STATISTICAL ANALYSIS PLAN

Project Number:	CP 0011
Study Title:	Five-Plus Year Follow-up to SMART (Surgical Multi-center Assessment of RF Ablation for the Treatment of Vertebrogenic Back Pain) Trial
Development Phase of Study:	Prospective Single Arm Post Market Study
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Statistical Analysis Plan based on Protocol Version:	CIP 0011 Rev A dated 5 April 2019
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Revisions to the Statistical Analysis Plan described herein must be approved through a formal written amendment with the exception of minor editorial changes to tables, figures, or listing shells, and any necessary textual clarifications for programmers that do not affect the stated analysis variables, study endpoints, or statistical methods.

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1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

510(k)	Premarket Notification per FDA
ANCOVA	analysis of covariance
BMI	body mass index
BVF	basivertebral foramen
BVN	basivertebral nerve
CI	confidence interval
CRF(s)	case report form(s)
eCRF(s)	electronic case report form(s)
FDA	Food and Drug Administration
ITT	intent-to-treat
LBP	low back pain
LSMean	least square mean
Max	maximum
MRI	magnetic resonance imaging
Min	minimum
n	number of observations
N	number of subjects (sample size)
ODI	Oswestry Disability Index
RF	radiofrequency
SAS®	Statistical Analysis System (SAS® Institute Inc., Cary, NC)
SD	standard deviation
VAS	visual analogue scale
VB	vertebral body

1. INTRODUCTION

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] Vertebal 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 disc 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 magnetic resonance imaging (MRI).

Following a successful pilot study[7], a 2:1 randomized, double-blind, sham-controlled trial demonstrated the safety and efficacy of intraosseous RF ablation of the BVN to treat CLBP in patients with Modic type 1 or 2 changes of the vertebral endplates. The SMART trial was conducted between 2011 to 2014 and enrolled 225 subjects at 15 sites (N=202) in the United States 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 low back pain 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 percent of patients and ODI ≥ 20-point improvement in 57.5 percent; VAS ≥ 1.5 cm improvement in 70.2 percent of patients. Patients receiving the Intracept Procedure also decreased utilization of opioids and spinal injections as compared to utilization prior to treatment.

The purpose of this study is to measure the long term (5 + years) effectiveness outcomes in subjects treated with the Intracept Procedure in this original SMART study population.

2. STUDY DESIGN

2.1 Overall Study Design

This study is a post-market, non-interventional, data collection of the long term (5 + year) follow-up in the 133 treatment arm subjects in the SMART trial in the U.S. The study will be conducted at the same thirteen U.S. study sites where the procedures occurred.

2.2 Study Objective

To evaluate the long term effectiveness outcomes of the Intracept Procedure for the relief of CLBP in the SMART trial treatment arm subjects.

2.3 Study Population

All US subjects that were randomized to the treatment arm of the original SMART Trial will be approached to participate in the long term (5 + year) follow-up study. A single study visit will be performed by an independent nurse CRA to collect the data.

2.4 Blinding

Not applicable to this study.

2.5 Study Assessments

ODI

The Oswestry Disability Index (ODI) is a validated questionnaire of low back pain-related disability.[10] 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.[11]. For the purposes of this study, this will be administered over the phone.

The ODI score will be calculated as follows:

> For each section of six statements the total score is 5; if the first statement is marked the score = 0; if the last statement is marked the score = 5. Intervening statements are scored according to rank. If more than one box is marked in each section, take the highest score.
>
> The ODI score may be summarized as:
>
> ODI Score = total score/(5 * number of questions answered) * 100

Scores will be rounded to a whole number for convenience.

Pain Score

The numeric pain rating scale that will be used for this study is a 10-point numeric scale based on the Visual Analogue Scale (VAS) pain rating questionnaire[12] used during the SMART study, 0 being no pain and 10 being worst imaginable pain. Respondents are asked to indicate what integer 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 points.[13] For the purposes of this study, this will be administered over the phone.

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.

Opioids, Injections, and Interventions

Patient treatments including opioid use in the past 30 days (prior to the study visit), injections in the past 12 months (prior to study visit), and interventions post the Intracept procedure will be collected on the case report form (CRF).

