Study Protocol

Title: Prospective Clinical Stu**D**y of Tri-planar Tarsometatarsal (TMT) Arthro**D**esis with Early Weight-Bearing after Lapiplasty® Proce**D**ure through a **Mini**-Incision™ Approach (**Mini3D**)

NCT number: NCT05082012

Document Date: April 4, 2023

Treace Medical Concepts, Inc.
100 Palmetto Park Place
Ponte Vedra, FL 32081

The Mini3D™ Study
CLINICAL STUDY PROTOCOL

Study Number: CP2021-1
Version date: 26Aug2021 / **Rev: E**

Regulatory Classification:	Check One: ☐ IDE ☒ Exempt ☐ Post-Market Surveillance
Name of Finished Product(s):	Mini-Incision™ Precision Instrument Set Lapiplasty® Mini-Incision™ System
Sponsor's Medical Monitor:	Robert D. Santrock, MD
Lead Principal Investigator:	Jody McAleer, DPM, FACFAS Jefferson City Medical Group Department of Podiatry

This study will be performed in compliance with the 21 CFR Parts 11 (Electronic Records; Electronic Signatures), 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 803 (Medical Device Reporting), International Conference on Harmonization (ICH) Guideline E6 for Good Clinical Practice (GCP); Declaration of Helsinki; Health Insurance Portability and Accountability Act (HIPAA) regulations; and Applicable state and local laws and regulations.

CONFIDENTIALITY STATEMENT

INVESTIGATOR SIGNATURE PAGE

I have read, understood, and agree to:

- Ensure that the requirements for obtaining informed consent are met;
- Conduct the clinical study in accordance with this protocol, including applicable local/state laws and regulations;
- Adhere to the publication policy of Treace Medical Concepts, Inc, as stated in the Clinical Study Agreement (CSA), for data collected during this study;
- Ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed of their obligations in meeting the above commitments;
- Complete all Case Report Forms and study documentation and relevant imaging assessments (as required) promptly to the Sponsor, TMC, Inc., or its authorized representatives.

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

I agree to comply with all other requirements regarding the obligation of clinical investigators and all other pertinent requirements of the sponsor and government agencies.

Investigator Signature: I have read and understood the contents of this protocol. I agree to follow and abide by the guidelines set forth in this document.

_____ _____

Signature of Principal Investigator Date

_____

Printed Name of Principal Investigator

Please scan, email or fax this signed page to:

Cara Bethell
Treace Medical Concepts, Inc
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PLEASE RETAIN THE ORIGINAL IN YOUR STUDY RECORDS

SPONSOR SIGNATURES

Protocol Name:	The **Mini3D™** Study
Protocol Number:	CP2021-1
Protocol Title:	Prospective Clinical Stu**D**y of Tri-planar Tarsometatarsal (TMT) Arthro**D**esis with Early Weight-Bearing after Lapiplasty® Proce**D**ure through a **Mini**-Incision™ Approach (**Mini3D**)
Name of Finished Product(s):	Mini-Incision™ Precision Instrument Set Lapiplasty® Mini-Incision™ System

Approvals:

DocuSigned by:
Shana Zink 4/5/2023
Shana Zink Date
SVP, Clinical Affairs, Reimbursement, & Medical Education
Treace Medical Concepts, Inc.

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Rachel Osbeck 4/11/2023
Rachel Osbeck Date
Sr. Vice President, QA/RA
Treace Medical Concepts, Inc.

CLINICAL STUDY PROTOCOL SYNOPSIS

Protocol Name:	The **Mini3D™** Study
Protocol Number:	CP2021-1
Protocol Title:	Prospective Clinical Stu**D**y of Tri-planar Tarsometatarsal (TMT) Arthro**D**esis with Early Weight-Bearing after Lapiplasty® Proce**D**ure through a **Mini**-Incision™ Approach (The **Mini3D™** Study)
Name of Finished Product(s):	Mini-Incision™ Precision Instrument Set Lapiplasty® Mini-Incision™ System
Development Phase:	Exempt, post market
Study Design:	This is a prospective, multicenter, unblinded study

Indication(s) of Device:	All medical devices used during this study are cleared for commercial distribution and are to be used in accordance with approved product labeling.
	
	The TMC Plating System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet. The system can be used in both adult and pediatric patients aged >12 years. In the foot, the system can be used for the following specific examples:
	
	• First metatarsal osteotomies for hallux valgus correction such as:
	  • Opening base wedge osteotomy
	  • Closing base wedge osteotomy
	  • Crescentic osteotomy
	  • Proximal Chevron osteotomy
	  • Distal Chevron osteotomy (Austin)
	• First metatarsal fracture fixation
	• Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
	• Flatfoot Osteotomies
	  • Lateral Column Lengthening (Evans Osteotomy)
	  • Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
	• Mid / Flatfoot Fusions
	  • LisFranc Arthrodesis and/or Stabilization
	  • 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
	  • Intercuneiform Fusions • Navicular-Cuneiform (NC) Fusion
	  • Talo-Navicular (TN) Fusion
	  • Calcaneo-Cuboid (CC) Fusion
	• Medial Column Fusion
	• Arthrodesis of the first metatarsophalangeal joint (MTP)

Objective(s):	The objectives of this study are to evaluate outcomes of the Lapiplasty® Procedure using the Lapiplasty® Mini-Incision™ System for patients in need of hallux valgus surgery: 1. To determine radiographic recurrence of hallux valgus and the timing of failure following hallux valgus correction with the Lapiplasty® Procedure. 2. To determine whether the Lapiplasty® Procedure effectively corrects anatomical alignment of the 1st metatarsal and sesamoids in all three planes. 3. To assess whether early weight-bearing (WB) after the Lapiplasty® Procedure affects the union rates or causes loss of 3-plane correction. 4. To evaluate the quality of life and pain scores following the Lapiplasty® Procedure.
Number of Subjects:	Up to 200 subjects will be treated in this study
Sites:	Up to 20 sites
Patient Population:	Patients 14 years through 58 years with symptomatic hallux valgus will be eligible to participate based on the inclusion and exclusion criteria defined in this protocol.
Inclusion Criteria:	Patients satisfying the following criteria will be considered the screening population and will be eligible for participation: 1. Male and females between the ages 14 and 58 years at the time of consent; 2. Closed physeal plates at the time of consent; 3. Intermetatarsal angle is between 10.0˚ - 22.0˚; 4. Hallux valgus angle is between 16.0˚ - 40.0˚; 5. Willing and able to adhere to early weight-bearing instructions post-operatively; 6. Capable of completing self-administered questionnaires; 7. Acceptable surgical candidate, including use of general anesthesia; 8. Female patients must be of non-childbearing potential or have a negative pregnancy test within 7 days prior to index procedure; 9. Willing and able to schedule index procedure within 3 months of consent and able to return for scheduled follow-up visits; 10. Willing and able to provide written informed consent.
Exclusion Criteria:	Patients satisfying the following criteria will not be eligible for participation: 1. Previous surgery for hallux valgus on operative side; 2. Previous surgeries on operative foot involving fusion of foot or ankle joints (other than hammertoe or lesser toes/digits); 3. Additional concomitant procedures outside of the 1st ray;

	4. Moderate or Severe osteoarthritis of the MTP joint based on radiographic imaging (including lack of evident crista) or positive grind test; 5. Symptomatic flatfoot or asymptomatic flatfoot (defined as calcaneal inclination <5˚and talonavicular subluxation/uncovering >50%); 6. BMI >40 kg/m²; 7. Current nicotine user, including current use of nicotine patch; 8. Current clinical diagnosis of diabetes with fasting plasma glucose > 126 mg/dL and/or HbA1c ≥7.0; 9. Current clinical diagnosis of peripheral neuropathy or by assessment on 4-point monofilament test; 10. Current clinical diagnosis of fibromyalgia; 11. Current clinical diagnosis of Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy (CRPS/RSD); 12. Current uncontrolled hypothyroidism; 13. Previously sensitized to titanium; 14. Currently taking oral steroids or rheumatoid biologics; 15. Currently taking immunosuppressant drugs; 16. Insufficient quantity or quality of bone to permit stabilization, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply such as peripheral vascular disease; 17. Active, suspected or latent infection in the affected area; 18. Use of synthetic or allogenic bone graft substitutes; 19. Current diagnosis of metatarsus adductus (defined as MAA ≥ 23˚); 20. Known keloid and hypertrophic scar forming; 21. Scheduled to undergo a same-day bilateral procedure. Patient agrees to refrain from the Lapiplasty® Procedure (or other hallux valgus procedures) on contralateral foot for minimum of 6 months post index procedure; 22. Patient has previously been enrolled into this study for a contralateral procedure; 23. Scheduled for any concomitant procedure that would alter patient's ability to early weight-bear post-procedure; 24. Patient requires an incision >4.0 cm to complete the procedure (determined pre-operatively or intra-operatively); 25. Patient is actively involved with a workman's compensation case or is currently involved in litigation; 26. Patient is currently or has participated in a clinical study in the last 30 days prior to signing informed consent or is considering participation in another research protocol during this study. Exceptions to this include survey clinical studies with no treatment or if subject is greater than 12 months post

	procedure in the Treace ALIGN3D™ study without ongoing protocol defined AE; these are not exclusionary; 27. Patient has a condition or finding that, in the opinion of the Investigator, may jeopardize the patient's well-being, the soundness of this clinical study, or could interfere with provision of informed consent, completion of tests, therapy, or follow-up.
Study Duration:	Anticipated subject duration will be 2 years post index procedure.
Study Endpoints:	**Primary:** Radiographic recurrence of hallux valgus deformity at 24 months for subjects with successful correction (defined as IMA <9.0°, HVA<15.0° and TSP as ≤ 3 at 6 weeks post-Lapiplasty® Procedure). Recurrence is defined by any two of the following three criteria being met at 24 months post-procedure: IMA of ≥12°, HVA ≥20° and TSP ≥4. **Secondary:** 1. Change in radiographic angular/positional alignment before and after the Lapiplasty® Procedure [Time Frame: pre-operatively, 6 weeks, 4 months, 6 months, 12 months, and 24 months, post-Lapiplasty® Procedure]. 2. Evaluate clinical/radiographic healing (union vs non-union). Non-union defined as lucency at TMT joint, hardware failure and/or loss of correction (recurrence), plus clinical pain at first TMT joint at 12 months post-Lapiplasty® Procedure. 3. Clinical complications through 24-month follow-up visit due to the Lapiplasty® System Implants, the Lapiplasty® Procedure, the post-operative weight-bearing protocol or health conditions that could affect other outcome measures. 4. Time to start weight-bearing in a boot, in days. 5. Time to start weight-bearing in shoes, in days. 6. Time to return to full unrestricted activity, in days. 7. Change in pain at the base of the big toe (bunion related) assessed via a Visual Analog Scale (VAS) at 0-14 days, 14-21 days, 6 weeks, 4 months, 6 months, 12 months and 24 months post-Lapiplasty® Procedure, in comparison to baseline visit pain. 8. Change in Quality of Life, (PROMIS-29, PROMIS-25 and MOxFQ) defined as the total score measured at 6 months, 12 months and 24 months post-Lapiplasty® Procedure, in comparison to baseline visit. 9. Change in Range of Motion - 1st MTP dorsiflexion and plantarflexion at 12 months and 24 months post-Lapiplasty® Procedure, in comparison to baseline visit. 10. Change, if any, in initial incision length during Lapiplasty® Procedure. 11. Change in radiographic foot length and width at 12 months post-Lapiplasty® Procedure in comparison to baseline visit.

	12. Change in swelling at 6 weeks and 4 months post-Lapiplasty® Procedure as compared to 0-14 day visit. 13. Change in scar quality at 4 months, 6 months, and 12 months post-Lapiplasty® Procedure in comparison to baseline visit. 14. Correlation between amount of time external positioner is actively used during Lapiplasty Procedure with necrosis, blistering, bruising and tissue ulceration events. **Secondary Endpoints – Health Economic Outcomes** All health economic endpoints are exploratory in nature. 1. Complications below that are related to the Lapiplasty® Procedure or the Lapiplasty® System Implants requiring subsequent secondary surgical interventions, defined as the following: 1) deviations/delay from normal operative plan 2) readmission to hospital 3) return to operating room 4) unscheduled visits due to complications 5) employment of home health services; a. Revisions b. Hardware removals c. Reoperations d. Supplemental fixations e. Wound healing requiring surgical intervention f. Infection at surgical site requiring surgical intervention 2. Time to return to work (or normal household activities if non-working), in days, while noting work status and work classification (sedentary, light work, medium work, heavy work, very heavy work). 3. Time to return to full work, in days (or full household activities if non-working), while noting work status and work classification (sedentary, light work, medium work, heavy work, very heavy work). 4. Post-operative physical therapy requirements required for recovery of the Lapiplasty® Procedure.

TREACE Medical Concepts, Inc.

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KEY PROTOCOL-SPECIFIC ACRONYMS AND ABBREVIATIONS

Acronyms/Abbreviation	Terms
AE	Adverse Event
AP	Anteroposterior
CORA	Center of Rotational Angulation
CRA	Clinical Research Associate
DJD	Degenerative Joint Disease
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
HV	Hallux Valgus
HVA	Hallux Valgus Angle
ICF	Informed Consent Form
IFU	Instructions for Use
ICH	International Conference on Harmonization
IMA	Intermetatarsal Angle
IRB	Institutional Review Board
MAA	Metatarsus Adductus Angle
MDR	Medical Device Reporting
MOxFQ	The Manchester-Oxford Foot Questionnaire
MTA	Metatarsus Adductus
MTP	Metatarsophalangeal
MTPJ	Metatarsophalangeal Joint
OA	Osteoarthritis
PE	Physical Exam
PHI	Protected Health Information
POSAS	Patient and Observer Scar Assessment Scale
PROMIS	Patient-Reported Outcomes Measurement Information System
ROM	Range of Motion
SAE	Serious Adverse Event
SAS	Science Analysis System
SOC	Standard of Care
SOP	Standard Operating Procedures
TMC	Treace Medical Concepts
TMT	Tarsometatarsal
TSP	Tibial Sesamoid Position
VAS	Visual Analog Scale
WB	Weight-Bearing

Schedule of Assessments

Study Activity	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Study Exit
	Baseline [1]	Index Procedure	0-14 Day follow-up	14-21 Day follow-up (+3 days)	6 Week follow-up (±2 weeks)	4 Month follow-up (±2 weeks)	6 Month follow-up (±1 month)	12 Month follow-up (±1 month)	24 Month follow-up (±2 months)	
Informed Consent	X									
Demographics	X									
Medical and Surgical History	X	X								
Targeted Physical Exam	X									
Height / Weight [2]	X									
Blood Collection, if required[3]	X									
4-Point Monofilament Test, if required [4]	X									
Radiographic Imaging[5]	X				X	X	X	X	X	
VAS Pain Scale	X		X	X	X	X	X	X	X	
POSAS						X	X	X	X	
QOL Measurements[6]	X						X	X	X	
Medications Review	X	X	X	X	X	X	X	X	X	
Digital Photos of Foot	X	X	X	X	X	X	X	X	X	
Clinical Exam of Foot	X		X	X	X	X	X	X	X	
Foot Measurements	X	X	X	X	X	X	X	X		
Pregnancy Test (if applicable) [7]	X									
Inclusion/Exclusion Criteria	X[8]	X[9, 10]								
Index Procedure		X								
Wound check/surgical site healing			X	X	X	X				
Return to Weight-Bearing Activities[11]			X	X	X	X	X			
Range of Motion[12]	X					X	X	X	X	
Secondary Surgical Interventions[13]			X	X	X	X	X	X	X	
Adverse Events Assessment[14]		X	X	X	X	X	X	X	X	
Radiographic Measurements[15]	X				X	X	X	X	X	
Health Economic Outcomes[16]			X	X	X	X	X	X	X	
General Satisfaction Questionnaire									X	
Study Exit										X

[1] Baseline visit study activities must occur within 90 days of the Index Procedure unless otherwise noted.
[2] BMI should be calculated from height and weight measurement to determine patient eligibility.
[3] Blood collection is required only if subject has diagnosis of diabetes to determine fasting plasma glucose levels or HbA1c.
[4] 4-point monofilament test is required only if subject has diagnosis of diabetes or if warranted by PI to assess for peripheral neuropathy.
[5] Three radiographic views of the operative foot should be obtained per visit (weight-bearing AP, lateral and axial views of operative foot). The axial view should be collected using the study provided axial positioner.
[6] QOL assessment tools – MOxFQ and PROMIS-29 (PROMIS-25 for ages 14-17).
[7] Pregnancy test, if applicable, completed within 7 days of Index Procedure. May be completed on day of Index Procedure.
[8] For the purposes of determining IMA, HVA and MAA for patient eligibility, measurements will be made according to institutional SOC. For the purposes of all data analysis, measurements made by the Central Radiologist will be utilized. If there are minor differences in baseline IMA, HVA and MMA measurements made by the central radiologist, the measurements of the PI/site will remain acceptable for determining patient eligibility.
[9] Confirm exclusion criterion "patient is not a current nicotine user" prior to start of anesthesia. If subject indicates current use of nicotine, patient should be considered a screen failure.
[10] If subject requires an incision >4.0 cm to complete the Lapiplasty® Procedure, the subject should be considered a screen failure.
[11]Documentation for return to weight bearing activities include time to start weight-bearing in boot, time to start weight-bearing in shoe, and time to full unrestricted activity.
[12]ROM - dorsiflexion and plantarflexion should be measured while subject is passive and non-weightbearing with the study provided goniometer.
[13]Secondary surgical interventions, Wound healing requiring intervention, infection requiring intervention, hardware removal, revision procedure of 1st ray, other complication requiring surgical intervention.
[14]Only AEs related to the Lapiplasty® Index Procedure or the Lapiplasty® System Implants will be recorded on the eCRF.
[15]Radiographic Measurements are completed by the Central Radiologist only.
[16]Health Economic Outcomes, see Secondary Endpoints for data to be recorded on eCRF.

