Clinical Evaluation of the Levita Robotic Platform

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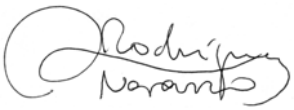

Sponsor Signature:_____

Sponsor Name: Alberto Rodriguez-Navarro, MD

CONFIDENTIALITY STATEMENT

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.

PROTOCOL REVIEW PAGE

STUDY TITLE: Clinical evaluation of the Levita Robotic Platform
PROTOCOL: CP007
REVISION: A

Investigator's Statement: I agree to conduct this clinical study in accordance with the design and specific provisions of this protocol; modifications to the study or protocol are acceptable only with a protocol amendment approved by the Study Sponsor and Ethics Committee (EC) if required. I agree to await EC approval for the protocol and informed consent before initiating the study, to obtain informed consent from subjects prior to their enrollment in the study, to collect and record data as required by this protocol and case report forms, submit all reports as required by this protocol, provide the requested financial information, and to maintain study documentation for the period of time detailed in this protocol.

Investigator Signature	*Date of Signature*
Investigator Name:	

Protocol Synopsis

Title:	Clinical Evaluation of the Levita Robotic Platform
Study Objective:	The purpose of this study is to evaluate the safety and feasibility of the Levita Robotic Platform (LRP) used with the Levita Magnetic Surgical System (MSS).
Study Design:	Prospective, multi-center, single-arm, open label study designed to assess the safety and feasibility of the use of the Levita Robotic Platform with the Levita Magnetic Surgical System in laparoscopic procedures.
Enrollment Size and Number of Sites:	Up to 100 subjects in up to 5 clinical sites in Chile
Subject Population:	All patients at least 18 years of age presenting for elective laparoscopic surgery are potential candidates.
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 LRP or both.
Feasibility Outcomes:	Ability to utilize the Levita MSS with the LRP as intended in laparoscopic procedures. The following outcomes will be considered in this feasibility study: 1. The LRP is able to engage, move, and decouple with the MSS as intended / controlled by the surgeon 2. The LRP 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 LRP. 4. The MSS or the LRP cannot be successfully used and due to a MSS or LRP performance issue the procedure must be converted to an open procedure.
Inclusion Criteria:	*Subjects must meet ALL of the following inclusion criteria to be eligible for participation in the study:* • Subject is at least 18 years of age • Subject is scheduled to undergo elective laparoscopic procedure • Subject signs a written Informed Consent Form (ICF) to participate in the study prior to any study required procedures

Exclusion Criteria:	*Subjects must be EXCLUDED from participation in this study if ANY of the following exclusion criteria are met:* • Subjects with pacemakers, defibrillators, or other electromedical implants • Subjects with ferromagnetic implants • Subjects with significant comorbidities: cardiovascular, neuromuscular, chronic obstructive pulmonary disease, and urological disease (renal failure) • Subjects with a clinical history of impaired coagulation confirmed by abnormal blood tests • Subject has an anatomical abnormality or disease of intended target tissue noted after initiation of index procedure that would prevent device use • Subject is pregnant or wishes to become pregnant during the length of study participation • Subject is not likely to comply with the follow-up evaluation schedule • Subject is participating in a clinical trial of another investigational drug or device
Study Duration / Follow-up Period	Subjects will be followed for 30 days post-procedure, with follow-up visits at hospital discharge and at 7 and 30 days post-procedure.
Clinical Sites and Site Principal Investigators*:	Francisco Riquelme, MD Hospital Salvador Santiago, Chile Ignacio Robles, MD Hospital de la FACH Santiago, Chile Clinica INDISA Santiago, Chile
Sponsor:	Levita Magnetics Alberto Rodriguez-Navarro, MD Title: CEO and Founder Email: CP007@levita.com Telephone: +1 (650) 204-0529

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

Investigator Agreement and Certification
Clinical Evaluation of the Levita Robotic Platform

I agree to participate in the clinical investigation of the Levita Robotic Platform and Magnetic Surgical System sponsored by Levita Magnetics (hereinafter "Study Sponsor"). I agree to conduct this investigation according to the requirements of the investigational plan provided by the Study Sponsor and in accordance with Good Clinical Practice requirements as outlined in ISO 14155 and conditions imposed by the reviewing Ethics Committee (EC). I agree to ensure informed consent is appropriately obtained from all subjects prior to inclusion in this study.

I understand that this investigation may be monitored by the Study Sponsor and/or a designee employed by Study Sponsor. 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 will provide financial information by completing a Levita Financial Disclosure Form and update it as necessary.

