COVER PAGE OF STUDY PROTOCOL

Study title:	**Prospective Clinical Evaluation of BD Spinal Needles**
Protocol number.:	**MDS-20EPSPEU001**
NCT number:	**NCT05214560**
Protocol version and date:	**v.3.0, 27- April - 2022**

Protocol Number: MDS-20EPSPEU001
Version: 3.0
Date: 27Apr2022

CONFIDENTIAL

TITLE PAGE

Protocol Title: Prospective Clinical Evaluation of BD Spinal Needles

Protocol Number: MDS-20EPSPEU001

Version Number: 3.0

Study Device: BD Spinal Needles: Quincke Type Point or Whitacre Pencil Point, packaged with or without Introducer

Study Type: Prospective, Observational, Post-Market

Sponsor Name: Becton, Dickinson & Company

Legal Registered Address: 1 Becton Drive,
Franklin Lakes, New Jersey 07417
US

Sponsor Contact: Gloria Viti
Clinical Project Manager
Global Clinical Development
Becton, Dickinson & Company
gloria.viti@bd.com
+39.345.2237718

Version History

Version Number	Date	Type
3.0	27 APR 2022	Administrative changes; addition of BD Spinal needles
2.0	15 JUL 2021	Revised study design
1.0	31 MAR 2021	Original

SPONSOR PROTOCOL APPROVAL

Signature below indicates approval of the protocol as written.

Individual or function	Name	Signature	Date
Business Unit Medical Affairs	Edward Maratea	*This document is signed electronically in the eTMF system*	
Business Unit Regulatory Affairs	John W Roberts	*This document is signed electronically in the eTMF system*	
Global Clinical Development Statistician	Milan Bimali	*This document is signed electronically in the eTMF system*	
Global Clinical Development Project Manager	Gloria Viti	*This document is signed electronically in the eTMF system*	

PROTOCOL SIGNATURE PAGE

Investigator Responsibilities

1. Prior to participation in this study, the Investigator or Institution must sign the Clinical Study Agreement (CSA) and obtain written approval from the appropriate Institutional Review Board (IRB)/Ethics Committee (EC).
2. The Investigator must receive BD-sponsored training prior to site activation. The Investigator is responsible for ensuring that all Sub-Investigators and clinical staff are adequately trained prior to performing any data collection or study-related procedures.
3. The Principal Investigator shall ensure that the study is conducted in accordance with the study protocol, any modifications as requested by the IRB/EC, the signed CSA, the ethical principles of the Declaration of Helsinki, Good Clinical Practice (ICH E6) / ISO 14155), and applicable national/regional regulations and laws.
4. If applicable, ensure that written informed consent is obtained from each participant prior to the conduct of any study procedure, using the current IRB/EC approved Informed Consent Form.

I have read and understand the contents of this study protocol. I agree to follow and abide by the requirements set forth in this document. I agree to conduct the trial in accordance with the study protocol, the signed Clinical Study Agreement, and Good Clinical Practice (GCP) as well as ISO regulations (e.g., ISO 14155). I agree to participate in BD-Sponsored training prior to performing any data collection or study-related procedures.

Agreed to by (Investigator):

_____
Printed Name – Investigator

_____
Signature – Investigator

_____
Site Number

_____
Date

PROTOCOL AMENDMENT SUMMARY OF CHANGES TABLE

Amendment 3.0 (27Apr2022)
This amendment is considered to be nonsubstantial based on the criteria set forth in Article 75 1. of the Regulation (EU) 2017/745 on Medical Devices because it neither significantly impacts the safety, or physical/mental integrity of participants nor the scientific value of the study.

Overall Rationale for the Amendment:
The rationale for the amendment is to include other BD spinal needles already available on the market with the same gauges listed in the protocol v.2.0, 15Jul2021 but different lengths.

Summary of Change Table

<table>
<tr><th>Location of Original Text</th><th>Original Text</th><th>New Text</th><th>Rationale for Change</th></tr>
<tr><td>Header/Title Page</td><td>15 Jul 2021</td><td>27 Apr 2022</td><td>Version Control</td></tr>
<tr><td>Header/Title Page</td><td>Version: 2.0</td><td>Version: 3.0</td><td>Version Control</td></tr>
<tr><td>Sponsor Protocol Approval</td><td>Yang Bai</td><td>Milan Bimali</td><td>Statistician change</td></tr>
<tr><td>Appendices: 16.1 BD Spinal Needles</td><td>N/A</td><td><table>
<tr><td>Quincke</td><td>408360</td><td>18G x 156 mm (6 in.)</td></tr>
<tr><td>Quincke</td><td>405211</td><td>20 G x 156 mm (6 in.)</td></tr>
<tr><td>Quincke</td><td>405148</td><td>22 G x 127 mm (5 in.)</td></tr>
<tr><td>Quincke</td><td>405149</td><td>22 G x 178 mm (7 in.)</td></tr>
<tr><td>Whitacre</td><td>409442</td><td>25 G x 119 mm (4 11/16 in.)</td></tr>
<tr><td>Whitacre</td><td>409443</td><td>27 G x 119 mm (4 11/16 in.)</td></tr>
</table></td><td>Additional BD Spinal needles with the same gauges and different lengths, already available on the market.</td></tr>
<tr><td>Appendices: 16.1 BD Spinal Needles – Kit/Set needle type</td><td>Kit/Set Needle Type: Whitacre Catalog Number: 405112 Description: 25 G x 103 mm (4 1/16 in.) Whitacre Set</td><td>N/A</td><td>Clarification: typo error.
Modification: The catalog number and related description have been removed because they were a repetition.</td></tr>
</table>

Location of Original Text	Original Text	New Text	Rationale for Change
Appendices: 16.1 BD Spinal Needles – Kit/Set needle type	Kit/Set Needle Type: Whitacre Catalog Number: 405113 Description: 27 G x 103 mm (4 1/16 in.) Whitacre Set	N/A	Clarification: typo error. Modification: The catalog number and related description have been removed because they were a repetition.

