TITLE PAGE

Protocol Number: C-17-TS16

Protocol Title: Multi-Center Pilot Study of truSculpt Device

Sponsor:
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Version, Date: Version 1, Dated July 28, 2017

Statement of Compliance
The study will be conducted in accordance with the design and specific provisions of this IRB approved protocol, in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

NOTE: The confidential information in the following document is provided to you as an Investigator, potential Investigator, or consultant for review by you, your staff, and applicable Institutional Review Board. By accepting this document, you agree that the information contained herein will not be disclosed to others, without written authorization from Cutera, Inc. except to the extent necessary to obtain informed consent from those persons to whom the device will be administered.

Protocol Signature Page – Principal Investigator

PROTOCOL C-17-TS16

Study Title: ***Multi-Center Pilot Study of truSculpt Device***

Protocol Version 1.0, Dated July 28, 2017

I have received and read the protocol dated **July 28, 2017** and agree to adhere to the requirements. I am aware that my adherence to the above protocol is mandatory and that any changes in the protocol or informed consent form must first be approved by Cutera, Inc. and the Institutional Review Board, except those changes necessary to eliminate apparent immediate hazards to subjects. I will provide copies of this protocol and all pertinent information to the study personnel under my supervision. I will discuss this material with them and ensure they are fully informed regarding their role in the study. I will ensure that the study is conducted in compliance with the protocol, Good Clinical Practice (GCP), and all applicable regulatory requirements, and with the reviewing Institutional Review Board (IRB) requirements. I agree to commence this study only after documented IRB approval is obtained.

Principal Investigator

_____ _____

Signature Date

_____

Printed Name

Table of Contents

Protocol Summary

Title	Multi-Center Pilot Study of truSculpt Device
Objective	An exploratory pilot study to evaluate the safety, efficacy and ergonomics of Cutera truSculpt device
Study Design	Multi-center, exploratory pilot study
Enrollment	Approximately 40 subjects at three sites within the US
Safety Endpoint	Incidence and severity of adverse device events.
Exploratory Endpoints	[redacted] [redacted]. GAIS at 12 weeks post first and final treatment from Baseline. [redacted]
Subject Population	Female and male subjects between the ages of 18-65
Planned Schedule	First subject enrolled: August 2017 Last subject last visit: May 2018

1 PURPOSE

The purpose of this pilot study is to evaluate the truSculpt device.

2 BACKGROUND INFORMATION

Unwanted excess fat pockets/bulges have been among the top concerns expressed by patients in the aesthetic field. Although surgical interventions produce the most definitive results with body contouring, these invasive methods require significant recovery time and come with inherent risks.

As a non-invasive option, laser, intense pulsed light (IPL), RF, or a combination of these technologies have been developed to reduce cellulite and body circumference with minimal recovery time and risks [1]. The tightening effect of the thermal energy generated by these devices has been used for reduction in cellulite and body circumference in areas including but not limited to arms, abdomen, thigh, back and flanks [2-14]. Although lasers and IPLs can target the deep dermal layers, the thermal effects of these devices are limited due to light scattering and energy absorption by water in the dermis.

RF, which is the most studied device in the non-ablative category, uses electrical current rather than light energy. Unlike light energy, radio waves can penetrate deeper depending on the frequency of operation. RF can be used with all Fitzpatrick skin types without jeopardizing epidermal integrity [15].

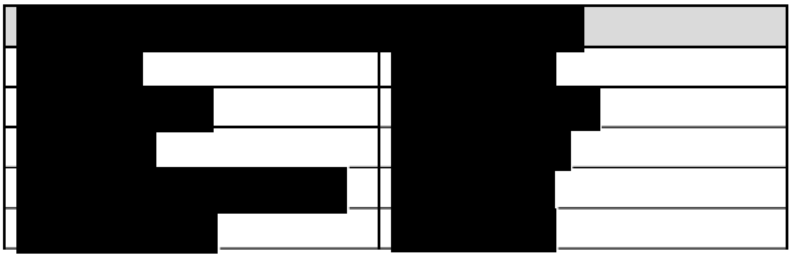
Magnitude of thermal energy generated is dependent on the resistance (impedance) of the target tissue. When RF energy is conducted electrically to tissue, heat is produced as the tissue's inherent resistance (impedance) converts the electrical current to thermal energy [(J) = I x R x T where I = current, R = tissue impedance, and T = time of application)]. Subcutaneous fat which is a high impedance tissue generates greater heat and accounts for the deeper thermal effects of RF devices [15-18].