Accepted by

Principal Investigator Signature	Printed name	date
Co-Investigator Signature	Printed name	date
Co-Investigator Signature	Printed name	date

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1 INTRODUCTION

1.1 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 (LRP) 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 LRP 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 Levita Robotic Platform when used with the Magnetic Surgical System for laparoscopic procedures.

2 SURGICAL SYSTEM DEVICE DESCRIPTION

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 1**). 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.

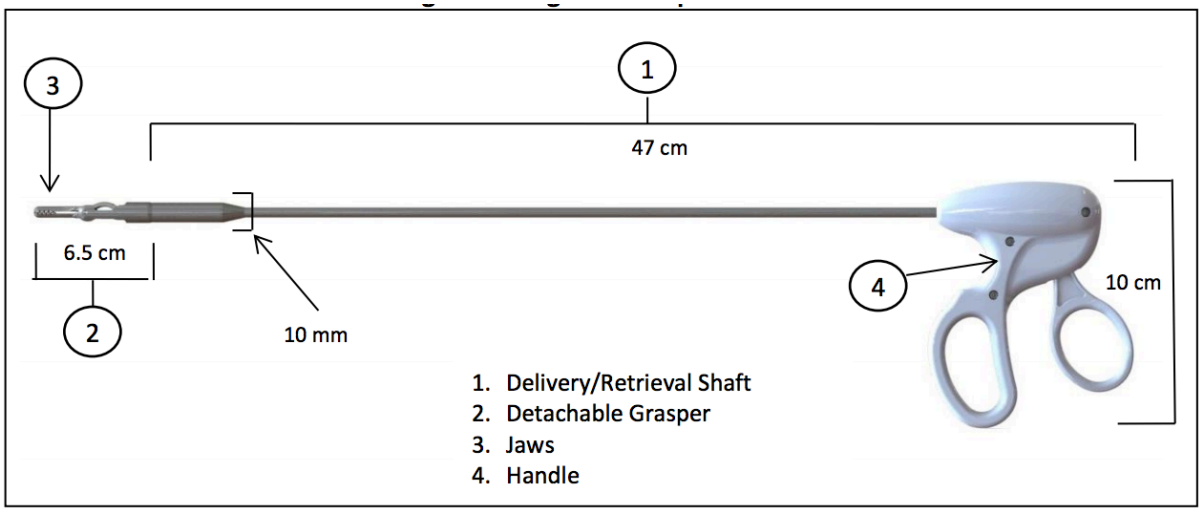

Figure 1. Magnetic Grasper Device

The Magnetic Controller mounted on the robotic arm (**Figure 2**) 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 LRP 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 LRP is re-usable, provided non-sterile to the user, and must be placed in an off-the-shelf sterile bag prior to use.

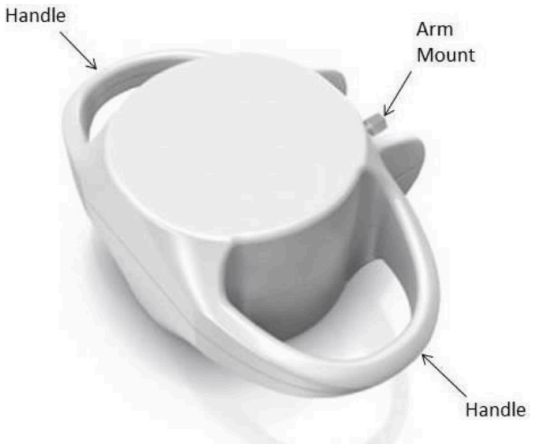

Figure 2. Magnetic Controller

The Levita Robotic Platform (**Figure 3**) includes two robotic arms, control unit(s), and control software. A handheld and/or foot-operated control pad allow for LRP control by the surgeon or surgical assistant. One arm of the LRP attaches the Magnetic Controller using the arm mount of the Magnetic Controller and the second robotic arm attaches a conventional laparoscopic camera.

