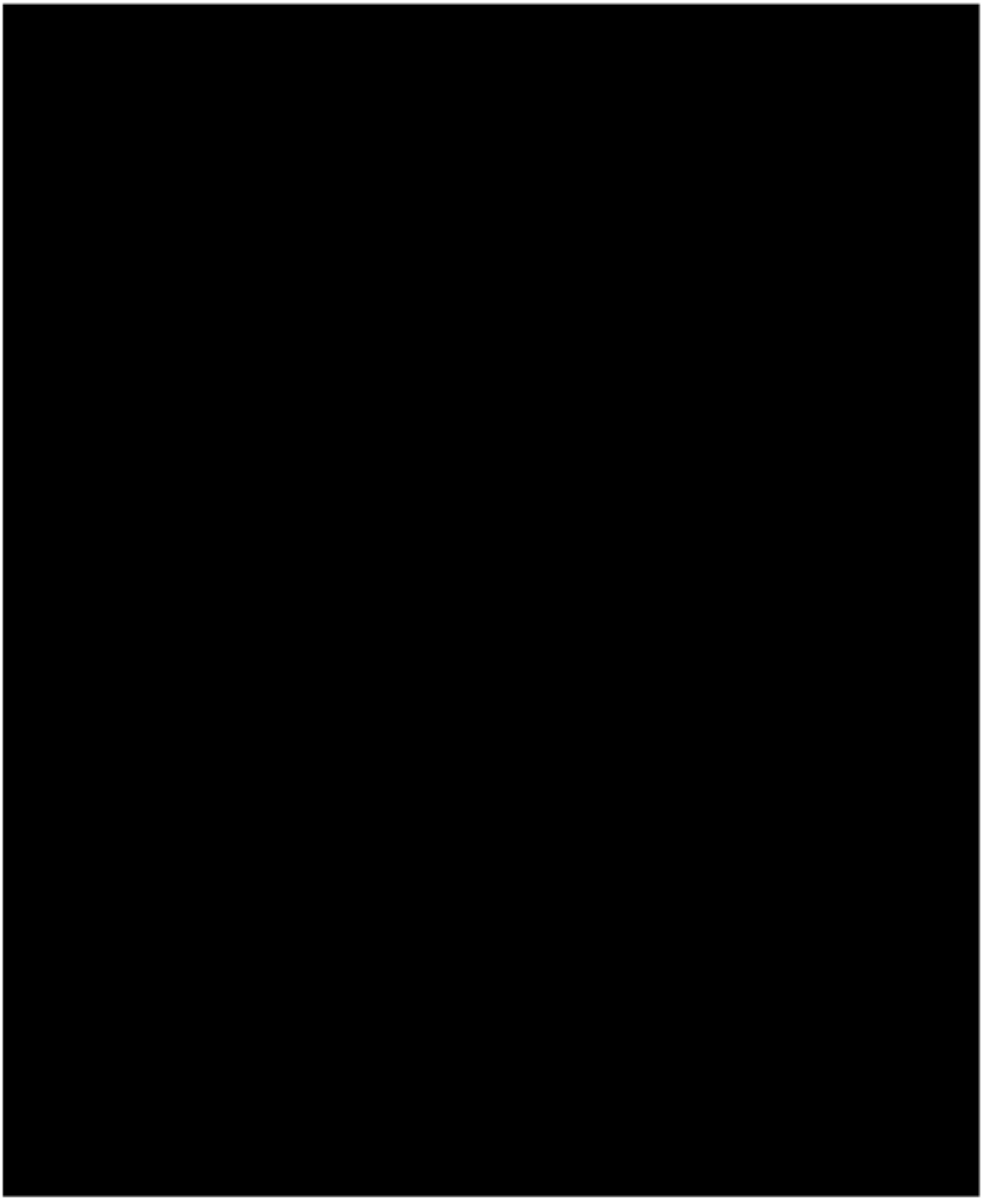
This page serves as title page only

Title:	A Prospective, Open-Label, Single-Arm Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain Long-term Follow Up (CLBP Single-Arm Long-term Follow-up Study)
Protocol Number:	**CD_3030_ Rev. B**
Device:	**INTRACEPT® INTRAOSSEOUS NERVE ABLATION SYSTEM**
Regulatory Status:	The device has FDA 510(k) clearance in the US and is CE marked in the EU for its intended purpose as defined in the Instructions for Use
Sponsor:	Relievant Medsystems 8500 Normandale Lake Blvd., Suite 2150 Minneapolis, MN 55437
Date:	**April 22, 2022**

