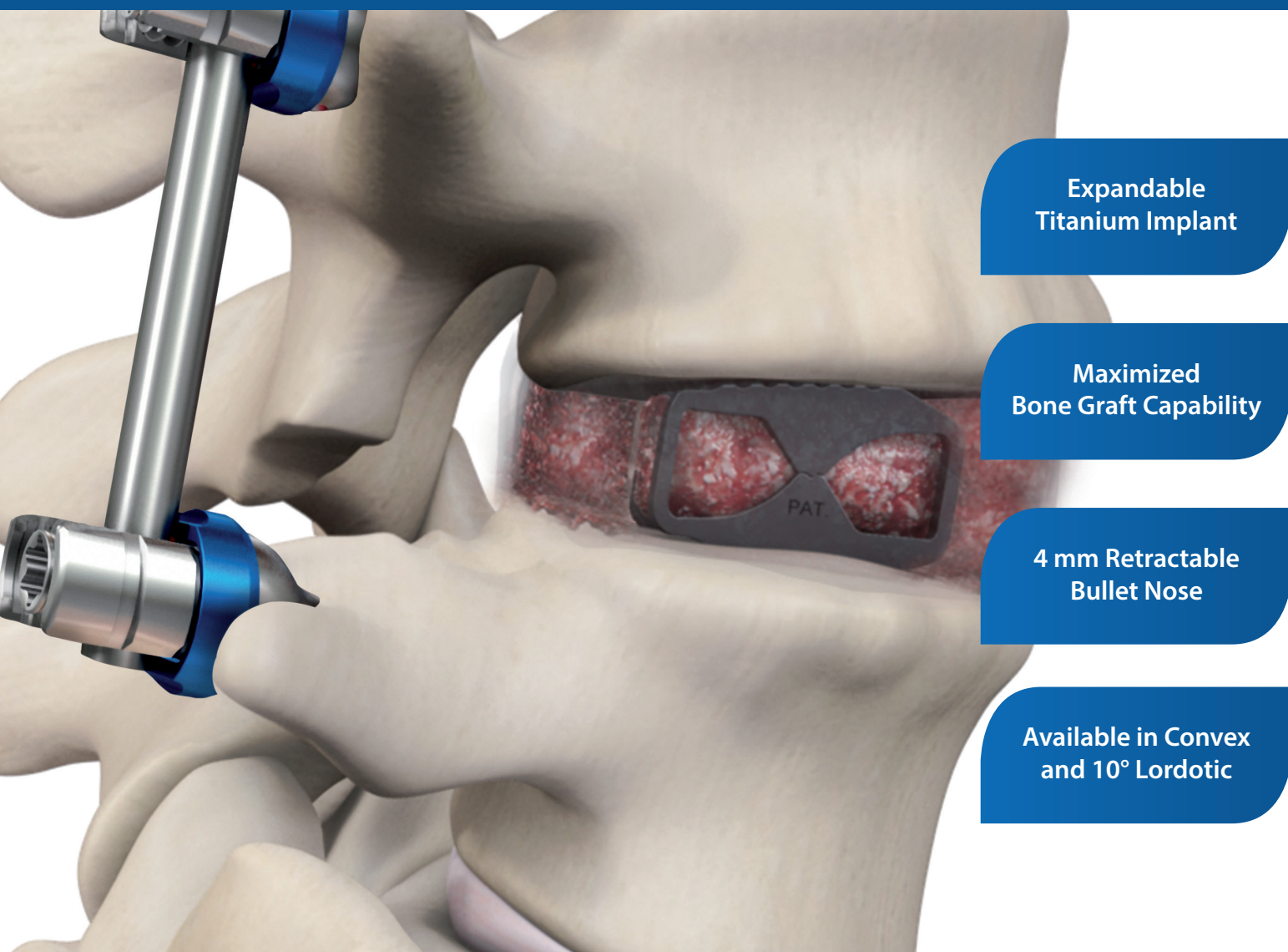


The Expandable Graft Chamber



Expandable
Titanium Implant

Maximized
Bone Graft Capability

4 mm Retractable
Bullet Nose

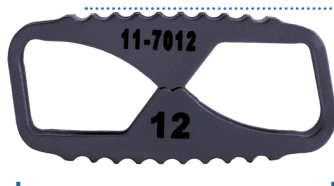
Available in Convex
and 10° Lordotic

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

Expandable Titanium



31mm unexpanded



25mm expanded

Final height measured at apex.