Abbreviations

ADE	Adverse Device Effect
AE	Adverse Event
BD	Becton Dickinson and Company
CFR	Code of Federal Regulations
CRF	Case Report/Record Form
CSA	Clinical Study Agreement
CSF	Cerebrospinal Fluid
CV	Curriculum Vitae
DMP	Data Management Plan
EDC	Electronic Data Capture
FDA	Food and Drug Administration
FDAAA	FDA Amendments Act of 2007
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
ICF	Informed Consent Form
ICMJE	International Committee of Medical Journal Editors
IRB/EC	Institutional or Independent Review Board/Ethics Committee
NDA	Non-Disclosure Agreement
PDPH	Post-Dural Puncture Headache
PI	Principal Investigator
RMV	Routine Monitoring Visit
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SoA	Schedule of Activities
SOP	Standard Operating Procedure
TMF	Trial Master File

1 PROTOCOL SUMMARY

1.1 Synopsis

Protocol Title	Prospective Clinical Evaluation of BD Spinal Needles	
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.	
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

Protocol Title	Prospective Clinical Evaluation of BD Spinal Needles
Design and Overview	This is a multi-center, prospective, observational, post-market study of participants who will receive neuraxial procedures with a BD Spinal Needle as part of their routine medical care. 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 procedure(s) performed, and device(s) used, will be left to the discretion of the participant's physician investigator. 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.
Study Device	<u>BD Spinal Needles</u> BD Spinal Needles are used to access anatomical structures in order to introduce medicines, image contrast agents, guide wires, or catheters. The BD Whitacre Pencil Point Spinal Needles are available in gauges from 22 – 27 and in lengths from 3 ½ inches to 5 inches. The BD Quincke Spinal Needles are available in gauges 18 – 27 and in lengths from 1 inch to 7 inches. BD Spinal Needles may be packed separately, with introducers, or in anesthesia trays.

Protocol Title	Prospective Clinical Evaluation of BD Spinal Needles
Participants	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. Inclusion Criteria: 1. Any patient, regardless of age or gender, for which the investigator has decided that a neuraxial procedure must be performed utilizing BD Spinal Needles as part of their routine medical care 2. Expected to be available for observation through the study period (7-days post procedure) 3. Provision of signed and dated informed consent form (Note: Consent of guardian or parent may be required for patients under the age of 18 years; participant assent may be required as well.) Exclusion Criteria: 1. Undergoing emergency surgery 2. Coagulopathy or bleeding disorder for which regional anesthesia poses an increased risk 3. History of neurological impairment or disease of the trunk or lower extremities. 4. Infection at or near the site of needle insertion 5. Previous spine surgery at the level involved in the study procedure
Intervention(s)/Procedure(s)	This is an observational, real-world study in patients who require a medical procedure utilizing a BD Spinal Needle. There are no study-specific procedures required for the participant other than informed consent and AE monitoring. Healthcare professionals performing the actual neuraxial procedures will complete a short survey after each procedure is performed to assess device performance.
Investigational Sites	Five or more sites located within the European Union
Study Duration	Per participant the study will last 7 days at maximum, the overall conduct of the study is expected to last approximately 8-10 months from first participant enrolled up to last participant having last visit.
Data Monitoring Committee	A Data Monitoring Committee will not be used in this study.
Regulatory Status	All BD devices utilized in this study as part of routine medical care are CE marked and commercially available. As such, this is a post-market study.

1.2 Schedule of Activities

Procedure / Study Phase	Screening/ Enrollment	Insertion (Day 0)	Through Day 7 Post-Insertion
Inclusion and Exclusion Criteria	X		
Informed Consent	X		
Baseline and Demography	X		
Limited Medical History	X		
Spinal Needle Procedure		X	
Procedure-Specific Information		X	
Ease of Use Survey		X	
AE Monitoring		X	X
Device deficiency monitoring		X	X

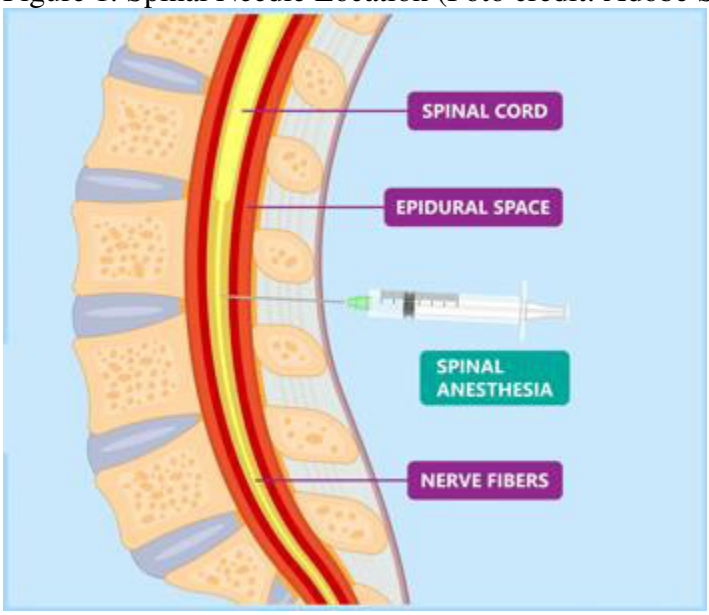
2 INTRODUCTION

Becton, Dickinson & Company manufactures a variety of devices used in neuraxial procedures including spinal needles and associated introducers. These devices are used in medical procedures utilizing well established methods.

