

SHURFIT 3D TITANIUM INTERBODY CAGES

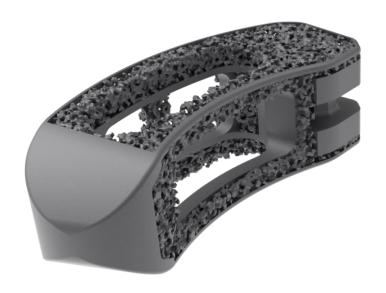






TABLE OF CONTENTS

ShurFi	it® 3D Titanium CURVED Interbody Fusion Device	
OVER'	VIEW	3
IMPLA	NT SPECIFICATIONS	5
INSTR	UMENTS	7
SURG	ICAL TECHNIQUE	12
	Patient Positioning	12
	Endplate Preparation	13
	Implant Selection	12
	Implant Insertion	13
	Implant Removal	17

SHURFIT® 3D TITANIUM CURVED INTERBODY SYSTEM

OVERVIEW

The ShurFit 3D Titanium Interbody Fusion Devices consist of implants with various heights and lengths to accommodate individual patient anatomy. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved. All components are manufactured from Ti-6Al-4V. All implants are supplied clean and "STERILE".

PRODUCT HIGHLIGHTS

- 3D Ti Structure
- Open Windows Coupled with 60% Porosity
- Interconnected Lattice Structure
- Internal Struts
- Large Graft Window
- Bulleted Leading Edge
- Multiple Lordotic Options

INDICATIONS

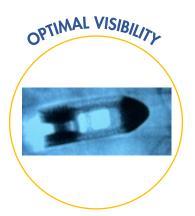
The ShurFit 3D Titanium Interbody Fusion Devices are indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space for the 3D Ti system.

The ShurFit 3D Titanium Interbody Fusion Devices are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used with supplemental fixation and autogenous autograft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.

Please refer to package insert (LBL-IFU-034 Rev A) for complete system description, indications and warnings.









SHURFIT® 3D TITANIUM CURVED INTERBODY SYSTEM

OVERVIEW

3D Ti Structure with Interconnected Lattice to help facilitate bony integration and reduce risk of migration

• Pore Size Range: 100 - 800µm

• Avg. Pore Size: 600µm

Open Windows Coupled with Reduced Density (~60% porosity) enhances intraoperative imaging and fusion assessment

Lattice Structure decreases cage stiffness reducing the risk of subsidence

Internal Struts increases overall support and allows for insert and rotate cage positioning

Large Window provides maximize bone graft material

Bulleted Leading Edge allows for ease of insertion

Position Marker ensures correct anatomical placement

Multiple Lordotic Options accommodates varying patient anatomies



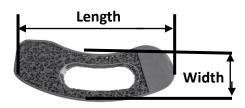


TLIF Interbody
Curved Cage
Length – 24, 28 & 32mm
Width – 9mm
Lordosis – 0°, 6°, & 12°
Heights – 7-14mm *