RF may be delivered in three different ways: 1) Monopolar when energy is applied as current between a single electrode tip and a grounding plate. 2) Bipolar when energy is applied between two points on the tip of a probe. 3) Unipolar when energy is delivered as the emission of electromagnetic radiation (EMR) rather than current and no grounding pad is necessary. This could be achieved by capacitive, inductive or resonant electrical coupling with the tissue.

[redacted]

temporary reduction in circumference of the abdomen [510(k) number K162512]. The treatment settings [redacted]

[redacted]



3 STUDY OBJECTIVES

The objectives of this exploratory pilot study are to evaluate the safety, efficacy and ergonomics of the Cutera truSculpt RF device.

4 STUDY DESIGN

This is a multi-center, pilot study in approximately 40 subjects, ages 18 to 65. Subjects may receive [redacted] treatments and will be followed at 12 weeks post [redacted] final treatment.

4.1 Study Endpoints

4.1.1 Safety Endpoint

- Incidence and severity of adverse device events.

4.1.2 Exploratory Endpoints

- [redacted]
- GAIS at 12 weeks post first and final treatment from Baseline.
- [redacted]

4.2 Study Duration

Subjects enrolled in this trial will be asked to participate for approximately 10 months, depending on treatment(s).

4.3 Study Assessments

4.3.1 Exploratory Assessments

[redacted]

Investigators will complete an assessment of the device along with the Global Aesthetic Improvement of the subjects from baseline vs. 12 weeks post first and last treatment.

[redacted]

4.3.2 Safety Assessments

Following the first treatment, adverse events (AEs) will be assessed post-treatment and at each subsequent visit using the following scale:

1= mild: requires minimal or no treatment and does not interfere with the subject's daily activities.
2= moderate: may cause some interference with functioning.
3= severe: interrupts subject's usual daily activity and may require treatment.

Treatment-related Discomfort:
After each treatment, subjects will be asked to rate the average amount of discomfort experienced during treatment and immediately after treatment using the Pain Rating Scale (VAS Scale) Appendix 2.

4.4 Study Discontinuation

Cutera, Inc. (the sponsor) has the right to terminate this study at any time. Reasons for terminating the study may include, but are not limited to, the following: incidence or severity of adverse events in this or other studies indicates a potential health hazard to subjects; subject enrollment is unsatisfactory; number of protocol deviations is unacceptable; data recording is inaccurate or incomplete; or questionable study site compliance with ICH-E6, Good Clinical Practice.

4.5 Investigator Selection

The Investigator(s) will be invited to participate in the study based on his or her medical specialty, experience conducting clinical research studies and experience in the use of RF devices for aesthetic indications. Access to potential study subjects and the Investigator's sincere interest in this study along with expressed willingness to cooperate with the study process and requirements are also considered.

5 STUDY POPULATION

5.1 Study Subject Recruitment and Selection

Approximately 40 male or female subjects, ages 18 to 65, who desire treatment with truSculpt. Subjects will be recruited to participate from the local population. Subjects may also be recruited from the

Investigator's existing patient database or from patients who present themselves to the study site requesting treatment. Only subjects who meet all eligibility criteria and who provide written informed consent will be enrolled into the study.

Each subject will be evaluated by the Investigator to assess his/her suitability for entry into the study according to the following inclusion and exclusion criteria.

