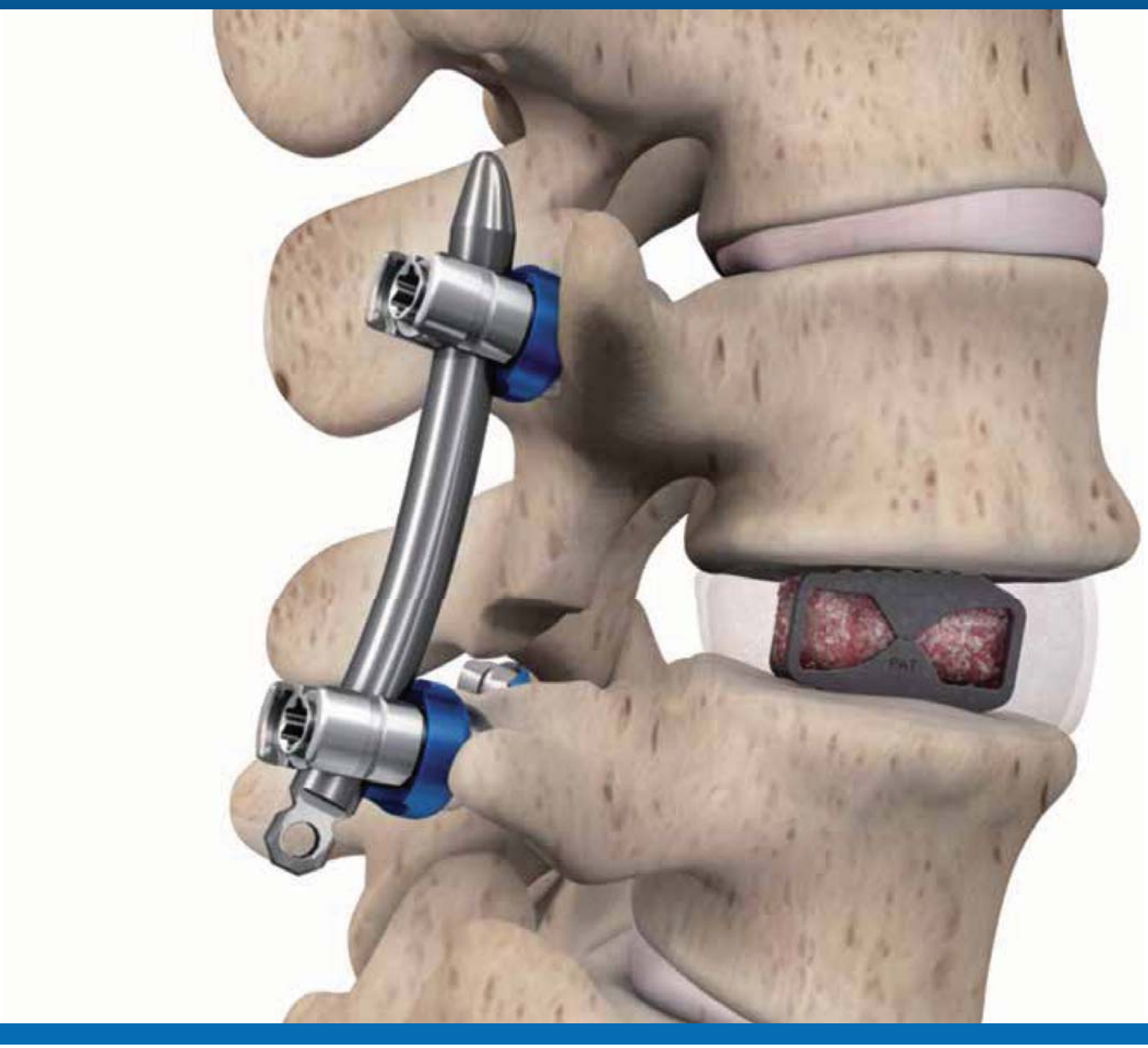
Leva® PX

Expandable 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 small insertion profile and in-situ expansion may ease insertion and help protect endplate integrity during placement. 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 and expansion.

A Special Thank You to Our Surgeon Advisors:

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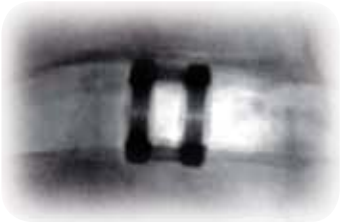
LEVA® INTERBODY DEVICE DESIGN RATIONALE

The Leva® Interbody Device System offers both expandable and fixed titanium implants. Both systems are optimized for ease of insertion and maximum bone grafting.

Maximum Bone Graft Capability

- Unique open architecture
- Maximum space for bone graft
- Up to 68.5%[1] of the total implant volume can be packed with bone graft



Posterior view of the Leva® PX implant

Post Expansion Grafting

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

4 mm Retractable Bullet Nose

- Allows easy insertion

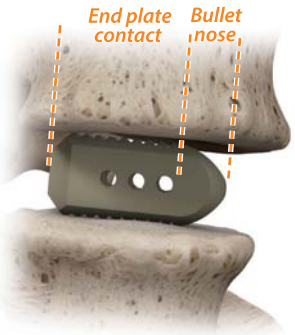
Leva® PF Interbody Device has the retractable bullet nose integrated to the inserter

Leva® PX Interbody Device has the retractable bullet nose on the implant

The retractable bullet nose is also designed to:

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

Typical PEEK Spacer



Leva® PX Interbody Device

[1]*Calculated using Leva® PX implant: 14 mm x 25 mm Convex*

LEVA® PX INTERBODY DEVICE : THE EXPANDABLE GRAFT CHAMBER

IMPLANT FOOTPRINTS

The Leva® PX interbody device is an expandable titanium implant optimized for ease of insertion and maximum bone grafting.