* Depending on lordosis

SHURFIT® LUMBAR CURVED IMPLANT CASE 72-BK-0021







Item No.	Description	Qty	Item No.	Description	Qty
72-CTA-2406*	3D Ti Curved Cage; 24 x 06mm 0°	3	72-CTA-2806*	3D Ti Curved Cage; 28 x 06mm 0°	3
72-CTB-2407	3D Ti Curved Cage; 24 x 07mm 6°	3	72-CTB-2807	3D Ti Curved Cage; 28 x 07mm 6°	3
72-CTB-2408	3D Ti Curved Cage; 24 x 08mm 6°	3	72-CTB-2808	3D Ti Curved Cage; 28 x 08mm 6°	3
72-CTB-2409	3D Ti Curved Cage; 24 x 09mm 6°	3	72-CTB-2809	3D Ti Curved Cage; 28 x 09mm 6°	3
72-CTB-2410	3D Ti Curved Cage; 24 x 10mm 6°	3	72-CTB-2810	3D Ti Curved Cage; 28 x 10mm 6°	3
72-CTB-2411	3D Ti Curved Cage; 24 x 11mm 6°	3	72-CTB-2811	3D Ti Curved Cage; 28 x 11mm 6°	3
72-CTB-2412	3D Ti Curved Cage; 24 x 12mm 6°	3	72-CTB-2812	3D Ti Curved Cage; 28 x 12mm 6°	3
72-CTB-2413	3D Ti Curved Cage; 24 x 13mm 6°	3	72-CTB-2813	3D Ti Curved Cage; 28 x 13mm 6°	3
72-CTB-2414	3D Ti Curved Cage; 24 x 14mm 6°	3	72-CTB-2814	3D Ti Curved Cage; 28 x 14mm 6°	3
72-CTC-2408	3D Ti Curved Cage; 24 x 08mm 12°	3	72-CTC-2808	3D Ti Curved Cage; 28 x 08mm 12°	3
72-CTC-2409	3D Ti Curved Cage; 24 x 09mm 12°	3	72-CTC-2809	3D Ti Curved Cage; 28 x 09mm 12°	3
72-CTC-2410	3D Ti Curved Cage; 24 x 10mm 12°	3	72-CTC-2810	3D Ti Curved Cage; 28 x 10mm 12°	3
72-CTC-2411	3D Ti Curved Cage; 24 x 11mm 12°	3	72-CTC-2811	3D Ti Curved Cage; 28 x 11mm 12°	3
72-CTC-2412	3D Ti Curved Cage; 24 x 12mm 12°	3	72-CTC-2812	3D Ti Curved Cage; 28 x 12mm 12°	3
72-CTC-2413	3D Ti Curved Cage; 24 x 13mm 12°	3	72-CTC-2813	3D Ti Curved Cage; 28 x 13mm 12°	3
72-CTC-2414	3D Ti Curved Cage; 24 x 14mm 12°	3	72-CTC-2814	3D Ti Curved Cage; 28 x 14mm 12°	3

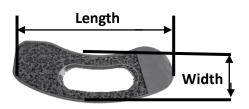
ShurFit 3D Ti Interbody Cages are provided in a sterile package. Carefully confirm the implant size that you desire from the outside label prior to opening the box or inside trays. The implants are packaged in a double-tray with a peel back lid for easy transfer into the sterile field. If the implant is opened and not used, the implant MAY NOT be sterilized and used again.

* By Request



SHURFIT® LUMBAR CURVED IMPLANT CASE 72-BK-0020







Item No.	Description	Qty	Item No.	Description	Qty
72-CTA-2806*	3D Ti Curved Cage; 28 x 06mm 0°	3	72-CTA-3206*	3D Ti Curved Cage; 32 x 06mm 0°	3
72-CTB-2807	3D Ti Curved Cage; 28 x 07mm 6°	3	72-CTB-3207	3D Ti Curved Cage; 32 x 07mm 6°	3
72-CTB-2808	3D Ti Curved Cage; 28 x 08mm 6°	3	72-CTB-3208	3D Ti Curved Cage; 32 x 08mm 6°	3
72-CTB-2809	3D Ti Curved Cage; 28 x 09mm 6°	3	72-CTB-3209	3D Ti Curved Cage; 32 x 09mm 6°	3
72-CTB-2810	3D Ti Curved Cage; 28 x 10mm 6°	3	72-CTB-3210	3D Ti Curved Cage; 32 x 10mm 6°	3
72-CTB-2811	3D Ti Curved Cage; 28 x 11mm 6°	3	72-CTB-3211	3D Ti Curved Cage; 32 x 11mm 6°	3
72-CTB-2812	3D Ti Curved Cage; 28 x 12mm 6°	3	72-CTB-3212	3D Ti Curved Cage; 32 x 12mm 6°	3
72-CTB-2813	3D Ti Curved Cage; 28 x 13mm 6°	3	72-CTB-3213	3D Ti Curved Cage; 32 x 13mm 6°	3
72-CTB-2814	3D Ti Curved Cage; 28 x 14mm 6°	3	72-CTB-3214	3D Ti Curved Cage; 32 x 14mm 6°	3
72-CTC-2808	3D Ti Curved Cage; 28 x 08mm 12°	3	72-CTC-3208	3D Ti Curved Cage; 32 x 08mm 12°	3
72-CTC-2809	3D Ti Curved Cage; 28 x 09mm 12°	3	72-CTC-3209	3D Ti Curved Cage; 32 x 09mm 12°	3
72-CTC-2810	3D Ti Curved Cage; 28 x 10mm 12°	3	72-CTC-3210	3D Ti Curved Cage; 32 x 10mm 12°	3
72-CTC-2811	3D Ti Curved Cage; 28 x 11mm 12°	3	72-CTC-3211	3D Ti Curved Cage; 32 x 11mm 12°	3
72-CTC-2812	3D Ti Curved Cage; 28 x 12mm 12°	3	72-CTC-3212	3D Ti Curved Cage; 32 x 12mm 12°	3
72-CTC-2813	3D Ti Curved Cage; 28 x 13mm 12°	3	72-CTC-3213	3D Ti Curved Cage; 32 x 13mm 12°	3
72-CTC-2814	3D Ti Curved Cage; 28 x 14mm 12°	3	72-CTC-3214	3D Ti Curved Cage; 32 x 14mm 12°	3

