# Statistical Analysis Plan (SAP)

# Protocol No. CAP-CP-001

| | |
|---|---|
| **Study Title:** | **A Multicenter, Prospective, Randomized, Subject Blinded Comparative Study of Axoguard® Nerve Cap and Neurectomy for the Treatment of Symptomatic Neuroma and Prevention of Recurrent End-Neuroma Pain "REPOSE"** |
| **Prepared For:** | **Axogen, Inc.**<br>**13631 Progress Blvd., Suite 400**<br>**Alachua, FL 32615** |
| **SAP Version:** | **Version 2.0** |
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# 1. Table of Contents

# 1. Glossary of Abbreviations

| | |
|---|---|
| AE | Adverse Event |
| AUC | Area Under Curve |
| CI | Confidence Interval |
| CIP | Clinical Investigational Plan; the "protocol" |
| CRF | Case Report Form |
| EDCS | Electronic Data Capture System |
| FHSQ | Foot Health Status Questionnaire |
| ITT | Intent-to-Treat |
| IQR | Interquartile Range |
| mITT | Modified Intent-to-Treat |
| MME | Morphine Milligram Equivalence |
| MQS | Medication Quantification Scale |
| PEE | Primary Efficacy Endpoint |
| PP | Per-Protocol |
| PROMIS® | Patient Reported Outcome Measurement Information System® |
| SAE | Serious Adverse Event |
| SAP | Statistical Analysis Plan |
| SD | Standard deviation |
| SP | Safety Population |
| UADE | Unanticipated Adverse Device Effect |
| VAS | Visual Analogue Scale |
| [redacted] | [redacted] |

# 2. Introduction

This document describes the statistical methods and data presentations to be used in the analysis of data from the post-market study, "Axogen Protocol CAP-CP-001: A Multicenter, Prospective, Randomized, Subject-Blinded Comparative Study of Axoguard® Nerve Cap and Neurectomy for the Treatment of Symptomatic Neuroma and Prevention of Recurrent End-Neuroma Pain "REPOSE."

Background information is provided for the overall study design and objectives in the study protocol (current version 3.0 dated 01MAR2021). Refer to the study specific data management plan and case report forms (CRFs) for additional details of study conduct and data collection.

The study evaluates symptomatic neuromas in the foot or ankle and will occur in two phases: a pilot study and a comparative study. The pilot phase study is a prospective single arm series in which all participants receive the Axoguard Nerve Cap following neurectomy. The comparative phase study is a prospective, randomized, controlled, participant-blinded comparative cohort comparing participants who receive the Axoguard Nerve Cap following neurectomy (Treatment) to those who undergo neurectomy alone (Control).

# 3. Objectives

## 3.1. Primary Objective

*Pilot study:* The primary objective of the pilot study is to evaluate changes in visual analog scale (VAS) pain scores at 3 months compared to baseline in participants who receive an Axoguard Nerve Cap following neurectomy.

*Comparative study:* The primary objective of the comparative study is to evaluate differences in VAS pain scores at 12 months between the two study groups: Axoguard Nerve Cap + neurectomy vs neurectomy alone.

## 3.2. Secondary Objectives

The secondary objectives of this study are to compare degree of recovery over time (measured by reduction in pain); quality of life; [redacted] for each treatment group within 12 months.

# 4. Study Overview

CAP-CP-001 is a multi-center, prospective, randomized, controlled, participant-blinded study in participants with a symptomatic neuroma in the foot or ankle. Fifteen (15) participants meeting inclusion/exclusion criteria will receive the Axoguard Nerve Cap in the pilot study. An additional eighty-six (86) participants meeting inclusion/exclusion criteria will be randomized in

a 1:1 ratio to receive either neurectomy alone or neurectomy plus the Axoguard Nerve Cap for this comparative study.

Neurectomy procedures will occur following the investigators' institutional standards-of-care. Placement of the Axoguard Nerve Cap will follow the manufacturer's written instructions-for-use. Participants will participate in this study for up to 13 months including the screening period. The study will consist of a screening visit, an operative visit, and 6 post-operative follow-up visits at 2 weeks, 1 month, 3 months, 6 months, 9 months, and 12 months.

Adverse events (AEs) will be collected to monitor participant safety, while the pain assessments - VAS pain score and Patient Reported Outcomes Measurement System (PROMIS®) Questionnaires; and Quality of Life questionnaires – Foot Health Status Questionnaire (FHSQ) [redacted] will be measured to determine efficacy. The primary efficacy endpoint for the pilot study is the change in VAS pain score at 3 months compared to baseline. The primary efficacy endpoint for the comparative study is the difference between treatment groups with respect to change in VAS pain score at 12 months compared to baseline.

## 5. Schedule of Assessments

This schedule can also be found in the protocol. A description of the assessment questionnaires can also be found in the protocol.

| Assessments | Visit 1* Screening [redacted] Pre-operative | Visit 2* Operative Day 0 Operative | Visit 3 Week 2 Day 14 [redacted] Post-Op | Visit 4 Week 4 Month 1 Day 30 [redacted] Assessment | Visit 5 Week 12 Month 3 Day 90 [redacted] Assessment | Visit 6 Month 6 Day 180 [redacted] Assessment | Visit 7 Month 9 Day 270 [redacted] Assessment | Visit 8 Month 12 Day 360 [redacted] EOS/ET |
|---|---|---|---|---|---|---|---|---|
| Informed Consent | X | | | | | | | |
| Inclusion/Exclusion Criteria | X | X | | | | | | |
| Relevant Medical History | X | | | | | | | |
| Demographics | X | | | | | | | |
| Neuroma Information | X | | | | | | | |
| Vital Signs[1] | X | X | X | X | X | X | X | X |
| Operative Information | | X | | | | | | |
| Randomization[2] | | X | | | | | | |
| Post-operative Care | | | X | | | | | |
| [redacted] | | [redacted] | | | | | | |
| Wound Assessment | | | X | X | | | | X |
| Pain Assessments[3] | X | X | X | X | X | X | X | X |
| Quality of Life Questionnaires[4] | X | | | X | X | X | X | X |
| [redacted] | | | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Daily Pain Medication Diary and Concomitant Medication Log [5] | X | X | X | X | X | X | X | X |
| Daily Pain Diary | X | X | X | X | X | X | X | X |
| Adverse Events | | X | X | X | X | X | X | X |
| [redacted] | | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

*Note: In some instances, Visit 1 and Visit 2 can occur on the same day.

