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Postmarket Outcomes Study for Evaluation of the Superion Spacer

PRESS 2

A4086

CLINICAL INVESTIGATION PLAN

Sponsored By

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Contact Information

Role	Contact
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2. Protocol Synopsis

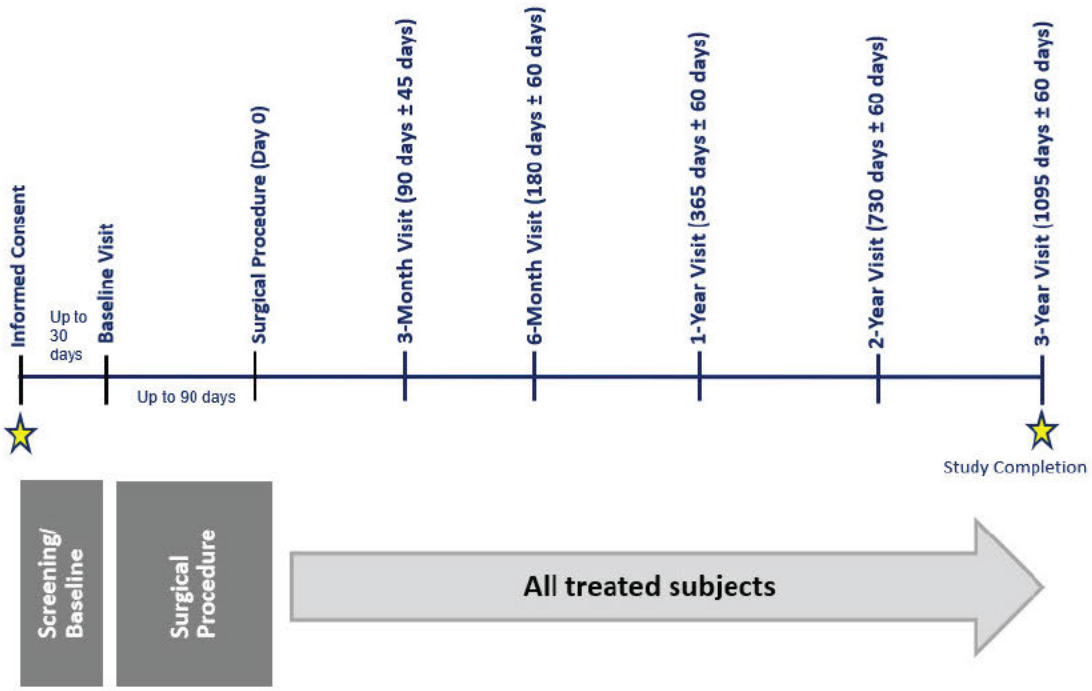
Postmarket Outcomes Study for Evaluation of the Superion Spacer PRESS 2	
Study Objective(s)	To compile real-world outcomes for Boston Scientific commercially approved Indirect Decompression Systems (IDS) in routine clinical practice, when used according to the applicable Instructions for Use.
Indication(s) for Use	The Superion® Indirect Decompression System (IDS) is intended to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, confirmed by X-ray, MRI and/or CT evidence of thickened *ligamentum flavum*, narrowed lateral recess, and/or central canal or foraminal narrowing. The Superion IDS is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain. The Superion IDS may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5. For this intended use, moderate degenerative lumbar spinal stenosis is defined as follows: • 25% to 50% reduction in the central canal and/or nerve root canal (subarticular, neuroforaminal) compared to the adjacent levels on radiographic studies, with radiographic confirmation of any one of the following: o Evidence of thecal sac and/or *cauda equina* compression o Evidence of nerve root impingement (displacement or compression) by either osseous or non-osseous elements o Evidence of hypertrophic facets with canal encroachment • AND Associated with the following clinical signs: o Presents with moderately impaired Physical Function (PF) defined as a score of ≥ 2.0 of the Zurich Claudication Questionnaire (ZCQ) o Ability to sit for 50 minutes without pain and to walk 50 feet or more.

Postmarket Outcomes Study for Evaluation of the Superion Spacer PRESS 2	
Commercial Device/System	Superion® IDS device
Study Design	Prospective, multi-center, global outcomes study
[redacted]	[redacted]
[redacted]	[redacted]
Clinical Endpoints	The following clinical endpoints will be included in this registry. Study assessments used to derive each endpoint are denoted in parenthesis. • Proportion of subjects with an improvement of 20 mm for low back pain at 3 months, 6 months, 1 year, 2 years, and 3 years post-procedure compared with Baseline (VAS) • Proportion of subjects with an improvement of 20 mm for leg pain at 3 months, 6 months, 1 year, 2 years, and 3 years post-procedure compared with Baseline (VAS) [redacted]

Postmarket Outcomes Study for Evaluation of the Superion Spacer PRESS 2	
	[redacted] [redacted] [redacted] • Percent Pain Relief at 3 months, 6 months, 1 year, 2 years and 3 years post-procedure compared with Baseline (PPR) • [redacted] [redacted] • Change in overall quality of life at 3 months, 6 months, 1 year, 2 years and 3 years post-procedure compared with Baseline (EQ-5D-5L) • [redacted] [redacted] [redacted]
Safety Parameters	Rates of occurrence of all device hardware and/or procedure related non-serious adverse events, all serious adverse events, and unanticipated adverse events through the end of the study.
[redacted]	[redacted]

Postmarket Outcomes Study for Evaluation of the Superion Spacer PRESS 2	
[redacted]	
Follow-up Schedule	Study events occur at the following time points for subjects: • Screening Period • Baseline (up to 30 days post Informed Consent) • Surgical Procedure (up to 90 days post Baseline Visit) • 3-Month visit (90 days ± 45 days post procedure) • 6-Month visit (180 days ± 60 days post-procedure) • 1-Year Visit (365 days ± 60 days post-procedure) • 2-Year Visit (730 days ± 60 days post-procedure) • 3-Year Visit (1,095 days ± 60 days post-procedure) The above study events will occur for previously enrolled PRESS subjects as applicable (i.e. to be completed study timepoints).
[redacted]	[redacted]
[redacted]	[redacted]
Inclusion Criteria	IC1. Scheduled to receive or previously received a commercially approved Boston Scientific Indirect Decompression System, per local Instructions for Use (IFU) IC2. Signed a valid, IRB approved informed consent form
Exclusion Criteria	EC1. Meets any contraindication in BSC Indirect Decompression Systems local IFU [redacted]
Statistical Methods	

Postmarket Outcomes Study for Evaluation of the Superion Spacer PRESS 2	
Primary Statistical Hypothesis	Descriptive statistics will be utilized to report the clinical endpoints and their changes from baseline at 3 months, 6 months, 1 year, 2 years, and 3 years post-procedure
Statistical Test Method	NA
Sample Size Parameters	NA



3. [redacted]

[redacted]

[redacted]

4. *Introduction*

4.1. *Background*

Lumbar Spinal Stenosis (LSS) is characterized as a narrowing of the spinal canal and/or the intervertebral foramina that decreases space for the neural elements in the lumbar region of the spine.[1-6] As early as the 1950's it was recognized by Verbiest[7] that structural narrowing of the vertebral canal could compress the *cauda equina* and produce neurogenic claudication symptoms. These include leg pain (and occasionally cramping, numbness, or weakness) on walking or standing which is relieved by sitting or spinal flexion.

Indirect Compression Systems (IDS) are an option in well-selected patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least 6 months of non-operative treatment. Additionally, IDS offer significant overall improvement in health-related quality of life with the most improvement in areas of physical functioning[8].