CONFIDENTIAL



1 SYNOPSIS

Protocol Title:	CLBP Single-Arm Long-term Follow-up Study
Protocol Number:	CD_3030_ Rev A
Sponsor:	Relievant Medsystems, Inc.
Objectives	The objective of this study is to evaluate the long-term effectiveness of the Intracept® Intraosseous Nerve Ablation System for the treatment of chronic low back pain (CLBP) in typical spine practices.
Regulatory Status	The Intracept® Intraosseous Nerve Ablation System is FDA 510(k) cleared and CE Marked for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least 6 months' duration that has not responded to at least 6 months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).
Study Design	This is a prospective, noninterventional, observational post market data collection of long-term effectiveness and satisfaction outcomes for the A Prospective, Open-Label, Single-Arm Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain (CLBP Single-Arm Study) population collected at three (3), four (4), and five (5) years post Intracept Procedure. Study sites will ask subjects about their interest in participating in this follow-up study. If a subject agrees to be contacted about participation the site will provide the subject's contact information to an independent clinical research associate (CRA) who will then obtain verbal informed consent. After consent is obtained, the independent CRA will collect the study data at three scheduled telephone study visits. Data will be analyzed by a third-party statistician.
Number of Subjects	47 subjects treated in original CLBP Single-Arm study will be given the option to participate in the study.
Number of Sites	Two (2) sites in the US

[redacted]	[redacted]
Efficacy Assessments	The following pain, function, and low back pain (LBP) treatment measurements will be collected at each telephone study visit: • Oswestry Disability Index (ODI) • LBP numeric pain score (NPS), Scale 0 to 10 • Opioid use for LBP in past 30 days • Injections for LBP in the past 12 months • Lumbar back interventions since last study visit • Return to activity and work status • Satisfaction survey

2 List of Abbreviations

510(k)	Premarket Notification, per FDA
AE	Adverse events
BVN	Basivertebral nerve
CE mark	Required for a medical device to be sold in the EU
CLBP	Chronic Low Back Pain
CRC	Clinical Research Coordinator
CRA	Clinical Research Associate
CRF	Case report form
eCRF	Electronic case report form
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonisation
ID	Identification
IRB	Institutional Review Board
ISO	International Organization for Standardization
ITT	Intent-to-Treat
L3, L4, L5	Lumbar vertebral levels
LBP	Low back pain
LSM	Least squares mean
MCID	Minimal clinically important difference
MRI	Magnetic resonance imaging
NPS	Numeric Pain Score
ODI	Oswestry Disability Index
PP	Per protocol
RF	Radiofrequency
RCT	Randomized Controlled Trial
S1	Sacral vertebral level one
SAE	Serious adverse event
US	United States of America
VAS	Visual Analog Scale pain tool

3 INTRODUCTION – CLINICAL EXPERIENCE TO DATE

Recent studies have demonstrated that vertebrogenic pain from degenerated or damaged vertebral endplates is an important source of chronic low back pain (CLBP).[1-6] Vertebral endplate damage can lead to cellular communication between the disc nucleus and the bone marrow, triggering inflammation in the intraosseous space.[4] The basivertebral nerve (BVN) within the vertebral body has nociceptors that receive pain signals from the damaged and inflamed endplate and transmit these pain signals to the central nervous system. Endplate damage and inflammation of the intraosseous space are visible as Modic changes on Magnetic Resonance Imaging (MRI).[4]

The Intracept device is a minimally-invasive intervention using a transpedicular approach to deliver radiofrequency (RF) energy to ablate the BVN. Once ablated, these nerves no longer transmit pain signals. The Intracept® Intraosseous Nerve Ablation System is FDA 510(k) cleared and CE Marked for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least 6 months duration that has not responded to at least 6 months of conservative care, and is also accompanied by either Type 1 or Type 2 Modic changes on MRI.

