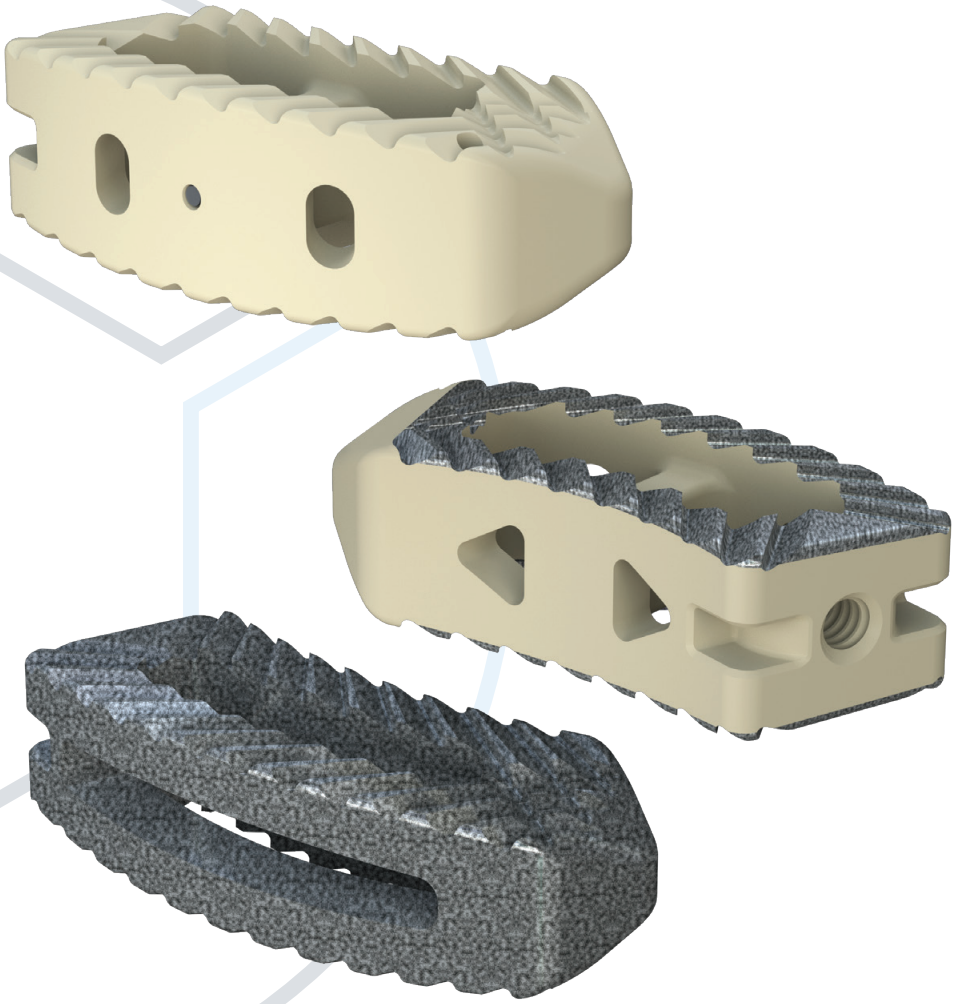
SAVANT™ TRANSFORAMINAL LUMBAR INTERBODY FUSION SYSTEM

LUMBAR INTERBODY



Surgical Technique Guide

CURITEVA®

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SAVANT™

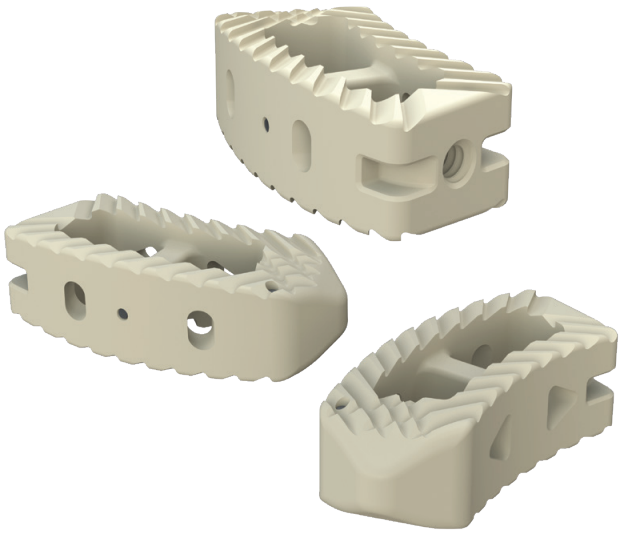
TRANSFORAMINAL LUMBAR INTERBODY FUSION SYSTEM

Disclaimer

The surgical technique shown is for illustrative purposes only. Proper surgical procedure is the responsibility of the medical professional. Please reference the package insert for additional information and system instructions.

SAVANT™ PEEK Transforaminal Lumbar Interbody Fusion System

The Savant PEEK Transforaminal Lumbar (TLIF) Interbody Fusion System anatomical design delivers intraoperative versatility and performance. The interbody is offered in multiple footprints, heights and lordosis providing an ideal fit for every patient. The Savant Interbody Fusion System features instrumentation that allows for better control and more precise implant placement.