The Superion Indirect Decompression System (IDS) was granted FDA approval in the U.S. in 2015. The Superion IDS is a minimally invasive spinal implant that treats LSS symptoms by limiting extension at the symptomatic level that compresses the neural elements and is designed for percutaneous surgical placement.

4.2. *Study Rationale*

The purpose of this outcomes study is to gather evidence documenting the clinical outcomes associated with treatment of moderate degenerative lumbar spinal stenosis using the Superion Indirect Decompression System (IDS).

5. (Commercial) Device Description (part of Standard of Care)

5.1. *Commercial Device Description*

The Superion® Indirect Decompression System (IDS) indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, confirmed by X-ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing.

The Superion Indirect Decompression System (IDS) (Superion implant) is approved by the Food and Drug Administration (FDA) and will be used per approved Instructions for Use (IFU) in this study.

Figure 5-1: Superion Indirect Compression System

6. Study Objectives and Endpoints

6.1. *Study Objectives*

The primary objective of this study is to compile real-world outcomes for Boston Scientific commercially approved Indirect Decompression Systems (IDS) in routine clinical practice, when used according to the applicable Instructions for Use.

[redacted]

6.2. *Clinical Endpoints*

The following clinical endpoints will be included in this registry. Study assessments used to derive each endpoint is denoted in parenthesis:

- Proportion of subjects with an improvement of 20 mm for low back pain at 3 months, 6 months, 1 year, 2 years and 3 years post-procedure compared with Baseline (VAS)
- Proportion of subjects with an improvement of 20 mm for leg pain at 3 months, 6 months, 1 year, 2 years and 3 years post-procedure compared with Baseline (VAS)
- [redacted]

[redacted]

[redacted]

- Percent Pain Relief at 3 months, 6 months, 1 year, 2 years and 3 years post-procedure compared with Baseline (PPR)

[redacted]

- Change in overall quality of life at 3 months, 6 months, 1 year, 2 years and 3 years post-procedure compared with Baseline (EQ-5D-5L)

[redacted]

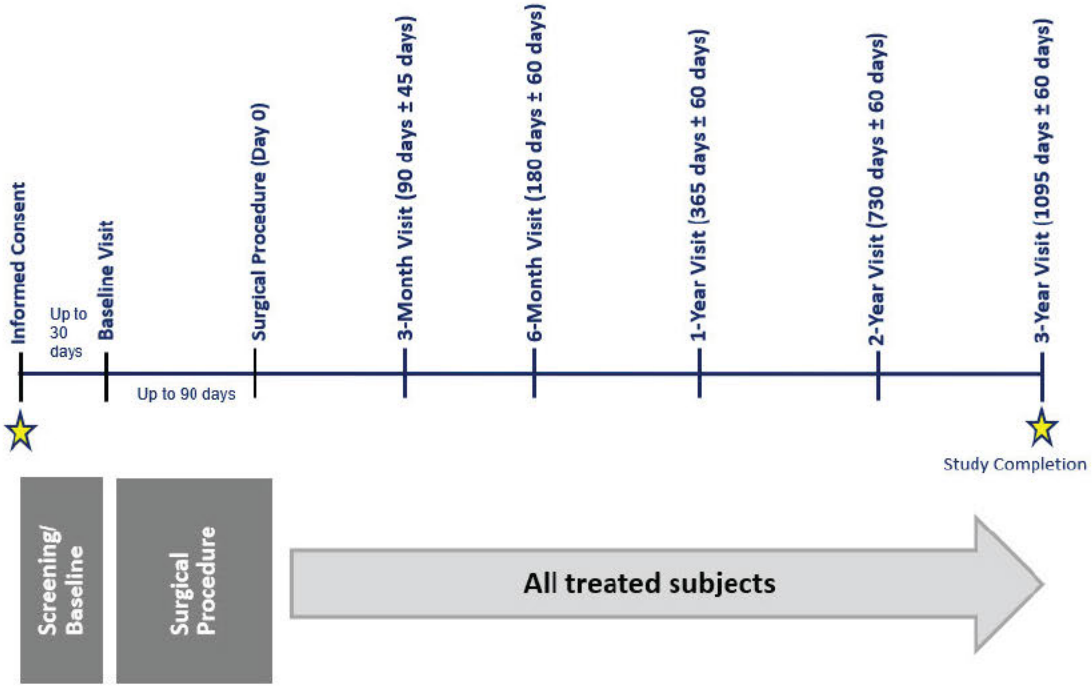
6.3. *Safety Parameters*

Rates of occurrence of all device hardware and/or procedure-related non-serious adverse events, all serious adverse events, and unanticipated adverse events through the end of the study.

7. Study Design

[redacted]

[redacted]



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8.2. *Inclusion Criteria*

Subjects who meet all of the following criteria (see Table 8.2-1) may be given consideration for inclusion in this clinical investigation, provided no exclusion criterion (see Section 8.3) is met.

Table 8.2-1: Inclusion Criteria

Inclusion Criteria	IC3.	Scheduled to receive or previously received a commercially approved Boston Scientific Indirect Decompression System, per local Instructions for Use (IFU)
	IC4.	Signed a valid, IRB approved informed consent form

8.3. *Exclusion Criteria*

Subjects who meet any one of the following criteria cannot be included in this study or will be excluded from this clinical study.

Table 8.3-1: Exclusion Criteria

Exclusion Criteria	EC1.	Meets any contraindication in BSC Indirect Decompression Systems local IFUCurrently diagnosed with a cognitive impairment, or exhibits any characteristic, that would limit the ability to assess pain relief or to complete study assessments in the opinion of the investigator

[redacted]

[redacted]

9. Subject Accountability

9.1. *Point of Enrollment*

A subject will be considered enrolled in the study when the Informed Consent Form (ICF) is signed. A subject will be considered implanted when a Superion IDS is successfully implanted.

9.2. *Withdrawal*

All subjects enrolled in the clinical study (including those withdrawn from the clinical study or lost to follow-up) shall be accounted for and documented. If a subject is withdrawn from the clinical investigation, the reason(s) shall be reported. If such withdrawal is due to problems related to investigational device safety or performance, the investigator shall ask for the subject's permission to follow his/her status/condition outside of the clinical study.

While study withdrawal is discouraged, subjects may withdraw from the study at any time, with or without reason and without prejudice to further treatment. In all cases of withdrawal or discontinuation, the Investigator will make all reasonable efforts to determine the reason for the subject's withdrawal. Subjects may be discontinued from the study for various reasons, which may include:

- Withdrawal of consent
- A safety concern defined by the Principal Investigator and/or Boston Scientific Neuromodulation (e.g., adverse event)
- Study non-compliance
- Inadequate use of device that may impact study outcomes
- Subject did not meet inclusion criteria or met an exclusion criterion after signing informed consent
- Surgical intervention that affects the Superion Indirect Decompression System
- Lost to follow-up
- Death of the subject

If device implantation is unsuccessful, the subject will be followed for 2 weeks post-implantation attempt to assess for procedure related adverse events. If Superion IDS is explanted, the subject should be followed for 30 days post-explant to assess for related adverse events and withdrawn. Subjects that undergo a revision or replacement procedure may continue in the study.

A subject is considered lost-to-follow-up after 3 unsuccessful contact attempts have been made to reach the subject (including those who relocate but cannot be transferred to another participating site). Staff at the participating site should make a good faith effort to contact the subject with three documented communication attempts, at least one of which must be in writing, sent via a traceable method.

[redacted]

Data collected up to the point of subject withdrawal or lost to follow-up may be used for study analysis in accordance with applicable regulations.

Withdrawn subjects will be followed per the End of Study Action Plan as described below.