5.1.1 Inclusion Criteria

To be included in the study, subjects must meet all of the following Inclusion Criteria:

1. Subject must be able to read, understand and sign the Informed Consent Form.
2. Female or Male, 18 to 65 years of age (inclusive).
3. Subject has visible fat bulges in the area to be treated.
4. Non-smoking for at least 6 months and willing to refrain from smoking for the duration of the study.
5. Subject must agree to not undergo any other procedure(s) in the treatment region during the study period.
6. Subject must adhere to the follow-up schedule and study instructions.
7. Subject must adhere to the same diet and/or exercise routine throughout the study, and agree to maintain the same weight throughout the study.
8. Willing to have digital photographs taken of the treatment area and agree to use of photographs for presentation, (educational and/or marketing), publications, and any additional marketing purposes.
9. For female subjects: not pregnant or lactating and is either post-menopausal, surgically sterilized, or using a medically acceptable form of birth control at least 3 months prior to enrollment and during the entire course of the study.

5.1.2 Exclusion Criteria

Subjects will be excluded from the study if they meet any of the following Exclusion Criteria:

1.	Participation in a clinical trial of another device or drug within 3 months of study participation, or during the study period.
2.	Any type of prior cosmetic treatment to the target area within 6 months of study participation.
3.	Any prior invasive cosmetic surgery to the target area, such as liposuction.
4.	Has a pacemaker, internal defibrillator, implantable cardioverter-defibrillator, nerve stimulator implant, cochlear implant or any other electronically, magnetically or mechanically activated implant.
5.	Has metal implant(s) within the body, such as artificial heart valves.
6.	Significant uncontrolled concurrent illness that in the opinion of the Investigator would make the subject unsuitable for inclusion.
7.	History of any disease or condition that could impair wound healing.
8.	History of keloid formation, hypertrophic scarring or abnormal/delayed wound healing.
9.	Skin abnormality in the treatment area that in the opinion of the Investigator would

	make the subject unsuitable for inclusion.
10.	Currently undergoing systemic chemotherapy or radiation treatment for cancer, or history of treatment in the target area within 3 months of study participation.
11.	As per the Investigator's discretion, any physical or mental condition which might make it unsafe for the subject to participate in this study or a condition that would compromise the subject's ability to comply with the study requirements.

5.2 Subject Numbering

If a subject completes the Informed Consent Form, meets the study eligibility criteria and is willing to participate, the subject will be assigned a study subject identification number. This number is comprised of a site number (which is provided by the sponsor) and a sequential subject number and the subject initials (first and last names).

5.2.1 Subject Discontinuation Criteria

If possible, every subject should remain in the study until completion of the required follow-up period. However, participation in this study is completely voluntary and a subject can choose to withdraw from the study at any time. Decision to withdraw will not affect or prejudice the subject's continued medical care in any way. In those instances, the investigator will attempt to obtain a final clinical assessment and an adverse device effect evaluation for the subject prior to this withdrawal. A subject will be considered lost to follow-up only after three unsuccessful, documented attempts to contact the subject have been made.

In addition, a subject can be discontinued for any of the following reasons: the Principal Investigator decides that continuing in the study would not be in the subject's best interest, a subject is noncompliant with the protocol, a subject has a serious reaction to the treatment, a subject develops any of the exclusion criteria during the study period or the study is stopped by the study sponsor.

6 STUDY PROCEDURES

[redacted]

7 ADVERSE EVENTS AND ADVERSE DEVICE EVENTS

[redacted]

[redacted]

7.2 Recording AEs/ADEs and SAEs/SADEs

All AEs/SAEs or ADEs/SADEs will be: (1) evaluated and must be recorded in the subject's study case report forms (CRFs); (2) monitored and tracked from the time of the first treatment.

