COVER PAGE OF STATISTICAL ANALYSIS PLAN

Study title:	**Prospective Clinical Evaluation of BD Spinal Needles**
Protocol number.:	**MDS-20EPSPEU001**
NCT number:	**NCT05214560**
Statistical Analysis Plan version and date:	**v.1.1, 28 - September - 2022**

Global Clinical Development
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Statistical Analysis Plan

Protocol Number/Version	MDS-20EPSPEU001/ 3.0
Protocol Title	Prospective Clinical Evaluation of BD Spinal Needles
SAP Date	September 28, 2022
Current Version	Version 1.1 (Administrative Change)
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Approval

Individual or Function	Name	Signature/Date
Statistician (Author)	Shuangshuang Fu	This document is signed electronically in the eTMF system
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Contents

List of Abbreviations and Definitions

ADE	Adverse Device Effect
AE	Adverse Event
BD	Becton Dickinson and Company
CRF	Case Report/Record Form
CSF	Cerebrospinal Fluid
ICF	Informed Consent Form
PDPH	Post-Dural Puncture Headache
PT	Preferred Terms
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOC	System Organ Class

1 Introduction

1.1 Background and Rationale

This study is designed to assess the safety and performance of the BD Spinal Needles mainly, but not limited to the purpose of providing clinical data required under EU regulation 2017/745.

1.2 Objectives and Endpoints

Objectives	Endpoints
Primary Safety	
Spinal Needle: Assess the incidence of post-dural puncture headache (PDPH)	Percentage of participants with a diagnosis of PDPH in the 7 days following the anesthesia procedure
Primary Performance	
Spinal Needle: Assess the incidence of successful needle placement	Percentage of successful needle placement in the subarachnoid space defined as the appearance of cerebrospinal fluid from the spinal needle hub
Secondary	
To assess the incidence of any needle or procedure-related adverse events (other than PDPH)	Incidence of device/procedure-related adverse events including but not limited to: • Spinal/epidural hematoma • Nerve damage (pain or weakness lower extremities) • Infection (Meningitis, spinal abscess) • Pain, skin redness, irritation at or near the skin puncture site • Backache

2 Study Description

2.1 Study Design

This is a multi-center, prospective, observational, post-market study designed to assess the real-world safety and efficacy of BD Spinal Needles used in an on-market fashion. Up to 150 adult and pediatric participants will be enrolled in the study.

Participants will be screened against study inclusion/exclusion criteria, consented, and enrolled in the study. After enrollment, the participant's demographic and limited medical history will be documented including the reason for the neuraxial procedure. The spinal needle procedure will be performed by the physician investigator.

Participants who withdraw or discontinue the study early (e.g., prior to day-7 post procedure follow-up) may be replaced.

2.2 Study Population

Participants will be recruited from the patient population treated at the investigational sites. Sites may choose to limit recruitment to specific areas of the hospital and/or to patients treated by specific healthcare providers. The inclusion/exclusion criteria are described in the protocol Section 5.

2.3 Randomization and Blinding

This is a single-arm study and randomization is not applicable.

2.4 Sample Size

The primary safety endpoint for spinal needles is the incidence of PDPH with an expected rate ranging from 0.3% to 3% based on literature review. With an incidence of PDPH of 3%, a sample size of 150 participants would lead to a precision of estimate less than 5% using Clopper Pearson exact method (precision of estimate is the distance between point estimate to the upper bound of 95% two-sided exact confidence interval). Additionally, with a sample size of 150 participants, the probability of observing at least one PDPH with is 91.1% when the expected rate of PDPH is 1.6%.

The primary efficacy endpoint for spinal needles is successful placement, defined as the spontaneous appearance of CSF, with an expected rate ranging from 90% to 100% based on literature review. With an expected placement success rate of 90%, a sample size of 150 participants would lead to a precision of estimate at approximately 5% using Clopper Pearson exact method.

2.5 Interim Analyses

No interim analysis is planned for the study.

2.6 Study Procedure

The physician investigator will perform the spinal needle procedure (to introduce medications or image contrast agents) based on the medical needs of the participant. The physician investigator will choose the vertebral interspace, participant position, procedure/ technique, and BD spinal needles. The participant will be monitored closely at regular intervals per practice guidelines and site policies.

The physician investigator will document the procedure in a standard procedure note. The note should include but is not limited to the equipment/devices used, participant position, interspace level, number of attempts, and any identified complication or adverse event. If used, spinal medications with amounts will also be documented. After the procedure is completed, the physician investigator will complete a short ease of use survey regarding the performance of the devices used. Physician performing procedure experience (years of experience, estimated number of spinal needle procedures performed and the education) data collected through an Inserter Experience Survey: data will be part of the final database; no analysis is planned. The data will be provided as Excel spreadsheet only.

The participant will be acutely monitored as required for their routine medical care and according to site policy. Complications or adverse events (e.g., PDPH) will be monitored for the 7-day period after the procedure. If the participant is discharged from the hospital during this time period, follow-up may be performed in a variety of ways including by telephone.

2.7 Endpoints

Refer to Section **Error! Reference source not found.**.

2.8 Acceptance Criteria

There are no acceptance criteria for the study device.

3 Intended Statistical Software and Data Information

3.1 Intended Statistical Software

All the analyses will be performed using Statistical Analysis System (SAS) Version 9.4 or above or R.

3.2 Data Information

Derived data specification can be found in Appendix 2.

4 Analysis Population Set(s)

4.1 Population Definitions

Enrolled: All participants who sign the ICF.

Evaluable: All participants in whom a neuraxial procedure is attempted, regardless of success**.** It will include the following participants in the Spinal Needle Procedure CRF page:

- Was spinal needle procedure performed: Equals 'Yes'.

Safety: All participants on whom an anesthesia procedure is performed. It will include the following participants in the Spinal Needle Procedure CRF page:

- Was there a spontaneous appearance of cerebrospinal fluid (CSF) emerging from the needle hub: Equals 'Yes'.

5 Statistical Analysis/Calculations

5.1 Primary Safety Endpoints

The primary safety endpoint is the incidence of post-dural puncture headache (PDPH) in the 7 days following the anesthesia procedure. It will be computed as the number of participants experiencing the event divided by the total number of patients on whom anesthesia procedure was performed; 95% confidence interval (exact method) will be calculated. The analysis will be performed on the safety population as defined in section 4.1. Subgroup analysis for the primary safety endpoint will also be performed by spinal needle type and gauge if data permits.

The incidence of PDPH will be based on response to the following question in the "Follow-up Assessments" CRF page: "During the required follow-up period, did the subject have a post-dural puncture headache?" Participants experiencing any severity (mild/moderate/severe) of PDPH will contribute to the incidence count in the numerator.