ETHICS

Institutional Review Board

The study will be conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki.

The study protocol, any protocol amendments, Informed Consent Form (ICF), any ICF amendments, and if applicable, any other written information provided to the subjects e.g., subject recruitment advertising, will be reviewed and approved by an Institutional Review Board (IRB) prior to implementation of any procedures required solely for the purposes of this study. Each Investigator must obtain IRB approval prior to consent of the first subject.

Prior to site initiation, a signed copy of the IRB approval letter identifying the study and site is required to be submitted to the sponsor signifying study approval.

Each Investigator must also maintain continuous IRB approval. Documentation of approval and renewals must be provided to the Sponsor and filed on site in the Investigator's Regulatory Binder. Additionally, amendments to the protocol will be submitted for review before implementation except when necessary to eliminate apparent immediate hazards to a subject. IRB approval is required to implement protocol amendments or to resume a suspended clinical investigation.

The occurrence of serious or unanticipated Adverse Events (AEs) during the study must be reported to the IRB as required by local or central IRB procedures.

Applicable Regulations

Regulations are to be followed as applicable including: 21 CFR Parts 11 (Electronic Records; Electronic Signatures), 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 803 (Medical Device Reporting). All surgical products used in this study are commercially available and will be used within current labeling and indications for use. Consequently, this study is not investigational and is exempt from 21CFR Part 54 (Financial Disclosure by Clinical Investigators) and 21CFR Part 812 (Investigational Device Exemptions) with the exception of 21CFR812.119 (Disqualification of a Clinical Investigator); International Conference on Harmonization (ICH) Guideline E6 for Good Clinical Practice (GCP); Declaration of Helsinki; Health Insurance Portability and Accountability Act (HIPAA) regulations; and Applicable state and local laws and regulations.

Subject Information and Consent

This informed consent process applies to participation in the study only (i.e., this process does not include consent required for any protocol allowed concurrent procedures). The surgeon will obtain the Institution's standard informed consent for surgery, which includes the Lapiplasty® Procedure.

In compliance with FDA regulations, no subject shall be enrolled in an investigation without provision of adequate informed consent. The Principal Investigator is responsible for ensuring that each subject enrolled in the study is given adequate informed consent. Failure to obtain and properly document this process is in violation of the US Code of Federal Regulations, the Declaration of Helsinki, and this study protocol.

The ICF must have the approval of the IRB. While some institutions may request modification of the ICF to satisfy specific institutional requirements, the use of a modified or unique ICF is permitted if it meets the requirement of 21 CFR Part 50 and is approved by the Sponsor. Informed consent of all subjects must be documented on an ICF in the primary language of the subject. All translated consent forms need IRB approval. Eligible U.S. subjects should also sign the Health Insurance Portability & Accountability Act form, if not combined with the ICF.

The Investigator or designee shall carry out the Informed Consent process on those subjects meeting the eligibility criteria. The informed consent process involves the following: giving a subject adequate information concerning the study, providing adequate opportunity (time) for the subject to consider all available options, responding to the subject's questions, ensuring that the subject has comprehended this information and finally, obtaining the subject's consent to participate in this study. All subjects in this study should be completely informed about the purpose, risks, benefits, and other pertinent details of this study. The informed consent process is careful to avoid the perception of any coercion or undue influence on, or inducement of, the subject to participate, and does not waive or appear to waive the subject's legal rights. The ICF is presented in native, non-technical language that is understandable to the subject. The ICF ensures important new information is provided to new and existing subjects throughout the clinical investigation.

The Informed Consent process is finalized by completion of the ICF. Following the explanation of the study intent, the Investigator or designee shall offer to answer any of the subject's questions. If the subject then agrees to participate, his or her willingness must be documented via signatures of the ICF.

This document must be signed and dated by the subject prior to any study related procedures or enrollment. No dates should be pre-populated or completed by someone other than the person providing the signature. The subject will be provided with a copy of the signed informed consent document.

During a subject's participation in the study, the subject will sign and date any amendment(s) to the informed consent document and a copy of the signed document will be provided to them.

STUDY ADMINISTRATIVE STRUCTURE

This study is sponsored by Treace Medical Concepts, Inc. and will be conducted in the US, under a single protocol approved by an IRB for each site prior to implementation at the study site.

The Principal Investigators (PI) at the study sites are required to be either a DPM or MD/DO qualified by education, experience and training to assume responsibility for the conduct of this study. Individual centers and investigators are selected based on their prior experience with the Lapiplasty® Procedure and use of the Lapiplasty® Mini-Incision™ System.

An Electronic Data Capture (EDC) system will be utilized by study site personnel to transfer study data from source records (medical records and/or source document worksheets) onto common electronic case report forms (eCRFs). The EDC system is a web-based, secure electronic software and is compliant with national and international GCP data protection/data privacy and electronic record/electronic signature (e.g., 21 CFR Part 11) regulatory requirements.

Serious Adverse Events (SAEs) and product quality problems (for products used during the index procedure), including potential and actual product use errors suspected to be associated with the use of a Food and Drug Administration (FDA) regulated drug, biologic, medical device or dietary supplement used during the course of this study will be reported by the PI to applicable authorities including the: 1) Sponsor (TMC); 2) IRB; 3) respective manufacturer(s); and/or 4) FDA via MedWatch Online Voluntary Reporting Process or Medical Device Reporting (MDR) as appropriate.

1.0 INTRODUCTION

Though the majority of hallux valgus (or "bunion") surgeries today are performed via a two-dimensional (2D) metatarsal osteotomy approach in which the metatarsal bone is cut and shifted over, this surgical approach has demonstrated unacceptably high long-term recurrence rates of up to 30-78%.[1,2] Recent research demonstrates that 87% of bunions[3] actually have three-dimensional (3D) deformities with abnormal frontal-plane rotation of the metatarsal bone, which cannot be addressed with a 2D metatarsal osteotomy. Correction of metatarsal rotation is critical for restoration of normal anatomic alignment, which left unaddressed, is associated with a 10.0-12.7 times likelihood of radiographic recurrence.[4,5] The Lapiplasty® Procedure (which was awarded a US patent on the surgical method) is a commercially available system that allows the surgeon to correct the bunion deformity at its apex and in all 3 anatomic planes (3D correction), including frontal-plane metatarsal rotation.

Correction at the 1st tarsometatarsal joint, also known as Lapidus fusion, provides the optimal surgical approach for true 3D anatomic restoration of the entire metatarsal bone, at the apex of the bunion deformity. However, the conventional Lapidus fusion technique has traditionally been a technically challenging procedure with high variability, requiring 6-8 weeks non-weightbearing, and furthermore does not directly address frontal-plane metatarsal rotation. The patented Lapiplasty® Procedure is designed to allow the surgeon to perform a Lapidus fusion in a much more controlled and reproducible manner, while also correcting frontal-plane rotation of the metatarsal (i.e., 3D correction) and returning the patient to weight-bearing typically in less than 2 weeks.[6]

A recent multicenter, retrospective study demonstrated the benefits of the Lapiplasty® Procedure. In the study, 72 hallux valgus patients (61 feet meeting 1-year endpoint) were treated with the Lapiplasty® Procedure with an early return to weight-bearing (average 10.5 days post-op). At average follow-up of 13.5 months, the results demonstrated 96.7% of patients maintained their 3-plane correction (intermetatarsal angle, hallux valgus angle, and tibial sesamoid position), and only 1.6% experienced a symptomatic nonunion complication[7].

In this study, we will evaluate the outcomes of patients in need of hallux valgus surgery that undergo the Lapiplasty® Procedure using the Lapiplasty® Mini-Incision™ System. The Lapiplasty® Mini-Incision™ System is designed to deliver the same patented Lapiplasty® Procedure providing 3-plane correction through a 3.5cm dorsal incision.

2.0 STUDY OBJECTIVES

The objectives of this study are to evaluate outcomes of the Lapiplasty® Procedure using the Lapiplasty® Mini-Incision™ System for patients in need of hallux valgus surgery:

1. To determine radiographic recurrence of hallux valgus and the timing of failure following hallux valgus correction with the Lapiplasty® Procedure.
2. To determine whether the Lapiplasty® Procedure effectively corrects anatomical alignment of the 1st metatarsal and sesamoids in all three planes.
3. To assess whether early weight-bearing after the Lapiplasty® Procedure affects the union rates or causes loss of 3-plane correction.
4. To evaluate the quality of life and pain scores following the Lapiplasty® Procedure.

3.0 STUDY ENDPOINTS

Primary:
Radiographic recurrence of hallux valgus deformity at 24 months for subjects with successful correction (defined as IMA <9.0°, HVA<15.0° and TSP as ≤ 3 at 6 weeks post-Lapiplasty® Procedure). Recurrence is defined by any two of the following three criteria being met at 24 months post-procedure: IMA of ≥12°, HVA ≥20° and TSP ≥4.

Secondary:

1. Change in radiographic angular/positional alignment before and after the Lapiplasty® Procedure [Time Frame: pre-operatively, 6 weeks, 4 months, 6 months, 12 months, and 24 months, post-Lapiplasty® Procedure].
2. Evaluate clinical/radiographic healing (union vs non-union). Non-union defined as lucency at TMT joint, hardware failure and/or loss of correction (recurrence), plus clinical pain at first TMT joint at 12 months post- Lapiplasty® Procedure.
3. Clinical complications through 24-month follow-up visit due to the Lapiplasty® System Implants, the Lapiplasty® Procedure, the post-operative weight-bearing protocol or health conditions that could affect other outcome measures.
4. Time to start weight-bearing in a boot, in days.
5. Time to start weight-bearing in shoes, in days.

6. Time to return to full unrestricted activity, in days.
7. Change in pain at the base of the big toe (bunion related) assessed via a Visual Analog Scale (VAS) at 0-14 days, 14-21 days, 6 weeks, 4 months, 6 months, 12 months and 24 months post-Lapiplasty® Procedure, in comparison to baseline visit pain.
8. Change in Quality of Life, (PROMIS-29, PROMIS-25 and MOxFQ) defined as the total score measured at 6 months, 12 months and 24 months post-Lapiplasty® Procedure, in comparison to baseline visit.
9. Change in Range of Motion - 1st MTP dorsiflexion and plantarflexion at 12 months and 24 months post-Lapiplasty® Procedure, in comparison to baseline visit.
10. Change, if any, in initial incision length during Lapiplasty® Procedure.
11. Change in radiographic foot length and width at 12 months post-Lapiplasty® Procedure in comparison to baseline visit.
12. Change in swelling at 6 weeks and 4 months post-Lapiplasty® Procedure as compared to 0-2 week visit.
13. Change in scar quality at 4 months, 6 months, and 12 months post-Lapiplasty® Procedure in comparison to baseline visit.
14. Correlation between amount of time external positioner is actively used during Lapiplasty Procedure with necrosis, blistering, bruising and tissue ulceration events.

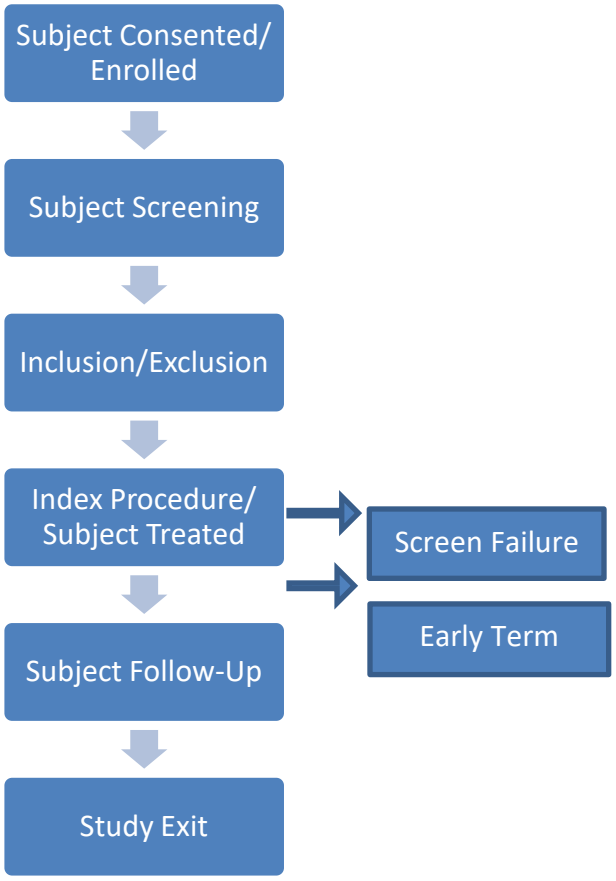
Secondary Endpoints – Health Economic Outcomes

All health economic endpoints are exploratory in nature.

1. Complications below that are related to the Lapiplasty® Procedure or the Lapiplasty® System Implants requiring subsequent secondary surgical interventions, defined as the following: 1) deviations/delay from normal operative plan 2) readmission to hospital 3) return to operating room 4) unscheduled visits due to complications 5) employment of home health services;
    a. Revisions
    b. Hardware removals
    c. Reoperations
    d. Supplemental fixations
    e. Wound healing requiring surgical intervention
    f. Infection at surgical site requiring surgical intervention
2. Time to return to work (or normal household activities if non-working), in days, while noting work status and work classification (sedentary, light work, medium work, heavy work, very heavy work).
3. Time to return to full work, in days (or full household activities if non-working), while noting work status and work classification (sedentary, light work, medium work, heavy work, very heavy work).
4. Post-operative physical therapy requirements required for recovery of the Lapiplasty® Procedure.

4.0 INVESTIGATIONAL PLAN

4.1 Overall Study and Design – Subject Disposition Diagram



Overall Study and Design – Description
Patients 14 years through 58 years with symptomatic hallux valgus will be eligible to participate based on the inclusion and exclusion criteria defined in this protocol.

The overall plan for all subjects consists of the following elements:

- Patients will be informed about the nature of the research, given the ICF to read, and if the patient understands and agrees to the procedure, they will be asked to provide written informed consent. Subjects are considered **enrolled** in the study when they have signed an informed consent;
- Subjects will undergo screening procedures during the baseline visit to determine if inclusion and exclusion criteria are satisfied and the subject is eligible for the study procedure;
- Subjects must meet all inclusion/exclusion criteria before being **treated** in the study. If any eligibility criteria (including intra-operative criteria) are not satisfied, the subject will be considered a screen failure and will not be considered treated in the study;
- Subjects will undergo the Lapiplasty® Procedure, per protocol. Subjects are considered **treated** in the study when biplanar plating at the TMT joint is complete **and** the incision length is confirmed to meet criteria;
- Subjects will be followed for up to 2 years post index procedure to evaluate outcomes and potential complications;
- Subjects will be assessed for AEs and will be instructed to notify the PI of any AEs that occur during the entire course of the study. Data will be recorded into subject source medical records.

4.2 Selection of Study Population

4.2.1 Recruitment

All patients who meet the inclusion criteria will be tracked on a Screening Log. Patients who meet inclusion criteria will be provided with the IRB approved ICF and will have the opportunity to read, understand, and have their questions answered prior to signing the ICF. If the patient agrees to participate in the study and signs consent, the ICF will be completed. The subject must sign and date the ICF prior to any study-specific procedures being performed. The person reviewing the ICF with the subject will also sign and date the ICF. The subject will be given a copy of the signed ICF to keep.

All subjects who sign the ICF will be documented on a paper Screening and Enrollment Log. All subjects who sign the ICF will be entered in the EDC.

Upon entering subject enrollment information into the EDC, each subject will be assigned a unique ID number sequentially in ascending order.

4.2.2 Enrollment and Treatment

- Subjects are considered **enrolled** in the study once the informed consent has been signed by the patient. Subjects who sign a consent document, but do not meet inclusion/exclusion criteria (including intra-operative criteria) will be considered a screen failure. Subjects are considered **treated** in the study when the biplanar plating is complete **and** the incision length is confirmed to meet criteria.

4.2.3 Inclusion Criteria

Patients satisfying the following criteria will be considered the screening population and will be eligible for participation:

1. Male and females between the ages 14 and 58 years at the time of consent;
2. Closed physeal plates at the time of consent;
3. Intermetatarsal angle is between 10.0˚ - 22.0˚;
4. Hallux valgus angle is between 16.0˚ - 40.0˚;
5. Willing and able to adhere to early weight-bearing instructions post-operatively;
6. Capable of completing self-administered questionnaires;
7. Acceptable surgical candidate, including use of general anesthesia;
8. Female patients must be of non-childbearing potential or have a negative pregnancy test within 7 days prior to index procedure;
9. Willing and able to schedule index procedure within 3 months of consent and able to return for scheduled follow-up visits;
10. Willing and able to provide written informed consent.

