CLINICAL PROTOCOL NUMBER: LMI22001

SAFETY AND EFFICACY EVALUATION OF THE MOSAIC ULTRA DEVICE

Sponsor: Lutronic Global

DATE: AUGUST 4, 2023

Draft or version number: 1.4

Confidential – Proprietary Information

SPONSOR STATEMENT AND SIGNATURE PAGE

Company Name:	Lutronic Global
Address:	Lutronic Global
Address:	19 Fortune Drive Billerica, MA 01821
Telephone:	888-588-7644
Study Devices:	Mosaic Ultra
Protocol Title:	Safety and Efficacy of the Mosaic Ultra Device
Protocol Number:	LMI22001
Original Protocol / Date:	10/17/2022
Final Protocol Version / Date:	6/1/2022

The investigation will be conducted in compliance with this clinical investigation plan (CIP), Good Clinical Practice (GCP) guidelines, including EN ISO 14155, the Declaration of Helsinki, and regulatory authority requirements.

Lutronic, Inc. (hereinafter "Study Sponsor") maintains responsibility for the ongoing safety of this clinical trial involving the evaluation of the DermaV Laser System. Study Sponsor will promptly notify all investigators, the responsible IRB(s), and the regulatory authorities of any findings from ongoing trial monitoring activities that could adversely affect the safety of participants, impact the conduct of the clinical study, or alter the IRB's approval to

continue the study, specifically within five working days of making an Unanticipated Adverse Device Effect (UADE) determination or 15 working days after first receiving notice of the UADE, within 10 days for Serious Adverse Event reports, and at least annually for routine reports. In the event that participant safety could be directly affected by study results after the study has ended, Study Sponsor will notify all investigators of these results to enable investigators to consider informing participants as soon as possible or at least within one year of study closure.
The following individuals are responsible for the content of the Clinical Investigational Plan:

Paul Cardarelli
Director, Clinical Affairs

Date

SPONSOR CONTACT INFORMATION

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Protocol Number:	LMI22001
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STATEMENT OF COMPLIANCE

I have thoroughly read and reviewed this clinical investigation plan (CIP) and hereby agree to participate in this clinical trial sponsored by Study Sponsor. I agree to conduct this investigation according to the requirements of the CIP provided by the Study Sponsor; and in accordance with Good Clinical Practice (GCP), as required by EN ISO 14155, the Declaration of Helsinki; Investigational Device Exemption (21 CFR Part 812); Protection of Human Subjects (45 CFR Part 46); and other applicable FDA regulations; and regulations of other relevant regulatory authorities; and conditions imposed by the reviewing Institutional Review Board (IRB) or Ethics Committee (EC). Except where necessary to eliminate an immediate hazard(s) to the trial participants, I agree that no deviation from, or changes to the CIP, will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB). I agree to ensure that appropriate informed consent is obtained from all participants prior to inclusion in this study. I also agree to supervise all testing of the device involving human participants, and to report to the Study Sponsor, within 24 hours, any adverse event that is serious, whether considered treatment-related or not. I am aware that the Study Sponsor reserves the right to discontinue this investigation at any time.

I understand that this investigation will be monitored by the Study Sponsor and/or a designee contracted or employed by the Study Sponsor. This monitoring will involve periodic inspection of my investigational site and ongoing review of the data that is submitted by me to the Study Sponsor. I am also aware that I may be inspected by a representative of the relevant regulatory authorities, including the United States Food and Drug Administration, to verify compliance with applicable regulations related to clinical research on human participants.

My current curriculum vitae and the curriculum vitae of physicians/licensed practitioners at this institution who will participate as co-investigators/sub-investigators in this study will be provided to the Study Sponsor. This curriculum vitae will include the extent and type of our relevant experience with pertinent dates and locations. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

I certify that I have not been involved in an investigation that was terminated for non-compliance at the insistence of the Study Sponsor, the IRB or EC, or other regulatory authorities. I agree to provide the Study Sponsor sufficient, accurate financial disclosure information. I also agree to update financial disclosure information if any relevant changes occur during the investigation and for one year following the completion of the study.

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

Accepted by:

Principal Investigator Signature	Principal Investigator Name	Date
Co-/Sub-Investigator Signature	Co-/Sub-Investigator Name	Date

LIST OF ABBREVIATIONS

TERM	DEFINITION	TERM	DEFINITION
AE	Adverse Event	ICH E6	International Conference on Harmonization Guidance for Industry, Good Clinical Practice: Consolidated Guidance
ADE	Adverse Device Effect	ICMJE	International Committee of Medical Journal Editors
ANCOVA	Analysis of Covariance	IDE	Investigational Device Exemption
BMI	Body Mass Index	IFU	Instructions for Use
CFR	Code of Federal Regulations	IPL	Intense Pulse Light
CGAIS	Clinician Global Aesthetic Improvement Scale	ISO	International Organization for Standardization
CIP	Clinical Investigation Plan	IRB	Institutional Review Board
CMP	Clinical Monitoring Plan	MOP	Manual of Procedures
CRF	Case Report Form	NRS	Numeric Rating Scale for pain assessment
CRO	Contract Research Organization	OHRP	Office for Human Research Protections
CV	Curriculum Vitae	PI	Principal Investigator
DCC	Data Coordination Center	PSQ	Patient Satisfaction Questionnaire
DSMB	Data Safety Monitoring Board	QA	Quality Assurance
EC	Ethics Committee	QC	Quality Control
eCRF	Electronic Case Report Form	SAE	Serious Adverse Event
ETE	Expected Treatment Effect	SAP	Statistical Analysis Plan
FDA	Food and Drug Administration	SADE	Serious Adverse Device Effect
FDAAA	Food and Drug Administration Amendments Act of 2007	SGAIS	Subject Global Aesthetic Improvement Scale
GAIS	Global Aesthetic Improvement Scale	SMC	Safety Monitoring Committee
GCP	Good Clinical Practice	SOP	Standard Operating Procedure
GLP	Good Laboratory Practice	UADE	Unanticipated Adverse Device Effect
GMP	Good Manufacturing Practice	USA	United States of America
HIPAA	Health Information Portability and Accountability Act	CGAIS	Clinical Global Aesthetic Improvement Scale
IB	Investigator's Brochure		
ICH	International Committee on Harmonization		

PROTOCOL SYNOPSIS

Protocol Number:	LMI22001
Protocol Title:	Safety and Efficacy of the Mosaic Ultra Device
Investigational Devices:	Mosaic Ultra
Development Phase:	Pilot
Study Objective:	Evaluate the Safety and Efficacy of the Mosaic Ultra 1550nm system for the treatment of skin tone and texture, facial rejuvenation, photoaging, wrinkles, scars, stretch marks, acne vulgaris and hair loss.
Brief Study Overview:	Prospective, Multi-Site, Non-Randomized study of up to 210 participants in two treatment groups • Group A: Clinical Treatment Arm (n=180) • Group B: Biopsy Arm (n=30) Subject's in Group A will be treated with the device with the recommended parameters based on pre-clinical testing and similar device parameters. Subjects will receive up to 5 treatments and then attend follow-ups 30 and 90-days post treatment. Subject's may be asked to participate in an optional biopsy portion of this arm Subject's in group B will be treated at pre-determined parameters based on regulatory body requirements. Subjects will return up to 3 months post treatment. 5 Biopsies will be collected prior to treatment and throughout the follow-up periods.
Number of Sites Enrolling Participants:	3 sites located in the United States
Sample Size:	N = up to 210 treated participants
Participant Population:	Healthy adults, male and female, at least 18 years old who meet the inclusion and exclusion criteria.
Inclusion Criteria:	• Non-smoking, Male or Female • Age 18 – 60 years old • Understands and accepts the obligation not to undergo any other procedures in the areas to be treated. • Participants who are willing and able to comply with all study participation requirements including returning for follow-up visits and abstaining from exclusionary procedures for the duration of the study. • OPTIONAL - Participants who are willing to undergo biopsies.
Exclusion Criteria:	• Previous surgical or cosmetic procedure to the target area in the last 6 to 12 months that could interfere with the treatment procedure • A study participant must not be pregnant or have been pregnant in the last 3 months • A recent history of smoking (6 months) • Presence of an active skin disease or condition that may affect wound healing (ie. diabetes myelitis; connective tissue disease; radiation therapy; or chemotherapy) • Seizure disorder caused by bright light • A history of thrombophlebitis • A history of acute infections • A history of heart failure

