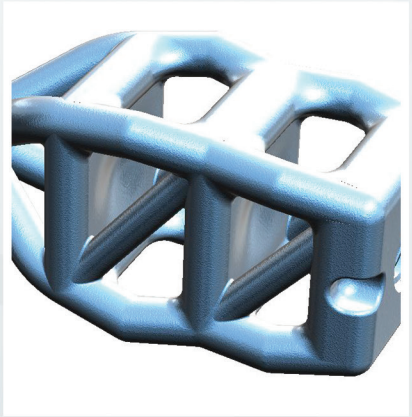
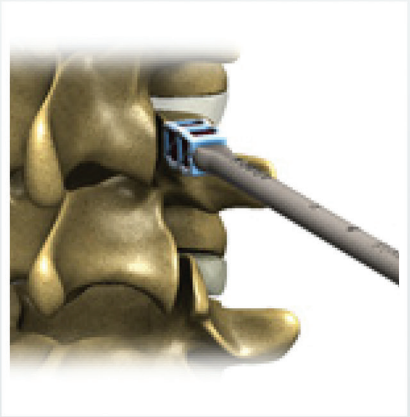
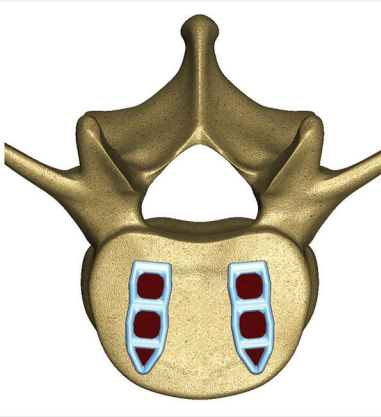
Zyston® Strut

Open Titanium Interbody Spacer System

Surgical Technique Guide







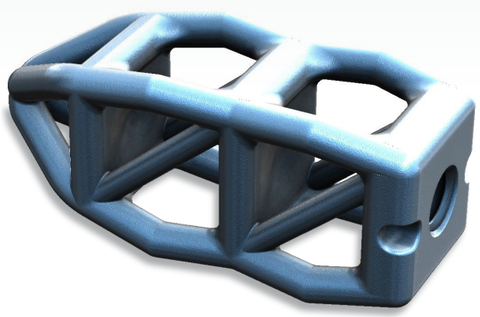
ZimVie

The Zyston Strut Open Titanium Interbody Spacer System uses additive manufacturing to create a unique architecture that allows the user to maximize graft volume prior to implantation.

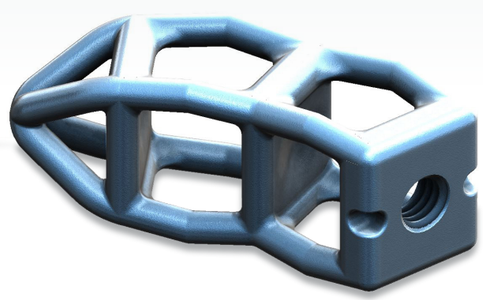
Table Of Contents

ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

Zyston Strut Open Titanium Interbody Spacer System Overview



Zyston Strut Straight



Zyston Strut Curve

The Zyston Strut Open Titanium Interbody Spacer System is a family of spinal fusion cages with open titanium geometry optimized for strength, graft capacity, and visualization. The implants are provided in a series of sizes to accommodate a range of patient anatomy and different surgical approaches. The system includes surgical instruments for insertion, manipulation, and removal of the implants.