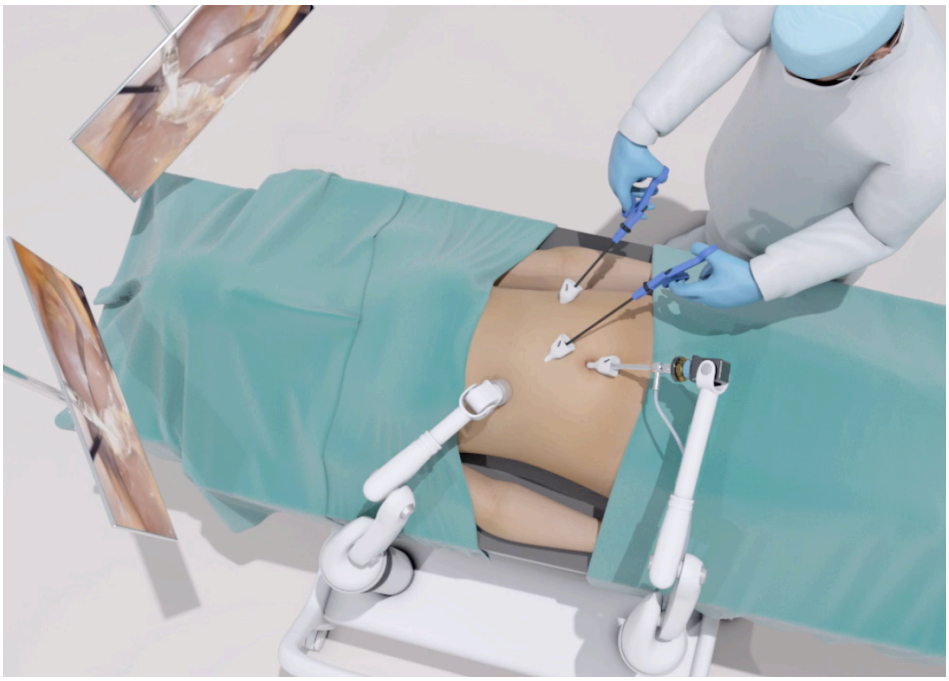

Figure 3. Levita Robotic Platform. One arm is mobilizing the External Magnetic Controller (external magnet) and the second arm is mobilizing a conventional laparoscopic camera.

The LRP is certified to international electrical safety and software standards for use in medical products. The design of the LRP 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 LRP is provided non-sterile to the user, and must be placed in an off-the-shelf sterile bag prior to use.

3 INDICATION FOR USE

The Magnetic Surgical System 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 in a hands-free manner.

4 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.

5 STUDY ENDPOINTS

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

5.1 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 LRP or both.

5.2 Feasibility Outcomes

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

1. The LRP is able to engage, move, and decouple with the MSS as intended / controlled by the surgeon
2. The LRP 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 LRP.
4. The MSS or the LRP cannot be successfully used and due to a MSS or LRP performance issue the procedure must be converted to an open procedure.

5.3 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

6 STUDY DESIGN

6.1 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 Levita

Robotic Platform with the Levita Magnetic Surgical System in laparoscopic procedures.

6.2 Sample Size and Number of Centers

The study will be conducted at up to five (5) clinical sites with a target maximum of 100 subjects in which the Robotic Platform and Levita Magnetic Surgical System is used for laparoscopic procedures.

6.3 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, and 7 and 30 days following surgery. The total study duration is expected to be approximately 13 months.

7 STUDY PROCEDURES

7.1 Subject Eligibility, Pre-Screening, and Exclusions

All subjects 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.

7.1.1 Inclusion Criteria

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

1. Subject is at least 18 years of age
2. Subject is scheduled to undergo elective laparoscopic procedure
3. Subject signs a written Informed Consent Form (ICF) to participate in the study prior to any study required procedures

7.1.2 Exclusion Criteria

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

1. Subjects with pacemakers, defibrillators, or other electromedical implants
2. Subjects with ferromagnetic implants
3. Subjects with significant comorbidities: cardiovascular, neuromuscular, chronic obstructive pulmonary disease, and urological disease (renal failure)

4. Subjects with clinical history of impaired coagulation confirmed by abnormal blood tests
5. Subject has an anatomical abnormality or disease of intended target tissue noted after initiation of index procedure that would prevent device use
6. Subject is pregnant or wishes to become pregnant during the length of study participation
7. Subject is not likely to comply with the follow-up evaluation schedule
8. Subject is participating in a clinical trial of another investigational drug or device

7.2 Enrollment and Written Informed Consent

Patients who pass initial pre-screening will be asked to sign the Informed Consent Form (See **Appendix 1**) before any study-specific tests or procedures are performed. The Investigator will inform the potential subject of the elements of the clinical study, including risks, potential benefits and required follow-up procedures, prior to obtaining the potential subject's informed consent. Enrollment may be non-sequential per the discretion of the study surgeon.

7.3 Screening/Baseline Evaluation

The Screening visit will occur within 30 days prior to the laparoscopic procedure.

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.

7.4 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

7.5 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

7.6 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**. 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.

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.

7.7 Unplanned Follow-up Visits

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

7.8 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.

7.9 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.

8 RISK / BENEFIT ANALYSIS

8.1 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.

8.2 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 petechaie
- 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.

8.3 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 LRP.

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.

