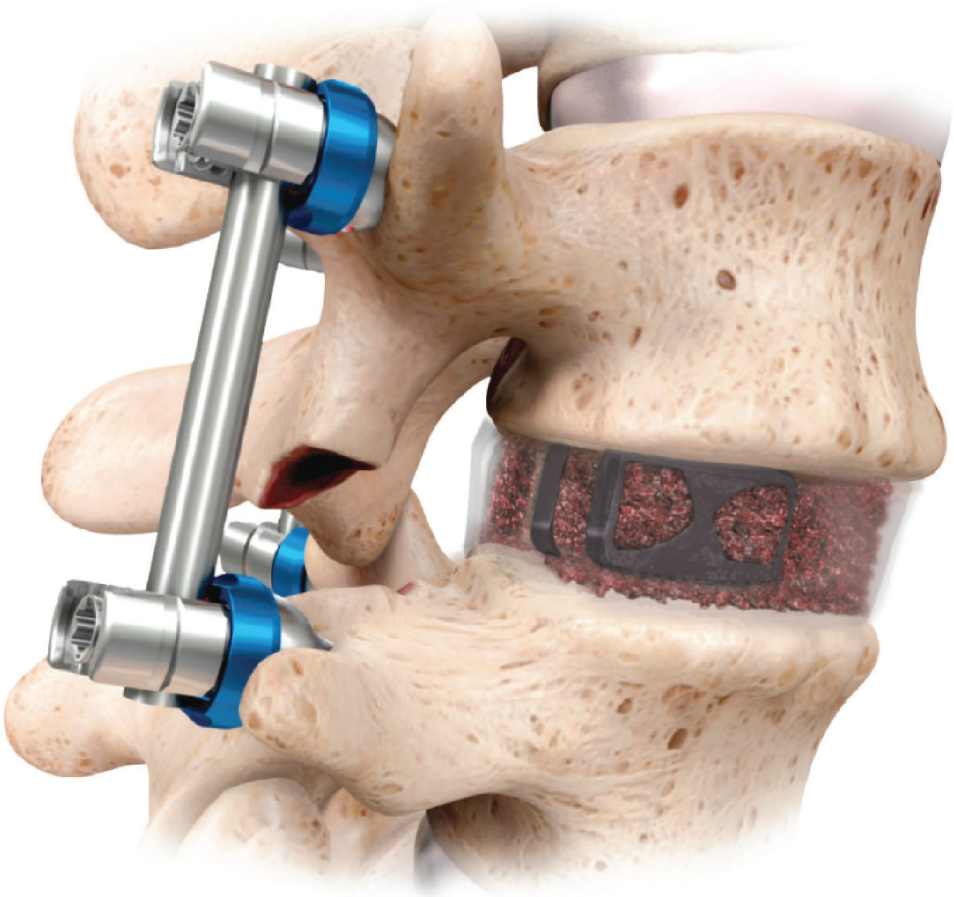
Leva® PF

Interbody Device

SURGICAL TECHNIQUE



SpineWave

Dedicated to making a difference. . .

Spine Wave's vision is to leverage our proprietary technology to provide spine surgeons with a broad, differentiated portfolio of expandable and other less invasive, more efficient solutions for real surgical challenges. We are dedicated to a surgeon-driven product development process to build and maintain a robust product pipeline. We aim to help people lead more active, productive and pain-free lives by restoring spinal function through highly differentiated surgical products.

The Leva® Interbody Device is a structurally-strong implant that is designed to provide segmental stabilization, disc height restoration and a unique open architecture for bone graft.

The implant's unique open architecture maximizes space for bone graft and enables complete bone grafting of both the implant and the surrounding disc space after its insertion.

A Special Thank You to Our Surgeon Advisors:

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LEVA® PF INTERBODY DEVICE: THE TITANIUM GRAFT CHAMBER

DESIGN RATIONALE

The Leva® Interbody Device is a fixed titanium implant that is optimized for ease of insertion and maximum bone grafting of the disc space through the cage.

Maximum Bone Graft Capability

- Unique open architecture
- Maximum space for bone graft
- Allow up to 75%* of the total implant volume to be packed with bone graft

Insertion

- Enables complete bone grafting of both the implant and the surrounding disc space after its insertion.