5.2 Primary Performance Endpoints

The primary performance endpoint is the incidence of successful needle placement in the subarachnoid space defined as the appearance of cerebrospinal fluid from the spinal needle hub. It will be computed as the number of

participants experiencing the event divided by the total number of subjects with needles attempted; 95% confidence interval (exact method) will be calculated. The analysis will be performed on the evaluable population as defined in section 4.1. Subgroup analysis for the primary performance endpoint will also be performed by spinal needle type and gauge if data permits.

The incidence of successful needle placement will be based on counts of "Yes" response to the following question in the "Spinal Needle Procedure" CRF page: "Was there a spontaneous appearance of cerebrospinal fluid (CSF) emerging from the needle hub?"

5.3 Secondary Safety Endpoints

The secondary safety endpoint is the incidence of any needle or procedure-related adverse events (other than PDPH). It includes (but is not limited to) the following events:

- Spinal/epidural hematoma
- Nerve damage (pain or weakness lower extremities)
- Infection (Meningitis, spinal abscess)
- Pain, skin redness, irritation at or near the skin puncture site
- Backache

Subject will be considered as having an event if the subject has the following responses for the three questions on the AE CRF Page listed below:

- Can the adverse event be allocated to one of the pre-defined adverse events according to the safety objectives : Not Equals 'PDPH'

  AND

- Relationship to surgical procedure: Equals 'Likely Related' or 'Related' OR Relationship to spinal needle: Equals 'Likely Related' or 'Related'

The incidence will be computed as the number of participants experiencing at least one of these events divided by the total number of evaluable patients; 95% confidence interval (exact method) will be calculated. The analysis will be performed on the evaluable population as defined in section 4.1. Subgroup analysis for the secondary safety endpoint will also be performed by spinal needle type and gauge if data permits.

6 Summary of General Study Data

6.1 Subject Disposition

The summary of the number of subjects in the enrolled population, evaluable population, safety population, as well as those that completed the study, and withdrew from the study with reason for withdrawal will be provided. Screen Failures will be summarized for each inclusion/exclusion criteria that was not met. Summary table will also be provided by site.

6.2 Protocol Deviations

A protocol deviation is defined as an event where the Investigator or site personnel did not conduct the study according to the protocol requirements. Any and all protocol deviations must be documented regardless of whether medically justifiable, Sponsor-approved or taken to protect the subject in an emergency.

Details regarding protocol deviations will be listed for evaluable participants.

6.3 Demographics and Baseline Variables

Demographics and baseline characteristics will be summarized with descriptive statistics for evaluable population. Summary statistics for categorical variables will include frequency and percentages, and for continuous variables will include mean, standard deviation (SD), minimum, median, and maximum. Demographic data (age (at signing informed consent), gender, race, body height, body weight, body mass index (BMI)) will be tabulated.

The demographic variables will include:

- Age (at signing informed consent)
- BMI
- Body Weight
- Body Height
- Sex
- Race

6.4 Medical/Surgical History

Medical history including surgical history will be tabulated and presented at participant-level for evaluable population. Summary tables will be presented for presence of relevant diseases besides primary diagnosis, targeted surgical history, targeted neurological impairment, and targeted anticoagulant therapy. The primary diagnosis for intervention, the reason for neuraxial procedure as well as the ASA classification will be tabulated.

6.5 Study Device Procedure

The data related to study device details and placement are recorded on the “Spinal Needle Procedure” section of eCRF page. The device procedure data will be summarized separately for spinal needle procedure, introducer, needle, and syringe for evaluable population.

6.6 Follow-up Visit Summary

Follow-up visit summary and listing will be presented for the evaluable population.

6.7 Ease of Use Survey

The results for ease of use survey will be presented separately for introducer, spinal needle, stylet, and syringe for evaluable population. The results of the insertion user questionnaire will be tabulated. For each question, the individual results will be tabulated. Additionally, for all scores, a numerical score will be applied (5 = very easy/ strongly agree; 1 = very difficult / strongly disagree) and basic statistics will be additionally presented. Data will be presented on the evaluable set.

6.8 Device Deficiency

Device failures, malfunctions or defects will be tabulated and presented on participant level for evaluable population. Details regarding device deficiencies will be listed.

7 Safety Analysis

An AE is defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in participants, users or other persons, whether or not related to study device and whether anticipated or unanticipated (ISO 14155:2020). In this study, AE collection will be limited to

those events judged by the investigator to be related or likely related to the neuraxial procedure and/or the BD Spinal Needles used in the procedure.

An overall summary including the number and percentage of subjects with at least one AE, total number of AEs, total number of SAEs, AEs by relationship to the Device/Index Procedure, and AEs by severity of the event will be summarized for the evaluable population.

AEs will be coded by using the Medical dictionary for regulatory activities version 24.1 (MedDRA). All verbatim terms will be coded to the lowest level term (LLT) and will be classified by primary System Organ Class (SOC) according to the MedDRA thesaurus. AEs will be tabulated by SOC and Preferred Term (PT). The number of entries, as well as the number and rate of affected participants will be reported. Additionally, AEs will be presented by severity.

SAEs and AEs which are related to device (adverse device effects [ADEs]), AEs which are related to procedure, or related to accessories (stylet and introducer) will be presented separately. All AEs will be listed together with start date of AE as well as duration of AE for AEs with complete dates.

8 Interim Analysis Plan

No interim analysis is planned for the study.

9 References

None.

10 SAP Revision History

Version Number	Rationale for Change	Section or Page Affected	Description of Change
1.0	Original SAP		
1.1	Administrative Change	Page 10	MedDRA version 24.0 is changed to 24.1

11 Appendix

Appendix 1 Tables/Listing/Figures Shell for Final Reporting

Appendix 2 Derived Data Specification

Signature Page for VV-TMF-248521 v2.0

Reason for signing: Finalize	Name: Shuangshuang Fu Role: Statistics and Clinical Data Date of signature: 28-Sep-2022 16:47:06 GMT+0000

Reason for signing: Finalize	Name: Gloria Viti Role: Clinical Project Management Date of signature: 28-Sep-2022 16:49:26 GMT+0000

Reason for signing: Finalize	Name: Lingzhi Li Role: Statistics and Clinical Data Date of signature: 28-Sep-2022 16:52:15 GMT+0000

Reason for signing: Finalize	Name: Edward Maratea Role: Global Medical Affairs Date of signature: 28-Sep-2022 17:04:22 GMT+0000

Signature Page for VV-TMF-248521 v2.0

STATISTICAL ANALYSIS PLAN – Appendix 1
Tables/Listings/Figures Shell

Protocol Number/Version	MDS-20EPSPEU001/Version 3.0
Protocol Title	Prospective Clinical Evaluation of BD Spinal Needles
Prepared By	Shuangshuang Fu
Version	1.1
Date	September 28, 2022

Contents

1. General Guidance on the Output Format

It is suggested that computer-generated outputs adhere to the following specifications.