9.3. *Subject Status and Classification*

Subjects are considered enrolled in the study at the time written informed consent is provided. Subjects who sign the informed consent form but do not meet all study eligibility criteria (i.e., screen failure), or withdraw prior to completion of the Baseline Visit, will not be implanted. Subjects that are enrolled but not implanted will be deemed as "enrolled" and their reason for ineligibility or withdrawal prior to implant will be documented.

The overall enrollment in the study will be capped to yield up to 3,000 subjects with an IDS implant. Per site enrollment will be capped initially at 30 newly implanted subjects. The initial cap can be increased based upon written communication of sponsor approval.

The study will implement an *Enrollment Communication Plan*. The plan will outline the specific activities, as well as the nature and timing of communications to investigators in order to minimize the risk of enrollment beyond the protocol-specified enrollment caps.

9.4. *End-of-Study Definition*

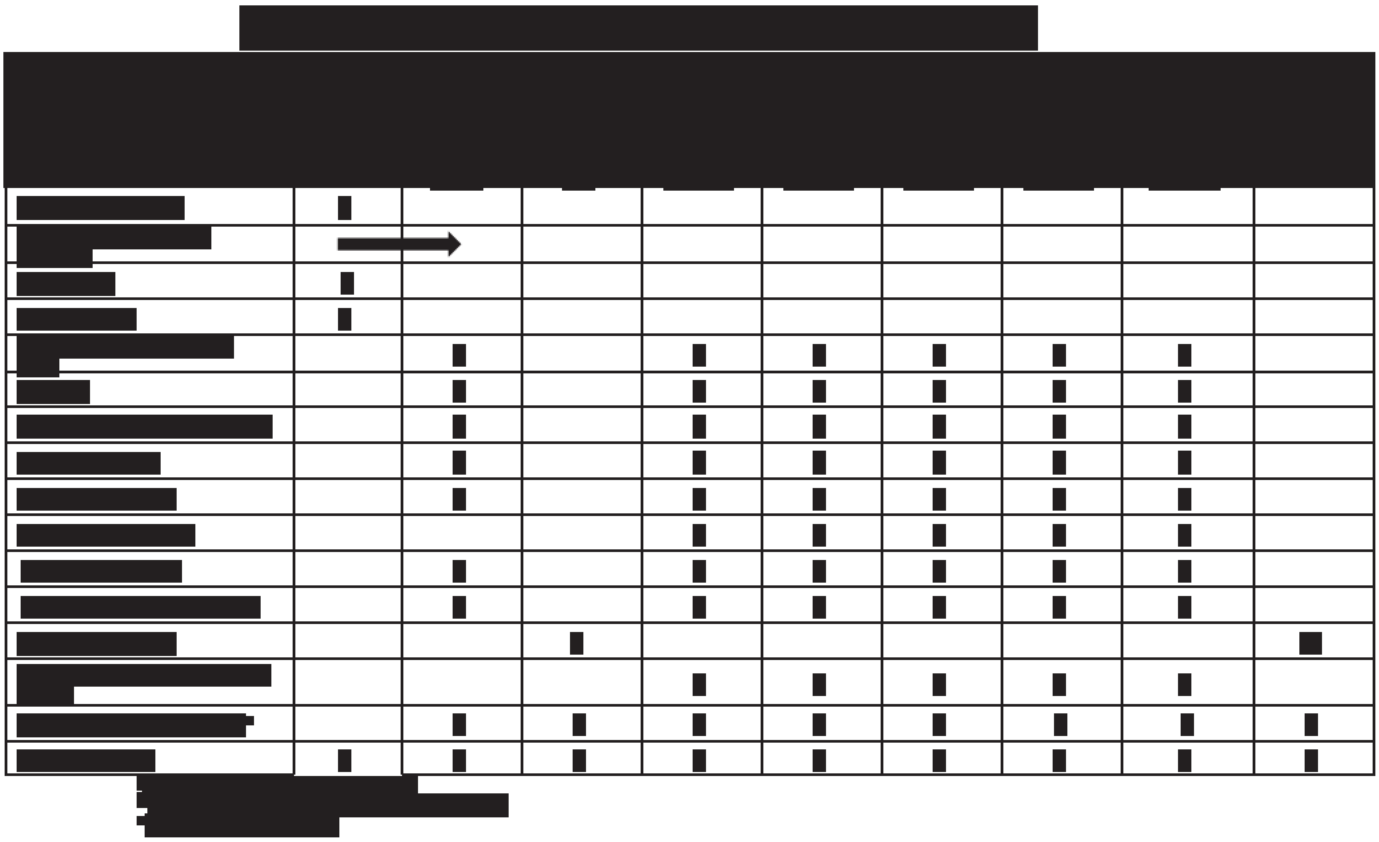
A clinical trial is considered completed when the last participant's last study visit has occurred. Upon end of study, subjects will be followed per standard of care.

10. Study Methods

10.1. *Data Collection*

The data collection schedules are shown in tables 10.1-1 (newly enrolled subjects) and 10.1-2 (previously enrolled/implanted subjects (under PRESS).

[redacted]



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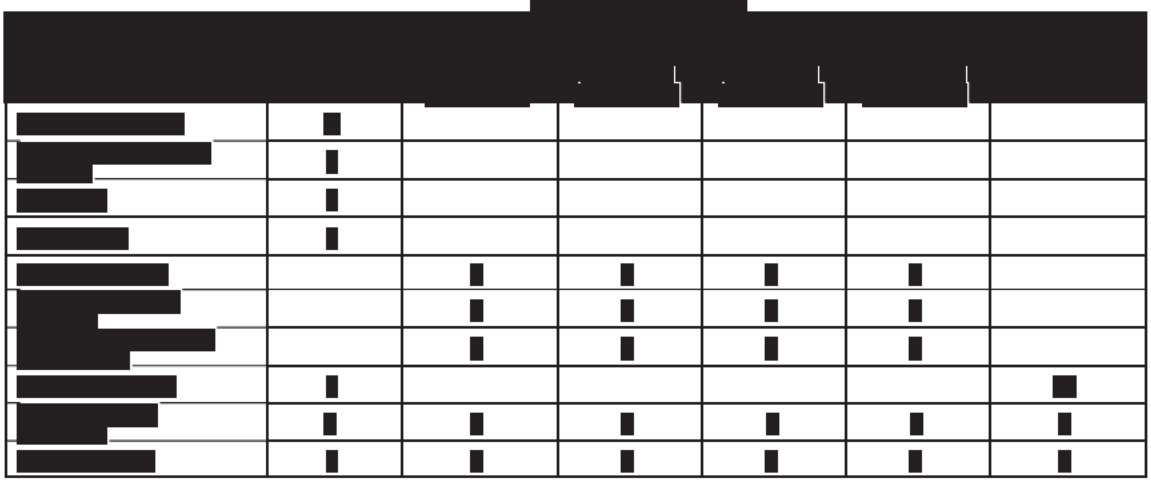

10.2. *Study Candidate Screening*

Subjects' eligibility for the study will be assessed based on study Inclusion and Exclusion criteria listed in Section 8.2 and 8.3, respectively. Subjects who have provided informed

consent and who have been determined to not meet all eligibility requirements will be withdrawn.

10.3. *Informed Consent*

Written Informed Consent must be obtained for all patients who are potential study candidates. Study candidates will be asked to sign the Informed Consent form before any study-specific tests or procedures are performed.

- The context of the study must be fully explained to the patient and patients must be given an opportunity to ask questions and have those questions answered to their satisfaction.
- Study personnel should explain to each potential participant that even if he or she agrees to participate in the study and signs an informed consent form, further testing might demonstrate that he or she is not eligible for the study.
- Written informed consent must be recorded appropriately by means of the subject's dated signature.
- The consent process must be documented in the subject's medical chart.