[1] Vital signs to include weight, seated systolic/diastolic BP measured in millimeters of mercury (mm Hg), HR (beats per minute), respiration rate (breaths per minute), and temperature in degrees Celsius (°C). Obtain at the beginning of each visit before any additional assessments are completed. Height will only be recorded one time at visit 1

[2] Comparative study only

[3] Pain Assessments: VAS and PROMIS® (for V2 Operative Day 0, VAS and PROMIS® performed prior to nerve block, and VAS performed again post nerve block – ONLY if nerve block is performed during screening visit).

[4] Quality of Life Questionnaires include: FHSQ [redacted]

[5] Daily Pain Medication Diary (including quantity, quality and class of pain medications) related to the nerve injury should be collected during Screening and Operative day and any changes/additions should be collected during the study.

## 6. Definitions and Terminology

Baseline
Baseline may be considered to be Day 0 (day of the procedure) or the screening period prior to Day 0 depending on appropriateness for the analysis.

Baseline Value
For purposes of analysis, the baseline value is defined as the value captured at the baseline assessment. If this value is not available, the most recent value obtained prior to the repair will be used for the baseline value.

Change from Baseline
Change from baseline will be calculated as post-baseline value – baseline value, unless otherwise noted.

Study Day
Study Day is defined relative to Day 0: Study Day = event date – date of Day 0.

Days on Study
Days on Study is the number of days from Day 0 to the date of study completion or early termination.

Completed Subjects
The treatment period is defined as the time period during which subjects are expected to be evaluated post implantation up to 12 months. Subjects who are evaluated at the last scheduled visit determined by the investigator at each site for each patient will be defined as study completers.

Lost to Follow-Up
For subjects who have not completed the study, who cannot be contacted, and who do not have a known reason for discontinuation (e.g., withdrew consent or adverse event, etc.), the reason for discontinuation will be "lost to follow-up".

Subject Non-Compliance
A subject is considered noncompliant if they fail to return for follow-up.

The Visual Analog or Analogue Scale for Pain
This pain scale is designed to present to the respondent a rating scale with minimum constraints. Respondents will mark the location on the 100-millimeter line corresponding to the amount of pain they experienced. VAS data are recorded as the number of millimeters from the left of the line with the range 0-100.

Patient Reported Outcome Measurement Information System Questionnaires
The PROMIS questionnaire is a set of person-centered measures that evaluates and monitors physical, mental, and social health in adults and children. Measures are applicable to the general

population and to those with chronic conditions. For this study, PROMIS measures will be used to monitor a subject's physical health/pain. The following six scales will be measured[1]:

- Physical function
- Pain intensity
- Pain interference
- Fatigue
- Sleep disturbance
- Pain behavior

For each scale, raw scores are calculated by summing each individual question score. Raw scores are converted to a standard score with a mean of 50 and standard deviation of 10. The score is not valid if any items are missing. Conversion tables are listed in Appendix B.

Foot Health Status Questionnaire

The FHSQ was developed to help better measure responsiveness in overall foot health status. Four scales will be measured[2]:

- Foot Function
- General Foot Health
- Footwear
- Foot Pain

Each scale has a score ranging from 0 to 100, with higher scores representing better foot health and quality of life. When fewer than 50% of responses for any one scale are missing, any missing values for that scale are assigned to the average value of the non-missing questions.

Scoring will be calculated by transforming the raw scores for each sub-domain into an easily interpretable 0 – 100 scale, with 0 indicating poorest foot health and 100 representing no problems. The following formula was used to convert the raw scores for each sub-domain:

$$X = \left(\frac{X_{raw} - X_{worst}}{X_{optimal} - X_{worst}}\right) \times S_{optimal}$$

