Postmarket Registry for Evaluation of the Superion® Spacer [PRESS Registry]

Protocol No.: 16-VISS-01 Rev C

July 20, 2016

Sponsor:
Vertiflex®, Inc.
1351 Calle Avanzado, Suite 100
San Clemente, CA 92673

INVESTIGATOR SIGNATURE PAGE

Title: Postmarket Registry for Evaluation of the Superion® Spacer [PRESS Registry]

Protocol No.: 16-VISS-01

Date: July 20, 2016

By signing this page, the Investigator acknowledges that:

He/she has read the protocol and agrees to comply with the protocol in accordance with Good Clinical Practices and use of the stipulated products as indicated in the protocol.

All patients will provide signed Informed Consent (provided by Sponsor) prior to enrollment in the registry.

Where/if applicable, Investigator agrees to conform to all procedures agreed to, or required by, the Institutional Review Board or Independent Ethics Committee.

All data relevant to the clinical evaluation and regarding the subject response and safety, as stipulated in the protocol, will be documented and provided to the Sponsor.

All *unanticipated* adverse device effects, and serious adverse device events that are definitely device- or procedure-related, will be reported as requested to the Sponsor within 24 hours.

_____ _____

Signature of Investigator Date

_____

Printed Name of Investigator

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Postmarket Registry for Evaluation of the Superion® Spacer

[PRESS Registry]

Protocol No. 16-VISS-01

PROTOCOL SYNOPSIS

Title	Postmarket Registry for Evaluation of the Superion® Spacer
Short Title	PRESS Registry
Protocol Number	16-VISS-01
Sponsor	Vertiflex® Inc. 1351 Calle Avanzado, Suite 100 San Clemente, CA 92673
Registry Treatment	Superion® Indirect Decompression System (IDS)
Control Treatment	None
Registry Design	Prospective, single arm, multi-center
Registry Objective	The purpose of this postmarket surveillance registry is to gather evidence documenting the performance and clinical outcomes associated with treatment of moderate degenerative lumbar spinal stenosis using the Superion® Indirect Decompression System (IDS) .
Registry Population	Patients ≥45 years of age suffering from symptoms of neurogenic intermittent claudication secondary to a confirmed diagnosis of moderate degenerative lumbar spinal stenosis at one or two contiguous levels from L1 to L5.
Number of Subjects	A minimum of one hundred (100) patients will be enrolled in the registry.
Number of Sites	A minimum of twenty (20) sites will participate.
Registry Enrollment	Approximately 12 months for a minimum of 100 patients.
Registry Duration	Patients included in the clinical registry will return for follow-up visits at 3 weeks, and 6 and 12 months post-treatment to collect data for the primary evaluation. Registry duration is approximately 24 months based upon 12 months' enrollment plus 12 month follow-up for 100 patients. Sponsor reserves the right to enroll additional patients.
Endpoints	• VertiFlex® Patient Satisfaction Survey: A score of ≥3 in each questionnaire component is considered clinically significant; • Visual Analogue Scale (VAS): An improvement in back and leg pain of 20 mm (on a 100 mm scale) vs. baseline is considered clinically significant. • Achievement of Self-Defined Functional Objective. A score of ≥3 is considered evidence of significant improvement in function.
Other Data Collected	• Reports of serious procedure- or device-related adverse events; • Intraoperative metrics including estimated blood loss, operative time, type of anesthesia, and time to discharge.

1 PURPOSE

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

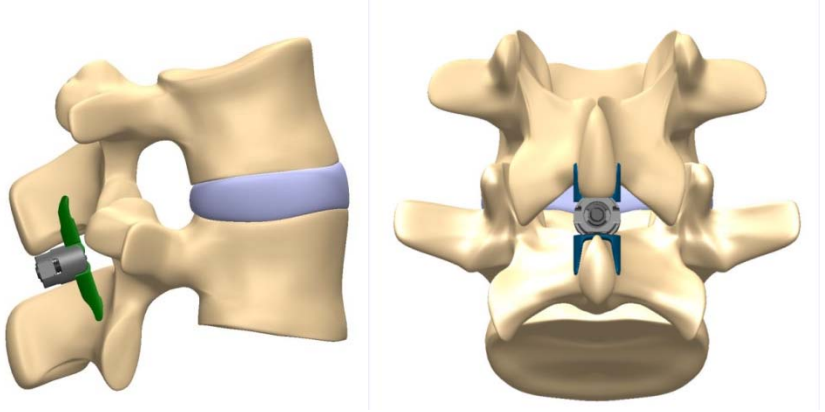
2 PRODUCT DESCRIPTION

The Superion® Indirect Decompression System (IDS) (Superion® implant) is a spinal implant designed to treat symptoms of neurogenic intermittent claudication secondary to moderate degenerative lumbar spinal stenosis, and is implanted by minimally-invasive methods through a cannula with patient under general or local anesthesia. The implant provides indirect decompression of spinal nerves, and functions as a spinal extension-blocker to prevent compression of neural elements in extension. The device was approved by the U.S. Food and Drug Administration (FDA) for commercialization in the U.S. via PreMarket Approval (PMA) on May 20, 2015.[1]

2.1 Device Description

The Superion® implant is available in five (5) sizes, from 8mm to 16mm in 2mm increments, to accommodate a range of spinal anatomy. It is composed of Titanium 6Al-4V alloy conforming to ASTM Standard Specification F136, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*. **Figure 1** depicts the implant in its final position after placement between the spinous processes.

