of a serious adverse event.

14.1.4 Unanticipated Serious Adverse Device Effect (USADE)

An USADE is a serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the investigational plan.

14.2 Adverse Event Reporting

Any adverse event that occurs during the course of the study must be reported using the Adverse Event (AE) Form in the CRFs and the Investigator must sign each report. The Investigator must determine whether the adverse event is serious or unanticipated, its severity, and the relationship of each adverse event to the investigational device or procedure. In addition, the Investigator will identify the date of onset and duration of the AE.

Pre-existing medical conditions or symptoms occurring prior to the laparoscopic procedure involving the MSS should not be reported as adverse events, unless there is a worsening of the pre-existing medical condition.

All serious adverse events, including unanticipated serious adverse device effects, must be reported to the Sponsor within 24 hours of the site first becoming aware of the event via email (CP008@levita.com). At a minimum,

the AE CRF should be provisionally completed, scanned and sent via email. The Sponsor will contact the site for additional information, if required.

For any adverse event that is ongoing at the time of the initial report, periodic follow-up information is required until the adverse event is resolved or is not expected to change. The site should submit relevant follow-up information related to the adverse event as soon as it is available. All adverse events will be monitored until they are adequately resolved or explained. If an AE continues after the study participation ends, the Sponsor and Investigator should discuss the need and/or methods for continued surveillance of the event.

Depending upon the nature and seriousness of the adverse event, the Sponsor may request the Investigator to provide copies of the subject's medical records (such as the subject's laboratory tests and hospital records, Investigator summaries, etc.) to document the adverse event. The Sponsor is available to respond to any medical issues that arise during the conduct of this study.

The Investigator will report all adverse events, including serious and unanticipated serious adverse device effects, to the reviewing EC according to the local reporting requirements. A copy of this EC communication should be sent to the Sponsor.

The Sponsor will ensure that safety reporting for the study is conducted in compliance with all pertinent requirements and regulations.

The Sponsor's evaluation of UADEs must be reported to the FDA, all reviewing ECs, and participating Investigators within 10 working days of knowledge of the event by the Sponsor. All UADE will be reported to the FDA according to regulatory reporting requirements found in CFR 812.46.

14.3 Adverse Event Severity

The Investigator must determine the severity of the adverse event according to the following definitions:

Mild The adverse event is noticeable to the subject but does not interfere with routine activity; the symptoms are easily tolerated and transient in nature.

Moderate The adverse event interferes with routine activity but responds to symptomatic therapy or rest; the symptoms are poorly tolerated and sustained.

Severe The adverse event significantly limits the subject's ability to perform routine activities despite symptomatic therapy. The adverse event requires medical or surgical treatment or results in hospitalization.

Life-Threatening The subject is at immediate risk of death.

14.4 Event Relationship

The following lists the potential event attribution categories.

14.4.1 Device Related

An adverse event is considered device-related when the clinical event has a reasonable time sequence associated with use of the investigational device and is unlikely to be attributed to concurrent disease or other procedures or medications. It is reasonable to believe that the device directly caused or contributed to the adverse event.

The Investigator will evaluate the relationship of the adverse event to the MSS and/or DRAA according to the following definitions:

Definite The adverse event is clearly related to the investigational device: the event has a temporal relationship to the investigational device, follows a known pattern of response, or is otherwise logically related to the investigational device, and no alternative cause is present.

Probable The adverse event is likely related to the investigational device: the event has a temporal relationship to the investigational device, follows a known or suspected pattern of response, or is otherwise logically related to the investigational device, but an alternative cause may be present.

Not likely The adverse event is unlikely related to the investigational device: the event does not follow a clear temporal relationship to the investigational device or does not follow a known pattern of response or is otherwise likely to be due to the subject's clinical state or other modes of therapy.

Not related The adverse event is clearly not related to the investigational device: the event has no temporal or other relationship to the administration of the investigational device, follows no known or suspected pattern of response, and an alternative cause is present.

Unknown Unable to determine the relationship based on all available information.

14.4.2 Procedure-Related

An adverse event is considered to be procedure-related when it is reasonable to believe that the event is associated with the index procedure and is not specific to the investigational device. Other products, surgical techniques, or medications required specifically for the procedure may have contributed to the occurrence of the event.