Leva® PF Interbody Device has a retractable bullet nose integrated to the inserter

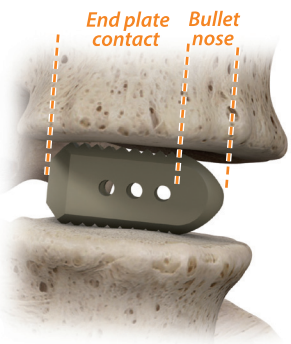
Retractable Bullet Nose

- Allows easy insertion

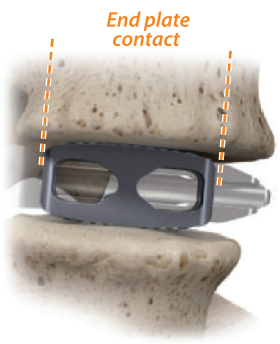
The retractable bullet nose is also designed to:

- Provide more room for bone graft anterior to the cage once inserter is retracted
- Enable end plate contact with the device along its full length

Typical PEEK Spacer



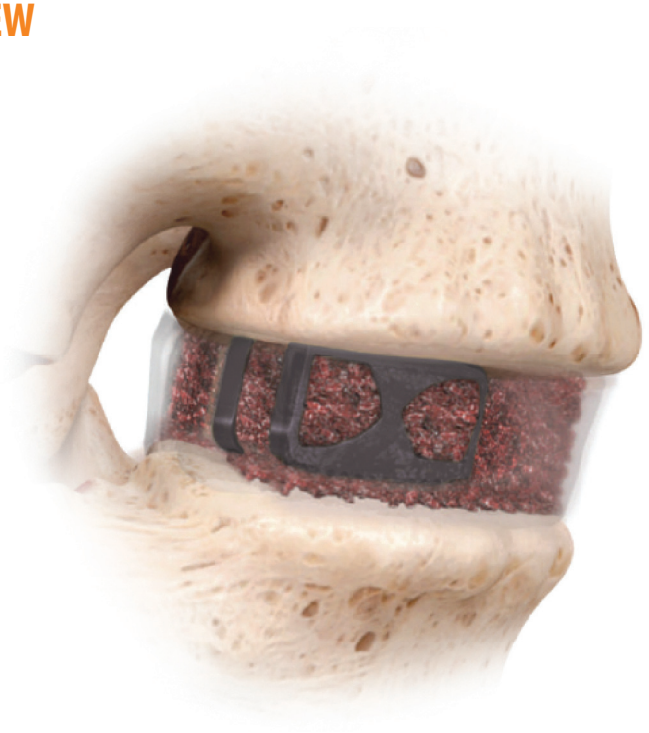
Leva® PF Interbody Device



14 mm implant. Data on file.