31 mm
unexpanded

25 mm
expanded

Final height measured at apex

Catalog #	Description	Label Color	Expansion Range[2]	Graft Volume in Cage
11-7107	Leva® PF 7 mm - 25 (L) x 10 (W) x 7 (H)	Yellow	7 mm Fixed	1.0 cc
11-7108	Leva® PF 8 mm - 25 (L) x 10 (W) x 8 (H)	Yellow	8 mm Fixed	1.1 cc
11-7109	Leva® PF 9 mm - 25 (L) x 10 (W) x 9 (H)	Yellow	9 mm Fixed	1.2 cc
11-7010	Leva® PX 10 mm - 25 (L) x 10 (W) x 10 (H)	Purple	8-10 mm	1.4 cc
11-7011	Leva® PX 11 mm - 25 (L) x 10 (W) x 11 (H)	Purple	9-11 mm	1.6 cc
11-7012	Leva® PX 12 mm - 25 (L) x 10 (W) x 12 (H)	Green	9-12 mm	1.8cc
11-7013	Leva® PX 13 mm - 25 (L) x 10 (W) x 13 (H)	Green	10-13 mm	1.9 cc
11-7014	Leva® PX 14 mm - 25 (L) x 10 (W) x 14 (H)	Green	11-14 mm	2.1 cc
11-7015	Leva® PX 15 mm - 25 (L) x 10 (W) x 15 (H)	White	11 - 15 mm	2.4 cc
11-7307	Leva® PF 7 mm - 22 (L) x 10 (W) x 7 (H)	Gray	7 mm Fixed	0.8 cc
11-7308	Leva® PF 8 mm - 22 (L) x 10 (W) x 8 (H)	Gray	8 mm Fixed	0.9 cc
11-7309	Leva® PF 9 mm - 22 (L) x 10 (W) x 9 (H)	Gray	9 mm Fixed	1.0 cc
11-7210	Leva® PX 10 mm - 22 (L) x 10 (W) x 10 (H)	Brown	8-10 mm	1.2 cc
11-7211	Leva® PX 11 mm - 22 (L) x 10 (W) x 11 (H)	Brown	9-11 mm	1.3 cc
11-7212	Leva® PX 12 mm - 22 (L) x 10 (W) x 12 (H)	Blue	9-12 mm	1.5 cc
11-7213	Leva® PX 13 mm - 22 (L) x 10 (W) x 13 (H)	Blue	10-13 mm	1.6 cc
11-7214	Leva® PX 14 mm - 22 (L) x10 (W) x 14 (H)	Blue	11-14 mm	1.8 cc

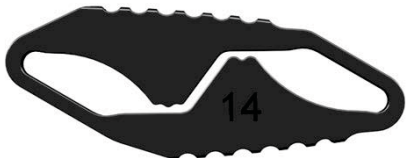
Note: The Leva® PX implant is designed to be fully expanded to final height.

[2] *Expansion range is defined as starting and final height.*

LEVA® PX INTERBODY DEVICE

IMPLANT FOOTPRINTS

The Leva® Interbody Device System is also available in a 10° lordotic option.



31 mm
unexpanded

25 mm
expanded

Final height measured at apex

Catalog #	Description	Label Color	Expansion Range[2]	Graft Volume in Cage
11-7022	Leva® PX 12 mm, 10° Lordotic - 25 (L) x 10 (W) x 12 (H)	Dashed Purple	10 - 12 mm	1.5 cc
11-7023	Leva® PX 13 mm, 10° Lordotic - 25 (L) x10 (W) x 13 (H)	Dashed Purple	11 - 13 mm	1.7 cc
11-7024	Leva® PX 14 mm, 10° Lordotic - 25 (L) x 10 (W) x 14 (H)	Dashed Green	11 - 14 mm	1.9 cc
11-7025	Leva® PX 15 mm, 10° Lordotic - 25 (L) x 10 (W) x 15 (H)	Dashed Green	12 - 15 mm	2.0 cc
11-7222	Leva® PX 12 mm, 10° Lordotic - 22 (L) x 10 (W) x 12 (H)	Dashed Brown	10 - 12 mm	1.3 cc
11-7223	Leva® PX 13 mm, 10° Lordotic - 22 (L) x 10 (W) x 13 (H)	Dashed Brown	11 - 13 mm	1.4 cc
11-7224	Leva® PX 14 mm, 10° Lordotic - 22 (L) x 10 (W) x 14 (H)	Dashed Blue	11 - 14 mm	1.6 cc

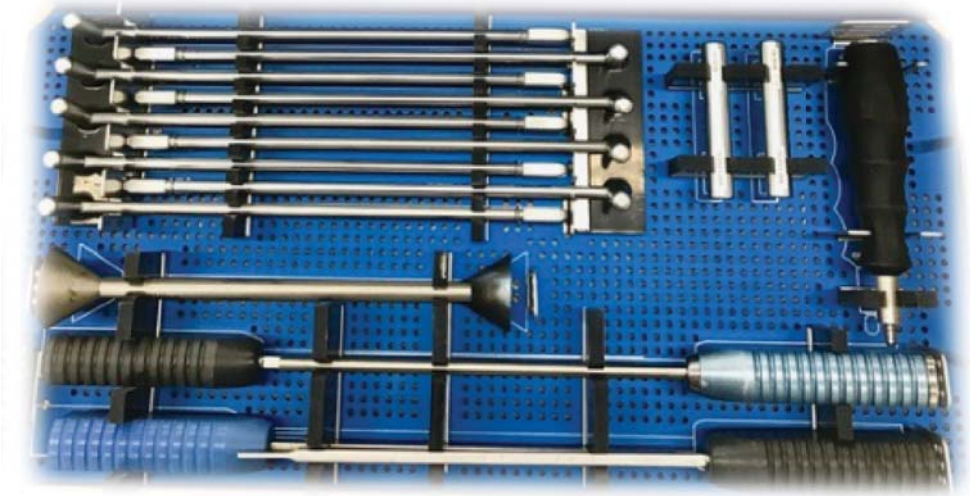
Note: The Leva® PX implant is designed to be fully expanded to final height.

[2] *Expansion range is defined as starting and final height.*

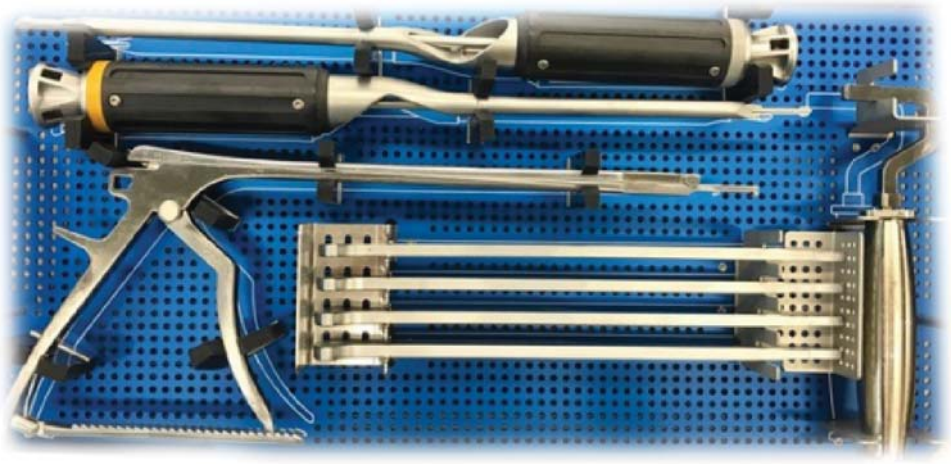
LEVA® PX INTERBODY DEVICE

INSTRUMENT OVERVIEW

Delivery Set One: Bottom Tray



Delivery Set One: Top Tray



Delivery Set Two: Top Tray

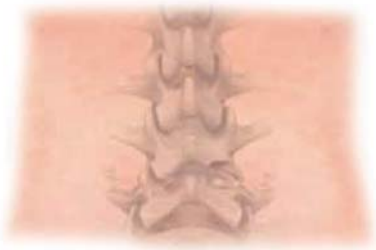
PRE-OPERATIVE PLANNING AND APPROACH

The Leva® Interbody Device is intended for posterior use.

