ID: 7053-PL01-2022

Study To Evaluate The Safety And Efficacy Of The MyEllevate® Procedure

NCT05590039

Document Date: June 14, 2022

INVESTIGATIONAL PLAN

PROTOCOL #: 7053-PL01-2022

PROSPECTIVE CLINICAL STUDY TO EVALUATE THE SAFETY AND EFFICACY OF THE MYELLEVATE® PROCEDURE

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SPONSOR:
CYNOSURE, LLC
5 CARLISLE ROAD
WESTFORD, MA 01886
PHONE: 800-886-2966
FAX: 978-256-6556

PROSPECTIVE CLINICAL STUDY TO EVALUATE THE SAFETY AND EFFICACY OF THE MYELLEVATE® PROCEDURE

INVESTIGATOR AGREEMENT

I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation.

I agree to inform any patients, or any persons used as controls if applicable, that the device(s) is/are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in and institutional review board (IRB) review and approval are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigations. I have read and understand the information in the device manual, including the potential risks and side effects of the device.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records and to make those records available for inspection. I further agree that Cynosure, Inc. or their designees shall have access to any source documents from which case report form information may have been generated.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators.

I will comply with the International Conference on Harmonization (ICH), Good Clinical Practice (GCP) guidance E6, FDA Good Clinical Practice Regulations (21 CFR parts 50, 56, and 812), Declaration of Helsinki (DoH) and the Health Human Service (HHS) Belmont Study Principals and Guidelines during the conduct of this study.

I have read the foregoing protocol and agree that it contains all necessary details for carrying out this study. I will conduct the study as outlined herein and will complete the study within the time designated.

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

I will disclose financial arrangements and interests in accordance with Financial Disclosure Rules (21 CFR part 54) and FDA Form 3455.

_____ _____

Investigator's Signature Date

_____

Name of Investigator (Typed or Printed)

_____

_____

_____

Address of Investigator (Typed or Printed)

SITE #1 CONTACT INFORMATION:
Principal Investigator Information:
John W. Decorato. M.D
Aesthetic Pavilion Ambulatory Surgery Center
531 W 2777 Hylan Blvd
Staten Island, NY 10306
Phone: 718-987-0300
Email: jwd@DrDecorato.com

SITE #2 CONTACT INFORMATION:
Principal Investigator Information:
Barry DiBernardo, M.D
New Jersey Plastic Surgery
29 Park Street
Montclair, NJ 07042
Phone: 973-509-2000
Email: drd@njpsmd.com

SPONSOR CONTACT INFORMATION:
David Canavan
Sr. Clinical Project Manager
Westford, MA 01886
Phone: 978-551-5786
Email: David.Canavan@cynosure.com

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I. Instructions for Use manual for MyEllevate
II. Informed Consent Form
III. Post Treatment Instructions

1.0 PURPOSE

1.1 Name and Intended Use

The procedure used in this study is called the MyEllevate® procedure.

The intended purpose of the MyEllevate® procedure used in this study is to assess the safety and efficacy of the procedure for soft tissue approximation and elevation of sub dermis and underlying muscle of the submentum & jawline.

1.2 Objectives

1. Primary Objective:
   - Safety assessment through the collection of Adverse Events.
2. Optional Assessments:
   - Collection of digital 2-D and/or 3-D photography.
   - Photographic evaluation with correct identification of pre-treatment images when compared to the 30 and 90 day follow-up images performed by blinded reviewers.
   - Principle Investigator assessment using the Global Aesthetic Improvement Scale (PGAIS) at the 30 and 90 day follow up visit.
   - Subject assessment using the Global Aesthetic Improvement Scale (SGAIS) at the 30 and 90 day follow up visit.
   - Subject satisfaction rates at the 30 and 90 day follow-up visit.

3. Additional Safety Objectives:
   - Collection of Discomfort/Pain Scores

1.3 Duration of the Investigation

The sponsor anticipates that all subjects can be enrolled within 3 months. If subject participates in all required visits, then the subject's participation in this study may last up to 4 months. It is anticipated that it will take approximately 3 months to analyze the data collected during this study. The total duration of this study is anticipated to last approximately 10 months.

2.0 PROTOCOL

2.1 Protocol Methodology and Analysis

Methodology:
Subjects are to be enrolled in this clinical study if they are a healthy male or female between the age of 18 – 65. Up to 10 subjects will be enrolled at 2 study centers. All subjects will attend a screening/pre-procedure visit which may be performed on the same day as the procedure visit but no more than 30 days prior to their procedure. Subjects will receive a phone call 1 week (1-10 days) after their procedure to record side effects. Subjects will return for follow up visits at 30 and 90 days post their procedure for efficacy and side effects assessments.

An unscheduled visit or phone call may be performed at any time during the study at the request of the subject or as deemed necessary by the site Investigator.

Analysis:
Upcoming generations are proving to have an interest in aesthetic treatments and will drive demand for innovated products, procedures, and practice design.[i] Due to this shift in patient base, practices need to evolve to adapt to the newer generational ideologies. There have been rapid advances in minimally invasive neck rejuvenation over the past few years and using innovative procedure offers great promise to our aging population. The MyEllevate® procedure used for soft tissue approximation and elevation of sub dermis and underlying muscle of the submentum and jawline needs to be further investigated to collect additional data to support the safety and efficacy of the procedure.

Relevance:
According to the 2020 Plastic Surgery Statistics Report, neck lifts are in the top 10 cosmetic surgical procedures performed, with over 160,000 surgeries performed despite the average 8.1 weeks most surgeons stopped performing elective surgical procedures for due to the COVID-19 pandemic.[ii] There was also a survey conducted by American Society of Plastic Surgeons (ASPS) during the pandemic which found that 11% of women surveyed indicated they are more interested in cosmetic plastic surgery or non-surgical procedures now than before COVID-19. [iii] Currently, the comparable procedures and/or treatments available for visible platysma bands, glands and/or sagging in the submentum, jawline and/or neck include, but not limited to, NeckTite and a neck lift. The limitations of current products on the market include different side effect profiles and how invasive the procedure is.