4.2.4 Exclusion Criteria

Patients satisfying the following criteria will not be eligible for participation:

1. Previous surgery for hallux valgus on operative side;
2. Previous surgeries on operative foot involving fusion of foot or ankle joints (other than hammertoe or lesser toes/digits);
3. Additional concomitant procedures outside of the 1st ray;
4. Moderate or Severe osteoarthritis of the MTP joint based on radiographic imaging (including lack of evident crista) or positive grind test;
5. Symptomatic flatfoot or asymptomatic flatfoot (defined as calcaneal inclination <5˚and talonavicular subluxation/uncovering >50%);
6. BMI >40 kg/m²;
7. Current nicotine user, including current use of nicotine patch;
8. Current clinical diagnosis of diabetes with fasting plasma glucose > 126 mg/dL and/or HbA1c ≥7.0;
9. Current clinical diagnosis of peripheral neuropathy or by assessment on 4-point monofilament test;
10. Current clinical diagnosis of fibromyalgia;
11. Current clinical diagnosis of Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy (CRPS/RSD);
12. Current uncontrolled hypothyroidism;
13. Previously sensitized to titanium;
14. Currently taking oral steroids or rheumatoid biologics;

15. Currently taking immunosuppressant drugs;
16. Insufficient quantity or quality of bone to permit stabilization, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply such as peripheral vascular disease;
17. Active, suspected or latent infection in the affected area;
18. Use of synthetic or allogenic bone graft substitutes;
19. Current diagnosis of metatarsus adductus (defined as MAA ≥ 23˚);
20. Known keloid and hypertrophic scar forming;
21. Scheduled to undergo a same-day bilateral procedure. Patient agrees to refrain from the Lapiplasty® Procedure (or other hallux valgus procedures) on contralateral foot for minimum of 6 months post index procedure;
22. Patient has previously been enrolled into this study for a contralateral procedure;
23. Scheduled for any concomitant procedure that would alter patient's ability to early weight-bear post-procedure;
24. Patient requires an incision >4.0 cm to complete the procedure (determined pre-operatively or intra-operatively);
25. Patient is actively involved with a workman's compensation case or is currently involved in litigation;
26. Patient is currently or has participated in a clinical study in the last 30 days prior to signing informed consent or is considering participation in another research protocol during this study. Exceptions to this include survey clinical studies with no treatment or if subject is greater than 12 months post procedure in the Treace ALIGN3D™ study without ongoing protocol defined AE; these are not exclusionary;
27. Patient has a condition or finding that, in the opinion of the Investigator, may jeopardize the patient's well-being, the soundness of this clinical study, or could interfere with provision of informed consent, completion of tests, therapy, or follow-up.

4.2.5 Removal of Subjects from Study

In accordance with the Declaration of Helsinki and the Code of Federal Regulations, a subject has the right to withdraw from the study at any time for any reason without prejudice to his/her future medical care by the physician or the institution. Should a subject (or subject's legally authorized guardian/representative) decide to withdraw, all efforts will be made to collect and report the final visit observations as thoroughly and timely as possible.

The primary reason for early termination and the date of termination will be recorded in the electronic case report form. Reasons may include:

Investigator Decision

If the subject experiences an adverse event or the Principal Investigator or Medical Monitor believes it is in their best interest to discontinue participation in the study for other reasons, they

will be withdrawn from the study.

Lost to Follow-up

When contact with the subject has been lost without completing the final visit assessment, and every attempt to contact has failed, the subject will be considered lost to follow-up. Final documentation regarding all attempts to contact the subject requesting their return for the final visit should be documented.

Withdrawal of Consent

The subject withdraws consent for participation in the study. Any method of contact with the subject in which they state they no longer want to participate in the study specific activities constitutes withdrawal of consent. When possible the reason for withdrawal will be documented.

Site Termination or Study Termination

A site or study may be terminated. When this occurs all subjects at the site will be withdrawn and documented as early termination. Reasons for site or study termination may include, but are not limited to the following:

- Administrative Concerns (e.g., inadequate subject enrollment, Investigator/institution non-compliance, change of business strategy, etc.);
- Safety Issues, including those due to non-compliance, which substantially affect the risk to benefit ratio of the study subjects at a site or for the study as a whole;
- Regulatory Body Mandate(s).

Other (which may include):

- Protocol deviation, noncompliance or violation;
- Sponsor recommendation;
- Device/index procedure failure, including subjects who had a previously unidentified medical history finding that made treatment with the Lapiplasty® Mini-Incision™ System unfeasible;
- Death.

5.0 PROCEDURE

5.1 General Description

Individual centers and investigators will be selected based on their expertise and proficiency in the Lapiplasty® Procedure utilizing the Lapiplasty® Mini-Incision™ System.

The term index procedure refers only to the use of the Lapiplasty® Mini-Incision™ System during the Lapiplasty® Procedure. All concomitant procedures leading up to and after the Lapiplasty® Procedure and use of any TMC devices are considered concurrent procedures and are to be conducted under the discretion of the surgeon in accordance to the hospital's standard of care.

Note: A recommended procedure is presented below. It is recognized that individual patient anatomic variation, surgical conditions, or surgeon preference may necessitate modifications to the outlined

procedures. Regardless, surgeons must adhere to all TMC device's instructions for use as outlined in the IFU. The Lapiplasty® Mini-Incision™ System will only be used by properly trained and qualified medical personnel in accordance with the Instructions for Use (IFU). Failure to properly follow instructions may result in improper functioning of the device(s). ***No non-Treace products are to be used for the procedures, unless deemed medically necessary by the PI.***

5.2 Lapiplasty® Procedure (Mini-Incision™ Approach) (Index Procedure)

5.2.1 Key Surgical Steps

Mini Dorsal Incision
Make a direct dorsal, 3.5cm (approximate) incision and release the 1st TMT joint with a sagittal saw and osteotome.

Triplanar Correction
Insert SpeedSeeker™ Instrument and apply Mini-Incision™ Positioner over the skin of 1st metatarsal to perform 3-plane correction.

Precision Cuts
Secure the Mini-Incision™ Cut Guide on the SpeedSeeker™ and make precision joint cuts with the correction held in place.

Controlled Compression
Apply the Lapiplasty® Compressor to bring the precision-cut joint surfaces together for controlled apposition of the arthrodesis site.

Plate Application
Utilize the Lapiplasty® Plate Holder to apply the locking plates dorsally and medially, securely positioning the PlantarPower™ Plate across the tension side of the joint.

Multiplanar Fixation
Low-profile Lapiplasty® Biplanar Plating is designed to provide multiplanar stability.

5.3 Post Index Procedure – Post-Operative Care and Weight-Bearing Instructions

The appropriate post-operative care and the timing to return the subject to weight-bearing is at the discretion of the Investigator/Institutional SOC and takes into consideration the subject's ability to safely begin weight-bearing. However, for purposes of this study, subjects should be bearing weight in a CAM boot by 3 weeks post-operatively. Below is a recommended approach for a patient's post-operative care.

- Subject may be either bandaged, put in splint/cast or put in boot at the time of surgery. If subject is fitted with CAM boot at discharge, the subject should be provided instructions on how to begin protected weight-bearing (see bullet 5). *The type of post-operative surgical protection utilized will be recorded on the eCRF. If subject is allowed to begin protected weight-bearing (in boot) at*

discharge, the date that the subject is allowed to start weight-bearing in the boot will be recorded on the eCRF.

- Subject is instructed to remain off the operative foot as much as possible for the first few days post-op. This is to limit bleeding and swelling and to allow soft tissues to recover.
- Subject leaves the surgery facility with crutches, walker, rolling knee scooter or wheelchair. *The type of post-operative mobility aid utilized will be recorded on the eCRF.*
- At the first post-op visit (00-14 days), bandages are removed, and the subject can be allowed to shower. Subject may wear an athletic sock. No bandages or splints are needed. The subject should be reminded of post-op care of the foot/surgical site.
- At the first or second post-op visit (0-14 days or 14-21 days), if the subject has not already been fitted for a CAM boot at discharge, the subject is fitted with a CAM boot (low or high). Subject should be provided with instructions on how to begin protected weight-bearing in the CAM boot and acceptable activities:
    - Subject is instructed to put weight on foot as tolerate in the restrictive boot.
    - Subject is instructed not to roll forward onto the big toe and should remain on flat foot.
    - Subject is instructed to remove the CAM boot multiple times daily and perform range of motion exercises for ankle and foot.

  NOTE: The subject must be fitted with a CAM boot and allowed to start protected weight-bearing no later than 3 weeks post-operatively. *The date that the subject is allowed to start weight-bearing in the boot will be recorded on the eCRF.*

  *NOTE: If the subject is unable to start weight-bearing by 3 weeks, the reason for the delay in weight-bearing should be documented on the eCRF as a protocol deviation. The subject should be brought in for an Unscheduled Visit (**See Section 7.10**) when they are ready to begin protected weight-bearing in the boot.*
- At the first or second post-op visit (0-14 days or 14-21 days), compression socks may be provided to the patient. The start date and the stop date (approx. by the 4-month visit) of use of the compression sock will be recorded.
- At the 6-week post-op visit, if the subject is clinically stable, patient can transition from the boot to a shoe (running or another athletic shoe). *The date that the subject is allowed to start to WB in a shoe will be recorded on the eCRF.* The transition from boot to shoe may occur over a period of days/weeks, depending on patient healing and tolerance. Subject are instructed that they can walk normally but are not to stand on toes, run, jump or do any other high impact activity.
- At the 4-month post-op visit, subjects are allowed to begin low impact exercise if they are clinically stable. *The date that the subject is allowed to start full unrestricted activities (i.e., running and jumping) will be recorded on the eCRF.*

5.4 Pain Management

The decision to administer pain medication therapy in the pre- and post-operative/follow-up setting is at the discretion of the Investigator/Institution taking into consideration the subject's ability to safely take pain medication therapy.

It is recommended that a multi-modal pain regimen be considered which would include, but not be limited to: ice, elevation, local & regional anesthesia, NSAIDs, acetaminophen, neuro-modulation drugs and narcotics.

The decision of which pain medications to use (if any) is left to the discretion of the Investigator. Pain medications taken for pain management during the pre- and post-operative/follow-up period will be recorded.

6.0 IDENTITY OF STUDY DEVICES

The devices utilized for the study include:

Mini-Incision™ Precision Instrument Set
Lapiplasty® Mini-Incision™ System

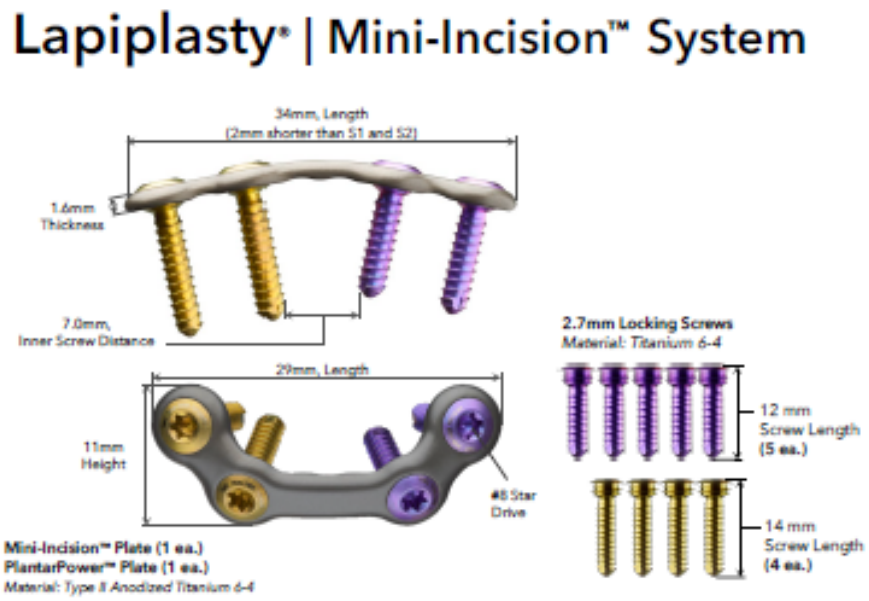
The TMC Plating System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet. The system can be used in both adult and pediatric patients aged >12 years.

All medical devices used during this study are cleared for commercial distribution and are to be used in accordance with approved product labeling.

Device Description
The Lapiplasty® Mini-Incision™ Precision Instrument Set includes the SpeedSeeker™ Instrument, the Mini-Incision™ Positioner, the Mini-Incision™ Cut Guide and the Plate Holder. These are reusable instruments and not unique to each patient. The actual components in the instrument pack may vary by site.

The Lapiplasty® Mini-Incision™ includes the Mini-Incision™ Plate and the PlantarPower™ Plate and locking screws. The PlantarPower™ Plate is uniquely contoured to span plantarly across the tension-side of the 1st TMT joint, while providing easy access to each locking screw without the need for extensive retraction of the mini dorsal incision. (See Figure 1)

Figure 1



6.1 Product Accountability

Commercially available devices will be utilized for the study subjects; therefore, product accountability and reconciliation records will not be required. Devices will not be provided by the sponsor. Study devices and instruments that are used during each procedure will be documented on the eCRFs as listed in Visit 2.

7.0 SUBJECT VISITS

Details for specific subject visit activities are found below and reflect the Schedule of Assessments table.

7.1 Visit 1 – Baseline

Subjects will be screened for study participation during the baseline visit. The procedures required for the baseline visit may be conducted during more than one visit. Some baseline procedures may have been completed as patient standard of care (including radiographic imaging) and therefore may be completed prior to informed consent and do not need to be repeated after consent.

The following procedures must be conducted within 90 days prior to the index procedure.

- Informed Consent
- Demographics [including foot size (length and width) of operative foot and work status/work classification]
- Relevant Medical and Surgical History, including any previous history of foot surgery and any pre-planned surgical foot procedures
- Targeted Physical Exam
- Height / Weight (including BMI calculation)
- Blood Collection – (fasting plasma glucose or HbA1c – only required if patient has current clinical diabetes diagnosis)
- 4-Point Monofilament Test (only required if patient has current clinical diabetes diagnosis or if suspicion of peripheral neuropathy based on medical history)
- Clinical Examination of Operative Foot
- Foot Measurements
- Range of Motion
- Radiographic Imaging
    - Weight-bearing AP, lateral and axial views of operative foot
- Radiographic Measurements
    - Note: For the purposes of determining IMA, HVA and MAA for patient eligibility, measurements will be made according to institutional SOC. For the purposes of all data analysis, measurements by the central radiologist will be utilized. If there are minor differences in baseline IMA, HVA and MAA measurements made by the central radiologist, the measurements of the PI/site will remain acceptable for determining patient eligibility.
- VAS Pain Scale
- QOL Measurements
- Digital photograph of operative foot, preferred but not required
- Medications Review
- Pregnancy Test (if female of childbearing potential)
    - Must be within 7 days of index procedure or may be completed on day of index procedure
- Inclusion/Exclusion Criteria

7.2 Visit 2 –Index Procedure

The following must be conducted:

- Exclusion Criteria (confirm patient has abstained from nicotine use prior to anesthesia)
- Medical History [if relevant medical history (e.g., related to bone quality or patient condition that does not exclude them from participation in study) is identified during index procedure]
- Foot Measurements
- Index Procedure
    - Start and stop time of tourniquet placement
    - Time of first incision and placement of final plate screw
    - Length of incision at start of procedure
    - Extension of incision and location of extension (proximal, distal or both), as applicable
    - Completion of lateral release
    - Use of SpeedSeeker™ device (or fulcrum and joint seeker)
    - Total length of time of use of Mini-Incision™ Positioner
    - Use of Mini-Incision™ Cut guide
    - Joint morphology of articular surface (uni-facet, bi-facet, or tri-facet), if feasible
    - Use of Compressor device
    - Use of Mini-Incision™ System
    - Use of Transverse Screw and location of screw placement, if applicable
    - Use of Interfrag Screw at TMT joint, if applicable
    - Use of additional plate screws (Long Screw Pack, FastPitch™ Screw Pack, other), if applicable
    - Use of Headless Screw for Akin procedure, if applicable
    - Length of incision after suturing complete
        - If incision required extension beyond >4.0 cm to complete Index Procedure, the subject will be treated as a screen failure.
- Digital photograph of operative foot, post-incision, not required
- Post-op surgical dressing/protection utilized
- Concomitant Procedures performed
- Deviations/Delays to Normal Operative Plan
- Medications Review (Pre-operative and Post-operative)
- Adverse Events Assessment, including Intra-Operative Procedural Complications
- Post-op Care instructions review
    - Post-op mobility assistance device utilized
- Post-op Weight-Bearing protocol instructions review

7.3 Visit 3 – 0-14 Day Follow-Up

The following must be conducted:

- Digital photograph of operative foot, not required
- Clinical Exam of operative foot
- Foot Measurements
- Wound Assessment/healing of surgical site including damage by external positioner
- VAS Pain Scale
- Post Operative use of compression sock, if applicable
- Return to Weight-Bearing Activities (CAM boot fitting, if not on day of surgery)
- Secondary Surgical Interventions
- Medications Review
- Adverse Event Assessment
- Health Economic Outcomes

7.4 Visit 4 – 14-21 Day Follow-Up (+ 3 days)

The following must be conducted:

- Digital photograph of operative foot, not required
- Clinical Exam of operative foot
- Foot Measurements
- Wound Assessment/healing of surgical site including damage by external positioner
- VAS Pain Scale
- Post Operative use of compression sock, if applicable
- Return to Weight-Bearing Activities (CAM boot fitting – if not at previous visit)
- Secondary Surgical Interventions
- Medications Review
- Adverse Event Assessment
- Health Economic Outcomes