2.6 Endpoint Adjudication

An independent orthopaedic surgeon will review medical records and radiologic images to determine diagnosis (pain location, etiology, and nature) resulting in an intervention (procedure and/or injections). All interventions will be adjudicated as either a treatment failure (ongoing or exacerbated CLBP of similar location, etiology and nature/severity to the pre-Intracept treatment pain) or not related (different location, etiology, or nature/severity).

3. EFFICACY AND SAFETY ENDPOINTS

3.1 Efficacy Endpoints

3.1.1 Primary Efficacy Endpoint

The primary effectiveness endpoint for this study is the mean improvement in ODI from baseline to 5+ years within treatment arm subjects.

3.1.2 Secondary Efficacy Endpoints

The secondary efficacy endpoints are:

- The mean reduction from baseline VAS in patient reported pain score (10-point VAS-basednumeric pain score) at 5 + years post treatment.
- Responder rates for ODI - proportion of subjects who achieve ≥ 10-point reduction in ODI from baseline to 5+ years post-treatment.
- Responder rates for pain rating - proportion of subjects who achieve a ≥ 1.5-point reduction in pain rating (VAS) from baseline to 5+ years post-treatment.
- The number and proportion of subjects in each quartile (≤ 24%, 25-49%, 50-74%, and 75-100%) for percent ODI reduction
- The number and proportion of subjects in each quartile (≤ 24% or less, 25-49%, 50-74%, and 75-100%) for percent VAS-based pain score reduction.
- The number and proportion of subjects with procedures for low back pain of the same Intracept treatment region post procedure.
- The number and proportion of subjects actively utilizing opioids for low back pain of the same treatment region (defined as > 25% of total dosage in 30 days prior to study visit).
- The number and proportion of subjects utilizing injections in the past 12 months for the treatment of low back pain of the same Intracept treatment region.
- Patient satisfaction with the Intracept Procedure.
- Composite endpoint of long term treatment success defined as:
    - ODI decrease of 10 or more at 5+ years
    - VAS-based pain score decrease of 2 or more at 5 + years
    - Not actively using opioids for LBP (defined as > 25% of total dosage used in 30 days prior to study visit)
    - No LBP procedures since the Intracept procedure (that is adjudicated as treatment failure due to same location, same etiology, same severity as baseline)
    - Not actively utilizing injections for low back pain treatment (in past 12 months and adjudicated as for same location, etiology, severity as baseline

No safety endpoints were collected in this post market study.

4. STATISTICAL AND ANALYTICAL PLANS

4.1 General Methodology

The SMART Five Plus Year Follow-up Study analysis will be performed when all US SMART treatment arm subjects have been approached to participate in the study, and all subjects who consented to participate, have completed their 5+ year follow-up study visit.

The number of subjects in the analysis and reasons for withdrawal will be summarized in a CONSORT flowchart. All subjects consenting to participate in the long term follow-up study will be reported as observed. No imputations are planned for missing data.

All statistical processing will be performed by Technomics Research LLC. The standard operating procedures (SOPs) of Tehcnomics Research LLC will be followed in the creation and quality control of all data displays and analyses. Analyses will be conducted using SAS® software Version 9.3 or later unless otherwise stated

Statistical tests will be two-sided and will be performed at the 0.05 level of significance.

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, and maximum. Appropriate inferential statistics will be used for the primary and secondary efficacy variables.

4.2 Baseline Definition

Intra-subject comparisons of baseline to 5+ years post procedure will be made unless otherwise stated. Baseline is defined as the last non-missing assessment at or before the baseline visit and prior to Intracept treatment.

4.3 Adjustments for Covariates

Baseline ODI score will be a covariate for the primary efficacy endpoint. The respective baseline value will be used as covariate in the secondary efficacy endpoints for VAS. No other planned analyses will include covariates.

4.4 Analyses and Data Monitoring

4.4.1 Demographic and Other Baseline Characteristics

Demographic and baseline characteristics responses will be summarized with descriptive statistics for the observed study population. A comparison of baseline demographics, co-morbidities, medical history and baseline values for ODI and VAS of the observed study population will be performed to the SMART trial full treatment arm group.