Testability:
The MyEllevate® device, had been previously cleared for use for use in soft tissue approximation and elevation of subdermis and underlying muscle. (FDA 510(k) K091061). This study will utilize the collection of photography and side effect data to assess the safety and efficacy of the procedure.

Compatibility:
Due to the increasing demand for aesthetic procedures, there is a need to treat visible platysma bands, glands and/or sagging in the submentum, jawline and/or neck in its earlier stages to optimize treatment outcomes. As a subject gets older or the condition worsens, their treatment may need to be more aggressive to get their body to respond the same way that a younger subject or less severe case may be able to respond.

Predictive power:
Although previous studies found this procedure to be effective for neck rejuvenation with few complications[iv], data collection of the side effect profile of this procedure needs to be further investigated to confirm the safety of this approach. Assuming that there is significant improvement, it would be appropriate to expect results in different areas where other procedures and devices have significant results.

2.2 Protocol Study Design

This is a prospective, open label, multi-center clinical study to collect safety and efficacy data on the MyEllevate® device.

2.3 Subject Selection Criteria

Subjects will meet the criteria described below:

Inclusion Criteria:

- A healthy male or female between the age of 18 – 65.
- Must have any or all the following: visible platysma bands, glands and/or sagging in the submentum, jawline and/or neck.
- Reads and understands English.
- Understands and accepts obligation not to receive any other procedures on the treatment area through the length of the study.
- Understands and accepts the obligation and is logistically able to be present for all visits.
- Is willing to comply with all requirements of the study and sign the informed consent document.

Exclusion Criteria:

- Is pregnant or of childbearing potential and not using medically effective birth control, or has been pregnant in the last 3 months, currently breast feeding or planning a pregnancy during the study.
- Is currently enrolled in an investigational drug or device trial, or has received an investigational drug or been treated with an investigational device within in the area to be treated 6 months (or at the discretion of the Investigator) prior to entering this study.
- Have received any treatments or procedures (including injectables such as Botox or fillers) in the area to be treated at least 4 months prior to treatment.
- Take antiplatelets, anticoagulants, thrombolytics, or anti-inflammatories.
- Have an active localized or systemic infection.
- Have an open wound in area being treated.
- Have a significant systemic illness or an illness localized in area being treated.
- Have had recent surgeries or problems in the treatment area (e.g. neck fracture, neck sprain, pinched nerve, spondylosis, arthritis in the neck).
- Have a history of thrombophlebitis.
- Have a history of heart failure or kidney disease.
- Have a history of allergic reaction or intolerance to the anesthesia used during the procedure.
- Have a history of poor wound healing.
- Have a history of poor circulation.
- Have a systemic autoimmune disease known to impair wound healing.
- Have a history of keloid formation.
- Currently enrolled in an investigational drug or device trial, or has received an investigational drug or been treated with an investigational device within the area to be treated 6 months (or at the discretion of the Investigator) prior to entering this study.
- Has any condition or is in a situation which in the investigators opinion may put the subject at significant risk, may confound study results or may interfere significantly with the subject's participation.

Be sure to list all concomitant medications taken or procedures performed before, during and after the trial

Subjects will be recruited for the study through the existing patient database and may also be recruited through advertisements.

Subject populations will not be eligible to participate in the study if they are vulnerable populations such as children, pregnant women, prisoners, institutionalized individuals, and any persons requiring a legally authorized representative as part of the consenting process.

Subject population characteristics that will not be eligible to participate in participate in the study include non-English speaking individuals and people who cannot read or comprehend English. Employees of the Investigator will be participating in the study.

2.4 Screening

Subjects will be asked questions about their medical history, may have a limited physical and their inclusion/exclusion criteria will be verified. Discontinuation of any concomitant medications (such as aspirin, NSAIDS, herbals, vitamins, diet pills) will be discussed, and post treatment instruction will be reviewed with the subject.

Procedure for the Limited Physical Exam:
If the investigator determines that a limited exam is necessary, the exam will be like a basic annual physical exam performed by a primary care doctor to determine general overall health. The limited medical exam may include all or any of the following; vital signs such as blood pressure, heart rate, respiratory rate and body temperature, general appearance, listening to the heart, lungs and abdomen with a stethoscope, head and neck exam, in addition to examining the throat, tonsils, teeth, ears, eyes and nose as well as a neurological exam such as testing muscle strength, reflexes, balance, sensory changes of the extremities and mental state.

2.5 Informed Consent Process and Enrollment

Subjects will be asked to review the post treatment instructions prior to signing the informed consent form and their involvement in the study. The Investigator will be responsible for assuring the subject understands how to use each support device (neck brace and chin strap) and understands all requirements of the post treatment instructions. Subjects will be informed of site's COVID-19 procedures that adhere to federal and state guidelines at this time. Subjects who sign the informed consent will be screened to confirm eligibility and, if eligible, will be assigned a subject identification number. Subjects will be de-identified through their subject identification number, which will be stored in a secure location. Subject identification numbers will be generated chronologically and assigned only to subjects who have met all the study selection criteria and have signed the informed consent form. The informed consent will be obtained prior to a subject's involvement in any study related procedures. A subject will be considered enrolled in the study once they have signed the informed consent form.

The following post treatment instructions will be reviewed:

- Resting:

When sleeping or lying down, should be positioned at a minimum incline of 45 degrees for first 10 days of recovery.

- Chin strap:
  Wear at all times for 3 days.
- Neck brace:
  Wear for 10 days while reading/watching TV/working on computer/looking down at phone.
  Secure neck brace every night before sleeping (to always keep head in neutral position).
- Icing:
  Remove dressings to ice the procedure area using frozen peas for 20 minutes every hour while awake. Don't apply directly on tissue use protective barrier i.e., paper towel.
- Bathing/ Hygiene:
  May shower, using mild soaps or baby shampoo (not streaming directly on face, shower with back facing shower head). No shaving for 10 days but trimming or clipping hair is acceptable.
- Avoid all alcohol consumption for 2 weeks after procedure.