Following a successful pilot study[7], three additional studies were conducted on the Intracept Procedure - two level 1 randomized controlled trials (RCT) and one single arm study:

3.1 SMART Trial:

- The SMART trial was a randomized, double-blinded, sham-controlled, multicenter, international, investigational device exemption (IDE) trial. It was conducted between 2011 to 2014 and enrolled 225 subjects at 15 sites (N=202) in the United States (US) and 3 sites (N=23) in Europe.[8] The primary requirements for inclusion in the trial were CLBP with a duration greater than 6 months; CLBP non-responsive to at least 6 months of non-surgical management; and Modic Type 1 or 2 changes at the vertebral endplates of the levels targeted for treatment.
- The primary efficacy endpoint for the original study was the 3-month change in Oswestry Disability Index (ODI) compared between the study arms. This comparison, as previously reported,[8] found that at 3 months the per-protocol (PP) treatment group exhibited a 20.5 Least Squares Mean (LSM) improvement in ODI compared to a 15.2 LSM improvement in the sham group ($p = 0.019$). The PP treatment arm subjects exhibited a durable ODI mean improvement (23.4 points) at 24 months. [9]
- In terms of percent improvement in ODI from baseline, these results translate into mean percentage improvements of 46.2% at 12 months and 53.7% at 24 months. Responder rates for ODI and LBP visual analogue scale (VAS) were also maintained through two years, with patients showing clinically meaningful improvements in both: ODI ≥ 10-point improvement in 76.4% of patients and ODI ≥ 20-point improvement in 57.5%; VAS ≥ 1.5 cm improvement in 70.2% of patients. Patients receiving the Intracept Procedure also decreased utilization of opioids and spinal injections as compared to utilization prior to treatment.
- Clinically significant outcomes of pain reduction and functional improvement were sustained in the treatment arm US subjects through a mean follow-up of 6.4 years. Mean ODI score improved from 42.81 at baseline to 16.86 at 5-year follow-up, a reduction of 25.95 points ($p < 0.001$). Mean reduction in VAS pain score was 4.38 points (baseline of 6.74,

$p < 0.001$). In total, 66% (66/100) of patients reported a > 50% reduction in pain, 47% reported a > 75% reduction in pain, and 34% of patients reported complete pain resolution. Composite responder rate using thresholds of ≥ 15-point ODI and ≥ 2-point VAS for function and pain at 5 years was 75%.[10]

3.2 INTRACEPT Study:

- This prospective, parallel, open-label, randomized controlled study conducted in 20 US sites, compared the effectiveness of intraosseous RF ablation of the BVN (BVN Ablation) to standard care for the treatment of CLBP in patients with primary vertebrogenic-CLBP. A total of 140 patients (66 BVN ablation and 74 standard care) with CLBP of at least 6 months duration, with Modic Type 1 or 2 vertebral endplate changes between L3 to S1, were randomized 1:1 to undergo either RF ablation of the BVN or continue standard care. The primary endpoint was a between-arm comparison of the mean change in ODI from baseline to 3 months post-treatment. Secondary outcome measures included LBP pain scores via VAS, combined ODI and VAS responder rates, SF-36, and EQ-5D-5L at 3, 6, 9, and 12-months post-procedure. An interim analysis to assess for superiority was prespecified and overseen by an independent data management committee (DMC) when a minimum of 60% of patients had completed their 3-month primary endpoint visit.
- The interim analysis showed clear statistical superiority ($p < 0.001$) for all primary and secondary patient-reported outcome measures in the BVN ablation arm compared to the standard care arm. This resulted in a DMC recommendation to halt enrollment in the study and offer early cross-over to the control arm. As a result, the study reported the outcomes of the 104 patients included in the intent-to-treat (ITT) analysis of the 3-month primary endpoint, which included 51 patients in the BVN ablation arm and 53 patients in the standard care arm. At baseline, the mean age was 50 years, mean ODI was 46.1 (severe pain disability) and mean VAS was 6.67 cm (on a 0 to 10 cm scale). More than 67% of patients reported experiencing LBP for greater than 5 years and more than 70% had received prior injections at baseline.
- Comparing the BVN ablation arm to the standard care arm, the mean changes in ODI at three months were -25.3 points versus -4.4 points, respectively, resulting in an adjusted difference of 20.9 points ($p<0.001$); mean changes in VAS were -3.46 versus -1.02, respectively, an adjusted difference of 2.44 cm ($p<0.001$).
- In the BVN ablation arm, 74.5% of patients achieved the minimal clinically important difference (MCID) of ≥ 10-point improvement in ODI, compared with 32.7% in the standard care arm ($p < 0.001$). With a MCID of 2.0 cm improvement in VAS, 72.5% of patients in the BVN ablation arm reached clinical success compared to 34.0% of patients in the standard care arm ($p<0.001$). No BVN ablation patients received a spinal injection prior to the 3-month endpoint, while in the standard care arm, 6 standard care patients (11%) received injections across 5 study sites.
- The study concluded that minimally invasive RF ablation of the BVN leads to significant improvement of pain and function at 3-months in patients with chronic vertebrogenic-related LBP.[11]
- The study also concluded that clinically significant outcomes of reduced pain and improved function are sustained through 12 and 24 months post BVN ablation. The 61 BVN ablation arm subjects with a 12 month visit demonstrated a 25.7 ± 18.5 point reduction in mean ODI