1.1 Document Headers

Unless otherwise specified, all computer-generated outputs should be produced in landscape mode. The required margins should be at least 1.25 inches on top (the binding margin [or left for portrait output]), at least 1 inch on right, left, and bottom.

All outputs should have the following header at the top of the page:

Becton Dickinson and Company Page n of N
Protocol: MDS-20SECUR001

All outputs should have the following footnote at the bottom of the page:

Program name: xxxxx.sas Date DDMMMYYYY:hhmmss

1.2 Presentation of Table Numbering and Titles within this Document

Each output should be identified by a numeral, and the output designation (e.g., Table 1) should be centred above the title. The title should be centered and capitalized. The title and table designation should be single-spaced but separated from the table by at least a double space.

Table No.
Table Title
Table Title continued (if necessary)
Study Population

The study population should be identified on the line immediately following the title.

Column headings should capitalized.

- For numeric variables, include "unit" in column heading when appropriate.
- Footnotes should be single spaced but separated by at least a double space from the bottom line of the table. The notes should be aligned vertically by the left vertical border of the table.
- If the categories are not ordered (e.g., race), then only those categories for which there is at least one subject represented in one or more groups should be included.
- An Unknown or Missing category should be added to any parameter for which information is not available for one or more subjects.

1. 3 Data Format

Unless otherwise specified, the estimated mean and median for a set of values should be printed out to one more decimal place than the individual units of measurement, and standard deviations should be printed out to one additional place further. For example, age (with raw data in whole years) should be presented as follows:

n	xx
Mean (SD)	xx.x (xx.xx)

Median	xx.x
Min – Max	xx - xx

P-values, if any, should be outputted in the format: “0.xxxx”, where xxxx is the value rounded to 4 decimal places. If the value is less than 0.0001 then should be displayed as ‘<0.0001’

Data in columns of a table should be formatted as follows:

- Alphanumeric values are left-justified
- Whole numbers (e.g., counts) are right-justified
- Numbers containing fractional portions are decimal-aligned

Unless otherwise specified, percentage values should be printed with one digit to the right of the decimal point (e.g., 12.8%, 5.4%). Less-than-signs “<0.1%” should be printed when values are >0.0 and <0.1% (not 0.0%).

Missing data should be represented on subject listings as either a hyphen (“-“) with a corresponding footnote (“- = unknown or not evaluated”), or as “N/A,” with the footnote “N/A = not applicable,” whichever is appropriate.

Dates should be printed in SAS DATE9. format (“DDMMMYYYY”: 01JUL2000). Missing portions of dates should be represented on subject listings as dashes (e.g. --JUL2000). Dates that are missing because they are not applicable for the subject should be outputted as “N/A”, unless otherwise specified.

Time should be printed in SAS TIME5. format (“HH:MM”: 17:30). Missing portions of time should be represented on subject listings as dashes (e.g. --:30). Times that are missing because they are not applicable for the subject should be outputted as “N/A”, unless otherwise specified.

2. Tables

Table 14.1.1 Subject Disposition

All Subjects

	Frequency (%)
Enrolled*	n
Screen Failure	n
Evaluable Population	n (100%)
Safety Population	n (%)
Completed the Study (as per study protocol)	n (%)
Discontinued from Study	n (%)
Adverse Event	n (%)
Device Deficiency	n (%)
Withdrawal of Consent	n (%)
Protocol Violation	n (%)
Investigator Decision	n (%)
Lost to follow up	n (%)
Death	n (%)
Study Termination by Sponsor or Authorities	n (%)
Other	n (%)

Note: The % is computed based on total enrolled (denominator) for rows up to evaluable population. For the rows after evaluable population, the % is computed based on evaluable population (denominator).

*There were 15 subjects who were enrolled but not treated with the study device, therefore not included in the evaluable population.

Table 14.1.2 Subject Disposition by Site

All Subjects

Site	Enrolled*	Evaluable Population	Safety Population	Completed the Study (as per study protocol)	Discontinued from Study
01	n	n (100%)	n (%)	n (%)	n (%)
02	n	n (100%)	n (%)	n (%)	n (%)
	n	n (100%)	n (%)	n (%)	n (%)
…	n	n (100%)	n (%)	n (%)	n (%)
Total	N	N	N	N	N

*There were 15 subjects who were enrolled but not treated with the study device, therefore not included in the evaluable population.

Table 14.1.3 Screen Failures

All Subjects

	(N=xxx)
Subjects Enrolled	n
Screen Failure	n (%)
Inclusion Criteria not Met	n (%)
I01	n (%)
I02	n (%)
I03	n (%)
Exclusion Criteria Met	n (%)
E01	n (%)
E02	n (%)
E03	n (%)
E04	n (%)
E05	n (%)

Table 14.1.4 Protocol Deviations

Evaluable Subjects

	(N=xxx)	
	By Events	By Subjects
Any Protocol Deviations	n	n (%)
Informed Consent	n	n (%)
Eligibility Criteria Not Met	n	n (%)
Safety Reporting	n	n (%)
Incomplete Procedure/Data	n	n (%)
Missed Procedure/Data	n	n (%)
Other	n	n (%)

Table 14.1.5 Demographics

Evaluable Population

	(N=xxx)
Age (Years)*	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min – Max	xx - xx
Sex	
Male	n/N (%)
Female	n/N (%)
Race	
Asian	n/N (%)
Black	n/N (%)
White	n/N (%)
Unknown	n/N (%)

Not Reported	n/N (%)
Other	n/N (%)
Height (cm)	
N	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min – Max	xx - xx
Weight (kg)	
N	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min – Max	xx - xx
BMI (kg/m2)	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min – Max	xx - xx

Note: Participants may select more than one race category.
*Age at signing informed consent.