	• Cancer, malignant disease, skin pathology, condition, or allergic reactions that could interfere with evaluation or with the use of typical ancillary medical treatments or care used before, during, or after treatments • Received or is anticipated to receive antiplatelets, anticoagulants, thrombolytics, vitamin E, or anti-inflammatories within 2 weeks prior to treatment • Intolerance or allergy to medications that could be prescribed before or after the procedure (eg, antibiotics, anesthesia) • A history of keloids • A history or evidence of poor wound healing • A history of coagulative disorder or current use of anticoagulant drugs within 2 weeks of study participation • Use of steroids within 2 weeks of study treatments • Patients with implanted pacemaker or defibrillator, or metal pins, or prosthetic joints within 4 cm of treatment area • History of psychoneurosis and/or a history of alcohol or drug abuse
Primary Endpoint:	• Group A: Evaluation of randomized before treatment and 3-month follow-up images by blinded evaluators • Group B: Complete wound healing following the treatment assessed by collected biopsies.
Secondary Endpoints:	• Adverse Event Assessment • Subject satisfaction • Physician satisfaction • Subject Clinical Global Aesthetic Improvement Scale • Physician Clinical Global Aesthetic Improvement Scale • Histological Evaluation
Safety Variables:	• Prior to treatment, the participant's medical history will be reviewed, pregnancy history will be documented, and a physical examination will be conducted. • At each subsequent visit, the participant will be queried about adverse events and changes in concomitant medications, and the treatment area will be visually examined.
Study Duration:	The duration from when the study opens to enrollment until completion of data analyses is anticipated to be 18 months.

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LIST OF FIGURES AND TABLES

1. KEY ROLES

Persons serving in key roles in the conduct or oversight of this clinical trial are listed in **Table 1.1-1** below.

1.1 INTERNAL RESPONSIBILITIES

TABLE 1: INTERNAL RESPONSIBILITIES

Name	Function	Address
Lutronic Global	Sponsor	19 Fortune Drive Billerica, MA 01821 Phone: 888.588.7644
Paul Cardarelli	Exec. Director, Clinical Research	Phone: 801.244.0058 Email: pcardarelli@lutronic.com

2. INTRODUCTION

2.1 BACKGROUND INFORMATION

2.1.1 DEVICE NAME AND INDICATIONS FOR USE

The Mosaic Ultra is an investigational device for dermatological treatments and skin regeneration procedures that require coagulation of soft tissues. The system emits 1550nm laser light at various pulse durations/configurations via optical fiber through a handpiece.

The Mosaic Ultra laser system is a 1550nm Er:Glass laser which delivers energy through an optical fiber system. The device is capable of using three different tips which are the roller tip, static tip (which comes in a circle, rectangle, and square format, as well as a comb tip. Laser energy is delivered when the device is activated via a foot switch. Patient comfort is managed using air cooling.

The clinical trial described in this protocol evaluates clinical outcomes associated with the treatment of various indications. The primary method of evaluation will be the assessment of before and after photography by blinded evaluators. Treated areas and results will be evaluated by both the physician and the subject for both satisfaction and CGAIS.

2.1.2 BRIEF SKIN CONDITION BACKGROUND AND TREATMENT OVERVIEW

The Mosaic Ultra can potentially treat skin tone and texture, facial rejuvenation, photoaging, wrinkles, scars, stetch marks, acne vulgaris and hair loss.

Pigmented lesions refer to a wide range of abnormalities that can be found on the skin, including not limited to lentigos (age spots), solar lentigos (sunspots), and ephelides (freckles). Many people develop brown lesions on their skin from chronic sun exposure, time, and other factors. These can appear on the face, hands, upper chest, and other locations and tend to make the skin look prematurely aged.

Uneven skin tone and skin texture can occur naturally over time as the skin is exposed to UV rays from the sun. This exposure causes the skin to produce melanin which results in the skin having dark spots resulting in the uneven tone.

This same exposure can cause a breakdown of the skin's natural collagen and elastin which typically support healthy skin. As the collagen and elastin breaks down it can cause the skin to dry out and become rougher resulting in an undesired skin texture.

Wrinkling occurs due to a variety of factors but results in the skin folding into itself and instead of appearing smooth the skin has folds, ridges, and creases. Wrinkles can occur as part of the natural ageing process, exposure to the sun, and a large variety of lifestyle and health habits.

Scars are marks on the skin that are left after the body heals from a wound and are typically a sign that the skin did not heal uniformly. Scars can occur due to a variety of wounds such as (but not limited to) acne inflammation, accidental injuries and cut and burns.

Stretch marks, also known as striae, occur when the skin has been rapidly stretched. The most common cause of stretch marks are pregnancy, but they can also occur if a person gains or loses weight in a short period of time. Stretch marks are typically smaller indented streaks and lines on the skin that can come in many colors such as pink, red, black, blue or purple.

Acne vulgaris is a very common skin issue that is a result of hair follicles under the skin becoming plugged or clogged. It results in small red bumps on the skin which can be painful to some patients due to the inflammation of the hair follicles.

Hair loss and hair thinning is a common issue where the hair stops naturally growing in certain spots and is typically only a concern when this occurs on the head. There are a variety of reasons this can occur but the general idea to treat this issue is by promoting cell proliferation, increasing overall cell survival and promoting the anagen phase of the hair follicles.

There are a variety of treatment options such as topical therapies (tretinoin or topical vitamin C), cryotherapy, and various lasers and energy delivery devices that have been developed to improve skin tone and texture, facial rejuvenation, photoaging, wrinkles, scars, stretch marks, acne vulgaris and hair loss.

2.1.3 Mechanism of Actions

The Mosaic Ultra is designed for specific clinical indications and emits 1550nm light. The light energy is directed to the treatment zone through an optical fiber coupled with a handpiece.

Laser use in dermatology relies on the basis that certain targets for energy absorption (chromophores) are capable of absorbing energy from specific wavelengths (absorptive band) without exclusively being targeted by their highest absorption peak. The working basis for this concept rests on the principles of selective photothermolysis, in which thermally mediated radiation damage is confined to chosen epidermal and/or dermal structures at the cellular or tissue structural levels. Tissues surrounding these targeted structures, including overlying or immediately neighboring cells, are spared, potentially reducing nonspecific, widespread thermal injury. The three main chromophores (hemoglobin, water, and melanin) in human skin all have broad absorption peaks of light energy, allowing them to be targeted using both broad and specific wavelengths of light.

