SAVANT®

ANTERIOR LUMBAR
INTERBODY FUSION SYSTEM

LUMBAR INTERBODY

Surgical Technique Guide

CURITEVA®

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SAVANT®
ANTERIOR 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® Titanium Anterior Lumbar Interbody Fusion System Featuring TRU-LOK® Technology

The Savant Titanium Anterior (ALIF) Lumbar Interbody Fusion 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 a variety of footprints, heights and lordotic angles offering an ideal fit for every patient.

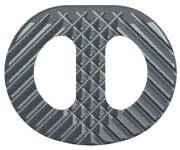
Titanium Interbody with TRU-LOK®

Part Number: Part Number: C264-XXXXYY-Z

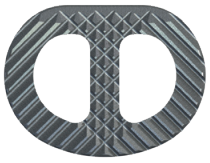
XXXX - Interbody Footprint, YY - Interbody Height, Z - Lordosis

- Titanium construction with surface texturing
- Footprints (mm): 30W x 24D, 35W x 26D, 40W x 28D
- 8 - 20mm, offered in 2mm increments
- Lordosis: 6° and 12°

30W x 24D



35W x 26D



40W x 28D

Savant Features

- Contoured, distracting leading edge to facilitate placement
- Oversized central and lateral graft windows for biologic seeding
- Micro-roughness surface texturing produces superior implant contact and construct stability
- Multi-directional teeth resist migration
- Designed to ensure a high degree of compressive strength and dimensional stability
- Open Architecture
- Comprehensive discectomy instruments
- Full range of Trials for proper sizing of implant height
- Center strut maximizes intervertebral surface contact to reduce the risk of subsidence and facilitate fusion

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

Titanium ALIF Interbodies with TRU-LOK Technology

30mm Width, 24mm Depth, 6°

Height	Catalog Number	Graft Volume (CC)
8mm	C264-302408-6	1.13
10mm	C264-302410-6	1.43
12mm	C264-302412-6	1.73
14mm	C264-302414-6	2.03
16mm	C264-302416-6	2.32
18mm	C264-302418-6	2.62
20mm	C264-302420-6	2.92

30mm Width, 24mm Depth, 12°

Height	Catalog Number	Graft Volume (CC)
10mm	C264-302410-12	1.16
12mm	C264-302412-12	1.49
14mm	C264-302414-12	1.81
16mm	C264-302416-12	2.14
18mm	C264-302418-12	2.47
20mm	C264-302420-12	2.80

35mm Width, 26mm Depth, 6°

Height	Catalog Number	Graft Volume (CC)
8mm	C264-352608-6	1.83
10mm	C264-352610-6	2.31
12mm	C264-352612-6	2.80
14mm	C264-352614-6	3.29
16mm	C264-352616-6	3.77
18mm	C264-352618-6	4.26
20mm	C264-352620-6	4.75

35mm Width, 26mm Depth, 12°

Height	Catalog Number	Graft Volume (CC)
10mm	C264-352610-12	1.83
12mm	C264-352612-12	2.36
14mm	C264-352614-12	2.90
16mm	C264-352616-12	3.44
18mm	C264-352618-12	3.98
20mm	C264-352620-12	4.51

40mm Width, 28mm Depth, 6°

Height	Catalog Number	Graft Volume (CC)
10mm	C264-402810-6	2.95
12mm	C264-402812-6	3.73
14mm	C264-402814-6	4.50
16mm	C264-402816-6	5.27
18mm	C264-402818-6	6.05
20mm	C264-402820-6	6.82

40mm Width, 28mm Depth, 12°

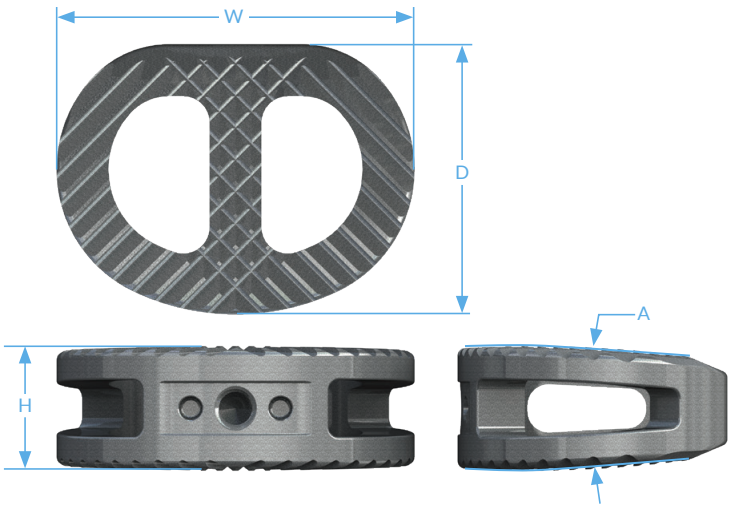
Height	Catalog Number	Graft Volume (CC)
10mm	C264-402810-12	2.90
12mm	C264-402812-12	3.60
14mm	C264-402814-12	4.31
16mm	C264-402816-12	5.01
18mm	C264-402818-12	5.71
20mm	C264-402820-12	6.42