2.6 Pre-Treatment Procedures

If the subject is of childbearing potential (i.e. females not post-menopausal or not surgically sterile), pregnancy verification will be required prior to their MyEllevate® procedure. Pregnancy verification will be performed by asking the subject if they are pregnant, the date of their last menstrual cycle, and be required to perform a urine pregnancy test at the site. A urine pregnancy test may also be conducted at the Investigator/clinician's discretion at any time during the study at the study center. If a urine pregnancy test is conducted, then a negative result must be obtained.

Urine Pregnancy Test Procedure:

1. A urine sample is tested mid-stream or by cup sample with an indicator stick.
2. Negative results are indicated on the indicator stick.

- Photographs will be taken prior to the procedure.

2.7 Treatment Procedures

- The defined study area will be identified and may be marked with a surgical marker.
- A local tumescent anesthetic, such as lidocaine, will be injected to the area prior to the procedure.
- The MyEllevate® device will be used in accordance with the Instructions for Use (IFU) manual.
- Subjects will be asked to report the general level of treatment discomfort/pain on a scale of 0 (none) to 10 (maximum intolerable pain).
- Photographs may be taken during treatment.

2.8 Post Treatment Procedures

- Adverse events will be documented after treatment.
- Photographs may be taken post treatment.
- Post treatment instructions will be reviewed with the subject.

- A diary will be handed to the subject to complete to track adverse events and when they were able to return to normal activities. They will need to bring this diary to all of their post procedure visits.

2.8 Follow Up

- Subjects will receive a phone call 1 week (1-10 days) after the procedure to record side effects.
- Subjects will return for follow up visits at 30 and 90 days after the procedure.
- Photographs will be taken and adverse events, and subject assessment (Subject Global Aesthetic Improvement Scale), and satisfaction will be documented.
- Any subject affected by COVID-19 that is not able to attend their follow up visits to complete the study will be asked to return to the site for a final follow up visit within 1 year of last treatment.

Some subjects may have an incomplete response or no response by the end of the study. At the end of the study, treatments/procedures using an FDA approved/cleared treatment method may be discussed with the subject and obtained at the cost of the subject.

2.10 Unscheduled Visits

An unscheduled visit may be performed at any time during the study at the subject's request or as deemed necessary by the site Investigator. The date and reason for the unscheduled visit will be recorded in the source documentation.

2.11 Replacement of Subjects

Replacement of subjects who have withdrawn or been withdrawn from the study will be allowed to be replaced with prior approval from the sponsor and/or IRB.

2.12 Schedule of Visits and Procedures

	Visit #1*	Visit #2	Call	Visit #3	Visit #4
Procedure	Screening and Pre-treatment Procedures	Device Use	Phone Call 1 Week Post Device Use (1-10 Days)	Follow Up 30 Days Post Device Use (+/- 1 Week)	Follow Up 90 Days Post Device Use (+/- 1 Week)
Medical History	X				
Pregnancy Verification	X	X			
Informed Consent	X				
Photographs (2D and/or 3D)	X	X		X	X
MyEllevate Procedure		X			
Parameters		X			
Treatment Discomfort/ Pain Evaluation		X			
Subject Diary		X		X	X
Subject Satisfaction Questionnaire				X	X
PGAIS				X	X

SGAIS				X	X
Adverse Events Assessment	X	X	X	X	X

*Screening and Pre-treatment Procedures may occur at the same time as the Device Use visit.

2.13 Evaluation Methods

Photographs:

Photographs (2D and/or 3D) will be taken at baseline and at the 30 and 90 day follow up visit to assess the efficacy and safety of treatment. 2D photography may be taken at any time during the procedure to document performance and/or adverse events.

Treatment Discomfort/Pain Evaluation:

Subjects will be asked to report the general level of treatment discomfort on a scale of 0 (none) to 10 (maximum intolerable pain) using the universal pain assessment tool (Appendix B)

Physician and Subject Questionnaire:

The Global Aesthetic Improvement Scale (GAIS) ranging from "worse" to "very much improved" will be used to judge the improvement as seen by the subject and Investigator.

Global Aesthetic Improvement Scale Assessment	
Rating	Description
1	**Very Much Improved-** Optimal cosmetic result in this subject
2	**Much Improved-** Marked improvement in appearance form the initial condition, but not completely optimal for this subject.
3	**Improved-** Obvious improvement in appearance from initial condition, but a re-treatment is indicated.
4	**No Change-** The appearance is essentially the same as the original condition.
5	**Worse-** The appearance is worse than the original condition.

Subject Questionnaire:

The subject will be asked their level of satisfaction using a 6-point Likert scale that ranges from "extremely satisfied" to "extremely unsatisfied."

Subject Satisfaction	
Rating	Description
6	Extremely Satisfied
5	Satisfied
4	Slightly Satisfied
3	Slightly Unsatisfied
2	Dissatisfied
1	Extremely Unsatisfied

Blinded Evaluation:

Three blinded independent reviewers will perform a photographic evaluation in which they will be asked to identify pre-treatment images when compared to post treatment images. The reviewers

will be Board Certified Dermatologist, Surgeons, and/or trained professionals and will be chosen based on availability and have relevant clinical experience. They will attend a training session prior to grading.

2.14 Adverse Event Recording

All data captured must be supported by the Investigator's timely assessment and documentation of the adverse event in the case report forms or source documents. All documented adverse events will be reviewed by the Sponsor or designee to determine whether the adverse event meets regulatory reporting requirements and to ensure timely adverse event reporting to meet local and global regulatory requirements. All adverse events must be followed until their resolution.

Adverse Events Pertaining to the MyEllevate® Procedure:
Mild discomfort during treatment may be experienced by the subject. Anticipated side effects include pain, edema (swelling) and erythema (redness), bleeding, bruising, and limitations in opening mouth.