2.1.4 Device Overview

The Mosaic Ultra laser system consists of the following components:

- Main system body
- Laser Delivery System (optical fiber with installed handpiece)
- Foot switch

FIGURE 1: MOSAIC ULTRA LASER SYSTEM COMPONENTS

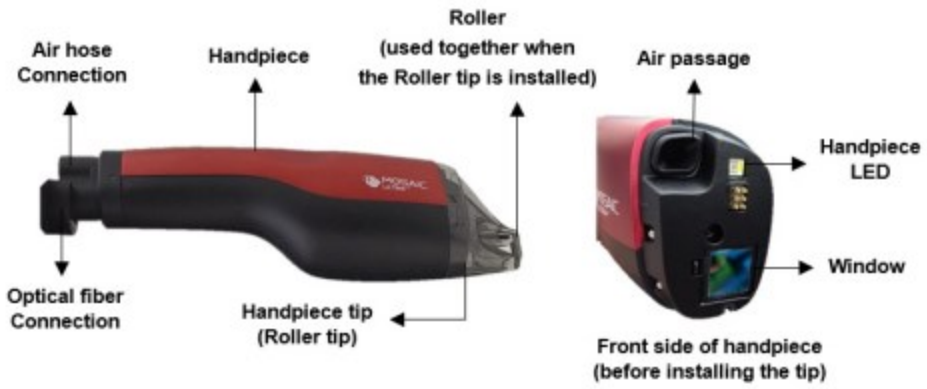

Figure 3.2 Handpiece configuration

Roller Tip (Roller Tip Body & Roller)	Static Tip (Sapphire)	Static Tip (Pill)	Comb Tip
			

TABLE 2: DEVICE SPECIFICATIONS

Items		**System Specificaionts**	
Laser wavelength		1550nm	
Laser medium		Er:Glass	
Laser delivery system		Optical fiber with handpiece installed	
Laser aiming beam		658nm, < 5mW	
Pulse energy		4 ~ 120mJ	
Pulse rate		115.4 ~ 447.4Hz	
Pulse duration		0.235 ~ 6.667ms	
Device Class	CDRH Class	Class IV	
	MDR Class	Class IIb	
	Applied Part Class	B	
	FDA Class	Class II	
Radiation Area (mm x mm)	Roller Tip	15x1	
	Static Tip	Circle (Diameter)	2, 4, 6, 8, 10, 12
		Rectangle	3x10, 5x10, 6x12, 8x12, 8x16, 8x20
		Square	2x2, 4x4, 6x6, 8x8, 10x10, 12x12, 16x16, 18x18, 20x20
	Comb Tip	12x2	
Laser radiation control		Foot switch	
Display system		10.1" Touch LCD Display	

Cooling system	Air cooling
IP rate	Main body: IPX0 Foot switch: IP68
Electrical specifications	AC100~240, 50Hz/60Hz (Fuse AC250V/6.3A) Max Power: 350VA

2.2 RATIONALE

In accordance with the definition of "Significant Risk Device" provided in 21 CFR 812.3, the device to be used in this study has been determined to be a Non-Significant Risk device based on the following:

a) It is not an implant.
b) It is not purported or represented to be for use in supporting or sustaining human life and do not present a potential for serious risk to the health, safety, or welfare of a participant.
c) It is not for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health.
d) Use of the device does not pose a serious risk to the health, safety, or welfare of a participant.

The current clinical plan is expected to evaluate the safety and effectiveness of the Mosaic Ultra laser system.

2.3 POTENTIAL RISKS AND BENEFITS

2.3.1 KNOWN POTENTIAL RISKS

This treatment modality was designed to inherently minimize the risk to the participant. As with any laser device treatment, there is a risk of adverse events, skin reactions or side effects. Expected side effects include:

- Discomfort: When a pulse is triggered, it may cause various degrees of discomfort. Some describe the sensation as stinging. A burning sensation may last for up to an hour after treatment.
- Blistering and burns
- Discoloration: Every laser treatment carries the possibility of permanent skin discoloration. Post-inflammatory hyperpigmentation and pigmentation are widely known complications of laser treatment.
- Eye injury: Protective glasses or goggles are provided for operators and assistants. It is extremely important to wear eye protection at all times during treatment to protect the eyes from accidental exposure to laser and serious injury.
- Infection: Every scar left on the skin carries the risk of infection. This risk of infection may also be associated with machines such as the MOSAIC ULTRA laser system. If detected, any infection should properly be treated with topical and/or systemic medications.
- Keloid formation: Scars may become thickened due to excessive growth of fibrous tissue.
- Prolonged redness: A mild case of temporary red spots is an expected reaction. However, if the red spots appear severe or last much longer than expected, do not repeat the treatment until the spots have disappeared. This reaction may vary by patient.

- Scarring: There is a possibility that scars may form due to treatment with the MOSAIC ULTRA laser system. Scars may form locally if treatment procedures are not properly followed, which may lead to exposure to laser, infection or physical irritation of the area such as wiping or rubbing.

- Delayed wound healing/skin textural changes: After laser treatment, the reepithelialization process may not proceed as expected due to the patient's physiological characteristics (e.g. lack of wound healing ability or poor care after treatment). This may result in undesirable changes to the skin texture.

- Temporary bruising

2.3.1.1 Minimization of Potential Risks

The risks listed above are minimized by treating a small area of the skin and noting the participant's sensation and inflammatory response. Potential risks will be further minimized or reduced by monitoring the participant during the treatment/exposure and observing the skin's response to receiving the treatment/exposure. If the treatment/exposure is not tolerated, the investigator (or delegated clinician) must stop administering the exposure for the participant's safety, and the participant will be followed for adverse events for through resolution of the adverse event and/or 30 days.

2.3.1.2 Safety Variables

Prior to the first exposure, the participant's medical history will be reviewed, pregnancy history will be documented, and a physical examination of the treatment area will be conducted to ensure it is free of open wounds. At each subsequent visit, the participant will be queried about adverse events and changes in concomitant medications, and the exposure area will be visually examined.

2.3.2 Known Potential Benefits

There is a potential benefit to participants of this study who are seeking improved appearance of pigmented lesions and vascular lesions of the face. Results of the study may contribute to further the development of the Lutronic Mosaic Ultra laser system.

3. OBJECTIVES AND PURPOSE

The objective of this study is evaluate the safety and effectiveness of the Mosaic Ultra laser system for the treatment of cutaneous lesions, periorbital wrinkles, acne scars, and surgical scars.
For subjects in group B, the primary objective will be evaluation of the histological changes via post-treatment biopsies to confirm appropriate wound healing post treatment

4. STUDY DESIGN AND AIM

4.1 Description of the Study Design

This study is a prospective clinical trial to be conducted at three clinical sites. Up to 210 participants will be enrolled and receive study treatment (total enrollment may be more than 210, due to screen failures) if they meet the inclusion/exclusion criteria and provide written informed consent. The study will be used to confirm parameters

and safety across a wide variety of clinical indications. Group A may have up to 180 subjects enrolled into the treatment arm, Group B may have up to 30 patients enrolled into the biopsy arm.

4.2 DURATION OF STUDY

The duration from when the study opens to enrollment until completion of data analysis is anticipated to be 18 months.

4.3 STUDY ENDPOINTS

4.3.1 PRIMARY ENDPOINT

The primary endpoint of this study is:

1. Group A: Selection of post-treatment images when randomized with baseline images as assessed by blinded evaluators
2. Group B: Evaluation of histological samples taken via punch biopsies to observe treatment effect and wound healing.

4.3.2 SECONDARY ENDPOINTS

The secondary endpoints of this clinical trial include:

1. Subject satisfaction
2. Physician satisfaction

Table 3: Satisfaction Scale

Score	Rating
6	Extremely Satisfied
5	Satisfied
4	Slightly Satisfied
3	Slightly Dissatisfied
2	Dissatisfied
1	Extremely Dissatisfied

3. Physician CGAIS
4. Subject CGAIS

Table 4: Clinical Global Aesthetic Improvement Scale[1]

Score	Rating	Description
5	Very Much Improved	Optimal cosmetic result in the subject
4	Much Improved	Marked improvement in appearance from the initial condition, but not completely optimal
3	Improved	Obvious improvement in appearance from initial condition, but further treatments may be beneficial
2	No Change	The appearance is essentially the same as the original condition
1	Worsened	The appearance is worse than the original condition

5. Adverse event assessment

4.4 SUCCESS CRITERIA

The study will be considered a success if the following criteria are met:

Group A: Clinical Treatment Arm

1. Blinded evaluators are able to correctly identify the post-treatment image at least 80% of the time
2. The adverse event and side effect profile are acceptable

Group B: Biopsy Arm

1. Wounds induced by the treatment device appropriately healed as assessed by histology.

5. PARTICIPANT ENROLLMENT AND WITHDRAWAL

5.1 PARTICIPANT ENROLLMENT

The study population will consist of male and female patients between 20 and 60 years old who have chosen to participate in this clinical trial as evidenced by execution of the informed consent document.