PEEK Interbody

Part Number: C404-XXXXYY-Z

XXXX - Interbody Footprint, YY - Interbody Height, Z - Lordosis

- PEEK construction
- Footprints (mm): 28L x 9W, 28L x 11W, 32L x 9W and 32L x 11W
- Heights: 6 – 16mm, offered in 1mm increments
- Lordosis: 0° or 8°

32L x 11W

32L x 9W

28L x 11W

28L x 9W

Savant Features

- Convex design offers a more accurate fit to the patient's anatomy
- Central and lateral graft windows for biologic seeding
- Contoured, distracting nose to facilitate placement
- Multi-directional teeth resist migration
- Strategically positioned tantalum markers for greater visualization and placement
- Comprehensive discectomy instruments
- Full range of Trials for proper sizing of implant height
- Angled lateral windows on anterior side of implant to retain bone graft during insertion
- Large back surface area for increased instrument interface
- Maximum surface area for endplate contact

SAVANT™ PEEK Transforaminal Lumbar Interbody Fusion System

PEEK TLIF Interbodies

28mm Length, 9mm Width, 0°

Height	Catalog Number
6mm	C404-280906-0
7mm	C404-280907-0
8mm	C404-280908-0
9mm	C404-280909-0
10mm	C404-280910-0
11mm	C404-280911-0
12mm	C404-280912-0
13mm	C404-280913-0
14mm	C404-280914-0
15mm	C404-280915-0
16mm	C404-280916-0

28mm Length, 11mm Width, 0°

Height	Catalog Number
6mm	C404-281106-0
7mm	C404-281107-0
8mm	C404-281108-0
9mm	C404-281109-0
10mm	C404-281110-0
11mm	C404-281111-0
12mm	C404-281112-0
13mm	C404-281113-0
14mm	C404-281114-0
15mm	C404-281115-0
16mm	C404-281116-0

32mm Length, 9mm Width, 0°

Height	Catalog Number
6mm	C404-320906-0
7mm	C404-320907-0
8mm	C404-320908-0
9mm	C404-320909-0
10mm	C404-320910-0
11mm	C404-320911-0
12mm	C404-320912-0
13mm	C404-320913-0
14mm	C404-320914-0
15mm	C404-320915-0
16mm	C404-320916-0

32mm Length, 11mm Width, 0°

Height	Catalog Number
6mm	C404-321106-0
7mm	C404-321107-0
8mm	C404-321108-0
9mm	C404-321109-0
10mm	C404-321110-0
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12mm	C404-321112-0
13mm	C404-321113-0
14mm	C404-321114-0
15mm	C404-321115-0
16mm	C404-321116-0

28mm Length, 9mm Width, 8°

Height	Catalog Number
7mm	C404-280907-8
8mm	C404-280908-8
9mm	C404-280909-8
10mm	C404-280910-8
11mm	C404-280911-8
12mm	C404-280912-8
13mm	C404-280913-8
14mm	C404-280914-8
15mm	C404-280915-8
16mm	C404-280916-8

28mm Length, 11mm Width, 8°

Height	Catalog Number
7mm	C404-281107-8
8mm	C404-281108-8
9mm	C404-281109-8
10mm	C404-281110-8
11mm	C404-281111-8
12mm	C404-281112-8
13mm	C404-281113-8
14mm	C404-281114-8
15mm	C404-281115-8
16mm	C404-281116-8

32mm Length, 9mm Width, 8°

Height	Catalog Number
7mm	C404-320907-8
8mm	C404-320908-8
9mm	C404-320909-8
10mm	C404-320910-8
11mm	C404-320911-8
12mm	C404-320912-8
13mm	C404-320913-8
14mm	C404-320914-8
15mm	C404-320915-8
16mm	C404-320916-8

32mm Length, 11mm Width, 8°

Height	Catalog Number
7mm	C404-321107-8
8mm	C404-321108-8
9mm	C404-321109-8
10mm	C404-321110-8
11mm	C404-321111-8
12mm	C404-321112-8
13mm	C404-321113-8
14mm	C404-321114-8
15mm	C404-321115-8
16mm	C404-321116-8

Interbody Details

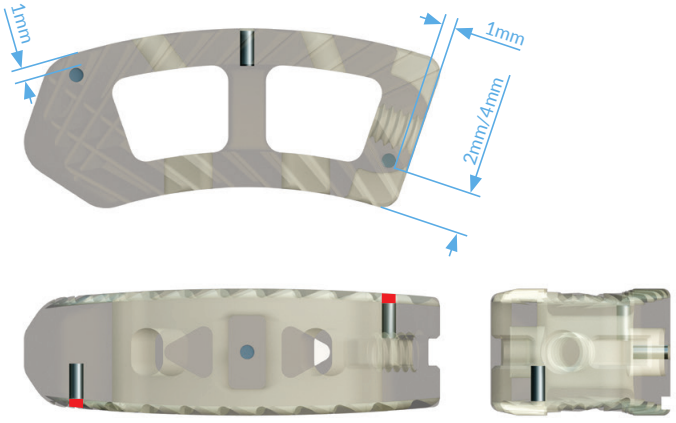
- Angled lateral windows on anterior side of implant
- Internal radius for 28 & 32mm length is 1.25”

Radiographic Markers

- 3 Pins per interbody – 2 lateral & 1 central
- Pin length: 2.5mm; 1mm diameter
- Lateral pins offset .64mm (tooth depth) from endplate (identified in red)
- Anterior pin centered on midline and flush against anterior wall

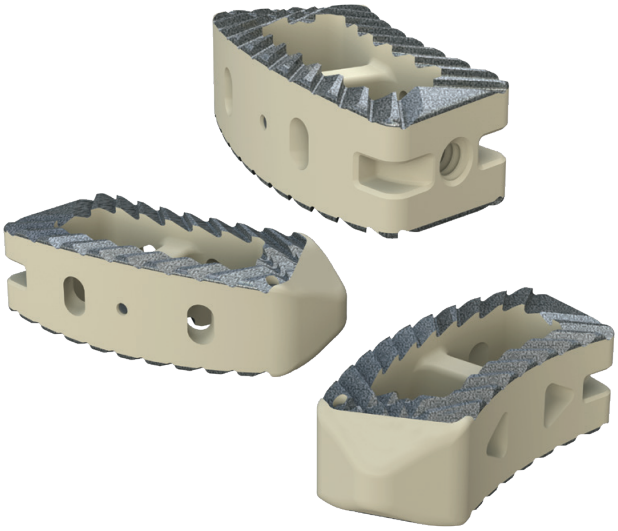
Lateral Windows

- 6mm - No Window
- 7 - 11mm - Standard Windows
- 12 - 16mm - Split Windows



SAVANT™ PEEK Transforaminal Lumbar Interbody Fusion System
Featuring Titanium Plasma Coating