Other possible side effects may include; dimpling, infection, poor wound healing, facial asymmetry, hematoma (fluid accumulation), numbness or other changes in skin sensation, temporary or permanent hair loss along incisions, scarring, burns (up to 3rd degree), tissue hardness, weakness of the lower lip, skin irregularities, skin discoloration, suture surfacing, deep venous thrombosis with cardiac or pulmonary sequelae, facial nerve paresis of the mandibular bands.

Adverse Events Pertaining to Anesthetic:
Pain and numbness may be experienced at the site of the injection. Other side effects may include redness, blanching, swelling, application site reaction, rash, infection, skin damage or nerve damage at the site of the injection. Temporary loss of sensation and muscle function at the site of injection, although uncommon, may also be experienced.

1% lidocaine (Lidocaine) with Epinephrine Injection
Lidocaine with epinephrine contains the preservative sodium metabisulfite which may cause allergic-type reactions including anaphylactic symptoms such as itching, hives, swollen areas of the body, and/or trouble breathing and life-threatening or less severe asthmatic episodes in certain susceptible people. If the subject has a reaction, medical attention may be provided or they may need to seek emergency care.

Adverse Events Pertaining to the Surgical Marker:
Using surgical marker has minimal risks and may produce effects on the body such as redness or a rash. Markings may remain visible for a few days or may be removed with alcohol.

Other Cautions:
Incomplete response or no response may occur since some subjects may not respond to treatment.

2.15 Statistical Analysis

2.15.1 Hypothesis

For this study to be considered a success, the side effect profile is acceptable to the Physician as it relates to this type of treatment.

For the additional assessments to be considered a success, the following must be true:

- Subject satisfaction will be ≥80%
- In cases where the subject's improvement is being graded on a scale, such as the GAIS scale, we will test the statistical significance of our results against a hypothetical population that would have no change (average score of 4).
- Correct identification of pre-treatment images when compared to post treatment (90 day) images will be ≥80%.
- Subject diaries are collected.

2.15.2 Sample Size Rationale

Based on the need for data collected from this study, it was determined that a total of 10 subjects will be required, including departures.

2.15.3 Patient Populations

Interim results may be collected and reported. All data will be analyzed at the end of the study. The primary analysis will be performed by the intention-to-treat approach. Everyone who begins the treatment is part of the study whether he or she completes the study or not. The most appropriate method of handling missing values will be chosen based on the individual trial goals, endpoints and context.

The analysis of demographic, medical history, and efficacy variables will be based on all patients who are randomized and receive at least one treatment. The analysis of safety data will be based on all patients who receive at least one treatment, and have at least some safety data.

2.15.4 Analysis of Demographic and Medical History Variables

Summaries will be prepared for all important demographic and medical history variables. For quantitative variables summaries will include the sample size, mean, median, standard deviation, minimum, and maximum. For these variables the treatment groups will be compared using either a t-test or a Wilcoxon Rank Sum test, as appropriate. For categorical variables the summaries will include the sample size and the number and percent of patients for each outcome. For these variables the treatment groups will be compared using Fisher's Exact test. Statistical significance will be declared if the two-sided p-value is < 0.05.

2.15.5 Analysis of Efficacy Variables

Additional efficacy variable is the change from baseline to Visit 4 (90 day follow up visit). Baseline is defined as the last assessment prior to the first treatment. The change from baseline to visits 3 and 4 will be analyzed using a Mixed Model Repeated Measures Analysis of Variance. A pairwise treatment group comparison at visit 4 will be performed using the results of this analysis. If a patient has no post-baseline assessment of the primary efficacy variable it will be assumed that the change from baseline to visit 4 is zero. The changes to visits 3 and 4 will be left as missing. Statistical significance with respect to the treatment group comparison at visit 4 will be declared if the two-sided p-value is < 0.05. For each treatment group, summaries will be prepared for both the observed assessment and the change from baseline. The summaries will include the sample size,

mean, median, standard deviation, minimum, and maximum. The statistical significance of the mean change from baseline for each treatment group will be determined using a paired t-test.

2.15.6 Analysis of Safety Variables
Safety will be assessed through the degree of pain/discomfort related to the procedure (universal pain scale) and the collection of Adverse Events throughout the course of the study. For each treatment group these variables will be summarized. The summaries will include the number and percent of patients for each outcome. No statistical comparisons will be performed for any of these variables.

3.0 RISK ANALYSIS AND MANAGEMENT

3.1 Risk Determination
This device study used in this study does not meet the FDA definition for a Significant Risk Device study per 21 CFR 812.3(m). Therefore, the sponsor determines that this is a non-significant risk device study.

Significant risk device means an investigational device that:
(1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
(2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
(3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
(4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

3.2 Risk Management
The Investigator in this clinical trial has been invited to participate based on his/her previous experience with the use of the system and/or similar systems and industry experience. Experience with treatments is the most critical element in managing subject risk in this trial.

In addition, as with any study, there is a risk of bias. Objective evaluation methods may be used in conjunction with subjective evaluation methods when feasible. The value of the compensation to the clinical investigator for conducting the study is not influenced by the study outcome. If photographic results are listed as the primary objective, they are to be evaluated by blinded evaluators who did not partake in the study. If information concerning investigator assessment of improvement or investigator satisfaction is collected, then it is not listed as an objective for the study.

All other known risks will be disclosed to the subject via the informed consent process. Since this is an elective procedure and the subjects are volunteers, it can be assumed that their signature on the informed consent is indicative of their agreement to accept the risks involved.

The risks to the subjects who participate in this study are the same as those for the subject undergoing similar non-ablative radiofrequency treatment. It is possible to have an adverse reaction to the MyEllevate® procedure. There may be some side effects that we don't know about yet.