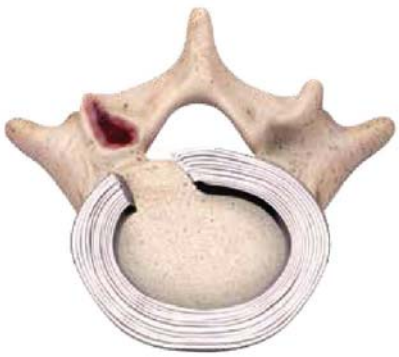
1 Perform pre-operative planning to ensure that the implant length and height offering is appropriate for the patient.

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.

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

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

FIGURE 2

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 difficult expansion, incomplete expansion and/or disruption of the vertebral endplate.

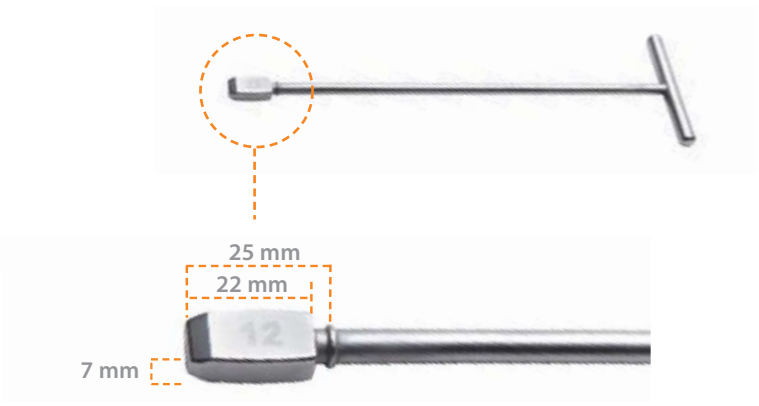


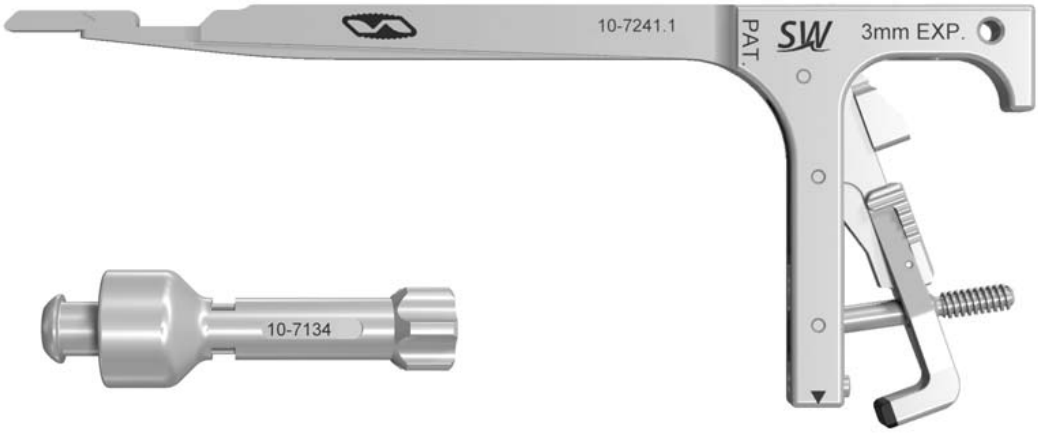
FIGURE 3

The Leva® Interbody Device system includes a Fixed (PF) and Expandable (PX) line

LEVA® INTERBODY DEVICE MIS INSERTER ASSEMBLY AND LOADING GUIDE

Inserter Handle

Loading Handle



Link Assembly

Counter Torque Handle

Handle Extension

STEP 1 INSERTER ASSEMBLY

Thread loading handle onto the inserter threaded post, turning clockwise until it bottoms out on the expansion arm. An audible click may be heard when the handle release captures the loading handle (Figure 4).

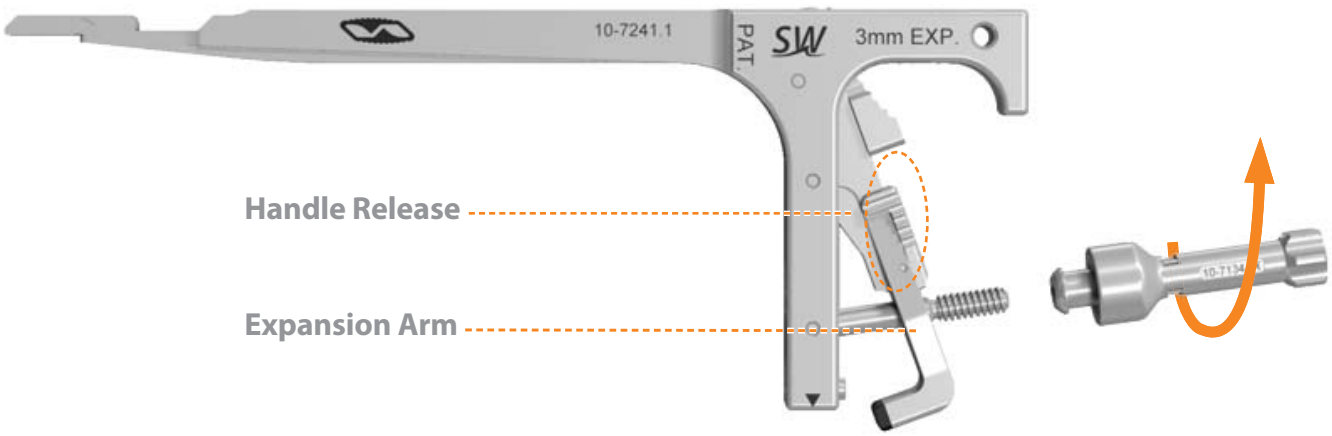
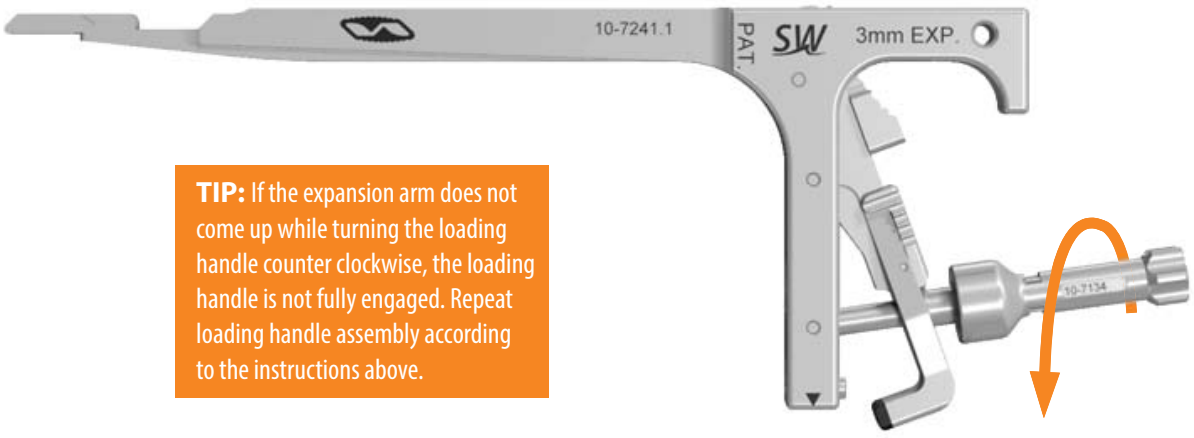


FIGURE 4

To reach the loading position, turn loading handle counter clockwise until it spins freely (Figure 5). The expansion arm must come up with the loading handle.