The Savant Titanium Plasma Coated Transforaminal Lumbar Interbody Fusion System (TLIF) is designed to offer immediate stability and long-term fixation. The interbody is manufactured out of PEEK with a titanium plasma spray coating. The titanium porous coating creates topographical properties and provides fluoroscopic endplate visualization. The interbody is offered in a variety of footprints, heights and angles.



PEEK Interbody with Coating

Part Number: C424-XXXXYY-ZCT

XXXX - Interbody Footprint, YY - Interbody Height, Z - Lordosis

- PEEK Construction with Titanium Plasma Coating
- Footprints (mm): 28L x 9W, 28L x 11W, 32L x 9W and 32L x 11W
- Heights: 6 – 16mm, offered in 1mm increments
- Lordosis: 0° or 8°

32L x 11W

32L x 9W

28L x 11W

28L x 9W

Savant Features

- Surface topography produces superior implant contact and construct stability
- Modulus of elasticity between cortical and cancellous bone for optimal load sharing
- Designed to ensure a high degree of compressive strength and dimensional stability
- Optimal Radiolucency
- Comprehensive discectomy instruments
- Full range of Trials for proper sizing of implant height
- Ergonomically shaped anterior edges
- Tantalum radiopaque markers to optimize visibility and placement
- Multi-directional teeth resist migration
- Self-distracting leading edge to facilitate implant insertion

SAVANT™ PEEK Transforaminal Lumbar Interbody Fusion System Featuring Titanium Plasma Coating

Titanium Plasma Coated PEEK TLIF Interbodies

28mm Length, 9mm Width, 0°

Height	Catalog Number
6mm	C424-280906-0CT*
7mm	C424-280907-0CT*
8mm	C424-280908-0CT*
9mm	C424-280909-0CT*
10mm	C424-280910-0CT*
11mm	C424-280911-0CT*
12mm	C424-280912-0CT*
13mm	C424-280913-0CT*
14mm	C424-280914-0CT*
15mm	C424-280915-0CT*
16mm	C424-280916-0CT*

28mm Length, 11mm Width, 0°

Height	Catalog Number
6mm	C424-281106-0CT*
7mm	C424-281107-0CT*
8mm	C424-281108-0CT*
9mm	C424-281109-0CT*
10mm	C424-281110-0CT*
11mm	C424-281111-0CT*
12mm	C424-281112-0CT*
13mm	C424-281113-0CT*
14mm	C424-281114-0CT*
15mm	C424-281115-0CT*
16mm	C424-281116-0CT*

32mm Length, 9mm Width, 0°

Height	Catalog Number
6mm	C424-320906-0CT*
7mm	C424-320907-0CT*
8mm	C424-320908-0CT*
9mm	C424-320909-0CT*
10mm	C424-320910-0CT*
11mm	C424-320911-0CT*
12mm	C424-320912-0CT*
13mm	C424-320913-0CT*
14mm	C424-320914-0CT*
15mm	C424-320915-0CT*
16mm	C424-320916-0CT*

32mm Length, 11mm Width, 0°

Height	Catalog Number
6mm	C424-321106-0CT*
7mm	C424-321107-0CT*
8mm	C424-321108-0CT*
9mm	C424-321109-0CT*
10mm	C424-321110-0CT*
11mm	C424-321111-0CT*
12mm	C424-321112-0CT*
13mm	C424-321113-0CT*
14mm	C424-321114-0CT*
15mm	C424-321115-0CT*
16mm	C424-321116-0CT*

28mm Length, 9mm Width, 8°

Height	Catalog Number
7mm	C424-280907-8CT*
8mm	C424-280908-8CT*
9mm	C424-280909-8CT*
10mm	C424-280910-8CT*
11mm	C424-280911-8CT*
12mm	C424-280912-8CT*
13mm	C424-280913-8CT*
14mm	C424-280914-8CT*
15mm	C424-280915-8CT*
16mm	C424-280916-8CT*

28mm Length, 11mm Width, 8°

Height	Catalog Number
7mm	C424-281107-8CT*
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32mm Length, 9mm Width, 8°

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32mm Length, 11mm Width, 8°

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13mm	C424-321113-8CT*
14mm	C424-321114-8CT*
15mm	C424-321115-8CT*
16mm	C424-321116-8CT*

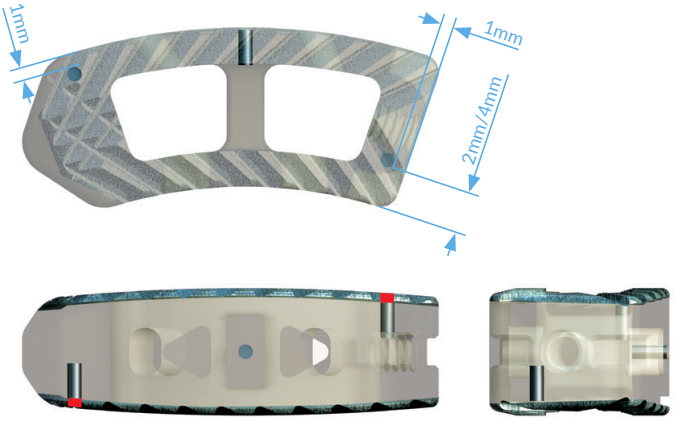
**Available by request*

Interbody Details

- Angled lateral windows on anterior side of implant
- Internal radius for 28 & 32mm length to be 1.25”