3.3 Risk Analysis

CONTEXT OF THE PROPOSED INVESTIGATION:
Aging of the neck is characterized by a loss of skin elasticity, and is often accompanied by increased submental fat, ptosis of the neck, and a weakening of the platysma muscle. As a result, the inferior border of the mandible often loses definition, prompting patients to seek surgical correction. Various surgical and nonsurgical techniques have been described to lift the neck, including laser skin resurfacing, submental liposuction, skin tightening procedures, skin excision procedures, platysmaplasty, suspension sutures, and modification of the digastric muscle. More invasive procedures carry increased risks of complications. Therefore, minimally-invasive procedures of the neck represent a safer approach to address the aging process of the neck and deliver the desired result of restoration.

ASSESSMENT OF RISKS OF THE PROPOSED INVESTIGATION:
The risk identified with the overall clinical investigation is the integrity of the data collected. There are multiple clinical mitigation strategies for the risks identified. Proper training on the device and protocol will be performed. Data from prior investigations will be utilized to minimize side effects and optimize treatment outcomes. Monitoring of the study will be implemented to minimize subject and data risks.

ASSESSMENT OF BENEFITS OF THE PROPOSED INVESTIGATION:
The subject may or may not have improvement for the indication treated.

CONSIDERATION OF PATIENT PREFERENCE INFORMATION:
Many physicians support the use of minimally invasive cosmetic treatments in response to high patient satisfaction of cosmetic results with the currently available procedures and device. However, there is still a level of interest in novel technologies that could reduce the risk of complications and the need for future treatments.

ASSESSMENT OF UNCERTAINTY:
There is uncertainty of the safety profile and efficacy results with the MyEllevate® procedure.

CONCLUSION:
This device is determined to be a non-significant risk study and will be using a device cleared for use by the FDA.

Patient population to be enrolled in this clinical study:
Total anticipated population: 10 Subjects
Age Range: 18 – 65 years of age
Gender: Male or Female
Condition: Visible platysma bands, glands and/or sagging in the submentum, jawline and/or neck.

4.0 DEVICE DESCRIPTION AND SPECIFICATIONS

Device Name	Date of 510(k)	Indication(s):
ICLED Surgical Suture System	09 October 2009 K091061	Indicated for soft tissue approximation and elevation of sub dermis and underlying muscle of the submentum & jawline

The ImplicitCare ICLED Surgical Suture System provides a minimally invasive means of performing reconstructive, plastic and cosmetic surgery procedures by eliminating the need for extensive subdermal undermining through a large incision. Rather, the suture is guided subcutaneously using rigid rods like blunt-tipped needles. The ICLED Surgical Suture System, is a sterile, single use device kit consisting of five (5) device components:

1.) Marking Tape: Intended to locate the marking sites of suture insertion. The backing of the tape is a medical acrylic adhesive

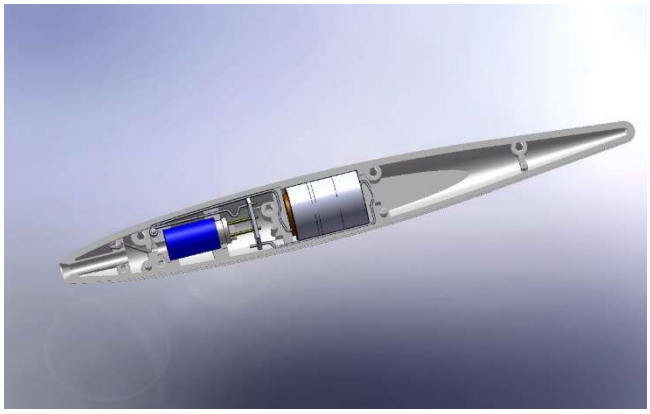
2.) Lancet: Intended to puncture the skin at the site of suture insertion. The Lancet creates a perforation just large enough to pass the Suturod™ and suture.

3.) Clearing Device: Intended to sweep away any dermal attachments for a 360° radius around the skin puncture made by the Lancet.This helps prevent “dermal tethering” as the suture is passed.

4.) Suturod™: Stainless steel, connected at the midpoint by a 100” (254 cm) length of USP 4-0 (1.5 Metric) TEVDEK® II braided nonabsorbable polyester Suture. The suture, acquired directly from Teleflex, is coated with polytetrafluoroethylene (PTFE) for improved handling characteristics and to reduce “tissue drag,” and is green in color.

5.) Light Tool (Handle): Contains an LED light source supplied by three (3) 1.55V silver oxide batteries, and which connects to the Suturod™ When connected, the light created by the LED passed through the fiber optic light pipe within the Suturod™ and Illuminates the distal tip. This permits visual verifications—through the dermis—of both the path and depth of the Suturod™ as it passed through the subdermal tissue.

Device Description	Device Image
Lancet: consists of a 400 seties stanless steel blade in a polycarbonate handle.	

Device Description	Device Image
Clearing Device: right angled 300 series stainless steel rod 0.078” in diameter extending from the distal end of a polycarbonate handpiece.	
Suturod™ Rod: The Suturod™ is 0.078” in diameter, 8.5” long, is composed of 300 series stainless steel, and is hollow, with a fiber optic light pipe running the length of the Suturod™ internally.	
Light Handle: Consists of a polycarbonate handle into which the end of a Suturod™ may be connected. Simple mechanical switch internal to the Light Handle illuminates the LED as the Suturod™ is connected. The LED is a 5mm white LED rated at 25mA maximum at 3.6V. The LED is powered by three (3) silver oxide “button cell” batteries within the Light Tool, each of which produces approximately 1.2V.	 

The device manufacturer is:
IMPLICITCARE, LLC
830 Challenger St, Suite 120 Brea, CA
92821 USA

5.0 MONITORING PROCEDURES

The Sponsor Standard Operating Procedure (SOP) for monitoring the investigative site will be followed. The sponsor will train the site following sponsor SOP's and may be present at initiation of treatment. The sponsor will also monitor the site periodically. The Investigator/Institution will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspections by providing direct access to source documents. The sponsor may request intermediate data following each visit to evaluate treatment progress. Case Report Forms will be reviewed for current data and Regulatory Binders will also be reviewed for correct documents. The sponsor will collect data at the end of the follow up period. The sponsor will list the study on clinicaltrials.gov when required by FDA regulations.