TIP: If the expansion arm does not come up while turning the loading handle counter clockwise, the loading handle is not fully engaged. Repeat loading handle assembly according to the instructions above.

FIGURE 5

STEP 2 SELECTING THE CORRECT LINK ASSEMBLY

The inserter handles have a number (2, 3 or 4) laser etched on top of the instrument. The link assemblies have a letter laser etched on top and on the side (A, B, C, D, E) (Figure 6a). The plaque (Figure 6b) is printed in the inserter tray.

Select the inserter handle and link assembly that match the alpha numeric combination corresponding to the color label on the implant box (Figure 6b).

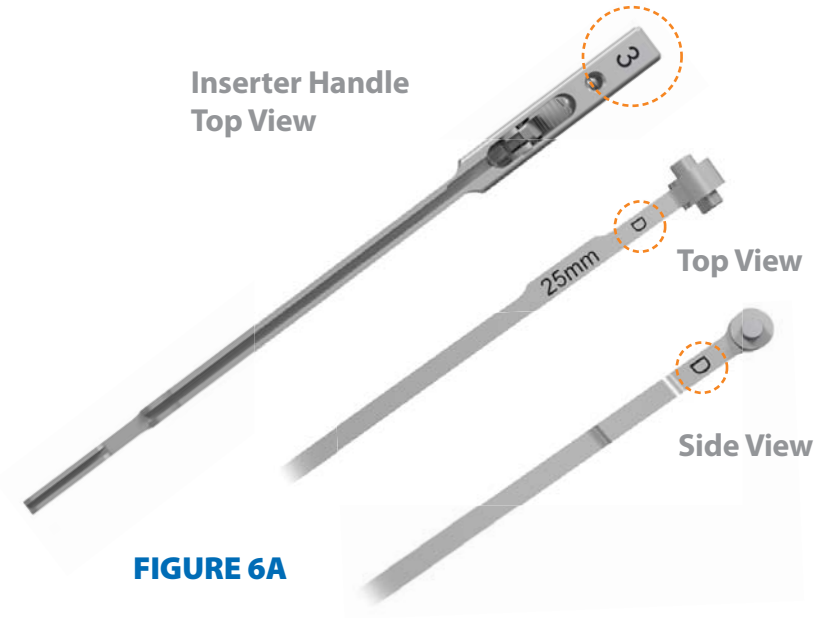


FIGURE 6A

IMPLANT LABEL	INSERTER
Brown	2A
Purple	2B
Blue	3C
Green	3D
White	4E

FIGURE 6B

Label Color	Inserter Handle/ Expansion Delta	Implant Length	Link Assembly	Final Apex Height
Brown	2 mm	22 mm	2A	10, 11 mm - Convex
Dashed Brown		22 mm	2A	12, 13 mm - 10° Lordotic
Purple		25 mm	2B	10, 11 mm - Convex
Dashed Purple		25 mm	2B	12, 13 mm - 10° Lordotic
Blue	3 mm	22 mm	3C	12, 13, 14 mm - Convex
Dashed Blue		22 mm	3C	14 mm - 10° Lordotic
Green		25 mm	3D	12, 13, 14 mm - Convex
Dashed Green		25 mm	3D	14, 15 mm - 10° Lordotic
White	4 mm	25 mm	4E	15 mm - Convex

To assemble the link assembly onto the inserter handle, pull back the single arrow button (Figure 7) and slide the link assembly into the fork shown in Figure 8. The implant length (22 mm or 25 mm) on the link assembly should be visible on top when properly assembled. Release the single arrow button to secure the link assembly (Figure 9).

FIGURE 7

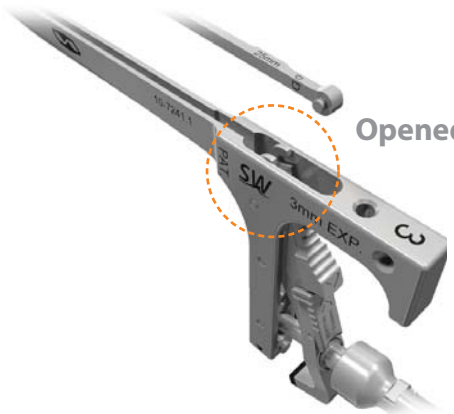


FIGURE 8

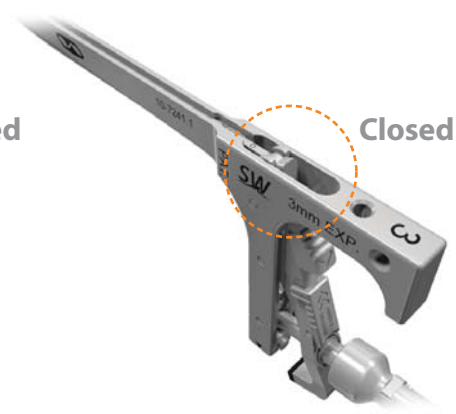


FIGURE 9

Hold the assembled inserter in your right hand so the implant image is visible on the side of the inserter. Hold the implant in your left hand so the size is readable. Match the orientation of the implant with the image on the inserter (Figure 10).

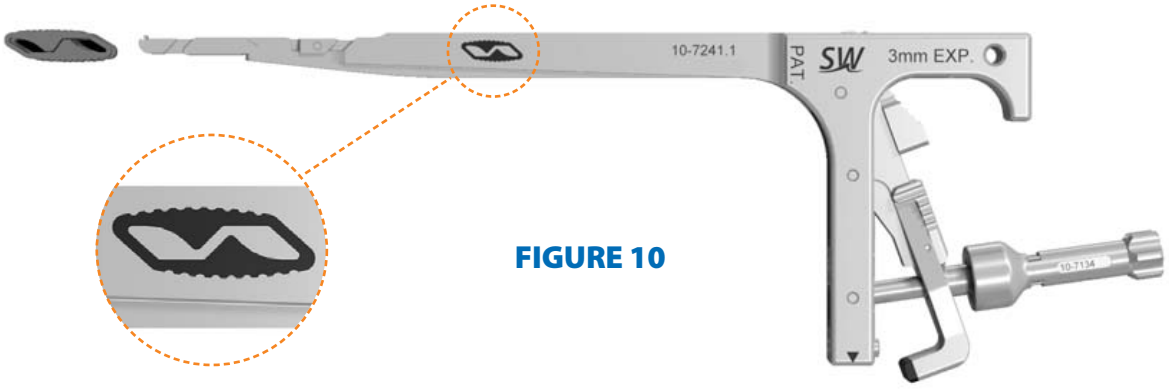


FIGURE 10

Insert the unexpanded implant onto the inserter until it is flush with the bottom edge of the inserter (Figure 11).