Radiographic Markers

- 3 Pins per interbody – 2 lateral & 1 central
- Pin length: 2.5mm; 1mm diameter
- Lateral pins offset .64mm (tooth depth) from endplate (identified in red)
- Anterior pin centered on midline and flush against anterior wall

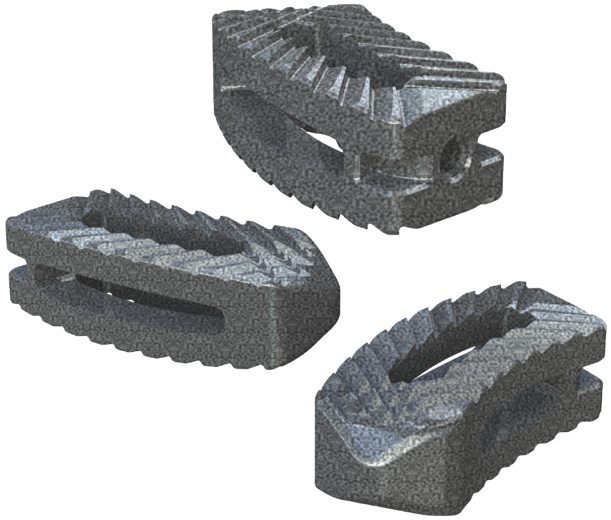


Lateral Windows

- 6mm - No Window
- 7 - 11mm - Standard Windows
- 12 - 16mm - Split Windows

SAVANT™ Titanium Transforaminal Lumbar Interbody Fusion System Featuring TRU-LOK® Technology

The Savant Titanium Tranforaminal Lumbar (TLIF) Interbody System features TRU-LOK®. The TRU-LOK® surface technology results in a proprietary micro-textured surface intended to provide an improved osteogenic environment. The micro-scale roughness of the TRU-LOK® surface technology is intended to reduce the potential for implant migration and to encourage enhanced osseointegration. The interbody is offered in multiple footprints, heights and lordosis offering an ideal fit for every patient. The Savant Lumbar Interbody Fusion System features instrumentation that allows for better control and more precise implant placement.

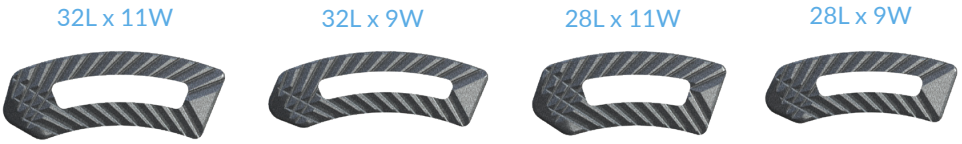


Titanium Interbody with TRU-LOK®

Part Number: C414-XXXXYY-Z

XXXX - Interbody Footprint, YY - Interbody Height, Z - Lordosis

- Titanium construction with surface texturing
- Footprints (mm): 28L x 9W, 28L x 11W, 32L x 9W and 32L x 11W
- 6 – 16mm, offered in 1mm increments
- Lordosis: 0° or 8°



Savant Features

- Open Architecture
- Convex design offers a more accurate fit to the patients anatomy
- Micro-roughness surface texturing produces superior implant contact and construct stability
- Central and lateral graft windows for biologic seeding
- Contoured, distracting nose to facilitate placement
- Aggressive anti-migration teeth resist expulsion
- Multi-directional teeth designed to prevent implant migration
- Comprehensive discectomy instruments
- Full range of Trials for proper sizing of implant height

SAVANT™ Titanium Transforaminal Lumbar Interbody Fusion System Featuring TRU-LOK® Technology

Titanium TLIF Interbodies with TRU-LOK® Technology

28mm Length, 9mm Width, 0°

Height	Catalog Number
6mm	C414-280906-0
7mm	C414-280907-0
8mm	C414-280908-0
9mm	C414-280909-0
10mm	C414-280910-0
11mm	C414-280911-0
12mm	C414-280912-0
13mm	C414-280913-0
14mm	C414-280914-0
15mm	C414-280915-0
16mm	C414-280916-0

28mm Length, 11mm Width, 0°

Height	Catalog Number
6mm	C414-281106-0
7mm	C414-281107-0
8mm	C414-281108-0
9mm	C414-281109-0
10mm	C414-281110-0
11mm	C414-281111-0
12mm	C414-281112-0
13mm	C414-281113-0
14mm	C414-281114-0
15mm	C414-281115-0
16mm	C414-281116-0

32mm Length, 9mm Width, 0°

Height	Catalog Number
6mm	C414-320906-0
7mm	C414-320907-0
8mm	C414-320908-0
9mm	C414-320909-0
10mm	C414-320910-0
11mm	C414-320911-0
12mm	C414-320912-0
13mm	C414-320913-0
14mm	C414-320914-0
15mm	C414-320915-0
16mm	C414-320916-0

32mm Length, 11mm Width, 0°

Height	Catalog Number
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8mm	C414-321108-0
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11mm	C414-321111-0
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13mm	C414-321113-0
14mm	C414-321114-0
15mm	C414-321115-0
16mm	C414-321116-0

28mm Length, 9mm Width, 8°

Height	Catalog Number
7mm	C414-280907-8
8mm	C414-280908-8
9mm	C414-280909-8
10mm	C414-280910-8
11mm	C414-280911-8
12mm	C414-280912-8
13mm	C414-280913-8
14mm	C414-280914-8
15mm	C414-280915-8
16mm	C414-280916-8