Patient Positioning

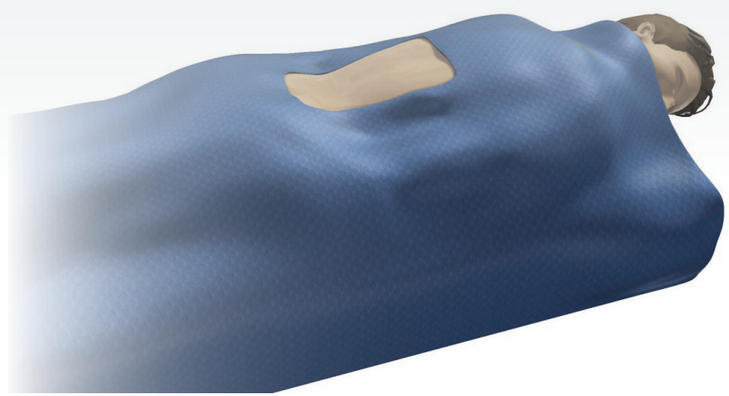


Figure 1
Patient positioning

Pre-surgery preparation

- Review and visually inspect all instrumentation for damage prior to sterilization
- Replace or add any necessary components for the planned surgery
- Surgeon must be fully experienced with the required spinal fusion techniques
- Read the Instructions for Use (IFU) for a product description and a list of warnings, cautions, contraindications, and risks
- Measure key radiographic landmarks to determine ideal alignment and implant size required for surgery

STEP 1

Patient Positioning

- Place the patient in the prone or knee-chest position on a radiolucent operating table. Adjust the table (as needed) so that the C-Arm provides true A/P images when at 90° and true lateral images at 0° ***(Figure 1)***.

Exposure and Endplate Preparation

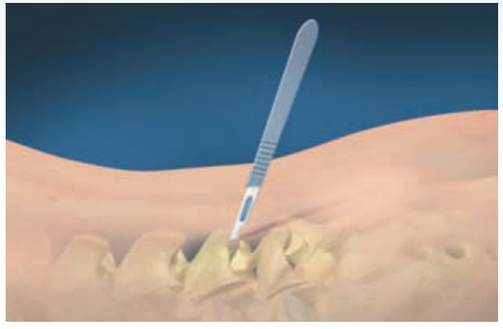


Figure 2
Incision area

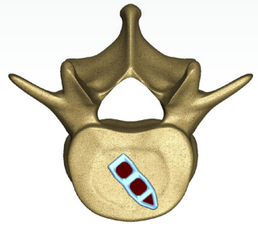


Figure 3a
Straight TLIF orientation

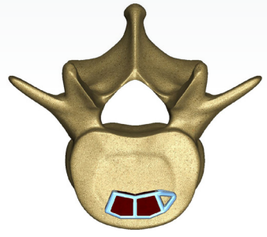


Figure 3b
Curve TLIF orientation

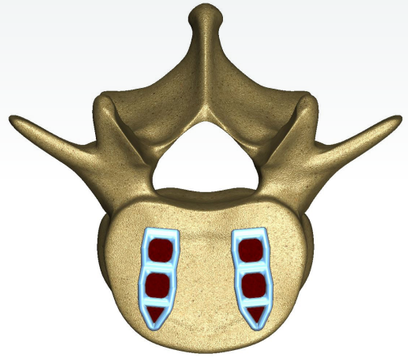


Figure 3c
PLIF orientation

STEP 2

Upon proper targeting of the affected level(s) a skin incision is made. The soft tissues are dissected and retracted providing the desired visualization of the bony anatomy ***(Figure 2)***.

Radiographic confirmation of levels with a marker attached to bone is recommended (ex. a spinal needle embedded in entrance to pedicle at junction of transverse process and superior facet).

TLIF Approach

- For an MIS procedure, the lateral inferior portion of the inferior facet of the superior vertebrae is removed with an osteotome, bur, or kerrison. The capsular portion of the ligamentum flavum is exposed and resected. The superior facet of the inferior vertebrae is resected with an osteotome, bur, or kerrison.
- For an open procedure, removal of the entire facet of the superior vertebrae may be necessary.
- The neural foramen and central spine canal are decompressed as necessary.
- The posterolateral portion of the annulus fibrosus is exposed and an annular window is created to gain access to the intervertebral space.
- A discectomy is performed with the use of retractors to ensure protection of neural elements.
- Endplate preparation should result in vascularization between the endplate and bone graft without weakening the cortical bone but still easing the insertion of the cage between the vertebral bodies.

  Note: *The ZimVie Spine posterior decompression and discectomy sets can be utilized for decompressive and discectomy procedures.*

  The cartilaginous endplates are removed utilizing the paddle scrapers , or curettes and/or rasps.