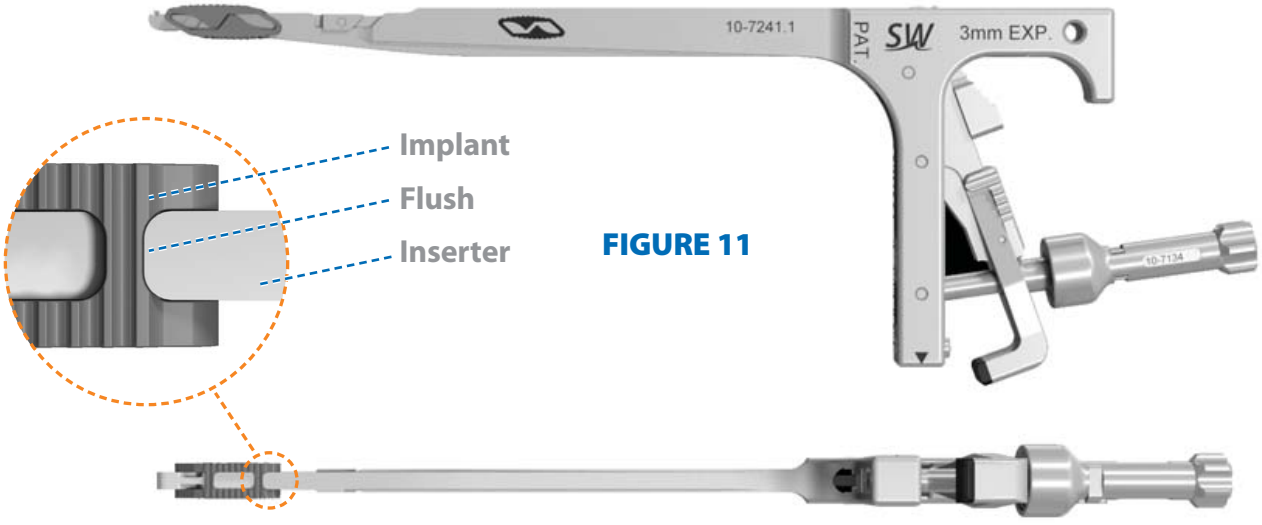


FIGURE 11

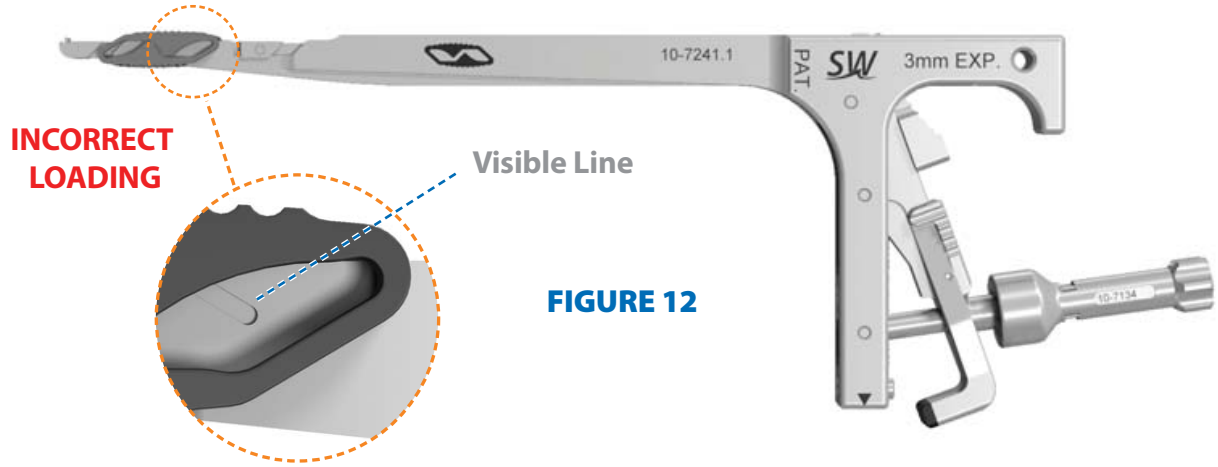


FIGURE 12

Note: If the implant is loaded incorrectly, a line will be visible (Figure 12).

Rotate the loading handle clockwise until it is finger tight (see Figure 13).

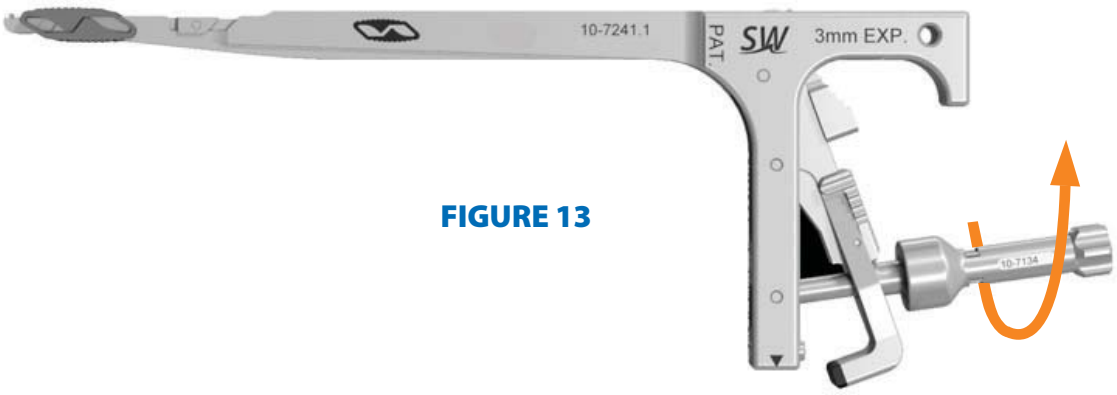


FIGURE 13

Attach the counter torque by screwing it into the proximal end of the inserter. The counter torque can be attached in three different orientations (see Figure 14).