Lateral Windows

- 8mm - No Window
- 10 – 20mm - Lateral Windows

Interbody Details

- 5mm wall thickness
- .75mm tooth depth



C255-100 ALIF Inserter

C255-200 ALIF Tamp

C255-300 ALIF Graft Packing Block

30mm Width, 24mm Depth, 6° Trial

Catalog Number	Height
C255-411	8mm
C255-413	10mm
C255-415	12mm
C255-417	14mm
C255-419	16mm
C255-4111	18mm
C255-4113	20mm

30mm Width, 24mm Depth, 12° Trial

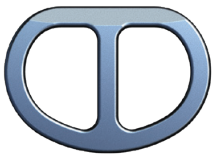
Catalog Number	Height
C255-4115	10mm
C255-4117	12mm
C255-4119	14mm
C255-4121	16mm
C255-4123	18mm
C255-4125	20mm

35mm Width, 26mm Depth, 6° Trial

Catalog Number	Height
C255-421	8mm
C255-423	10mm
C255-425	12mm
C255-427	14mm
C255-429	16mm
C255-4211	18mm
C255-4213	20mm

35mm Width, 26mm Depth, 12° Trial

Catalog Number	Height
C255-4215	10mm
C255-4217	12mm
C255-4219	14mm
C255-4221	16mm
C255-4223	18mm
C255-4225	20mm



40mm Width, 28mm Depth, 6° Trial

Catalog Number	Height
C255-432	10mm
C255-434	12mm
C255-436	14mm
C255-438	16mm
C255-4310	18mm
C255-4312	20mm

40mm Width, 28mm Depth, 12° Trial

Catalog Number	Height
C255-4313	10mm
C255-4315	12mm
C255-4317	14mm
C255-4319	16mm
C255-4321	18mm
C255-4323	20mm

Anterior Lumbar Disc Prep Instrument Guide

C295-400	12mm Straight Osteotome

C295-500	20mm Cobb Elevator
C295-510	25mm Cobb Elevator

C295-600	4mm Angled Up Curette
C295-610	8mm Angled Up Curette

C295-620	6mm Angled Left Curette

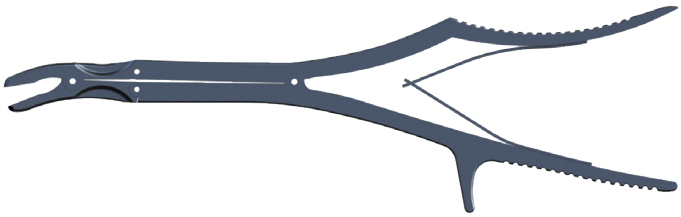
C295-630	6mm Angled Right Curette

C295-640	4mm Ring Curette
C295-650	8mm Ring Curette

C295-660	4mm x 11mm Tear Drop Curette

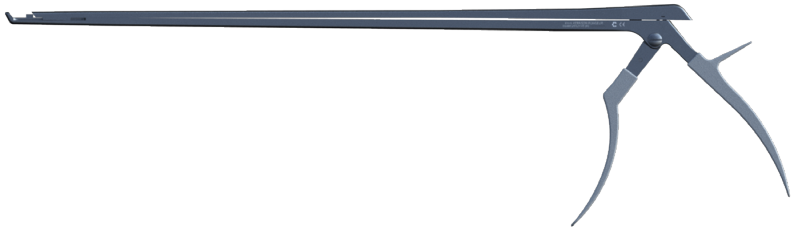
C295-670	8mm x 20mm Box Broach

C295-700	8mm Angled Up, Double Sided, Rasp



C295-300	8mm Bone Rongeur

C295-100	4mm Pituitary Rongeur
C295-110	8mm Pituitary Rongeur



C295-200	4mm Kerrison Rongeur
C295-210	8mm Kerrison Rongeur

C445-210	Slotted Mallet

C445-220	Slap Hammer

SAVANT®
Surgical Technique

Step 1: Patient Positioning and Approach

Place the patient in a supine position appropriate for an anterior approach on a radiolucent operating table. Once the patient is placed on the table, use lateral C-Arm fluoroscopy to visualize the lumbar spine and target the appropriate levels. **(Figure 1)**