Table 14.1.6 Primary Diagnosis

Evaluable Population

	(N= xxx)
Primary diagnosis for intervention	
Surgery of lower extremities	n (%)
Surgery of lower abdomen	n (%)
Surgery of perineum	n (%)
Surgery of hips and pelvis	n (%)
Obstetric	n (%)
Other	n (%)
Reason for neuraxial procedure	
Anesthesia	n (%)
Analgesia	n (%)
Other	n (%)
ASA classification	
I	n (%)
II	n (%)
III	n (%)
IV	n (%)
V	n (%)

Table 14.1.7 Follow-up Visit Summary

Evaluable Population

Day 7 Follow-up Visit	(N=xxx)
At the clinic	n/N (%)
By phone	n/N (%)
No	n/N (%)

Table 14.1.8 Medical/Surgical History and Concomitant Diseases

Evaluable Population

Characteristics	(N=xxx)
Presence of relevant diseases other than primary diagnosis: Yes	n (%)
Targeted surgical history: Yes	n/N (%)
Targeted neurological impairment of lower extremities: Yes	n/N (%)
Targeted anticoagulant therapy: Yes	n/N (%)

Table 14.1.9 Study Device and Placement - Spinal Needle Procedure

Evaluable Population

Characteristics	(N=xxx)
Spinal needle procedure performed: Yes	N
Participant position during spinal needle procedure	
Lateral	n/N (%)
Sitting	n/N (%)
Other	n/N (%)
Aseptic technique	
Chlorhexidine	n/N (%)
Betadine	n/N (%)
Other	n/N (%)
Local anaesthesia	
Lidocaine 1%	n/N (%)
Lidocaine 2%	n/N (%)
Other	n/N (%)
Lumbar interspace[1]	
L2-3	n/N (%)
L3-4	n/N (%)
L4-5	n/N (%)
Other	n/N (%)
Number of Puncture attempts[2]	
1	n/N (%)
2	n/N (%)
…	n/N (%)

Number of Interspace levels attempts[3]	
1	n/N (%)
…	n/N (%)
Paresthesia verbalized by patient	
No	n/N (%)
Yes	n/N (%)
Left	n/N (%)
Right	n/N (%)
Spontaneous appearance of cerebrospinal fluid (CSF) emerging from the needle hub:	n/N (%)
Yes	n/N (%)
No	n/N (%)
Attempt to aspirate CSF before injecting anaesthetic	
No	n/N (%)
Yes	n/N (%)
Successful Attempt to aspirate CSF before injecting anaesthetic: Yes	n/N (%)
Attempt to aspirate CSF after injecting anaesthetic	
No	n/N (%)
Yes	n/N (%)
Successful Attempt to aspirate CSF after injecting anaesthetic: Yes	n/N (%)
Spinal anaesthesia levels measured:Yes	n/N (%)
Maximum spinal anaesthesia level right measured: Yes	n/N (%)
Maximum spinal anaesthesia level left measured:Yes	n/N (%)

Note: The denominator for computing percentage for participant position, aseptic technique, local anaesthesia, and lumbar interspace is the total number of participants on whom spinal needle procedure is performed and with non-missing values for the question.

[1] Lumbar interspace refers to last try

[2] It is the number of different needles attempted

[3] The number of interspace levels attempts refers to the number of different lumbar interspace

Table 14.1.10 Study Device and Placement - BD Spinal Introducer

Evaluable Population

Characteristics	(N=xxx)
BD Spinal needle introducer usage: Yes	n/N (%)
BD Spinal needle introducer type*	
405160 / 20 G / 32 mm	n/N (%)
405260 / 20 G / 32 mm	n/N (%)
400756 / 20 G / 32 mm	n/N (%)
400755 / 18 G / 32 mm	n/N (%)
400499 / 20 G / 32 mm	n/N (%)
405261 / 22G / 32 mm	n/N (%)

*Only list the introducer type used.

Table 14.1.11a Study Device and Placement - BD Spinal Needle

Evaluable Population

Characteristics	(N=xxx)
BD spinal needle usage: Yes	n/N (%)

BD spinal needle specifications (Needle Type / Gauge / Length):	
Whitacre / 22 G / 90 mm	n/N (%)
…	n/N (%)
Whitacre / 27 G / 119 mm	n/N (%)
BD kit/set needle usage: Yes	n/N (%)
BD kit/set needle type:	
25 G x 90 mm BD Whitacre spinal needle, Thin Wall / 20G x 32 mm Introducer	n/N (%)
25 G x 103 mm (4-1/16 in.) Whitacre Set / 20G x 32 mm Introducer	n/N (%)
27 G x 103 mm (4-1/16 in.) Whitacre Set / 22G x 32 mm Introducer	n/N (%)
27 G x 90 mm BD Whitacre spinal needle / 22G x 32 mm Introducer	n/N (%)
25 G x 90 mm BD Quincke spinal needle / 20G x 32 mm Introducer	n/N (%)
26 G x 90 mm BD Quincke spinal needle / 20G x 32 mm Introducer	n/N (%)
27 G x 90 mm BD Quincke spinal needle / 22G x 32 mm Introducer	n/N (%)

Note: The denominator for computing percentage for device type is the total number of participants on whom device was used.

Table 14.1.11b Study Device and Placement - BD Spinal Needle (Spinal Needle and Kit combined)

Evaluable Population

Characteristics	(N=xxx)
BD spinal needle usage: Yes	n/N (%)
BD spinal needle specifications (Needle Type / Gauge / Length):	
Whitacre / 22 G / 90 mm	n/N (%)
…	n/N (%)
Whitacre / 27 G / 119 mm	n/N (%)

Table 14.1.12 Study Device and Placement - BD Syringe

Evaluable Population

Characteristics	(N=xxx)
BD syringe usage: Yes	n/N
BD syringe size (ml)	
1	n/N (%)
3	n/N (%)
5	n/N (%)
10	n/N (%)
20	n/N (%)
Other	n/N (%)
BD Syringe type	
Luer Lock	n/N (%)
Luer Slip	n/N (%)
Other	n/N (%)
BD Syringe Material	
Glass	n/N (%)
Plastic	n/N (%)

Table 14.1.13 Device Failure/Deficiency

Evaluable Population

	(N=xxx)
Number of Subjects who reported at least one Device Failure	n/N (%)
Total Number of Device Failures	n
Total Number of Device Failures associated with Adverse Event	n/N (%)
Time of Device Failure	n/N (%)
Before device exposure	n/N (%)
During device insertion	n/N (%)
After insertion procedure	n/N (%)
Device Component that was Deficient	n/N (%)
Spinal Needle	n/N (%)
Introducer	n/N (%)
Stylet	n/N (%)
Syringe	n/N (%)
Other	n/N (%)
Reason for Device Deficiency	n/N (%)
Malfunction	n/N (%)
Use Errors	n/N (%)
Inadequate Labels	n/N (%)
Other	n/N (%)
Adverse event associated with device deficiency	n/N (%)
Device deficiency that could have led to SADE	n/N (%)

Note: The denominator for computing percentage for rows corresponding to device failures is the total number of device failures.

Table 14.2.14 Primary Performance Endpoint

Evaluable Population

Characteristics	% (95% CI)
Successful needle placement in the subarachnoid space	n/N (%) (xx.x%, xx.x%)

Note: The denominator includes all participants in whom a neuraxial procedure is attempted.

Table 14.2.14a Primary Performance Endpoint for Subjects Using Whitacre Needle

Evaluable Population
Programing Note: Follow the same format as Table 14.2.14.

Table 14.2.14b Primary Performance Endpoint for Subjects Using Quincke Needle

Evaluable Population
Programing Note: Follow the same format as Table 14.2.14.