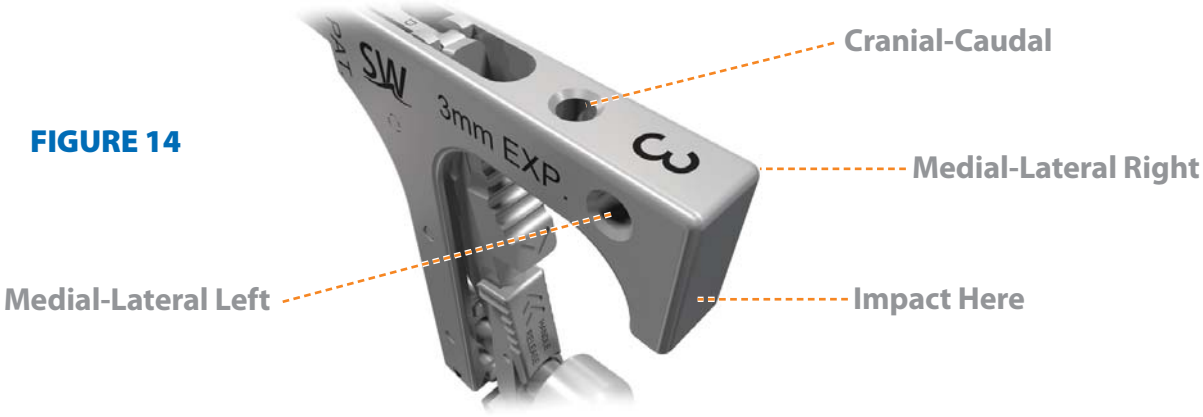


FIGURE 14

STEP 3 INSERTION INTO THE DISC SPACE

Once properly loaded, the implant is inserted into the desired position in the disc space. If necessary the inserter may be impacted on the back of the inserter handle (Figure 14). Caution: **DO NOT IMPACT ON THE LOADING HANDLE.**

Use intra-operative x-ray and/or fluoroscopy to confirm proper position in the A/P and lateral plane as well as the orientation of the device within the boundaries of the vertebral column (see Figure15).

FIGURE 15

Once the implant is inside the disc space and the proper location has been confirmed, assemble the handle extension onto the loading handle (See Figure 16). Do not impact with the handle extension attached.

FIGURE 16

STEP 4 EXPANDING THE IMPLANT

Ensure that the handle extension is fully engaged with the loading handle prior to expanding implant (Figure 17).

FIGURE 17

To expand the Leva® PX Device, turn the handle extension clockwise until a hard stop is reached (Figure 18).

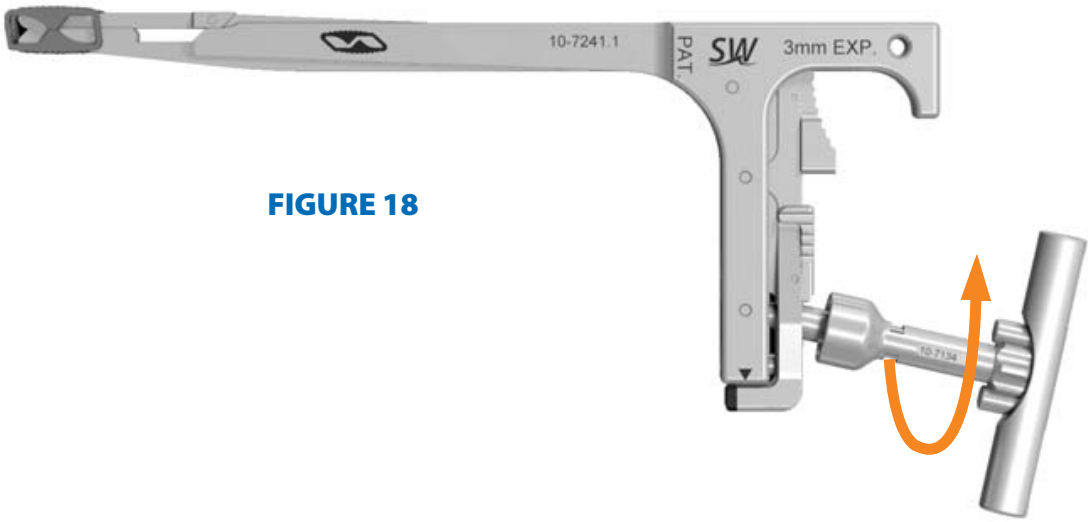


FIGURE 18

The implant will be fully expanded when the two pyramids align with each other.

Note: The Leva® PX Interbody Device is designed to be fully expanded. Failure to fully expand and lock may increase the risk of the device experiencing a partial or full return to the unexpanded state.

Confirming full expansion:

After reaching the hard stop:

- Turn handle extension counter clockwise three half turns or until the arrow is pointing in the black area.
- **REMOVE HANDLE EXTENSION.**
- Turn the loading handle clockwise until a hard stop is felt.
- If the point of the arrow indicator is in the black zone area or lined up with the black zone of the expansion arm, the implant is **NOT FULLY EXPANDED** and must be removed (Figure 19).
- If the point of the arrow indicator is pointing in the area outside the black zone of the expansion arm, the Leva® implant is **FULLY EXPANDED** (Figure 20).

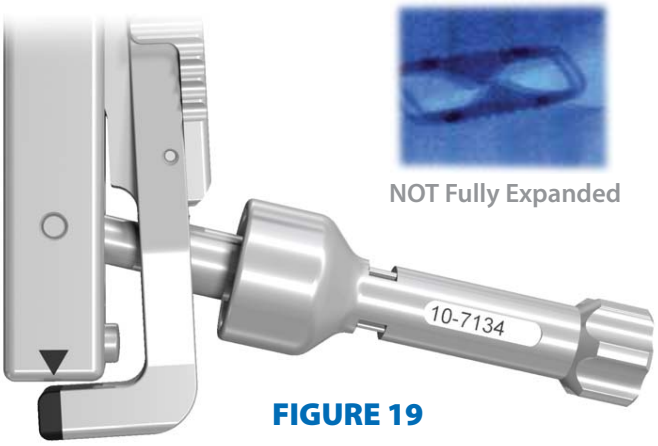


FIGURE 19

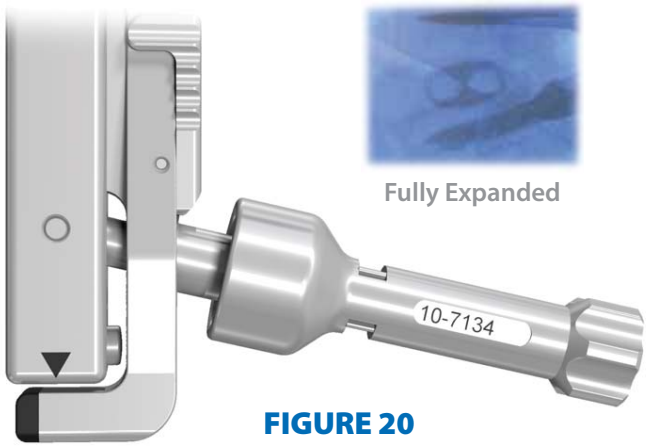


FIGURE 20

Note: A partially expanded implant should be removed and replaced.