28mm Length, 11mm Width, 8°

Height	Catalog Number
7mm	C414-281107-8
8mm	C414-281108-8
9mm	C414-281109-8
10mm	C414-281110-8
11mm	C414-281111-8
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13mm	C414-281113-8
14mm	C414-281114-8
15mm	C414-281115-8
16mm	C414-281116-8

32mm Length, 9mm Width, 8°

Height	Catalog Number
7mm	C414-320907-8
8mm	C414-320908-8
9mm	C414-320909-8
10mm	C414-320910-8
11mm	C414-320911-8
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13mm	C414-320913-8
14mm	C414-320914-8
15mm	C414-320915-8
16mm	C414-320916-8

32mm Length, 11mm Width, 8°

Height	Catalog Number
7mm	C414-321107-8
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13mm	C414-321113-8
14mm	C414-321114-8
15mm	C414-321115-8
16mm	C414-321116-8

Interbody Details

- Internal radius for 28 & 32mm length to be 1.25”

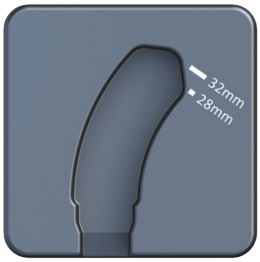
Lateral Windows

- 6 - 7mm x 0° - No Window
- 7 - 8mm x 8° - No Window
- 7 - 16mm x 0° - Single Window
- 9 - 16mm x 8° - Single Window

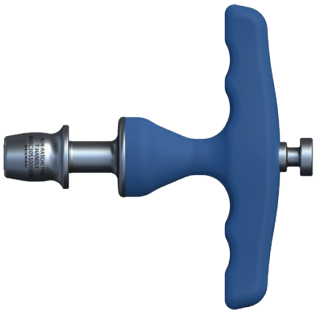
Instrument Guide

C305-100	TLIF/PLIF Inserter

C305-500	Straight Tamp



C405-700	TLIF Graft Packing Block



C305-1000	T-Handle, 1/4", Non-Ratcheting

9mm Width Parallel TLIF Trials	
C405-300	6mm (H) x 9mm (W)
C405-301	7mm (H) x 9mm (W)
C405-302	8mm (H) x 9mm (W)
C405-303	9mm (H) x 9mm (W)
C405-304	10mm (H) x 9mm (W)
C405-305	11mm (H) x 9mm (W)
C405-306	12mm (H) x 9mm (W)
C405-307	13mm (H) x 9mm (W)
C405-308	14mm (H) x 9mm (W)
C405-309	15mm (H) x 9mm (W)
C405-310	16mm (H) x 9mm (W)

11mm Width Parallel TLIF Trials	
C405-311	6mm (H) x 11mm (W)
C405-312	7mm (H) x 11mm (W)
C405-313	8mm (H) x 11mm (W)
C405-314	9mm (H) x 11mm (W)
C405-315	10mm (H) x 11mm (W)
C405-316	11mm (H) x 11mm (W)
C405-317	12mm (H) x 11mm (W)
C405-318	13mm (H) x 11mm (W)
C405-319	14mm (H) x 11mm (W)
C405-320	15mm (H) x 11mm (W)
C405-321	16mm (H) x 11mm (W)

9mm Width Lordotic TLIF Trials	
*C405-350**	*7mm (H) x 9mm (W)*
*C405-351**	*8mm (H) x 9mm (W)*
*C405-352**	*9mm (H) x 9mm (W)*
*C405-353**	*10mm (H) x 9mm (W)*
*C405-354**	*11mm (H) x 9mm (W)*
*C405-355**	*12mm (H) x 9mm (W)*
*C405-356**	*13mm (H) x 9mm (W)*
*C405-357**	*14mm (H) x 9mm (W)*
*C405-358**	*15mm (H) x 9mm (W)*
*C405-359**	*16mm (H) x 9mm (W)*

11mm Width Lordotic TLIF Trials	
*C405-360**	*7mm (H) x 11mm (W)*
*C405-361**	*8mm (H) x 11mm (W)*
*C405-362**	*9mm (H) x 11mm (W)*
*C405-363**	*10mm (H) x 11mm (W)*
*C405-364**	*11mm (H) x 11mm (W)*
*C405-365**	*12mm (H) x 11mm (W)*
*C405-366**	*13mm (H) x 11mm (W)*
*C405-367**	*14mm (H) x 11mm (W)*
*C405-368**	*15mm (H) x 11mm (W)*
*C405-369**	*16mm (H) x 11mm (W)*

**Available by request*

Posterior Lumbar Disc Prep Instrument Guide

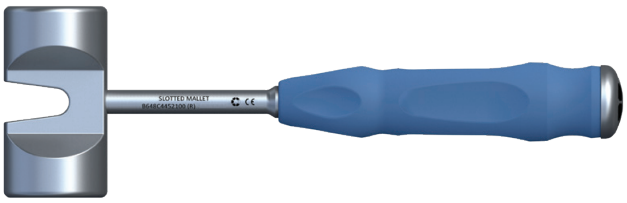
C445-100 8mm Straight Rasp, Bayoneted

C445-105 8mm Angled Left Rasp, Bayoneted

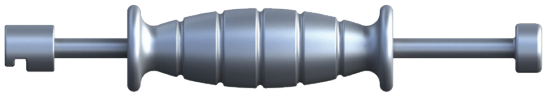
C445-110 8mm Angled Right Rasp, Bayoneted