  Note: *The paddle scrapers are available in 1 mm increments from 6-16 mm in the posterior discectomy set.*

Bilateral PLIF Approach

- The lateral inferior portion of the inferior facet of the superior vertebrae is removed with an osteotome, bur, or kerrison. The capsular portion of the ligamentum flavum is exposed and resected. The superior facet of the inferior vertebrae is resected with an osteotome, bur, or kerrison.
- Repeat the process on the contralateral side.
- The neural foramen and central spine canal are decompressed as necessary.
- The posterolateral portion of the annulus fibrosus is exposed and an annular window is created to gain access to the intervertebral space.
- A discectomy is performed with the use of retractors to ensure protection of neural elements.
- Endplate preparation should result in vascularization between the endplate and bone graft without weakening the cortical bone but still easing the insertion of the implant between the vertebral bodies.

  Note: *The ZimVie Spine posterior decompression and discectomy sets can be utilized for decompressive and discectomy procedures.*

  The cartilaginous endplates are removed utilizing the paddle scrapers , or curettes and/or rasps.

  Note: *The paddle scrapers are available in 1 mm increments from 6-16 mm in the posterior discectomy set.*

Distraction and Implant Selection

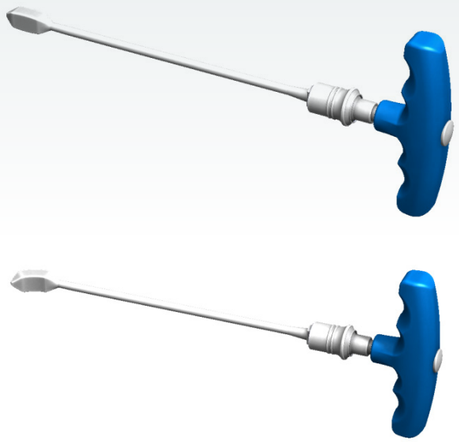


Figure 4
Trials

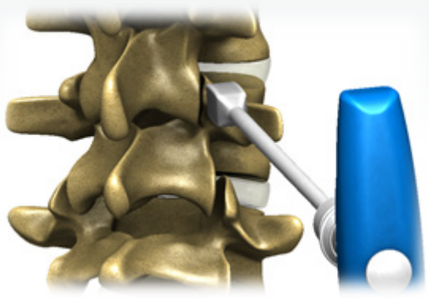


Figure 5
Trial insertion

STEP 3

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

- Attach the appropriate size trial to the modular T-handle.

  Note: *The trials of the Zyston Strut Open Titanium Interbody Spacer System are available in 1 mm increments from 6 mm-16 mm.*
- Insert the trial into the annulotomy window and position within the intervertebral space. Confirm positioning with A/P and lateral fluoroscopy.
- Repeat the trial process until the desired amount of distraction is achieved within the intervertebral space.

The height and length of the implant are determined from the final trial.

Note: *The Zyston Strut Open Titanium Interbody Spacer System trials mimic the length, height and width of the implant.*

Confirm the position and proper size of the trial using fluoroscopy:

- **A/P View:** Lateral coverage
- **Lateral View:** Length, height, lordosis, and anteroposterior positioning (the posterior edge of the cage should end 2 to 5 mm away from the posterior vertebral walls)

- Once the proper size is determined, remove the trial from the intervertebral space and select the corresponding implant.