STEP 5 REMOVING THE INSERTER FROM THE LEVA® INTERBODY DEVICE

Turn the loading handle counter clockwise until the inserter is in the initial load position (Figure 21). Pull the inserter straight back, paying attention not to twist or rotate the inserter. Place finger along the top length of the instrument during removal to maintain link assembly position.

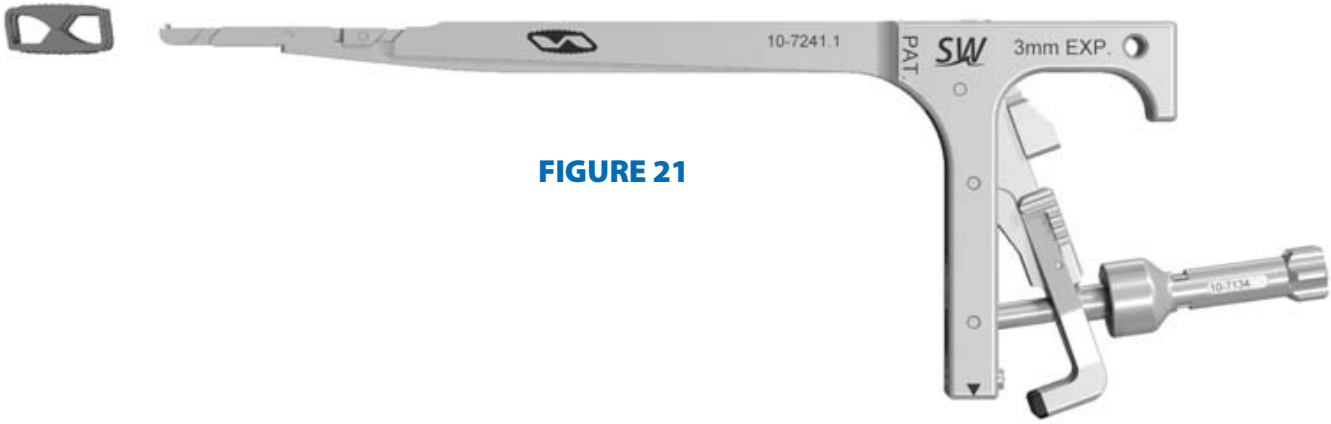


FIGURE 21

LEVA® INTERBODY DEVICE

GRAFTING

The implant is intended to be filled with autograft post expansion using a bone funnel, pick-ups or the GraftMag® Graft Delivery System. The implant's unique open architecture maximizes space for bone graft. The complete bone grafting of both the implant and the surrounding disc space occurs after its insertion and expansion.

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 22).

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

FIGURE 22

Grafting with GraftMag® Graft Delivery System

The GraftMag® Graft Delivery System is an optimal solution technique for filling the implant post expansion. 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 entire prepared disc space.

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

Grafting the Leva® implant, AP view

Grafting the Leva® implant, Lateral view

Note: Contrast has been added to the graft material for better visualization.

LEVA® PX INTERBODY DEVICE

DEVICE REMOVAL

Removing the Leva® PX Interbody Device:

The Leva® PX Expandable implant is designed to be a permanent implant.

The removal instrument is used to engage, collapse and retrieve the implant from the disc space. If removal is necessary, the following steps should be followed:

1. Clear the central channel of the implant of tissue.
2. Present the removal instrument to the proximal end of the implant.
3. Insert the distal end of the removal instrument into the central channel of the implant.
4. Hook to distal end of implant with distal end of instrument.
5. Squeeze removal instrument handle until it captures the implant and it is held securely.
6. Fully squeeze handle to collapse the implant.
7. A slap hammer may be used to facilitate the retrieval.

Refer to Leva® Interbody Device IFU for more information about the device.

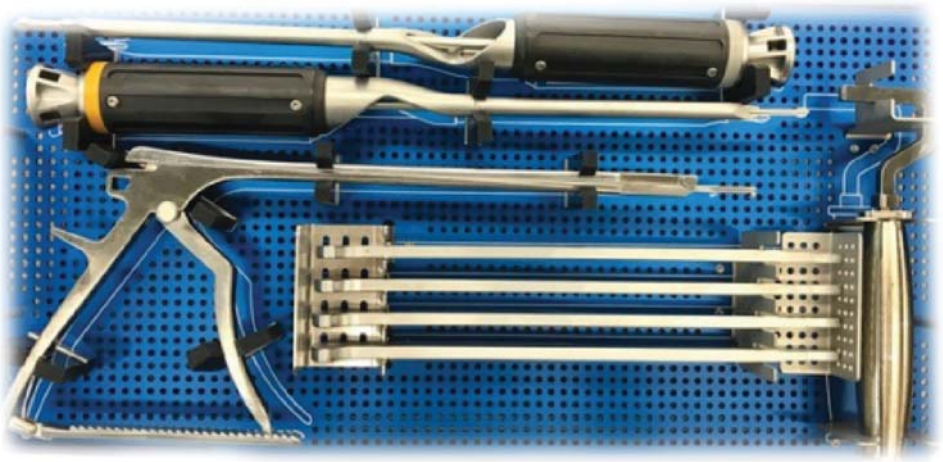
LEVA® PF INTERBODY DEVICE: THE TITANIUM GRAFT CHAMBER

IMPLANT OVERVIEW

The Leva® PF 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.

The implant configurations listed below are provided for those instances where a 7, 8 or 9 mm implant is desired.

Instrumentation used to facilitate insertion of the Leva® PF implant is provided in Delivery Set 2 tray.



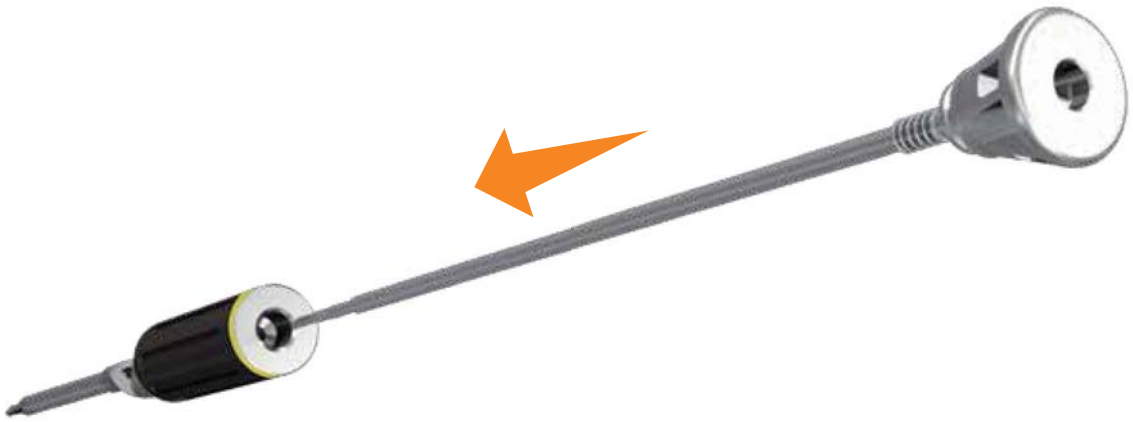
Catalog #	Description	Graft Volume in Cage
11-7107	Leva® PF 7 mm - 25 (L) x 10 (W) x 7 (H)	1.0 cc
11-7108	Leva® PF 8 mm - 25 (L) x 10 (W) x 8 (H)	1.1 cc
11-7109	Leva® PF 9 mm - 25 (L) x 10 (W) x 9 (H)	1.2 cc
11-7307	Leva® PF 7 mm - 22 (L) x 10 (W) x 7 (H)	0.8 cc
11-7308	Leva® PF 8 mm - 22 (L) x 10 (W) x 8 (H)	0.9 cc
11-7309	Leva® PF 9 mm - 22 (L) x 10 (W) x9 (H)	1.0 cc