9 STATISTICAL SECTION

9.1 Statistical Methods

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

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

9.2 Sample Size Justification

This is a single-arm, multi-center, investigational study to understand the safety and feasibility of the use of the LRP with the MSS. A sample size of 100 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 100 subjects will provide appropriate information regarding the safety and feasibility of the LRP and MSS in laparoscopic procedures.

10 DATA MANAGEMENT

10.1 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 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 NCR 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.

10.2 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. If warranted, a data clarification form or communication will be used to query the Investigator.

11 MONITORING AND QUALITY CONTROL PROCEDURES

11.1 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.

11.2 Monitoring and Auditing

Monitoring visits to the clinical sites may be made periodically during the study, to ensure that all aspects of the current, approved protocol/amendment(s) are followed.

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 and 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

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 and original documents and records such as hospital and clinic charts, consent forms, laboratory records, and pharmacy dispensing records.

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 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.

11.3 Device Accountability

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.

12 ADVERSE EVENTS

12.1 Definitions

12.1.1 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 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.

12.1.2 Serious Adverse Event (SAE)

An adverse event is considered a SAE if it:

- Led to death
- Led to a serious deterioration in the health of the subject, that either resulted in:
  a) A life-threatening illness or injury, or
  b) A permanent impairment of a body structure or a body function, or
  c) In-patient hospitalization, or prolongation of existing hospitalization, or

d) medical or surgical intervention to prevent permanent life-threatening illness or injury or permanent impairment to body structure or a body function.

- Led to fetal distress, fetal death or a congenital abnormality

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

12.1.3 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.

12.1.4 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.

12.2 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 intensity, and the relationship of each adverse event to the investigational device or procedure.

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 (CP007@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.

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 unanticipated serious adverse device effects, to the EC according to the EC 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.

12.3 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.

12.4 Event Relationship

The following lists the potential event attribution categories.

12.4.1 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 LRP 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.

12.4.2 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.

12.5 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.

12.6 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.

13 STUDY ADMINISTRATION

13.1 Statement of Compliance

The clinical investigations will be in accordance with the ethical principles of the Declaration of Helsinki (59th WMA General Assembly, Seoul, October 2008) and ICH-GCP Guidelines. The clinical investigation shall not commence until approval by the EC. Any additional requirements imposed by the EC or regulatory authority shall be followed. The Sponsor shall maintain a Clinical Trial Liability Policy with an insurance company.

13.2 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.

13.3 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. A template Informed Consent is provided in Appendix 1.

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.

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.

13.4 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.

Administrative changes that do not affect the benefit/risk ratio or scientific validity of the study (e.g., editorial changes for clarity) may be made with just approval from the Sponsor and will be documented as a protocol revision.

13.5 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.

13.6 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)

13.7 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. 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.

13.8 Criteria for Terminating Study

Levita Magnetics reserves the right to terminate the study but intends only to exercise this right for valid scientific or 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:

- The discovery of an unexpected, significant, or unacceptable risk to subjects enrolled in the study.
- A decision on the part of Levita Magnetics to suspend or discontinue further regulatory submissions for the device.

13.9 Criteria for Suspending/Terminating an Investigational Site

Levita Magnetics reserves the right to stop the enrollment of subjects at an investigational site at any time after the study initiation visit if no subjects have been enrolled or if the center has multiple or severe protocol violations without justification or fails to follow remedial actions.

Possible reasons for suspending/terminating a study center include:

- Failure to obtain written Informed Consent.
- Failure to report SAE or USADE to Levita Magnetics within 24 hours of knowledge.
- Failure to complete data forms prior to the scheduled monitoring visits.
- Loss of (or unaccounted for) investigational product inventory.

13.10 Sponsor Responsibilities

The Sponsor, Levita Magnetics, is responsible for selecting qualified Investigators and providing them with the information and materials necessary to conduct this trial appropriately, ensuring appropriate monitoring of the investigation, that EC review and approval are obtained, and ensuring

that the Investigators and the reviewing EC are promptly notified of significant new information about this investigation.

Specifically, the Sponsor will be responsible for:

- Securing compliance with the clinical protocol, Investigators' agreement, and local regulations;
- Conducting evaluations of all adverse events;
- Controlling the distribution of the device(s) under investigation;
- Maintaining records and reports;
- Analyzing and reporting data;
- Designating appropriately qualified medical personnel to be available to advise on study related medical questions or problems

13.11 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.
- Be 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.
- Control any investigational device(s) stored at their site.
- 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.

14 REFERENCES

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15 REVISION HISTORY

Revision	Date	Description of Change
A	12 January 2021	Initial release