The Investigator will evaluate the relationship of the adverse event to the procedure according to the following definitions:

Definite The adverse event is clearly related to the procedure: the event has a temporal relationship to the procedure, follows a known pattern of response, or is otherwise logically related to the procedure, and no alternative cause is present.

Probable The adverse event is likely related to the procedure: the event has a temporal relationship to the procedure, follows a known or suspected pattern of response, or is otherwise logically related to the procedure, but an alternative cause may be present.

Not likely The adverse event is unlikely related to the procedure: the event does not follow a clear temporal relationship to the procedure or does not follow a known pattern of response, or is otherwise likely to be due to the subject's clinical state or other modes of therapy.

Not related The adverse event is clearly not related to the procedure: the event has no temporal or other relationship to the procedure, follows no known or suspected pattern of response, and an alternative cause is present.

Unknown Unable to determine the relationship based on all available information.

14.5 Subject Death

Any subject death during the investigation must be reported to Levita Magnetics within 24 hours of Investigator's knowledge of the death. The Adverse Event CRF must be completed and include a complete description of the relevant details of the death. A copy of the death records, death certificates and an autopsy report (if performed) are required to be sent to the Sponsor. In addition, subject death must be reported to the EC in accordance with EC requirements.

14.6 Device Deficiency

All device deficiencies related to the identity, quality, durability, reliability, safety or performance (includes malfunctions, use errors, and inadequate labeling) of the device shall be documented. Sponsor will assess all device deficiencies that could have led to a serious adverse device effect.

In the event of a suspected malfunction or device deficiency, the investigational device should be returned to the Sponsor for analysis. Instructions for returning the investigational device will be provided by the Sponsor.

15 STUDY ADMINISTRATION

15.1 Statement of Compliance

The rights, safety, and wellbeing of clinical investigation subjects shall be protected consistent with the ethical principles outlined in the Declaration of Helsinki. This shall be understood, observed and applied at every step in this clinical investigation.

It is expected that all parties will share in the responsibility for ethical conduct in accordance with their respective roles in the investigation. The Sponsor and the Investigator shall avoid improper influence or inducement of the patient, Monitor, Investigator, or other parties participating in or contributing to the clinical investigation.

The Investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6; 21 CFR, part 50, the Declaration of Helsinki, CIOMS, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002). The Sponsor shall maintain a Clinical Trial Liability Policy with an insurance company.

15.2 Ethics Committee (EC) Approval

The study protocol shall be reviewed and approved by the Investigator's EC prior to subject enrollment. All proposed changes to the investigational plan must be reviewed and approved by the Sponsor in writing prior to implementation. Significant changes to the investigational plan must be approved in writing by the Sponsor and the EC prior to implementation. A significant change is one which may increase the risk or present a new risk to a subject, or which may adversely affect the scientific validity of the study.

Prior to allowance of study enrollment, a signed copy of the EC approval letter identifying the clinical study and investigational site is required to be submitted to the Sponsor. Investigators are responsible for obtaining and maintaining annual renewal of the study by their EC (or according to renewal schedule imposed by the EC). Evidence of renewal and continued EC approval must be provided to the Sponsor accordingly.

15.3 Informed Consent

Written informed consent is mandatory and must be obtained from all subjects as per local regulations, prior to their participation in the study.

Informed consent will be obtained as outlined in 21 CFR Part 50 and the ICH Guideline Good Clinical Practice E6(R2), 9 November 2016).

It is the responsibility of the Investigator to ensure written informed consent from each subject is obtained prior to the initiation of any study-related procedures.

Study participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

Study personnel fully knowledgeable in the purposes and procedures of the study will approach all prospective study participants. The facilities and settings in which prospective participants will be presented with the opportunity to learn about and consent to participation in the study will provide them sufficient quiet and unhurried time to be informed of the study and to ask questions prior to the initiation of study procedures. Study personnel will, after presenting the study to prospective participants, assess the subject's understanding and autonomy by asking the subject to explain the study in his/her own words.

Once that step is completed, consent will be able to be given by the subject signing the consent form. A copy of the consent form will be given to all consented participants for their records.

Signed subject consent forms must be retained in the study files by the Investigator and be available for review by the Sponsor and/or regulatory agencies, as applicable.