Additionally, ODI, VAS and AE histories will be compared to demonstrate that the LTFU subjects are missing at random and are not systematically different from the retained subjects.

4.4.2 Primary Efficacy Analysis

The efficacy analysis will be conducted all consented treated subjects with a 5+ year study visit. Results will be reported for observed data only; missing values will not be imputed.

The primary analysis will test the mean improvement in ODI from baseline to 5+ years as an intra-patient comparison. The mean change will be analyzed with an ANCOVA with a covariate of baseline ODI score. See Appendix A - Table 8.

If $p \leq 0.05$ then it may be concluded that a significant functional improvement was demonstrated in axial low back pain subjects treated with the Intracept procedure and that the treatment is durable to mean follow-up for the long term study.

A comparison will be be made between the ITT (as treated cohort) and a Intracept only treated cohort (with those subjects that had additional procedures such as RF Ablation, microdiscectomy, fusion, etc. removed).

4.4.3 Secondary Efficacy Analysis

Results will be reported for observed data only; missing values will not be imputed.

4.4.3.1 ODI Responder Rates

Responder rates for ODI will be determined by the proportion of subjects who achieve ≥ 10, 15, and 20-point reductions in ODI from Baseline to 5+ years post-treatment.

4.4.3.2 Pain Score

The mean change will be analyzed with an ANCOVA with a covariate of baseline VAS score. See Appendix A - Table 9.

Responder rates for numeric pain scores (VAS scale 0 to 10) will be determined by the proportion of subjects who achieve ≥ 1.5 and 2.0 point reductions in pain score from Baseline to 3 months.

4.4.3.3 Regression to the Mean

Regression to the mean analyses for ODI and VAS will be performed as supplemental analyses. See Appendix A - Table 11.

4.4.3.4 Treatment Success

Intracept long term treatment success rates will be determined by the proportion of subjects who meet the composite definition of treatment success at 5+ years.

4.4.3.5 Patient Satisfaction

The Patient Satisfaction survey responses will be summarized using descriptive statistics.

5. APPENDIX A – ANALYSIS TABLES

Table 1 - Summary of Screening (Enrolled Subjects)	
	SMART 5+ Year US Treatment Arm Cohort (N=132)
Enrolled (Consented)	% (n/N)
Study Non-Participation Reason	% (n/N)
Declined Participation	% (n/N)
Subject Withdrew Consent	% (n/N)
LTFU	% (n/N)
Death	% (n/N)
Other	% (n/N)

Table 2 - Demographic Information			
Characteristic	SMART Treated Subjects in 5+ Yr Follow-up N = XX	SMART Treated Subjects Not in 5+ Year Follow-up N = XX	t-test of Means or Exact Test of Proportions
Age (years)	Mean + SD, Median, Range	Mean + SD, Median, Range	
Gender:			
Male	% (n/N)	% (n/N)	
Female	% (n/N)	% (n/N)	

Table 3 – Baseline Social/Socioeconomic/Work History			
Characteristic	SMART Treated Subjects in 5+ Yr Follow-up N = XX	SMART Treated Subjects Not in 5+ Year Follow-up N = XX	t-test of Means or Exact Test of Proportions
Baseline Working Status			
Working	% (n/N)	% (n/N)	
Working Full-Time	% (n/N)	% (n/N)	
Working Part-Time	% (n/N)	% (n/N)	
Not Working	% (n/N)	% (n/N)	
Short-Term Disability	% (n/N)	% (n/N)	
Not Working Due to Back Pain	% (n/N)	% (n/N)	
Unemployed	% (n/N)	% (n/N)	
Retired	% (n/N)	% (n/N)	
Other	% (n/N)	% (n/N)	
Time since last worked (for subject not working due to back pain)	Mean + SD, Median, Range	Mean + SD, Median, Range	

Table 4 – Baseline Characteristics			
Characteristic	SMART Treated Subjects in 5+ Yr Follow-up N = XX	SMART Treated Subjects Not in 5+ Year Follow-up N = XX	t-test of Means
Baseline ODI	Mean + SD, Median, Range	Mean + SD, Median, Range	
Baseline VAS	Mean + SD, Median, Range	Mean + SD, Median, Range	