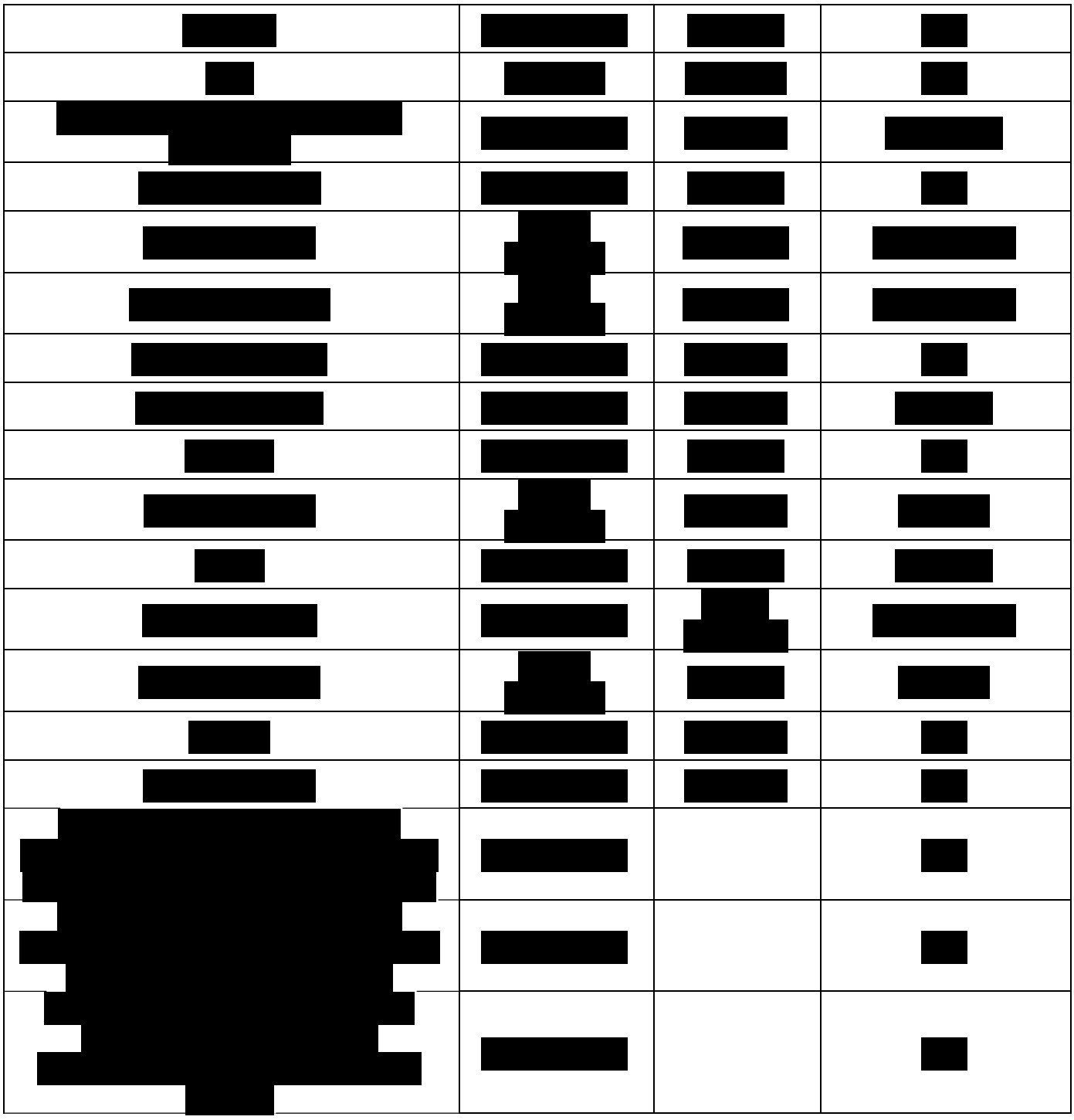
At each contact with the subject, the investigator must seek information on AEs/ADEs/SADEs by specific questioning and, as appropriate, by examination. AEs/ADEs/SADEs may be observed by the investigator and/or clinical research staff, elicited from the subject and/or family member or volunteered by the subject. All observed and volunteered adverse signs and symptoms, anticipated or unanticipated, regardless of severity or frequency, will be recorded in the case histories (medical chart and CRFs). Included in the description should be the nature of the sign or symptom, the date of onset, date of resolution (duration), the severity, anticipated or unanticipated, the relationship to study treatment or other therapy, the action taken (if any), and the outcome.