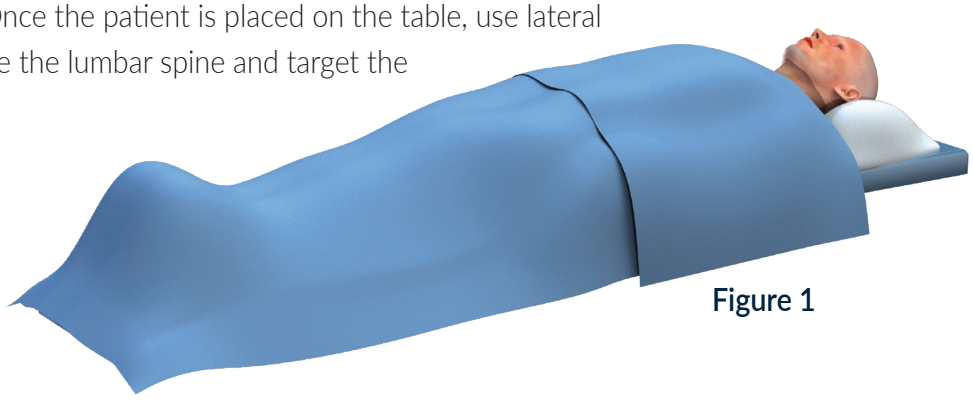


Figure 1

Step 2: Surgical Approach to the Disc

To approach the disc space, a vertical to slightly oblique skin incision is made over the targeted levels. The Anterior Disc Preparation set can be used to expose the disc and remove the disc material. Prepare the vertebral endplates by removing the superficial cartilaginous layers.

Step 3: Discectomy and Endplate Preparation

Perform a standard discectomy used with an anterior lumbar discectomy and fusion procedure. Use Osteotomes, Curettes, Rongeurs or Rasps to adequately prepare the endplates, removing the superficial layers of the cartilaginous endplates and enhancing the vascular supply to the fusion site. **(Figure 3a, 3b)**

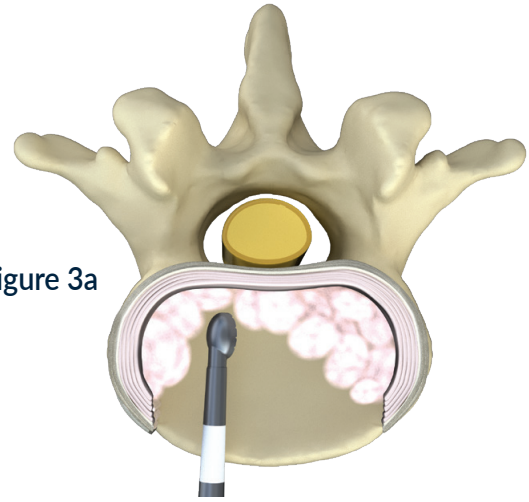


Figure 3a

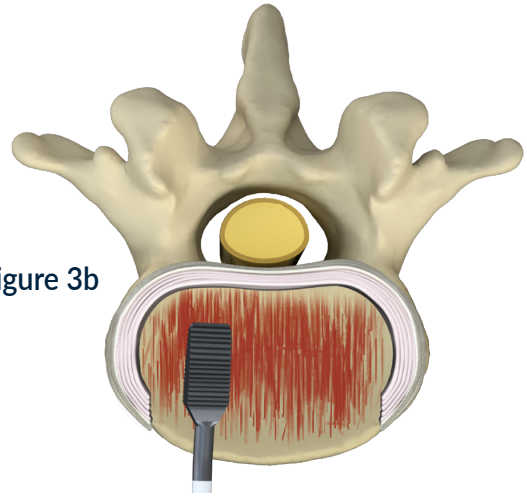


Figure 3b

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

CAUTION: Excessive scraping may weaken the endplates and cause the implant to subside.

Note: The posterior and lateral walls of the annulus should be preserved to provide peripheral support.