Table 14.2.14c Primary Performance Endpoint for Subjects Using Whitacre Needle by Needle Gauge

Evaluable Population

Gauge	% (95% CI)
22 G	n/N (%) (xx.x%, xx.x%)
…	n/N (%) (xx.x%, xx.x%)
25 G	n/N (%) (xx.x%, xx.x%)

Table 14.2.14d Primary Performance Endpoint for Subjects Using Quincke Needle by Needle Gauge

Evaluable Population
Programing Note: Follow the same format as Table 14.2.14c.

Table 14.2.15 Primary Safety Endpoint

Safety Population

Characteristics	% (95% CI)
Post-dural puncture headache	n/N (%) (xx.x%, xx.x%)

Note: The denominator includes all participants in whom an anesthesia procedure was performed.

Table 14.2.15a Primary Safety Endpoint for Subjects Using Whitacre Needle

Safety Population
Programing Note: Follow the same format as Table 14.2.15.

Table 14.2.15b Primary Safety Endpoint for Subjects Using Quincke Needle

Safety Population
Programing Note: Follow the same format as Table 14.2.15.

Table 14.2.15c Primary Safety Endpoint for Subjects Using Whitacre Needle by Needle Gauge

Safety Population

Gauge	% (95% CI)
22 G	n/N (%) (xx.x%, xx.x%)
…	n/N (%) (xx.x%, xx.x%)
25 G	n/N (%) (xx.x%, xx.x%)

Table 14.2.15d Primary Safety Endpoint for Subjects Using Quincke Needle by Needle Gauge

Safety Population
Programing Note: Follow the same format as Table 14.2.15c.

Table 14.2.16 Post-dural Puncture Headache - Severity Levels

Safety Population

	(N=xxx)*
No Headache	n/N (%)
Mild Headache	n/N (%)
Moderate Headache	n/N (%)
Severe Headache (bedridden but not requiring hospitalization)	n/N (%)
Severe Headache (requiring hospitalization)	n/N (%)

*There were 2 subjects who were lost to follow-up and did not answer the question.

Table 14.2.16a Post-dural Puncture Headache for Subjects Using Whitacre Needle - Severity Levels

*There were 2 subjects who were lost to follow-up and did not answer the question.

Safety Population
Programing Note: Follow the same format as Table 14.2-16.

Table 14.2.16b Post-dural Puncture Headache for Subjects Using Quincke Needle - Severity Levels

Safety Population
Programing Note: Follow the same format as Table 14.2-16.

Table 14.2.16c Post-dural Puncture Headache for Subjects Using Whitacre Needle - Severity Levels by Needle Gauge

Safety Population

Post-dural Puncture Headache Severity Levels by Needle Gauge	(N=xxx)*
22 G	
No Headache	n/N (%)
Mild Headache	n/N (%)
Moderate Headache	n/N (%)
Severe Headache (bedridden but not requiring hospitalization)	n/N (%)
Severe Headache (requiring hospitalization)	n/N (%)
…	
No Headache	n/N (%)
Mild Headache	n/N (%)
Moderate Headache	n/N (%)
Severe Headache (bedridden but not requiring hospitalization)	n/N (%)
Severe Headache (requiring hospitalization)	n/N (%)
25 G	
No Headache	n/N (%)
Mild Headache	n/N (%)
Moderate Headache	n/N (%)
Severe Headache (bedridden but not requiring hospitalization)	n/N (%)
Severe Headache (requiring hospitalization)	n/N (%)

*There were 2 subjects who were lost to follow-up and did not answer the question.

Table 14.2.16d Post-dural Puncture Headache for Subjects Using Quincke Needle - Severity Levels by Needle Gauge

Safety Population
Programing Note: Follow the same format as Table 14.2.16c.

Table 14.2.17 Secondary Safety Endpoints

Evaluable Population

Level	% (95% CI)
Device/Procedure Related Adverse Events	n/N (%) (xx.x%, xx.x%)
Spinal/epidural hematoma	n/N (%) (xx.x%, xx.x%)
Nerve damage	n/N (%) (xx.x%, xx.x%)

Backache	n/N (%) (xx.x%, xx.x%)
Infection (Meningitis, spinal abscess)	n/N (%) (xx.x%, xx.x%)
Pain, skin redness, irritation at or near the skin puncture site	n/N (%) (xx.x%, xx.x%)

Note: A patient can experience more than one device related adverse events.

Table 14.2.17a Secondary Safety Endpoints –Subjects Using Whitacre Needle

Evaluable Population
Programing Note: Follow the same format as Table 14.2.17.

Table 14.2.17b Secondary Safety Endpoints – Subjects Using Quincke Needle

Evaluable Population
Programing Note: Follow the same format as Table 14.2.17.

Table 14.2.17c Secondary Safety Endpoints –Subjects Using Whitacre Needle by Needle Gauge

Evaluable Population

Device/Procedure Related Adverse Events by Needle Gauge	**% (95% CI)**
22 G	
Device/Procedure Related Adverse Events	n/N (%) (xx.x%, xx.x%)
Spinal/epidural hematoma	n/N (%) (xx.x%, xx.x%)
Nerve damage	n/N (%) (xx.x%, xx.x%)
Backache	n/N (%) (xx.x%, xx.x%)
Infection (Meningitis, spinal abscess)	n/N (%) (xx.x%, xx.x%)
Pain, skin redness, irritation at or near the skin puncture site	n/N (%) (xx.x%, xx.x%)
…	
25 G	
Device/Procedure Related Adverse Events	n/N (%) (xx.x%, xx.x%)
Spinal/epidural hematoma	n/N (%) (xx.x%, xx.x%)
Nerve damage	n/N (%) (xx.x%, xx.x%)
Backache	n/N (%) (xx.x%, xx.x%)

Infection (Meningitis, spinal abscess)	n/N (%) (xx.x%, xx.x%)
Pain, skin redness, irritation at or near the skin puncture site	n/N (%) (xx.x%, xx.x%)
…	n/N (%) (xx.x%, xx.x%)

Table 14.2.17d Secondary Safety Endpoints – Subjects Using Quincke Needle by Needle Gauge

Evaluable Population
Programing Note: Follow the same format as Table 14.2.17c.

Table 14.2.18 Ease of Use Survey - Completion Status

Evaluable Population

	(N=xxx)
Ease of Use Survey completed: Yes	xx.x% (n/ N)

Table 14.2.19 Ease of Use Survey – Introducer

Evaluable Population

	(N=xxx)
Ease of use of the introducer	
1 Very Difficult	n/N (%)
2 Difficult	n/N (%)
3 Neither Difficult nor Easy	n/N (%)
4 Easy	n/N (%)
5 Very Easy	n/N (%)
Agreement on whether introducer facilitated placement of spinal needle	
1 Strongly Disagree	n/N (%)
2 Disagree	n/N (%)
3 Neither Agree nor Disagree	n/N (%)
4 Agree	n/N (%)
5 Strongly Agree	n/N (%)

Note: The denominator for computing percentages is the total number of participants who completed the ease of use survey for Introducer.