C445-115 10mm Straight Osteotome, Bayoneted

C445-120 10mm Curved Osteotome, Bayoneted



C445-210 Slotted Mallet



C445-220 Slap Hammer

C445-165 Nerve Root Retractor, Bayoneted

C445-125 4mm Straight Curette, Bayoneted

C445-130 4mm Angled Left Curette, Bayoneted

C445-135 4mm Angled Right Curette, Bayoneted

C445-140 4mm Push Curette, Bayoneted

C445-145 4mm Pull Curette, Bayoneted

C445-150 7mm Ring Curette, Bayoneted

C445-155 7mm Rake Curette, Bayoneted

C445-160 12mm Cobb Elevator, Bayoneted

C445-800	Shaver / Distractor, 6mm

C445-801	Shaver / Distractor, 7mm

C445-802	Shaver / Distractor, 8mm

C445-803	Shaver / Distractor, 9mm

C445-804	Shaver / Distractor, 10mm

C445-805	Shaver / Distractor, 11mm

C445-806	Shaver / Distractor, 12mm

C445-807	Shaver / Distractor, 13mm

C445-808	Shaver / Distractor, 14mm

C445-809	Shaver / Distractor, 15mm

C445-810	Shaver / Distractor, 16mm

SAVANT™
Surgical Technique

Disclaimer

Each surgical step applies to all material types but the illustrations only show PEEK.

Step 1: Patient Positioning

Place the patient in a prone position on a radiolucent operating table that promotes suitable exposure and re-stores sagittal alignment. A/P and lateral fluoroscopy should be used to identify and target the appropriate levels. **(Figure 1)**

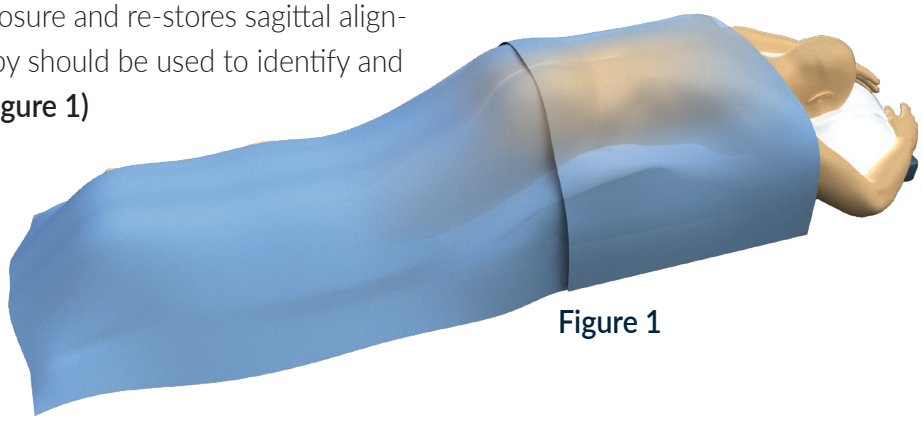
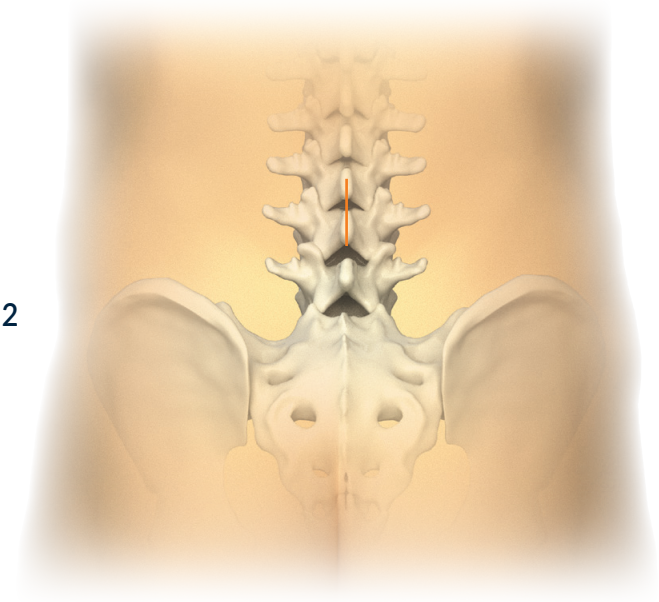


Figure 1

Step 2: Surgical Approach to the Disc

A midline incision provides exposure of the interlaminar space and facet joints at the indicated level. Pedicle screws of the surgeon's preference are inserted into the pedicles of the vertebrae adjacent to the disc space to be fused. Using a combination of surgical instruments appropriately selected by the surgeon, a laminotomy, laminectomy and/or facetectomy, is performed, along with the removal of the ligamentum flavum, to gain access to the disc space and identify neural and bony anatomy. **(Figure 2)**

Figure 2



Step 3: Discectomy and Endplate Preparation

Perform a standard discectomy using Paddle Shavers, Osteotomes, Curettes or Rasps to prepare the implant bed. **(Figure 3a, 3b)**

Note: Adequate preparation of the endplates is important to facilitate vascularization of the bone graft.