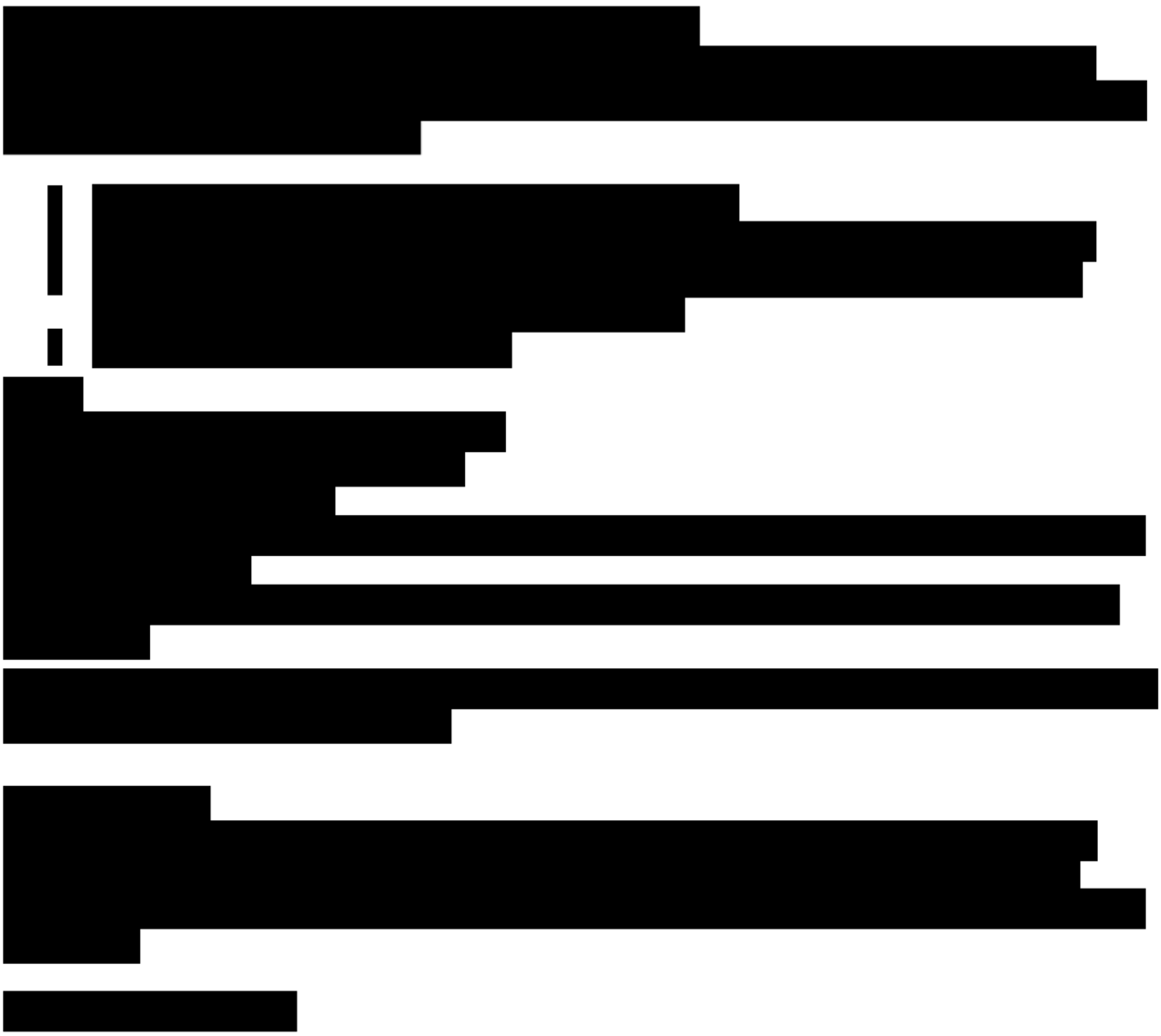
where,
$X_{raw}$ = Total score of the sub-domain
$X_{worst}$ = Score of the poorest state of foot health
$X_{optimal}$ = Score of the optimal foot health
$S_{optimal}$ = Highest score of the new scale

Foot Function:
$X_{worst}$ = 20
$X_{optimal}$ = 4
$S_{optimal}$ = 100

Foot Health:
$X_{worst} = 10$
$X_{optimal} = 2$
$S_{optimal} = 100$

Footwear:
$X_{worst} = 3$
$X_{optimal} = 15$
$S_{optimal} = 100$

Foot Pain:
$X_{worst} = 20$
$X_{optimal} = 4$
$S_{optimal} = 100$



[redacted]

Daily Pain Diary

A daily pain diary will be provided to each subject at the Screening visit (V1) and a new diary will be dispensed to the subject at Visits 2 through 7 to track incidence, frequency, and severity of pain (using a 10-point scale) daily. The diary will be reviewed and collected at each study visit (by the site team with the subject) prior to completing the scheduled pain assessments (VAS/PROMIS). The diary will also help track the use of subject pain medicine administration by reminding the subject to complete the Daily Pain Medication Diary for any pain medication/treatment taken by the subject at the time of the foot pain.

Daily Pain Medication Diary

A Daily Pain Medication Diary will be provided to each subject to take home and complete each day and will be reviewed at all visits. The subject will present the medication diary at each study visit for review by the site team and a new diary will be dispensed to the subject at each visit. The diary will be used to summarize pain medications by any use.

Opioid pain medications taken will be converted to morphine milligram equivalent (MME) where such conversions are available to summarize pain medications by quantity of use. For opioid and non-opioid pain medications, the Medication Quantification Scale[4] (MQS) conversion will be used to convert medications to a comparable score. The MQS is a broader approach to quantifying medication consumption that captures non-opioid classes of medications without an equivalency to morphine. Unlike MME, two factors (detriment weight and dosage level) multiplied together scale the medication to a single score. Additionally, drugs will be categorized according to type of medication and the quantity taken will be summarized.

Recurrence of Symptomatic Neuroma

Subjects will be assessed for recurrence of symptomatic neuroma at the 3, 6, 9, and, 12 Month visits. The assessment intervals for each visit are as follows:

- Month 3 Visit: 6 Weeks after Operative Day 0 until Month 3 Visit
- Month 6 Visit: Month 3 Visit until Month 6 Visit
- Month 9 Visit: Month 6 Visit until Month 9 Visit
- Month 12 Visit: Month 9 Visit until Month 12 Visit

A subject is considered to have had a recurrence of symptomatic neuroma if all of the following conditions are met:

- Subject experiences a pain level greater than 1 on the 10-point scale of the daily pain diary at least one time during the assessment interval

- The average daily dose of morphine (mg/day) calculated using morphine equivalent dosing during the assessment interval is higher than the average daily dose during the baseline interval (between Screening visit and Operative Day 0)
- VAS pain score is higher at assessment visit than at baseline visit

[redacted]

Adverse Event

An AE is defined as any untoward event (including abnormal lab findings) experienced by a subject (whether or not considered product-related by the site Investigator or Sponsor) after the patient consents to participate in the trial. All AEs that occur during or after study product implantation/device insertion must be recorded in the subject's medical record and reported on the adverse event CRF.

Serious Adverse Events

A serious adverse event (SAE) is any untoward medical occurrence that occurs per the following definition.