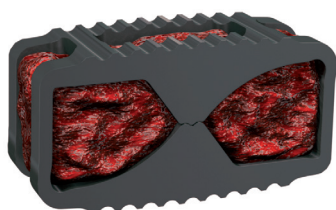


31mm unexpanded



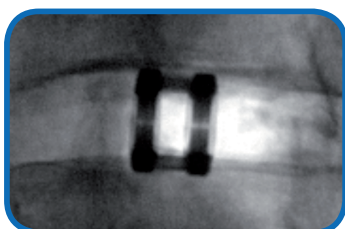
25mm expanded

Final height measured at apex.



Maximum Bone Graft Capability

- Unique open architecture
- Maximum space for bone graft
- Up to 68.5%² of the total implant volume can be packed with bone graft.



Posterior View of the Leva® PX implant

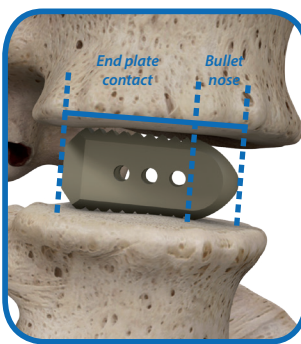
Post expansion grafting

- The Leva® PX Interbody Device enables complete bone grafting of both the implant and the surrounding disc space after its insertion and expansion.

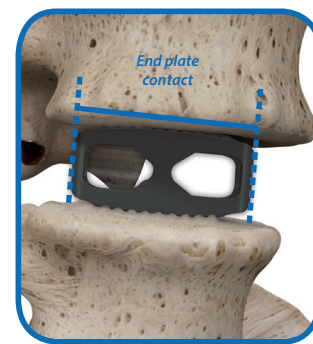
4 mm Retractable Bullet Nose



Typical PEEK Spacer



Leva® PX Interbody Device



- Allows easy insertion
- Provides more room for bone graft once expanded
- Enables end plate contact with the device along its full length.

¹ 14mm (H) X 25mm (L) Lordotic shown. For sizing chart refer to table on page 4.

² 14mm implant.

Leva® PX Interbody Device Case review:

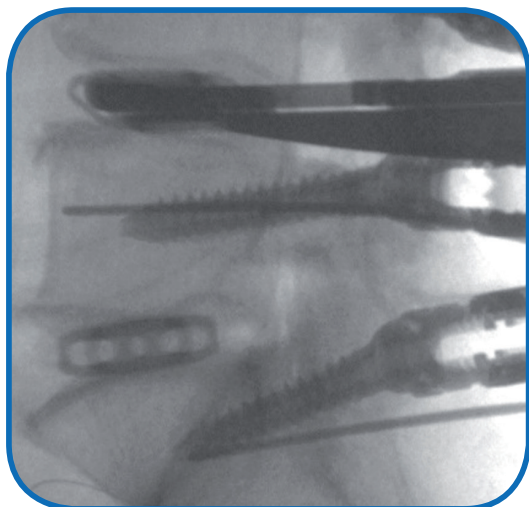
Patient Profile:

66 y.o. male with chronic bilateral radiculopathy, neurogenic claudication, and low back pain due to bilateral foraminal stenosis at L4-5 and L5-S1 and instability at L4-5.

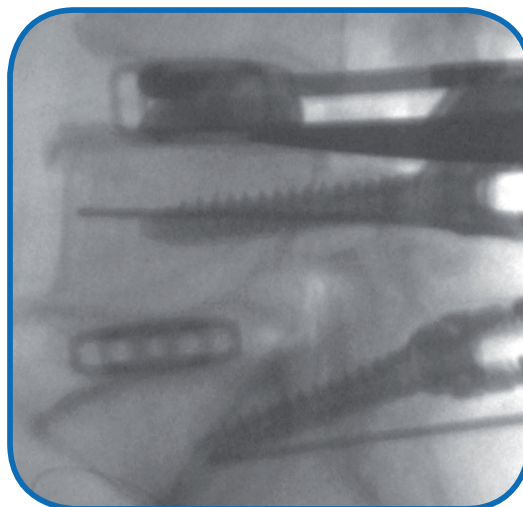
Treatment:

Patient was treated at L4-5 and L5-S1 with MIS TLIF with Sniper® MIS Screws, fixed Leva® 25mm (L) X 10mm (W) X 8mm (H) implant at L5-S1 and expandable Leva® 25mm (L) X 10mm (W) X 12mm (H) (9-12mm) implant at L4-5 (9 -12 mm).