All SAEs/SADEs, anticipated or unanticipated, must be reported to Cutera immediately but not later than 5 working days. The SADE must be recorded in: (1) the CRF and (2) a written report must be submitted to Cutera within five (5) working days after the investigator first learns of the event and is to include a full description of the event and sequelae, in the format detailed by the Cutera Serious Adverse Event Form

7.3 Follow-up of Subjects after AEs

All reported AEs/ADEs/SAEs/SADEs should be followed until resolution or until the subject's participation in the study ends. Resolutions of AEs/ADEs/SAEs/SADEs are to be documented on the appropriate CRFs. All ADEs that result in permanent discontinuation from this clinical trial, whether serious or not, should also be reported on the subject Non-Completion of Study Form.

8 POTENTIAL RISKS / BENEFITS



8.2 Potential Benefits

The subjects may or may not benefit from the treatment with the study device. Potential benefit is improved appearance of treated area. There is no guarantee of success.

9 DATA ANALYSIS PLAN

9.1 Sample Size

This is an exploratory pilot study and 40 subjects has been deemed appropriate for evaluation of the device.

9.2 Analysis Sets

The analysis sets will include all enrolled subjects who complete treatment.

9.3 Analysis of Efficacy/Exploratory Endpoints

Formal hypothesis testing and statistical analysis are not planned for this study.

9.4 Safety Analyses

Device-related and procedure-related adverse effects (AEs) will be tabulated and analyzed. For a given AE term, counting will be done by subject, not by event, i.e. for a subject reporting the same AE more than once, the event will be counted only once, at the most severe and longest duration. The number and percentage of subjects experiencing each AE Term will be descriptively summarized.

10 STUDY MANAGEMENT AND ADMINISTRATIVE PROCEDURES

[redacted]

[redacted]

10.3 Protocol Compliance

The principal investigator must comply with all terms of the protocol.

10.3.1 Protocol Amendments

Neither the principal investigator nor the sponsor will modify or alter this protocol without first obtaining the concurrence of the other party (with the exception of amendments which involves mitigating a medical emergency or immediate health risk to the subject). The party initiating an amendment must confirm it clearly in writing and it must be signed and dated by the sponsor and the principal investigator. IRB approval must be obtained before implementation of an amendment.

10.3.2 Protocol Deviations

All protocol deviations must be clearly described on the case report form (i.e., Cutera Protocol Deviation Form). Deviations from the protocol may include but are not limited to subject's failure to attend scheduled visit during a visit window, and incomplete or incorrect study procedures. Any medical emergency or immediate health risk to the subject which results in a protocol deviation and must be reported to the sponsor within 5 working days

Significant protocol deviations must be reported to IRB according to their policies.

[redacted]

[redacted]

10.5 Subject Confidentiality

This study preserves the confidentiality of all subjects under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. The following safeguards will be in place to protect the privacy of the individuals who are the subjects of the health information to be used in the research and the confidentiality of that information:

[redacted]

not be disclosed.

10.6 Publication Policy

The investigator shall have the right to publish the results of the study. Unless mutually agreed upon in writing, prior to submission for publication of any manuscript, poster, presentation, abstract or other written or oral material describing the results of the study, the investigator shall allow sponsor to review manuscript, poster presentation, abstract or other written or oral material which describes the results of the study for the purpose only of determining if any patentable information is disclosed. At the sponsor's request, the investigator shall withhold any publication or presentation to permit sponsor to seek patent protection and to remove any confidential information from all publications.

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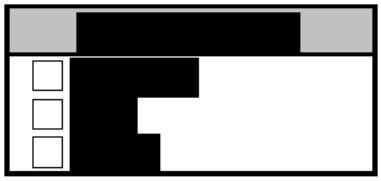

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