7.5 Visit 5 – 6 Week Follow-Up (± 2 weeks)

The following must be conducted:

- Digital photograph of operative foot, not required
- Radiographic Imaging (axial view may be missed if patient is unable to use positioning block due to post-operative range of motion limitations)
- Clinical Exam of operative foot
- Foot Measurements
- Wound assessment/healing of surgical site including damage by external positioner
- VAS Pain Scale
- Post Operative use of compression sock, if applicable

- Return to Weight-Bearing Activities
- Secondary Surgical Interventions
- Medications Review
- Adverse Event Assessment
- Health Economic Outcomes
- Radiographic Measurements

7.6 Visit 6 – 4 Month Follow-Up (± 2 weeks)

The following must be conducted:

- Digital photograph of operative foot, not required
- Radiographic Imaging
- Clinical Exam of operative foot
- Foot Measurements
- Wound assessment/healing of surgical site including damage by external positioner
- VAS Pain Scale
- Post Operative use of compression sock, if applicable
- POSAS
- Range of Motion
- Return to Weight-Bearing Activities
- Secondary Surgical Interventions
- Medications Review
- Adverse Event Assessment
- Health Economic Outcomes
- Radiographic Measurements

7.7 Visit 7 – 6 Month Follow-Up (± 1 month)

The following must be conducted:

- Digital photograph of operative foot, not required
- Radiographic Imaging
- Clinical Exam of Operative Foot
- Foot Measurements
- POSAS
- QOL Measurements
- VAS Pain Scale
- Range of Motion
- Return to Weight-Bearing Activities
- Secondary Surgical Interventions
- Medications Review

- Adverse Event Assessment
- Health Economic Outcomes
- Radiographic Measurements

7.8 Visit 8 - 12 Month Follow-Up (± 1 month)

The following must be conducted:

- Digital photograph of operative foot, not required
- Radiographic Imaging
- Clinical Exam of Operative Foot, including Clinical Pain Assessment at 1st TMT Joint
- Foot Measurements
- POSAS
- QOL Measurements
- VAS Pain Scale
- Range of Motion
- Secondary Surgical Interventions
- Medications Review
- Adverse Event Assessment
- Health Economic Outcomes
- Radiographic Measurements

7.9 Visit 9 – 24 Month Follow-Up (± 2 months)

The following must be conducted:

- Digital photograph of operative foot, not required
- Radiographic Imaging
- Clinical Exam of Operative Foot, including Clinical Pain Assessment at 1st TMT Joint
- POSAS
- QOL Measurements
- VAS Pain Scale
- Range of Motion
- General Satisfaction Questionnaire (Appendix 10)
- Secondary Surgical Interventions
- Medications Review
- Adverse Event Assessment
- Health Economic Outcomes
- Radiographic Measurements

7.10 Unscheduled Visit

If a subject requires an unscheduled visit due to a complication associated with the Lapiplasty® Procedure or Lapiplasty® device, for suspected non-union or for additional follow-up on start of WB activities, the following should be conducted:

- Reason for Visit (complication/adverse event, suspected non-union or WB instructions)
- Clinical Exam of Operative Foot
- Return to WB Activities, if applicable
- Adverse Event Assessment
- Radiographic Imaging (if required due for assessment of complication)

7.11 Study Exit

At study exit the following must be collected.

- Study Exit Date
- Exit Reason

7.12 Study Visit Descriptions

All study procedures should be conducted at the investigational site.

Demographics – Date of birth (age), sex, race, ethnicity, foot size (length and width) and work status including work classification (sedentary, light work, medium work, heavy work, very heavy work – see **Appendix 1** for definitions). Foot size measurements must be done with study provide tool.

Relevant Medical and Surgical History – Medical history includes, but is not limited to, relevant comorbidities (documentation of nicotine use status, any immunosuppressive disease, any endocrine disease, diabetes, osteoporosis, hypertension, cerebrovascular disease, chronic kidney disease, depression, rheumatoid arthritis, psoriatic arthritis, fibromyalgia, and peripheral neuropathy). Any relevant medical conditions that are identified during the index procedure, which were not identified during the baseline visit, should be recorded as medical history (not as an adverse event or surgical complication).

Relevant surgical history includes, but is not limited to, previous operative foot surgery (including a previous Lapiplasty procedure on opposing study foot). Any planned surgical interventions should also be recorded.

Targeted Physical Examination: A targeted physical exam (PE) will be conducted according to institutional SOC. If any findings are noted during the PE, the finding should be recorded in the source documents as medical history, as appropriate.

Height/Weight – will be collected according to institutional SOC. BMI should be calculated to determine if the patient is eligible to participate in the study.

Medication Review: All medications, including vitamins or nutritional supplements currently prescribed to, or taken by, the subject shall be recorded in the subject's source documents. If Vitamin D is taken by the subject, it must be recorded on the eCRFs. Anti-inflammatory medications/medications that affect

swelling, medications taken as part of the multi-modal pain therapy or medications taken for pain related to surgery, or bunion/foot pain or medications for complications due to procedure (e.g. antibiotics for a surgical site infection) also must be recorded on the eCRFs.

Blood Collection – HgbA1c or fasting plasma glucose must be measured only for any patient that has a clinical diagnosis of diabetes, prior to confirming the patient is eligible to participate in the study.

4-Point Monofilament Test – Test must be conducted per institutional SOC for any patient that has a clinical diagnosis of diabetes, prior to confirming the patient is eligible to participate in the study.

Radiographic Imaging – Image collection will be conducted per institutional SOC but must include the following views at each timepoint: weight-bearing AP, lateral and axial (6-week follow-up axial view optional). A positioning block will be provided and must be utilized for the axial view. A radiographic imaging protocol will be provided for instructions on collection and transmission of the radiographs for the radiographic measurements.

VAS Pain Scale – See **Appendix 2**. The subject should be requested to read the Mankoski Pain Scale Definitions prior to completing the scale. The subject should be instructed to rate pain associated with the base of the big toe (bunion related) for the operative foot only.

QOL Measurements: See **Appendix 3**. The MOxFQ and PROMIS-29 (PROMIS-25 for ages 14-17) will be collected per the questionnaire instructions. The same version of the PROMIS (25 or 29) questionnaire completed at baseline on a subject must be used for all follow-up visits for comparability of results.

Wound Assessment/Healing of surgical site: – Evaluation of all incision site(s) to assess for wound healing/surgical site healing. Normal/expected pain, swelling, redness, etc. does not require documentation as an adverse event. However, infections or wound healing complications requiring treatment/intervention or pain, swelling, redness, etc. that is considered substantially worse than anticipated should be recorded as an AE. In addition, damage caused specifically by the external positioner must be documented in eCRF. Potential complications due to external positioner may include, but not be limited to, necrosis, bruising, blistering, and/or tissue ulceration. If complications occur, they should be recorded as Adverse Events and Product Complaints. It is ultimately the decision of the PI to assess any undesirable medical condition and report as an AE.

Clinical Exam of Operative Foot – The clinical examination of the operative foot should include, but not be limited to, inspection and palpitation of foot, assessment of hallux position, MTP joint range of motion and pain at the TMT joint (measured with manual stress exam and palpation of joint), pain under the 2nd and/or 3rd toe at the ball of the foot, neurovascular exam including assessment for neuropathy, range of motion, passive correction of deformity, any other associated deformities. A dermatology examination of the operative foot should also be performed. Any callus, skin inflammation, blisters or sores that occur at the MTP should be recorded.

Adverse Event Assessment: Refer to description of collection of Adverse Events (**refer to Section 10.1**). This specifically includes complications of treatment intervention including wound/incision healing requiring intervention, hardware removal, revision procedure of the 1st ray and any other complication requiring surgical intervention.

Foot Measurements–

Baseline and Pre-operatively

Using a flexible tape measure, measure the circumference of the forefoot using the most prominent projection at the medial 1st metatarsal head and the lateral 5th metatarsal head as the starting reference points. Measure in a circumferential manner. Remove slack from the tape so that it lays flat on the skin.

Using a flexible tape measure, measure the circumference of the foot using the 1st TMT articulation as the starting reference point. Determine the position of the TMT via manipulation of the metatarsal through a dorsiflexion/plantarflexion movement. Palpation and visualization of the joint puckering through the soft tissue will allow for the approximation of this landmark. Mark the area with a surgical marking pen for reference. If this is unsuccessful in allowing the surgeon to determine the level, a metallic bb marker can be placed on the skin and plain film radiographic imaging can be utilized to approximate the anatomy. Determine the TMT position and measure in a circumferential manner. Remove slack from the tape so that it lays flat on the skin.

Using a flexible tape measure, measure the circumference of the ankle using the medial and lateral malleolus as reference points. Hold the measuring tape just superior to the inferior edge of the medial malleolus. Wrap the tape around the ankle, remove all slack and ensure the tape is flat on the lateral malleolus. The measurement should be made perpendicular to the longitudinal axis of the tibia and fibula.

Measure the circumference of the mid-calf at the tibia. Approximate the Myotendinous junction of the gastroc. Measure the distance from this landmark to the popliteal fossa. Determine the midline and measure in a circumferential manner. Remove slack from the tape so that it lays flat on the skin.

Post-operatively

Using a flexible tape measure, measure the circumference of the forefoot using the most prominent projection at the medial 1st metatarsal head and the lateral 5th metatarsal head as the starting reference points. Measure in a circumferential manner. Remove slack from the tape so that it lays flat on the skin.

Using a flexible tape measure, measure the circumference of the foot using the midpoint of the surgical incision as the starting reference point. Determine the midline and measure in a circumferential manner. Remove slack from the tape so that it lays flat on the skin.

Using a flexible tape measure, measure the circumference of the ankle using the medial and lateral malleolus as reference points. Hold the measuring tape just superior to the inferior edge of the medial malleolus. Wrap the tape around the ankle, remove all slack and ensure the tape is flat on the lateral malleolus. The measurement should be made perpendicular to the longitudinal axis of the tibia and fibula.

Measure the circumference of the mid-calf at the tibia. Approximate the Myotendinous junction of the gastroc. Measure the distance from this landmark to the popliteal fossa. Determine the midline and measure in a circumferential manner. Remove slack from the tape so that it lays flat on the skin.

Range of Motion – Dorsiflexion and plantarflexion should be measured while subject is passive and non-weightbearing with the study provided goniometer. To measure ROM, the arms of goniometer should be lined up parallel to longitudinal axis of the 1st metatarsal and proximal phalanx of the hallux with the axis at the center of rotation of the first metatarsal head.

Radiographic Measurements - Radiographic measurements will be analyzed by a third-party independent radiologist and entered into Clindex. The radiographic measurements that will be collected, at a minimum, are provided in **Appendix 4**. Additional exploratory radiographic measurements may be collected without requiring a protocol amendment.

Index Procedure – **See Section 7.2** for complete list of data collected during the Index Procedure. Concomitant procedures of the 1st ray should also be recorded. These include but are not limited to, akin osteotomy, bone graft harvest (synthetic or allogenic bone graft substitutes are not permitted), intercuneiform stabilization, traditional medial eminence resection, rongeur of the medial capsular ridge, and/or dorsal metatarsal bone resection. No concomitant procedures that alter the post-operative WB instructions are permitted (including evans and other calcaneal osteotomies, lesser TMT joint fusions, lisfranc or metatarsus adductus). Any complications during the procedure or deviations to the normal operative plans must also be recorded.

POSAS: See **Appendix 9.** The Patient and Observer Scar Assessment Scale will be collected per the Assessment instructions.

Return to Weight-Bearing Activities – The actual date that the subject was allowed to start to return to weight-bearing activities (protected WB in CAM boot, shoe and full unrestricted activities) should be recorded. The number of days from index procedure will be calculated by Clindex. **See Section 5.3** for post-operative care and weight-bearing instructions.

Secondary Surgical Interventions: Any adverse event/complication that requires a subsequent secondary surgical intervention should be recorded. The reason for the subsequent surgical intervention and the action taken should be recorded. Subsequent secondary surgical interventions are defined as revisions, hardware removals, reoperations, supplemental fixations or other surgical intervention due to wound healing issues or infections at surgical site.

Health Economic Outcomes: The date the subject was allowed to return to work (or normal household activities if non-working), should be recorded while noting work status and work classification (sedentary, light work, medium work, heavy work, very heavy work). The date the subjects was allowed to return to full work (or full household activities if non-working), should be recorded while noting work status and work classification (sedentary, light work, medium work, heavy work, very heavy work – See **Appendix 1** for definitions). Any post-operative physical therapy requirements required for recovery of Lapiplasty® Procedure should be recorded. Any employment of home health services and the reason should be recorded.

8.0 DATA MANAGEMENT AND INTEGRITY

8.1 Data Completion and Record Keeping

8.1.1 Source Documents

Source documents are documents on which information regarding subjects are first recorded. PI subject files or hospital records generally are the basis of source document information. This may include but is not limited to, original subject files, hospital/clinic records, original recordings/tracing, and digital images from automated instruments, X-ray films, and laboratory results.

Source documents must be retained by the PI as part of the subject's permanent medical record. The information in the source documents is used to complete the eCRFs. All information captured on the eCRFs should be completely and accurately supported in source documentation. Study Monitors will verify data reported on eCRFs with site source documents. Any additional information relevant to the study should be included in the source documents. Any deviations from the study protocol or procedures should be recorded in the source documents. The PI will retain originals of all source documents, subject consent forms, and study data.

8.1.2 Data Collection

An EDC system will be utilized by study site personnel to transfer study data from source records (medical records and/or source document worksheets) onto common eCRFs. This system is a web-based, secure electronic software application. This system is designed, developed, and maintained in a manner that is compliant with national and international GCP data protection/data privacy and electronic record/electronic signature (e.g., 21 CFR Part 11) regulatory requirements. The platform software has been validated in accordance with 21 CFR Part 11, European Commission's Directive on Data Protection and US Safe Harbor Certification. Prior to being released for data entry, validation of the study level components (i.e., data entry screens, associated edit checks and workflow) will be conducted in accordance with approved user acceptance testing procedures. Access to this system will be controlled so that only authorized users will have the ability to enter into the system. The system is considered a closed system according to 21 CFR Part 11 Electronic Records; Electronic Signatures.

The EDC system will be used to facilitate the collection of all study data at the site. Designated site personnel will be responsible for entering subject data into the EDC system. All external and Sponsor internal users will be trained on the EDC application at a level dependent on their planned function.

An EDC User Manual will be available to assist in the collection and entry of source data into the electronic casebook.

Investigative study sites will be asked to enter subject data into the eCRFs no later than 2 weeks from the time the subject was seen for their scheduled study visit.

Detailed description of the eCRF components is included in the eCRF Completion Instructions. These will be provided to the Investigators prior to initiating subject enrollment. The respective eCRFs must be fully completed for each subject and signed electronically.

Data collected during the clinical investigation for each subject will be maintained as accurately and

completely as possible with entries into an electronic data capture system provided by TMC. The personal data recorded on all documents, including copy documents, and within the system will be regarded as confidential. The Investigator will be responsible for the timing, completeness and accuracy of the details entered within the electronic data capture system. All data entered into the database must have supporting source documentation in the subject's medical records.

Data will be entered into the electronic data capture system by members of the Investigational study site team who have received training in the use of the system. The system will generate data queries at the point of data entry based on validation checks defined by TMC. Such validation checks will primarily be focused on validation of key variables including selected subject demographics, appropriate value ranges and date checks. Resolution of the queries will be the responsibility of the Principal Investigator and investigation team members. Following completion of all data queries on each eCRF, the Principal Investigator will be responsible for reviewing and confirming agreement to the data within the system.

The Investigator must record the subject's participation in this clinical investigation in the subject's hospital notes. In addition, the Investigator must keep a separate list of all subjects entered into this clinical investigation showing each subject's name, date of birth and assigned subject number (for identification purposes). A Subject Identification Log will be provided in the Investigator's File for this purpose.

8.1.3 Data Correction

Corrections to eCRFs will be prompted via automated electronic edit checks and queries manually created by reviewers. The corrections and the individual making the correction(s) to the eCRF will be made within the EDC system.

8.1.4 Investigator Regulatory Binder

Each Investigator must maintain an accurate, complete and current copy of the Investigator Regulatory Binder. Upon receipt of copies of changes or revision updates to the Binder from the Sponsor, the Investigator will add the updated document to the Regulatory Binder. If an Investigator holds multiple copies of the Regulatory Binder, then all copies must be updated with the current revisions.

8.1.5 Study Correspondence

Each Investigator and all personnel from the investigational site will maintain records of all correspondence, electronic, written, and verbal, relating to any aspect of the clinical investigation. The records are maintained in the Investigator Regulatory Binder consisting of, but not limited to correspondence with other participating clinical investigators, the reviewing IRB, and the Sponsor. The Clinical Research Associate (CRA) will examine the contents of the correspondence.

8.1.6 Data Privacy

Subjects will be made aware that their personal data will be collected and processed in accordance with data protection legislation including the Health Insurance Portability and Accountability Act of 1996

(HIPAA). Subjects will be asked to sign an Authorization for Release of Personal Health Information (PHI) for the purpose of this investigation. This authorization may be combined with the ICF depending on local IRB preference. Results from the Clinical Investigation may be published. However, subject confidentiality will be maintained at all times, and it will not be possible to identify individual subjects from any data presented.

