Prospective, multi-center, single-arm, open label study designed to assess the safety and feasibility of Liver Retraction with the Levita Magnetic Surgical System: Extended Magnetic Grasper Device

Investigational Product:	**MSS: MGD-Ext**
Protocol Name:	**Enhanced Magnetic Liver Retraction**
Protocol Number:	**LVT009**

Revision: B
19 Jun 2024

This study is confidential in nature. All information related to this study is considered proprietary and should not be made available to those not directly involved in this study. Authorized recipients of this information include Investigators and co-Investigators, other health care personnel necessary to conduct the study, and Clinical Investigation Ethics Committees and Institutional Review Boards. The personnel provided with data from this study are hereby informed of its confidential and proprietary nature. Release of these data to individuals other than those listed above requires the prior written permission of Levita Magnetics.

1. ADMINISTRATIVE INFORMATION

1.1 CONTACTS

Medical, Clinical, and Operational Support

Sponsor Name:	Levita Magnetics
Sponsor Telephone Number:	+1 650-204-0529
Sponsor Email:	CP009@levita.com
Manufacturer and Sponsor Address:	Levita Magnetics Corp. 453 Ravendale Dr, Suite G Mountain View, CA 94043 USA

1.2 Sponsor Protocol Approval

Representatives of Levita Magnetics

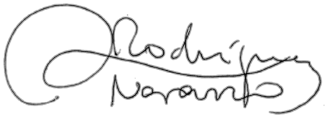
This study will be conducted with the highest respect for the individual participants in accordance with the requirements of this clinical study protocol and in accordance with the following:

The ethical principles that have their origin in the Declaration of Helsinki.

International Conference for Harmonisation Harmonised Tripartite Guideline for Good Clinical Practice E6 (ICH GCP E6).

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

SIGNATURES



9 July 2024

Dr. Alberto Rodríguez Navarro, CEO Levita Magnetics — Date

July 9, 2024

Dr. Dana Portenier, Medical-Expert Duke University — Date

Investigator Agreement and Certification
Clinical Evaluation of Magnetic Surgical System: Extended Magnetic Grasper Device

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 ISO 14155. 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.

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 data in accordance with the protocol. I further agree not to originate or use the name of Levita Magnetics and/or Magnetic Surgical System: Extended Magnetic Grasper Device 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 Liver Retraction with the Levita Magnetic Surgical System: Extended Magnetic Grasper Device**
Protocol Number	LVT009
Investigational Device	Magnetic Surgical System: Extended Magnetic Grasper Device
Device Description	Compared to the Magnetic Surgical System (MSS) that is cleared for market in the U.S. per 510(k) K223673 and commercially available in Chile, the investigational device (MSS Version 2) comprises the same external Magnetic Controller and a modified version of the cleared Magnetic Grasper Device with a longer Grasper Tip (12.5 cm compared to 6.5 cm).
Study Objective	The purpose of this study is to evaluate the safety and effectiveness of the Extended Magnetic Grasper Device in patients undergoing bariatric and/or hiatal hernia procedures, as a liver retractor grasping the liver and/or the tissue surrounding the crus of the diaphragm.
Study Design	Prospective, multi-center, single-arm, open label study.
Enrollment Size and Number of Sites	Up to 30 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 bariatric and/or hiatal hernia surgery are potential candidates.
Rationale	Levita has developed an alternative system to provide liver retraction with a Version 2 of the Magnetic Grasper Device that can be attached to the liver or the tissue surrounding the crus of the diaphragm.