(p<0.001), and a 3.8 ± 2.7 cm VAS reduction (p<0.001) from baseline at 12 months, with 64% demonstrating ≥50% reduction in pain and 29% pain free. Similarly, the former SC patients who elected BVN ablation 61 (92%) demonstrated a 25.9 ± 15.5 point mean ODI reduction (p<0.001) from baseline at 6 month post-BVN ablation.[12] In the 58 BVNA patients completing a 24-month visit, ODI and VAS improved 28.5 ± 16.2 points (from baseline 44.5; p<0.001) and 4.1 ± 2.7 cm (from baseline 6.6; p<0.001), respectively. A combined responder rate of ODI ≥ 15 and VAS ≥ 2 was 73.7%. A ≥ 50% reduction in pain was reported in 72.4% of patients and 31.0% were pain-free at 2 years.[13]

3.3 A Prospective, Open-Label, Single-Arm Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain (CLBP Single-Arm Study):

- A prospective, single-arm, open label study was completed to evaluate the effectiveness of intraosseous RF ablation of the BVN for the treatment of vertebrogenic related CLBP in typical spine practice settings using permissive criteria for study inclusion. Forty-seven (N=47) consecutive patients with CLBP of at least 6 months duration and with Modic Type 1 or 2 vertebral endplate changes between L3 to S1, were treated with RF ablation of the BVN in up to 4 vertebral bodies. The primary endpoint was patient-reported change in ODI from baseline to 3 months post-procedure. Secondary outcome measures included change in VAS, SF-36, EQ-5D-5L, and responder rates.
- An analysis was conducted when 28 treated patients had completed their 3-month primary endpoint visit. Results of this interim analysis of N=28 patients showed mean change in ODI at three months post treatment was -30.07+14.52 points (p<0.0001); mean change in VAS was -3.50+2.33 (p<0.0001). Ninety-three percent (93%) of patients achieved a ≥ 10-point improvement in ODI and 75% reported ≥ 20-point improvement. Because the results were significant for all primary and secondary endpoints, and the co-occurring INTRACEPT RCT had recently been halted for superiority, new enrollments in the CLBP Single Arm Study were stopped.[14]
- The full cohort (N=47) was followed for 12 months post BVN ablation and improvements in pain and function remained significant.[15] Forty-five (N=45) (95.7%) subjects completed a 12-month follow-up visit. Mean reduction in ODI at 12 months was 32.31±14.07 (p<0.001) with 88.89% (40/45) patients reporting a ≥15 point ODI decrease at 12 months. Mean VAS pain score decrease was 4.31±2.51 at 12 months (p<0.001) and more than 68% reported a 50% reduction in VAS pain scale. Minimally invasive RF ablation of the BVN demonstrated a significant improvement in pain and function in this population of real-world patients with chronic vertebrogenic-related LBP out to 12 months.[15]

The purpose of this study is to measure the long-term effectiveness outcomes at 3+, 4 and 5 years post treatment in subjects treated with the Intracept Procedure in the original A Prospective, Open-Label, Single-Arm Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain Single-Arm described above in section 3.3.