LEVA® PF INTERBODY DEVICE

INSERTER ASSEMBLY

Fixed Handle

Fixed Inner Shaft



Insert fixed inner shaft into the proximal
end of the handle three quarter through.
For implant loading refer to instruction on page 24.

LEVA® PF INTERBODY DEVICE

IMPLANT LOADING

The Leva® PF fixed interbody implants are labelled to show apex heights.
Leva® PF implant labels are color coded to match the corresponding inserter handle ring.

Outer Handle Ring	Label Color	Implant Length	Final Apex Height
Gray	Gray	22 mm	7, 8, 9 mm- Convex
Yellow	Yellow	25 mm	7, 8, 9 mm- Convex

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.

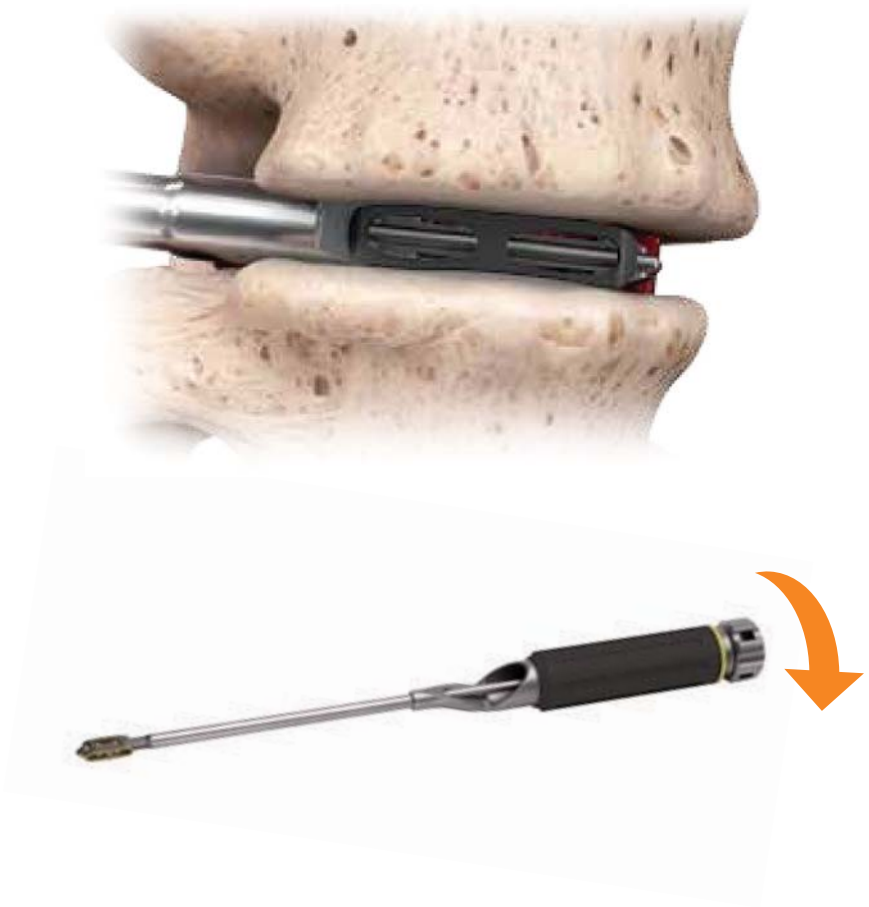
4 Secure the implant by threading the proximal knob clockwise to a hard stop.

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.



Grafting

For grafting technique of the Leva® PF Interbody Device, refer to grafting technique for Leva® PX Interbody Device on page 19.

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® PX • DELIVERY SET ONE

10-7101

Catalog #	Description
10-7240.1	Leva® PX Purple/ Brown Inserter Assembly - 2 mm
10-7131.2	Leva® PX Purple Link Assembly
10-7131.3	Leva® PX Brown Link Assembly
10-7241.1	Leva® PX Green/ Blue Inserter Assembly - 3 mm
10-7132.2	Leva® PX Green Link Assembly
10-7132.3	Leva® PX Blue Link Assembly
10-7242.1	Leva® PX White Inserter Assembly - 4 mm
10-7133.2	Leva® PX White Link Assembly
10-7134	Loading Handle
10-7129	Long Handle Assembly - Counter Torque
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
10-7055	Sizer - 15 mm
10-7062	Small Flat Paddle Tamp
10-7063	Large Flat Paddle Tamp
10-7080	Tabbed Bone Funnel
10-1054	Round Tamp
10-1252	Rectangular Funnel
10-1253	Rectangular Plunger
10-7018	Handle Extension

LEVA® PX • DELIVERY SET TWO

10-7102

Catalog #	Description
10-7014	Leva® Expandable Removal Instrument
10-7043.1	Outer Handle Assy - (L) 22 mm - (H) 7-8-9 mm
10-7043.2	Inner Shaft Assy - (L) 22 mm - (H) 7-8-9 mm
10-7035.1	Outer Handle Assy - (L) 25 mm - (H) 7-8-9 mm
10-7035.2	Inner Shaft Assy - (L) 25 mm - (H) 7-8-9 mm
10-2008	Slap Hammer
10-7026	Bone Tamp, 7 mm - 9 mm
10-7027	Bone Tamp, 10 mm-11 mm
10-7028	Bone Tamp, 12 mm-14 mm
10-7029	Bone Tamp, 15 mm

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® Implant is available in both a fixed and an expandable configuration.
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.
- The Leva® Implant is only intended to be deployed once.
- 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.
- The Expandable Implant is not intended to be left implanted in an unexpanded state.
- If the implant is left implanted without being fully expanded, the risk increases of the implant returning to its unexpanded state, which may lead to early breakage.
- 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 notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name, catalog number, lot number(s), your name and address, the nature of the complaint, and notification 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 STERILIZATION sections of the package insert for the Inserter instrument.

PATENT INFORMATION

Covered by one or more U.S. patents or patent applications. See www.spinewave.com/contact_legal.html

NOTES

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