training may result in poor patient outcomes and/or increased rates of adverse events.

Potential Adverse Events:

The following potential adverse events may occur as a result of interspinous process decompression with the Superion™ Interspinous Spacers:

Superion™ Interspinous Spacers Related:

- implant dislodgement/migration;
- implant not positioned correctly;
- fracture of the spinous process;
- remodeling of surrounding tissues;
- additional surgery, which could include removal of the implant;
- foreign body reaction due to wear debris or implant material;
- neurological system compromise;
- paralysis;
- wound dehiscence or delayed healing;
- pain/discomfort at the operative site.

Surgery Related:

- reaction to anesthesia;
- myocardial infarction;
- infection;
- blood vessel damage/bleeding;
- deep vein thrombosis;
- hematoma;
- pneumonia;
- neurological system compromise;
- stroke;
- nerve injury or spinal cord damage;
- paralysis;
- thromboembolism;
- wound dehiscence or delayed healing;
- pain/discomfort at the operative site;
- death.

STORAGE

The Superion™ Interspinous Spacers and instruments should be stored in a clean and dry area until ready for use.

INSTRUCTIONS FOR USE

The surgeon implanting the Superion™ Interspinous Spacers is expected to be fully educated and trained in the procedures necessary to implant the device. Refer to the Superion™ Interspinous Spacers Surgical Technique Manual for recommended implantation procedures.

The techniques for implanting the Superion™ Interspinous Spacers should be reviewed by the surgeon prior to use of the system. Proper selection of patients, and good compliance of patients with instructions for postoperative care and behavior, are critical to the realization of a successful procedure. All patients contemplating implantation of this device should be apprised of the risks associated with the procedure, as well as the limitations of activities the patient will face following surgery. The surgeon is expected to provide detailed instructions to the patient regarding postoperative activity. The surgeon should inspect the components and instruments of the Superion™ Interspinous Spacers system before surgery to assure that all necessary components are present.

The Superion™ Interspinous Spacers are designed to be implanted percutaneously with minimal trauma to surrounding tissues and structures, and as such, may be an appropriate first intervention in patients who have failed to respond to prolonged conservative, non-surgical therapies.

STERILE

FOR SINGLE USE ONLY

Sterility

The Superion™ Interspinous Spacers are supplied “STERILE” and intended for single patient use only. DO NOT RESTERILIZE THIS PRODUCT. The sterility can only be assured if the packaging is intact. Do not use this device if the STERILE packaging has been opened or damaged. Contact your VertiFlex® Clinical representative for replacement. Remove all packaging material prior to use. Only sterile implants should be used in surgery.

CAUTION: Federal (USA) law restricts these devices to sale by, or on the order of, a licensed physician.

WARNINGs

The Superion™ Interspinous Spacers are intended to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of 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 narrowing. The Superion™ Interspinous Spacers is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/foot/groin pain, with or without back pain. The Superion™ Interspinous Spacers may be implanted at one or two adjacent lumbar levels in patients in whom operative treatment is indicated at no more than two levels.

CONTRAINDICATIONS

The Superion™ Interspinous Spacers are contraindicated in patients with:

- an allergy to titanium or titanium alloy;
- spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in place; such as:
  - significant instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4);
  - an ankylosed segment at the affected level(s);
  - acute fracture of the spinous process, pars interarticularis, or laminae fracture (unilateral or bilateral);
  - significant scoliosis (Cobb angle >10 degrees);
- Cauda equina syndrome defined as neural compression causing neurogenic bladder or bowel dysfunction;
- diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or equivalent method) in the spine or hip that is more than 2.5 S.D. below the mean of adult normals in the presence of one or more fragility fractures;
- active systemic infection, or infection localized to the site of implantation.

PACKAGING

All packages containing implants should be intact upon receipt. Damaged packaging may indicate the presence of unsafe product. If the product packaging is damaged, the product should not be used and should be returned.

The Superion™ Interspinous Spacers are designed to be implanted percutaneously with minimal trauma to surrounding tissues and structures, and as such, may be an appropriate first intervention in patients who have failed to respond to prolonged conservative, non-surgical therapies.

CAUTION: The Superion™ Interspinous Spacers are manufactured from titanium alloy, which is known to produce MRI artifacts. Patients should be warned to produce MRI artifacts. Patients should be warned to produce MRI artifacts.

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VertiFlex® Interspinous Spacer

CARE AND HANDLING OF
SURGICAL INSTRUMENTATION

Product Description:
The instruments shipped with this insert are designed for use in orthopaedic surgical procedures for implantation of Superion® Interspinous Spacers manufactured by VertiFlex®, Inc. Prior to use of these instruments, please refer to the product instructions-for-use specific to the Superion® Interspinous Spacer and the surgical procedure to be followed.

Precautions:
1. VertiFlex®, Inc., instruments should only be used with VertiFlex®, Inc., implants. Do not attempt to use with other competitive devices.
2. Use caution during cleaning and sterilization so as not to damage delicate instruments.
3. Only sterile instruments should be used in surgery.
4. Wear appropriate clothing and protective garb when handling biologically-contaminated instruments.
5. Avoid application of excessive stress on surgical instrumentation.
6. Avoid use of abrasive cleaners on surgical instrumentation.
7. Store instruments only in a dry, protected environment.
8. Carefully read and follow any package insert which accompanies the implants to be used with this instrumentation.
9. Instruments must be cleaned and sterilized before they are returned to the manufacturer for any reason.
10. Carefully inspect all instruments prior to use. Do not use an instrument that is severely marred or worn, or a cutting instrument with dull edges. Note that at some point in time, instruments may wear out and should be replaced.