4 STUDY DESIGN

4.1 Overview

The CLBP Single-Arm Long-Term Follow-up study is a prospective, noninterventional, observational post market data collection of the effectiveness, ongoing safety, and satisfaction

outcomes for patients previously treated with the Intracept Procedure. This trial will be conducted according to Good Clinical Practice (GCP) guidelines, including participant verbal informed consent and Independent Review Board (IRB) approval and oversight.

4.2 Objective

To evaluate the long-term effectiveness outcomes of the Intracept Procedure for the relief of chronic low back pain in the original CLBP Single-Arm Study patients.

4.3 Scope and Study Population

The 47 subjects who received the Intracept procedure in the original CLBP Single-Arm Study will be contacted and given the option to participate in this study.

4.4 [redacted]

[redacted]

5 PROTOCOL

This study involves contacting original CLBP Single-Arm Study subjects to seek participation in a data collection of current low back pain, functional status, recent treatments and patient satisfaction. The study will be overseen at each participating study site by a primary investigator and clinical research coordinator (CRC). Telephone visits and data collection will be conducted by an independent study-wide CRA.

5.1 Study Visits

Participants in the study will have three (3) study visits over a period of up to 3+ years based on the timing of their Intracept procedure. Study visits will be conducted via telephone by an independent CRA. Participants will provide verbal informed consented and then answer study questions via telephone study visits at 3+ years, 4 years, and 5 years post Intracept Procedure.

Study subjects who received treatment in the original CLBP Single-Arm Study are eligible to participate in this long-term follow-up data collection. Each study site will make initial contact with the prior study subject and discuss the follow-up study to discern if the subject is interested in participating. The same unique subject ID number used in the CLBP Single-Arm Study will be assigned to the subject. Study participant logs will include subject ID, date(s) of contact and date of agreement/declination to participate and will be maintained by the study site and independent CRA.

Upon subject agreement to participate in the study, the site CRC will forward subject contact information to the independent CRA who will contact the subjects, obtain verbal informed consent, and schedule the telephone study visit. The independent CRA will conduct the telephone study visit, be responsible for the collection of all data elements, and enter data into the designated clinical database.

Study Exit

Subjects will be considered to have completed the study after the 5-year follow-up visit is complete.

5.2 Study Withdrawal/Termination

A subject may withdraw from the study at any time if he/she no longer wishes to participate. If subjects elect to withdraw or is terminated from the study, the independent CRA should inquire about the reason and document details accordingly on the study completion CRF.

If a subject does not respond to at least three documented contact attempts such that the follow-up visit does not occur, the visit will be documented as a "missed visit". Subjects who miss a follow-up visit should still be contacted again for their next scheduled study visit. It is important that continued attempts be made to re-establish contact at subsequent study visits. A subject should not be deemed lost to follow-up and withdrawn from the study until the independent CRA has documented sufficient efforts at achieving subject contact or until the 5-year follow-up study visit window closes for the last subject who received the Intracept procedure.

6 ENDPOINTS

6.1 Primary Effectiveness Endpoint

The primary effectiveness endpoint for this study is the mean improvement in ODI from baseline to 5 years post Intracept treatment.

6.2 Secondary Effectiveness Endpoints

Secondary effectiveness endpoints are:

a) The mean improvement in ODI from baseline to 3 years post treatment

b) The mean improvement in ODI from baseline to 4 years post treatment

c) The mean reduction from baseline VAS in patient reported pain score (10-point VAS-based numeric pain score) to each timepoint

d) The number and proportion of subjects in each quartile (≤ 24% or less, 25-49%, 50-74%, and 75-100%) for percent pain score reduction in low back pain from baseline at each timepoint

e) Responder rates for ODI: proportion of subjects who achieve ≥ 10-Point, ≥ 15-point and ≥ 20-point reduction in ODI from baseline for each timepoint

f) Responder rates for pain rating: proportion of subjects who achieve a ≥ 2.0-point reduction in pain score from baseline for each timepoint

g) Composite responder rate at each timepoint defined as:

    1) ODI decrease of ≥15
    2) NPS decrease of ≥2

h) Composite responder rate at each timepoint defined as:

    1) ODI decrease of ≥15
    2) NPS decrease of greater than 50%

i) Composite endpoint of long-term treatment success at each timepoint defined as:

    1) ODI decrease of ≥15
    2) NPS decrease of ≥2
    3) No injections for the same low back pain etiology and location as treatment location
    4) No pain intervention or surgery for the same low back pain etiology and location as treatment location

j) The number and proportion of subjects with surgical interventions for low back pain of the same treatment region post the Intracept procedure at each timepoint

k) The number and proportion of subjects actively utilizing (defined as >25% of total dosage in 30 days prior to study visit) opioids for low back pain of the same treatment region at each timepoint

l) The number and proportion of subjects utilizing injections since the last study visit for low back pain of the same treatment region at each timepoint

m) Work impact: number of missed workdays in past 30 days at each timepoint and number of days in bed in past 30 days

n) Patient satisfaction with the Intracept Procedure at each timepoint

Ongoing safety will be evaluated at each time. SAEs potentially related to the procedure, device, or the spine will be reported and evaluated for relatedness.

7 STATISTICAL ANALYSIS

7.1 Statistical Methods

The mean change in ODI from baseline to five years is the primary endpoint for this study. Baseline is defined as the last non-missing assessment at or before the baseline visit and prior to the Intracept treatment from the original CLBP Single-Arm Study.

Statistical tests will be two-sided and will be performed at the 0.05 level of significance. Statistical differences will be tested using Student's t-tests. An analysis of covariance (ANCOVA) will also be performed using baseline ODI measurements for the primary endpoint. Baseline NPS will be used as a covariate for the secondary pain reduction endpoint. No other planned analyses will include covariates.

Descriptive statistics will be used for secondary endpoints and will include the number and percentage of subjects in each category. For continuous parameters, descriptive statistics will include n (number of subjects), mean, SD, median, minimum, maximum, and confidence intervals.

Results will be for observed values only. No imputations will be made for missing data.

8 DESCRIPTION OF STUDY ASSESSMENTS

8.1 Oswestry Disability Index

The Oswestry Disability Index (ODI) is a validated questionnaire of low back pain-related disability.[16] It assesses the impact of low back pain on activities of daily living and participation and includes 10 questions. It is scored on a scale of 0 (no disability) to 100 (complete disability), with categories of 0-20 (minimal disability), 21-40 (moderate disability), 41-60 (severe disability), 61-80 (crippling back pain), and 81-100 (bed-bound or exaggerating). The minimally clinically important difference for this tool is considered to be 10 points.[17] For the purposes of this study, this will be administered over the phone.

8.2 Pain Rating Scale for Back Pain Assessment

The numeric pain score (NPS) that will be used for this study is a 10-point numeric scale based on the Visual Analogue Scale (VAS) pain rating questionnaire,[18] with 0 being no pain and 10 being worst imaginable pain. Respondents are asked to indicate what number on the scale corresponds to their perceived level of pain in their low back. Subjects will be specifically instructed to report their level of low back pain as an average for the last seven days. Studies have shown that a minimally clinically important difference in VAS is considered to be approximately 1.5 cm.[19] For the purposes of this study, this will be administered over the phone by asking subjects to rate their average pain in the past seven days on a scale of 1 to 10, with 0 being no pain and 10 being worst pain imaginable.

8.3 Patient Satisfaction

Satisfaction will be assessed with a short, non-validated questionnaire about degree of improvement, satisfaction with treatment, and willingness to repeat the treatment for the same outcome.

8.4 Opioid Medications

Patient-reported opioid usage for CLBP will be captured. Medication type, prescribed dosage, and average daily dose for the last 30 days will be documented on the source document worksheet.

8.5 Injections & Interventions

Patient-reported injections and interventions (i.e. RF ablations) for low back pain since the Intracept procedure or last study visit will be collected. Date, type, and location on back of each injection or intervention will be recorded.