Table 5 – Baseline Low Back Pain History			
Characteristic	SMART Treated Subjects in 5+ Yr Follow-up N = XX	SMART Treated Subjects Not in 5+ Year Follow-up N = XX	t-test of Means or Exact Test of Proportions
Length of Time Experience LBP			
< 6 months	% (n/N)	% (n/N)	
6 months to < 1 year	% (n/N)	% (n/N)	
1 year to < 2 years	% (n/N)	% (n/N)	
2 years to < 3 years	% (n/N)	% (n/N)	
3 years to < 5 years	% (n/N)	% (n/N)	
> 5 years	% (n/N)	% (n/N)	
# of days a Week Subject Experiences Low Back Pain	Mean + SD, Median, Range	Mean + SD, Median, Range	
Modic Type by Level & Endplate			
L3 Superior Endplate	% (n/N)	% (n/N)	
Modic I	% (n/N)	% (n/N)	
Modic II	% (n/N)	% (n/N)	
L3 Inferior Endplate	% (n/N)	% (n/N)	
Modic I	% (n/N)	% (n/N)	
Modic II	% (n/N)	% (n/N)	
L4 Superior Endplate	% (n/N)	% (n/N)	
Modic I	% (n/N)	% (n/N)	
Modic II	% (n/N)	% (n/N)	
L4 Inferior Endplate	% (n/N)	% (n/N)	
Modic I	% (n/N)	% (n/N)	
Modic II	% (n/N)	% (n/N)	
L5 Superior Endplate	% (n/N)	% (n/N)	
Modic I	% (n/N)	% (n/N)	
Modic II	% (n/N)	% (n/N)	
L5 Inferior Endplate	% (n/N)	% (n/N)	
Modic I	% (n/N)	% (n/N)	
Modic II	% (n/N)	% (n/N)	
S1 Superior Endplate	% (n/N)	% (n/N)	
Modic I	% (n/N)	% (n/N)	
Modic II	% (n/N)	% (n/N)	

Table 6 – Baseline Low Back Treatment History			
Characteristic	SMART Treated Subjects in 5+ Yr Follow-up N = XX	SMART Treated Subjects Not in 5+ Year Follow-up N = XX	t-test of Means or Exact Test of Proportions
Medications			
Opioid Medications	% (n/N)	% (n/N)	
Total Opioid Equianalgesic Average Daily Dose in 7 days prior to Baseline	Mean + SD, Median, Range	Mean + SD, Median, Range	
Injections	% (n/N)	% (n/N)	
Epidural Injections	% (n/N)	% (n/N)	
Facet Injections	% (n/N)	% (n/N)	
Other Injections	% (n/N)	% (n/N)	

Table 7 – RF Ablation Table			
Characteristic	SMART Treated Subjects in 5+ Yr Follow-up N = XX	SMART Treated Subjects Not in 5+ Year Follow-up N = XX	t-test of Means or Exact Test of Proportions
VB Treated			
L3	% (n/N)	% (n/N)	
L4	% (n/N)	% (n/N)	
L5	% (n/N)	% (n/N)	
SI	% (n/N)	% (n/N)	

5+ Year Follow-up Study Endpoints:

Tables 8 and 9 will be performed for both the ITT (as treated) population and the Intracept treated only population.

Table 8 – Primary Endpoint Results	
	SMART 5+ Yr Follow-up Subjects **N = XX**
	Mean ± SD (N), Median [Interquartile Range], Range or % (n/N)
Time of Assessment	
Years since Index Procedure	Mean + SD, Median, Range
Percent with at Least 5 years of Follow-up	% (n/N)
ODI	**(N=XX)**
Baseline ODI Score (Mean + SD, Median, Range)	Mean + SD, Median, Range
5+ Year ODI Score (Mean + SD, Median, Range)	Mean + SD, Median, Range
Mean change in ODI score from baseline to 5+ Years post-treatment	Mean + SD, Median, Range (*p-value*)
ODI Responder Rates	
Subjects with ≥ 10-point ODI decrease	% (n/N) (*p-value*)
Subjects with ≥ 15-point ODI decrease	% (n/N) (*p-value*)
Subjects with ≥ 20-point ODI decrease	% (n/N) (*p-value*)
ODI Response Quartiles	
Subjects with ≤ 24% or less decrease	% (n/N)
Subjects with 25-49% decrease	% (n/N)
Subjects with 50-74% decrease	% (n/N)
Subjects with 75-100% decrease	% (n/N)
	(p-value)