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.
Feasibility Outcomes	Ability to adequately mobilize the liver to achieve an effective exposure of the target tissue. Adequate mobilization is not achieved if it is necessary to use another liver retractor during the 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 bariatric and/or hiatal hernia procedures. • Willing and able to provide a written Informed Consent Form (ICF) to participate in the study prior to any study required procedures.
Exclusion Criteria	*Subjects 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. • American Society of Anesthesiologists (ASA) score of III or IV. • Significant comorbidities: cardiovascular, neuromuscular, chronic obstructive pulmonary disease, and urological disease (renal failure). • Clinical history of impaired coagulation confirmed by abnormal blood tests. • Individuals has signs of hepatic abnormality (e.g.: cirrhosis, liver failure, increase in liver enzymes, etc.). • 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 Tisné Santiago, Chile Pablo Marín, MD Clínica Colonial Santiago, Chile Ignacio Robles, MD Clínica INDISA Santiago, Chile
Medical Expert	Dana Portenier, MD Chief of Bariatrics and Metabolic Surgery Duke University, Durham, NC, 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
CFR	Code of Federal Regulations
CRF	Case Report Form
EC	Ethics Committee
Ext	Extended
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GDP	Good Documentation Practice
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
LOS	Length of Stay
MC	Magnetic Controller
MGD	Magnetic Grasper Device
MIS	Minimally Invasive Surgery
MSS	Magnetic Surgical System
N/A	Not Applicable
N/D	Not Done
OR	Operating Room
PACU	Post Anesthesia Care Unit
PD	Protocol Deviation
PI	Principal Investigator
PP	Per Protocol
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SD	Standard Deviation
SDV	Source Document Verification
SOC	Standard of Care
SOP	Standard Operating Procedures
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 most intra-abdominal procedures. One of the key components of laparoscopic surgery, of any surgery for that matter, 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, such as the liver, can block or obscure the surgical view. A number of surgical instruments (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 to use them, leading to potentially increased risk of postoperative pain and additional scars, as well as incision-related complications such as injury to major blood vessels and bowel, infection, incision-related hernias, scarring and chronic incisional pain. The interest in less invasiveness in surgery is aimed at reducing the number of abdominal incisions, providing 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 International Corp. has developed the Levita® Magnetic Surgical System (MSS) that can be used for tissue/organ mobilization and does not require an additional abdominal wall puncture/incision. The MSS is comprised of a Magnetic Grasper and an external Magnetic Controller. The Magnetic Grasper Device is compatible with a 10 mm laparoscopic port. The Magnetic Grasper Device is placed internally during laparoscopic surgery and is mobilized by the external magnetic field of the Magnetic Controller through the abdominal wall.

When used for liver mobilization, the Magnetic Surgical System delivers and attaches its Detachable Grasper tip to the liver border. The handle portion of the Magnetic Grasper Device is then removed from the body, leaving the Detachable Grasper attached to the liver and the introduction port available for use by another instrument. With the Detachable Grasper attached to the liver, the external Magnetic Controller is placed external to the abdominal wall, thereby attracting the Detachable Grasper for the purposes of liver mobilization. The Magnetic Controller can then be moved freely, facilitating unrestricted shaft-less tissue mobilization. At the end of the procedure, the Detachable Grasper is decoupled from the Magnetic Controller, recoupled with the Magnetic Grasper Device handle and removed from the patient.

The safety and effectiveness of the Levita Magnetic Surgical System has been demonstrated in multiple studies (Rivas et al, Haskins, et al, Luengas et al, Welsh et al, Davis et al) and is FDA cleared for liver retraction in bariatric procedures.

Nevertheless, the current system can present some limitations when a clear exposure of the hiatus is needed. In order to overcome that limitation, a Version 2 of the Grasper Tiphas been developed with a longer total length. Whereas the original Grasper Tip of the Magnetic Grasper Device is 6cm long, the Version 2 Grasper Tip is 12.5cm long. This will enable retraction of the liver in a different way in that Version 2 not only grasps the liver, but also may be used to grasp the tissue surrounding the crus of the diaphragm for increased retraction of the liver for better exposure of the target tissue.

This current study is intended to evaluate the safety and effectiveness of this new version of the Magnetic Surgical System for liver mobilization and expand the understanding of the Magnetic Surgical System as a tool for less invasive surgery.