Table 14.2.20 Ease of Use Survey - Spinal Needle

Evaluable Population

	(N=xxx)
Ease of spinal needle insertion	
1 Very Difficult	n/N (%)
2 Difficult	n/N (%)

3 Neither Difficult nor Easy	n/N (%)
4 Easy	n/N (%)
5 Very Easy	n/N (%)
Ease of spinal needle withdrawal after placement	
1 Very Difficult	n/N (%)
2 Difficult	n/N (%)
3 Neither Difficult nor Easy	n/N (%)
4 Easy	n/N (%)
5 Very Easy	n/N (%)

Note: The denominator for computing percentages is the total number of participants who completed the ease of use survey for Spinal Needle.

Table 14.2.21 Ease of Use Survey – Stylet

Evaluable Population

	(N=xxx)
Agreement on whether stylet helped to determine the direction of spinal needle tip: Yes	n (%)
Agreement on whether stylet functioned properly during spinal needle placement	
1 Strongly Disagree	n/N (%)
2 Disagree	n/N (%)
3 Neither Agree nor Disagree	n/N (%)
4 Agree	n/N (%)
5 Strongly Agree	n/N (%)
Ease of stylet removal from the spinal needle after placement	
1 Very Difficult	n/N (%)
2 Difficult	n/N (%)
3 Neither Difficult nor Easy	n/N (%)
4 Easy	n/N (%)
5 Very Easy	n/N (%)

Note: The denominator for computing percentages is the total number of participants who completed the ease of use survey for Stylet.

Table 14.2.22 Ease of Use Survey – Syringe

Evaluable Population

	(N=xxx)
Ease of reading syringe graduations when preparing the dose for spinal injection	
1 Very Difficult	n/N (%)
2 Difficult	n/N (%)
3 Neither Difficult nor Easy	n/N (%)
4 Easy	n/N (%)
5 Very Easy	n/N (%)
Ease of securely connecting between the syringe and the spinal needle hub	
1 Very Difficult	n/N (%)
2 Difficult	n/N (%)
3 Neither Difficult nor Easy	n/N (%)
4 Easy	n/N (%)
5 Very Easy	n/N (%)
Ease of disconnecting the syringe from the spinal needle after injection	
1 Very Difficult	n/N (%)
2 Difficult	n/N (%)
3 Neither Difficult nor Easy	n/N (%)
4 Easy	n/N (%)
5 Very Easy	n/N (%)

Note: The denominator for computing percentages is the total number of participants who completed the ease of use survey for Syringe.

Table 14.3.1.1 Summary of Adverse Events

Evaluable Population

	(N=xxx)	
	By Events	By Subjects
Any Adverse Events	xxx	n (%)
Severity		
Mild	xxx	n (%)
Moderate	xxx	n (%)
Severe	xxx	n (%)
Relationship to Procedure[1]		
Related	xxx	n (%)
Likely Related	xxx	n (%)
Unlikely Related	xxx	n (%)
Not Related	xxx	n (%)
Relationship to Spinal Needle		
Related	xxx	n (%)
Likely Related	xxx	n (%)
Unlikely Related	xxx	n (%)
Not Related	xxx	n (%)
Relationship to Stylet		
Related	xxx	n (%)
Likely Related	xxx	n (%)
Unlikely Related	xxx	n (%)
Not Related	xxx	n (%)
Relationship to Introducer		
Related	xxx	n (%)
Likely Related	xxx	n (%)
Unlikely Related	xxx	n (%)
Not Related	xxx	n (%)
Relationship to Syringe		
Related	xxx	n (%)
Likely Related	xxx	n (%)
Unlikely Related	xxx	n (%)
Not Related	xxx	n (%)
Any Serious AE (SAE)	xxx	n (%)
Relationship to Procedure[1]		
Related	xxx	n (%)
Likely Related	xxx	n (%)
Unlikely Related	xxx	n (%)
Not Related	xxx	n (%)
Relationship to Spinal Needle		
Related	xxx	n (%)
Likely Related	xxx	n (%)
Unlikely Related	xxx	n (%)

		(N=xxx)
Not Related	xxx	n (%)
Relationship to Stylet		
Related	xxx	n (%)
Likely Related	xxx	n (%)
Unlikely Related	xxx	n (%)
Not Related	xxx	n (%)
Relationship to Introducer		
Related	xxx	n (%)
Likely Related	xxx	n (%)
Unlikely Related	xxx	n (%)
Not Related	xxx	n (%)
Relationship to Syringe		
Related	xxx	n (%)
Likely Related	xxx	n (%)
Unlikely Related	xxx	n (%)
Not Related	xxx	n (%)
Death	xxx	n (%)
Any ADEs[2]	xxx	n (%)

[1] The adverse event eCRF page requests the relationship with the surgical procedure and not with the procedure according to the protocol's definition, by mistake. A query was raised for every adverse event reported by the sites in order to clarify the issue and to update the adverse event page accordingly.

[2] ADEs are defined as any adverse events related or likely related to the spinal needle device.

For by-subject summaries, subjects are counted in the highest severity or most-related category.

Table 14.3.1.2 Subjects with Adverse Events by Body System and Preferred Term

Evaluable Population

Body System Preferred Term	(N=xxx)
Any Adverse Events	xxx
Any Subjects with at least one AE	n(xx.x%)
Blood and Lymphatic Disorders	n(xx.x%)
Anemia	n(xx.x%)
Thrombocytopenia	
….	
Cardiac Disorders	
Myocardial Infarction	
….	

MedDRA dictionary version 24.1 was used for coding.
Body system organ class and preferred term are sorted alphabetically.

Table 14.3.1.3 Subjects with Adverse Events by Body System and Preferred Term and Severity

Evaluable Population

	(N=xxx)		
Body System Preferred Term	Mild	Moderate	Severe
Any Adverse Events	xxx	xxx	xxx
Any Subjects with at least one AE	n (xx.x%)	n (xx.x%)	n (xx.x%)
Blood and Lymphatic Disorders	n (xx.x%)	n (xx.x%)	n (xx.x%)
Anemia	n (xx.x%)	n (xx.x%)	n (xx.x%)
Thrombocytopenia	n (xx.x%)	n (xx.x%)	n (xx.x%)
….			
Cardiac Disorders			
Myocardial Infarction			
….			

Subjects are only counted once with the highest level of severity.
Body system organ class and preferred term are sorted alphabetically.