5.1.1 INFORMED CONSENT

Investigators have ethical and legal responsibilities to ensure that the protocol is clearly explained to each participant considered for enrollment in the study. Compliance with this requirement should be documented on a written Informed Consent Form approved by the reviewing IRB. Each Informed Consent Form will include the elements required by FDA regulations in 21 CFR Part 50.

The IRB-approved Informed Consent Form will be signed by the study personnel obtaining consent. The participant will be given a copy of the signed Informed Consent Form. The investigative site will keep the original on file.

Written informed consent will be obtained from all participants (and/or parents, guardians, legal representatives) before any study-related procedures, including any pre-treatment screening procedures, are performed. Investigators, or delegated study personnel, may discuss the availability of the study and the possibility for entry with a potential participant without first obtaining consent. Informed consent must be obtained and documented prior to initiation of any procedures that are performed solely for the purpose of determining eligibility for research.

5.1.2 PRE-TREATMENT RECRUITING/SCREENING

Participants will be recruited from the study site's patient database or IRB-approved advertisement and then subsequently screened. Study site personnel will explain the design and purpose of the study to potential study participants. Participants interested in participating will visit the study site where informed consent will be obtained.

5.1.2.1 SCREEN FAILURES

A screening failure participant is one from whom informed consent is obtained and is documented in writing (ie, participant signs an Informed Consent Form), but who does not receive a test spot exposure visit because of failure to meet all of the eligibility criteria. Screening failure participants will be included in the total number of participants enrolled (ie, all participants consented), but not counted towards the total participants treated.

5.2 PARTICIPANT INCLUSION CRITERIA

Participants must meet all of the following criteria for study enrollment:

- Non-smoking, Male or Female
- Age 20 – 60 years old
- Understands and accepts the obligation not to undergo any other procedures in the areas to be treated.
- Participants who are willing and able to comply with all study participation requirements including returning for follow-up visits and abstaining from exclusionary procedures for the duration of the study.
- Participants who are willing to undergo biopsies.

5.3 PARTICIPANT EXCLUSION CRITERIA

Participants will be excluded if they meet any of the following criteria:

* Previous surgical or cosmetic procedure to the target area in the last 6 to 12 months that could interfere with the treatment procedure
* A study participant must not be pregnant or have been pregnant in the last 3 months
* A recent history of smoking (6 months)
* Presence of an active skin disease or condition that may affect wound healing (ie. diabetes myelitis; connective tissue disease; radiation therapy; or chemotherapy)
* Seizure disorder caused by bright light
* A history of thrombophlebitis
* A history of acute infections
* A history of heart failure
* Cancer, malignant disease, skin pathology, condition, or allergic reactions that could interfere with evaluation or with the use of typical ancillary medical treatments or care used before, during, or after treatments
* Received or is anticipated to receive antiplatelets, anticoagulants, thrombolytics, vitamin E, or anti-inflammatories within 2 weeks prior to treatment
* Intolerance or allergy to medications that could be prescribed before or after the procedure (eg, antibiotics, anesthesia)
* A history of keloids
* A history or evidence of poor wound healing
* A history of coagulative disorder or current use of anticoagulant drugs within 2 weeks of study participation
* Use of steroids within 2 weeks of study treatments
* Patients with implanted pacemaker or defibrillator, or metal pins, or prosthetic joints within 4 cm of treatment area
* History of psychoneurosis and/or a history of alcohol or drug abuse

After participants have provided informed consent and met the inclusion/exclusion criteria, the study procedures described in the following section will be performed.

5.3 STRATEGIES FOR RECRUITMENT AND RETENTION

Participants will be recruited from the site's patient database. The next appointment should be scheduled prior to the participant leaving the current appointment.

All participants who have signed an Informed Consent Form, except for screen failures, will be considered enrolled in the study. Participants who complete the study duration will be considered to have completed the study. Any participant who does not return for a scheduled follow-up visit will be contacted at least twice by telephone to

determine the cause for the missed visit and to try to get the participant scheduled for the follow-up. A new visit will be scheduled as soon as possible. All participants should be followed until completing the study follow-up or until study discontinuation (withdrawal) for other reasons. The reason for study discontinuation should be documented for each participant. Participants will be deemed "Lost-to-Follow-up" if they have not returned within six weeks after the last follow-up target. For any participant deemed lost-to-follow-up, at least three attempts to contact the participant must be documented (the attempts must be two phone calls/emails and a registered letter).

5.3.1 Participant Payment

Participant visits where treatments are delivered will not be compensated. Screening/Baseline visit will not be compensated. Participants in Group A, the clinical treatment arm, will be compensated $50 for attending the 30- and 90-day follow-up visits. Participants who are selected and choose to participate in the elective skin biopsy of Group A or who are enrolled in Group B, the biopsy arm, will receive $100 per biopsy.

5.4 Participant Withdrawal or Termination

All participants have the right to withdraw at any point during the study without prejudice. The investigator can discontinue any participant, at any time, if medically necessary. Participants must be discontinued from the investigation by the investigator at any time for any of the following reasons:

- Withdrawal of informed consent.
- Pregnancy (no further study-related treatments will be performed; however, the follow-up visit will be completed if the study treatments has been completed and the participant will be followed to term, called after the pregnancy, child birth, and/or pregnancy termination, and queried for abnormalities or complications).
- Any AEs for which treatment continuation would constitute an unacceptably high-risk for the participant.

The reason for any participant's withdrawal should be documented on the appropriate study-specific data form.

5.5 Premature Termination or Suspension of the Study or a Study Site

The study or a study site can be prematurely terminated or suspended by the sponsor. Reasons for termination of the study or a study site may include, but are not limited to, the following:

- Participant enrollment is unsatisfactory.
- The risks and benefits of continuing the study have been reassessed, and the risks outweigh any potential benefits.
- The incidence of AEs constitutes a potential health hazard to the participants.
- New scientific data do not justify a continuation of the study.
- The investigator or study site exhibit serious and/or persistent non-adherence to the protocol, the Declaration of Helsinki, EN ISO 14155, and/or applicable regulatory requirements.
- The sponsor decides to terminate the study at any time for any other reason.

Furthermore, the study may be prematurely ended if the regulatory authority or the IRB has decided to terminate or suspend approval for the study, the study site, or the investigator.

If the study is prematurely terminated or suspended for any reason, the investigator must inform the participants and assure appropriate follow-up treatment. Within the timeframes noted in applicable regulations, the sponsor will promptly inform the investigators, study sites, the IRB, and regulatory authorities of the termination or suspension of the study, as well as provide reasons for the action.

6. STUDY PROCEDURES AND SCHEDULE

6.1 STUDY IMAGES

Standardized baseline and follow-up images will be taken. All participant photos must be taken in a standardized format. Review each item on the checklist below every time study photos are taken to ensure "Standardized Images" are taken.

PRIOR TO TAKING PHOTOGRAPHS:

- ☐ Natural Skin; skin washed, and no make-up
- ☐ Jewelry removed
- ☐ For any body part being treated, ensure a black background is in place
- ☐ Treatment area may be marked with a surgical marker prior to photographs

WHILE TAKING PHOTOGRAPHS:

- ☐ Ensure photograph is in focus
- ☐ For facial images, take five images: front, left 45°, left 90°, right 45°, right 90°
- ☐ For all other body parts, take one to three images to adequately capture the participant

AFTER TAKING PHOTOGRAPHS *(before participant leaves the office)*:

- ☐ Ensure all views have been taken
- ☐ Ensure all photographs are in focus
- ☐ Ensure lighting is consistent
- ☐ Ensure all follow-up photographs are similar to baseline images in views, angles, lighting, placement, and distance.