4. SURGICAL SYSTEM DEVICE DESCRIPTION

The Levita Magnetic Surgical System (MSS) is composed of two handheld instruments: a Magnetic Grasper Device and an external Magnetic Controller.
The Magnetic Grasper Device (**Figure 1**) is comprised of two main components: a Detachable Grasper and a Delivery/Retrieval Shaft. 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 compatible with a ≥ 10 mm laparoscopic port. The Magnetic Grasper Device is single-use, disposable, and provided sterile to the user.

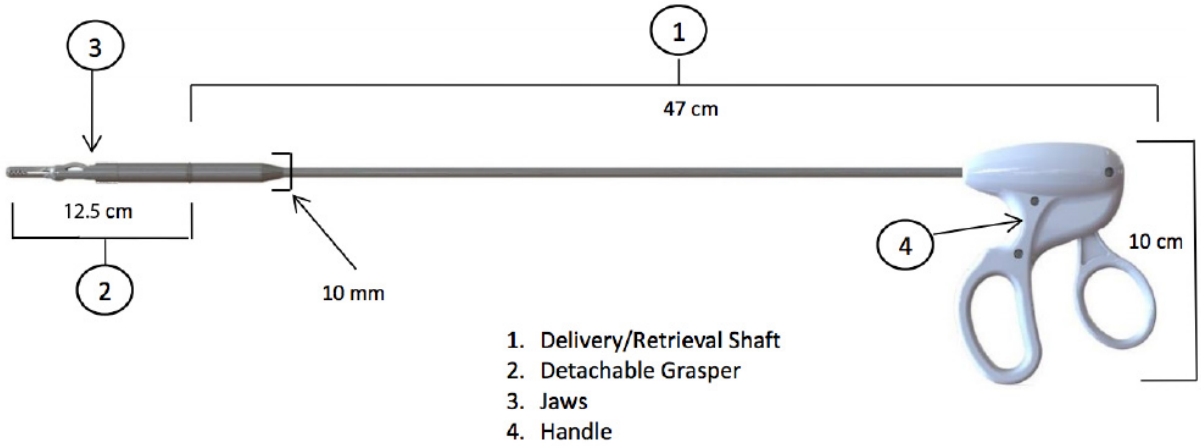


Figure 1. Magnetic Grasper Device

The Magnetic Controller (**Figure 2**) is a single unit with handles that is held external to the body and emits a magnetic field that attracts the Detachable Grasper. Once the Detachable Grasper is attached to the desired tissue and detached from the Delivery/Retrieval Shaft, the Magnetic Controller is placed external to the body to magnetically attract the Detachable Grasper to manipulate the target tissue. Adjusting the distance between the Magnetic Controller and the Detachable Grasper will modulate the magnetic attraction used for tissue retraction/manipulation. If desired, the user can connect the Magnetic Controller to a commercially available surgical support arm that is compatible with a hexagon-shaped mounting stem or connected to a surgeon controlled arm (MARS™ system). The external Magnetic Controller is re-usable, provided non-sterile to the user, and must be placed in an off-the-shelf sterile bag prior to use.

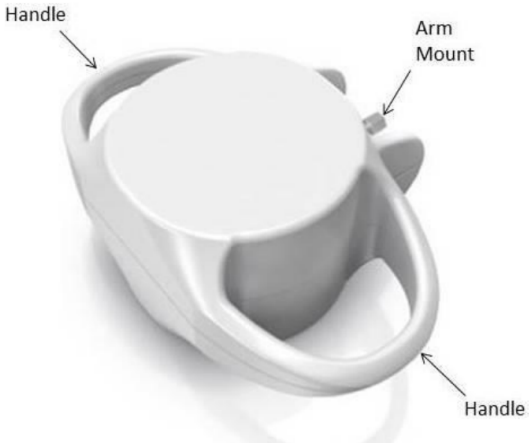


Figure 2. Magnetic Controller

The Magnetic Grasper Device is actuated via its handle with two distinct scissor-type motions to open and close the Detachable Grasper jaws and to release the Detachable Grasper from the Delivery/Retrieval Shaft. The Magnetic Grasper Device can be used for mobilization in the same manner as a conventional tissue grasper, or its Detachable Grasper can be released and used with the external Magnetic Controller. When the Detachable Grasper is released from the Delivery/Retrieval Shaft, the Delivery/Retrieval Shaft can be removed and mobilization of the tissue can be achieved through the magnetic attraction between the Detachable Grasper and the external MC. This access port is therefore available for use with other surgical tools. When the procedure is completed, the Delivery/Retrieval Shaft may be reinserted to retrieve the Detachable Grasper.