- Results in death;
- Is immediately life threatening – in the opinion of the site Investigator, the participant was at substantial risk of dying at the time of the event, or use or continued use of the device might have resulted in the death of the subject;
- Requires in-patient hospitalization or prolongation of existing hospitalization. Complications that occur during hospitalization are adverse events, and if a complication prolongs hospitalization, the event is considered serious. Emergency room visits that do not result in overnight hospital admissions should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage);
- Results in a Congenital Anomaly / Birth Defect – suspect that exposure to the device prior to conception or during pregnancy may have resulted in an adverse outcome in the child; or
- Requires Intervention to Prevent Permanent Impairment or Damage – medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of the device.
- Other Serious (Important Medical Events) – when the event does not fit the other outcomes, but the event may jeopardize the subject and may require medical or surgical intervention (treatment) to prevent one of the other outcomes.

Unanticipated Adverse Device Effects

An unanticipated adverse device effect (UADE) is defined as any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the Investigational Plan or application (including a supplementary plan or

application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Concomitant Medications
Concomitant medications are those medications taken after the procedure. This definition includes medications started prior to the procedure but continuing concomitantly afterward. Concomitant medications will be analyzed similarly to those reported in the Daily Pain Medication Diary utilizing MME dosing and MQS score conversions.

Previous Medications
Previous medications are those medications started and stopped prior to the procedure.

# 7. General Statistical Considerations

## 7.1. Sample Size and Power

A total of 101 participants (15 pilot; 86 comparative/randomized) at up to 20 sites will be enrolled.

For the pilot study, 15 evaluable participants received the open label Axoguard Nerve Cap. [redacted]

For the comparative study, 86 evaluable participants will be selected for enrollment. [redacted]

## 7.2. Randomization and Masking

For the comparative study, participants will be centrally randomized 1:1 to one of two treatment groups – neurectomy plus Axoguard Nerve Cap or neurectomy alone – in accordance with a computer-generated randomization schedule to achieve a total of 86 target repairs.

For participants presenting with multiple neuromas during randomization to treatment, multiple neuromas may be included in the study. The primary neuroma will be identified by the investigator prior to randomization. This repair will be utilized for all analyses. Additional (secondary) treated neuromas must meet the same inclusion/exclusion criteria and receive the same treatment (as randomized: Axoguard Nerve Cap or Neurectomy). Whether being treated for

one or multiple neuromas, the acceptability for either treatment shall be decided prior to randomization of the participant.

While blinding the surgeon to treatment is not possible, blinding the participant is possible and all efforts should be taken to preserve this blind. Randomization will be used to assign the participant to a treatment group intra-operatively. Therefore, the participant will be blinded to the treatment used. Direct verbal or written communication regarding treatment identification beyond what is required at an institution for recording the surgical procedures is prohibited.

### 7.3. Handling of Missing Data and Protocol Violations

Every effort will be made to obtain the VAS pain score data at each scheduled evaluation from all participants who have been randomized, especially at 12 months, since this is the primary efficacy endpoint (PEE). Missing data will be imputed for the primary endpoint only. [redacted]

All other endpoints will be analyzed with the data available.

No accommodation will be made for a treatment protocol violation unless the proportion of major violations exceeds 5%. In this case, a sensitivity analysis will be done for the primary endpoint only comparing the results when all participants are included, and when those with major protocol violations are excluded. If the results differ, the analysis with the participants included will be the primary analysis.

Major protocol violations include:

1. Treating the participant with a non-study treatment or with a study treatment to which the participant was not randomized.
2. Assessing an endpoint by a method other than described in the clinical investigational plan (CIP).
3. Failing to report a primary endpoint for any reason other than the death of the participant or the participant leaves the study unrelated to the study treatment.

### 7.4. Analysis Populations

#### 7.4.1. Intent-to-Treat Population

For the pilot study, the intent-to-treat (ITT) population will include all participants who received the study device and completed at least one post-baseline assessment of efficacy.

For the comparative study, the ITT population will include all participants who were randomized, received the study device or underwent neurectomy, and completed at least one post-baseline assessment of efficacy.

The ITT population will be the analysis population for the primary endpoint. Treatment assignment will be based on the treatment as randomized.

#### 7.4.2. Modified Intent-to-Treat Population

For the comparative study, the modified intent-to-treat (mITT) population will be the subset of the ITT population who completed at least one post-baseline assessment of efficacy. Treatment assignment will be based on the treatment as received.

The mITT population will be the primary analysis population for the secondary and tertiary endpoints. It will also be one of the analysis populations for the sensitivity analysis of the primary endpoint by running the analysis with the ITT population and then with the mITT population.

#### 7.4.3. Per-Protocol Population

For the comparative study, the per-protocol (PP) population will include all participants in the mITT population who have an endpoint for the analysis in question and have experienced no conditions that may confound study outcomes, such as sustaining a foot injury during study follow-up. Treatment assignment will be based on the treatment as received. If there are no participants with confounding events or conditions, this population will not be used.

The PP population will be the analysis population for sensitivity analyses of all endpoints by running the analyses with the primary (default) population (either the ITT or mITT) and then again with the PP.

#### 7.4.4. Safety Population

For the pilot study and comparative study, the safety population (SP) will include all participants who had the study device inserted or underwent neurectomy. This population will be used for all safety analyses. Treatment assignment will be based on the treatment received.

# 8. Analysis Methods

## 8.1. General

Data collected from each study part will be analyzed separately. Descriptive statistical methods will be used to summarize the data from this study. Unless stated otherwise, the term "descriptive statistics" refers to number of events (n), mean, median, standard deviation (SD), interquartile range (IQR), minimum, and maximum for continuous data and frequencies and percentages for categorical data.

The term 'treatment group' refers to the type of procedure conducted, either Axoguard Nerve Cap (AXOG) or Neurectomy (NEUR). All statistical analyses will be conducted with validated statistical software package like SAS or Stata.