6.2 STUDY SCHEDULE

Table 5: Study Schedule

Group A – Clinical Treatment Arm – Schedule and Planned Activities

	Screening	**Treatment**	**Post Treatment Follow-Up (optional)** 1-7days post Tx	**Follow-Up** 30-day post final TX	**Follow-Up** 90-day post final TX
Visit Number	**1**	**2, 4, 6, 8, 10**	**3, 5, 7, 9, 11**	**12**	**13**
Study Day #	**0**	**0 – 140**	**1-147**	**170 (±7)**	**230 (±14)**
Screening Activities	X				
Pregnancy Test	X	X			
Photographs		X	X	X	X
Device Treatment		X			
Biopsy (optional)		X	X	X	X
Adverse Event Assessment		X	X	X	X
Subject Evaluations				X	X
Physician Evaluation				X	X

Group B – Biopsy Arm – Schedule and Planned Activities

	Screening (Visit 1)	Treatment (Visit 2)	Follow-Up Phone Call	Follow-Up Biopsy	Follow-Up Biopsy
Visit Number	**1**	**2**	**3**	**4, 5**	**6**
Study Day #	**0**	**0**	**2 (±1)**	**4 (±1), 12 (±2)**	**19 - 90**
Screening Activities	X				
Pregnancy Test	X	X			
Photographs		X		X	X
Biopsy		X	X	X	X
Adverse Event Assessment		X	X	X	X

6.2.1 Unscheduled Visit

Any unscheduled visit or examination should be documented in the participant's medical record and adverse event form (if applicable) stating the reason for the visit and any actions taken. The Sponsor should be notified of the unscheduled visit.

6.3 Study Treatment

Participants in Group A, the clinical treatment arm, will receive up to 5 treatments at the investigator's discretion using the Mosaic Ultra Treatment Parameter Guidelines as a starting point for the treatment parameters. Treatments will occur 2-6 weeks apart depending on the clinical indication being treated. Participants in Group B, the biopsy arm, will only receive one treatment with pre-determined parameters in a discrete area of the body (such as abdomen, buttocks, back).

6.3.1 Pre-Treatment Medications

No pre-treatment medication prior to study treatment.

6.3.2 Participant Preparation for Study Treatment

The investigator, sub-investigator, or delegated clinician will first identify the skin areas to which treatment/exposure is to be performed. Treatment records will be maintained in accordance with this protocol. Skin in treatment area should be cleansed with mild cleaner. No lotion, make-up, perfume, powder, or oil should be present on the area to be treated. Area will be fully cleansed prior to treatment. Test spots will be done as per the Mosaic Ultra guidelines to ensure the device settings are appropriate for the skin type (with adjustments to be made to the device settings as determined appropriate from observation of the reaction of the test spots).

6.3.3 Study Treatment

All study treatments will be performed by the investigator, sub-investigator, or delegated clinician (ie, study exposure clinician as designated by the principal investigator). Participants will receive up to 5 treatments at the investigator's discretion using the Mosaic Ultra Treatment Parameter Guidelines as a starting point for the treatment parameters. The participants will be monitored during the exposure. The participant's pain levels will be monitored using a standard pain scale assessment (0-10). The average pain score will be recorded. Participants in Group B, the biopsy arm, will receive treatment in a discrete area such as the back, abdomen, or buttocks.

6.3.4 Acute Responses

For all exposures, acute responses (eg, erythema or edema) will be observed by the study exposure clinician and recorded after exposure. If any Serious Adverse Events (SAE) are noted, an SAE Form should be completed.

6.3.5 Post-Treatment Care

Participants will be advised:

- Do not use any scrubbing product for one week after treatment.
- Do not use functional cosmetics (eg, retinol, AHA) for 2 days.
- Avoid saunas for at least one week.
- Do not use cosmetic products (toner, lotion) containing alcohol. They may cause skin irritation. Use a mild moisturizer.
- Apply sun block cream (SPF 30, PA++) everyday, to prevent PIH. It is advisable to wear a hat and take an umbrella when going outside for 30 days after the procedure.
- Skin Dryness are normal reactions associated with the thermal effect, so please apply moisturizing cream frequently.

For subjects in Group B, post-biopsy instruction will be provided to the participant. The participant will be instructed to not fully submerge the biopsy site in water. The bandage or coverings for the biopsy site should be changed on a daily basis and should also be changed if it becomes wet or damp. The subject will also be told that once a scab or new skin begins to grow over the area and that the bleeding from the biopsy site has stopped they can discontinue the wound treatment regimen and remove the bandage.

Other post-treatment procedures will be considered and used as deemed by a clinician to be standard and reasonable care. Participants will be instructed that blistering, bleeding, oozing, strong pain, excessive swelling persisting for more than 48 hours, or signs of infection (eg, itching; pus; drainage; fever; chills) are cause for immediate concern.

There is a risk of an allergic reaction to the anesthetic or oral medication used in treatment and/or the biopsy. An allergic reaction to the anesthetic may cause: hives, itching, swelling, faintness, low blood pressure, difficulty breathing, and life-threatening shock. In the event of the aforementioned infection or allergic reaction scenarios, immediate emergencies (medically unstable) must be triaged in emergency care.

If the aforementioned side-effects are not an immediate emergency (medically stable), participants should contact the investigator and/or his designee, to be evaluated and potentially treated at no cost to the participant. An unscheduled visit will be arranged so that the Investigator can clinically evaluate and photograph these findings.

6.3.6 Elective Skin Biopsy

Some study-site locations may offer an elective skin biopsy for histological evaluations. The biopsy is considered a safe, low-risk procedure.

The biopsy procedure will involve collecting a small sample of skin from the participant in a discreet location. The punch biopsy, a tool that is usually circular at the extraction site, removes a small, round sample of the epidermis, dermis, and superficial fat (while leaving the extracted layers intact).

Prior to biopsy, participant skin will be cleaned and dried by the treating clinician. The punch instrument is pressed vertically into the skin and then rotated clockwise and counterclockwise between the fingertips. A small "give" can be felt as the device cuts through the epidermis and dermis, down to the superficial layer of subcutaneous fat.
The punch biopsy tool is designed to collect tissue very quickly (to reduce pain) and is also designed to reduce the risks of bleeding through precision. However, some temporary pain and minor bleeding can occur at the biopsy site. The biopsy site will be covered with a bandage. There is a small risk of infection and participants must commit to taking care of biopsy site. Participants will be advised to regularly clean the biopsy site with mild soap and water, and to keep it bandaged (a simple bandaid is often enough) until it is fully healed (approximately one month).

For patients participating in the Group B of the study, the intended treatment area of the subject will be marked and photographed prior to treatment and a control biopsy will be taken. The first biopsy (Day 0, control) will be collected at this time. A normal treatment will be then be conducted using pre-determined laser parameters. Subject will then have a biopsy taken immediately post treatment from the treated area.

6.4 Follow-Up Visits

Post-treatment follow-ups may occur up to 7 days post-treatment. These follow-ups are optional and may be conducted in-phone, over email, or in-person as determined by the clinician. If an optional post-treatment follow-up is determined necessary by the clinician the subject will be notified before the end of their treatment visit and the visit will be scheduled at that time. Adverse events will be evaluated at this visit. If subject has elected to participate in the biopsy portion of the study then a biopsy may also be collected at this visit.

In-person follow up visits will occur 30±7 and 90±14 days post final treatment. Adverse events will be assessed at these visits. Subjects will be asked to rate their satisfaction (Table 3) with their overall results as well as grade their improvement on the CGAIS (Table 4).

Subjects in Group B will then return 3 and 14 days post treatment to have an additional biopsy collected from the treated area. Subject's will then return for a final follow-up for biopsy collection between 19 and 90 days post treatment. Photos will be taken at all visits to ensure proper collection of biopsies as well as to capture the skin response.

6.5 Concomitant Medications

All concomitant prescription medications taken during study participation will be recorded on the appropriate study-specific data form. For this protocol, a prescription medication is defined as a medication that can be prescribed only by a properly authorized/licensed clinician. Medications to be reported on the data form and entered on the CRF are concomitant prescription medications, over-the-counter medications, and non-prescription medications.

7. ASSESSMENT OF SAFETY

7.1 Specifications of Safety Parameters

7.1.1 Definition of an Expected Treatment Effect (ETE) and an Adverse Event (AE)

An expected treatment effect is defined as any typical treatment side-effect of the study devices of mild to moderate severity and lasting up to a typical maximum duration. An adverse event is defined as any new medical problem, or exacerbation of an existing problem, experienced by a participant while enrolled in the study, whether or not it is considered device-related by the investigator. All ETEs and AEs will be collected during the conduct of this trial.