2.1 Background

Neuraxial procedures may be performed for a variety of reasons including administration of medications (i.e., anesthesia; analgesia) and introduction of contrast agents, guidewires, or catheters. Neuraxial anesthesia is used for many indications including analgesia or surgical anesthesia for lower abdominal or lower extremity procedures or labor and delivery. (1) Neuraxial procedures are performed by placing a needle between vertebrae and injecting medication into the subarachnoid space (for spinal anesthesia; Figure 1). Spinal anesthesia is usually administered as a single injection. (2)

Figure 1. Spinal Needle Location (Foto credit: Adobe Stock 378168029)



2.2 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 European Union (EU) regulation 2017/745.

2.3 Risk/Benefit Assessment

In this study, data are generated from participants in which the BD Spinal Needles (BD Needles) are being used as indicated in the instructions for use. Other than scheduled follow-up assessments, no additional study-specific procedures are being performed. Risks associated with study participation are no different than those the participant would encounter as part of their required medical care. The risks presented in Section 2.3.1 are associated with neuraxial procedures/anesthesia and are not unique or specific to the use of BD Needles.

2.3.1 Risk Assessment

Potential Risk of Clinical Significance	Summary of Data/Rationale for Risk	Mitigation Strategy
Study Interventions: BD Spinal Needles		
In spinal procedures, larger diameter needles and cutting needle tips are both associated with an increased risk of post-dural puncture headache (PDPH)	Clinical literature (3; 4)	Physicians should select the smallest diameter needle sufficient to support the specific procedure
Study Procedures		
Neuraxial procedures may be associated with the following risks: • Inadequate or failed anesthesia • Hemodynamic changes, most commonly hypotension • Post-dural puncture headache (spinal only) • Localized pain • Localized skin irritation • Urinary retention (temporary) • Nerve injury (rare) • Spinal-epidural hematoma (rare) • Infection	Clinical literature (5; 6; 7; 8; 9)	• Physicians should select the smallest diameter needle sufficient to support the specific procedure • Patient blood pressure and heart rate should be closely monitored throughout the procedure and after medication administration • Only physicians with sufficient training and experience should perform neuraxial anesthesia procedures
Other		
Not applicable		

2.3.2 Benefit Assessment

There are no direct benefits to participants in the study.

2.3.3 Overall Benefit: Risk Conclusion

Due to the observational nature of this study, there is no anticipated benefit to an individual participant. Likewise, because a participant will undergo a spinal needle procedure regardless of their participation in the study, there are no anticipated study-specific risks.

3 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

4 STUDY DESIGN

4.1 Overall Design

This is a multi-center, prospective, observational, post-market study of participants who will receive neuraxial procedures with a BD Spinal Needle as part of their routine medical care. 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 procedure(s) performed, and device(s) used, will be left to the discretion of the participant's physician investigator.

4.1.1 Spinal Needle 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.

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.

4.2 Scientific Rationale for Study Design

This study is designed to assess the real-world safety and efficacy of BD Spinal Needles used in an on-market fashion. The observational design will ensure that study activities have no direct impact on the endpoints being assessed and that they represent outcomes typically associated with standard medical use of the study devices.

4.2.1 Participant Input into Design

Not applicable.

4.3 End of Study Definition

A participant is considered to have completed the study if he/she has completed all phases of the study including the 7-day post-procedure follow-up assessment.

The end of the study is defined as the date of the last study assessment of the last participant in the study.

5 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.

5.1 Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Any patient, regardless of age or gender, for which the investigator has decided that a neuraxial procedure must be performed utilizing BD Spinal Needles as part of their routine medical care
2. Expected to be available for observation through the study period (7-days post procedure)
3. Provision of signed and dated informed consent form (Note: Consent of guardian or parent may be required for patients under the age of 18 years; participant assent may be required as well.)

5.2 Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

1. Undergoing emergency surgery
2. Coagulopathy or bleeding disorder for which regional anesthesia poses an increased risk
3. History of neurological impairment or disease of the trunk or lower extremities.
4. Infection at or near the site of needle insertion
5. Previous spine surgery at the level involved in the study procedure

5.3 Lifestyle Considerations

Because of the real-world design of this study, there are no study-specific restrictions other than those typically associated with use of a study device (e.g., keeping the insertion area clean and dry).

5.4 Screen Failures

Screen failures are not anticipated due to the observational nature of the study.

5.5 Vulnerable Population

As the instruction for use of the BD Spinal Needles do not foresee any limitations in terms of subject age or status and the study aims to collect observational data on clinical

use, the study will also consider participants under 18 years of age, or participants requiring a legal authorized representative. Also pregnant and breastfeeding subjects aren't excluded from study participation. As the study device will be used as intended, this population is considered to be not exposed to any additional risk due to the study participation.

Some participating clinical sites may decide to not include vulnerable subjects as per their hospital policy or may not include minors as the participating department treats only adults.

6 STUDY INTERVENTIONS

6.1 Investigational/Test Devices

BD Spinal Needles are used to access anatomical structures in order to introduce medicines, image contrast agents, guide wires, or catheters. The BD Whitacre Pencil Point Spinal Needles are available in gauges from 22 – 27 in a 3½ inch length. The BD Quincke Spinal Needles are available in gauges 18 – 27 and in lengths from 1½ inch to 3½ inches. BD Spinal Needles may be packed separately, with introducers, or in anesthesia trays. See Appendix 16.1 for a list of BD Spinal Needles included in this study.

6.2 Control Device/Standard of Care

This is a single-arm study; no control device(s) will be used.

6.3 Ancillary Devices/Products

Neuraxial procedures are conducted under strict aseptic technique and require the physician to wear cap, mask, sterile gloves, and optional sterile gown. The site will be covered with a sterile drape and prepped with an appropriate antiseptic agent. Materials used to comply with aseptic technique will be provided by the site according to their site-specific requirements.