5. INDICATION FOR USE

The Magnetic Surgical System is designed for grasping the liver and the tissue surrounding the crus of the diaphragm and retract the liver in bariatric and/or hiatal hernia procedures to facilitate access to and visualization of the surgical site (**Figure 3**).

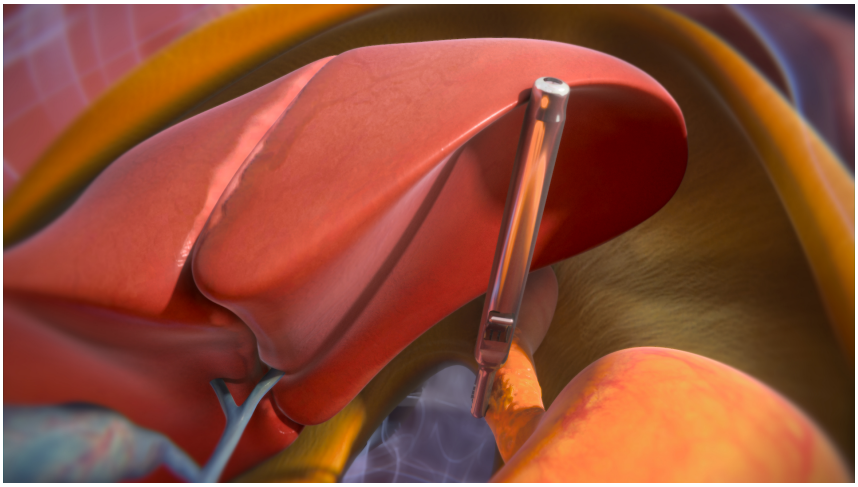


Figure 3. Intended Use

6. STUDY PURPOSE AND OBJECTIVE

The purpose of this study is to evaluate the safety and effectiveness of the Levita Magnetic Surgical System Version 2 in patients undergoing bariatric and/or hiatal hernia procedures.

7. STUDY ENDPOINTS

The following endpoints will be evaluated in all subjects who undergo bariatric and/or hiatal hernia procedures using the Magnetic Surgical System.

7.1 Safety Outcomes

All adverse events will be captured and reported. Adverse events will be further summarized by relatedness to the device and/or procedure, seriousness and level of severity.

7.2 Feasibility Outcomes

Ability to adequately mobilize the liver to achieve an effective exposure of the target tissue. Adequate mobilization is not achieved if it is necessary to use another liver retractor during the 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).
- Estimated blood loss.
- Device malfunctions.

8. STUDY DESIGN

8.1 Overview

This is a prospective, multicenter, single-arm, open label study designed to assess the safety and effectiveness of the Levita Magnetic Surgical System: Extended Magnetic Grasper Device in bariatric and/or hiatal hernia procedures.

8.2 Sample Size and Number of Centers

The study will be conducted at up to three (3) study sites with a target maximum of 30 subjects in which the Levita Magnetic Surgical System is used for liver mobilization.

8.3 Study Duration

Enrollment of subjects in this study is anticipated to take up to 6 months. Clinical follow-up evaluations will be conducted at discharge, and 7 and 30 days following surgery. The total study duration is expected to be approximately 7 months.

9. STUDY PROCEDURES

9.1 Subject Eligibility, Pre-Screening, and Exclusions

All subjects presenting for elective bariatric and/or hiatal hernia procedures are potential candidates and will be screened for eligibility. 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

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

- At least 18 years of age.
- Scheduled to undergo elective bariatric and/or hiatal hernia procedures.
- 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

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

- Individuals with pacemakers, defibrillators, or other electromedical implants.
- Individuals with ferromagnetic implants.
- American Society of Anesthesiologists (ASA) score of III or IV.
- Significant comorbidities: cardiovascular, neuromuscular, chronic obstructive pulmonary disease, and urological disease (renal failure).
- Clinical history of impaired coagulation confirmed by abnormal blood tests.
- Individuals has signs of hepatic abnormality (e.g.: cirrhosis, liver failure, increase in liver enzymes, etc.).
- 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.