Cage Preparation

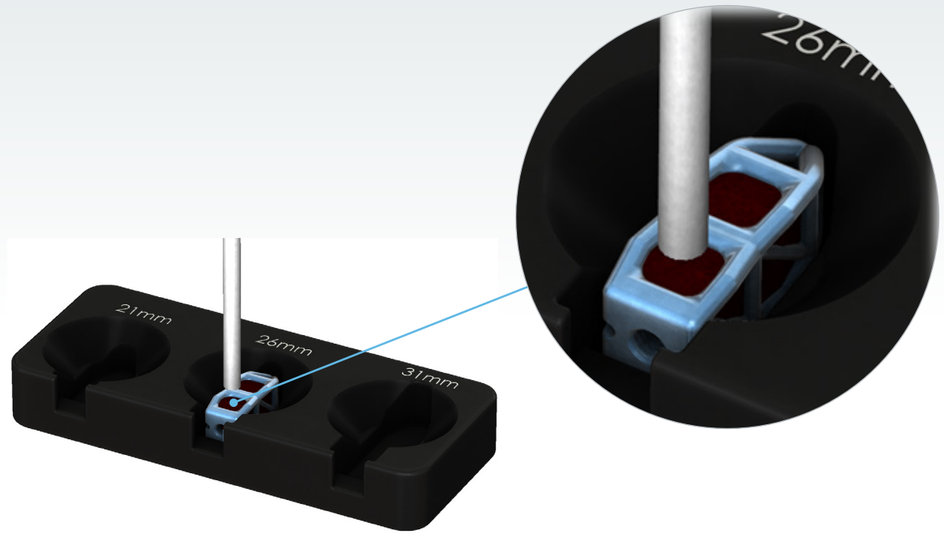


Figure 6
Graft packing

STEP 4

Graft Packing

Zyston Strut implants are provided sterile. After selecting and opening the correct implant, and prior to packing the implant with graft, it is recommended to pack the anterior portion of the disc space with graft prior to placement of the device.

- Remove the implant of the desired size from the implant carrying case and transfer it to the sterile field using proper sterile technique.

The Zyston Strut System comes with graft packing blocks to assist in packing graft into the open cavities of the device.

- Graft Packing Block, Straight
- Graft Packing Block, Curve

Each packing block has pockets associated with the various implant lengths.

- Place the implant in the appropriate pocket, and manually place graft in the windows of the device. To pack graft into the cavities, utilize the small round tamp. Pack the device until each of the two main cavities are full.

Implant to Cage Inserter Assembly

Figure 7
Inline inserter

Figure 8
MIS inserter

STEP 5

The Zyston Strut Open Titanium Spacer System comes complete with two inserters specific to the needs of the individual procedure.

- Inline inserter *(Figure 7)*
- MIS inserter *(Figure 8)*

Both instruments assemble to the implant and function in the same manner.

- After determining the preferred inserter, slide the designated inner shaft into the corresponding inserter. Align and insert the inner threaded rod into the threaded hole on the cage.
- Tighten the cage on the inserter by turning the inserter knob.
- Guide selected Zyston Strut implant, loaded with graft, onto the inserter, ensuring that the tabs at the distal end of the inserter mate with the cutouts along the medial/lateral walls of the implant. Turn the proximal knob of inserter clockwise until tight.

Implantation

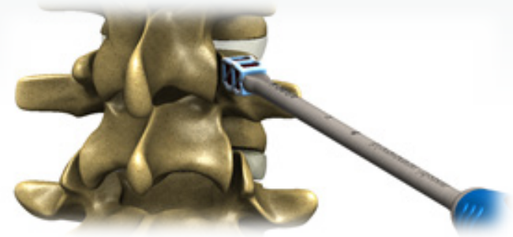


Figure 9
Implant insertion

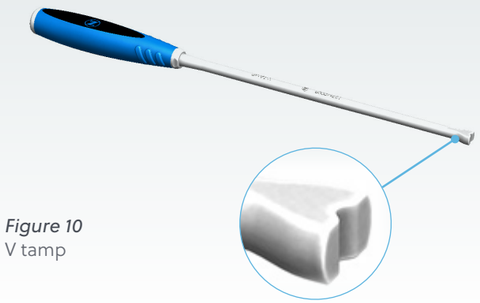


Figure 10
V tamp

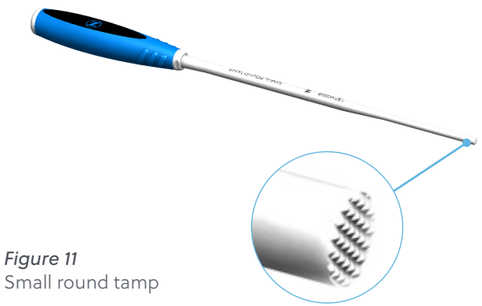


Figure 11
Small round tamp

STEP 6

- Insert the Zyston Strut Titanium Implant through the annulotomy window. Using gentle force, impact the implant to the desired position within the intervertebral space.
- Verify final positioning with A/P and lateral fluoroscopy.
- Upon final confirmation of position, turn the proximal knob of the inserter counter clockwise and remove the inserter from the implant.
- Final positioning of the implant can be achieved with the V tamp or the small round tamp.
- Repeat the process as necessary.