The monitoring plan for this study is outlined in the Cynosure Monitoring Plan.

ASSIGNED CLINICAL RESEARCH MONITOR:
Monitor #1
Name: Kristy Luis
Institution: Cynosure, LLC
Address: 5 Carlisle Rd. Westford, Ma

6.0 LABELING

Sample labeling will follow FDA regulations and the sponsor standard operating procedure. If applicable, the MyEllevate® device label will include, (in accordance with 801.1):

Statement: "CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use."

Additionally, the label or other labeling will describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.

Directions for use are contained in the MyEllevate® IFU.

7.0 CONSENT MATERIALS

Forms and informational materials which are provided to the subject during the informed consent process are listed below:

Form/Informational Material Description
Post Treatment Instructions

Informed Consent Form

8.0 INSTITUTIONAL REVIEW BOARD INFORMATION

This protocol, informed consent forms, and any amendments to the protocol will be reviewed by the appropriate Institutional Review Board prior to initiation. The study will not be initiated without the approval from the Institutional Review Board.

IRB Contact Information:
IRB Name: Allendale Investigational Review Board
IRB Chairperson: Robert Staab
IRB Address: 30 Neck Rd. Old Lyme, CT 06371
Phone: 860-434-5872
Fax: 860-434-5892
Email: Rta1ali1@aol.com

9.0 OTHER INSTITUTIONS

If a part of the study is conducted by an institution that has not previously been identified within the Investigational plan each institution's contact information will be documented below;

No other institutions will be part of this study.

10.0 ADDITIONAL RECORDS AND REPORTS

If this is an IDE study, additional records and reports will be maintained on the investigation in addition to those prescribed in 21 CFR 812 sub-part G. If this is a non-IDE study, the study summary will be maintained on the investigation and may include those prescribed in 21 CFR 812 sub-part G.

Additional Records and Reports:

Report	Submit To	Description/Constraints
N/A	N/A	This is a non-IDE study; no additional records or reports will be maintained.

11.0 PREGNANCY

Females may not participate in this study if they are pregnant, breastfeeding, were pregnant within the last three months or are planning a pregnancy during the study.

If the subject thinks they have become pregnant during the study, it is important that they inform the Investigator immediately. If she becomes pregnant or thinks that she may be pregnant, she will be removed from the study and will be asked to perform a final evaluation similar to the final follow-up visit. The Investigator may request to track the pregnancy and will report the pregnancy to the Sponsor.

12.0 SUBJECT WITHDRAWAL

The subject is free to withdraw from this study at any time. The subject must inform the Investigator immediately if they intend to withdraw. To terminate the subject's participation in this study, they must contact the Investigator at the contact information listed on page one of the informed consent form. They will be asked to come to the study clinic or Investigators office to complete a final follow up visit and may be asked to perform end of study procedures. Their decision to participate in this study or to withdraw from this study will not influence the availability of their future medical care and will involve no penalty or loss of benefits to which they are otherwise entitled.

The Investigator in charge of the study can remove the subject from this study without their consent for any reason, including, but not limited to:

a) His/her judgment that any condition or circumstance may jeopardize their welfare or the integrity of the study.
b) Their failure to follow the instructions of the Investigator(s).
c) If the study is stopped by the sponsor and/or Investigators participating in the study prior to completion.

Data collected prior to withdrawal will be used in data analysis but after withdrawal no further data will be collected.

13.0 PHOTOGRAPHY

Standardized photographs will be taken of the treatment area. The subject will be asked to remove jewelry, make-up, and lotions prior to each photo session. Photographs will be taken with an appropriate high-resolution digital camera. Camera settings (lighting, distance, background, polarization, etc.) will be reproduced at each visit, so that photographs are suitable for comparison. Photographs will be taken of the treatment area for study purposes. If the subject does not wish to have their photographs taken, they cannot be in the study.

14.0 ADVERSE REACTIONS DEFINITIONS AND REPORTING REQUIREMENTS

All adverse events that occur, starting from the time of the first treatment, will be recorded in the source documents and Case Report Forms (CRF).

Adverse Events (AE) occurring will be captured and followed until the condition resolves, stabilizes, is otherwise explained, or the subject is lost to follow-up. Subjects will be instructed that they may contact the Investigator at any time throughout the course of the study.

The Investigator and/or designated study staff will review each event and assess its relationship to the study device (not related, unlikely, possible, probable, and highly probable). The following definitions will be used for rating relationship to the MyEllevate® procedure:

- Not related – The event is clearly related to other factors such as the subject's clinical state, therapeutic interventions, or concomitant medications administered to the subject.
- Unlikely – The event was most likely produced by other factors such as the subject's clinical state, therapeutic interventions, or a concomitant medication administered to the subject; and does not follow a known response pattern to the investigational product.
- Possible – The event follows a reasonable temporal sequence from the time of investigational product administration; **and/or** follows a known response pattern to the study sampling sessions; **but** could have been produced by other factors such as the subject's clinical state, therapeutic interventions, or concomitant medications administered to the subject.
- Probable – The event follows a reasonable temporal sequence from the time of investigational product administration; **and** follows a known response pattern to the investigational product; **and** cannot be reasonably explained by other factors such as the subject's clinical state, therapeutic interventions, or concomitant medications administered to the subject.
- Highly Probable – The event follows a reasonable temporal sequence from the time of investigational product administration; **and** follows a known response pattern to the investigational product; **and** cannot be reasonably explained by other factors such as the subject's clinical state, therapeutic interventions, or concomitant medications administered to the subject; **and** either occurs immediately following investigational product administration, **or** improves on stopping the investigational product, **or** reappears on repeat exposure, **or** there is a positive reaction at the application site.

  Each adverse event reported will be graded on a 3-point severity. Using the following definitions for rating severity will be used:
- Mild – easily tolerated, causing minimal discomfort, and not interfering with normal everyday activities.
- Moderate – sufficiently discomforting and may interfere with normal everyday activities.
- Severe – incapacitating and/or preventing normal everyday activities.