Research study candidates in the State of California will also be provided with the California Experimental Patient's Bill of Rights.

Subjects using a BSC mobile app have the option of providing access to mobile app data at any time as part of the study.

10.4. *Screening*

Subjects undergo screening related procedures to determine eligibility for the study. If a subject fails to meet all the eligibility criteria, they will be withdrawn.

Note: Key Indications for Use include:

- Persistent leg, buttock or groin pain, with or without back paid, that was relieved by lumbar flexion
- Moderate spinal stenosis at one or two levels from L1-L5
- Persistently symptomatic with unsuccessful response to at least 6 months of conservative treatment

For full list of Indications, please consult the current IDS Instructions for Use

Opioid medications will be collected and any adverse event occurring after the subject is enrolled (i.e. signing the Informed Consent Form) will be documented.

Subjects who participated in PRESS registry and received a Superion IDS implant maybe transferred/enrolled.

[redacted]

events then withdrawn from the study. Acute opioid pain medications may be taken.

[redacted]

[redacted]

10.12. *Study Completion*

All subjects will be followed through completion of the 3-Year Visit or study withdrawal as defined in section 9.2.

10.13. *Source Documents*

Table 10.15-1 summarizes source data requirements for this study. Any information first captured on an electronic data collection platform or within the EDC system on eCRF evaluations, assessments or questionnaires, not initially documented in another record, is considered the source documentation.

It is preferable that original source documents are maintained, when available. In lieu of original source documents, certified copies are required to be maintained. A certified copy is a copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.

Source documentation includes but is not limited to those items noted in Table 10.15-1.

Table 10.13-1: Source Documentation Requirements

Requirement	Disposition
Hospital records and/or clinic and office charts including the evidence of but not limited to inclusion/exclusion criteria, informed consent, procedures, exams, IDS procedure(s) and devices	Retained at investigational site

[redacted]

[redacted]

Table 10.13-1: Source Documentation Requirements

Requirement	Disposition
used, evaluations, laboratory results, medications, assessment of adverse events.	
Assessments and questionnaires	Retained at investigational site and/or electronic data collection platform/EDC
Imaging films/prints documenting implant location	Retained at investigational site

11. Statistical Considerations

11.1. *Clinical Endpoints*

A number of clinical endpoints are included (but not limited to) in this study, as described below. Continuous variables will be summarized using descriptive statistics which include number of non-missing observations, mean, median, standard deviation, minimum, maximum. For categorical variables, descriptive statistics include frequencies, and percentages of categories. Estimates of all endpoints will be reported, as well as the 95% confidence intervals. Hypothesis test of change from baseline for the continuous variables may be performed when it is appropriate.

- Proportion of subjects with an improvement of 20 mm for low back pain at 3 months, 6 months, 1 year, 2 years and 3 years post-procedure compared with Baseline (VAS)
- Proportion of subjects with an improvement of 20 mm for leg pain at 3 months, 6 months, 1 year, 2 years and 3 years post-procedure compared with Baseline (VAS)
- [redacted]

[redacted]

- Percent Pain Relief at 3 months, 6 months, 1 year, 2 years and 3 years post-procedure compared with Baseline (PPR)

[redacted]

- Change in overall quality of life at 3 months, 6 months, 1 year, 2 years and 3 years post-procedure compared with Baseline (EQ-5D-5L)

[redacted]

11.2. *General Statistical Methods*

11.2.1. Statistical Methods

Descriptive statistics will be utilized to report the clinical endpoints and their changes from Baseline at 3 months, 6 months, 1 year, 2 years and 3 years post-procedure.

11.2.2. Analysis Sets

- **Intent-to-Treat (ITT) Population**: All subjects who receive treatment with the study device.
- **Per Protocol (PP) Population**: All subjects who receive treatment with the study device, with no major protocol deviations.
- **Safety Population**: All subjects who sign the IRB/EC/REB-approved written Informed Consent form

11.2.3. Control of Systematic Error/Bias

Selection of patients will be made from the Investigator's usual patient population. All patients meeting the inclusion/exclusion criteria and having signed the Informed Consent Form will be eligible for participation in the study. The reasons for exclusion, for subjects who sign an informed consent form but do not have a study procedure, will be indicated in EDC. Boston Scientific will report to the ethic committee any evidence of fraud, including deliberate tampering with the selection of subjects.

11.2.4. [redacted]

[redacted]

11.2.5. Data Analyses

All statistical analyses will be done using the SAS System software, version 8.2 or later (Copyright © 2000 SAS Institute Inc., SAS Campus Drive, Cary, North Carolina 27513, USA. All rights reserved). Additional details on these analyses can be found in the Statistical Analysis Plan.

11.2.6. Subgroup Analyses

Subgroup analyses will be performed as appropriate, for example, treatment indication, age, gender, etc.

11.2.7. Justification of Pooling

The investigation is a multi-center trial, where all centers will be trained to use the same study protocol. The appropriateness of pooling data from multiple centers is necessarily enhanced by training all participating centers to follow the same protocol, with clearly defined inclusion and exclusion criteria for study participation. However, if an interaction is present between treatment and center effects, the results may not be strictly poolable. Thus, in order to protect against improperly pooling data from all study centers, a formal analysis may be conducted to assess the appropriateness of pooling the data.

11.2.8. Multivariable Analyses

No formal covariate analyses are planned.

11.2.9. Changes to Planned Analyses

Any changes to the planned statistical analyses made prior to performing the analyses will be documented in an amended protocol approved prior to performing the analyses. Changes from the planned statistical methods after performing the analyses will be documented in the clinical study report along with a reason for the deviation.

12. Data Management

12.1. *Data Collection, Processing, and Review*

Subject data will be recorded in a limited access secure electronic data capture (EDC) system.

Subjects using a BSC mobile app have the option of providing access to mobile app data at any time as part of the study.

The clinical database will reside on a production server hosted by Medidata EDC System. All changes made to the clinical data will be captured in an electronic audit trail and available for review by the sponsor or its representative. The associated Rave software and database have been designed to meet regulatory compliance for deployment as part of a validated system compliant with laws and regulations applicable to the conduct of clinical studies pertaining to the use of electronic records and signatures. Database backups are performed regularly.

The Investigator provides his/her electronic signature on the appropriate electronic case report forms (eCRFs) in compliance with local regulations. A written signature on printouts of the eCRFs must also be provided if required by local regulation. Changes to data previously submitted to the sponsor require a new electronic signature by the Investigator acknowledging and approving the changes.

Visual and/or electronic data review will be performed to identify possible data discrepancies. Manual and/or automatic queries will be created in the Medidata EDC system and will be issued to the site for appropriate response. Site staff will be responsible for resolving all queries in the database.

All access to the clinical database will be changed to "Read only" after all data is either "Hard Locked" or "Entry Locked". Once acceptance of the final report or finalization of publications (as applicable) is received, final database storage and archiving activities can begin. Once all of the closeout activities are completed a request to IT is submitted to have the "Database Locked" or Decommissioned and all database access revoked.

12.2. *Electronic Questionnaires*

Questionnaires in electronic form may be collected directly using an electronic data collection platform at the clinical site (e.g. iPad). After completion by the subject or a clinician, data from the electronic questionnaires are transmitted directly into the EDC system.

12.3. *Study Assessments*

[redacted]

[redacted]

[redacted]

12.4. *Data Retention*

The Principal Investigator or his/her designee or Investigational site will maintain all essential study documents and source documentation that support the data collected on the study subjects in compliance with applicable regulatory requirements.