Table 9 – Secondary Endpoints Results	
	SMART 5+ Yr Follow-up Subjects N = XX
10 Point VAS Numeric Pain Scale	
Baseline VAS Score (Mean + SD, Median, Range)	Mean + SD, Median, Range
5+ Year VAS Score (Mean + SD, Median, Range)	Mean + SD, Median, Range
Mean change in VAS score from baseline to 3 months post-treatment	Mean + SD, Median, Range (*p-value*)
VAS Responder Rates	
% of subjects with ≥ 1.5 Pt VAS decrease	% (n/N) (*p-value*)
% of subjects with ≥ 2.0 Pt VAS decrease	% (n/N) (*p-value*)
VAS Response Quartiles	
Subjects with ≤ 24% or less decrease	% (n/N)
Subjects with 25-49% decrease	% (n/N)
Subjects with 50-74% decrease	% (n/N)
Subjects with 75-100% decrease	% (n/N)
	(p-value)

Table 10 – Regression to the Mean Analysis	
	SMART 5+ Yr Follow-up Subjects N = XX
Regression to the Mean	
Average change in ODI in CONTROL group between baseline and 1 year	Mean, N, 95% CI, t-test p (Ho: δ=0)
Average change in ODI in CONTROL group between baseline and 2 years	Mean, N, 95% CI, t-test p (Ho: δ=0)
Average change in ODI in INTRACEPT group between baseline and 1 year	Mean, N, 95% CI, t-test p (Ho: δ=0)
Average change in ODI in INTRACEPT group between baseline and 2 years	Mean, N, 95% CI, t-test p (Ho: δ=0)
Average change in ODI in INTRACEPT group between baseline and 5+ years	Mean, N, 95% CI, t-test p (Ho: δ=0)
Time (per year) effect on ODI in INTRACEPT group	Mean, N, 95% CI, rm F-test p (Ho: time=0)
Average change in VAS in CONTROL group between baseline and 1 year	Mean, N, 95% CI, t-test p (Ho: δ=0)
Average change in VAS in CONTROL group between baseline and 2 years	Mean, N, 95% CI, t-test p (Ho: δ=0)
Average change in VAS in INTRACEPT group between baseline and 1 year	Mean, N, 95% CI, t-test p (Ho: δ=0)
Average change in VAS in INTRACEPT group between baseline and 2 years	Mean, N, 95% CI, t-test p (Ho: δ=0)
Average change in VAS in INTRACEPT group between baseline and 5+ years	Mean, N, 95% CI, t-test p (Ho: δ=0)
Time (per year) effect on VAS in INTRACEPT group	Mean, N, 95% CI, rm F-test p (Ho: time=0)

Table 11 – Comparison of SMART Endpoints			
Characteristic	**SMART Treated Subjects in 5+ Yr Follow-up N = XX**	**SMART Treated Subjects Not in 5+ Year Follow-up N = XX**	**t-test of Means or Exact Test of Proportions**
Change in ODI (Baseline to 3 Months)	Mean + SD, Median, Range	Mean + SD, Median, Range	
Change in VAS (Baseline to 3 Months)	Mean + SD, Median, Range	Mean + SD, Median, Range	
ODI Responders (≥ point ODI reduction)	% (n/N)	% (n/N)	