Use of additional devices may be required depending on the procedure being performed. If an ancillary device used is a BD device (e.g., spinal needle introducer) information on their performance will be captured as part of the ease-of-use survey.

6.4 Device Labeling

This is a post-market study in which devices are used in an on-label fashion. Sites will utilize shelf-stock devices as routinely labeled by the manufacturer.

6.5 Treatment Allocation and Measures to Minimize Bias

This is a real-world study in which study devices are used as part of the required medical care for participants. The choice of the specific device is left to the discretion of the clinician.
All patients potentially fulfilling the inclusion/exclusion criteria will be sequentially offered participation in this study when they attend for a clinical visit prior to performance of neuraxial procedure. This rule will allow to avoid any selection bias, since all the patients will be proposed the study in chronological order when they attend a regular clinic visit.

7 STUDY PROCEDURES AND ASSESSMENTS

- Study activities procedures and their timing are summarized in the Schedule of Activities (SoA, Section 1.2).
- Protocol waivers or exemptions are not allowed.
- Adherence to the study design requirements, including those specified in the SoA, is essential and required for study conduct.
- All inclusion/exclusion criteria must be reviewed to confirm that potential participants meet all eligibility criteria.
- Procedures conducted as part of the participant's routine clinical management (e.g., blood count) and obtained before signing of the ICF may be utilized for screening or baseline purposes provided the procedures met the protocol-specified criteria and were performed within the time frame defined in the SoA.

7.1 Study duration

The study duration per participant will last 7 days at maximum, the overall conduct of the study is expected to last approximately 8-10 months from first participant enrolled up to last participant having last visit.

7.2 Screening and Enrollment

After screening against inclusion/exclusion criteria, potential participants will be provided with detailed information about the study. For details on the Informed Consent process, please refer to section 14.2. A participant will be considered enrolled once informed consent (including assent as applicable) is signed. Enrolled participants will be assigned a unique participant number.

7.3 Medical History / Baseline Assessments

After enrollment, participant baseline and demographic information will be documented, including, but not limited to:

- Age
- Gender
- Height and Weight (for calculated body mass index)

- Primary diagnosis
- Limited medical history (e.g., surgical history, anticoagulant therapy)
- ASA Class (I, II, III, IV) (if appropriate)
- Reason for neuraxial procedure

7.4 Neuraxial Procedure

Choice of the specific BD Spinal Needle, gauge, and length required for an individual participant is left to the discretion of the clinician. The device, participant, and insertion site will be prepared according to standard medical practices and site-specific procedures. The device will be inserted, its location confirmed, and the device utilized according to the specific medical needs of the participant and site-specific protocols and procedures.

7.4.1 Spinal Needle Procedure

After the spinal needle procedure is performed, information about the insertion procedure will be documented, including, but not limited to:

- Date and time of insertion
- Participant position
- Use of aseptic technique
- Use of local anesthesia
- Interspace
- Needle type, gauge, and length
- Introducer (if used)
- Number of insertion attempts (including interspace levels)
- Medications/agents injected (type, dose, volume) (if appropriate)
- Maximum spinal block level measured (left and right) (if appropriate)
- Adverse events/complications (including but not limited to study endpoints)
- Device deficiencies/failures
- Physician performing procedure experience (e.g., years of experience, estimated number of spinal needle procedures performed)

7.5 Ease of Use Procedure Survey

After the neuraxial procedure data is recorded, the physician investigator will complete a short survey to assess the performance of the BD devices used in the procedure.

7.6 Participant Follow-Up

Participants will be followed through 7-days post procedure to assess for adverse events/complications. Assessments may be performed in a variety of ways, including by telephone, if the participant has been discharged from the hospital prior to day-7 post procedure. Additional information may also be collected if appropriate.

During the required follow-up period the following data will be collected:

- 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
- Incidence of post-dural puncture headache, including grading as follows,
  - 0: No headache
  - 1: Mild headache, not interference with daily activities
  - 2: Moderate headache, some interference with daily activities
  - 3: Severe headache, bedridden
  - 4: Severe headache, requires hospitalization or prolonged hospitalization

8 PARTICIPANT DISCONTINUATION/WITHDRAWAL

8.1 Discontinuation/Withdrawal

- A participant may withdraw from the study at any time at his/her own request or may be withdrawn at any time at the discretion of the investigator or sponsor for safety, behavioral, compliance, or administrative reasons. This is expected to be uncommon.
- At the time of discontinuing from the study, no further data will be collected for the participant.
- If the participant withdraws consent for disclosure of future information, the sponsor may retain and continue to use any data collected before such a withdrawal of consent.
- Participants who withdraw or discontinue the study early (e.g., prior to day-7 post procedure follow-up) may be replaced.

8.2 Lost to Follow-Up

A participant will be considered lost to follow-up if he or she repeatedly is unable to be contacted by the study site.

9 ADVERSE EVENTS AND DEVICE DEFICIENCIES

9.1 Definitions of Events

9.1.1 Adverse Events (AEs)

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.

Pre-existing conditions should be considered as part of the participant's medical history and should not be reported as an AE unless there is a substantial increase in severity or frequency of the condition, which has not been attributed to natural history. Likewise, planned hospital visits and/or hospital stays should not be considered as adverse events. Exacerbation of an existing condition should be reported as an AE if the event meets the protocol definition of an AE.

The clinical course of the event will be followed according to accepted standards of medical practice until the event resolves, stabilizes, or in the opinion of the Investigator, is no longer considered clinically significant. The Investigator must supply the Sponsor with information concerning the follow up and/or resolution of the AE.