ShurFit 3D Ti Interbody Cages are provided in a sterile package. Carefully confirm the implant size that you desire from the outside label prior to opening the box or inside trays. The implants are packaged in a double-tray with a peel back lid for easy transfer into the sterile field. If the implant is opened and not used, the implant MAY NOT be sterilized and used again.

* By Request

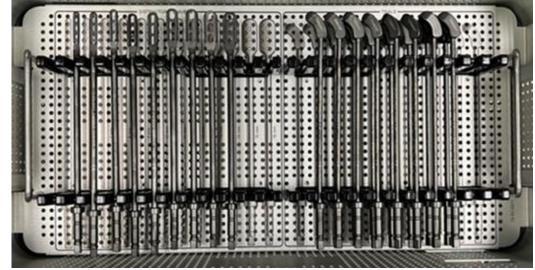


SHURFIT® LUMBAR CURVED INSTRUMENT TRAY

72-BK-020X Top Level

1-9 Upper Level

10-19 Lower Level



20-27 Upper Level

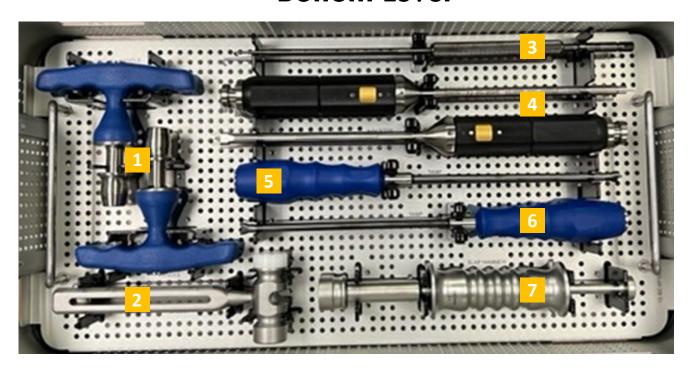
28-34 Lower Level

#	Item No.	Description	Qty
1	72-PS-9506	Paddle Shaver, 6mm	1
2	72-PS-9507	Paddle Shaver, 7mm	1
3	72-PS-9508	Paddle Shaver, 8mm	1
4	72-PS-9509	Paddle Shaver, 9mm	1
5	72-PS-9510	Paddle Shaver, 10mm	1
6	72-PS-9511	Paddle Shaver, 11mm	1
7	72-PS-9512	Paddle Shaver, 12mm	1
8	72-PS-9513	Paddle Shaver, 13mm	1
9	72-PS-9514	Paddle Shaver, 14mm	1
10	72-DS-9505	Paddle Distractor, 5mm	1
11	72-DS-9506	Paddle Distractor, 6mm	1
12	72-DS-9507	Paddle Distractor, 7mm	1
13	72-DS-9508	Paddle Distractor, 8mm	1
14	72-DS-9509	Paddle Distractor, 9mm	1
15	72-DS-9510	Paddle Distractor, 10mm	1
16	72-DS-9511	Paddle Distractor, 11mm	1
17	72-DS-9512	Paddle Distractor, 12mm	1
18	72-DS-9513	Paddle Distractor, 13mm	1
19	72-DS-9514	Paddle Distractor, 14mm	1