Table 12 – Opioids & Injections Utilization	
	SMART 5+ Yr Follow-up Subjects N = XX
Opioid Use	
Subjects Taking Opioids at Baseline	% (n/N)
Subjects actively taking Opioids in last 30 days (5+ Year Follow-up Visit)	% (n/N)
Opioid Dosage (in subjects taking opiods)	
Opioid Dosage at Baseline	Mean + SD, Median, Range
Opioid Dosage at 5+ years post treatment	Mean + SD, Median, Range
Epidural Injections	
Subjects with prior injections at baseline	Mean + SD, Median, Range
Subjects with injections in 12 months prior to 5+ year post treatment visit	Mean + SD, Median, Range
Subjects with injections for low back pain treatment in the same location as Intracept treatment (in the past 12 months):	Mean + SD, Median, Range
Mean # of injections per subject in 12 months prior to baseline	% (n/N)
Mean # of injections per subject in 12 months prior to 5+ year post treatment visit	% (n/N)
Time to first injection for low back pain in same location post Intracept Procedure	Mean + SD, Median, Range

Table 13 – Surgical Interventions	
	SMART 5+ Yr Follow-up Subjects N = XX
Number (%) of subject reporting a procedure	% (n/N)
Number of procedures	% (n/N)
Re-intervention Rate over Time 1 Year 2 Year 5 Year	 S% (95% CI) S% (95% CI) S% (95% CI)
Type of procedure:	
Discectomy	% (n/N)
Lumbar fusion	% (n/N)
RF Ablation	% (n/N)
Other	% (n/N)
At the same level of Intracept treatment?	
Yes	% (n/N)
No	% (n/N)
Time to intervention (post Intracept procedure)	Mean + SD, Median, Range
Same etiology and level as Intracept treatment	Mean + SD, Median, Range
Different etiology or level from Intracept treatment	Mean + SD, Median, Range

Table 14 – Pain Status at 5 + Years	
	SMART 5+ Yr Follow-up Subjects N = XX
Pain Status	
Constant	% (n/N)
Intermittent	% (n/N)
No Pain	% (n/N)
Experiencing Pain	
Same location as prior to Intracept Procedure	% (n/N)
Different location from prior to Intracept Procedure	% (n/N)
Same nature as prior to Intracept Procedure	% (n/N)
Different nature from prior to Intracept Procedure	% (n/N)
Time (per year) effect on VAS in INTRACEPT group	Mean, N, 95% CI, rm F-test p (Ho: time=0)

Table 15 – Durability at 5 + Years	
	SMART 5+ Yr Follow-up Subjects N = XX
Number (%) of subjects reporting a re-intervetion (lumbar procedure adjudicated as same location and etiology as Intracept procedure)	% (n/N)
Number (%) of subjects reporting actively using opioids (defined as > 25% of total prescribed dosage in 30 days prior to visit)	%(n/N)
Number (%) of subjects reporting low back pain injections in same treatment location as Intracept.	% (n/N)
Number (%) of subjects reporting less than 2 point decrease in pain (in same location) compared to baseline	% (n/N)
Number (%) of subjects reporting less than 10 point decrease in ODI compared to baseline	% (n/N)
Number (%) of subjects reporting at least one of the above	% (n/N)
Intracept **therapy success** rate at 5 plus years (none of the below criteria are met) The following is the definition of **therapy success:** a. ODI decrease of 10 or more at 5+ years b. VAS decrease of 2 or more at 5 + years c. No procedures since the Intracept procedure (that is adjudicated as treatment failure due to same location, same etiology, same severity as baseline) d. No injections (in past 12 months and adjudicated as for same location, etiology, severity as baseline) e. Not actively taking opioids (defined as > 25% of total dosage in 30 days prior to study visit)	% (n/N)

Table 16 – Patient Satisfaction	
	Subject Frequency
How do you feel your condition is post the Intracept Procedure?	
Improved	% (n/N)
Slightly	% (n/N)
Much	% (n/N)
Vastly	% (n/N)
No Change	% (n/N)
Worsened	% (n/N)
Slightly	% (n/N)
Much	% (n/N)
Vastly	% (n/N)
I am satisfied with the results of my surgery	
Yes	% (n/N)
No	% (n/N)
All things considered; I would have the surgery again for the same condition	
Yes	% (n/N)
No	% (n/N)
Were you able to resume the activity level you enjoyed prior to onset of your low back pain?	
Yes	% (n/N)
No	% (n/N)

6. APPENDIX B - REFERENCES

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