The informed consent form and any other written information provided to subjects will be revised whenever important new information becomes available, or if there is an amendment to the protocol which necessitates a change to the content of subject information and/or to the consent form. The Investigator will inform the subject of changes in a timely manner and will ask the subject to confirm his/her continuation in the study by signing a revised consent form.

Any revised informed consent form and other written information provided to subjects must receive approval from the EC and Sponsor prior to use.

Subjects may withdraw consent at any time throughout the course of the trial. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

15.4 Protection of Patient Confidentiality

At all times throughout the clinical investigation, confidentiality will be observed by all parties involved. All data shall be secured against unauthorized access. Privacy and confidentiality of information about each patient shall be preserved in the reports and in any publication. Each patient participating in this study will be assigned a unique identifier. All CRFs will be tracked, evaluated, and stored using only this unique identifier.

The investigational site will maintain a confidential study patient list (paper or electronic) identifying all enrolled participants. This list will contain the assigned study patient's unique identifier and name. The Site Principal Investigator (PI) bears responsibility for keeping this list confidential. This list will not be provided to the Sponsor and is only to be used at the study center.

Monitors and auditors will have access to the study patient list and other personally identifying information of study subjects to ensure that data reported in the CRF corresponds to the person who signed the Informed Consent Form (ICF) and the information contained in the original source documents. Such personally identifying information may include, but is not limited to, the patient's name, address, date of birth, gender, race, and medical record number.

Any source documents copied for monitoring purposes by the Sponsor will have patient identifiable information redacted and be identified by using the assigned patient's unique identifier in an effort to protect patient confidentiality.

15.5 Amending the Protocol

This protocol is to be followed exactly and will only be altered by written amendments. Amendments must be approved by all parties responsible for approving the protocol prior to implementation. The Informed Consent and CRFs will be reviewed to ensure these are amended if necessary.

15.6 Protocol Deviations/Violations and Medical Emergencies

A protocol deviation or violation is a failure to comply with the requirements of the clinical study as specified in the protocol. Examples of protocol deviations include late visits, missed visits, and required follow-up testing not completed. An example of a protocol violation includes enrollment of a study subject who

fails to meet inclusion/exclusion criteria as specified in the protocol or failure to obtain informed consent. Each Investigator shall conduct this clinical study in accordance with the study protocol and any conditions required by the reviewing EC.

Deviations/violations from clinical protocol requirements will be reviewed and evaluated on an ongoing basis and, as necessary, appropriate corrective actions put into place. Levita Magnetics accepts the right of the Investigator to deviate from the protocol in an emergency when necessary to safeguard the life or the physical well-being of a study subject, but such deviation must be reported within **24 hours** of implementation to the EC and Sponsor.

15.7 Pre-Study Documentation Requirements

Prior to shipment of investigational product, the following documents must be provided to Levita Magnetics:

- Signed protocol/protocol amendments
- Signed and dated Investigator Agreement(s)
- A copy of the written EC approval of the protocol
- A copy of the written EC approval of the Informed Consent Form
- Signed and dated Curriculum Vitae of the Investigator(s)
- Copy of the Investigator(s)' current medical license(s), or equivalent
- Signed and dated Financial Disclosure Form(s)

15.8 Record Retention

The Investigator will maintain all essential trial documents and source documentation that support the data collected on the study subjects in compliance with ICH/GCP guidelines. Documents must be retained until at least 2 years have elapsed since the date the investigation is completed or terminated, or the records are no longer required to support a regulatory submission or local requirements; whichever date is later. These documents will be retained for a longer period of time by agreement with Levita Magnetics or in compliance with other regulatory requirements. The Investigator will take measures to ensure that these essential documents are not accidentally damaged or destroyed. To avoid error, the study site should contact Levita prior to the destruction of study records to ensure that they no longer need to be retained. In addition, Sponsor should be contacted if the Investigator plans to leave the investigational site so that arrangements can be made for the handling or transfer of study records. If for any reason the Investigator withdraws responsibility for maintaining these essential documents, custody must be transferred to an individual who will assume responsibility. Levita Magnetics must receive written notification of this custodial change.