#	Item No.	Description	Qty
20	72-TC-0607	Curved Cage Trial, 7mm x 6°	1
21	72-TC-0608	Curved Cage Trial, 8mm x 6°	1
22	72-TC-0609	Curved Cage Trial, 9mm x 6°	1
23	72-TC-0610	Curved Cage Trial, 10mm x 6°	1
24	72-TC-0611	Curved Cage Trial, 11mm x 6°	1
25	72-TC-0612	Curved Cage Trial, 12mm x 6°	1
26	72-TC-0613	Curved Cage Trial, 13mm x 6°	1
27	72-TC-0614	Curved Cage Trial, 14mm x 6°	1
28	72-TC-1208	Curved Cage Trial, 8mm x 12°	1
29	72-TC-1209	Curved Cage Trial, 9mm x 12°	1
30	72-TC-1210	Curved Cage Trial, 10mm x 12°	1
31	72-TC-1211	Curved Cage Trial, 11mm x 12°	1
32	72-TC-1212	Curved Cage Trial, 12mm x 12°	1
33	72-TC-1213	Curved Cage Trial, 13mm x 12°	1
34	72-TC-1214	Curved Cage Trial, 14mm x 12°	1

SHURFIT® LUMBAR CURVED INSTRUMENT TRAY

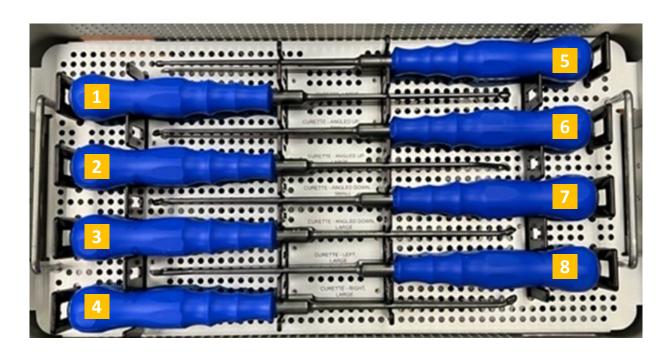
72-BK-020X Bottom Level



#	Item No.	Description	Qty
1	72-CH-0001	Fixed 1/4" T-Handle	2
2	37-IN-0084	Mallet	1
3	72-RH-1000	Implant Remover	1
4	72-IN-1001	Curved Inserter	2
5	72-IN-9001	Curved Corner Tamp	1
6	72-IN-9002	Curved Flat Tamp	1
7	72-SH-9000	Slap Hammer	1

SHURFIT® LUMBAR DISC PREP

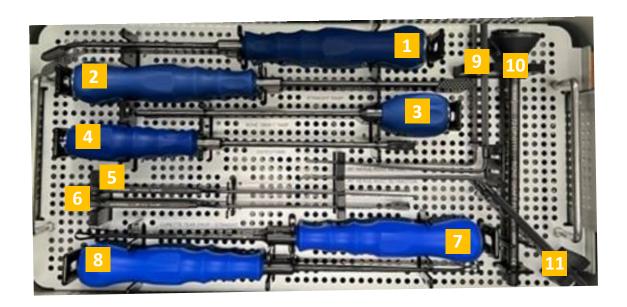
72-BK-101X Top Level



#	Item No.	Description	Qty
1	72-DC-0022	#4 Curette Straight, Serrated	1
2	72-DC-0032	#4 Curette Angled Up, 30°, Straight, Serrated	1
3	72-DC-0042	#4 Curette Angled Down, 30°, Straight, Serrated	1
4	72-DC-0052	#4 Curette, Right, Serrated	1
5	72-DC-0021	#2 Curette Straight, Straight, Serrated	1
6	72-DC-0031	#2 Curette Angled Up, 30°, Straight, Serrated	1
7	72-DC-0041	#2 Curette Angled Down, 30°, Straight, Serrated	1
8	72-DC-0051	#4 Curette, Left, Serrated	1