Implant Repositioning/Removal

Removal And Repositioning Hook

C-Clamp

Slap Hammer

Slap Hammer Adapter

Figure 12
Removal and reposition instruments

A removal and repositioning hook and C-clamp are provided for repositioning and removal of the device if either of the implant inserters are unable to re-engage the implant threads.

The removal and repositioning hook can be engaged with various features of the implant to provide adjustments to the implant position, or fully remove the device.

If the removal and repositioning hook cannot be engaged with the implant, the C-clamp can be utilized to clamp onto the device and adjust the implant position, or fully remove the device.

A slap hammer is provided with a threaded slap hammer adapter which is compatible with the proximal feature on the outer shaft of each of the implant inserters and C-clamp, as well as the handle of the removal and repositioning hook.

- Assemble the adapter to the slap hammer by threading the adapter onto the distal end of the slap hammer until tight.

  Note: *The handle can be used to tighten shaft to adapter.*
- "Hook" the adapter onto the groove at the proximal portion of the instrument. Pull the slap hammer proximal as necessary to remove the implant.

Supplemental Fixation and Closure

STEP 7

The Zyston Strut Open Titanium Spacer System must be used in conjunction with supplemental fixation cleared by FDA for use in the lumbar spine.

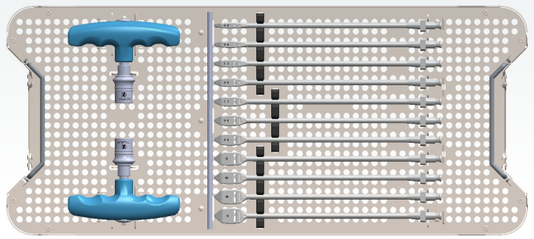
Implant supplemental fixation according to the recommended surgical technique for the specific system being used.

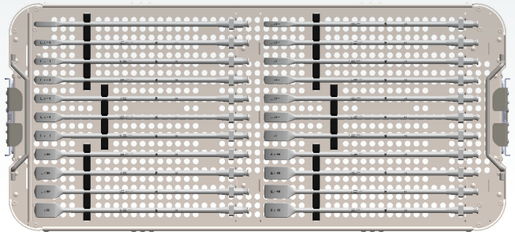
Closure is performed per facility aseptic protocols.

Prior to cleaning and sterilization remove the inner shafts from the implant inserters and the C-clamp.