7.1.2 Definition of Serious Adverse Event (SAE)

Each adverse event should be assessed for its seriousness. The definition below should be used for this assessment. Please note that the term serious adverse event is not synonymous with a "severe" adverse event, which may be used to describe the intensity of an event experienced by the participant.

An adverse event should be classified as serious if it meets any of the following criteria:

a. Death
   Death was an outcome of the adverse event.
b. Life-threatening
   The participant was at substantial risk of dying at the time of the adverse event or use or continued use of the device.
c. Hospitalization (initial or prolonged)
   Admission to the hospital or prolongation of hospitalization was a result of the adverse event.
d. Disability or Permanent Damage
   The adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions (ie, the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life).
e. Congenital Anomaly/Birth Defect
   Exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
f. Required Intervention to Prevent Permanent Impairment or Damage (Devices)
   Medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure (either situation suspected to be due to the use of a medical product).
g. Other Serious (Important Medical Events)
   The event does not fit the other outcomes, but the event may jeopardize the participant and may require medical or surgical intervention (treatment) to prevent one of the other outcomes.

Non-serious adverse events are all events that do not meet the criteria for a "serious" adverse event.

7.1.3 Definition of Unanticipated Adverse Device Effects (Events)

An unanticipated adverse device effect is defined as "any serious adverse effect on health or safety, or any life-threatening problem, or death caused by, or associated with, a device; if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan, or application (including supplementary application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects."

7.2 Classification of an Event

7.2.1 Severity of Event

Each adverse event should be assessed for its severity, or the intensity of an event experienced by the participant, using the following classifications:

1 = Mild Discomfort noticed, but no disruption to daily activity
2 = Moderate Discomfort sufficient that reduces or affects normal daily activity
3 = Severe Inability to work or perform normal daily activity

7.2.2 Relationship to the Investigational Device

The investigator should assess the relationship of the adverse event to the investigational device. The relationship should be assessed using the categories presented in **Table 5**.

TABLE 2: RELATIONSHIP BETWEEN ADVERSE EVENTS AND INVESTIGATIONAL DEVICE

Definite	Definite relationship exists between the device/procedure and an adverse event
Probably Related	A reasonable causal relationship between the device/procedure and an adverse event is more likely than not.
Possibly Related	A reasonable relationship exists between the device/procedure and an adverse event, but the causal relationship is unclear or lacking.
Not Likely Related	A temporal relationship exists between the device/procedure and an adverse event, but there is no reasonable causal relationship. For example the adverse event occurs in a time frame, which makes a causal relationship to device treatment improbable.
Unrelated	No relationship between treatment with the device/procedure and the adverse event exists.

7.2.3 Expectedness

Reported events will be categorized as Expected Treatment Effects if the event meets the definition of any typical treatment side-effect of study devices of mild to moderate severity and lasting up to a typical maximum duration.

7.3 Time Period and Frequency for Event Assessment and Follow-up

The occurrence of an AE or SAE may come to the attention of study personnel during a study visit or upon review by a study monitor. All ETEs and AEs will be captured on the appropriate data form. Information to be collected includes event description, date of onset, clinician's assessment of seriousness and severity, relationship to study device/treatment (assessed only by those with the training and authority to make a determination), actions taken, and date of event resolution. All AEs occurring while on study must be documented appropriately regardless of relationship. All ETEs/AEs assessed as "not yet resolved" must continue to be followed via telephone contact, by email, or clinic visit every 7 days or sooner (as per the physician's direction until event resolution or stabilization or tissue resection).

A pre-existing condition should not be reported as an adverse event unless there has been a substantial increase in severity or frequency of the problem that has not been attributed to natural history.

Changes in the severity of an event will be documented to allow for a determination if the event should be re-categorized from an ETE to AE.

The PI will record all reportable events, with start dates, occurring any time after informed consent is obtained until seven days (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of ETEs/AEs/SAEs since the last visit. Events will be followed for

outcome information until resolution or stabilization.

7.4 Reporting Procedures

7.4.1 Adverse Event Reporting

Any new medical problem, or an exacerbation of an existing condition, reported from the time the informed consent form is signed must be followed until the last study visit after the last study treatment/exposure or until event resolution.
AEs will not be followed up after the final study visit.

7.4.2 Serious Adverse Event Reporting

Serious adverse events must be reported to the Sponsor as soon as possible, preferably within 24 hours but in no event later than 72 hours. Any AE considered serious by the PI or Sub-investigator, or which meets the definition of an SAE included in **Section 7.1.2. Definition of Serious Adverse Event** must be documented on an SAE data form.

The Sponsor will conduct an investigation. If the Sponsor determines that the investigation presents an unreasonable risk to participants, all investigations or parts of the investigation presenting that risk will be terminated as soon as possible. The investigator must report serious adverse events to the reviewing IRB according to the IRB regulations at the study site.

7.4.3 Unanticipated Adverse Device Effect Reporting

If an unanticipated adverse device effect occurs, the study investigator shall complete the appropriate study-specific data form, and submit to the study sponsor and to the reviewing IRB as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect. The study sponsor contact information is provided in **Section 1. Key Roles**. The study sponsor is responsible for conducting an evaluation of an unanticipated adverse device effect and shall report the results of such evaluation to FDA and to all reviewing IRBs and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter the sponsor shall submit such additional reports concerning the effect (as FDA requests).

7.4.4 Reporting of Pregnancy

Each pregnancy that starts during the participant's study participation must be reported by the investigator to the Sponsor within 24 hours of learning of its occurrence. Pregnancies and pregnancy follow-up should be reported on an Adverse Event form. Pregnancy follow-up should describe the outcome of the pregnancy, including any voluntary or spontaneous discontinuation; details of the birth; the presence or absence of any congenital abnormalities, birth defects, maternal or newborn complications, and their relationship to the device or treatment/exposure. Each pregnancy must be reported as a non-serious AE if the participant has received at least one study treatment/exposure. The following criteria should be followed:

a. If a participant becomes pregnant after the Baseline visit and all study treatments/test spot exposure have been completed, the participant should continue to be followed for the duration of the pregnancy.
b. If a participant becomes pregnant after the Baseline visit but before any study treatments/test spot exposures, the participant should be exited from the study.

c. If a participant becomes pregnant after the Baseline visit but before all study treatments/test spot exposures have been completed, additional study treatments/test spot exposures should be discontinued and the participant should continue to be followed for the duration of the pregnancy.

7.4.5 Reporting of Deaths

The investigator must notify the Sponsor as soon as possible, preferably within 24 hours but in no event later than 48 hours, of learning of a participant's death, regardless of whether the death is related or unrelated to the investigational device. The investigator should attempt to determine, as conclusively as possible, whether the death is related to the device. The cause of death and the investigator's discussion regarding whether or not the death was device-related should be described in a written report. The investigator must report death to the reviewing IRB according to the IRB regulations at the study site.

8. CLINICAL MONITORING

Clinical site monitoring is conducted to ensure that the rights and well-being of human participants are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirement(s).