9.1.2 Serious Adverse Events (SAEs)

A serious adverse event is defined by ISO 14155:2020 as an adverse event that led to any of the following:

a. death;
b. serious deterioration in health of the participant, users, or other persons as defined by one or more of the following:
    1. a life-threatening illness or injury, or
    2. a permanent impairment of a body structure or a body function including chronic disease, or
    3. in-patient hospitalization or prolonged hospitalization, or
    4. medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
c. fetal distress, fetal death, a congenital abnormality or birth defect including physical or mental impairment.

9.1.3 Adverse Device Effect (ADE) / Serious Adverse Device Effect (SADE)

An adverse device effect is defined as any adverse event that is considered to be related to the use of an investigational medical device. This definition includes any event resulting from insufficiencies or inadequacies in the instructions for use, deployment, implantation, installation, or operation or any malfunction of the investigational device (study device) and includes any event that is a result of a user error.

A serious adverse device effect (SADE) is defined as an ADE that has resulted in any of the consequences characteristic of an SAE.

9.1.4 Unanticipated (Serious) Adverse Device Effect (UADE/USADE)

An unanticipated (serious) adverse device effect (UADE/USADE) is any (serious) adverse device effect on health or safety or any life-threatening problem or death caused by, or associated with, a study device, which by its nature, incidence, severity, or outcome has not been identified in the current instructions for use and/or current version of the risk analysis report, or any other unanticipated serious problem associated with a device that relates to the rights, safety or welfare of participants.

UADEs/USADEs will be reported to the appropriate governing body per ISO 14155:2020.

9.2 Severity of Adverse Events

Each AE shall be assessed for its severity, or the intensity of an event, experienced by the participant according to the criteria below.

Severity Rating	Description
Mild	Event, signs, or symptoms that do not interfere with the participant's daily activity, are usually considered self-limiting, can be treated with non-prescription type medications, and do not require medical intervention
Moderate	Event may interfere or cause low level inconvenience with the participant's daily activity. Requires medical intervention and/or treatment; however, unlikely to require hospitalization or be considered potentially life-threatening in nature
Severe	Event may cause significant discomfort to the participant and/or interferes with the participant's daily activity. Requires medical intervention and/or treatment to preclude a permanent impairment; may be life threatening and/or require hospitalization

9.3 Relationship of Adverse Event to Device(s)/Procedure

Each AE will be assessed for its relationship to the study device or procedure according to the following guidelines.

A. Assess each AE for its relationship to the device or procedure.

- Device Related: This category should be restricted to AEs directly attributable to the study device used in the neuraxial access procedure.

- Procedure: A procedure includes any study-related activity performed during the neuraxial procedure.

B. The following categories shall be used for assigning the certainty of the relatedness.

Relatedness	Description
Not Related	Event is independent of study intervention and/or evidence exists that the event is related to another etiology. There must be an alternative etiology documented by the clinician.
Unlikely Related	Event in which the temporal relationship to study intervention makes a causal relationship improbable (e.g., the event did not occur within a reasonable time of the study device use) and in which underlying disease provides plausible explanations (e.g., the participant's clinical condition other concomitant treatments).
Likely Related	Event in which there is evidence to suggest a causal relationship and the influence of other factors is less likely. The event occurs within a reasonable time after use of the study device and is less likely to be attributed to concurrent disease.
Related	Event in which there is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out. The event occurs in a plausible time relationship to use of the study device and cannot be explained by concurrent disease.

9.4 Reporting of Events

For all adverse events, all sections of the appropriate Case Report Form (CRF) must be completed.

All SAEs, SADEs, and/or UADEs/USADEs must be reported to the Sponsor via the electronic CRF without unjustified delay and within three (3) working days of the site/investigator becoming aware of the event.

It is the responsibility of the Investigator to report adverse events to individual Institutional Review Boards (IRBs)/Ethics Committees (ECs) and/or regulatory authorities according to the local regulations in each participating country.

9.5 Safety Committees

A safety committee will not be used in this study.

9.6 Device Deficiencies

The Investigator will record a device deficiency if a device used in the study, which is or appears to be inadequate with respect to its identity, quality, durability, reliability usability, safety or performance due to mechanical failure, malfunction, or defect. Device deficiencies also include use errors and inadequacy in the information supplied by the manufacturer including inadequate labeling. This applies to: devices used to treat the participant, or devices in which the package was opened, but the device was not used for treatment, or devices with which treatment was attempted, but the device did not remain through the entire study procedure/period.

All mechanical failures, malfunctions, missing components, and defects of the study devices will be recorded on the appropriate Case Report Form and will be promptly reported to the Sponsor. The device(s) should be returned to the Sponsor as outlined in the site's regulatory binder if requested.

If the device deficiency was associated with an AE, the reporting provisions for AEs, ADEs, SAEs, SADEs and UADEs/USADEs apply.

Reported deficiencies will be investigated and reported under 21 CFR part 803 Medical Device Reporting by the Sponsor if necessary, or as required by appropriate national laws and regulations. The site may be contacted to provide additional information to allow the Sponsor to conduct a thorough investigation.

It is the responsibility of the Investigator to notify the IRB/EC of such device deficiencies in accordance with the IRB/EC and/or the Competent Authority's local regulations.

9.7 Serious Health Threat

During the course of the study, device deficiencies or adverse events will be assessed if they constitute a serious health threat. The serious health threat is a signal from any adverse event or device deficiency that indicates an imminent risk of death or a serious deterioration in the health of subjects, users or other persons, and that requires prompt remedial action for other subjects, users or other persons. Serious health threat includes the possibility of multiple deaths occurring at short intervals, or other significant and unexpected serious adverse events that can be regarded as a potential serious health hazard in subjects, users or other persons and which are possibly related to the investigation device use.