Figure 1: Superion® Indirect Decompression System (IDS) *in situ*



Lateral View **A/P View**

[1]For a complete Summary of Safety and Effectiveness Data (SSED) derived from the clinical trial supporting FDA approval of the Superion® PMA, please refer to the SSED posted on the FDA website at http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140004b.pdf.

The device may be implanted under general or local (e.g., conscious sedation) anesthesia. A percutaneous or mini-open approach is used for placement of a cannula via sequential dilation. A sizing tool is employed to determine the proper device size, and the Superion® implant is then inserted through the cannula and deployed under fluoroscopic guidance between spinous processes at the level to be treated. The implant serves thereafter to maintain distraction between the spinous processes while preserving motion. This maintains the intervertebral space and prevents narrowing of the canal by limiting extension at that level. Where a second, contiguous level is also symptomatic, the same procedure is used to place a Superion® implant at that level.

2.2 Indications for Use

Patients will conform to indications and contraindications delineated in the Superion® labeling.

3 POSTMARKET SURVEILLANCE PROCEDURES

3.1 Registry Design

The PRESS registry is a prospective, single arm, multi-center registry intended to collect clinical experience with use of the Superion® Indirect Decompression System (IDS) in the treatment of moderate degenerative lumbar spinal stenosis. A minimum of twenty (20) sites will be selected to participate, enrolling a minimum of one hundred (100) patients.

Patient selection will conform to labeled indications for use, and physicians will treat patients in accordance with physician labeling and the Superion® Surgical Technique Manual. All physicians must have completed training in the use of the device provided by Vertiflex®.

3.2 Registry Endpoints

Registry endpoints will include the following outcomes reflective of clinical effectiveness:

- Vertiflex® Patient Satisfaction Survey: A score of ≥3 in each questionnaire component will be deemed a clinically meaningful outcome.
- Visual Analogue Scale (VAS), Back and Leg Pain: An improvement of 20 mm (on a 100 mm scale) from baseline is considered a clinically meaningful outcome.
- Achievement of Self-Defined Functional Objective. A score of ≥3 is considered evidence of significant improvement in function.

In addition, other information to be collected will include:

- Reports of Serious Adverse Events (SAEs) determined by the Investigator to be definitely procedure- or device-related.

Perioperative information that will be collected includes:

- Type of anesthesia
- Operative time (min.)
- Estimated blood loss (cc)
- Time to discharge (hrs.)

3.3 Duration and Extent of Registry

Patients included in this registry will be assessed pre-operatively for eligibility in accordance with labeled indications for use, and will return for follow-up visits at 3 weeks (±2 weeks), 6 months (±2 months), and 12 months (±2 months) post-treatment. Designed to enroll a minimum of one hundred (100) patients, Vertiflex® may elect to enroll additional patients.

3.4 Registry Population and Source of Patients

The registry population will consist of male and female patients ≥45 years of age, with symptoms of neurogenic intermittent claudication and a confirmed diagnosis of moderate degenerative lumbar stenosis at one or two contiguous levels from L1 to L5, meeting the labeled indications for use of the Superion® Indirect Decompression System (IDS) . Patients will be identified and recruited by treating clinicians and/or their designated research staff. The clinician Investigator at each site is responsible for verifying that a potential registry patient meets all eligibility criteria, as described in the labeled indications for use, and is not contraindicated.

Patients will be considered evaluable after Informed Consent has been signed, the Investigator has verified eligibility, and Vertiflex® has assigned a unique patient identifier number.

3.5 Registry Procedures

Data will be collected from all patients participating in the registry pre-operatively, intra-operatively, and at follow-up visits at 3 weeks (±2 weeks), 6 months (±2 months), and 12 months (±2 months) post-treatment (See Visit Schedule, Appendix A). Data will be recorded on approved Case Report Forms provided by Vertiflex®. Procedures associated with individual visits are as follows:

3.5.1 Pre-Operative Assessment

The following information will be collected and documented on the Pre-Operative Assessment Case Report Form (Appendix B) by the Investigator or his/her authorized clinical research staff at the time of pre-operative assessment:

Confirmation of Eligibility

All potential registry participants shall be confirmed as meeting eligibility requirements, as described in labeled indications for use and contraindications.