The Principal Investigator or his/her designee will take measures to prevent accidental or premature destruction of these documents. If for any reason the Principal Investigator or his/her designee withdraws responsibility for maintaining these essential documents, custody must be transferred to an individual who will assume responsibility and BSC must receive written notification of this custodial change. Sites are required to inform Boston Scientific in writing where paper or electronic files are maintained in case files are stored off site and are not readily available.

13. Deviations

An Investigator must not make any changes or deviate from this protocol, except to protect the life and physical well-being of a subject in an emergency. An investigator shall notify the sponsor and the reviewing IRB/EC/REB, and the regulatory authority if applicable, of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency, and those deviations which affect the scientific integrity of the clinical investigation. Such notice shall be given as soon as possible, but no later than 5 working days after the emergency occurred, or per prevailing local requirements, if sooner than 5 working days.

All deviations from the investigational plan, with the reason for the deviation and the date of occurrence, must be documented and reported to the sponsor using the EDC system. Sites may also be required to report deviations to the IRB/EC/REB, and/or the regulatory authority, per local guidelines and/or national/government regulations.

Deviations will be reviewed and evaluated on an ongoing basis and, as necessary, appropriate corrective and preventive actions (including regulatory authority and/or IRB/EC/REB notification, site re-training, or site discontinuation/termination) will be put into place by the sponsor.

The sponsor will not approve protocol waivers.

14. Compliance

14.1. *Statement of Compliance*

This clinical investigation is financed by the study sponsor. Before the investigational site can be "Authorized to Enroll," the investigational site must enter into a Clinical Study Agreement with the sponsor that details the financing of the study as well as the rights and obligations of the investigational site and the investigator.

This study will be conducted in accordance with 21 CFR parts 50, 56, 54 and 814.82, European Medical Device Regulations, the spirit of EN ISO 14155: Clinical Investigation of

Medical Devices for Human Subjects – Good Clinical Practice, the relevant parts of the ICH Guidelines for Good Clinical Practices, ethical principles that have their origins in the Declaration of Helsinki, and pertinent individual country laws and regulations. The study shall not begin until the required approval/favorable opinion from the IRB/EC/REB and/or regulatory authority has been obtained, if appropriate. Also, the study shall not begin prior to issuance of the site Authorization to Enroll, as provided by the sponsor. Any additional requirements imposed by the IRB/EC/REB or regulatory authority shall be followed, if appropriate.

14.2. *Investigator Responsibilities*

The Principal Investigator of an investigational site is responsible for ensuring that the study is conducted in accordance with the Clinical Study Agreement, the clinical investigation plan, ISO 14155, ethical principles that have their origins in the Declaration of Helsinki, any conditions of approval imposed by the reviewing IRB/EC/REB, and prevailing local and/or country laws and/or regulations, whichever affords the greater protection to the subject.

The Principal Investigator's responsibilities include, but are not limited to, the following.

- Prior to beginning the study, sign the Clinical Study Agreement and comply with the Investigator responsibilities as described in such Agreement.
- Prior to beginning the study, sign the Protocol Signature page documenting his/her agreement to conduct the study in accordance with the protocol.
- Provide his/her qualifications and experience to assume responsibility for the proper conduct of the study and that of key members of the site team through up-to-date curriculum vitae or other relevant documentation and disclose potential conflicts of interest, including financial, that may interfere with the conduct of the clinical study or interpretation of results.
- Make no changes in or deviate from this protocol, except to protect the life and physical well-being of a subject in an emergency; document and explain any deviation from the approved protocol that occurred during the clinical investigation.
- Create and maintain source documents throughout the clinical study and ensure their availability with direct access during monitoring visits or audits; ensure that all clinical-investigation-related records are retained per requirements.
- Ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.
- Record, report, and assess (seriousness and relationship to the device/procedure) every adverse event as applicable per the protocol and observed device deficiency.
- Report to sponsor, per the protocol requirements, all reportable events.
- Report to the IRB/EC/REB and regulatory authorities any SAEs and device deficiencies that could have led to a SADE and potential/USADE or UADE, if required by applicable

laws or regulations or this protocol or by the IRB/EC/REB, and supply BSC with any additional requested information related to the safety reporting of an event.

- Ensure devices are used in accordance with the Instructions for Use.
- Allow the sponsor to perform monitoring and auditing activities and be accessible to the clinical research monitor or auditor and respond to questions during monitoring visits or audit(s).
- Allow and support regulatory authorities and the IRB/EC/REB when performing auditing activities.
- Ensure that informed consent is obtained in accordance with applicable laws, this protocol and local IRB/EC/REB requirements.
- Provide adequate medical care to a subject during and after a subject's participation in a clinical study in the case of adverse events, as described in the Informed Consent Form (ICF).
- Inform the subject of the nature and possible cause of any adverse events experienced.
- As applicable, provide the subject with necessary information on the IDS system, treatment and follow-up instructions and care.
- Inform the subject of any new significant findings occurring during the clinical investigation, including the need for additional medical care that may be required.
- Provide the subject with well-defined procedures for possible emergency situations related to the clinical study and make the necessary arrangements for emergency treatment.
- Ensure that clinical medical records are clearly marked to indicate that the subject is enrolled in this clinical study.
- Ensure that, if appropriate, subjects enrolled in the clinical investigation are provided with some means of showing their participation in the clinical investigation, together with identification and compliance information for concomitant treatment measures (contact address and telephone numbers shall be provided).
- Inform, with the subject's approval or when required by national regulations, the subject's personal physician about the subject's participation in the clinical investigation.
- Make all reasonable efforts to ascertain the reason(s) for a subject's premature withdrawal from clinical investigation while fully respecting the subject's rights.
- Ensure that an adequate investigation site team and facilities exist and are maintained and documented during the clinical investigation.

All investigators will provide their qualifications and experience to assume responsibility for their delegated tasks through up-to-date curriculum vitae or other relevant documentation and disclose potential conflicts of interest, including financial, that may interfere with the conduct of the clinical study or interpretation of results.

14.3. *Delegation of Responsibility*

When specific tasks are delegated by an investigator, including but not limited to conducting the informed consent process, the Principal Investigator is responsible for providing appropriate training, are competent to perform the tasks they have been delegated and adequate supervision of those to whom tasks are delegated. Where there is a sub investigator at a site, the sub investigator should not be delegated the primary supervisory responsibility for the site. The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study.

14.4. *Institutional Review Board / Ethics Committee*

The investigational site will obtain the written and dated approval/favorable opinion of the IRB/EC/REB for the clinical investigation before recruiting subjects and implementing all subsequent amendments, if required.

A copy of the written IRB/EC/REB approval of the protocol (or permission to conduct the study) and ICF, must be received by the sponsor before recruitment of subjects into the study and shipment of investigational product/equipment. Prior approval must also be obtained for other materials related to subject recruitment or which will be provided to the subject.

Any amendment to the protocol will require review and approval by the IRB/EC/REB before the changes are implemented to the study. All changes to the ICF will be IRB/EC/REB approved; a determination will be made regarding whether a new ICF needs to be obtained from participants who provided consent, using a previously approved ICF. Annual IRB/EC/REB approval and renewals will be obtained throughout the duration of the study as required by applicable local/country laws or regulations or IRB/EC/REB requirements. Copies of the study reports and the IRB/EC/REB continuance of approval must be provided to the sponsor.

14.5. *Sponsor Responsibilities*

All information and data sent to BSC concerning subjects or their participation in this study will be considered confidential by BSC and will be kept confidential in accordance with all applicable laws and regulations. Only authorized BSC personnel and/or a BSC representative including, but not limited to Contract Research Organization (CRO), will have access to this information. Authorized regulatory personnel have the right to inspect and copy all records pertinent to this study. Study data collected during this study may be used by BSC for the purposes of this study, publication, and to support future research and/or other business purposes, such as overseeing and improving the performance of its device, new medical research and proposals for developing new medical products and procedures. All data used in the analysis and reporting of this study or shared with a third-party researcher will be without identifiable reference to specific subjects.