- Monitoring for this study will be performed by the Sponsor or Sponsor contract monitor.
- Clinical study site and data monitoring will be conducted via both centralized and on-site monitoring.
    - Centralized data monitoring will focus primarily on:
        - Ongoing, real-time review of clinical data supporting safety, and primary and secondary study-defined endpoints, specifically:
            - Tracking the occurrence of adverse events and expected treatment effects.
        - Ongoing, real-time review of clinical data as entered on Case Report Forms (CRF):
            - Initial study consent was obtained for all enrolled participants;
            - Eligibility for study participation of all enrolled participants;
            - Verification of protocol compliance and data completeness.
        - Ongoing, real-time evaluation of data trends to identify outliers, unexpected trends, or holes in data collection;
        - Ongoing, real-time evaluation of study photographs.
    - Centralized monitoring requires timely data entry and timely uploading of completed CRFs to the study HIPAA compliant cloud-based system (eg ,no later than seven working days after a study visit has occurred).
    - On- site monitoring visits will include:
        - Review of primary/secondary endpoint data source documents;
        - Confirmation that participant randomization is being completed appropriately (if applicable);
        - Confirmation that study blinding is maintained (if applicable);
        - Confirmation of appropriate execution of the PGAIS, SGAIS, PSQ, or other study-specific scales;
        - Note any other study-specific study design items requiring on-site confirmation.
    - General on-site monitoring tasks will include:
        - Review of study conduct and progress at each investigative site (eg, protocol compliance, participant recruitment, etc).
        - Confirmation that written informed consent was obtained and documented at the time

of screening, using an appropriate version of an IRB-approved ICF, and participant eligibility is confirmed.

- Confirmation that all expected treatment effects, adverse events, and/or protocol deviations noted in site records are appropriately documented on study-specific CRFs.
- Identification and resolution of any device performance issues;
- Review of the investigator's study records, study management documents and participant informed consent documents.
- Confirmation that all investigative site personnel with study-related responsibilities are adequately trained and that the applicable training records are maintained in the Site Regulatory Binder.
- Confirmation that study-related responsibilities of site personnel are appropriately documented on the Delegation of Responsibility Log and the log is maintained in the Site Regulatory Binder.
- Reconciliation of the Device Disposition Log against device inventory and confirmation that study devices are kept in a secure location.
- Confirmation that required regulatory documents are present in the Site Regulatory Binder and are current and correct.
- Ensure that all findings, conclusions, and any actions taken to correct deficiencies noted during an on-site monitoring visit are documented in a site monitoring report.

- On-site monitoring frequency
  - An on-site monitoring visit will be completed at each study site at least one time during the course of this clinical trial.
  - The frequency of site monitoring visits may be adjusted based on a number of factors, including but not limited to:
    - Duration of the study;
    - Number of participants enrolled;
    - Number of investigators/sites;
    - Complexity of the study;
    - The level of the study site's experience in conducting and overseeing clinical trials;
    - The quality of the data documented on study-specific data forms and entered into the study database;
    - Number of outstanding issues from previous visits.

9. STATISTICAL ANALYSIS

9.1 STATISTICAL AND ANALYTICAL PLANS

The primary analysis of efficacy will be by study group and will be based on the evaluable treated participants; hence, only those participants who received complete study treatments and completed a 30-day/90-day follow-up visit post-the-final-treatment-visit, and who have evaluable post-treatment images, will be included in the analysis. Analyses of safety will include all participants who received (complete or incomplete) study treatment.

9.2 ANALYSIS DATASETS

The following analysis sets will be defined for the statistical analysis of this investigation:

Safety Evaluation Set (SES)
Subset of all participants who received the investigational treatment.

Full Analysis Set (FAS)
Subset of participants in SES that received complete treatments have primary effectiveness data available.

Per Protocol Set (PPS)
Subset of all participants who received complete treatments and have completed the study without major protocol deviations.

9.3 DATA SUMMARY

At the conclusion of the study the data will be analyzed and summarized in a report. Categorical values (such as sex, ethnicity, satisfaction results, etc.) will have both their number of occurrences as well as the frequency of those occurrences reported. For continuous variables (such as age, treatment pain scores, etc.) the minimum, maximum, average, median, and standard deviation will all be reported.

10. SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA / DOCUMENTS

Source documents are defined as the results of original observations and activities of a clinical investigation. Source documents will include, but are not limited to, study-specific data forms, progress notes, electronic data, computer printouts, screening logs, and recorded data from automated instruments. All source documents pertaining to this study will be maintained by the investigators and made available for inspection by authorized persons.
Following written SOPs, the clinical study monitors will verify that the clinical trial is conducted, and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirements.
The investigational site will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by local and regulatory authorities.

11. ETHICS/PROTECTION OF HUMAN PARTICIPANTS

11.1 ETHICAL STANDARD

This clinical study will be conducted in accordance with the Protection of Human Subjects Regulations, including Subpart B Informed Consent of Human Subjects (21 CFR Part 50); the Institutional Review Board Regulations (21 CFR Part 56); the Financial Disclosure by Clinical Investigators Regulations (21 CFR Part 54); and the Investigational Device Exemptions Regulations (21 CRF Part 812), and the ICH E6.

11.2 INSTITUTIONAL REVIEW BOARD

Prior to initiation of any study procedures, the protocol, informed consent, and recruitment materials, and all participant materials will be submitted to a duly constituted IRB for view and approval. In addition, any amendments

to the protocol or Informed Consent Form will be reviewed and approved by the IRB. The Sponsor must receive a letter documenting IRB approval at the clinical site prior to the initiation of the study.
The investigator is responsible for providing the appropriate reports to its reviewing IRB during the course of the clinical study. These reports will include:

1. Informing the IRB of the study progress periodically as required, but at least annually;
2. Reporting any unanticipated adverse device effects within 10 working days of first learning of the event;
3. Reporting any deviations from the clinical protocol to protect the life or well-being of a participant, in the case of an emergency, within five working days after the emergency occurred;
4. Reporting the use of the device without obtaining informed consent from a participant within five working days of the event; and
5. Providing any other reports requested by the IRB.

The IRB must be notified of study completion within 30 days of the final visit of the last participant and should be provided with a summary of the results of the study by the investigator.

11.3 Informed Consent Process

11.3.1 Consent/Assent and Other Informational Documents Provided to Participants

Consent forms describing in detail the study device, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention/administering study product.

11.3.2 Consent Procedures and Documentation

Informed consent will be obtained from all participants prior to study participation. Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Extensive discussion of risks and possible benefits of participation will be provided to each participant. Consent forms will be IRB-approved, and the participant will be asked to read and review the document. The investigator, or investigator-delegated study personnel, will explain the research study to the participant and answer any questions that may arise. All participants will receive a verbal explanation in terms suited to their comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. The participants may withdraw consent at any time throughout the course of the trial. A copy of the informed consent document will be given to the participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

11.4 Participant and Data Confidentiality

All information generated in this study must be considered highly confidential and must not be disclosed to any persons not directly concerned with the study without prior written permission from the Sponsor. Authorized regulatory officials and Sponsor personnel (or its representatives) will be allowed full access to inspect the records. All investigational devices and/or other materials collected will be used solely in accordance with this protocol, unless otherwise agreed to in writing by the Sponsor.

Participants should be identified only by initials and unique participant numbers on study-specific data forms. If necessary, their full names may be made known to a regulatory agency or other authorized officials.

12. DATA HANDLING AND RECORD KEEPING

12.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the clinical trial staff at the site, under the supervision of the site PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

During each participant's visit to the clinic, study data will be documented by study personnel on study-specific data forms (CRFs). In addition, study personnel will record progress notes to document all significant observations, and any contact with a participant by telephone or other means that provides significant clinical information will also be documented in the progress notes as described above.

For transmission to the Sponsor, information from the study progress notes and other source documents will be promptly transcribed to study-specific data forms (CRFs). In this clinical trial, study-specific data forms (CRFs) may also serve as source documents. Transcription of study data onto study-specific data forms should be completed and uploaded within seven days of the study visit.

Copies of the CRF serving as source documents must be maintained for each participant enrolled in the study. Data reported in the CRF derived from source documents should be consistent with the source documents or the discrepancies should be explained and captured in a progress note and maintained in the participant's official study record.

Any changes to information in the study progress notes, other source documents, and data forms will be initialed and dated in ink on the day the change is made by a site study staff member authorized to make the change. Changes will be made by striking a single line through erroneous data, and clearly entering the correct data. If the reason for the change is not apparent, a brief explanation for the change will be written in the source documentation by the clinician.