In the event of an FDA audit, the Investigator must allow FDA access to the study records for inspection and copying. The Investigator must inform Levita

Magnetics of any FDA audit and provide Levita with a copy of Form FDA 483 (List of Observations) if issued.

15.9 Site Close-out

At the time of the site close-out visit, the Monitor will collect all outstanding study documents, ensure that the Investigator's files are accurate and complete, review record retention requirements with the Investigator, make a final accounting of all study supplies, and ensure that all applicable requirements are met for the study. The observations and actions made at this visit will be documented in a final closeout report.

15.10 Study Suspension or Early Termination

Levita Magnetics reserves the right to terminate the study but intends only to exercise this right for valid scientific, administrative reasons, or reasons related to protection of subjects. Investigators and associated ECs will be notified in writing in the event of termination.

Possible reasons for study termination include:

- Unexpectedly high occurrence of adverse events unknown to date in respect to their nature, severity, or duration, or the unexpected incidence of known adverse events
- Obtaining new scientific knowledge that shows that the study is no longer valid or necessary
- Insufficient recruitment of patients
- Unanticipated adverse device effect (UADE) presenting an unreasonable risk to participants (Sponsor may terminate the study immediately)

If the study is discontinued or suspended prematurely, the Sponsor shall promptly inform all Investigator(s) / Investigational center(s) of the termination or suspension and the reason(s) for this. The IRB shall also be informed promptly and provided with the reason(s) for the termination or suspension by the Sponsor or by the Site PI / investigational center(s). Regulatory authorities and the personal physicians of the patients may also need to be informed if deemed necessary.

15.11 Criteria for Suspending/Terminating an Investigational Site

Levita Magnetics reserves the right to stop the enrollment of subjects or terminate an investigational site at any time after the study initiation visit for any of the following reasons:

- Failure to obtain written Informed Consent.
- Failure to report SAE or USADE to Levita Magnetics within 24 hours of knowledge.

- Repeated failure to complete Case Report Forms (CRFs) Loss of (or unaccounted for) investigational product inventory.
- Repeated protocol violations
- Failure of Investigator to comply with training or Instructions for Use
- Failure to screen at least 1 patient and within any 2-week period
- Persistent non-compliance with the protocol
- Persistent non-compliance with EC or regulatory requirements

15.12 Sponsor Responsibilities

The Sponsor, Levita Magnetics, has the overall responsibility of the study and will work to ensure compliance with the Investigational Plan, elements of ICH Guideline Good Clinical Practice E6(R2), 9 November 2016, signed study agreements and 21 CFR 812.2(b).

The Sponsor will be responsible for, but not limited to, conducting the following tasks:

- Select qualified Investigators
- Select qualified Monitors and other contract study personnel
- Provide the Investigational Plan and any subsequent amendments
- Sign the protocol
- Provide appropriate information and device training to Investigators and study site staff
- Promptly inform the Investigators and where applicable Institutional Review Boards (IRBs), if the study is prematurely terminated or suspended and the reason for the termination or suspension
- Provide protocol initiation training to include investigational device instructions for use, the Investigational Plan, CRF completion guidelines, and guidelines for obtaining informed consent
- Coordinate ongoing communication with Monitors and study sites to resolve any problems concerning the protocol or data collection. Every effort will be made to ensure compliance with the protocol
- Retain ownership of all clinical data generated in this study and control the use of the data for purposes of regulatory submissions to the FDA.
- Protect patient confidentiality
- Collect, store, and keep secure, at a minimum, the following documents:
- A current Curriculum Vitae and if applicable, medical license of each Investigator
- The name of the institutions where the study will be conducted
- The IRB approval, in writing, and relevant correspondence
- Correspondence with FDA (as required)
- Investigator Agreement
- Protocol Signature Page
- Appropriate insurance certificates (as necessary) e.g., CLIA/CAP

- IRB Approved ICF
- Names / contact information for Monitor(s)
- Copies of signed and dated CRFs
- Records of any adverse events and adverse device effects
- Statistical analyses and underlying supporting data
- Final report
- The Sponsor will be responsible for maintaining study records per 21 CFR 812.140(b) and ICH E6 (R1) and ICH E6(R2).
- The Sponsor will be responsible for monitoring the investigation per 21 CFR 812.46 and ICH E6 (R1) and ICH E6(R2).
- The Sponsor will be responsible for reporting per 21 CFR 812.50(b).