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 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.

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.
- Conversion to open surgical procedure.
- The need for an additional surgical tool to mobilize the liver.
- Estimated blood loss.
- Video recording of the overall procedure.
- Adverse events.
- Device malfunctions.

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 **¡Error! No se encuentra el origen de la referencia..** 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 visit window 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 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	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 Levita Magnetic Surgical System 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, and a faster recovery.

10.2 Risks

There are risks associated with use of the Levita Magnetic Surgical System 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 which included *in vivo* performance testing, human factors testing, non-clinical performance testing, biocompatibility testing, sterilization validation, reprocessing validation and shelf-life validation. Additionally, careful labeling, instructions for use (IFU) and training are provided as detailed below.

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 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 simulation models using the 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 will 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 SECTION

11.1 Statistical Methods

Data collected in the study will be presented using various descriptive statistics. Descriptive summaries will be the basis of study reports to generate an overall summary of the safety and effectiveness for the device.

Descriptive tables will be produced for baseline characteristics including demographics and medical history.

Missing data on study endpoints will be described.

11.2 Sample Size Justification

This is a single-arm, multicenter investigational study and considering the pivotal trial that supported the first marketing authorization in the United States for use of the device in cholecystectomy procedures, enrollment of 30 subjects is expected to provide appropriate evidence of safe and effective use of MSS in this additional subject population.

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.

11.4 Safety

All adverse events for participants in the safety population will be reported. See **Section 14** for definitions

- Serious Adverse Events.
- Non-serious Adverse Events.
- 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 plays a crucial role in ensuring the ongoing safety and efficacy of the trial. The interim analysis will involve an evaluation of accumulated data after 15 subjects to assess the predefined endpoints.

12. DATA MANAGEMENT

12.1 Data Collection

Data will be collected on paper case report forms (CRF) supplied by the Sponsor. The Site Principal Investigator is responsible for the accuracy and completeness of all study documentation.

Corrections to the CRF must be corrected 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 NCR paper (or equivalent) so that both the site and monitor/Sponsor will have copies of the CRFs. The second copy 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. The subject ID is assigned at the time of consent. The subject ID format will be ##-###. The first part of the ID (##) represents the Site ID. The second part of the ID (###) represents the unique subject number. For example, the third subject as site 01 would have subject ID 01-003. 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 into the Levita database, monitoring, as detailed below, will 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 submit 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 (GCP), 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 Good Clinical Practice, the protocol and the device including Instructions For Use and management of a magnetic device. 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:

- Enrolled subjects are appropriately consented.
- Regulatory and study documents are complete and current.
- The protocol is appropriately followed.
- Protocol and any 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, dispensed and accounted for.
- Study facilities continue to be acceptable for the conduct of the study.
- The site Principal Investigator continues to assume primary responsibility for the study.

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 Director of Clinical Operations 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 Director of Clinical Operations 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

Access to investigational devices shall be controlled and used only in the clinical investigation by trained and delegated investigators 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, expired, or malfunctioning investigational device, 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" (SAE) 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 (CP009@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 serious adverse events, including serious and unanticipated serious adverse device effects, to the reviewing EC according to the EC 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 Levita Magnetic Surgical System 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 for potential regulatory reporting requirements.

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 shipment of investigational devices, 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 IFU.
- 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.
- Complete and provide signed Financial Disclosure information prior to the study and maintain this information for the duration of 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.
- Comply with all required elements of this 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.
- 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

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17 REVISION HISTORY

Revision	Date	Description of Change
A	04 January 2024	Initial release
B	19 June 2024	Addition of Interim Analysis to section 11.7 and changes to protocol number from CP009 to LVT009.