Information received during the study will not be used to market to subjects; subject names will not be placed on any mailing lists or sold to anyone for marketing purposes.

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15. Monitoring

Monitoring will be performed during the study to assess continued compliance with the protocol and applicable regulations. In addition, the clinical research monitor verifies that study records are adequately maintained, that data are reported in a satisfactory manner with respect to timeliness, adequacy, and accuracy, and that the Principal Investigator continues to have sufficient staff and facilities to conduct the study safely and effectively. The Principal Investigator/institution guarantees direct access to original source documents by BSC personnel, their designees, and appropriate regulatory authorities.

The sponsor will put a plan in place to document the specific monitoring requirements.

The study may also be subject to a quality assurance audit by BSC or its designees, as well as inspection by appropriate regulatory authorities. It is important that the Principal Investigator and relevant study personnel are available during on-site monitoring visits or audits and that sufficient time is devoted to the process.

16. Potential Risks and Benefits

16.1. *Instructions for Use*

Please refer to the Instructions for Use for an overview of anticipated adverse (device) effects, and risks associated to the commercial device(s).

16.2. *Risks associated with Participation in the Clinical Study*

The subject might find it difficult, uncomfortable, or tiresome to complete study visits, evaluate the device, and/or questionnaires.

16.3. *Possible Interactions with Concomitant Medical Treatments*

No possible interactions have been identified for use of the Superion ID System concomitant with any specific medications. However, there may be some risk that is unknown.

The Superion ID System is MRI Conditional. Patients may undergo MRI safely when conditions described in the Instructions for Use are followed.

16.4. *Risk Minimization Actions*

Additional risks may exist. Risks can be minimized through compliance with this protocol, performing procedures in the appropriate hospital environment, adherence to subject selection criteria, close monitoring of the subject's physiologic status during research procedures and/or follow-ups and by promptly supplying BSC with all pertinent information required by this protocol.

16.5. *Anticipated Benefits*

The potential clinical benefit of the Superion ID System is reduction in the symptoms of neurogenic claudication. Other benefits known to occur from this symptom relief are increased functionality and quality of life for the patient. They may also have decreased use of analgesics, including opioids.

16.6. *Risk to Benefit Rationale*

The risk evaluation for the Superion ID System determined that all hazards attributed to the Superion ID System and overall remaining residual risks after implementations of the required mitigations have been evaluated. Based on the risk evaluation results, the potential benefit provided by the Superion ID System to treat neurogenic intermittent claudication secondary to a diagnosis of moderate lumbar spinal stenosis outweighs the remaining

residual risk. As the overall residual risk meets BSN's criteria, the Superion ID System is acceptable for use in a clinical setting.

17. Safety Reporting

17.1. *Reportable Events by investigational site to Boston Scientific*

It is the responsibility of the investigator to assess and report to BSC any event which occurs in any of following categories:

- All Serious Adverse Events, regardless of relationship.
- All Device Deficiencies
- Device and/or procedure related non-serious adverse events
- New findings/updates in relation to already reported events

When possible, the medical diagnosis should be reported as the Event Term instead of individual symptoms.

If it is unclear whether or not an event fits one of the above categories, or if the event cannot be isolated from the device or procedure, it should be submitted as an adverse event and/or device deficiency.

Any reportable event, experienced by the study subject after informed consent, whether or prior to, during or subsequent to the procedure, must be recorded in the eCRF.

Underlying diseases and chronic conditions are not reported as AEs unless there is an increase in severity or frequency during the course of the investigation. Death should not be recorded as an AE but should only be reflected as an outcome of one (1) specific SAE (see Table 17.2-1 for AE definitions).

Refer to Instructions for Use for the known risks associated with the commercial device(s).

17.2. *Definitions and Classification*

Adverse event definitions are provided in Table 17.2-1. Administrative edits were made on the safety definitions from applicable regulations and guidance including (but not limited to) 21 CFR Part 812, ISO 14155 and EU MDR 2017/745 for clarification purposes.

Table 17.2-1: Safety Definitions

Term	Definition
Adverse Event (AE) *Ref: ISO 14155* *Ref: MDGC 2020-10/1*	Any untoward medical occurrence, unintended disease or injury, or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the study medical device and whether anticipated or unanticipated. **NOTE 1**: This includes events related to the study medical device or comparator. **NOTE 2**: This definition includes events related to the procedures involved. **NOTE 3**: For users or other persons, this definition is restricted to events related to the study medical device.

Table 17.2-1: Safety Definitions

Term	Definition
Adverse Device Effect (ADE) *Ref: ISO 14155* *Ref: MDGC 2020-10/1*	Adverse event related to the use of the study medical device **NOTE 1**: This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the study medical device. **NOTE 2**: This definition includes any event resulting from use error or from intentional misuse of the study medical device. **NOTE 3**: This includes 'comparator' if the comparator is a medical device.
Serious Adverse Event (SAE) *Ref: ISO 14155* *Ref: MDGC 2020-10/1*	Adverse event that led to any of the following: a) death, b) serious deterioration in the health of the subject, users or other persons as defined by either: 1) a life-threatening illness or injury, or 2) a permanent impairment of a body structure or a body function, including chronic diseases, or 3) in-patient hospitalization or prolongation of existing 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) foetal distress, foetal death, or a congenital abnormality or birth defect including physical or mental impairment. **NOTE 1:** Planned hospitalization for a pre-existing condition, or a procedure required by the clinical investigational plan, without a serious deterioration in health, is not considered a serious adverse event.
Serious Adverse Device Effect (SADE) *Ref: ISO 14155* *Ref: MDGC 2020-10/1*	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
Unanticipated Adverse Device Effect (UADE) *Ref: 21 CFR Part 812*	Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
Unanticipated Serious Adverse Device Effect (USADE) *Ref: ISO 14155* *Ref: MDGC 2020-10/1*	Serious adverse device effect which by its nature, incidence, severity, or outcome has not been identified in the current risk assessment. **NOTE 1**: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk assessment.
Device Deficiency *Ref: ISO 14155*	An inadequacy of a medical device related to its identity, quality, durability, reliability, usability, safety or performance. **NOTE 1**: Device deficiencies include malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling.

Table 17.2-1: Safety Definitions

Term	Definition
Ref: MDGC 2020-10/1	**NOTE 2**: This definition includes device deficiencies related to the device under study or the comparator.
The following definitions will be used for defining hospitalization or prolongation of hospitalization for SAE classification purposes:	
Hospitalizations	Hospitalization does not include: • emergency room visit that does not result in in-patient admission Note: although an emergency room visit does not itself meet the definition for hospitalization, it may meet other serious criteria (e.g. medical or surgical intervention to prevent permanent impairment or damage) • elective and pre-planned treatment/surgery for a pre-existing condition that is documented in the subject's record at the time of consent/enrollment • admission for social reasons and/or respite care in the absence of any deterioration in the subject's general condition (e.g. subject is homeless, caregiver relief) • pre-planned, protocol-specified admission related to the clinical study (e.g. procedure required by protocol)
Prolongation of hospitalization	In-patient admission to the hospital that is prolonged beyond the expected standard duration for the condition under treatment. Note: new adverse events occurring during the hospitalization are evaluated to determine if they prolonged hospitalization or meet another SAE criteria.