8.1.7 Record Retention, Inspection, and Custody

The PI must maintain all documentation related to the study until notified by the Sponsor. The PI will allow representatives of the Sponsor, IRB, the FDA, or other government regulatory agencies to inspect all study records, eCRFs, and corresponding portions of the subject's office and/or hospital medical records at regular intervals during the study. These inspections are to verify adherence to the protocol, integrity of the data being captured on the eCRFs, and compliance with applicable regulations.

Subject medical records will be kept confidential. Study reports will not identify subjects by name. These reports may be submitted to the FDA and/or regulatory authorities.

If custody of the records is transferred, notice of such a transfer should be given to the Sponsor no later than ten (10) working days after the transfer occurs.

The Investigator should retain copies of all documents pertaining to this clinical investigation (including source documentation, the informed consent document and any other documents to identify the subjects) for at least 2 years after this clinical investigation is completed. In addition, if the Clinical Investigator moves/retires, etc., he/she should provide TMC Inc. the name and address of the person who will look after and be responsible for the subjects' clinical investigation related records.

8.1.8 Medical Dictionary Coding

Medical dictionary coding will be performed using a coding thesaurus algorithm. The MedDRA will be used upon data entry and query resolution for AEs and SAEs, via automated and manual coding processes.

8.1.9 Data Quality Assurance

Quality control and quality assurance processes implemented during this study to ensure subject safety rights, and welfare are protected and to foster data integrity are characterized below.

8.1.10 Investigator Training - Protocol Specific Training

Protocol training will be scheduled once IRB approval is obtained, and the Clinical Study Agreement is executed. TMC will train the study site on the protocol and that training will be documented. It is ultimately the responsibility of the Investigator to ensure all clinical site personnel participating in this study are trained.

The index procedure may only be performed by qualified investigators, familiar with the Lapiplasty® Procedure and related study procedures and techniques.

8.1.11 Monitoring

This study will be monitored by the sponsor to ensure:

- The rights, safety and well-being of the subjects are protected;
- The reported study data is accurate, complete, and verifiable from source documents; and
- The conduct of the study is in compliance with the currently approved protocol/amendment(s), applicable GCPs, and with applicable local/regional regulatory requirements.

TMC, as Sponsor of this study, will be responsible for monitoring this study. The CRA duties are to aid the Principal Investigator in the production and maintenance of complete, legible, well-organized and easily retrievable data. In addition, the CRA will be responsible for assuring the Principal Investigator understands the protocol and all applicable regulations. Approaches to monitoring include on-site visits and may include remote visits, as appropriate, and the rationale and frequency for monitoring will be at the Sponsor's discretion. The extent and nature of monitoring will be predetermined and based on considerations such as the objective, design, complexity, and endpoints of the study and mutually agreed to by the Sponsor. The frequency of monitoring will be determined for each site based on factors including: the planned enrollment, the rate of enrollment, and the current study conduct. Study conduct can be evaluated remotely based on compliance percentage, discrepancy rate and discrepancy type. CRAs will be trained on and comply with established standard operating procedures as well as a written monitoring plan specified by the Sponsor.

To perform the monitoring role effectively, the CRA must verify eCRF entries with source documents. The CRA must be given access to primary subject data which supports the information recorded on the eCRF, i.e. hospital notes, appointment books, original laboratory records, etc. Access to these documents must also be given to the regulatory authorities in the instance of an external inspection. Since a subject has the right to refuse access to these documents on the grounds of confidentiality, consent to access is included in the informed consent document, which the subject signs.

The Principal Investigator will receive reasonable notification prior to each monitoring visit during the course of this clinical investigation. At each visit, the Principal Investigator will be expected to cooperate with the CRA for the review and verification of eCRFs and any additional records that may have been previously arranged between the Principal Investigator and the CRA.

8.2 Changes to Protocol, Protocol Deviations and Protocol Amendments

8.2.1 Changes to Protocol

The Investigator should not implement any deviation from, or changes to the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB of an amendment, except where necessary to eliminate an immediate hazard(s) to study subjects, or when the change(s) involves only logistical or administrative aspects of the study (e.g., change in CRA(s), change of telephone number(s)). In the event of an emergency situation, the Investigator must notify the CRA or TMC immediately. A full written report of the situation must be forwarded to the IRB who approved the original protocol and TMC within 10 working days of the event.

8.2.2 Protocol Deviations

The Investigator agrees to conduct the study in accordance with this protocol; however, protocol deviations may occur during the course of the study. Protocol deviations are events occurring during the conduct of the study which are not in compliance with the protocol and for which an amendment has not been granted. Protocol deviations can be committed by the Sponsor, the PI, or the study subject. A deviation can be identified by a number of sources. Potential sources include but are not limited to: a member of the PI's staff, the CRA during monitoring visits, or a member of the data management or statistical groups when entering or analyzing data. The PI or PI's representative are encouraged to contact the CRA or TMC as soon as possible upon observing a protocol deviation. Regardless of the source, it is crucial to document the deviation and record all corrective actions. Protocol deviations will be reported in the final report.

The process for capturing deviations will be detailed in the monitoring plan. The process will require that documentation describe the deviation, and appropriate actions taken and will be included in the study file for the respective PI and subject. The study site representative will be advised to record the deviation and relevant discussion with the Sponsor about the deviation in the subject's source documentation.

Protocol deviations affecting the scientific soundness of the study or the rights, safety, or welfare of the subjects, will be reported by the PI, as required by the IRB.

Protocol deviations will be summarized and grouped into relevant categories for analysis and may include, but are not limited to, subjects who:

- Entered the study although they did not satisfy the eligibility criteria;
- Completed incorrect version of PROMIS based on age of subject
- Did not return to protective weight-bearing activities by 3 weeks (+3 days);
- Received Lapiplasty® Procedure (or other hallux valgus procedures) on contralateral foot less than 6 months after initial index procedure; or
- Developed withdrawal criteria during the study but were not removed from study participation.

8.2.3 Protocol Amendments

If it becomes necessary to amend the protocol, then the nature of the amendment will be agreed upon by the Sponsor and the Principal Investigator(s) and this will be recorded with a justification for the amendment. The appropriate IRBs will be informed of amendments prior to implementation of the change.

9.0 STATISTICAL CONSIDERATIONS

In this prospective, single arm, non-comparative study, the analyses will be mainly descriptive. Inferential statistical methods, if applied, will be utilized to highlight the data aspect of interest. Unless otherwise specified, statistical tests will be 2-sided using a 0.05 statistical significance level. Corresponding 95% confidence intervals will be presented as appropriate. No corrections for multiple

testing will be applied. Full details of all statistical issues and planned statistical analyses will be specified in a separate statistical analysis plan, which will be finalized prior to the locking of the study database.

9.1 Analysis of the Conduct of the Study

The number of subjects enrolled in the study will be tabulated by the center. A subject disposition table will be tabulated, and will include the number of subjects enrolled, treated, and completing the study. Subject discontinuations and reasons for discontinuation will be summarized.

9.2 Sample Size

There is no formal sample size calculation as this is a single arm study and is descriptive in nature. A sample size of 200patients is chosen, ensuring the feasibility of the study as clinical findings suggest that the bunion recurrence rate after the Lapiplasty® Procedure is low.

9.3 Analysis Population

Intent-to-Treat (ITT) population: The ITT population is defined as all enrolled subjects who were treated with the Lapiplasty® Procedure using the Mini-Incision™ System.

Per-Protocol (PP) Population: The per-protocol population is defined as all enrolled subjects who were treated with the Lapiplasty® Procedure using the Mini-Incision™ System who did not experience a major protocol violation. Major protocol violations include, but are not limited to, subjects who:

- Entered the study although they did not satisfy the eligibility criteria;
- Completed incorrect version of PROMIS based on age of subject;
- Did not return to protective weight-bearing activities by 3 weeks (+3 days);
- Received Lapiplasty® Procedure (or other hallux valgus procedures) on contralateral foot less than 6 months after initial index procedure; or
- Developed withdrawal criteria during the study but were not removed from study participation.

9.4 Analysis of Study Endpoints

All analyses of efficacy, safety, and health economic endpoints will use the ITT population. If the PP and ITT populations differ considerably, the PP population may be used for supportive efficacy analyses to evaluate the influence of major protocol violations on key endpoints.

9.5 Missing Data

Efficacy and health economic analyses will be based on available data, without imputation for missing values. For the Quality of Life outcomes, missing data will be handled as specified in the PROMIS-29, PROMIS-25 and MOxFQ scoring manuals. For safety analyses, missing event dates will be imputed as follows:

- If only month and year are reported, then day is assigned as the 15th of the month

- If only year is reported, then month and day is assigned as July 1st

9.6 Interim Analyses

Interim analyses will be performed during the study according to patient enrollment and availability of data of interest. Interim analyses will be used to provide early information about the safety and efficacy of the procedure and may be used for internal decision making, hypothesis generation, abstraction/publication for major orthopedic conferences, or other purposes, as applicable. Interim analyses will follow the methods in the statistical analysis plan.

9.7 Safety Analyses

AEs related to the Lapiplasty® Procedure and the Lapiplasty® devices will be reported on the eCRF. These AEs will be listed and descriptively summarized for all subjects. No formal statistical hypothesis will be tested.

9.8 Detailed Analysis Plan

Prior to database closure, a detailed statistical analysis plan will be finalized to completely specify the statistical procedures to be applied to the data by the statistician who will conduct the analysis. The plan will amplify the methods discussed in this protocol, will address any protocol changes that would affect the analysis, and will provide a rationale for any changes to the analysis.

10.0 SAFETY MONITORING

Subject safety will be monitored throughout the course of this study by monitoring for Adverse Events and Product Complaints related to the Lapiplasty® Mini-Incision™ System Implants, the Lapiplasty® Mini-Incision™ Precision Instrument Set. The Lapiplasty® devices used during the index procedure for the clinical study have been cleared for marketing by the FDA and are being used within the current labeling and indications for use. Any event that occurs that may have caused or contributed to a death or serious injury or that indicates that the devices have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur will be reported in compliance with 21 CRF Part 803.

In addition to general surgical risks (risks associated with anesthesia, infection, damage to nerves and blood vessels, and bleeding or blood clots), additional risks specifically associated with the Lapiplasty® System Implants are as follows:

- Infection or adverse reaction for a foreign body;
- Pain, discomfort, or abnormal sensations due to the presence of the implant;
- Loosening, bending, cracking or fracture of the components or loss of fixation of bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures;
- Loss of anatomic position with nonunion or malunion with rotation or angulation;
- Migration of the implant, loosening of the implant;
- Delayed correction in alignment;
- Decrease in bone density due to stress shielding;

- Bursitis;
- Additional surgery if the device is not placed in the correct position.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture is healed. If any of these complications occur, the surgeon must make the final decision on implant removal.

There may also be other risks that are unforeseen at this time. The complete Risk/Benefit Assessment is found in **Appendix 5**.

10.1 Adverse Events

10.1.1 Definition of an Adverse Event

Adverse Event (AE): any undesirable clinical occurrence or change from a patient's baseline (pre-index procedure) condition, whether it is device related or not.

Adverse Event Identification: a condition that is one of the following:

a. A unique symptom or event that is a change from the subject's baseline status
b. A series of symptoms or events that can be categorized as a single entity
c. A specific diagnosis responsible for a clinical change
d. A worsening or exacerbation of a pre-existing condition

10.2 Serious Adverse Events

10.2.1 Definition of a Serious Adverse Event

Serious Adverse Event (SAE): any adverse event is considered serious if it results in death, is life threatening, requires hospitalization (initial or prolonged), results in disability or permanent damage, causes congenital anomaly/birth defect, requires intervention to prevent impairment or damage, or other serious (important medical events) which may jeopardize the subject and may require medical or surgical intervention to prevent one of the above outcomes.

Note: "Death" should not be reported as an adverse event. The cause of death should be reported as an adverse event. The only exception is "Sudden Death" when the cause is unknown.

10.2.2 Subject Death

Subject death during the investigation must be reported by the Investigator (or designee) by completing the Study Exit eCRF in the database along with the cause of death. The electronic Adverse Event Form is necessary if the event was related to the Lapiplasty® devices or placement of the device. In addition, subject death must be reported to the IRB in accordance with IRB requirements.

10.2.3 Adverse Event Classification

The investigator is required to provide:

- Time interval of the event – The time interval of the occurrence of the adverse event should be assessed in relationship to timing of the index procedure (Lapiplasty® Procedure)
- Date of event onset and outcome of the event, or date of death

- Severity of the event – (Mild, Moderate, Severe)
- Action taken for medical management of the event
- Relationship of the event – it is the PIs responsibility to assess the relationship of an AE and provide primary cause. Events will be categorized by relationship to the Lapiplasty® System Implants, the Lapiplasty® System Reusable Instruments, or the index procedure (Lapiplasty® Procedure).
- Adverse events will be assessed to determine if the event meets the definition of a serious adverse event.

10.2.4 Reporting Adverse and Serious Adverse Events

The investigator (or designee) will record all AEs (both serious and non-serious and regardless of relationship) in the source documents. The Investigator at each participating site is responsible for reporting AEs and SAEs to TMC only when they are related to the Lapiplasty® Procedure, the Lapiplasty® Mini-Incision™ System Implants and Lapiplasty® Mini-Incision™ Precision Instrument Set. AEs related to the Lapiplasty® Procedure or Lapiplasty® devices will be reported on the eCRF. The CRF allows the investigator to indicate whether an adverse event is related to the Lapiplasty® System devices or Lapiplasty® Procedure (index procedure).

- Use a separate Adverse Event Form to document each event
- The Adverse Event Form must be electronically signed by the Investigator
  Note: It is the responsibility of the Investigator to inform their IRB of SAEs as required by their IRB procedures and in conformance with FDA requirements.

For the purposes of this study, the following adverse events are not considered reportable (recorded on eCRF) because they are normally expected to occur in conjunction with surgical treatment for hallux valgus procedures or are associated with customary and standard care of patients undergoing surgical treatment of hallux valgus or other protocol approved and acceptable concomitant procedures. If any of these events are **beyond what is normally expected** after the Lapiplasty® Procedure, they should be reported as AEs. However, the decision to report any AEs is ultimately the decision and responsibility of PI.

- Post-operative pain/post-procedure pain
- Minor, localized tenderness, swelling, induration, oozing, etc. at surgical site
- Temporary numbness or tingling at surgical site
- Elevated White Blood Cell count without signs and symptoms of infection
- Stiffness/weakness of joint
  Note: Subjects will undergo general anesthesia and therefore will also be subject to general anesthesia-associated complications and morbidity. These are also not considered reportable (recorded on eCRF) adverse events.

Any pre-planned surgical procedures

- Any pre-planned surgical foot procedures at the time of informed consent will not be considered reportable (recorded on eCRF) adverse events (whether hospitalization is required or not).

All Serious Adverse Events that are related to the index procedure or the Lapiplasty® devices must be reported by the Investigator by submitting the AE eCRF to TMC within 10 days of becoming aware of

the AE and recorded on the Serious Adverse Event Source Document Collection Form. Any event determined by the Investigator to be life threatening or to have led to death should be reported within 24 hours.

The Investigator shall send a written report including a narrative description of the SAE to TMC within three (3) working days of the initial report. The Investigator should follow all unresolved SAEs until the events are resolved, or the subject has exited the study, or the AE is otherwise explained.

11.0 PRODUCT COMPLAINTS

11.1 Product Complaint Definition

A product complaint is any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution. A product complaint may or may not be associated with an AE/SAE.

11.2 Source of Product Complaint Data

Means of obtaining product complaint data include review of the subject's medical records or observation by the PI and/or study staff, TMC employees observing study cases or identified by the Central Radiologist during review of radiographs. The PI and/or study staff are responsible for completing the required study documentation and the eCRFs.

11.3 Medical Device Reporting and Product Complaints

All reported device observations, malfunctions, or failures for the Lapiplasty® System products (Implants and Reusable Instruments) will be reported on the **Product Experience Report** (**Appendix 6**) within 10 days of observation of the Product Complaint via email to pe@treace.net. In the event of a suspected observation or device problem, the device shall be returned to the sponsor for analysis. The **Investigational Device Observation** eCRF should be completed, for the Lapiplasty® System Implants only, within 10 days of a suspected observation or device problem. Any device observations, malfunctions or failures for the Reusable Instruments will be reported by established TMC standard operating procedures, unless it is associated with a reportable AE/SAE.

Whenever an event involving a TMC device is subject to reporting under that Medical Device Reporting (MDR) regulation, TMC shall submit to the FDA the appropriate reports required by MDR within the time frames as identified in 21 CFR Part 803. Criteria for reporting malfunctions and potentially serious injuries is based on interpretations of medical intervention, potential for serious injury, and impact of a malfunction to a device's essential functionality. TMC will follow applicable internal quality system procedures which are in compliance with reporting obligations as required by 21 CFR Part 803 and 21 CFR Part 820: Code of Federal Regulations, Quality System Regulations.

Possible Product Complaints

- Intra-Operatively
  - Device malfunction or failures
  - Injury or bone fractures
- Post-Operatively
  - Revision surgery (due to pain, discomfort, infection, wound healing complications,

hardware removal, malunion, or non-union)
    - Infection or allergic reaction
    - Injury
- Radiographically
    - Broken hardware (screw/plate)
    - Loose, bent, cracked, fractured screw/plate
    - Bone infection
    - Migration of screw/plate
    - Bone fractures

12.0 STUDY OVERSIGHT

12.1 Independent Oversight

An independent central radiologist will perform the radiographic measurements for all sites/subjects. Any notable outliers in radiographic measurements/result will be reviewed by the medical monitor and/or the lead PI for resolution.