### 8.2. Control of Type 1 Error

Type I error will not be controlled in this study in order to understand the potential benefits of Axoguard Nerve Cap regardless of the studywise error rate.

### 8.3. Stopping Rules and Withdrawal Data Requirements

There are no stopping rules for halting the trial for this study.

If a participant discontinues from the study, the reason given must be recorded in source documentation and the end of study page on the CRF or in the electronic data capture system (EDCS). If the participant is being withdrawn because of an AE, that AE must be indicated as the reason for withdrawal. Participants who discontinue from the study are not replaced.

## 9. Endpoints and Analyses

### 9.1. Primary Efficacy

#### 9.1.1. Endpoint

The primary efficacy endpoint for the pilot study is change from baseline in VAS pain score at 3 months.

The primary efficacy endpoint for the comparative study is change from baseline in VAS pain score at 12 months.

#### 9.1.2. Analysis

For the pilot study, the VAS pain score and change from baseline value will be summarized with descriptive statistics. The change from baseline will be calculated as [redacted]

For the comparative study, the VAS pain score and change from baseline value at 12 months will be summarized by treatment group and visit with descriptive statistics. In addition, tests of non-inferiority and superiority of Axoguard Nerve Cap to neurectomy with respect to VAS pain score will be conducted using closed testing procedures. [redacted]

[redacted]

[redacted]

[redacted]

## 9.2. Secondary Efficacy

### 9.2.1. Endpoints and Analyses

For the comparative study, all secondary endpoints will be summarized by visit with descriptive statistics by treatment group and using a comparative analysis.

| Endpoint | Analysis |
|---|---|
| 1. The change from baseline of PROMIS Pain Behavior Scale score at Month 12 | The treatment groups' scores will be compared with a t-test. |
| 2. The change from baseline of FHSQ in the General Foot Health Scale score at Month 12. | The treatment groups' scores will be compared with a t-test. |
| 3. The change from baseline of quantity, quality and class of pain medication use as quantified by MME dosing at Month 12. | The MME will be compared in the treatment groups using a t-test. |
| 4. The change from baseline of quantity, quality and class of pain medication use as quantified by the MQS score at Month 12. | The MQS score will be compared in the treatment groups using a t-test. |
| 5. Recurrence of symptomatic neuroma at Month 12. (Note: Assessments at each visit will be independent. For example, it is possible for a subject to have a recurrence at Month 3 and not have a recurrence at Month 6.) | Proportion of patients with recurrence will be compared between the treatment groups using a Fisher's exact test. |

| Endpoint | Analysis |
|---|---|
| 6. The Area Under Curve (AUC) of daily pain diary scores and VAS scores during the 12 months following the procedure. | The AUC will be compared in the treatment groups using a t-test or other appropriate statistical test as determined by a biostatistician. |

## 9.3. Safety

### 9.3.1. Endpoints

The following measures will be collected and assessed for both the pilot and comparative studies.

Primary safety endpoints:

1. The rate of occurrence of SAEs at 3 months.
2. The rate or occurrence of AEs or UADEs at 3 months.

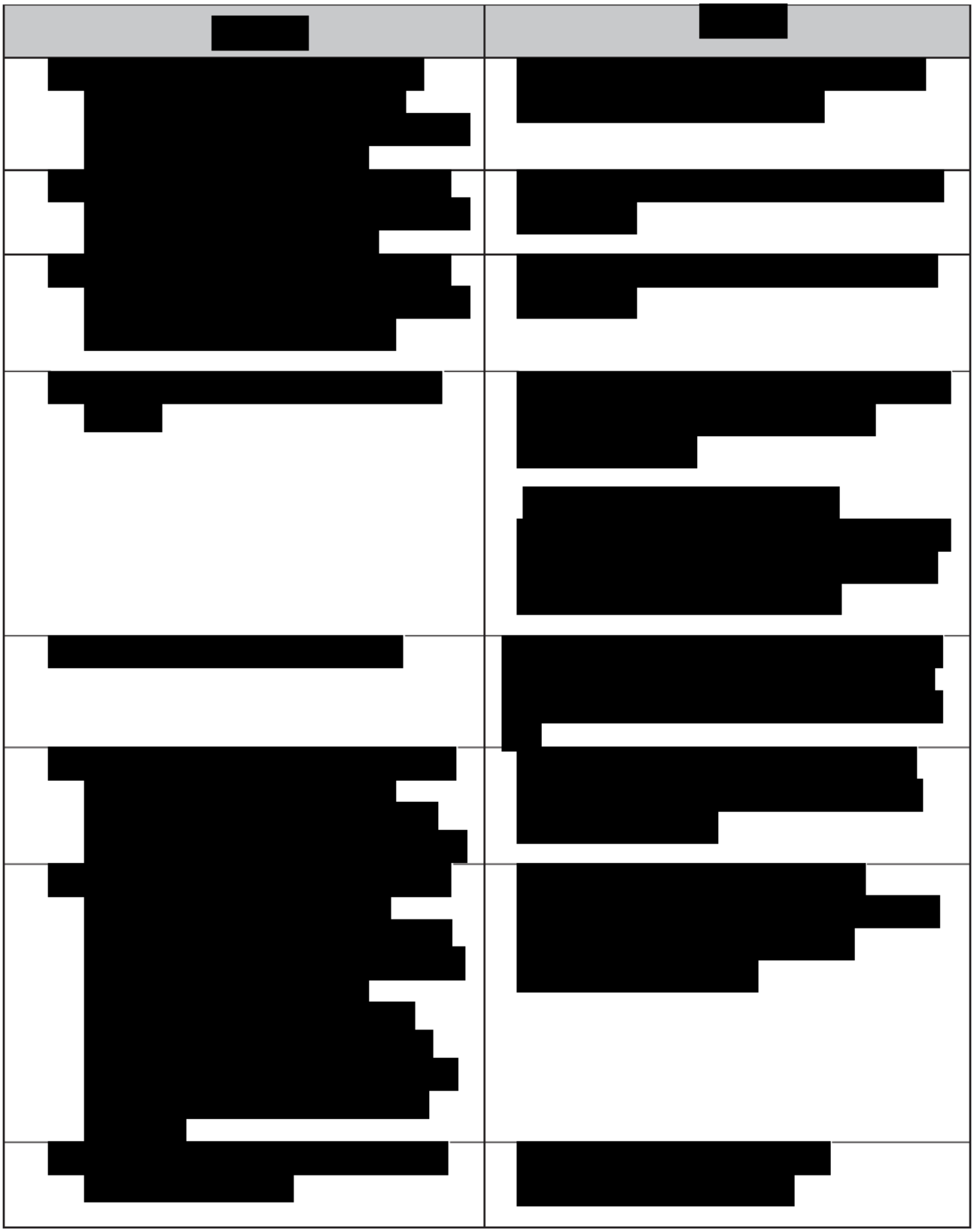
Secondary Safety Endpoints:

The rate of occurrence of SAEs, AEs and/or UADEs at 6, 9 and 12 months.

### 9.3.2. Analyses

All AEs will be summarized by seriousness, relatedness to the treatment (as assessed by the participant's physician) and severity. All AEs will be listed for individual participants.

## 9.4. Tertiary/Exploratory Efficacy



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## 10. Protocol Deviations

This study is intended to be conducted as described in the protocol. In the event of a significant deviation from the protocol due to an emergency, accident, or mistake, the investigator or designee must contact the sponsor at the earliest possible time by telephone. This will allow an early joint decision regarding the participant's continuation in the study. This decision will be documented by the investigator and the sponsor and reviewed by the monitor. Protocol deviations will be recorded on a deviation log at each site and tracked outside of the study database.

## 11. References

1. Healthmeasures.net. (2018). PROMIS. [online] Available at: http://www.healthmeasures.net/explore-measurement-systems/promis [Accessed 3 Oct. 2018].

2. FHSQ. (2018). Home. [online] Available at: https://www.fhsq.org/ [Accessed 3 Oct. 2018].

[redacted]

4. Harden, R. Norman, et al. "Medication Quantification Scale Version III: update in medication classes and revised detriment weights by survey of American Pain Society Physicians." *The Journal of Pain* 6.6 (2005): 364-371

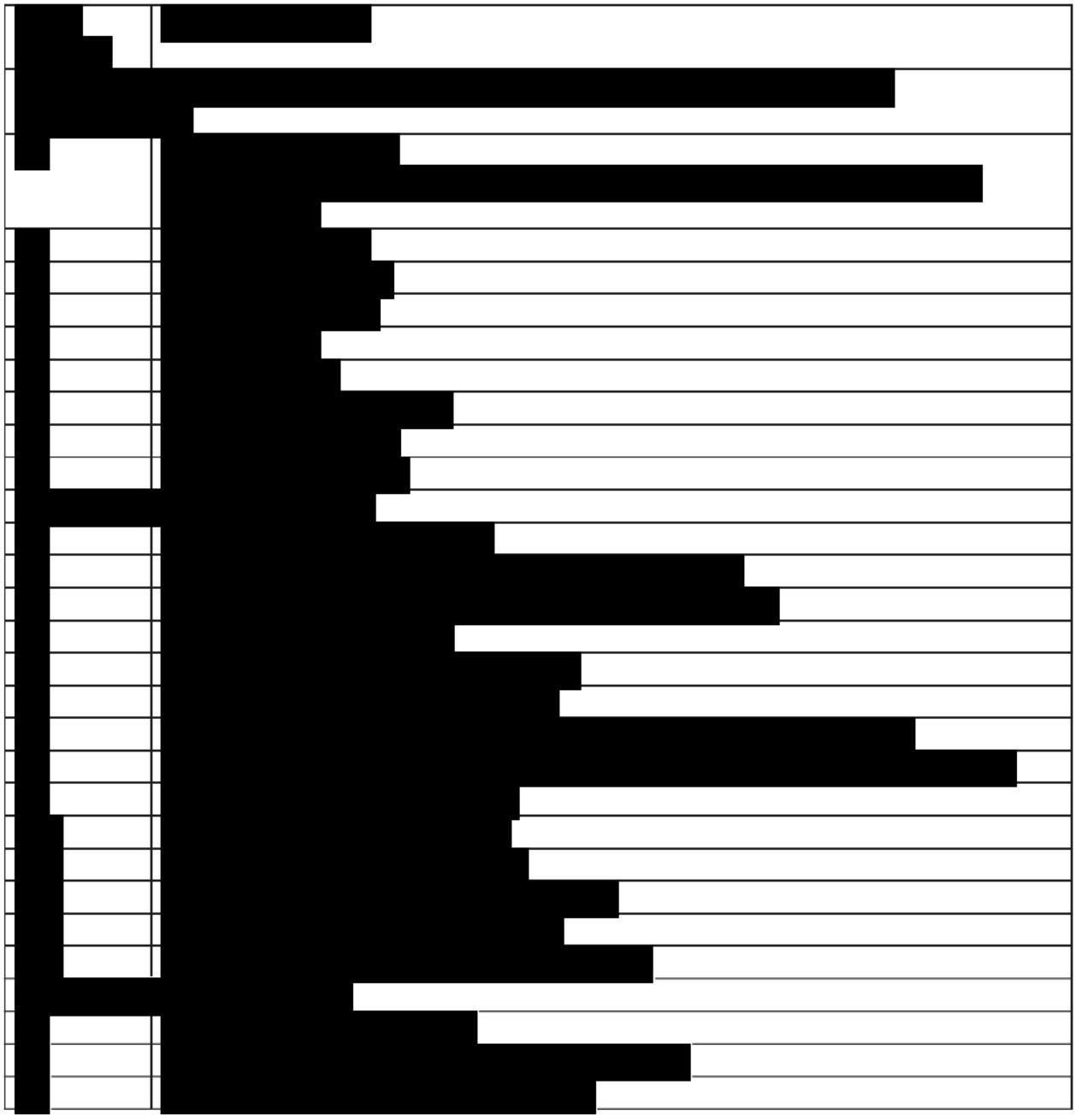
## 12. Reviewed and Approved By

| [redacted] | [redacted] |
| --- | --- |
| [redacted] | [redacted] |
| [redacted] | [redacted] |