10 STATISTICAL METHODS

The statistical analysis plan will be finalized prior to database lock and will include a more technical and detailed description of the statistical analyses described in the following sections. This section includes a summary of the planned statistical analyses of the primary and secondary endpoints.

10.1 Overview of Study Design

This is a multi-center, prospective, observational study to assess the overall safety and performance of the BD Spinal Needles.

10.2 Sample Size Considerations

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.

10.3 Analysis Population

The following populations are defined:

Population	Description
Enrolled	All participants who sign the ICF
Evaluable	All participants in whom a neuraxial procedure is attempted, regardless of success

10.4 Primary Endpoints

The incidence rate for the primary safety endpoints will be calculated as the number of participants experiencing the event divided by the total number of evaluable patients; 95% confidence interval (exact method) will be calculated. The same approach will be used for primary efficacy endpoints.

10.5 Secondary Endpoint(s)

For each complication listed as a secondary endpoint, the incidence of each complication will be calculated by dividing the number of participants experiencing the event by the total number of participants; 95% confidence intervals will be calculated where appropriate.

10.6 Other Analyses

For other data not specifically captured under primary or secondary endpoints (e.g., participant position; medications administered), summary statistics for categorical variables will include frequency counts and proportions and for continuous variables mean, standard deviation, minimum, median and maximum. Further details will be included in the final Statistical Analysis Plan (SAP).

11 DATA COLLECTION AND RECORD MAINTENANCE

11.1 Case Report Forms

The Investigator is responsible for ensuring the completeness and accuracy of all study documentation.

All required clinical data will be collected/documented in sponsor-provided electronic Case Report Forms (CRFs). Applicable national and local regulations are followed on the handling of electronic data. Modification of the CRFs will only be made if deemed necessary by the Sponsor and/or the appropriate regulatory body.

Site numbers and participant numbers will be used to track participant information throughout the study. Participant personal information will be pseudonymized/de-identified.

11.2 Source Documentation

Original or certified copies of all relevant clinical findings, observations, and other activities throughout the clinical investigation must be recorded and maintained in the medical and/or study file of each enrolled participant. Where there is no prior written or electronic record of data, such as clinical surveys, these data may be recorded directly on the CRF(s) and the CRF is then considered to be the source.

11.3 Data Management

Data management is the responsibility of the Sponsor or their designee. Data from completed CRFs will be managed in a secured, controlled database. A Data Management Plan (DMP) will be developed that outlines the procedures used for recording, data tracking, data review, database cleaning, issuing/resolving data queries and securing of electronic data system as well as the procedures for validations and data storage will also be contained within the DMP.

11.4 Record Retention

The Investigator shall retain all study records for a minimum of ten (10) years after the date on which the study is terminated/completed. Study records may be stored longer if required by national law or other local rules. The data for some of these records may be

available in computerized form but the final responsibility for maintaining study records remains with the Investigator.

The Investigator may withdraw from the responsibility to maintain records for the period required by transferring custody of the records to any other person who will accept responsibility for retaining them. Notice of a transfer shall be given to the Sponsor not later than ten (10) working days after the transfer occurs.

12 QUALITY CONTROL AND ASSURANCE

12.1 Control of Study Products

In this observational, real-world study, shelf-stock of study devices will be used. Clinicians may choose and use any study device that is available for use in their institution and that is medically appropriate for use in study participant. No special controls are required in this study.

12.2 Monitoring

The Sponsor will designate trained and qualified personnel to monitor the progress of this clinical study in accordance with established standard operating procedures and the study-specific Monitoring Plan.

Prior to study start, a study initiation visit (SIV) will be conducted to review with the Investigator(s) and staff the provisions and proper conduct of this study. This visit will include a detailed review of this protocol, verification that all necessary documents are on file at the investigational site and confirmation of IRB/EC approvals.

During the study, routine monitoring visits (RMVs) will be conducted to assure the site continues to adhere to the protocol, the investigator agreement, and regulations regarding conduct of clinical studies. The Monitor will confirm that the ICF to be used is the version approved by the IRB/EC, confirm the applicable national privacy laws have been followed, verify that all necessary documents are on file at the investigational site and confirm that there are provisions to continue and maintain all documents and records throughout the study as required by applicable regulations. These monitoring visits will assess continued protocol compliance, adequate participant enrollment, accurate data reporting, monitoring of participant safety through identification and/or review of any device-related AEs, UADEs, or SAEs, device accountability, continued maintenance and calibration of study-specific equipment (if applicable), and continued IRB/EC acceptance of the study.

At the completion of the study, the Monitor will conduct a final close-out visit (COV). The purpose of this visit may include but is not limited to collecting all outstanding study data documents, confirming that the Investigator’s files are accurate and complete, reviewing the record retention requirements with the Investigator, ensuring that all applicable requirements for closure of the study are met.

12.3 Audits and Inspections

If the study is selected for audit by the Sponsor or if there is an inspection by the appropriate Health Authorities, the Investigator and her/his team will make themselves available during the visit. The Investigator must agree to the inspection of all study related records and give the auditor/inspector direct access to source documents for verification of data on CRFs. The participant's anonymity must be ensured, and data checked during the audit must remain confidential.

As soon as the Investigator is aware of an upcoming inspection/audit by the Health Authorities, he/she will promptly inform the Sponsor. As agreed with the Investigator, Sponsor personnel may be present at the site during the inspection.

12.4 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.

Except when necessary to protect the life or physical well-being of a participant, protocol deviations are not permitted. The Sponsor and the investigational site's IRB/EC must be notified immediately if an emergency situation arises in which the safety of a participant may require immediate intervention different than that defined in the protocol. This must be followed by written confirmation that describes the emergency action and outcomes, within five (5) working days from the date of the emergency action in accordance with the governing IRB/EC's requirement.