LEVA® PF INTERBODY DEVICE

IMPLANT OVERVIEW

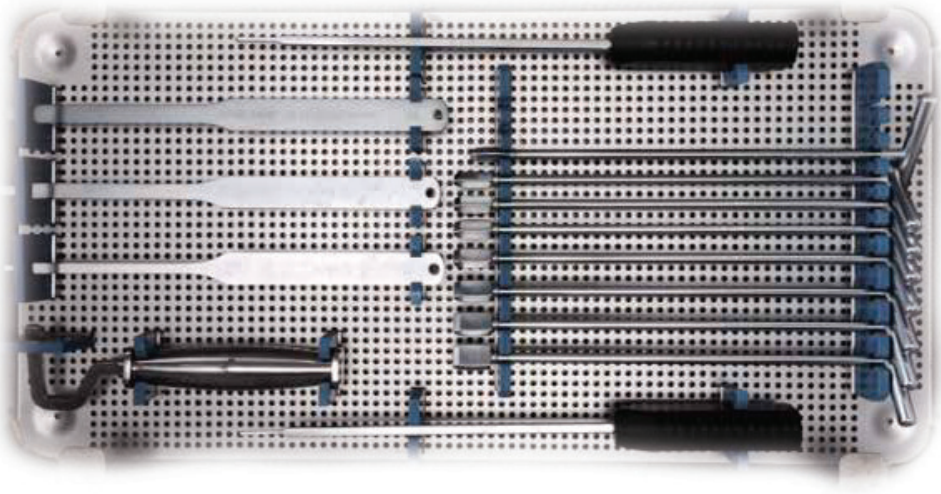


Catalog #	Description	Graft Volume in Cage
11-7107	Leva® PF 7 mm - 25 (L) x 10 (W) x 7 (H)	1.0 cc
11-7108	Leva® PF 8 mm - 25 (L) x 10 (W) x 8 (H)	1.1 cc
11-7109	Leva® PF 9 mm - 25 (L) x 10 (W) x 9 (H)	1.2 cc
11-7110	Leva® PF 10 mm - 25 (L) x 10 (W) x 10 (H)	1.6 cc
11-7111	Leva® PF 11 mm - 25 (L) x 10 (W) x 11 (H)	1.7 cc
11-7112	Leva® PF 12 mm - 25 (L) x 10 (W) x 12 (H)	1.8 cc
11-7113	Leva® PF 13 mm - 25 (L) x 10 (W) x 13 (H)	2.1 cc
11-7114	Leva® PF 14 mm - 25 (L) x 10 (W) x 14 (H)	2.2 cc
11-7307	Leva® PF 7 mm - 22 (L) x 10 (W) x 7 (H)	0.8 cc
11-7308	Leva® PF 8 mm - 22 (L) x 10 (W) x 8 (H)	0.9 cc
11-7309	Leva® PF 9 mm - 22 (L) x 10 (W) x 9 (H)	1.0 cc
11-7310	Leva® PF 10 mm - 22 (L) x 10 (W) x 10 (H)	1.3 cc
11-7311	Leva® PF 11 mm - 22 (L) x 10 (W) x 11 (H)	1.4 cc
11-7312	Leva® PF 12 mm - 22 (L) x 10 (W) x 12 (H)	1.5 cc
11-7313	Leva® PF 13 mm - 22 (L) x 10 (W) x 13 (H)	1.8 cc
11-7314	Leva® PF 14 mm - 22 (L) x 10 (W) x 14 (H)	1.9 cc

LEVA® PF INTERBODY DEVICE

INSTRUMENT OVERVIEW

Top Tray



Bottom Tray

LEVA® PF INTERBODY DEVICE

PRE-OPERATIVE PLANNING AND APPROACH

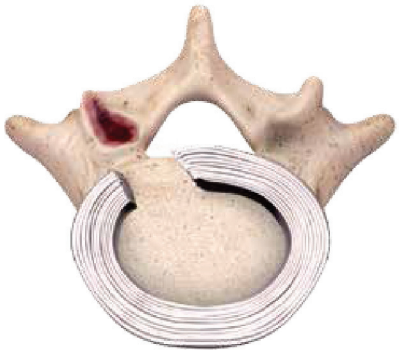
The Leva® Interbody Device is intended for posterior use.

1 Perform pre-operative planning to ensure that the implant length and height offering is appropriate for the patient.

2 The patient is placed in the prone position for optimal access to the targeted level(s).

3 Expose the operative segment.

DISC PREPARATION



1 Expose the disc space and remove disc material with the help of commonly used surgical instruments such as rongeurs, curettes, rasps and other appropriate instruments.

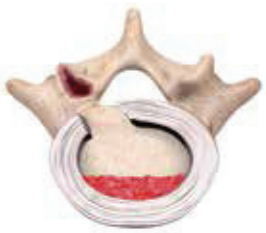
2 A meticulous nucleus removal and endplate preparation maximizes the amount of space available for bone graft to fill the disc space.

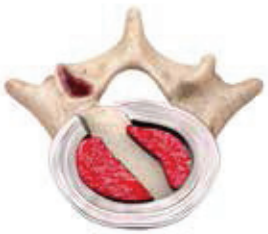
PRE-PACKING OF GRAFT MATERIAL

1 Once the site preparation is complete, the disc space is pre-packed with autograft.

2 Sweep graft material to appropriate location using a tamp. A sizer should be used to confirm positioning and to compact the graft material.

Quantity of bone graft shown is for illustration purposes only and will vary from patient to patient.





LEVA® PF INTERBODY DEVICE

SIZING

1 Sizers are inserted into the disc space with the laser marked size towards the endplates. All sizers insert at 7 mm in height (Figure 1).

2 Begin with the smallest sizer (7 mm) and insert into the disc space.

3 Rotate sizers 90 degrees to distract and assess the disc height (Figure 2). The sizers have depth markings to help assess length (Figure 3).

4 Sequentially use larger sizers until the optimal fit is achieved based on tactile feedback. The final sizer should fit snugly in the disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment and should be confirmed using fluoroscopy and tactile feel.