Informed Consent

All patients seeking to participate in the registry, and whose eligibility has been confirmed by the Investigator, will be required to sign Sponsor-provided Informed Consent prior to enrollment.

Demographic Information

Date of birth, gender, height, weight, and smoking history will be collected.

Establishment of Self-Defined Functional Objective

3.5.2 Intra-Operative Assessment

Perioperative metrics will be collected and documented on the Treatment Case Report Form (Appendix B) at the time of treatment, including:

- Device size(s)
- Device lot number(s)
- Surgical level(s) treated
- Type of anesthesia
- Duration of surgery (min.), measured from start of anesthesia administration to completion of skin closure
- Estimated blood loss (cc)
- Time to discharge (hrs.), measured from completion of skin closure to discharge from treating facility

In addition, any intra-operative complications/serious adverse events deemed by the Investigator to be definitely procedure- or device-related will be documented, as described in §4.

3.5.3 Post-Operative Follow-Up Assessments

At each follow-up visit, i.e., at 3 weeks (±2 weeks), 6 months (±2 months), and 12 months (±2 months) post-treatment, the following information will be collected and documented on the Follow-Up Visit Case Report Form (Appendix B):

- Patient identification number and initials, and date of follow-up visit and follow-up interval (e.g., 3 weeks, 6 or 12 months, etc.) will be recorded by the Investigator and/or his/her authorized clinical research staff.
- Patients will complete a Vertiflex® Patient Satisfaction Survey. A score of ≥3 in each questionnaire component will be deemed a clinically meaningful outcome.
- Patients will complete a Visual Analogue Scale (VAS) for each leg, and for back pain. An improvement of 20 mm (on a 100 mm scale) from baseline is considered a clinically meaningful outcome.
- Patients will indicate the extent to which they have achieved their Self-Defined Functional Objective, on a 1 to 5 scale, with 1 indicating no progress at all, and 5 indicating complete achievement.

In addition, the Investigator and/or his/her authorized clinical research staff will collect and document:

- Reports of any Serious Adverse Events (SAEs) occurring since the last visit, and determined by the Investigator to be definitely procedure- or device-related.

4 SERIOUS ADVERSE EVENTS (SAEs)

All Serious Adverse Events (SAEs) deemed by the Investigator to be **definitely procedure- or device-related** must be documented on the SAE Case Report Form (Appendix B).

4.1 Serious Adverse Events

An adverse event is regarded as a **Serious Adverse Event (SAE)** if the injury or illness:

A) Results in death
B) Is life-threatening,
C) Results in or prolongs hospitalization
D) Results in permanent impairment of a body function or permanent damage to a body structure, or
E) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

The Vertiflex® Clinical Research group must be notified of all **Serious Procedure- or Device-Related Adverse Events** within 24 hours at:

Vertiflex®, Inc., Clinical Research
1351 Calle Avanzado, Suite 100
San Clemente, CA 92673 USA
Tel: (866) 355-4675
Fax: (949) 940-1475
clinical@vertiflex.net

5 TERMINATION OF PARTICIPATION

Patients may voluntarily withdraw from the registry at any time for any reason. The Investigator(s) may elect to withdraw a subject from the registry at any time due to lack of compliance or for any reason unrelated to the registry treatment if such a decision is in the patient's best medical interest.

6 DEVICE EXPLANT AND RETRIEVAL

In the event of a device removal, the device and the Investigator's written explanation of the event will be sent to Vertiflex® following instructions from Vertiflex®.

7 INVESTIGATOR RESPONSIBILITIES

Investigators will be deemed responsible for the following:

- This registry must have initial and continuing approval (at least annually) from an Institutional Review Board (IRB) responsible for approving clinical studies.
- Acquisition of signed Informed Consent from each patient before performing any registry-related activities.
- Conduct of the registry in conformance with this protocol, and with Good Clinical Practices.

8 Vertiflex® OBLIGATIONS

8.1 Investigator(s) Training

Vertiflex® will provide appropriate training to each Investigator that includes didactic and hands-on elements, e.g., cadaver lab, sawbones model. Training will including surgical procedures in accordance with the Superion® Surgical Technique Manual, selection of appropriate implant sizes, instrumentation for implantation, indications for use of the device, contraindications, and management of complications. Vertiflex® will also provide appropriate training to the operating room staff at each investigational site, where applicable.

8.2 Vertiflex® Registry Termination

Vertiflex® may close enrollment or terminate the registry at any site, at any time, for non-compliance to GCP guidelines or this protocol, or for other valid reason.

8.3 Registry Monitoring

Vertiflex® may elect to monitor the registry during its active phase. Any such monitoring visits will be scheduled by prior arrangement with the Investigator, and monitoring will be carried out in compliance with GCP guidelines.

9 LIST OF APPENDICES

Appendix A: Visit Schedule

Appendix B: Case Report Forms