Step 4: Distraction and Implant Selection

Select the appropriate Trial and attach to the Inserter. Load the Trial onto the Inserter by aligning the anti-rotation features and threading the central stylus into the Trial. Heights start at 8mm and increase sequentially by 2mm 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 4a, Figure 4b)**

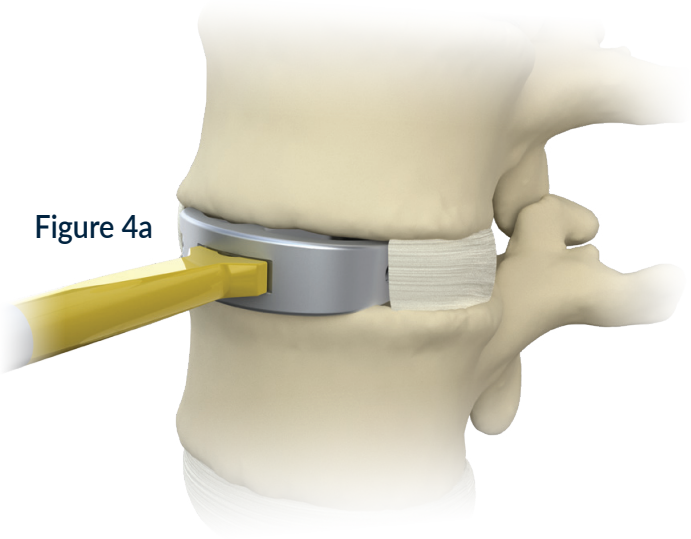


Figure 4a

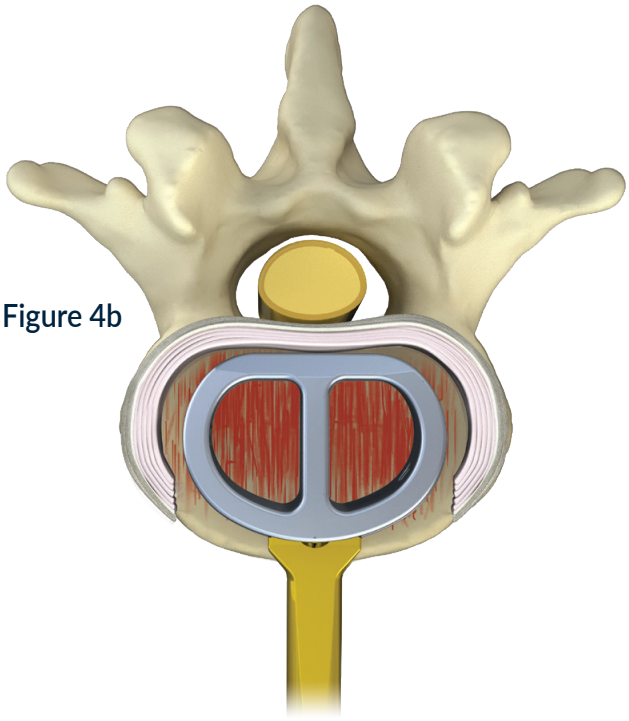


Figure 4b

Note: A secure fit is desirable to maintain disc height and to stabilize the segment. Start with the smallest height, progressing to taller heights until the desired fit is achieved.

CAUTION: Care should be taken to avoid plunging Trial instrumentation into surrounding neurological structures.

Step 5: 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. The Graft Packing Block and Tamp can be utilized to pack the implant with grafting material. **(Figure 5a, Figure 5b, Figure 5c)**

Figure 5a

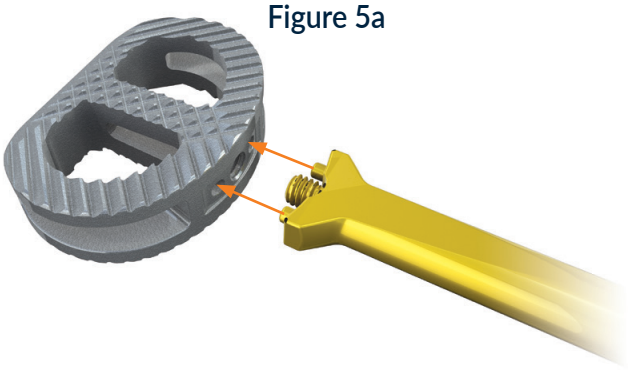
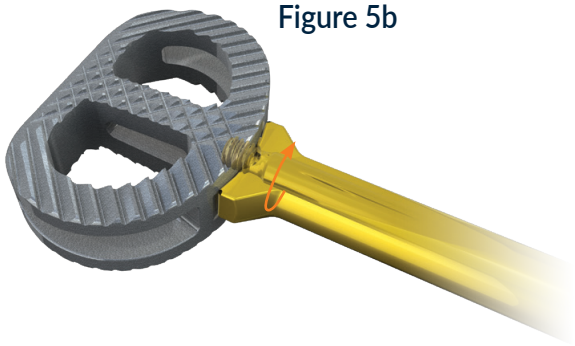