Inspection:
Please inspect the instruments prior to use for possible damage, unacceptable wear, or non-functioning components. Damaged instruments should not be used or sterilized. Contact your local sales representative for repair or replacement.

How Supplied
The Superion® Interspinous Spacer surgical instruments are supplied non-sterile, and must be properly cleaned and sterilized prior to use.

Cleaning
- Remove all labels and packaging materials before cleaning and sterilization.
- Contaminated devices and trays must be cleaned thoroughly by trained personnel prior to disinfection or sterilization.
- It is recommended that no more than 2 hours elapse from point of use to cleaning, to reduce the potential for drying of biological residues.
• Always place contaminated Interspinous Gauge, Inserter, and Driver devices in vertical orientation with distal tip positioned downwards to allow drainage and prevent accumulation of soil.
• Particular attention must be paid when rinsing and washing devices having articulating features/surfaces, and those with inner lumens.

**Manual Cleaning**

• As soon as possible after use, rinse devices under running tap water (20-40°C) to soften and remove any accumulations of residues, paying particular attention to devices with lumens and/or articulating surfaces and features. Rinse devices for a minimum of 1 minute and ensure devices are free of visually identifiable residual buildup. Continue rinsing until the absence of any residues is visually verified.
• After rinsing, prepare Alconox or equivalent hospital grade detergent according to manufacturer instructions relevant for the type (e.g., blood) and amount of residue on devices. Fully immerse the devices for a minimum of 10 minutes. Actuate any articulating devices repeatedly (5 to 10 times) while immersed in the solution to ensure complete penetration of cleaning detergent. Conduct ultrasonic cleaning for a minimum of 10 minutes, especially for devices with lumens and/or articulating surfaces and features.
• Using only non-abrasive nylon brushes, clean all surfaces of the devices to remove any residues. Pay particular attention to the rough distal portion of the Interspinous Reamer, and all moving parts/articulating surfaces of the Interspinous Gauge and the Inserter. Actuate articulating devices repeatedly (5 to 10 times) while brushing in order to clean between moving parts. Remove any residue buildup in or between any lumens and other hard to reach places. Continue cleaning until the absence of any residues is visually verified.
• For cannulated devices, use non-abrasive nylon cannula brushes to remove any residual buildup in inner lumens. Continue cleaning until the absence of any residues is visually verified.
• Remove the devices from the Alconox/equivalent bath and thoroughly rinse with running deionized or reverse osmosis water (20-40°C) for a minimum of 1 minute to remove detergent. Actuate devices with moving parts repeatedly (5 to 10 times) while rinsing in order to rinse between moving parts, paying particular attention to lumens and other hard to reach places.
• Inspect all devices prior to sterilization for evidence of wear, damage, or missing parts.

**Mechanical (Automatic) Cleaning**

• As soon as possible after use, and prior to placing the devices into a legally-marketed mechanical (automatic) washer, conduct ultrasonic cleaning for a minimum of 10 minutes in Alconox or equivalent hospital grade detergent according to manufacturer’s instructions relevant for the type (e.g., blood) and amount of residue on devices.
• Place Interspinous Gauge, Inserter, and Driver devices in vertical orientation with distal tip positioned downwards to allow drainage for a minimum of 2 minutes.

Follow the mechanical (automatic) washer manufacturer’s instructions for cleaning, using Enzol or equivalent hospital grade detergent.

**Sterilization**

The Superion® Interspinous Spacer surgical instruments are supplied **NON-STERILE** and must be sterilized before use. The recommended sterilization process is high temperature steam autoclave sterilization. It is also recommended that the trays be double wrapped using FDA-cleared sterilization wraps. The recommended sterilization cycle will produce a Sterility Assurance Level of at least 10^-6.

**THE VALIDATED CYCLE IS:**

| Method: Steam  |
| Cycle: Pre-vacuum  |
| Temperature: 270°F (132°C)  |
| Exposure Time: 4 minutes  |
| Drying Time: 30 minutes  |

Do not stack trays during sterilization.

All packages should be intact upon receipt. Damaged packaging may indicate the presence of unsafe product. If the product packaging is damaged, the product should not be used and should be returned. The product must be handled, stored, and opened in such a way that it is protected from inadvertent damage or contamination. The product may be placed into use only after following recommended cleaning and sterilization instructions.

**Storage**

The Superion® Interspinous Spacer and instruments should be stored in a clean area until ready for use.

**Instructions for Use**

The surgeon implanting the Superion® Interspinous Spacer is expected to be fully educated and trained in the techniques necessary to implant the device.

Refer to the Superion® Interspinous Spacer **Surgical Technique Manual Revision G** for recommended implantation procedures.

The techniques for implanting the Superion® Interspinous Spacer should be reviewed by the surgeon prior to use of the system.

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