SHURFIT® LUMBAR DISC PREP

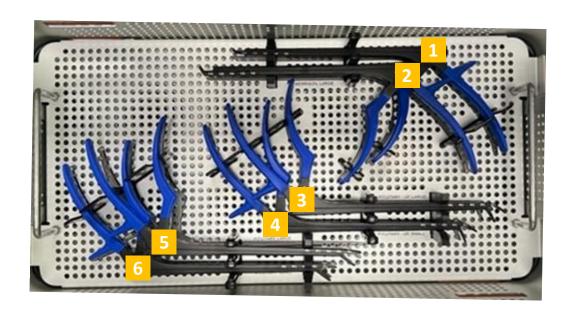
72-BK-101X Middle Level



#	Item No.	Description	Qty
1	72-RS-9007	9mm Wide Rasp, Double Sided; Curved Rasp	1
2	72-RS-9006	9mm Wide Rasp, Double Sided; Straight Rasp	1
3	72-DP-0121	Bone Graft Tamp	1
4	72-DP-0130	8mm Wide Osteotome	1
5	72-DP-0101	45° Nerve Hook, Straight	1
6	72-DP-0091	Penfield, #4 Pull, Straight	1
7	72-DC-0011	Curette Tear Drop - Straight 8mm	1
8	72-DC-0012	Curette Tear Drop - Angle (30°) 8mm	1
9	72-DP-0002	90° Nerve Root Retractor	1
10	72-DP-0111	Bone Graft Funnel	1
11	72-DP-0001	45° Nerve Root Retractor	1

SHURFIT® LUMBAR DISC PREP

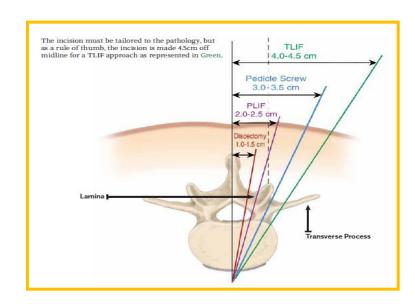
72-BK-101XBottom Level



#	Item No.	Description	Qty
1	72-DK-0062	Kerrison, 40°, Straight, 2mm	1
2	72-DK-0064	Kerrison, 40°, Straight, 4mm	1
3	72-DP-0074	Pituitary - Up, Straight, 4mm	1
4	72-DP-0072	Pituitary - Up, Straight, 2mm	1
5	72-DP-0084	Pituitary - Straight, 4mm	1
6	72-DP-0082	Pituitary - Straight, 2mm	1

The following technique describes the unilateral insertion of a single implant into the disc space through a transforaminal lumbar interbody fusion (TLIF) approach or anywhere in between based on the pathology being addressed and surgeon preference. This technique may be performed through an open, less invasive or minimally invasive procedure.

Note: This surgical technique is intended as a guide only. It is recommended that the surgeon be thoroughly trained before proceeding. The surgeon must consider the needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the ShurFit 3D Titanium Interbody Cage Instructions For Use for complete information on indications, contraindications, precautions, warnings, potential adverse effects, sterilization and packaging





Place the patient in the prone position and drape in a manner consistent with surgical facility protocol. (Figure 1) Utilizing A/P and lateral fluoroscopic imaging and palpation of the patient anatomy, identify and mark the affected level.



Figure 1

2 ENDPLATE PREPARATION

Create a skin incision at the targeted affected level(s) and dissect and retract the soft tissue.

Remove the inferior facet of the superior vertebrae with an osteotome, burr, or kerrison. Expose and resect the capsular portion of the ligamentum flavum. Excise the superior facet of the inferior vertebrae with an osteotome, burr, or Kerrison. (Figure 2)

Decompress the neural foramen and central spinal canal as necessary. Expose the posterolateral portion of the annular fibrosis and create an annular window to gain access to the intervertebral space.

Additional distraction can be achieved with Paddle Distractors (72-DS-95XX). (Figure 2a)

Securely attach the T-handle to the Paddle Shaver (72-PS-95XX). Utilize the Paddle Shaver to prepare the disc space and remove the superficial layers of the cartilaginous endplates. (Figure 2b)





Figure 2



Figure 2a



Figure 2b

3 IMPLANT SELECTION

At the surgeon's discretion, posterior distraction of the vertebral space may be performed.

Insert the appropriate Trial (72-TC-XXXX)into the annulatomy window and position within the disc space. (Figure 3)

Confirm proper positioning with A/P and lateral fluoroscopy.

Repeat the trial process until the desired amount of distraction is achieved within the disc space. The height and length of the implant are determined from the final Trial.

A Slap Hammer (72-SH-9000) may be used in positioning or removing the Trial.