12.2 INVESTIGATOR RECORDS AND REPORTS

12.2.1 INVESTIGATOR RECORDS

Prior to participation in the investigation, the investigator must provide the following documentation to the Sponsor:

- Investigator Agreement, signed by the investigator, which lists any physicians who will be involved in conducting the investigation under the direction of the primary investigator;
- A copy of the principal investigator's, sub-investigator's, other delegated study clinicians' curriculum vitae;
- A letter signed by the chairperson of the IRB overseeing the conduct of this study indicating that the IRB has reviewed and approved this investigational plan; and
- A copy of the IRB-approved Informed Consent Form.

During the study, investigators are required to maintain on file the following accurate, complete, and current records relating to this study as described in 21 CFR §812.140. A summary of these records is listed below:

- All correspondence and required reports, which pertain to the study.
- Records of receipt, use, or disposition of study devices, including the type and quantity of devices; the dates of receipt; the serial numbers; the names of all persons who received, used, or disposed of each device; and why and how many units of the device have been returned to the Sponsor, repaired, or otherwise disposed.
- Records of each participant's case history and exposure to the device.

- Signed and dated consent forms.
- Relevant observations, including records concerning adverse events, condition of each participant upon entering and results of diagnostic tests.
- Study-specific data forms and corrections to the forms.
- Protocol and amendments.
- Participant recruiting materials.
- Investigator curriculum vitae.

12.2.2 Investigator Reports

Investigators are required to prepare and submit to the Sponsor the following complete, accurate, and timely reports on this investigation, when required. These reports, which are listed below, are required by 21 CFR §812.150; additional reports may be requested by the Sponsor:

- The investigator will notify the Sponsor of a participant death occurring during the investigation, as soon as possible, preferably within 24 hours of learning of the participant's death, but in no event later than 48 hours. The investigator will notify the reviewing IRB of a participant death as specified by the IRB.
- The investigator will notify the Sponsor of any unanticipated adverse device effects within 48 hours after learning of the effect. The investigator will notify its reviewing IRB of any unanticipated adverse device effects, as soon as possible, but no later than 10 working days after learning of the effect.
- The investigator will notify the Sponsor of the withdrawal of IRB approval, as soon as possible, but no later than five working days after learning of the withdrawal.
- The investigator will provide current progress reports to the Sponsor and reviewing IRB at regular intervals and at least on an annual basis.
- The investigator will notify the Sponsor and reviewing IRB of any deviation from the investigational plan to protect the life and physical well-being of a participant in an emergency, as soon as possible, but no later than five working days after the emergency occurred.
- The investigator will notify the Sponsor and reviewing IRB that an informed consent was not obtained from a participant, as soon as possible, but no later than five working days after such an occurrence.

The investigator will provide a final summary report to the Sponsor and reviewing IRB within three months after termination or completion of the study.The investigator will provide any other information upon the request of an IRB, FDA, or the Sponsor.

12.3 Study Records Retention

The investigator is responsible for retaining the necessary records, including a copy of the protocol, device labeling, study-specific data forms, medical records, original reports of test results, all study-related correspondence, a record of written informed consent, and any other documents pertaining to the conduct of this study.

FDA regulations require all investigators participating in investigational device studies to maintain detailed clinical records during the investigation and for a period of at least two years after the latter of the following two dates:

1. The date on which the investigation is terminated or complete; or
2. The date the records are no longer required for purposes of supporting a premarket approval application.

The investigator must not dispose of any records relevant to this study without either:

1. Obtaining written permission from the Sponsor; or
2. Providing an opportunity for the Sponsor to collect such records.

The investigator shall take responsibility for maintaining adequate and accurate electronic or hard copy source documents of all observations and data generated during this study. Such documentation is subjected to inspection by the Sponsor and the FDA.

12.4 PROTOCOL DEVIATIONS

This study should be conducted as described in this protocol, except for an emergency situation in which the protection, safety, and well-being of a participant requires a protocol deviation, based on the judgment of the investigator (or a responsible, appropriately trained professional designated by the investigator). If the deviation from the protocol is necessary to protect the physical well-being of a participant in an emergency, such protocol deviations must be reported to the Sponsor and the reviewing IRB as soon as possible, but no later than five working days after the emergency occurred.

In the event of a significant deviation from the protocol due to an accident or mistake, the investigator or designee must contact the Sponsor at the earliest possible time by telephone to discuss the deviation and its impact on the study and participant continuation in the study. These discussions will be documented by the investigator and the Sponsor and reviewed by the monitor.

12.5 PUBLICATION AND DATA SHARING POLICY

The data produced by this Lutronic-sponsored study is the sole property of Lutronic. Thereby, abstracts, publications and presentations of this data must be pre-approved by Lutronic in writing (e-mail approval is acceptable). The Sponsor must also be provided with the opportunity to review all investigator-prepared abstracts, publications, or presentations. A period of thirty (30) days for presentational materials and abstracts and forty-five (45) days for manuscripts will be required for review and comment by the Sponsor's Clinical Research Department. These requirements acknowledge the Sponsor's responsibility to evaluate such publications for their accuracy, to ascertain whether Confidential Information is being inappropriately released, to provide the Principal Investigator with information which may not yet have been available to him/her, and to provide input from co-authors regarding content and conclusions of the publication or presentation. If requested in writing by the Sponsor, the Institution will withhold publication to protect the potential patentability of any invention described therein and/or make available to fulfill regulatory requirements.

Notwithstanding the foregoing, the Investigator agrees that if the study is part of a multi-center study, the first publication of the results of the study shall be made in conjunction with the results from the Investigators at the other study centers as a multi-center publication.

13. STUDY ADMINISTRATION

13.1 STUDY INVESTIGATORS

All Investigators will be experienced with aesthetic treatments using a variety of accepted clinical modalities.

13.2 AMENDMENT POLICY

The investigator will not make any changes to this protocol without prior written consent from the Sponsor and subsequent approval by the IRB, except if the deviation from the protocol is necessary to protect the life and physical well-being of a participant in an emergency. Such protocol deviations must be reported to the Sponsor and the reviewing IRB as soon as possible, but no later than five working days after the emergency occurred.

Any permanent change to the protocol, whether it is an overall change or a change for specific study center(s), must be handled as a protocol amendment. Any amendment to the protocol that appears necessary as the study progresses will be fully discussed by the investigator(s) and the Sponsor. If agreement is reached regarding the need for an amendment, the Sponsor will write the amendment. The written amendment must be submitted to the chairman of the IRB identified with this responsibility. Except for "administrative amendments," investigators must await IRB approval of protocol amendments before implementing the change(s). Administrative amendments are defined to have no effect on the validity of the data or information resulting from the completion of the approved protocol, or the relationship of likely patient risk to benefit relied upon to approve the protocol; the scientific soundness of the investigational plan or protocol; and the right, safety or welfare of the human participants involved in the investigation.

When, in judgment of the chairman of the IRB, the investigators, and/or the Sponsor, the amendment to the protocol substantially alters the study design and/or increases the potential risk to the participant, the currently approved written Informed Consent Form will require similar modification. In such cases, repeat informed consent will be obtained from participants enrolled in the study before continued participation.

14. CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial.

REFERENCES

1. Dibernardo, Gabriella & DiBernardo, Barry. (2018). Prediction of Treatment Outcomes for Neck Rejuvenation Utilizing a Unique Classification System of Treatment Approach Using a 1440-nm Side-Firing Laser. Aesthetic Surgery Journal. 38. S43-S51. 10.1093/asj/sjy066.

APPENDIX A: DEVICE OPERATOR MANUAL

See attached document

APPENDIX B: MOSAIC ULTRA TREATMENT GUIDELINES

See attached document

PROTOCOL REVISIONS LOG

VERSION	DATE	SIGNIFICANT REVISIONS
V1.0	27 October 2022	Initial IRB Submission
V1.1	7 November 2022	Fixed page numbering in footer, clarified Dr. Ibrahimi as PI
V1.2	12 December 2022	Expanded the biopsy portion of the study into a more detailed secondary study group; updated language as appropriate. Broaded enrollement age from 20-60 to 18-60.
V1.3	1 June 2023	Expanded protocol to include a second site. Increased biopsy group enrollment to 30 to account for data required by FDA.