Figure 5b



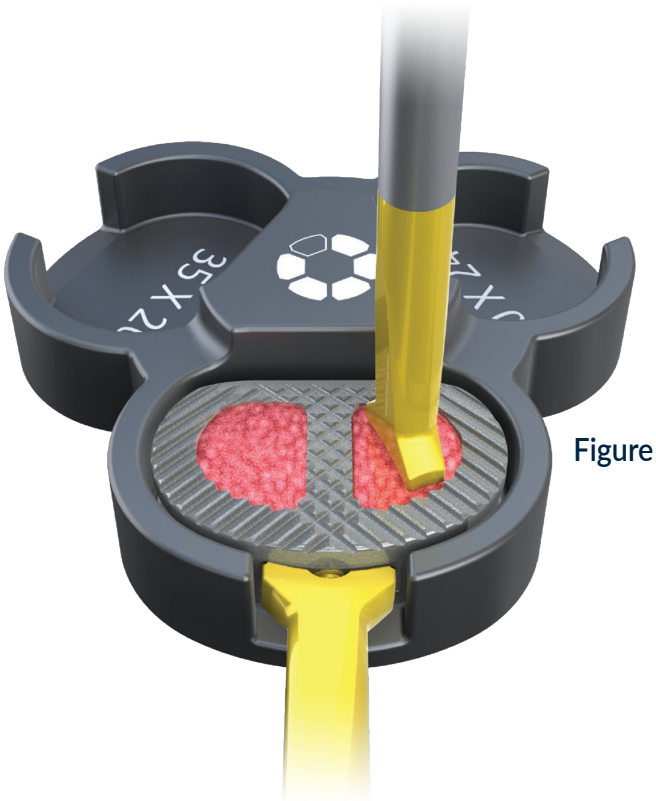


Figure 5c

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

Step 6: Implant Insertion

Insert the implant mounted on the Inserter into the disc space using fluoroscopy to confirm the position and placement of the implant. **(Figure 6a, Figure 6b)**

To disengage the implant from the Inserter, unthread the knob on the end of the Inserter.

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

Figure 6a

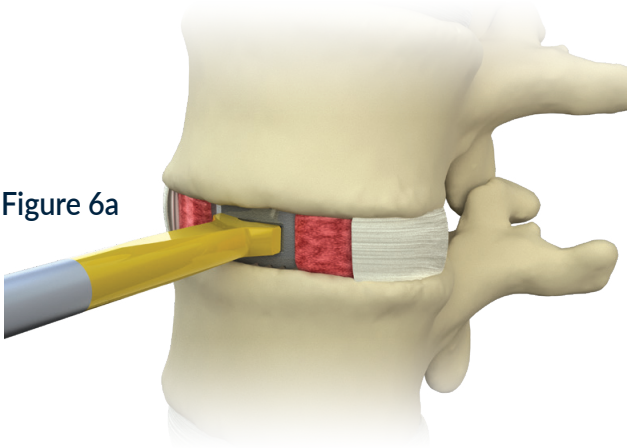
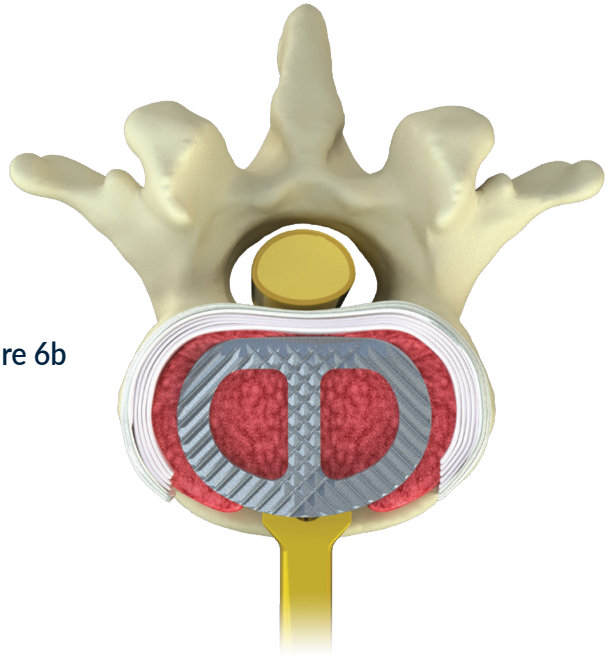


Figure 6b



Step 7: Supplemental Fixation

Use of supplemental fixation is required with the Savant ALIF implant. Failure to provide supplemental fixation may result in displacement or expulsion of the implant.

Step 8: Implant Removal (optional)

Attach Inserter into implant and thread Inserter into threads of implant until tightened and gently remove implant from disc space. If necessary, distract inferior and superior to the implant for removal.

Note: Do not attempt to remove the construct unless it is completely exposed to avoid inadvertent injury to the vessels.

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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