Curved Cage Trial 72-TC-06XX 72-TC-12XX



Slap Hammer (72-SH-9000)

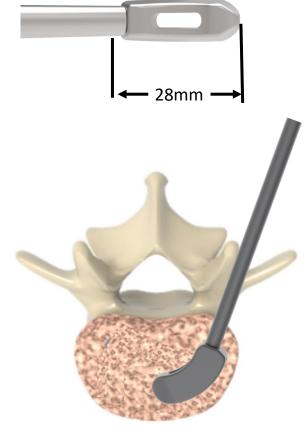


Figure 3)

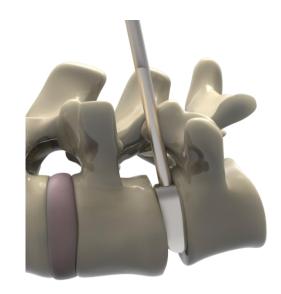


Figure 3 (Lateral)

IMPLANT INSERTION

Based on the final Trial, select the appropriate size implant.

Insert bone graft material to the large window of the implant.

Press the Curved Inserter's (72-IN-1001) Gold Button and rotate the back knob on the Inserter counterclockwise so that the Inserter distal tangs are in a fully open position. (Figure 4)

Position the distal tips of the Inserter securely onto the Octagonal Post of the implant. While holding the implant on the Inserter, rotate the back knob on the Inserter clockwise to the Closed position to tighten the implant onto the Inserter. (Figure 4a)

Note: Do not overtighten the Inserter to the implant.



Curved Inserter 72-IN-1001

CCW to Fully Open



Figure 4a Figure 4a



Insert the implant into the disc space. (Figure 4b)

Turn the Back Knob counter-clockwise to loosen the implant. This will allow the implant to rotate into position in the disc space after impaction.

NOTE: If re-positioning of the Implant is required, turn the Back Knob clockwise to fully lock the Inserter to the Implant prior to re-positioning.

Confirm final implant position via A/P and lateral fluoroscopy.

To disengage the implant, press the gold button and rotate the back knob on the Inserter counterclockwise to the fully open position and remove the Inserter.

Fixed position of the implant can be achieved using the Curved Tamp (72-IN-9001). Figures 4C & 4d)



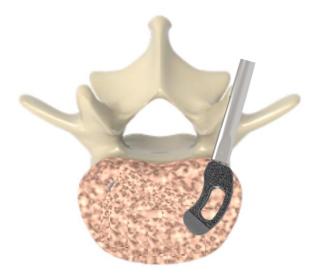


Figure 4b

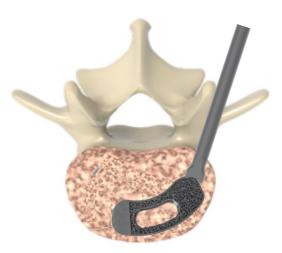


Figure 4c



Figure 4d

5 IMPLANT REMOVAL

If required, the implant can be removed using the Inserter and Slap Hammer. Position the distal tip of the Inserter securely around the Cage's Octagonal Post. (Figure 5) While holding the implant on the Inserter, rotate the back knob on the Inserter to tighten. Attach the Slap Hammer to the Inserter and remove the implant from the disc space.

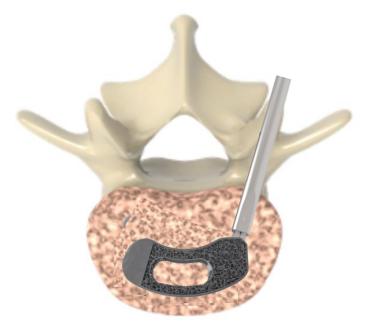


Figure 5





Precision Spine, Inc.

2050 Executive Drive, Pearl, MS 39208

Customer Service: 1.888.241.4773

Phone: 601.420.4244 Toll Free: 877.780.4370

Fax: 601.420.5501

www.precisionspineinc.com

Caution: Federal (USA) law restricts these devices to sale by, or on the order of, a physician. ShurFil® and Precision Spine® are trademarks of Precision Spine, Inc. Copyright 2023 Precision Spine, Inc. All rights reserved. P/N LBL-STG-050 Rev. C 01/2023