It is the Investigator's responsibility to ensure that there are no deviations from the Protocol. Except in an emergency, when a protocol deviation is planned or anticipated, the Sponsor should be contacted for approval. Any and all deviations must be recorded on the appropriate CRF regardless of whether medically justifiable or sponsor approved. Upon evaluation by the Sponsor, actions may be required to prevent additional deviations, such as retraining of the site, implementation of additional site procedures, and more frequent monitoring. If these steps fail, more serious measures, up to and including termination of enrollment at the site.

13 ADMINISTRATIVE REQUIREMENTS

13.1 Investigator and Site Selection

The Investigator must be of good standing as an Investigator and knowledgeable in relevant areas of clinical research to ensure adherence to the requirements of this protocol, including the protection of human participants. Other site personnel must have appropriate research experience and infrastructure to ensure adherence to this protocol

and enrollment of sufficient numbers of evaluable participants. The curriculum vitae (CV) of the Investigator(s), Sub-Investigator(s) and Study Coordinator(s) will be maintained in the Sponsor's files as documentation of qualification by training and experience.

The Principal Investigator will sign the Investigator Agreement pages of this protocol, agreeing to comply with all applicable regulations and the requirements of this study per the clinical study agreement.

Any site that is deactivated prior to initial enrollment, either by the Sponsor or by the individual site itself, may be replaced.

13.2 Training

Each Investigator and appropriate site personnel will be trained on this protocol, study requirements and if needed study devices during the Site Initiation Visit. All training will be documented and filed at the investigational site and with the Sponsor.

13.3 Required Documents

An Investigator may not screen or enroll participants until authorized to do so by the Sponsor. At a minimum, the following documentation should be received by the Sponsor prior to the commencement of study activities:

- Fully executed Non-disclosure Agreement (NDA) between PI/site and Sponsor;
- CVs, signed and dated within 2 years of study start for the PI and Sub-Investigator(s);
- CVs for Study Coordinator(s);
- Signed CSA by PI/site (or designee);
- Signed Protocol Signature Page by PI;
- Signed Financial Disclosure Statement by PI and Sub-Investigator(s)]
- Completed and Signed Training Log by PI and Sub-Investigator(s);
- Study Personnel Identification list]
- Written approval from the IRB/EC of both the protocol and ICF, and any other applicable protocol specific material; and
- IRB/EC Membership List, Assurance of Compliance Form, or equivalent.

13.4 Insurance

Where required by local regulation, insurance coverage will be provided by BD for study participants.

13.5 Publication Policy

The sponsor believes that results of applicable clinical studies should be published in peer-reviewed literature in a timely, accurate, complete and balanced manner, regardless of study outcomes, whenever possible. As such, at the conclusion of this study, an article may be prepared for publication in a reputable scientific journal. Formal presentation(s) or publication(s) of data collected from this study will be considered as a joint publication by the investigator(s) and the appropriate personnel of the Sponsor. Authorship will be based on generally accepted criteria of the ICMJE (International Committee of Medical Journal Editors) and determined by mutual agreement.

The publication of the principal results from any single-center experience within the study is not allowed until the preparation and publication of the multicenter results. Exceptions to this rule require the prior approval of the Sponsor. The analysis of other pre-specified and non-pre-specified endpoints will be performed by the Sponsor or its designee. Such analyses, as well as other proposed investigations or manuscripts will require the approval of the Sponsor.

13.6 Study Registration

While this is a non-interventional study and does not meet the FDA Amendments Act of 2007 (FDAAA) criteria for clinical study registration, the study will be registered on www.clinicaltrials.gov. The Sponsor will register the study on local registries if applicable. The content of the publicly accessible database(s) will be updated throughout the conduct of the clinical study and the results will be entered after study completion in order to made publicly available the results of the study.

13.7 Termination of Study

The Sponsor reserves the right to suspend enrollment or terminate the study at any time for any reason. If suspicion of an unacceptable risk, including serious health threat to subjects, arises during the study, the Sponsor may suspend the study while the risk is assessed. The sponsor shall terminate the clinical investigation if an unacceptable risk which cannot be controlled is confirmed.

The Sponsor may suspend enrollment or terminate the study at a specific investigational site for reasons including, but not limited to, inadequate data collection, low participant enrollment rate, achievement of the total enrollment, conditions imposed by the reviewing IRB/EC and/or non-compliance with this protocol or other clinical research requirements. Written notice will be submitted to the Investigator in advance of such termination.

In the event of study suspension or termination, the Sponsor will send a report outlining the circumstances to the IRB/EC, and all Investigators and Regulatory Authorities as required by regulation.

14 ETHICAL AND REGULATORY CONSIDERATIONS

14.1 IRB/EC Approval

Investigators or designees must submit the study protocol, Informed Consent Form (if applicable), and all other locally required documentation to an appropriate IRB/EC and obtain study-specific written approval (favorable opinion) before being allowed to participate in the study. Before commencement of the study, the Investigator or designee must provide the Sponsor with written documentation of such approval. The IRB/EC must give written renewal of the original approval at least annually to continue the study, if applicable per local regulations. A copy of the written renewal must be provided to the Sponsor.

The IRB/EC will be notified of any amendments to the protocol, as well as possible associated information and consent form changes, where applicable, and written approval (favorable opinion) will be obtained prior to implementation, as applicable.

The Investigator or designee is responsible for fulfilling any conditions of approval imposed by the IRB/EC, such as regular safety reporting, study timing, etc. The Investigator or designee will provide the Sponsor with copies of such reports.