NOTES:

1. Hospitalizations occurring for the purpose of performing a planned procedure as per routine care such as implant procedures, or follow-up visits, are not to be reported as a SAE. However, complications or adverse events that occur during the planned procedure should be reported as (S)AEs if they meet the protocol specified definitions.
2. Elective/planned hospitalization(s) need not be reported as an SAE. However, complications or adverse events that occur during an elective/planned hospitalization, should be reported as (S)AEs if they meet the protocol specified definitions.
3. In the event of subject death during the conduct of the study, efforts should be made to perform an autopsy.
4. Lack of efficacy/decreased therapeutic response should not be reported as AEs. Clinical sequelae, other than pain, that occur as a result of lack of efficacy/decreased therapeutic response should be reported as AEs.
5. Clinically significant worsening of the pattern of intensity or distribution of Baseline pain symptoms should be reported as an AE.
6. Device deficiencies, including, but not limited to device/lead migrations, which are not associated with an adverse clinical outcome should only be reported as device deficiencies. However, if a device deficiency precipitates an AE, the AE should be

reported in the *Adverse Event* eCRF and the device deficiency should be documented in the *Device Deficiency* eCRF.

17.3. *Relationship to Study Device(s) and/or Study Procedure*

The Investigator must assess the relationship of the reportable AE to the study device hardware and/or study procedure. See criteria in table 17.3-1.

Table 17.3-1: Criteria for Assessing Relationship of Study Device or Procedure to Adverse Event

Classification	Description
Not Related *Ref: MDGC 2020-10/1*	Relationship to the device or procedures can be excluded when: - - the event has no temporal relationship with the use of the study device or the procedures related to the use of the study device; - the serious event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible; - the discontinuation of medical device application or the reduction of the level of activation/exposure - when clinically feasible – and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the serious event; - the event involves a body-site or an organ that cannot be affected by the device or procedure; - the serious event can be attributed to another cause (e.g. an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors); - the event does not depend on a false result given by the study device used for diagnosis, when applicable; - In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.
Possibly Related *Ref: MDGC 2020-10/1*	The relationship with the use of the study device, or the relationship with procedures is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed or no information has been obtained should also be classified as possible.
Probably Related *Ref: MDGC 2020-10/1*	The relationship with the use of the study device, or the relationship with procedures seems relevant and/or the event cannot be reasonably explained by another cause.
Causal Relationship *Ref: MDGC 2020-10/1*	The serious event is associated with the study device or with procedures beyond reasonable doubt when: - the event is a known side effect of the product category the device belongs to or of similar devices and procedures;

	- the event has a temporal relationship with the study device use/application or procedures; - the event involves a body-site or organ that -the study device or procedures are applied to; -the study device or procedures have an effect on; - the serious event follows a known response pattern to the medical device (if the response pattern is previously known); - the discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the serious event (when clinically feasible); - other possible causes (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out; - harm to the subject is due to error in use; - the event depends on a false result given by the study device used for diagnosis, when applicable; - In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.

17.4. *Investigator Reporting Requirements*

The communication requirements for reporting to BSC are as shown in Table 17.4-1.

Table 17.4-1: Investigator Reporting Requirements

Event Classification	**Communication Method**	**Communication Timeline post-market studies*** (*EU MDR 2017/745, MDCG 2020-10/1*: GUIDELINES ON A MEDICAL DEVICE VIGILANCE SYSTEM)
Serious Adverse Event	Complete AE eCRF page with all available new and updated information.	• Within 10 calendar days after becoming aware of the event or as per local/regional regulations. • Reporting required through the end of the study.
	Provide all relevant source documentation (de-identified/ pseudonymized) for reported event.	• When documentation is available • Upon request of sponsor
Serious Adverse Device Effects	Complete AE eCRF page with all available new and updated information.	• Within 3 calendar days of first becoming aware of the event or as per local/regional regulations. • Reporting required through the end of the study
	Provide all relevant source documentation (de-identified/ pseudonymized) for reported event.	• When documentation is available • Upon request of sponsor

Table 17.4-1: Investigator Reporting Requirements		
Event Classification	**Communication Method**	**Communication Timeline post-market studies*** (*EU MDR 2017/745, MDCG 2020-10/1*: GUIDELINES ON A MEDICAL DEVICE VIGILANCE SYSTEM)
Device Deficiencies (including but not limited to malfunctions, use errors and inadequacy in information supplied by the manufacturer, including labeling) Note: Any Device Deficiency that might have led to a serious adverse event if a) appropriate action had not been taken, intervention had not occurred, or if circumstances had been less fortunate is considered a reportable event.	Complete applicable eCRF form with all available new and updated information.	• Within 3 calendar days of first becoming aware of the event. Reporting required through the end of the study
	Provide all relevant source documentation (de-identified/ pseudonymized) for reported event.	• Upon request of sponsor
Adverse Event including Adverse Device Effects	Complete AE eCRF page, which contains such information as date of AE, treatment of AE resolution, assessment of seriousness and relationship to the device.	• Adverse Events: In a timely manner but recommend within 30 business days after becoming aware of the information • Adverse Device Effects: In a timely manner but not later than 30 business days after becoming aware of the information • Reporting required through the end of the study • Upon request of sponsor
	Provide all relevant source documentation (de-identified/ pseudonymized) for reported event.	

17.5. *Boston Scientific Device Deficiencies*

Device deficiencies (including but not limited to malfunctions, use errors, and inadequacy in the information supplied by the manufacturer) will be documented and reported to BSC. If possible, the device(s) under study should be returned to BSC for analysis. Instructions for returning the investigational device(s) will be provided to study sites. Device deficiencies should also be documented in the subject's source records.

Device deficiencies are not adverse events. However, an adverse event that results from a device deficiency would be recorded as an adverse event on the appropriate eCRF.

17.6. *Reporting to Regulatory Authorities / IRB/ECs / Investigators*

BSC is responsible for reporting adverse event information to all participating Principal Investigators, IRBs/ECs/REBs and regulatory authorities, as applicable.

The Principal Investigator is responsible for informing the IRB/EC/REB, and regulatory authorities of UADEs and SAEs as required by local/regional regulations.

17.7. *Subject Death Reporting*

Death should not be recorded as an adverse event but should only be reflected as an outcome of one (1) specific SAE.

18. Informed Consent

Subject participation in this clinical study is voluntary. Informed Consent is required from each subject or his/her legally authorized representative. The Investigator is responsible for ensuring that Informed Consent is obtained prior to the use of any investigational devices, study-required procedures and/or testing, or data collection.

The obtaining and documentation of Informed Consent must be in accordance with the principles of the Declaration of Helsinki, ISO 14155, any applicable national regulations, and local Ethics Committee and/or Regulatory authority, as applicable. The ICF must be accepted by BSC and approved by the site's IRB/EC/REB, or central IRB/EC/REB, if applicable.

Boston Scientific will provide a study-specific template of the ICF to investigators participating in this study. The ICF template may be modified to meet the requirements of the investigative site's IRB/EC/REB. Any modification requires acceptance from BSC prior to use of the form. The ICF must be in a language understandable to the subject and if needed, BSC will assist the site in obtaining a written consent translation. Translated consent forms must also have IRB/EC/REB approval prior to their use. Privacy language shall be included in the body of the form or as a separate form as applicable.

The process of obtaining Informed Consent shall at a minimum include the following steps, as well as any other steps required by applicable laws, rules, regulations and guidelines:

- be conducted by the Principal Investigator or designee authorized to conduct the process,
- include a description of all aspects of the clinical study that are relevant to the subject's decision to participate throughout the clinical study,
- avoid any coercion of or undue influence of subjects to participate,
- not waive or appear to waive subject's legal rights,
- use native language that is non-technical and understandable to the subject or his/her legal representative,
- provide ample time for the subject to consider participation and ask questions if necessary,
- ensure important new information is provided to new and existing subjects throughout the clinical study.