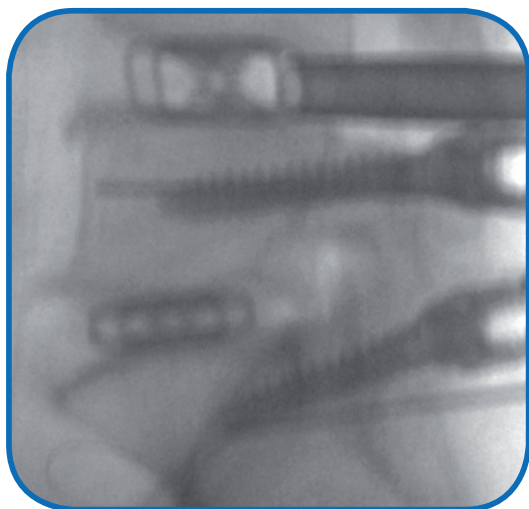
L4-5 Leva® Interbody Device pre-expansion (9mm)



L4-5 Leva® Interbody Device post-expansion (12mm)



L4-5 disc space before packing bone graft with funnel in place



L4-5 cage with 13 cc of bone graft packed through the cage.



Clinical Observations

- Leg pain improved within 2 weeks, low back pain improved within 3 months post-operatively.
- Cage expansion increased the disc height and foraminal height bilaterally.
- Open cage geometry allowed for easy packing of 13 cc's of bone graft material through specialized funnels post-expansion using the same small annulotomy of the MIS TLIF approach.

The results documented in this case are unique to this patient. Results may vary. There are risks associated with minimally invasive spine surgery. Please refer to the product package insert for complete product information, including contraindications, warnings and precautions, and possible adverse effects.

The Leva® System is an intervertebral body fusion device intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Leva® 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.

Catalog #	Description	Label Color	Expansion Range	Graft Volume
11-7107	Leva® PF 7mm - 25 (L) x10 (W) x7 (H)	Yellow	7mm Fixed	0.9cc
11-7108	Leva® PF 8mm - 25 (L) x10 (W) x8 (H)	Yellow	8mm Fixed	1.0cc
11-7109	Leva® PF 9mm - 25 (L) x10 (W) x9 (H)	Yellow	9mm Fixed	1.1cc
11-7010	Leva® PX 10mm - 25 (L) x10 (W) x10 (H)	Purple	8 - 10mm	1.4cc
11-7011	Leva® PX 11mm - 25 (L) x10 (W) x11 (H)	Purple	9 - 11mm	1.6cc
11-7012	Leva® PX 12mm - 25 (L) x10 (W) x12 (H)	Green	9 - 12mm	1.8cc
11-7013	Leva® PX 13mm - 25 (L) x10 (W) x13 (H)	Green	10 - 13mm	1.9cc
11-7014	Leva® PX 14mm - 25 (L) x10 (W) x14 (H)	Green	11 - 14mm	2.1cc
11-7307	Leva® PF 7mm - 22 (L) x10 (W) x7 (H)	Gray	7mm Fixed	0.8cc
11-7308	Leva® PF 8mm - 22 (L) x10 (W) x8 (H)	Gray	8mm Fixed	0.9cc
11-7309	Leva® PF 9mm - 22 (L) x10 (W) x9 (H)	Gray	9mm Fixed	1.0cc
11-7210	Leva® PX 10mm - 22 (L) x10 (W) x10 (H)	Brown	8 - 10mm	1.2cc
11-7211	Leva® PX 11mm - 22 (L) x10 (W) x11 (H)	Brown	9 - 11mm	1.3cc
11-7212	Leva® PX 12mm - 22 (L) x10 (W) x12 (H)	Blue	9 - 12mm	1.5cc
11-7213	Leva® PX 13mm - 22 (L) x10 (W) x13 (H)	Blue	10 - 13mm	1.6cc
11-7214	Leva® PX 14mm - 22 (L) x10 (W) x14 (H)	Blue	11 - 14mm	1.8cc

11-7022	Leva® PX 12mm, 10° Lordotic - 25 (L) X10 (W) X 12 (H)	Dashed Purple	10 - 12mm	1.5cc
11-7023	Leva® PX 13mm, 10° Lordotic - 25 (L) X10 (W) X 13 (H)	Dashed Purple	11 - 13mm	1.7cc
11-7024	Leva® PX 14mm, 10° Lordotic - 25 (L) X10 (W) X 14 (H)	Dashed Green	11 - 14mm	1.9cc
11-7025	Leva® PX 15mm, 10° Lordotic - 25 (L) X10 (W) X 15 (H)	Dashed Green	12 - 15mm	2.0cc
11-7222	Leva® PX 12mm, 10° Lordotic - 22 (L) X10 (W) X 12 (H)	Dashed Brown	10 - 12mm	1.3cc
11-7223	Leva® PX 13mm, 10° Lordotic - 22 (L) X10 (W) X 13 (H)	Dashed Brown	11 - 13mm	1.4cc
11-7224	Leva® PX 14mm, 10° Lordotic - 22 (L) X10 (W) X 14 (H)	Dashed Blue	11 - 14mm	1.6cc

SPINEWAVE

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