14.2 Informed Consent and Confidentiality

Prior to any study activity, the Investigator (or designee) must explain to each participant* in layman's terms, the nature of the study, its purpose, expected duration, and the risks and benefits of study participation. Also, the participant* will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them. All applicable national privacy laws (e.g., General Data Protection Regulation [GDPR] requirements in the E.U.) will be followed in this study. The participants* must be informed of their right to withdraw from the study at any time and for any reason without sanction, penalty, or loss of benefits to which they are otherwise entitled, and that withdrawal from the study will not jeopardize their future medical care. Participants* will be informed of their right to new information and/or findings relating to the clinical study, and the process by which this information is made available. After this explanation, given sufficient time to decide whether to participate before entering the study, the participant* must voluntarily provide consent by signing the form, including date and time of signature, in accordance with ISO 14155. The participant* will receive a copy of his/her signed ICF. The informed consent process should be documented in the participant's medical record.

*Note: If the participant is under the age of 18 years, participants' parent(s) or legal guardian must provide their informed consent and the child must provide assent, depending on local EC requirements, by personally signing and dating the respective consent form prior to begin of this study.

14.3 Confidentiality

Participant confidentiality must be strictly held in trust by the Investigator, study staff, and the Sponsor. Participant confidentiality and anonymity will be maintained by removal of identifiers from any data, documentation, or clinical samples submitted to the Sponsor.

Any data collected meeting the definition of protected/confidential health information or personal identifying information will be collected and maintained using the designated authorizations and following privacy procedures as specified in the applicable regulatory authority regulations including the European Union General Data Protection Regulation (GDPR).

The Sponsor Monitor, authorized representatives of the sponsor, and/or applicable regulatory authorities may inspect all documents and records required to be maintained by the Investigator. The Investigator/Site will permit access to such records.

14.4 Regulatory Status

The study devices are CE marked and will be studied in a post-market fashion in Europe.

14.5 Statement of Compliance

This clinical investigation will be conducted in compliance with the protocol and following regulatory requirements:

- ISO14155:2020 (Good Clinical Practice);
- EU MDR (Council Regulation 2017/745 of 5 April 2017);
- Ethical principles of the Declaration of Helsinki, in its current revision; and
- Applicable sections of the national laws and regulations.

The clinical investigation will not commence at a clinical site until approval (favorable opinion) from the respective IRB/EC has been received. All additional requirements imposed by the IRB/EC(s) will be followed. Involvement of the national competent authorities (e.g., by notification, seeking authorization) will be accomplished as required by national laws and regulations.

15 REFERENCES

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16 APPENDICES

16.1 BD Spinal Needles

Needle Type	Catalog Number	Description
Whitacre	401995	22 G x 90 mm (3 1/2 in.)
Whitacre	405104	24 G x 90 mm (3 1/2 in.), Thin Wall
Whitacre	402050	25 G x 90 mm (3 1/2 in.), Thin Wall
Whitacre	402051	27 G x 90 mm (3 1/2 in.)
Quincke	405247	18 G x 75 mm (3 in.)
Quincke	405248	18 G x 90 mm (3 1/2 in.)
Quincke	405249	19 G x 75 mm (3 in.)
Quincke	405250	19 G x 90 mm (3 1/2 in.)
Quincke	405251	20 G x 38 mm (1 1/2 in.)
Quincke	405252	20 G x 75 mm (3 in.)
Quincke	405253	20 G x 90 mm (3 1/2 in.)
Quincke	405254	22 G x 38 mm (1 1/2 in.)
Quincke	405244	22 G x 64 mm (2 1/2 in.)
Quincke	405255	22 G x 75 mm (3 in.)
Quincke	405256	22 G x 90 mm (3 1/2 in.)
Quincke	405240	23 G x 90 mm (3 1/2 in.)
Quincke	405245	25 G x 51 mm (2 in.)
Quincke	405257	25 G x 90 mm (3 1/2 in.)
Quincke	405246	25G x 75 mm (3.5 in.)
Quincke	405234	25 G x 119 mm (4 11/16 in.)
Quincke	405258	26 G x 90 mm (3 1/2 in.)
Quincke	405259	27 G x 90 mm (3 1/2 in.)
Quincke	405243	25 G x 25 mm (1 in.), Neonatal Lumbar
Quincke	408360	18G x 156 mm (6 in.)
Quincke	405211	20 G x 156 mm (6 in.)
Quincke	405148	22 G x 127 mm (5 in.)
Quincke	405149	22 G x 178 mm (7 in.)
Whitacre	409442	25 G x 119 mm (4 11/16 in.)
Whitacre	409443	27 G x 119 mm (4 11/16 in.)

Kit/Set Needle Type	Catalog Number	Description
Whitacre	405076	25 G x 90 mm BD™ Whitacre spinal needle, Thin Wall
Whitacre	405075	27 G x 90 mm BD™ Whitacre spinal needle
Whitacre	405112	25 G x 103 mm (4-1/16 in.) Whitacre Set
Whitacre	405113	27 G x 103 mm (4 1/16 in.) Whitacre Set
Quincke	405084	25 G x 90 mm BD™ Quincke spinal needle
Quincke	405065	26 G x 90 mm BD™ Quincke spinal needle
Quincke	405069	27 G x 90 mm BD™ Quincke spinal needle
Quincke	405068	29 G x 90 mm (3 1/2 in.) Spinal Set

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Reason for signing: Finalize	Name: Gloria Viti Role: Clinical Project Management Date of signature: 27-Apr-2022 12:09:58 GMT+0000

Reason for signing: Finalize	Name: Edward Maratea Role: Medical Monitor Date of signature: 27-Apr-2022 18:28:40 GMT+0000

Reason for signing: Finalize	Name: John Roberts Role: Regulatory Affairs Date of signature: 29-Apr-2022 16:15:12 GMT+0000

Reason for signing: Finalize	Name: Milan Bimali Role: Statistics & Programming Date of signature: 29-Apr-2022 17:12:31 GMT+0000

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