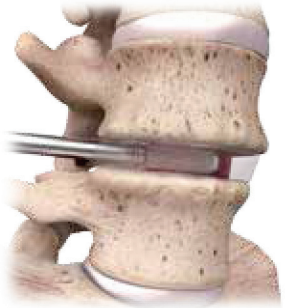


FIGURE 1

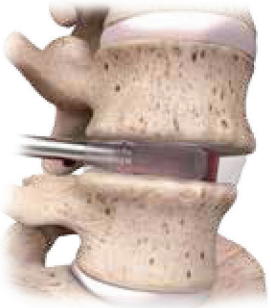


FIGURE 2

The Leva® Interbody Device is recommended to be sized to final height

Caution:
Using an implant that is smaller than the available disc space may result in less than optimal stability. Using an implant that is larger than the available disc space may result in disruption of the vertebral endplate.

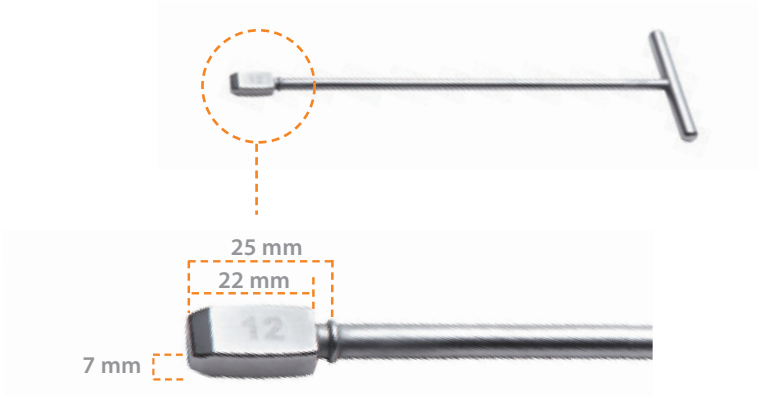


FIGURE 3

LEVA® PF INTERBODY DEVICE

INSERTER ASSEMBLY

25 mm PF Inserter

Black Fixed Handle

- Small Outer Handle (7, 8, 9 mm) 10-7036.1
- Medium Outer Handle (10, 11, 12 mm) 10-7037.1
- Large Outer Handle (13, 14 mm) 10-7038.1

Fixed Inner Shaft

- Small Inner Shaft 10-7036.2
- Medium Inner Shaft 10-7037.2
- Large Inner Shaft 10-7038.2

22 mm PF Inserter

Gray Fixed Handle

- Small Outer Handle (7, 8, 9 mm) 10-7045.1
- Medium Outer Handle (10, 11, 12 mm) 10-7046.1
- Large Outer Handle (13, 14 mm) 10-7047.1

Fixed Inner Shaft

- Small Inner Shaft 10-7045.2
- Medium Inner Shaft 10-7046.2
- Large Inner Shaft 10-7047.2

Leva® PF outer handle and inner inserter shafts are marked with corresponding catalog numbers for easy identification of combination.

Insert fixed inner shaft into the proximal end of the handle three quarter through.

LEVA® PF INTERBODY DEVICE

IMPLANT LOADING

The Leva® PF fixed interbody implants are labeled to show apex heights.

Implant Height	Implant Length	Handle Color and Catalog Number	Inner Shaft Size and Catalog Number
7, 8, 9 mm	25 mm	Black • 10-7036.1	Small • 10-7036.2
10, 11, 12 mm	25 mm	Black • 10-7037.1	Medium • 10-7037.2
13, 14 mm	25 mm	Black • 10-7038.1	Large • 10-7038.2
7, 8, 9 mm	22 mm	Gray • 10-7045.1	Small • 10-7045.2
10, 11, 12 mm	22 mm	Gray • 10-7046.1	Medium • 10-7046.2
13, 14 mm	22 mm	Gray • 10-7047.1	Large • 10-7047.2

1 Hold implant in the orientation shown.

2 Slide implant onto distal tip of the handle. Fully seat implant against shoulder of handle.

3 Advance inner shaft fully into the instrument and implant.

4 Secure the implant by threading the proximal knob clockwise to a hard stop.

LEVA® PF INTERBODY DEVICE

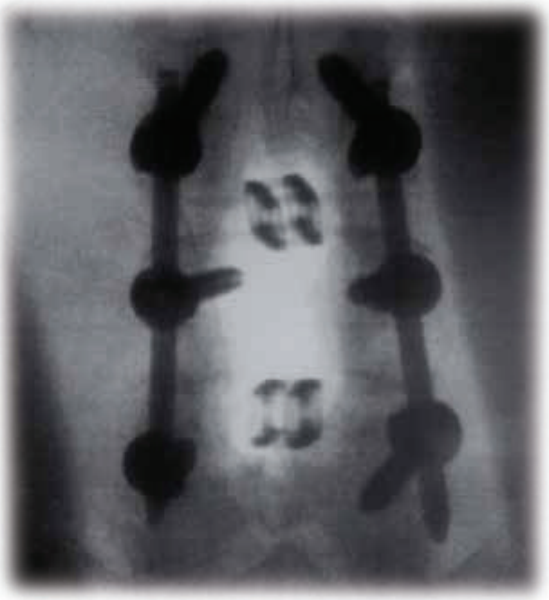
INSERTION

Insert the device into the disc space in the desired position and orientation. Use intra-operative imaging to confirm proper position and orientation of the device within the boundaries of the vertebral column.