A Serious Adverse Event (SAE) is any adverse device experience that results in any of the following outcomes: death, a life-threatening adverse device experience, in-patient hospitalization or prolongation of hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may or may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse device experience when, based upon appropriate medical judgment, they may jeopardize the subject or subject may require medical or surgical intervention to prevent one of the outcomes listed in this definition

If any of the above adverse events are serious as defined by the FDA Code of Federal Regulations (CFR), Title 21, special procedures will be followed. All serious adverse events will be reported within 24 hours of acknowledgment to the Sponsor whether or not the serious events are deemed sampling session-related. All serious event reporting will adhere to 21 CFR part 812 and the IRB will be notified accordingly.

The SAE information will be entered into the database and a desk copy of the complete SAE report will be submitted to the study file.

Adverse events, whether serious or non-serious, will be followed until the condition is resolved, stabilized, otherwise explained or the subject is lost to follow-up. Adverse events will be captured throughout the study and where appropriate, medical tests and examinations will be performed to document the resolution of event(s). Outcomes may be classified as resolved, improved, unchanged, worse, fatal, unknown or lost to follow-up. Following the resolution of any study-associated adverse events there will be no further adverse event reports for that subject.

Reporting Adverse Events:

Report	Submit To	Description/Constraints
Adverse Events, Unanticipated Adverse Device Effect	IRB and Sponsor	If an unforeseen complication is determined to be an unanticipated adverse device effect, the investigator's report must be submitted within 10 working days after the investigator first learns of the effect.
Serious Adverse Events	IRB and Sponsor	The sponsor must be notified within 24 hours of serious adverse events. The IRB must be notified within 1 working day of serious adverse events as defined by FDA guidelines.

15.0 PROTOCOL DEVIATIONS

All requests for protocol deviations by the Investigator must be communicated to the sponsor in writing and if accepted by the Sponsor must be approved by the IRB. If a deviation occurs, the Investigator must inform the Sponsor as soon as possible. The Sponsor will notify the IRB in accordance with IRB specific policies.

16.0 CONFIDENTIALITY AND DISCLOSURE OF MEDICAL INFORMATION

As part of this study the Investigator and the team at the research facility will keep records of subject participation in the study. These study records will include personal information that the subjects provide including age, sex, etc., the results of the study, information about response to treatments, photographs taken during the study and other medical information relating to participation in the study.

Under federal law the study records cannot be used or disclosed by the Investigator for research purposes unless subjects sign the informed consent authorization.

Some or all of the test results, photographs and other information will be reported to Cynosure, LLC, the manufacturer of the test device (Sponsor), and consultants that are helping conduct the study. The Sponsor and its consultants will analyze and evaluate these results and information and may report them to the U.S. Food Administration and the FDA, Institutional Review Board or other regulatory agencies in the United States and/or foreign countries. The subject's study records will be assigned a code number by the study team and they will ordinarily not be identified by name in

the study records that are sent to the Sponsor and its consultants. However, The Sponsor, the Institutional Review Board and its consultants will have the right to see the complete study records, including the subject's name, and might choose to do so. If reports or articles are written about the study, the subject will not be identified by name in them however your study information and photographs may be used.

The research facility will review and use the study records only for purposes of this study. They will keep the subject's identity confidential and, except for the disclosures described above, will not disclose the study records to other parties unless disclosure is required by law. Once the research facility discloses information in the study records, photographs or medical records to the Sponsor or its consultants, the information will no longer be protected by federal law. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. However, the Sponsor and its consultants will only use information for purposes of the study and will not disclose your study records to parties other than; the FDA or other regulatory agencies in the United States and/or foreign countries, unless disclosure is required by law. If reports or articles are written about the study, subjects will not be identified by name in them however, subject study information and photographs may be used.

Study records will be kept at the research facility according to applicable regulations and policies and may be kept indefinitely following the completion of the study. Subjects will not have the right to review their records while the research is in progress. However, they will be able to review their records after the research has been completed.

17.0 CLINICAL RESEARCH CONDUCT

The study will be conducted in accordance with the protocol, International Conference on Harmonization (ICH) GCP guidelines, applicable regulations and guidelines governing clinical study conduct and ethical principles that have their origin in the Declaration of Helsinki. The investigator must ensure that the study is conducted in accordance with the provisions as stated in the FDA regulations and complies with the applicable local or regional regulatory requirements.

18.0 REPORTING FOR THE STUDY

A study summary report will be generated. It will include a description of the clinical conduct of the study and results.

Study Summary Reporting:

Report	Submit To	Description/Constraints
Deviation from Investigational Plan	IRB and Sponsor	A deviation performed in an emergency to protect the life or physical well-being of a patient necessitates notification of the IRB and sponsor. The Investigator's report must be submitted within 5 working days after the emergency occurred. Deviations in a non-emergency situation require notification to sponsor prior to implementation

Failure to Obtain Informed Consent	IRB and Sponsor	The Investigator must make notification within 5 working days after device use, using the Protocol Deviation CRF. The report must include a brief description of the circumstances justifying the failure to obtain informed consent.
Final Report	IRB and Sponsor	The Investigator must submit a final report within 3 months after termination or completion of the investigation.
Withdrawal of IRB approval	Sponsor	The Investigator must report a withdrawal of the reviewing IRB approval within 5 working days.
Progress Report	IRB, Monitor and Sponsor	The Investigator must submit progress reports at regular intervals, and as required by the IRB, but in no event less than annually.

19.0 DISCLOSURE

The Principal Investigator and Cynosure employees and consultants have signed confidentiality agreements with the sponsor. This confidentiality agreement ensures that all information provided to the Investigator or Data Management and Statistics group dealing with the study and information obtained during the study will be regarded as confidential.