Works Cited

Bibliography

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[4.] Okuda R, et al. The Shape of the Lateral Edge of the First Metatarsal Head as a Risk Factor for Recurrence of Hallux Valgus. J Bone Joint Surg Am. 2007; 89:2163-72.

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[7.] Ray JJ, et al., Multicenter Early Radiographic Outcomes of Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing. Foot Ankle Int. 2019; 40(8):955-960.

13.0 APPENDICES

APPENDIX 1 – WORK CLASSIFICATION

Exertional levels as outlined in the Standards of U.S. Department of Labor as defined in the Dictionary of Occupational Titles (DOT)

• SEDENTARY: work involves exerting up to 10 pounds of force occasionally or a negligible amount of force frequently to lift, carry, push, pull, or otherwise move objects, including the human body. Sedentary work involves sitting most of the time but may involve walking or standing for brief periods of time. Jobs may be defined as Sedentary when walking and standing are required only occasionally, and all other Sedentary criteria are met.

• LIGHT: work involves exerting up to 20 pounds of force occasionally, or up to 10 pounds of force frequently, or a negligible amount of force constantly to move objects. Physical demand requirements are in excess of those for Sedentary Work. Even though the weight lifted may be only a negligible amount, a job/occupation is rated Light Work when it requires: (1) walking or standing to a significant degree; (2) sitting most of the time while pushing or pulling arm or leg controls; or (3) working at a production rate pace while constantly pushing or pulling materials even though the weight or the materials is negligible. (The constant stress and strain of maintaining a production rate pace, especially in an industrial setting, can be and is physically demanding of a worker even though the amount of force exerted is negligible.)

• MEDIUM: work involves exerting 20 to 50 pounds of force occasionally, or 10 to 25 pounds of force frequently, or an amount greater than negligible and up to 10 pounds constantly to move objects. Physical demand requirements are in excess of those for Light Work.

• HEAVY: work involves exerting 50 to 100 pounds of force occasionally, or 25 pounds of force constantly to move objects. Physical demand requirements are in excess of those for Medium Work.

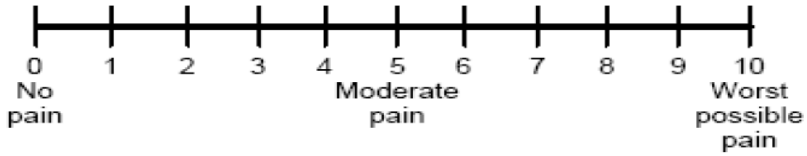
•VERY HEAVY: work involves exerting 100 pounds of force occasionally, or 50 pounds of force constantly to move objects. Physical demand requirements are in excess of those for Heavy Work.

APPENDIX 2A – VISUAL ANALOG SCALE

Visual Analog Scale (VAS)
Foot Pain Intensity

Read Each Scale Definition And Answer According To Current Pain In Your Foot

0–10 Numeric Pain Rating Scale



Mankoski Pain Scale Definitions

0- Pain Free
1- Very minor annoyance- occasional minor twinges. No medication needed.
2- Minor annoyance- occasional strong twinges. No medication needed.
3- Annoying enough to be distracting. Mild painkillers take care of it. (Aspirin, Ibuprofen.)
4- Can be ignored if you are really involved in your work, but still distracting. Mild painkillers remove pain for 3-4 hours.
5- Can't be ignored for more than 30 minutes. Mild painkillers ameliorate pain for 3-4 hours.
6- Can't be ignored for any length of time, but you can still go to work and participate in social activities. Stronger painkillers (Codeine, narcotics) reduce pain for 3-4 hours.
7- Makes it difficult to concentrate, interferes with sleep. You can still function with effort. Stronger painkillers are only partially effective.
8- Physical activity severely limited. You can read and converse with effort. Nausea and dizziness set in as factors of pain.
9- Unable to speak. Crying out or moaning uncontrollably- near delirium.
10- Unconscious. Pain makes you pass out.

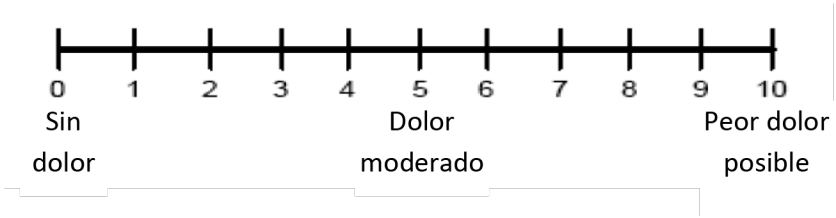
APPENDIX 2B – VISUAL ANALOG SCALE – US-SPANISH TRANSLATION

Escala analógica visual (VAS)

Intensidad del dolor de pie

Escala de calificación numérica del dolor de 0 a 10

0–10 Numeric Pain Rating Scale



Definiciones de la escala del dolor de Mankoski

0- Libre de dolor
1- Malestar muy menor, punzadas menores ocasionales. No necesita medicación.
2- Malestar menor, punzadas fuertes ocasionales. No necesita medicación.
3- Suficiente malestar para generar distracción. Los analgésicos leves lo solucionan (aspirina, ibuprofeno).
4- El malestar puede ignorarse si está realmente concentrado/a en su trabajo, pero sigue siendo una distracción. Los analgésicos leves eliminan el dolor de 3 a 4 horas.
5- El malestar no puede ignorarse durante más de 30 minutos. Los analgésicos leves alivian el dolor de 3 a 4 horas.
6- El malestar no puede ignorarse durante ningún período de tiempo, pero puede ir a trabajar y participar en actividades sociales. Los analgésicos más fuertes (codeína, narcóticos) reducen el dolor de 3 a 4 horas.
7- El malestar complica la concentración, interfiere con el sueño. Puede seguir funcionando con esfuerzo. Los analgésicos más fuertes solo son parcialmente eficaces.
8- La actividad física está limitada gravemente. Puede leer y conversar con esfuerzo. Las náuseas y los mareos se establecen como factores de dolor.
9- Incapaz de hablar. Quejas o gritos de manera incontrolable, cerca del delirio.
10- Queda inconsciente. El dolor le provoca desmayos.

APPENDIX 3A – QUALITY OF LIFE (QOL) TOOLS (PROMIS-29, PROMIS-25 and MOxFQ)

PROMIS–29 Profile v2.1

Please respond to each question or statement by marking one box per row.

	Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
PFA11	Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA21	Are you able to go up and down stairs at a normal pace?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA23	Are you able to go for a walk of at least 15 minutes?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA53	Are you able to run errands and shop?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Anxiety **In the past 7 days…**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
EDANX01	I felt fearful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX40	I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX41	My worries overwhelmed me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX53	I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Depression **In the past 7 days...**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
EDDEP04	I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP06	I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP29	I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP41	I felt hopeless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Fatigue **During the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
HI7	I feel fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
AN3	I have trouble starting things because I am tired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

PROMIS–29 Profile v2.1

	Fatigue **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
FATEXP41	How run-down did you feel on average? ...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP40	How fatigued were you on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Sleep Disturbance **In the past 7 days…**	**Very poor**	**Poor**	**Fair**	**Good**	**Very good**
Sleep109	My sleep quality was.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	In the past 7 days…	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
Sleep116	My sleep was refreshing.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep20	I had a problem with my sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep44	I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Ability to Participate in Social Roles and Activities	**Never**	**Rarely**	**Sometimes**	**Usually**	**Always**
SRPPER11_CaPS	I have trouble doing all of my regular leisure activities with others.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
SRPPER18_CaPS	I have trouble doing all of the family activities that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
SRPPER23_CaPS	I have trouble doing all of my usual work (include work at home)	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
SRPPER46_CaPS	I have trouble doing all of the activities with friends that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Pain Interference **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
PAININ9	How much did pain interfere with your day to day activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ22	How much did pain interfere with work around the home?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ31	How much did pain interfere with your ability to participate in social activities?.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ34	How much did pain interfere with your household chores?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

PROMIS–29 Profile v2.1

Pain Intensity

In the past 7 days…

Global07	How would you rate your pain on average?.....	☐ 0 **No pain**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **Worst pain imaginable**

PROMIS Pediatric Profile v2.0 – Profile-25

Pediatric Profile-25

Please respond to each question or statement by marking one box per row.

	Physical Function Mobility **In the past 7 days…**	**With no trouble**	**With a little trouble**	**With some trouble**	**With a lot of trouble**	**Not able to do**
225R1r	I could do sports and exercise that other kids my age could do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
4124R1r	I could get up from the floor	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
2707R2r	I could walk up stairs without holding on to anything	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
5022R1r	I have been physically able to do the activities I enjoy most	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Anxiety **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
2220R2r	I felt like something awful might happen	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
712R1r	I felt nervous	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5044R1r	I felt worried	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
34598R1r	I worried when I was at home	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Depressive Symptoms **In the past 7 days...**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
5041R1r	I felt everything in my life went wrong	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
711R1r	I felt lonely	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
228R1r	I felt sad	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3952aR2r	It was hard for me to have fun	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Fatigue **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
4239aR2r	Being tired made it hard for me to keep up with my schoolwork	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2878R1r	I got tired easily	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Last update: 20 July 2016

 Page 1 of 2

	Fatigue In the past 7 days…	Never	Almost Never	Sometimes	Often	Almost Always
4241R2r	I was too tired to do sports or exercise.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4196R1r	I was too tired to enjoy the things I like to do	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Peer Relationships **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
5018R1r	I felt accepted by other kids my age.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5068R1r	I was able to count on my friends	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5066R1r	My friends and I helped each other out.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
233R2r	Other kids wanted to be my friend	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Pain Interference **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
3793R1r	I had trouble sleeping when I had pain.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9004r	It was hard for me to pay attention when I had pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2046R1r	It was hard for me to run when I had pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2049R1r	It was hard for me to walk one block when I had pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Pain Intensity
In the past 7 days…

9033R1r	How bad was your pain on average? ...	☐ 0 **No pain**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **Worst pain you can think of**

SUBJECT Signature		**Date** (DD/MMM/YYYY)	

TREACE Medical Concepts, Inc.

Manchester-Oxford Foot Questionnaire (MOxFQ)

English version for the United States

Prior to completing the questionnaire please complete the following:-

Today's Date:

				2	0		
M	M	D	D	Y	Y	Y	Y

On which side of your body is the affected foot **for which you are receiving treatment**?

Left ❑

Right ❑

Both ❑

If you said 'both', please complete the first questionnaire thinking about the right side. A second questionnaire, for the left side, will follow.

TREACE
Medical Concepts, Inc.

PROBLEMS WITH YOUR FOOT

Please check (✓) one box for each statement.

1. During the past 4 weeks this has applied to me:

I have pain in my foot

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

2. During the past 4 weeks this has applied to me:

I avoid walking long distances because of pain in my foot

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

3. During the past 4 weeks this has applied to me:

I change the way I walk due to pain in my foot

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

4. During the past 4 weeks this has applied to me:

I walk slowly because of pain in my foot

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

5. During the past 4 weeks this has applied to me:

I have to stop and rest my foot because of pain

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

6. During the past 4 weeks this has applied to me:

I avoid some hard or rough surfaces because of pain in my foot

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

TREACE
Medical Concepts, Inc.

7. During the past 4 weeks this has applied to me:

I avoid standing for a long time because of pain in my foot

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

8. During the past 4 weeks this has applied to me:

I catch the bus or use the car instead of walking, because of pain in my foot

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

9. During the past 4 weeks this has applied to me:

I feel self-conscious about my foot

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

10. During the past 4 weeks this has applied to me:

I feel self-conscious about the shoes I have to wear

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

11. During the past 4 weeks this has applied to me:

The pain in my foot is more painful in the evening

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

12. During the past 4 weeks this has applied to me:

I get shooting pain in my foot

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

TREACE
Medical Concepts, Inc.

13. During the past 4 weeks this has applied to me:

The pain in my foot prevents me from carrying out my work/everyday activities

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

14. During the past 4 weeks this has applied to me:

I am unable to do all my social or recreational activities because of pain in my foot

None of the time	Rarely	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

15. During the past 4 weeks...

How would you describe the pain you usually have in your foot?

None	Very mild	Mild	Moderate	Severe
☐	☐	☐	☐	☐

16. During the past 4 weeks...

Have you been troubled by pain from your foot in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
☐	☐	☐	☐	☐

Finally, please check that you have answered each question.

Thank you very much.

APPENDIX 3B – QUALITY OF LIFE (QOL) TOOLS (PROMIS-29, PROMIS-25 and MOxFQ) – US-SPANISH TRANSLATIONS

PROMIS®–29 Profile v2.1

Responda a cada pregunta o enunciado marcando una casilla por línea.

	Capacidad de funcionamiento físico	**Sin dificultad**	**Con poca dificultad**	**Con alguna dificultad**	**Con mucha dificultad**	**No puedo hacerlo**
PFA11	¿Puede realizar tareas, como pasar la aspiradora o trabajar en el jardín?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA21	¿Puede subir y bajar escaleras a un paso normal?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA23	¿Puede salir a caminar durante 15 minutos por lo menos?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA53	¿Puede hacer mandados (recados) y compras?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Ansiedad **En los últimos 7 días…**	**Nunca**	**Rara vez**	**Algunas veces**	**A menudo**	**Siempre**
EDANX01	Sentí miedo	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX40	Tuve dificultad para concentrarme en otra cosa que no fuera mi ansiedad	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX41	Mis inquietudes fueron demasiado para mí	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX53	Me sentí intranquilo/a	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Depresión **En los últimos 7 días...**	**Nunca**	**Rara vez**	**Algunas veces**	**A menudo**	**Siempre**
EDDEP04	Sentí que no valía nada	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP06	Me sentí indefenso/a (que no podía hacer nada para ayudarme)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP29	Me sentí deprimido/a	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP41	Me sentí desesperanzado/a	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Agotamiento **En los últimos 7 días...**	**Nada**	**Un poco**	**Algo**	**Mucho**	**Muchísimo**
HI7	Me siento agotado/a	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
AN3	Tengo dificultad para comenzar las cosas porque estoy cansado/a	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	En los últimos 7 días…					
FATEXP41	¿Qué tan rendido/a se sintió en promedio?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP40	¿Qué tan agotado/a estuvo en promedio?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Spanish (Universal)
15 July 2021

PROMIS®–29 Profile v2.1

	Trastornos del sueño **En los últimos 7 días…**	**Muy mala**	**Mala**	**Pasable**	**Buena**	**Muy buena**
Sleep109	La calidad de mi sueño fue	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	En los últimos 7 días…	**Nada**	**Un poco**	**Algo**	**Mucho**	**Muchísimo**
Sleep116	Mi sueño fue reparador	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep20	Tuve problemas para dormir	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep44	Tuve dificultad para dormirme	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Capacidad para participar en roles y actividades sociales	**Nunca**	**Rara vez**	**Algunas veces**	**A menudo**	**Siempre**
SRPPER11_CaPS	Tengo problemas para realizar con otras personas todas mis actividades habituales de tiempo libre	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
SRPPER18_CaPS	Tengo problemas para realizar todas las actividades con mi familia que quiero hacer	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
SRPPER23_CaPS	Tengo problemas para realizar todo mi trabajo habitual (incluya el trabajo en el hogar)	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
SRPPER46_CaPS	Tengo problemas para realizar todas las actividades con mis amigos/as que quiero hacer	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Efectos del dolor **En los últimos 7 días…**	**Nada**	**Un poco**	**Algo**	**Mucho**	**Muchísimo**
PAININ9	¿En qué medida el dolor interfirió en sus actividades diarias?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ22	¿En qué medida el dolor interfirió en el trabajo en el hogar?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ31	¿En qué medida el dolor interfirió en su capacidad para participar en actividades sociales?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ34	¿En qué medida el dolor interfirió en sus tareas domésticas?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Intensidad del dolor
En los últimos 7 días…

Global07	En promedio, ¿cómo calificaría su dolor?	☐ 0 **Ningún dolor**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **El peor dolor imaginable**

Spanish (Universal)
15 July 2021

Perfil pediátrico-25

Responde a cada pregunta o enunciado marcando una casilla por línea.