When the implant is in desired position, the inserter is disengaged from the implant by turning the proximal knob counter clockwise and partially pulling the inner shaft out (by 2" or 5 cm). Once disengaged, the inserter is removed.

AP View

Lateral View



LEVA® PF INTERBODY DEVICE

GRAFTING

The implant is intended to be filled with autograft using a bone funnel, pick-ups or the GraftMag® Graft Delivery System. The implant's unique open architecture maximizes space for bone graft.

Grafting with a Funnel

This guide shows the grafting technique using a bone funnel and a large flat paddle tamp.

1 Place the funnel at the proximal end of the implant.

2 With the help of a plunger, back fill the inside of the implant with autograft material.

3 Bone tamps may be used to push and compact autograft material into the device (Figure 4).

Caution:
Do not impact on the funnel or plunger when grafting the Leva® Interbody Device.

FIGURE 4

Grafting with GraftMag® Graft Delivery System

The GraftMag® Graft Delivery System is an optimal solution for filling the implant post insertion.
The system offers a disposable option that allows the surgeon to deliver a large amount of bone graft quickly and efficiently. The open architecture of Leva® Interbody Device and the GraftMag® Graft Delivery System uniquely enable the complete, rapid, easy, and safe grafting of both the implant and the prepared disc space.

Note: *See GraftMag® Graft Delivery System Surgical Technique for more information.*

REMOVAL

Clear the central channel of the implant of tissue.
Use the inserter to re-engage the implant.
A slap hammer may be used to remove the implant if necessary.

LEVA® PF INTERBODY DEVICE SET

Catalog #	Description
10-7036.1	Fixed Inserter - Black Outer Handle 7, 8, 9 mm (25 mm)
10-7036.2	Fixed Inserter - Inner Shaft 7, 8, 9 mm (25 mm)
10-7037.1	Fixed Inserter - Black Outer Handle 10, 11, 12 mm (25 mm)
10-7037.2	Fixed Inserter - Inner Shaft 10, 11, 12 mm (25 mm)
10-7038.1	Fixed Inserter - Black Outer Handle 13, 14 mm (25 mm)
10-7038.2	Fixed Inserter - Inner Shaft 13, 14 mm (25 mm)
10-7045.1	Fixed Inserter - Gray Outer Handle 7, 8, 9 mm (22 mm)
10-7045.2	Fixed Inserter - Inner Shaft 7, 8, 9 mm (22 mm)
10-7046.1	Fixed Inserter - Gray Outer Handle 10, 11, 12 mm (22 mm)
10-7046.2	Fixed Inserter - Inner Shaft 10, 11, 12 mm (22 mm)
10-7047.1	Fixed Inserter - Gray Outer Handle 13, 14 mm (22 mm)
10-7047.2	Fixed Inserter - Inner Shaft 13, 14 mm (22 mm)
10-7047	Sizer - 7 mm
10-7048	Sizer - 8 mm
10-7049	Sizer - 9 mm
10-7050	Sizer - 10 mm
10-7051	Sizer - 11 mm
10-7052	Sizer - 12 mm
10-7053	Sizer - 13 mm
10-7054	Sizer - 14 mm
10-7023	Fixed Bone Tamp, 7-8-9 mm
10-7024	Fixed Bone Tamp, 10-11-12 mm
10-7025	Fixed Bone Tamp, 13-14 mm
10-1166	Round Funnel
10-1054	Round Tamp
10-1252	Rectangular Funnel
10-1253	Rectangular Plunger
10-7062	Small Flat Paddle Tamp
10-7063	Large Flat Paddle Tamp
10-2008	Slap Hammer

Important information on the Leva® Interbody Device

PRODUCT DESCRIPTION

The Leva® Implant is an intervertebral body fusion device fabricated from commercially pure titanium (ASTM F-67).

The Leva® Spacer System Implant is intended to be used with the Leva® Inserter Instrument to implant the device.