## 13. Appendix A: List of Tables, Listings, and Figures

[redacted]

[redacted]



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| --- | --- |
| [redacted] | [redacted] |

## 14. Appendix B: PROMIS Questionnaire Scoring Conversion Tables

| Physical Function | | |
|---|---|---|
| Raw Summed Score | T-score | Standard Error of T-Score |
| 6 | 21.0 | 3.8 |
| 7 | 25.0 | 2.7 |
| 8 | 27.1 | 2.4 |
| 9 | 28.8 | 2.2 |
| 10 | 30.1 | 2.1 |
| 11 | 31.3 | 2.0 |
| 12 | 32.3 | 2.0 |
| 13 | 33.2 | 1.9 |
| 14 | 34.2 | 1.9 |
| 15 | 35.0 | 1.9 |
| 16 | 35.9 | 1.9 |
| 17 | 36.8 | 1.9 |
| 18 | 37.6 | 1.9 |
| 19 | 38.5 | 1.9 |
| 20 | 39.3 | 1.9 |
| 21 | 40.2 | 1.9 |
| 22 | 41.2 | 1.9 |
| 23 | 42.1 | 1.9 |
| 24 | 43.2 | 2.0 |
| 25 | 44.3 | 2.0 |
| 26 | 45.6 | 2.2 |
| 27 | 47.1 | 2.3 |
| 28 | 48.9 | 2.7 |
| 29 | 51.3 | 3.0 |
| 30 | 59.0 | 6.2 |

| Pain Intensity | | |
|---|---|---|
| Raw Summed Score | T-score | Standard Error of T-Score |
| 3 | 30.7 | 4.5 |
| 4 | 36.3 | 3.1 |
| 5 | 40.2 | 3.0 |
| 6 | 43.5 | 3.0 |
| 7 | 46.3 | 3.0 |
| 8 | 49.4 | 2.9 |

| | | |
|---|---|---|
| 9 | 52.1 | 2.8 |
| 10 | 54.5 | 2.9 |
| 11 | 57.5 | 3.1 |
| 12 | 60.5 | 3.1 |
| 13 | 64.1 | 3.8 |
| 14 | 67.4 | 4.2 |
| 15 | 71.8 | 5.0 |

| Pain Interference | | |
|---|---|---|
| Raw Summed Score | T-score | Standard Error of T-Score |
| 8 | 40.7 | 5.9 |
| 9 | 47.9 | 2.4 |
| 10 | 49.9 | 1.8 |
| 11 | 51.2 | 1.5 |
| 12 | 52.3 | 1.4 |
| 13 | 53.2 | 1.4 |
| 14 | 54.1 | 1.4 |
| 15 | 55.0 | 1.4 |
| 16 | 55.8 | 1.4 |
| 17 | 56.6 | 1.4 |
| 18 | 58.1 | 1.3 |
| 19 | 58.1 | 1.3 |
| 20 | 58.8 | 1.3 |
| 21 | 59.5 | 1.3 |
| 22 | 60.2 | 1.3 |
| 23 | 60.8 | 1.3 |
| 24 | 61.5 | 1.3 |
| 25 | 62.1 | 1.3 |
| 26 | 62.8 | 1.3 |
| 27 | 63.5 | 1.3 |
| 28 | 64.1 | 1.3 |
| 29 | 64.8 | 1.3 |
| 30 | 65.5 | 1.3 |
| 31 | 66.2 | 1.3 |
| 32 | 66.9 | 1.3 |
| 33 | 67.7 | 1.3 |
| 34 | 68.4 | 1.3 |
| 35 | 69.2 | 1.3 |

| | | |
|---|---|---|
| 36 | 70.1 | 1.4 |
| 37 | 71.0 | 1.4 |
| 38 | 72.1 | 1.6 |
| 39 | 73.5 | 2.0 |
| 40 | 77.0 | 3.5 |

| Fatigue | | |
|---|---|---|
| Raw Summed Score | T-score | Standard Error of T-Score |
| 8 | 33.1 | 4.8 |
| 9 | 38.5 | 2.7 |
| 10 | 41 | 2.2 |
| 11 | 42.8 | 2 |
| 12 | 44.3 | 1.9 |
| 13 | 45.6 | 1.8 |
| 14 | 46.9 | 1.8 |
| 15 | 48.1 | 1.8 |
| 16 | 49.2 | 1.8 |
| 17 | 50.4 | 1.8 |
| 18 | 51.5 | 1.7 |
| 19 | 52.5 | 1.7 |
| 20 | 53.6 | 1.7 |
| 21 | 54.6 | 1.7 |
| 22 | 55.6 | 1.7 |
| 23 | 56.6 | 1.7 |
| 24 | 57.5 | 1.7 |
| 25 | 58.5 | 1.7 |
| 26 | 59.4 | 1.7 |
| 27 | 60.4 | 1.7 |
| 28 | 61.3 | 1.7 |
| 29 | 62.3 | 1.7 |
| 30 | 63.3 | 1.7 |
| 31 | 64.3 | 1.7 |
| 32 | 65.3 | 1.7 |
| 33 | 66.4 | 1.7 |
| 34 | 67.5 | 1.7 |
| 35 | 68.6 | 1.7 |
| 36 | 69.8 | 1.8 |
| 37 | 71 | 1.8 |