	Capacidad de funcionamiento físico-Movilidad **En los últimos 7 días…**	**Sin dificultad**	**Con poca dificultad**	**Con alguna dificultad**	**Con mucha dificultad**	**No pude hacerlo**
235R1r	Pude practicar los mismos deportes y ejercicios que hacían otros niños/as de mi edad.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
4124R1r	Pude levantarme del piso (suelo).	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
2707R2r	Pude subir escaleras sin agarrarme a nada.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
5023R1r	He podido hacer físicamente las actividades que más me gustan.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Ansiedad **En los últimos 7 días…**	**Nunca**	**Casi nunca**	**A veces**	**A menudo**	**Casi siempre**
2220R2r	Sentí que podría pasar algo terrible.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
713R1r	Me sentí nervioso/a.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5044R1r	Me sentí preocupado.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3459bR1r	Me preocupé cuando estaba en casa.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Síntomas de depresión **En los últimos 7 días…**	**Nunca**	**Casi nunca**	**A veces**	**A menudo**	**Casi siempre**
5041R1r	Sentí que todo me salía mal en la vida.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
711R1r	Me sentí solo/a.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
228R1r	Me sentí triste.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3952aR2r	Me resultó difícil divertirme.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Agotamiento **En los últimos 7 días…**	**Nunca**	**Casi nunca**	**A veces**	**A menudo**	**Casi siempre**
4239aR2r	El cansancio hizo que fuera difícil para mí estar al día con las tareas escolares.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2876R1r	Me cansé fácilmente.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Spanish (Universal)
06 July 2020

	Agotamiento **En los últimos 7 días…**	**Nunca**	**Casi nunca**	**A veces**	**A menudo**	**Casi siempre**
4241R2	Estuve demasiado cansado/a para practicar deportes o hacer ejercicio.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4196R1r	Estuve demasiado cansado/a para disfrutar de las cosas que me gusta hacer.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Relaciones entre iguales **En los últimos 7 días…**	**Nunca**	**Casi nunca**	**A veces**	**A menudo**	**Casi siempre**
5018R1r	Me sentí aceptado/a por los otros niños/as de mi edad.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5058R1r	Pude contar con mis amigos/as.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5055R1r	Mis amigos/as y yo nos ayudamos.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
233R2r	Otros niños/as quisieron ser mis amigos/as. .	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Efectos del dolor **En los últimos 7 días…**	**Nunca**	**Casi nunca**	**A veces**	**A menudo**	**Casi siempre**
3793R1r	Tuve problemas para dormir cuando sentí dolor.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9004r	Cuando tuve dolor, me fue difícil prestar atención.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2045R1r	Cuando tuve dolor, me fue difícil correr.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2049R1r	Cuando tuve dolor, me fue difícil caminar una manzana (cuadra).	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Intensidad del dolor
En los últimos 7 días…

9033R1	En promedio, ¿cómo dirías que es tu dolor?	☐ 0 **Ningún dolor**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **El peor dolor que te puedas imaginar**

Cuestionario sobre el Pie de Manchester-Oxford (MOxFQ)

Versión en español para Estados Unidos

Antes de completar el cuestionario, complete lo siguiente:

La fecha de hoy:

				2	0			
M	M	D	D	A	A	A	A	

De qué lado del cuerpo está el pie afectado **para el que está recibiendo o recibió tratamiento.**

Izquierdo ❑
Derecho ❑
Ambos ❑

Si respondió 'ambos', complete el primer cuestionario pensando en el lado derecho. A continuación, habrá un segundo cuestionario para el lado izquierdo.

Encierre en un círculo según corresponda: **Derecho/Izquierdo**

Marque una casilla (✓) por cada enunciado.

1.	**Durante las últimas 4 semanas he experimentado lo siguiente:** Tengo dolor en el pie				
Nunca ☐	Rara vez ☐	Algunas veces ☐	La mayor parte del tiempo ☐	Todo el tiempo ☐	
2.	**Durante las últimas 4 semanas he experimentado lo siguiente:** Evito caminar largas distancias a causa del dolor en el pie				
Nunca ☐	Rara vez ☐	Algunas veces ☐	La mayor parte del tiempo ☐	Todo el tiempo ☐	
3.	**Durante las últimas 4 semanas he experimentado lo siguiente:** Tengo que cambiar la forma de caminar debido al dolor en el pie				
Nunca ☐	Rara vez ☐	Algunas veces ☐	La mayor parte del tiempo ☐	Todo el tiempo ☐	
4.	**Durante las últimas 4 semanas he experimentado lo siguiente:** Camino lentamente debido al dolor en el pie				
Nunca ☐	Rara vez ☐	Algunas veces ☐	La mayor parte del tiempo ☐	Todo el tiempo ☐	
5.	**Durante las últimas 4 semanas he experimentado lo siguiente:** Tengo que detenerme y dejar descansar el pie debido al dolor				
Nunca ☐	Rara vez ☐	Algunas veces ☐	La mayor parte del tiempo ☐	Todo el tiempo ☐	
6.	**Durante las últimas 4 semanas he experimentado lo siguiente:** Evito algunas superficies duras o irregulares debido al dolor en el pie				
Nunca ☐	Rara vez ☐	Algunas veces ☐	La mayor parte del tiempo ☐	Todo el tiempo ☐	

7.	**<u>Durante las últimas 4 semanas</u> he experimentado lo siguiente:**				
	Evito estar de pie por largo tiempo debido al dolor en el pie				
	Nunca ☐	Rara vez ☐	Algunas veces ☐	La mayor parte del tiempo ☐	Todo el tiempo ☐
8.	**<u>Durante las últimas 4 semanas</u> he experimentado lo siguiente:**				
	Tomo el autobús o uso el carro en lugar de caminar, debido al dolor en el pie				
	Nunca ☐	Rara vez ☐	Algunas veces ☐	La mayor parte del tiempo ☐	Todo el tiempo ☐
9.	**<u>Durante las últimas 4 semanas</u> he experimentado lo siguiente:**				
	Me siento acomplejado por el pie				
	Nunca ☐	Rara vez ☐	Algunas veces ☐	La mayor parte del tiempo ☐	Todo el tiempo ☐
10.	**<u>Durante las últimas 4 semanas</u> he experimentado lo siguiente:**				
	Me siento acomplejado por los zapatos que me tengo que poner				
	Nunca ☐	Rara vez ☐	Algunas veces ☐	La mayor parte del tiempo ☐	Todo el tiempo ☐
11.	**<u>Durante las últimas 4 semanas</u> he experimentado lo siguiente:**				
	El dolor en el pie es más intenso al anochecer				
	Nunca ☐	Rara vez ☐	Algunas veces ☐	La mayor parte del tiempo ☐	Todo el tiempo ☐
12.	**<u>Durante las últimas 4 semanas</u> he experimentado lo siguiente:**				
	Siento dolores punzantes en el pie				
	Nunca ☐	Rara vez ☐	Algunas veces ☐	La mayor parte del tiempo ☐	Todo el tiempo ☐

13. Durante las últimas 4 semanas he experimentado lo siguiente:

El dolor en el pie me impide llevar a cabo mi trabajo/mis actividades cotidianas

Nunca	Rara vez	Algunas veces	La mayor parte del tiempo	Todo el tiempo
☐	☐	☐	☐	☐

14. Durante las últimas 4 semanas he experimentado lo siguiente:

No puedo realizar todas mis actividades sociales o recreativas debido al dolor en el pie

Nunca	Rara vez	Algunas veces	La mayor parte del tiempo	Todo el tiempo
☐	☐	☐	☐	☐

15. Durante las últimas 4 semanas...

¿Cómo describiría el dolor que usualmente siente en el pie?

Ninguno	Muy leve	Leve	Moderado	Intenso
☐	☐	☐	☐	☐

16. Durante las últimas 4 semanas...

¿Le ha molestado el dolor en el pie cuando está en la cama por la noche?

Ninguna noche	Solo 1 o 2 noches	Algunas noches	La mayoría de las noches	Todas las noches
☐	☐	☐	☐	☐

Por último, compruebe que haya contestado todas las preguntas.

Muchas gracias.

APPENDIX 4 – RADIOGRAPHIC MEASUREMENTS

NOTE: The following measurements will be collected at a minimum by the Central Radiologist. Visit 1 measurements made by the Central Radiologist are not utilized for determining patient eligibility. Additional measurements may be collected for exploratory purposes without amendment to the protocol.

Visit 1

- IMA (Intermetatarsal angle)
- HVA (Hallux Valgus Angle)
- Lateral Round Sign Present
- TSP (Tibial Sesamoid Position)
- MAA (Metatarsus Adductus)
- Metatarsal Rotation
- Sesamoid Subluxation
- Sagittal-Plane 1st Metatarsal Position
- Meary's Angle
- AP Talar -1st Metatarsal Angle
- Osseous Foot Width
- 1-2 Metatarsal Length
- MTP (Metatarsal Phalangeal) Osteoarthritis
- Metatarsal-Sesamoid Osteoarthritis
- DMAA
- Sagittal 1st Ray Length

Visit 5

- IMA (Intermetatarsal angle)
- HVA (Hallux Valgus Angle)
- Lateral Round Sign Present
- TSP (Tibial Sesamoid Position)
- MAA (Metatarsus Adductus)
- Metatarsal Rotation
- Post-Operative Metatarsal Rotation
- Sesamoid Subluxation
- Sagittal-Plane 1st Metatarsal Position
- Meary's Angle
- AP Talar -1st Metatarsal Angle
- MTP (Metatarsal Phalangeal) Osteoarthritis

- Metatarsal-Sesamoid Osteoarthritis
- Hardware issues, potential complications or adverse events based on radiographic review

Visits 6 -9

- IMA (Intermetatarsal angle)
- HVA (Hallux Valgus Angle)
- Lateral Round Sign Present
- TSP (Tibial Sesamoid Position)
- MAA (Metatarsus Adductus)
- Metatarsal Rotation
- Post-Operative Metatarsal Rotation
- Sesamoid Subluxation
- Sagittal-Plane 1st Metatarsal Position
- Meary's Angle
- AP Talar -1st Metatarsal Angle
- Osseous Foot Width
- 1-2 Metatarsal Length
- MTP (Metatarsal Phalangeal) Osteoarthritis
- Metatarsal-Sesamoid Osteoarthritis
- DMAA
- Sagittal 1st Ray Length
- Lucency at arthrodesis: Yes/No
- Hardware Failure (transverse screw)
    - If Yes, location of screw(s): C1-C2 or C1-M2
- Hardware Failure (screws or plates at 1st TMT Joint)
- Hardware issues, potential complications or adverse events based on radiographic review

APPENDIX 5 – RISK/BENEFIT ASSESSMENT

Summary: The Mini3D™ study is being undertaken to evaluate outcomes of the Lapiplasty® Procedure for patients in need of hallux valgus surgery. Subjects meeting inclusion/exclusion criteria and undergoing the Lapiplasty® Procedure will participate in this study. The risks of participation are offset by the potential for clinical and functional benefits.

1.0 POTENTIAL BENEFITS:

The potential benefit to study subjects outweighs the risks of participation in this study. Benefits may include but are not limited to, the following:

- Clinical improvement – patients may experience effective and long-lasting correction of the anatomical alignment of the entire metatarsal bone in all three planes, naturally removing the bump and straightening the toe.
- Functional improvement – patients may experience the ability to put weight on their foot within days after their surgery, allowing them to return to normal activities within 4-6 weeks. Patients may also experience improved patient satisfaction and improve pain caused by the bunion after the Lapiplasty® Procedure through a Mini-Incision™ Approach.
- Post-operative experience improvement – patients may experience less pain and scarring after the Lapiplasty® Procedure through a Mini-Incision™ approach.
- Overall advancement of medical and scientific knowledge – Information obtained from this study may further our understanding of how early weight-bearing after the Lapiplasty® Procedure impacts healing of the bone and recurrence of the bunion over time.

There may be other benefits that are unforeseen at this time.

2.0 POSSIBLE RISKS AND DISCOMFORTS:

Risk Category: Minimal

Independent from this research study, the patient is already a candidate for hallux valgus treatment with the Lapiplasty® Procedure in the commercial setting. The Lapiplasty® System is cleared for use and in this research study it is used in accordance with approved product labeling. All risks for this procedure will have been discussed between the patient and the surgeon and a surgical consent will have been signed. Similarly, anesthetic risks will have been discussed and anesthetic consent will have been signed. The participant will have been fully informed of the risks of this study.

Possible risks and discomforts that may be associated with the use of the Lapiplasty® Procedure and Lapiplasty® System (Implants and Reusable Instruments):

- Infection or adverse reaction for a foreign body;
- Pain, discomfort, or abnormal sensations due to the presence of the implant;
- Loosening, bending, cracking or fracture of the components or loss of fixation of bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures;

- Loss of anatomic position with nonunion or malunion with rotation or angulation;
- Migration of the implant, loosening of the implant;
- Delayed correction in alignment;
- Decrease in bone density due to stress shielding;
- Bursitis;
- Additional surgery if the device is not placed in the correct position.

Possible risks and discomforts that may be associated with the use of the Lapiplasty® Mini-Incision™ Positioner:

- Necrosis;
- Bruising;
- Blistering;
- Tissue ulceration.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture is healed. If any of these complications occur, the surgeon must make the final decision on implant removal.

There may also be other risks that are unforeseen at this time.

3.0 MINIMIZATION OF RISKS

Measures which will be taken to minimize risks related to the study include:

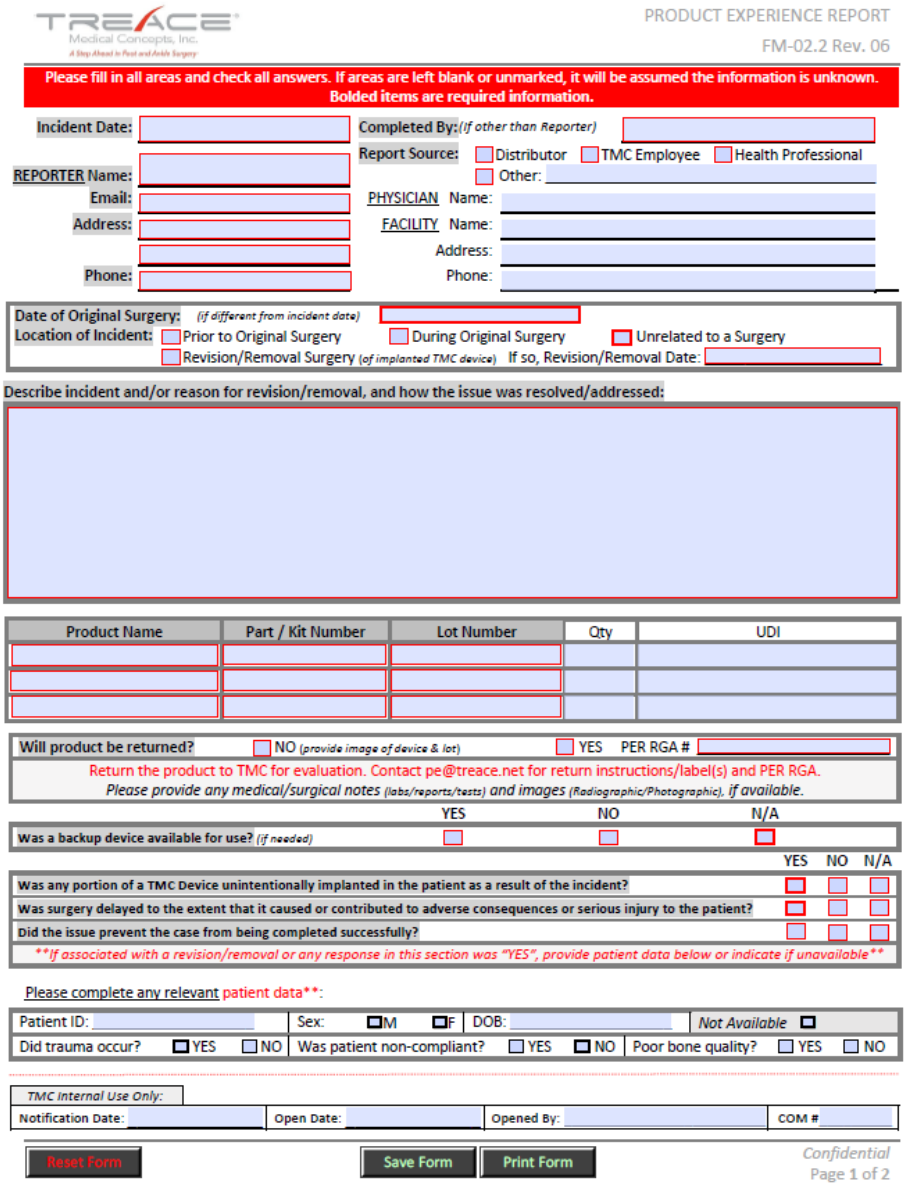
- Investigators selected for participation in this study will have experience in treating patients with hallux valgus and performing surgical procedures.
- Investigators selected for participation in this study will be qualified to complete study index procedure (Lapiplasty® Procedure) and are experienced in the use of the Lapiplasty® Mini-Incision™ (Implants and Reusable Instruments).
- Well defined clinical study protocol, including specific inclusion/ exclusion criteria to enroll appropriate patients in the trial.
- Close patient monitoring during the Lapiplasty® Procedure and patient follow-up period.

Alternative to Participation: Patients may decline participation in the study and would be treated with the same standard of care.

CONCLUSION: This clinical study is justified because the study sponsor and clinical investigators believe the potential benefits outweigh the potential risks.

APPENDIX 6 – PRODUCT EXPERIENCE REPORT

NOTE: An **example** of the Product Experience Report form is provided below. The form may be updated by Treace Medical Concepts, Inc. and does not require an amendment to the study protocol. Sites will be provided current revisions of the Product Experience Report form, as required, if revisions are made to the form through the course of the study.



PRODUCT EXPERIENCE REPORT
FM-02.2 Rev. 06

Please fill in all areas and check all answers. If areas are left blank or unmarked, it will be assumed the information is unknown.
Bolded items are required information.

Incident Date:
Completed By: (if other than Reporter)
Report Source: Distributor TMC Employee Health Professional Other:
REPORTER Name:
Email:
Address:
Phone:
PHYSICIAN Name:
FACILITY Name:
Address:
Phone:

Date of Original Surgery: (if different from incident date)
Location of Incident: Prior to Original Surgery During Original Surgery Unrelated to a Surgery
Revision/Removal Surgery (of implanted TMC device) If so, Revision/Removal Date:

Describe incident and/or reason for revision/removal, and how the issue was resolved/addressed:

Product Name	Part / Kit Number	Lot Number	Qty	UDI

Will product be returned? NO (provide image of device & lot) YES PER RGA #
Return the product to TMC for evaluation. Contact pe@treace.net for return instructions/label(s) and PER RGA.
Please provide any medical/surgical notes (labs/reports/tests) and images (Radiographic/Photographic), if available.