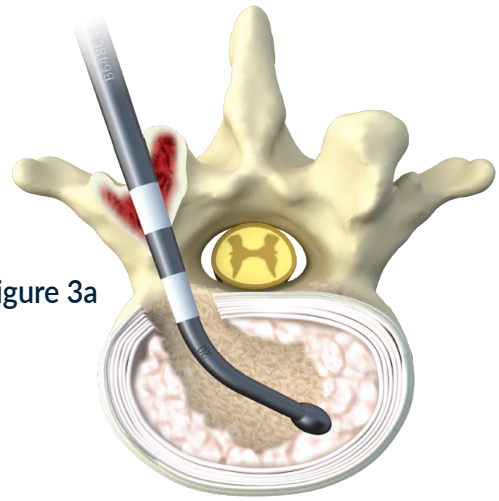


Figure 3a

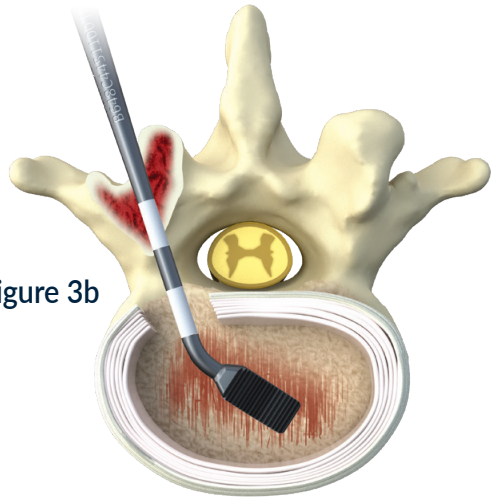


Figure 3b

Step 4: Distraction

Proper distraction is essential to restore desired disc height. Assemble the desired size of the Paddle Shaver/Distractor onto the T-Handle and insert into the disc space. **(Figure 4a)** Rotating the Paddle Shaver/Distractor clockwise will shave the endplates **(Figure 4b)** and rotating the Paddle Shaver/Distractor counterclockwise 90° will provide blunt distraction. **(Figure 4a)**

Note: The Distractors are depth marked from 20 – 40mm to aid in visualization.

Note: There are length indicators visible under fluoroscopy.

Figure 4a

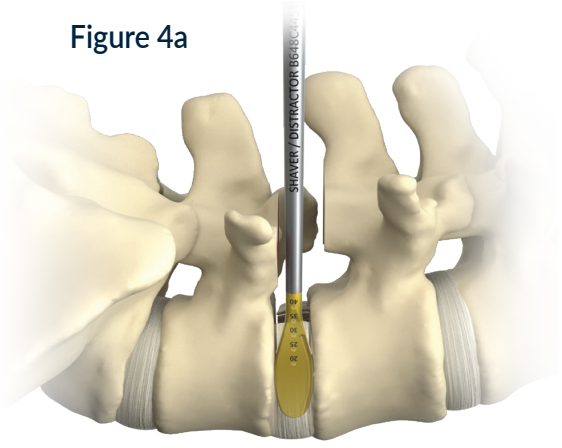
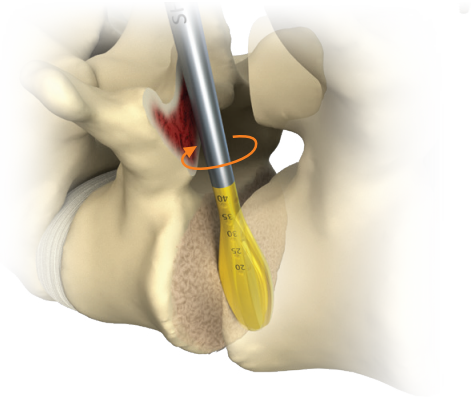


Figure 4b



Step 5: Implant Selection

Assemble the desired Trial onto the T-Handle. Trials are 9mm and 11mm wide and 32mm long with length indicators that are visible with fluoroscopy. The vertical slot represents the 28mm implant and the end of the Trial body represents the 32mm implant. Heights start at 6mm and increase sequentially by 1mm increments. If necessary, impact the Trial assembly to confirm the position and fit of the Trial. Use A/P and lateral fluoroscopy to confirm proper placement and trajectory. Once the proper size is determined, remove the Trial from the intervertebral space.

A Slap Hammer is available in the Disc Preparation Set for assisting in removing the Trial assembly from the Disc Space. **(Figure 5a, 5b)**

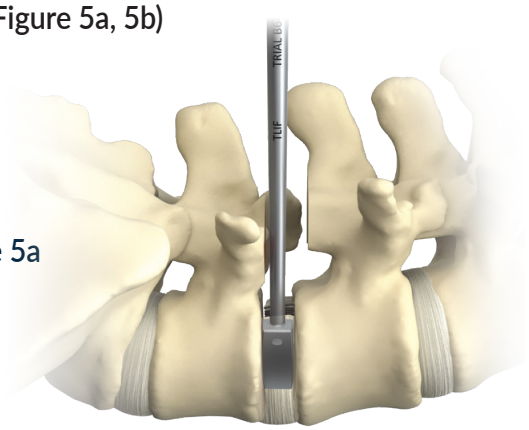


Figure 5a

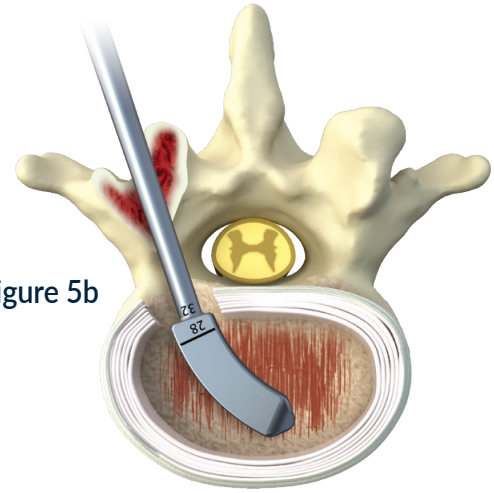


Figure 5b

Step 6: Implant Preparation

Select the appropriate implant size and attach to the Inserter. Load implant onto the inserter by aligning anti-rotation features and threading central stylus into implant. Once the implant is fully engaged on the Inserter, fill the implant with autologous bone, allograft or other bone grafting material. **(Figure 6a, 6b)**

Alternatively, utilize the Graft Block and Tamp to pack the implant with grafting material. **(Figure 6c)**

Note: The graft should be flush with the upper and lower surfaces of the implant.