8.6 Surgeries

Back surgeries performed since the Intracept Procedure or last study visit will be documented. Date, type, and location within the back/spine of each surgical procedure will be recorded.

8.7 Injections, Interventions, and Surgeries Adjudication

An independent physician will review all available medical records and radiologic images obtained by the study site to determine diagnosis (pain location, etiology, and nature) resulting in an intervention (procedure and/or injections) or surgery. All interventions and surgeries will be adjudicated as either a treatment failure (ongoing or exacerbated CLBP of similar location, anatomy, etiology /pain source, and nature/severity to the pre-Intracept treatment pain) or not related (different location, anatomy, etiology/pain source, or nature/severity). The independent physician will also review all medical records and radiologic images obtained by the study site to determine or evaluate reported adverse events.

9 Study Risk Analysis

This study is categorized as a non-significant risk study with minimal risk to subjects. The primary risk to study participants is a loss of confidentiality. This risk will be mitigated through assignment of the unique Subject ID number from the original CLBP Single-Arm Study and de-identification of data. Subject contact information will only be utilized by an authorized study-wide independent CRA (under patient consent) for purposes of conducting the study visits.

10 IRB Approval, Informed Consent, Data Collection, Data Handling, and Record Keeping

10.1 Institutional Review Board (IRB) Approval

This study will be conducted under IRB review and approval of the protocol, the verbal informed consent documentation/process, subject stipend, and study materials. The study will not commence before verbal consent is received.

10.2 Informed Consent

Verbal informed consent shall be obtained and documented before a subject has their first telephone visit. It is the responsibility of the independent CRA to ensure that verbal informed consent is obtained from the subject and documented, before any study follow-up activity is undertaken.

10.3 Confidentiality

Subject medical information obtained for this study is confidential, and disclosure to third parties other than those authorized for the study and IRB regulatory oversight is prohibited. Subjects will only be identified by the unique study ID assigned to them for the study. Data will be de-identified in a manner compliant with HIPAA regulations.

Upon the subject's consent to participate, the independent CRA will conduct the telephone study visits. All study visit data is provided directly by the subject during the telephonic study visit. A release of medical records will be obtained from the subject prior to accessing subject's medical records for adverse event and additional pain interventions / surgeries review and adjudication review .

Data generated by this study must be available for inspection upon request by representatives of the FDA, national and local health authorities, the Sponsor or its designee, and the IRB for the study site, if appropriate.

10.4 Source Documents

Source data includes all information, such as original records of clinical findings, observations, or other activities in a clinical study necessary for the reconstruction and evaluation of the study. Source data for this study are the patient-reported outcomes and medication use which may be recorded on the source document worksheets by the independent CRA and then entered into the designated clinical database; these will serve as the primary data collection instruments for this study.

The assigned, study-wide independent CRA will be responsible for conducting the three-, four- and five-year telephone visits, collecting the requested data at the visits, and timely completion and submission of data into the clinical database. Medical records received via medical release will be considered the source data for injections, medications, additional pain interventions or surgeries, and adverse events. The clinical database will be considered the source data for any data collected verbally from the study subject and entered directly into the clinical database.

10.5 Regulatory Compliance

The Intracept System is FDA 510(k) cleared and CE marked.

This study is for data collection only and will be conducted in compliance to applicable regulations and ICH/GCP Guidelines. The investigator and all research staff participating in this study are expected to adhere to the protocol, applicable privacy laws, and any approval requirements imposed by the IRB. The investigator has the further responsibility of adherence to the Investigator Agreement and to maintain the contents of the Regulatory Binder.

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10.7 Record Retention

It is the Investigator's responsibility to retain study essential documents for at least 2 (two) years after completion of the study. Source documents and copies of de-identified patient permission forms and verbal consent documentation will be retained for a period of 2 (two) years post the completion of the study.

[redacted]

12 PUBLICATION POLICY

The results of this study will be reported regardless of whether the outcomes favor the Intracept Procedure. Relievant Medsystems retains the right to review any submitted publications for accuracy and product confidential information prior to submission. The study will be registered on www.clinicaltrials.gov. Data reporting and authorship of manuscripts will be based on International Journal Editors' guidelines for authorship.

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