Please refer to the package insert accompanying the Leva® Inserter Instrument for important information on its use.

NOTE: Please refer to the package label of the Leva® Spacer System implant for the implant dimensions.

INTENDED USE

The Leva® Spacer System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Leva® Spacer System is to be used with autogenous bone graft and with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

CONTRAINDICATIONS

The Leva® Spacer System is contraindicated for:

- Morbid obesity
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
- Degenerative disease, other than Degenerative Disc Disease (DDD)
- Any case where the implants or components selected would be either too large or too small to achieve a successful result
- Uncorrectable coagulopathy or hemorrhagic diathesis
- Allergy to any component of the treatment procedure
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation
- Fever or leukocytosis
- Inadequate tissue coverage over the operative site or inadequate bone stock, or bone quality
- Anatomy or other factor that prohibits safe surgical access to the surgical body
- Spondylolisthesis unable to be reduced to Grade 1
- Pediatric case or case where patient still has general skeletal growth
- Active infection
- Any patient unwilling or unable to follow postoperative instructions
- Mental illness
- Pregnancy
- Any case in which fusion is not needed
- Prior fusion at the level to be treated
- Any case not described in the indications

HOW SUPPLIED - STERILIZATION

The Leva® Implant is supplied STERILE. Do not use if package is opened or damaged. SINGLE USE ONLY. This device is sterilized by exposure to gamma radiation. DO NOT RESTERILIZE.

STORAGE

Store in a cool, dry place.

WARNINGS AND PRECAUTIONS

- Surgical implants must never be reused. SINGLE-USE ONLY.
- Never reuse a surgical implant under any circumstances. Even when a removed implant appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.
- Do not use if package is opened or damaged or if expiration date has passed.
- This device is not intended to be the sole means of spinal support. The Leva® Implant must be used with additional internal spinal instrumentation.
- Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and vascular or visceral injury.
- The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Placement and adjustment of the Leva® Implant must only be done with the Leva® Inserter Instrument supplied with the system.
- Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fusion device.
- Provide the patient with adequate instructions for postoperative care. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on them in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration and damage to nerves or blood vessels.

- A successful result is not always achieved in every surgical case. This is especially true in spinal surgery where other patient conditions may compromise the results.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Preoperative and operative procedures, including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of the surgery.
- Proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.
- The Leva® Implant has not been evaluated for safety and compatibility in the MR environment. The Leva® Implant has not been tested for heating or migration in the MR environment.

POSSIBLE ADVERSE EFFECTS

All of the potential adverse events or complications associated with spinal fusion surgery with internal instrumentation are possible. Possible adverse events with the use of this system include but are not limited to:

- Early or late loosening of the components.
- Implant migration.
- Disassembly, bending, and /or breakage of any or all of the components.
- Implant material sensitivity, or allergic reaction to a foreign body, including tumor formation and/or autoimmunedisease.
- Infection, early or late.
- Dural tears, pseudomenigocele, fistula, persistent CSF leakage, meningitis.
- Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss and/or spasms.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Bone loss or decrease in bone density due to stress shielding.
- Subsidence of the device into the vertebral body or bodies.
- Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of spinal mobility or function resulting in inability to perform the activities of daily living.
- Pseudarthrosis, delayed union and/or mal-union.
- Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the autograft or at the autograft harvest site.
- Autograft donor site complications including pain, fracture, infection, or wound healing problems.
- Herniated nucleus pulposis, disc disruption or degeneration at, above, or below the level of surgery.
- Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise.
- Wound necrosis or wound dehiscence.
- Reproductive system compromise, including sterility. Loss of consortium, sexual dysfunction and retrograde ejaculation.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

PRODUCT COMPLAINTS

Any Health Care Professional who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify SPINE WAVE, INC. If any SPINE WAVE, Inc. product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, Spine Wave, Inc. should be notifed immediately by telephone, fax or written correspondence. When fling a complaint please provide the component(s) name, catalog number, lot number(s), your name and address, the nature of the complaint, and notifcation of whether a written report is requested.

INSERTER INSTRUMENT PROCESSING

Process the Inserter instruments (clean, lubricate with water soluble product such as instrument milk, and sterilize) as specified in the CLEANING AND DECONTAMINATION, LUBRICATION and STERILZATION sections of the package insert for the Inserter instrument.

PATENT INFORMATION

Covered by one or more U.S. patents or pattent applications.
See *www.spinewave.com/legal-notice.html*

NOTES

SPINE WAVE

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