Table 14.3.1.4 Subjects with Device-Related Adverse Events by Body System and Preferred Term and Device

Evaluable Population

	(N=xxx)			
Body System Preferred Term	Spinal Needle	Stylet	Introducer	Syringe
Any Adverse Events	xxx	xxx	xxx	xxx

Any Subjects with at least one AE	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Blood and Lymphatic Disorders	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Anemia	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
Thrombocytopenia	n (xx.x%)	n (xx.x%)	n (xx.x%)	n (xx.x%)
….				
Cardiac Disorders				
Myocardial Infarction				
….				

Programming note: Related includes related and likely related.
Body system organ class and preferred term are sorted alphabetically.

Table 14.3.1.5 Subjects with Procedure-Related Adverse Events by Body System and Preferred Term

Evaluable Population

Body System Preferred Term	(N=xxx)
Any Procedure-related* Adverse Events	xxx
Any Subjects with at least one Procedure-related AE	n (xx.x%)
Blood and Lymphatic Disorders	n (xx.x%)
Anemia	n (xx.x%)
Thrombocytopenia	n (xx.x%)
….	
Cardiac Disorders	n (xx.x%)
Myocardial Infarction	n (xx.x%)

* The adverse event eCRF page requests the relationship with the surgical procedure and not with the procedure according to the protocol's definition, by mistake. A query was raised for every adverse event reported by the sites in order to clarify the issue and to update the adverse event page accordingly.

Programming note: Related includes related and likely related.
Body system organ class and preferred term are sorted alphabetically.

Table 14.3.1.6 Subjects with Serious Adverse Events by Body System and Preferred Term

Evaluable Population

Body System Preferred Term	(N=xxx)
Any Serious Adverse Events	xxx
Any Subjects with at least one Serious AE	n (xx.x%)

Blood and Lymphatic Disorders	n (xx.x%)
Anemia	n (xx.x%)
Thrombocytopenia	n (xx.x%)
….	
Cardiac Disorders	n (xx.x%)
Myocardial Infarction	n (xx.x%)

Table 14.3.1.7 Subjects with Adverse Device Effects (ADEs) by Body System and Preferred Term

Evaluable Population

Body System Preferred Term	(N=xxx)
Any Adverse Device Effects	xxx
Any Subjects with at least one Adverse Device Effects	n (xx.x%)
Blood and Lymphatic Disorders	n (xx.x%)
Anemia	n (xx.x%)
Thrombocytopenia	n (xx.x%)
….	
Cardiac Disorders	n (xx.x%)
Myocardial Infarction	n (xx.x%)

Table 14.3.1.8 Subjects with Serious Adverse Device Effects (SADEs) by Body System and Preferred Term

Evaluable Population

Body System Preferred Term	(N=xxx)
Any Serious Adverse Device Effects	xxx
Any Subjects with at least one Serious Adverse Device Effects	n (xx.x%)
Blood and Lymphatic Disorders	n (xx.x%)
Anemia	n (xx.x%)
Thrombocytopenia	n (xx.x%)
….	
Cardiac Disorders	n (xx.x%)
Myocardial Infarction	n (xx.x%)

Table 14.3.1.9 Summary of Actions Taken and Outcome for Adverse Events

Evaluable Population

	(N=xxx)

Any Adverse Events	xxx
Actions Taken	
None	n (xx.x%)
Medication prescribed	n (xx.x%)
Hospitalization	n (xx.x%)
Device removed	n (xx.x%)
Surgery	n (xx.x%)
Other	n (xx.x%)
Outcome	
Recovered / resolved	n (xx.x%)
Recovered with sequelae / resolved with sequelae	n (xx.x%)
Not recovered / not resolved	n (xx.x%)
Fatal	n (xx.x%)
Unknown	n (xx.x%)
Any ADEs	xxx
Severity	
Mild	n (xx.x%)
Moderate	n (xx.x%)
Severe	n (xx.x%)
Actions Taken	
None	n (xx.x%)
Medication prescribed	n (xx.x%)
Hospitalization	n (xx.x%)
Device removed	n (xx.x%)
Surgery	n (xx.x%)
Other	n (xx.x%)
Outcome	
Recovered / resolved	n (xx.x%)
Recovered with sequelae / resolved with sequelae	n (xx.x%)
Not recovered / not resolved	n (xx.x%)
Fatal	n (xx.x%)
Unknown	n (xx.x%)

Programming note: The denominator is the number of events.

Listing 14.3.1.1 Death

Evaluable Population

Site/Subject ID	Age/Sex	Date of Device Placement	Date of Death	Primary Cause of Death

3. Listings

Listing 16.2.1.1 Subject Disposition

Enrolled Population

Site ID	Subject ID	Date ICF signed	Agreed to Use the Study Data for Further Research	Completed the Study per Protocol	Date of Study Completion/Withdrawal	Subject Status at the End of Study/Reason for discontinuation	Safety Set	Evaluable Set
DE-01	201	10/May/2022	yes	Yes		Completed	yes	yes
				No				

Listing 16.2.1.2 Subjects with Screen Failures

Enrolled Population

Site/Subject ID	Did the Subject Meet All Eligibility Criteria?	If Eligibility not met, Inclusion Criteria Not Met/Exclusion Criteria Met
101001	No	INCL03: Subject must be willing and able to comply with protocol requirements, including all study visits and procedure.

Listing 16.2.1.3 Subject Visit

Evaluable Population

Site ID	Subject ID	Date of Screening/Enrollment Visit	Date of Follow-up Visit: 7 Days Post Procedure	Was 7 Days Post Procedure Follow-up Visit Performed?
				At the clinic
				By phone
				No

Listing 16.2.2 Protocol Deviations

Enrolled Population

Site/Subject ID	Deviation number	Category	Date of Deviation	Description of protocol deviation	Outcome

Listing 16.2.3.1 Demographics

Evaluable Population

Site ID	Subject ID	Age (Years)	Sex	Race	Height(cm)	Weight (kg)	BMI (kg/m2)

Listing 16.2.3.2 Primary Diagnosis

Evaluable Population

Site/ Subject ID	Primary diagnosis for intervention	Start date	Reason for neuraxial procedure	ASA PS classification
	Surgery of lower extremities		Anaesthesia	
	Other/Specify		Other/Specify	

Listing 16.2.3.3 Medical/Surgical History and Concomitant Diseases

Evaluable Population

Site/Subject ID	Age/Sex	Presence of relevant diseases other than primary diagnosis	Targeted surgical history	Targeted neurological impairment of lower extremities	Targeted anticoagulant therapy	Medical History Event Term	Start date	Ongoing	Stop date
		Yes	Yes	Yes	Yes			Yes	
		No	No	No	No			No	