20.0 RESPONSIBILITY OF THE INVESTIGATOR

The Investigator is responsible for ensuring that the clinical study is performed in accordance with the International Conference on Harmonization (ICH), Good Clinical Practice (GCP) guidance E6, FDA Good Clinical Practice Regulations, Declaration of Helsinki (DoH) and the Health Human Service (HHS) Belmont Study. Investigators will supply information to the sponsor such that the sponsor can comply with the Financial Disclosure Rules.

21.0 PROCEDURE FOR AMMENDMENTS TO PROTOCOL

No deviations from this protocol will be permitted, except in a medical emergency, without the approval of the Sponsor. Any amendment to this study will be discussed by the Investigator and the Sponsor. If agreement is reached concerning the need for modification, this will be made in a formal amendment to the protocol.

All revisions and/or amendments to the protocol must be approved in writing by the appropriate Institutional Review Board.

22.0 TERMINATION OF STUDY

The Sponsor reserves the right to discontinue this study for administrative reasons at any time. The Investigator reserves the right to discontinue the study for safety reasons at any time in collaboration with the Sponsor.

23.0 DATA SECURITY

To ensure the privacy and confidentiality of data for this protocol, the data will be stored on a restricted access location on a company server. Access to the project directory containing the data will be limited to the Investigators and research staff. Information about data security awareness is promoted through user training and education, supplemented by policies and procedures. Password protection will be used for all transactions that allow viewing, editing, and analysis of data, or that provide access to data fields derived from the original source documents.

24.0 REPORT OF PRIOR INVESTIGATIONS

The report of prior investigations or predicates are:

Device	Determination	510(k)
Featherlift Extended Length Aptos Threads (Contour Threads)	Meets the criteria for exemption from IDE regulations, non-significant risk	K041593
FaceTite™	Meets the criteria for exemption from IDE regulations, non-significant risk	K151793

Protocol	Device	IRB Name	Determination	Initial IRB Approval Date
7053-RETRO-2022	MyEllevate ®	AIRB	Meets the criteria for exemption from IDE regulations, non-significant risk	3/3/2022

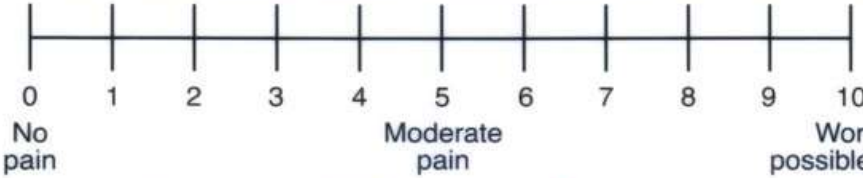
APPENDIX A:
Protocol Revisions Tracker

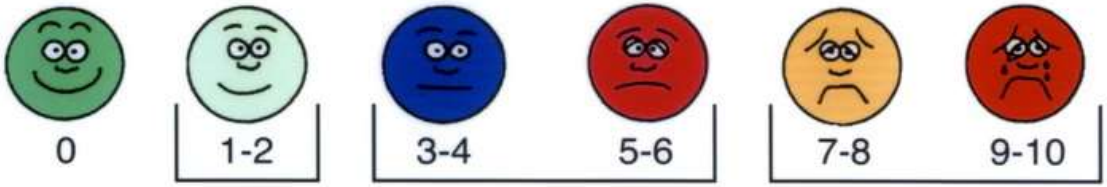
Version Date	Editor	Description
June 5, 2022	Kristy Luis	IRB Submission
June 14, 2022	Kristy Luis	IRB Response

APPENDIX B:

UNIVERSAL PAIN ASSESSMENT TOOL

This pain assessment tool is intended to help patient care providers assess pain according to individual patient needs. Explain and use 0-10 Scale for patient self-assessment. Use the faces or behavioral observations to interpret expressed pain when patient cannot communicate his/her pain intensity.





ACTIVITY TOLERANCE SCALE	NO PAIN	CAN BE IGNORED	INTERFERES WITH TASKS	INTERFERES WITH CONCENTRATION	INTERFERES WITH BASIC NEEDS	BEDREST REQUIRED
SPANISH	NADA DE DOLOR	UN POQUITO DE DOLOR	UN DOLOR LEVE	DOLOR FUERTE	DOLOR DEMASIADO FUERTE	UN DOLOR INSOPORTABLE
FRENCH	AUCUNE DOULEUR	LÉGÈRE DOULEUR	DOULEUR MODÉRÉE	FORTE DOULEUR	TRÈS FORTE DOULEUR	DOULEUR EXTRÊME
GERMAN	KEINE SCHMERZEN	LEICHTE SCHMERZEN	MÄSSIGE SCHMERZEN	STARKE SCHMERZEN	SEHR STARKE SCHMERZEN	EXTREME SCHMERZEN
JAPANESE	痛みなし	軽い痛み	中程度の痛み	ひどい痛み	非常にひどい痛み	最悪の痛み

REFERENCES

[i] Sherber, N. S., MD FAAD. (2018). The Millennial Mindset. *Journal of Drugs in Dermatology, 17*(12), 1340-1342.

[ii] American Society of Plastic Surgeons. (2020) Plastic Surgery Statics Report. Available at https://www.plasticsurgery.org/documents/News/Statistics/2020/plastic-surgery-statistics-full-report-2020.pdf

[iii] American Society of Plastic Surgeons. (2020) American Society of Plastic Surgeons Unveils COVID-19's Impact and Pent-Up Patient Demand Fueling the Industry's Current Post-Pandemic Boom. Available at https://www.plasticsurgery.org/news/press-releases/american-society-of-plastic-surgeons-unveils-covid19s-impact-and-pent-up-patient-demand-fueling-the-industrys-current-post-pandemic-boom

[iv] Gregory P. Mueller, Norman Leaf, Sherrell J. Aston, Corbett W. Stone, The Percutaneous Trampoline Platysmaplasty: Technique and Experience With 105 Consecutive Patients, Aesthetic Surgery Journal, Volume 32, Issue 1, January 2012, Pages 11–24, https://doi.org/10.1177/1090820X11429939