| | | |
|---|---|---|
| 38 | 72.4 | 2 |
| 39 | 74.2 | 2.4 |
| 40 | 77.8 | 3.7 |

| Sleep Disturbance | | |
|---|---|---|
| Raw Summed Score | T-score | Standard Error of T-Score |
| 8 | 28.9 | 4.8 |
| 9 | 33.1 | 3.7 |
| 10 | 35.9 | 3.3 |
| 11 | 38.0 | 3.0 |
| 12 | 39.8 | 2.9 |
| 13 | 41.4 | 2.8 |
| 14 | 42.9 | 2.7 |
| 15 | 44.2 | 2.7 |
| 16 | 45.5 | 2.6 |
| 17 | 46.7 | 2.6 |
| 18 | 47.9 | 2.6 |
| 19 | 49.0 | 2.6 |
| 20 | 50.1 | 2.5 |
| 21 | 51.2 | 2.5 |
| 22 | 52.2 | 2.5 |
| 23 | 53.3 | 2.5 |
| 24 | 54.3 | 2.5 |
| 25 | 55.3 | 2.5 |
| 26 | 56.3 | 2.5 |
| 27 | 57.3 | 2.5 |
| 28 | 58.3 | 2.5 |
| 29 | 59.4 | 2.5 |
| 30 | 60.4 | 2.5 |
| 31 | 61.5 | 2.5 |
| 32 | 62.6 | 2.5 |
| 33 | 63.7 | 2.6 |
| 34 | 64.8 | 2.6 |
| 35 | 66.1 | 2.7 |
| 36 | 67.5 | 2.8 |
| 37 | 69.0 | 3.0 |
| 38 | 70.8 | 3.2 |
| 39 | 73.0 | 3.5 |

| | | |
|---|---|---|
| 40 | 76.5 | 4.4 |

| Pain Behavior | | |
|---|---|---|
| Raw Summed Score | T-score | Standard Error of T-Score |
| 20 | 32.9 | 0.53 |
| 21 | 38.0 | 0.38 |
| 22 | 40.6 | 0.33 |
| 23 | 42.4 | 0.30 |
| 24 | 43.8 | 0.27 |
| 25 | 45.0 | 0.25 |
| 26 | 46.0 | 0.23 |
| 27 | 46.9 | 0.21 |
| 28 | 47.7 | 0.20 |
| 29 | 48.4 | 0.19 |
| 30 | 49.0 | 0.18 |
| 31 | 49.6 | 0.18 |
| 32 | 50.2 | 0.17 |
| 33 | 50.7 | 0.16 |
| 34 | 51.2 | 0.16 |
| 35 | 51.7 | 0.16 |
| 36 | 52.1 | 0.15 |
| 37 | 52.6 | 0.15 |
| 38 | 53.0 | 0.15 |
| 39 | 53.4 | 0.15 |
| 40 | 53.8 | 0.14 |
| 41 | 54.2 | 0.14 |
| 42 | 54.6 | 0.14 |
| 43 | 55.0 | 0.14 |
| 44 | 55.3 | 0.14 |
| 45 | 55.7 | 0.14 |
| 46 | 56.0 | 0.14 |
| 47 | 56.4 | 0.14 |
| 48 | 56.7 | 0.14 |
| 49 | 57.1 | 0.14 |
| 50 | 57.4 | 0.14 |
| 51 | 57.8 | 0.14 |
| 52 | 58.1 | 0.14 |
| 53 | 58.5 | 0.14 |

| | | |
|---|---|---|
| 54 | 58.8 | 0.13 |
| 55 | 59.1 | 0.13 |
| 56 | 59.5 | 0.14 |
| 57 | 59.8 | 0.14 |
| 58 | 60.1 | 0.14 |
| 59 | 60.5 | 0.14 |
| 60 | 60.8 | 0.14 |
| 61 | 61.1 | 0.14 |
| 62 | 61.5 | 0.14 |
| 63 | 61.8 | 0.14 |
| 64 | 62.2 | 0.14 |
| 65 | 62.5 | 0.14 |
| 66 | 62.9 | 0.14 |
| 67 | 63.2 | 0.14 |
| 68 | 63.5 | 0.14 |
| 69 | 63.9 | 0.14 |
| 70 | 64.3 | 0.14 |
| 71 | 64.6 | 0.14 |
| 72 | 65.0 | 0.14 |
| 73 | 65.3 | 0.14 |
| 74 | 65.7 | 0.14 |
| 75 | 66.0 | 0.14 |
| 76 | 66.4 | 0.14 |
| 77 | 66.8 | 0.14 |
| 78 | 67.2 | 0.14 |
| 79 | 67.5 | 0.14 |
| 80 | 67.9 | 0.14 |
| 81 | 68.3 | 0.14 |
| 82 | 68.7 | 0.14 |
| 83 | 69.1 | 0.14 |
| 84 | 69.6 | 0.15 |
| 85 | 70.0 | 0.15 |
| 86 | 70.5 | 0.15 |
| 87 | 70.9 | 0.15 |
| 88 | 71.4 | 0.16 |
| 89 | 71.9 | 0.16 |
| 90 | 72.5 | 0.17 |
| 91 | 73.0 | 0.17 |
| 92 | 73.7 | 0.18 |

| | | |
|---|---|---|
| 93 | 74.3 | 0.19 |
| 94 | 75.1 | 0.20 |
| 95 | 76.0 | 0.22 |
| 96 | 76.9 | 0.24 |
| 97 | 78.1 | 0.26 |
| 98 | 79.5 | 0.29 |
| 99 | 81.2 | 0.33 |
| 100 | 83.7 | 0.39 |