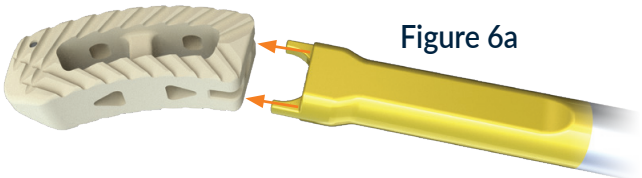


Figure 6a

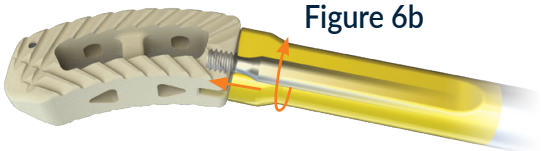


Figure 6b

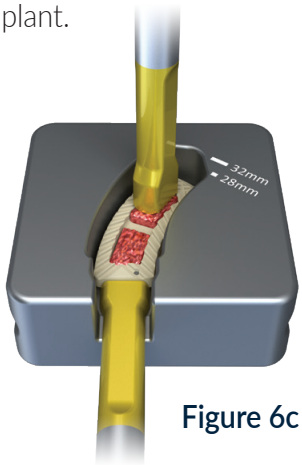


Figure 6c

Step 7: Implant Insertion

Prior to implant insertion, bone graft material may be placed anteriorly or contralaterally. Under fluoroscopy, insert the implant mounted on the Inserter into the disc space. The final position should be across the midline with the length of the device perpendicular to the midline. Once in position, remove all instruments and fill the remaining disc space with bone graft.

Note: A Tamp is available for tamping the implant into final position.

To disengage the implant from the Inserter, unthread the knob on the end of the Inserter. **(Figure 7a, 7b)**

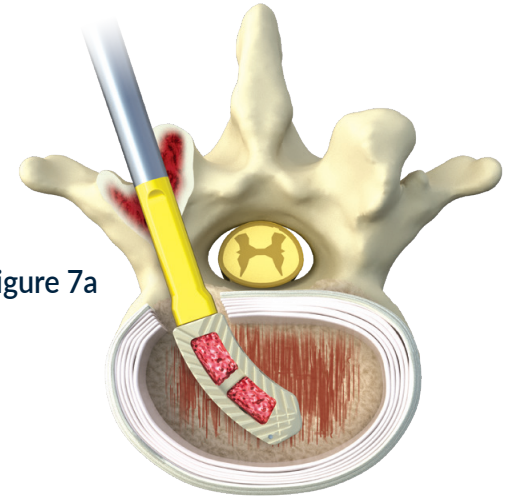


Figure 7a

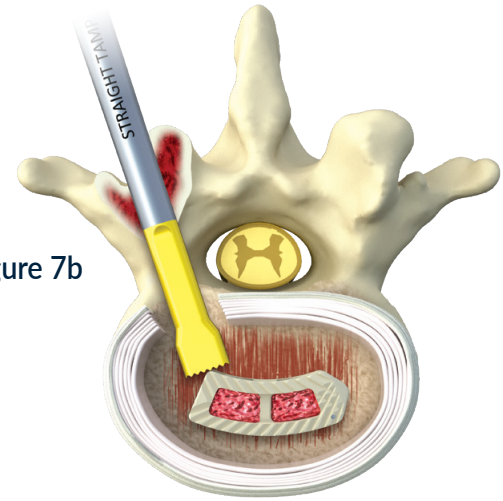


Figure 7b

Step 8: Implant Removal (optional)

Attach inserter into implant posteriorly and thread inserter into threads of implant until tightened. Gently remove implant from disc space. If the implant cannot be easily removed, a Cobb elevator, Slap Hammer or Osteotome should be used to loosen the bone to implant interface. **(Figure 8)**

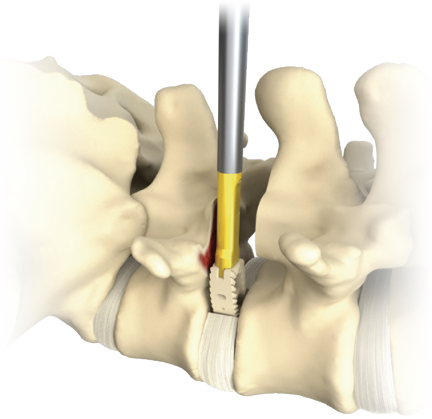


Figure 8

Indications for Use:

The Savant Lumbar Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 – S1. DDD is defined as back pain of discogenic origin 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). Implants are intended to be used with autograft and/or allograft bone (comprised of cancellous and/or corticocancellous bone graft) and supplemental spinal fixation systems that have been cleared for use in the lumbar spine. Patients should receive at least six (6) months of non-operative treatment prior to treatment with the device.

Contraindications:

Contraindications for the Savant Lumbar Interbody Fusion System are comparable to those of other systems of similar design, and include, but are not limited to:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients unwilling or unable to follow post- operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems, or in any case requiring the mixing of metals from different components.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.
- Reuse or multiple uses.

Cautions, Precautions and Warnings:

Cautions:

Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.

Do not use components of the Savant Lumbar Interbody Fusion System with components from any other manufacturer.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with other objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic implants, none of the Savant Lumbar Interbody Fusion System components should ever be reused under any circumstances.

Precautions:

The implantation of properly selected and placed system implants and components should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The Savant Lumbar Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Savant Lumbar Interbody Fusion System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Warnings:

This device system is not intended to be the sole means of spinal support. Its use without a bone graft or in cases that develop into a nonunion will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and compliance of the patient will greatly affect the results.

The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.

The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through Curiteva customer support representatives.

Notes

Notes

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