The ICF shall always be signed and personally dated by the subject under the applicable laws, rules, regulations and guidelines and by the investigator and/or an authorized designee

responsible for conducting the informed consent process. The original signed ICF will be retained by the site and a copy of the signed and dated document and any other written information must be given to the person signing the form.

Failure to obtain subject consent will be reported by BSC to the applicable regulatory authority according to their requirements (e.g., FDA requirement is within 5 working days of learning of such an event). Any violations of the informed consent process must be reported as deviations to the sponsor and local regulatory authorities (e.g. IRB/EC/REB), as appropriate.

If new information becomes available that can significantly affect a subject's future health and medical care, that information shall be provided to the affected subject(s) in written form via a revised ICF or, in some situations, enrolled subjects may be requested to sign and date an addendum to the ICF. In addition to new significant information during a study, other situations may necessitate revision of the ICF, such as if there are amendments to the applicable laws, protocol, a change in Principal Investigator, administrative changes, or following annual review by the IRB/EC/REB. The new version of the ICF must be approved by the IRB/EC/REB. Acceptance by Boston Scientific is required if changes to the revised ICF are requested by the site's IRB/EC/REB. The IRB/EC/REB will determine the subject population to be re-consented.

19. Committees

19.1. *Safety Monitoring Process*

The BSC Medical Safety group reviews unmonitored data as soon as the event is reported, on a continuous basis. During scheduled monitoring activities, clinical research monitors will support this continuous review through their review of source document and other data information. The BSC Medical Safety group includes a physician with necessary therapeutic and subject matter expertise to evaluate and classify the events into the categories outlined above.

20. Suspension or Termination

20.1. *Premature Termination of the Study*

Boston Scientific reserves the right to terminate the study at any stage but intends to exercise this right only for valid scientific or business reasons and reasons related to protection of subjects. Investigators, associated IRB/EC/REBs, and regulatory authorities, as applicable, will be notified in writing in the event of study termination.

20.2. *Criteria for Premature Termination of the Study*

Possible reasons for premature study termination include, but are not limited to, the following.

- Suspicion of an unacceptable risk. In this case, the sponsor shall suspend the clinical investigation while the risk is assessed. The sponsor shall terminate the clinical investigation if an unacceptable risk which cannot be controlled is confirmed.
- Instructions by the IRB/EC/REB or regulatory authorities to suspend or terminate the clinical investigation.
- An enrollment rate far below expectation that prejudices the conclusion of the study.
- A decision on the part of Boston Scientific to suspend or discontinue development of the device.

20.3. *Termination of Study Participation by the Investigator or Withdrawal of IRB/EC Approval*

Any investigator, or associated IRB/EC/REB or regulatory authority may discontinue participation in the study or withdraw approval of the study, respectively, with suitable written notice to Boston Scientific. Investigators, associated IRB/EC/REBs, and regulatory authorities, as applicable, will be notified in writing in the event of these occurrences.

20.4. *Requirements for Documentation and Subject Follow-up*

In the event of premature study termination, a written statement as to why the premature termination has occurred will be provided to all participating sites by Boston Scientific. The IRB/EC/REB and regulatory authorities, as applicable, will be notified. Detailed information on how enrolled subjects will be managed thereafter will be provided.

In the event an IRB/EC/REB terminates participation in the study, participating investigators, associated IRB/EC/REBs, and regulatory authorities, as applicable, will be notified in writing. Detailed information on how enrolled subjects will be managed thereafter will be provided by Boston Scientific.

In the event a Principal Investigator terminates participation in the study, study responsibility will be transferred to another investigator, if possible. In the event there are no opportunities to transfer Principal Investigator responsibility; detailed information on how enrolled subjects will be managed thereafter will be provided by Boston Scientific.

The Principal Investigator or his/her designee must return all study-related documents and investigational product to Boston Scientific, unless this action would jeopardize the rights, safety, or welfare of the subjects.

20.5. *Criteria for Suspending/Terminating a Study Site*

Boston Scientific reserves the right to stop the inclusion of subjects at a study site at any time after the study initiation visit if no subjects have been enrolled or if the site has multiple or severe protocol violations/noncompliance without justification and/or fails to follow remedial actions.

In the event of termination of site participation, all study devices and testing equipment, as applicable, will be returned to BSC unless this action would jeopardize the rights, safety or

well-being of the subjects. The IRB/EC/REB and regulatory authorities, as applicable, will be notified. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

21. Study Registration and Results

21.1. *Study Registration*

To comply with applicable laws and regulations, the study will be registered on a publicly accessible database.

21.2. *Clinical Investigation Report*

Study results will be made available in accordance with the legal requirements and the recognized ethical principles, in accordance with the Boston Scientific Policy. A Clinical Investigation Report will be made available to all investigators, IRB/EC/REB and regulatory authorities, as applicable in accordance with the Boston Scientific Policy and local requirements. As applicable an abbreviated Clinical Investigation Report will be made available on a publicly accessible database.

22. Publication Policy

BSC requires disclosure of its involvement as a sponsor or financial supporter in any publication or presentation relating to a BSC study or its results. BSC may submit study results for publication (regardless of study outcome) following the conclusion or termination of the study. Boston Scientific adheres to the Contributorship Criteria set forth in the Uniform Requirements of the International Committee of Medical Journal Editors (ICMJE; http://www.icmje.org). In order to ensure the public disclosure of study results in a timely manner, while maintaining an unbiased presentation of study outcomes, BSC personnel may assist authors and investigators in publication preparation provided the following guidelines are followed:

- All authorship and contributorship requirements as described above must be followed.
- BSC involvement in the publication preparation and the BSC Publication Policy should be discussed with the Coordinating Principal Investigator(s) and/or Executive/Steering Committee at the onset of the project.
- The First and Senior authors are the primary drivers of decisions regarding publication content, review, approval, and submission.

The data, analytic methods, and study materials for this clinical trial may be made available to other researchers in accordance with the Boston Scientific Data Sharing Policy (https://www.bostonscientific.com/).

23. Bibliography

[redacted]

24. Abbreviations and Definitions

24.1. *Abbreviations*

Abbreviations are shown in Table 24.1-1.

Table 24.1-1: Abbreviations

Abbreviation/Acronym	Term
ADE	Adverse device effect
AE	Adverse event
BSC	Boston Scientific Corporation
BSN	Boston Scientific Neuromodulation
CFR	Code of Federal Regulations
CRF	Case report form
CRO	Contract research organization
EC	Ethics Committee
eCRF	Electronic case report form
ESAP	End of study action plan
FDA	Food and Drug Administration
GCP	Good clinical practice
HCP	Health care personnel

Table 24.1-1: Abbreviations

Abbreviation/Acronym	Term
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDS	Indirect Decompression System
IFU	Instructions for Use
IPD	Interspinous Process Decompression
IRB	Institutional Review Board
ISO	International Organization for Standardization
ITT	Intent to treat
ODI	Oswestry Disability Index
PF	Physical Function
PGI-C	Patient Global Impression of Change
REB	Research Ethics Board
PPR	Percent Pain Relief
RUI	Resource Utilization Inventory
SADE	Serious adverse device effect
SAE	Serious adverse event
UADE	Unanticipated adverse device effect
USADE	Unanticipated serious adverse device effect
VAS	Visual analog scale
ZCQ	Zurich Claudication Questionnaire

24.2. *Definitions*

Detailed definitions or descriptions are provided in applicable sections of the protocol.