	YES	NO	N/A
Was a backup device available for use? (if needed)			

	YES	NO	N/A
Was any portion of a TMC Device unintentionally implanted in the patient as a result of the incident?			
Was surgery delayed to the extent that it caused or contributed to adverse consequences or serious injury to the patient?			
Did the issue prevent the case from being completed successfully?			

If associated with a revision/removal or any response in this section was "YES", provide patient data below or indicate if unavailable

Please complete any relevant patient data**:

Patient ID:	Sex: M F	DOB:	Not Available		
Did trauma occur? YES NO	Was patient non-compliant? YES NO	Poor bone quality? YES NO			

TMC Internal Use Only:

Notification Date:	Open Date:	Opened By:	COM #

Reset Form Save Form Print Form

Confidential
Page 1 of 2

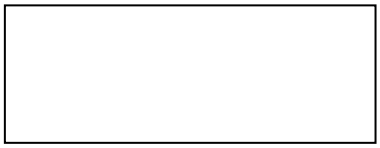
APPENDIX 7 – SUBJECT FOLLOW-UP VISIT CARD

Exact layout of card may vary. Information will remain consistent.

SIDE 1	SIDE 2
Mini3D™ Lapiplasty® Clinical Study	Site Contact Information for Study Related Questions:
	CONTACT DETAILS OF YOUR STUDY DOCTOR
Study Protocol Number: CP2021-1	Name:
Subject's Name:	Address:
Subject's Study Number:	City: State:
	Telephone:
Your Next Study Visit is scheduled for:	
	Alternative Contact Name:
Visit (insert visit #): (insert scheduled visit date)	Phone:
Thank you for participating in this important clinical study to evaluate the outcomes of the Lapiplasty® Procedure that could help patients long into the future.	On behalf of everyone involved with this clinical study, we want to Thank You for your participation. Don't hesitate to contact the medical team to answer any questions you may have.

APPENDIX 8 – ADVERTISEMENT/FLIER FOR IRB APPROVAL

Mini3D™ Clinical Study (CP2021-1)

Planned for multimedia advertising: Waiting Room Flier, Newspaper, Billboard, Radio Script, Hospital Journal, Website, Facebook, email blog, email blast to client base, Posters, mailed letters, and other modes of media as identified. Imagery (or site/facility specific information) may be added to advertisement for use at the local site level.
Clinical Research Study for the Treatment of Bunions
Painful Bunion? 
If you are suffering from a painful bunion, or are considering bunion surgery, you may qualify for a medical research study to evaluate the outcomes of an FDA-cleared surgical treatment for bunion correction.
To qualify, you must meet of the study criteria including: • Must be between 14-58 years of age • Have a qualifying bunion that requires surgical correction While participating in this study, data on your procedure outcomes will be collected and you will be asked to complete assessments so that the study sponsor can learn more about your experience with this procedure.
To find out more about this study and to see if you qualify, please ask to speak with (insert name) or call (insert number) and reference the “Lapiplasty© Mini3D™ Clinical Study”.
You may be compensated for study-related time and travel.
Insert PI Name Insert full site address Insert Phone

APPENDIX 9A –

THE PATIENT AND OBSERVER SCAR ASSESSMENT SCALE (POSAS)

POSAS Observer scale

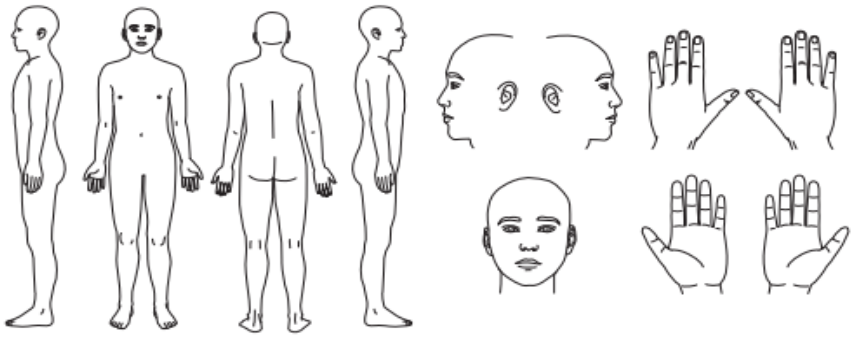
The Patient and Observer Scar Assessment Scale v2.0 / EN

Date of examination: _____ **Name of patient:** _____

Observer: _____ _____

Location: _____ **Date of birth:** _____

Research / study: _____ **Identification number:** _____



1 = normal skin worst scar imaginable = 10

PARAMETER	1	2	3	4	5	6	7	8	9	10	CATEGORY
VASCULARITY	○	○	○	○	○	○	○	○	○	○	PALE | PINK | RED | PURPLE | MIX
PIGMENTATION	○	○	○	○	○	○	○	○	○	○	HYPO | HYPER | MIX
THICKNESS	○	○	○	○	○	○	○	○	○	○	THICKER | THINNER
RELIEF	○	○	○	○	○	○	○	○	○	○	MORE | LESS | MIX
PLIABILITY	○	○	○	○	○	○	○	○	○	○	SUPPLE | STIFF | MIX
SURFACE AREA	○	○	○	○	○	○	○	○	○	○	EXPANSION | CONTRACTION | MIX
OVERALL OPINION	○	○	○	○	○	○	○	○	○	○	

Explanation

The observer scale of the POSAS consists of six items (vascularity, pigmentation, thickness, relief, pliability and surface area).
All items are scored on a scale ranging from 1 ('like normal skin') to 10 ('worst scar imaginable').
The sum of the six items results in a total score of the POSAS observer scale. Categories boxes are added for each item. Furthermore, an overall opinion is scored on a scale ranging from 1 to 10.
All parameters should preferably be compared to normal skin on a comparable anatomic location.

Explanatory notes on the items:

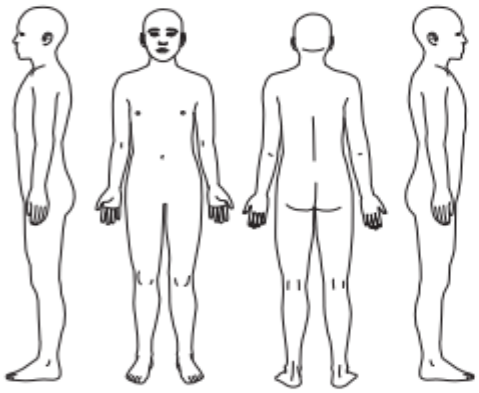
- **VASCULARITY** Presence of vessels in scar tissue assessed by the amount of redness, tested by the amount of blood return after blanching with a piece of Plexiglas
- **PIGMENTATION** Brownish coloration of the scar by pigment (melanin); apply Plexiglas to the skin with moderate pressure to eliminate the effect of vascularity
- **THICKNESS** Average distance between the subcutical-dermal border and the epidermal surface of the scar
- **RELIEF** The extent to which surface irregularities are present (preferably compared with adjacent normal skin)
- **PLIABILITY** Suppleness of the scar tested by wrinkling the scar between the thumb and index finger
- **SURFACE AREA** Surface area of the scar in relation to the original wound area

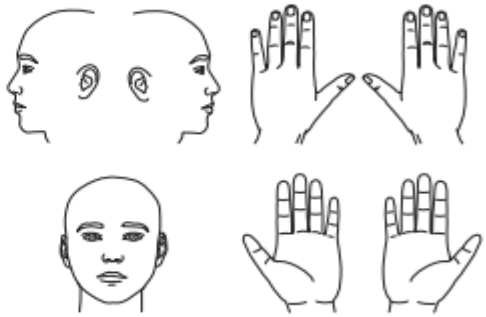
TREACE
Medical Concepts, Inc.

POSAS Patient scale

The Patient and Observer Scar Assessment Scale v 2.0 / EN

Date of examination:	**Name of patient:**
Observer:	
Location:	**Date of birth:**
Research / study:	**Identification number:**





	1 = no, not at all … yes, very much = 10
HAS THE SCAR BEEN PAINFUL THE PAST FEW WEEKS?	1 2 3 4 5 6 7 8 9 10
HAS THE SCAR BEEN ITCHING THE PAST FEW WEEKS?	1 2 3 4 5 6 7 8 9 10

	1 = no, as normal skin … yes, very different = 10
S THE SCAR COLOR DIFFERENT FROM THE COLOR OF YOUR NORMAL SKIN AT PRESENT?	1 2 3 4 5 6 7 8 9 10
S THE STIFFNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?	1 2 3 4 5 6 7 8 9 10
S THE THICKNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?	1 2 3 4 5 6 7 8 9 10
S THE SCAR MORE IRREGULAR THAN YOUR NORMAL SKIN AT PRESENT?	1 2 3 4 5 6 7 8 9 10

	1 = as normal skin … very different = 10
WHAT IS YOUR OVERALL OPINION OF THE SCAR COMPARED TO NORMAL SKIN?	1 2 3 4 5 6 7 8 9 10

APPENDIX 9B –

THE PATIENT AND OBSERVER SCAR ASSESSMENT SCALE (POSAS) – US-SPANISH TRANSLATIONS

Escala POSAS para el observador

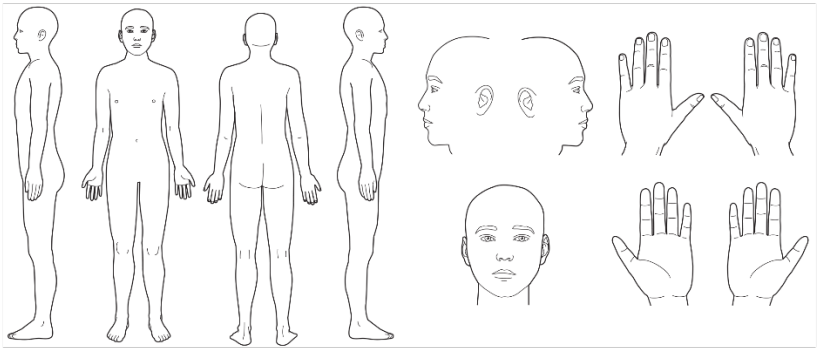
The Patient and Observer Scar Assessment Scale v2.0 / ES

Fecha de la evaluación: **Nombre del paciente:**

Observador:

Ubicación: **Fecha de nacimiento:**

Investigación / estudio: **Número de identificación:**



	1 = piel normal									la peor cicatriz imaginable = 10	
PARÁMETRO	1	2	3	4	5	6	7	8	9	10	**CATEGORÍA**
VASCULARIZACIÓN	○	○	○	○	○	○	○	○	○	○	PÁLIDA | ROSADO | ROJA | PÚRPURA | MIXTA
PIGMENTACIÓN	○	○	○	○	○	○	○	○	○	○	HIPO | HIPER | MIXTA
GROSOR	○	○	○	○	○	○	○	○	○	○	MÁS GRUESA | MÁS DELGADA
RELIEVE	○	○	○	○	○	○	○	○	○	○	MÁS | MENOS | MIXTO
ELASTICIDAD	○	○	○	○	○	○	○	○	○	○	FLEXIBLE | RÍGIDA | MIXTA
SUPERFICIE	○	○	○	○	○	○	○	○	○	○	EXPANSIÓN | CONTRACCIÓN | MIXTA
OPINIÓN GENERAL	○	○	○	○	○	○	○	○	○	○	

Explicación

La escala POSAS para el observador consta de seis parámetros (vascularización, pigmentación, grosor, relieve, elasticidad y superficie).
Todos los parámetros se califican según una escala que va del 1 ('piel normal') al 10 ('la peor cicatriz imaginable').
La suma de los seis parámetros constituye la puntuación total de la escala POSAS para el observador. En cada parámetro se agregan categorías. Además, se califica la opinión general según una escala que va del 1 al 10.
Todos los parámetros se deben comparar preferiblemente con la piel normal de una ubicación anatómica equivalente.

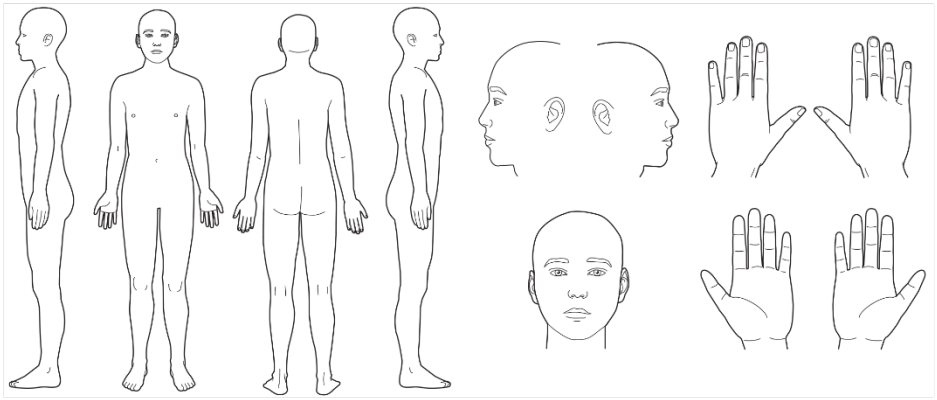
Notas explicativas sobre los parámetros:

- **VASCULARIZACIÓN** Presencia de vasos sanguíneos en el tejido cicatrizado, que se evalúa según la cantidad de enrojecimiento que ocurre por la cantidad de sangre que regresa después de presionar con una pieza de Plexiglass.
- **PIGMENTACIÓN** Coloración café o marrón de la cicatriz debido a un pigmento (la melanina). La pieza de Plexiglass se presiona con fuerza moderada contra la piel para eliminar el efecto de la vascularización.
- **GROSOR** Distancia media entre el borde subcuticular-dérmico y la superficie epidérmica de la cicatriz.
- **RELIEVE** Magnitud de las irregularidades superficiales presentes (de preferencia en comparación con la piel normal adyacente).
- **ELASTICIDAD** Flexibilidad de la cicatriz probada al arrugar la cicatriz entre el pulgar y el índice.
- **SUPERFICIE** Área de la cicatriz con relación al área original de la herida.

Escala POSAS para el paciente

The Patient and Observer Scar Assessment Scale v2.0 / ES

Fecha de la evaluación:	**Nombre del paciente:**
Observador:	
Ubicación:	**Fecha de nacimiento:**
Investigación / estudio:	**Número de identificación:**



	1 = no, para nada … sí, mucho = 10
¿LE HA DOLIDO LA CICATRIZ EN LAS ÚLTIMAS SEMANAS?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
¿LE HA ESTADO PICANDO LA CICATRIZ EN LAS ÚLTIMAS SEMANAS?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○

	1 = no, como la piel normal … sí, muy diferente = 10
¿TIENE LA CICATRIZ UN COLOR DIFERENTE AL DE SU PIEL NORMAL EN ESTE MOMENTO?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
¿TIENE LA CICATRIZ UNA RIGIDEZ DIFERENTE A LA DU SU PIEL NORMAL EN ESTE MOMENTO (ES DECIR, NO ES IGUAL DE RÍGIDA)?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
¿TIENE LA CICATRIZ UN GROSOR DIFERENTE AL DE SU PIEL NORMAL EN ESTE MOMENTO (ES DECIR, NO ES IGUAL DE GRUESA)?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
¿ES LA CICATRIZ MÁS IRREGULAR QUE SU PIEL NORMAL EN ESTO MOMENTO?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○

	1 = como la piel normal … muy diferente = 10
¿CUÁL ES SU OPINIÓN GENERAL SOBRE LA CICATRIZ COMPARADA CON LA PIEL NORMAL?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○

APPENDIX 10A – GENERAL SATISFACTION QUESTIONNAIRE

General Satisfaction Questionnaire - Lapiplasty® Procedure through a Mini-Incision™ Approach					
Would you recommend the procedure to your relatives?	Yes	No			
Would you undergo the same procedure again?	Yes	No			
Rate your satisfaction on the following <u>specific</u> aspects of the procedure:					
Pain:	Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied
Function:	Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied
Alignment:	Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied
Aesthetics:	Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied
Rate your <u>overall</u> satisfaction with results of the procedure:	Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied

APPENDIX 10B – GENERAL SATISFACTION QUESTIONNAIRE – US-SPANISH TRANSLATION

Procedimiento Lapiplasty®
Mediante el método Mini-Incision™

¿Recomendaría el procedimiento a sus familiares?	Sí	No			
¿Volvería a someterse al mismo procedimiento?	Sí	No			
Califique su grado de satisfacción sobre los siguientes aspectos específicos del procedimiento:					
Dolor:	Muy insatisfecho	Insatisfecho	Neutro	Satisfecho	Muy satisfecho
Función:	Muy insatisfecho	Insatisfecho	Neutro	Satisfecho	Muy satisfecho
Alineación:	Muy insatisfecho	Insatisfecho	Neutro	Satisfecho	Muy satisfecho
Estética:	Muy insatisfecho	Insatisfecho	Neutro	Satisfecho	Muy satisfecho
Califique su grado de satisfacción general con los resultados del procedimiento:	Muy insatisfecho	Insatisfecho	Neutro	Satisfecho	Muy satisfecho