15.13 Investigator Responsibilities

Selected Investigators are responsible for items as detailed below:

- Agree to sign and adhere to the Investigator Agreement.
- Obtain approval from the EC including subsequent protocol amendments and changes to the Informed Consent form and obtaining annual EC approval and renewal throughout the duration of the study.
- Await EC approval, as well as any additional hospital requirements prior to requesting written informed consent from any potential study subject or prior to allowing any subject to participate in the study.
- Agree to participate in Investigator meetings, if scheduled, by Levita Magnetics.
- Willing to perform and be capable of performing treatment procedures as outlined in this protocol.
- Conduct or supervise the trial as written in the clinical protocol (e.g., perform testing and follow-up as specified, especially during personnel transitions).
- Agree to obtain written Informed Consent before any study specific procedures are performed and ensure the rights, safety, and welfare of human subjects in the study.
- Control any investigational device(s) stored at their site.
- Understand the investigational device, including potential risks and side effects.
- Be aware of, and comply with, GCP and applicable regulatory requirements.
- Permit monitoring and auditing by the Sponsor, and inspection by the appropriate regulatory authorities.
- Have available an adequate number of qualified staff and adequate facilities to properly conduct the study.
- Ensure study personnel are adequately informed about the protocol, the investigational device and study-related duties and functions.

- Ensure that all associates and study team members are informed about their duties and obligations.
- Monitor and report all adverse events, protocol violations, and unanticipated problems that occur during the study.
- Maintain accurate study records, submit data to Sponsor, if applicable, and make the data available for monitoring and inspection.
- Complete Data Forms for each subject.
- Maintain the study EC approval, and inform Sponsor of withdrawal of EC approval
- Submit progress reports and final reports to EC and/or Sponsor
- Notify the Sponsor and/or EC of any study protocol deviations (PDs) or Serious Adverse Event (SAE), Serious Adverse Device Effect (SADE) or Unanticipated Adverse Device Effect (UADE) within 24 hours of knowledge of the event.
- Maintaining study records per 21 CFR 812.140(a) and ICH E6 (R1) and ICH E6(R2).

Each Investigator will provide a completed Financial Disclosure statement confirming that they have no personal financial interest connected to the study or Sponsor, prior to study initiation and upon request at later time points in the study if needed.

The Investigator is responsible for maintaining study records for every subject participating in the study. The study center will also maintain *original* source documents from which study-related data are derived.

16 REFERENCES

Davis MJ, Ortega CB, Portenier D, Park C, Sudan R, Yoo J, Seymour K, Chen S, Schimpke S, Guerron AD. Magnetic surgery for liver retraction: An Incision-less approach for less invasive bariatric surgery. SAGES Annual Meeting Abstract 2018.

Ghezzi TL, Corleta OC. 30 Years of Robotic Surgery. *World J Surg* 2016;40(10):2550-7. doi:10.1007/s00268-016-3543-9

Haskins IN, Strong AT, Allemang MT, Bencsath KP, Rodriquez JH, Kroh MD. Magnetic surgery: first U.S. experience with a novel device. *Surg Endosc.* 2018;32(2):895-899. DOI 10.1007/s00464-017-5762-z.

Nguyen NT, Smith BR, Reavis KM, Nguyen X-MT, Nguyen B, Stamos MJ. Strategic laparoscopic surgery for improved cosmesis in general and bariatric surgery: analysis of initial 127 cases. *J Laparoendosc Adv Surg Tech A*. 2012;22(4):355-361. doi:10.1089/lap.2011.0370.

Rivas H, Robles I, Riquelme F, et al. Magnetic Surgery. *Ann Surg*. 2018;267(1):88-93. doi:10.1097/SLA.0000000000002045.

Tan A, Ashrafian H, Alasdair JS, Mason SE, Harling L, Athanasiou T, Darzi A. Robotic surgery: disruptive innovation or unfulfilled promise? A systematic review and meta-analysis of the first 30 years. *Surg Endosc* 2016;30(10):4330-52 doi:10.1007/s00464-01604752-x

17 REVISION HISTORY

Revision	Date	Description of Change
A	13 September 2022	Initial release