Listing 16.2.4 Device Deficiency

Evaluable Population

Site ID	Subject ID	DD number	Date of Deficiency	Timing of Deficiency	Deficient Component	Deficiency Reason	Intervention Required	Device Available for Evaluation or Returned to The Manufacturer	Association with AE / Could have led to SADE	Additional Info
	XXX		DD-MM-YYYY	During device insertion	Spinal needle	Use errors	Resolved with repositio			

							ning device			
					Other/Specify	Other/Specify	Other/Specify			

Listing 16.2.5.1 Study Device and Placement - Spinal Needle Procedure (Part 1)

Evaluable Population

Site/Subject ID	Age/Sex	Spinal needle procedure performed/ If No, reason	Date of procedure	Start time of procedure (When introducer is introduced)	End time of procedure (When spinal needle is removed)		Participant position	Aseptic technique	Local anaesthesia	Lumbar interspace[1]	Number of Puncture attempts[2]
		Yes					Lateral Position				
		No/Reason					Other/Specify	Other/Specify	Other/Specify	Other/Specify	

[1] Lumbar interspace refers to last try

[2] It is the number of different needles attempted

Listing 16.2.5.2 Study Device and Placement - Spinal Needle Procedure (Part 2)

Evaluable Population

Site/Subject ID	Number of Interspace levels attempts[1]	Paresthesia verbalized by patient	Spontaneous appearance of cerebrospinal fluid (CSF) emerging from the needle hub	Attempt to aspirate CSF before injecting anaesthetic	Successful Attempt to aspirate CSF before injecting anaesthetic	Attempt to aspirate CSF after injecting anaesthetic	Successful Attempt to aspirate CSF after injecting anaesthetic	Spinal anaesthesia levels measured	Maximum spinal anaesthesia level right measured	Maximum spinal anaesthesia level left measured
		Yes/Left							Yes/Th10	Yes/Th10
		Yes/Right	No/Reason							

[1] The number of interspace levels attempts refers to the number of different lumbar interspace

Listing 16.2.5.3 Study Device and Placement – BD Spinal Needle Introducer and Spinal Needle (Part 3)

Evaluable Population

Site/Subject ID	Age/Sex	BD Spinal needle introducer usage	BD Spinal needle introducer type	BD Spinal needle introducer expiration date	BD spinal needle usage	BD spinal needle specifications	BD spinal needle expiration date

Listing 16.2.5.4 Study Device and Placement – BD Kit/Set Needle and Syringe (Part 4)

Evaluable Population

Site/Subject ID	Age/Sex	BD kit/set needle usage	BD kit/set needle type	BD kit/set needle expiration date	BD syringe usage	BD syringe catalog number	BD syringe expiration date	BD syringe size	BD Syringe type	BD Syringe Material
								Other/Specify	Other/Specify	

Listing 16.2.5.5 Concomitant Procedure

Evaluable Population

Site/ Subject ID	Concomitant Procedure Number	Procedure Name	Date Of Procedure (Start Date-End Date)	Indication	Adverse Event No.	Medical History No.	Device Deficiency No.

If there will be not data for concomitant procedure, a listing will be not released

Listing 16.2.6.1 Ease of Use Survey (Part 1)

Evaluable Population

Site/ Subject ID	Was the Ease of Use Survey completed	Date of completion	Ease of use of the introducer	Agreement on whether introducer facilitated placement of spinal needle	Ease of spinal needle insertion	Ease of spinal needle withdrawal after placement
	Yes		1 Very Difficult /Additional detail	1 Strongly Disagree/Additional detail	1 Very Difficult /Additional detail	1 Very Difficult/Additional detail
	No		5 Very Easy	2 Disagree/Additional detail	5 Very Easy	5 Very Easy

Listing 16.2.6.2 Ease of Use Survey (Part 2)

Evaluable Population

Site/ Subject ID	Agreement on whether stylet helped to determine the direction of spinal needle tip	Agreement on whether stylet functioned properly during spinal needle placement	Ease of stylet removal from the spinal needle after placement	Ease of reading syringe graduations when preparing the dose for spinal injection	Ease of securely connecting between the syringe and the spinal needle hub	Ease of disconnecting the syringe from the spinal needle after injection
	Yes	4 Agree	1 Very Difficult//Additional detail	1 Very Difficult/Additional detail	1 Very Difficult/Additional detail	1 Very Difficult/Additional detail
	No/Explain	5 Strongly Agree	5 Very Easy	5 Very Easy	5 Very Easy	5 Very Easy

Listing 16.2.7.1 Adverse Events (Part 1)

Evaluable Population

Site/Subject ID	Adverse Event Number	System organ class/ Preferred term/ Adverse event (Reported)	Predefined Adverse Events According to The Safety Objectives	Date Of the First Awareness Of The Site About AE	Start Date (Study Day[1])	Ongoing	End Date (Study Day[2])	AE Duration (Days)[3]	Outcome	Severity	Who Experienced the Adverse Event?
101001		Backache							Recovered/Resolved		

[1]Study Day= Event Start Date – Procedure Date
[2]Study Day= Event End Date – Procedure Date
[3]AE Duration= Event End Date – Event Start Date +1

Listing 16.2.7.2 Adverse Events (Part 2)

Evaluable Population

Site/Subject ID	Adverse Event Number	System organ class/ Preferred term/ Adverse event (Reported)	Relation to Surgical Procedure	Relation to Spinal Needle	Relation to Stylet	Relation to Introducer	Relation to Syringe	Action Taken	Relation to Device Deficiency	SAE	Additional Information
101001		Backache	Not Related	Not Related	Not Related	Not Related	Not Related			No	

Listing 16.2.7.3 Serious Adverse Event

Evaluable Population

Site/Subject ID	Event ID	System organ class/	Start Date (Study Day)[1]	Ongoing	End Date (Study Day)[1]	AE Duration (Days)[2]	Serious Criteria	Admission Date (Study Day)[1]	Discharge Date (Study Day)[1]
1002			No				Require in-patient or prolonged hospitalization		

Only SAEs are included.

[1]Study Day= Event Date – Procedure Date
[2]AE Duration= Event End Date – Event Start Date +1

Listing 16.2.8 Comment Log

Evaluable Population

Site/ Subject ID	Age/ Sex	Comment number	Visit	Form / Assessment	Comment

If there will be not data for comment log, a listing will be not released

Listing 16.2.9 Follow-up Assessments

Evaluable Population

Site/Subject ID	Did the subject have a post-dural puncture headache during the required follow-up period?	Did the subject experience spinal / epidural hematoma?	Did the subject experience nerve damage (pain or weakness lower extremities)?	Did the subject experience infection (meningitis, spinal abscess)?	Did the subject experience pain at or near the skin puncture site?	Did the subject experience skin redness at or near the skin puncture site?	Did the subject experience irritation at or near the skin puncture site?	Did the subject experience backache related to the neuraxial procedure?
	0: No Headache	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	1: Mild Headache; no interference with daily activities	No	No	No	No	No	No	No