Instrument Kits

Standard Trial Kit
Kit Number: PCR100M5101

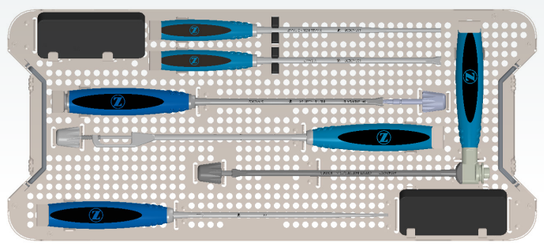


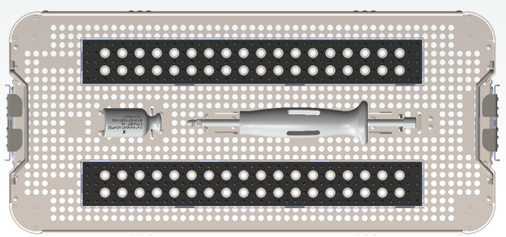


DESCRIPTION	QTY	PART NUMBER
T-Handle	2	130M0025
Curve Trial (L x W x H)		
28 x 10 x 06 mm	1	136M2806
28 x 10 x 07 mm	1	136M2807
28 x 10 x 08 mm	1	136M2808
28 x 10 x 09 mm	1	136M2809
28 x 10 x 10 mm	1	136M2810
28 x 10 x 11 mm	1	136M2811
28 x 10 x 12 mm	1	136M2812
28 x 11 x 13 mm	1	136M2813
28 x 11 x 14 mm	1	136M2814
28 x 11 x 15 mm	1	136M2815
28 x 11 x 16 mm	1	136M2816
33 x 10 x 06 mm	1	136M3306
33 x 10 x 07 mm	1	136M3307
33 x 10 x 08 mm	1	136M3308
33 x 10 x 09 mm	1	136M3309
33 x 10 x 10 mm	1	136M3310
33 x 10 x 11 mm	1	136M3311
33 x 10 x 12 mm	1	136M3312
33 x 11 x 13 mm	1	136M3313
33 x 11 x 14 mm	1	136M3314
33 x 11 x 15 mm	1	136M3315
33 x 11 x 16 mm	1	136M3316

DESCRIPTION	QTY	PART NUMBER
Straight Trial (L x W x H)		
26 x 10 x 06 mm	1	139M2606
26 x 10 x 07 mm	1	139M2607
26 x 10 x 08 mm	1	139M2608
26 x 10 x 09 mm	1	139M2609
26 x 10 x 10 mm	1	139M2610
26 x 10 x 11 mm	1	139M2611
26 x 10 x 12 mm	1	139M2612
26 x 11 x 13 mm	1	139M2613
26 x 11 x 14 mm	1	139M2614
26 x 11 x 15 mm	1	139M2615
26 x 11 x 16 mm	1	139M2616

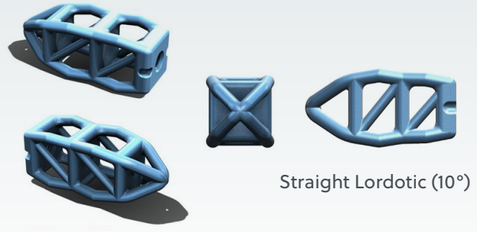
Standard Trial Kit
Kit Number: PCR100M4101





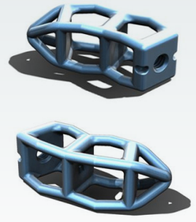
DESCRIPTION	QTY	PART NUMBER
Straight Packing Block	1	137M0000
Curve Packing Block	1	137M0001
Small Round Tamp	1	137M0008
V Tamp	1	137M0009
Reposition Hook	1	137M0015
Slap Hammer	1	137M0016
Slap Hammer Adapter	1	137M0017
Outer Shaft C Clamp	1	137M0019
Inner Shaft C Clamp	1	137M0020
Outer Shaft Inline Inserter	1	137M0002
Inner Shaft Inline Inserter	1	137M0003
Outer Shaft MIS Inserter	1	137M0004
Inner Shaft MIS Inserter	1	137M0005

Implant Kits



Straight Convex

Straight Lordotic (10°)



Curve Parallel

Curve Lordotic 10°

Zyston Strut Straight Convex Implant Kit
Kit Number: PCR1000M0111

SIZE (L X W X H)	PART NUMBER
21 x 10 x 07 mm	101M2107
26 x 10 x 07 mm	101M2607
31 x 10 x 07 mm	101M3107
21 x 10 x 08 mm	101M2108
26 x 10 x 08 mm	101M2608
31 x 10 x 08 mm	101M3108
21 x 10 x 09 mm	101M2109
26 x 10 x 09 mm	101M2609
31 x 10 x 09 mm	101M3109
21 x 10 x 10 mm	101M2110
26 x 10 x 10 mm	101M2610
31 x 10 x 10 mm	101M3110
21 x 10 x 11 mm	101M2111
26 x 10 x 11 mm	101M2611
31 x 10 x 11 mm	101M3111

SIZE (L X W X H)	PART NUMBER
21 x 10 x 12 mm	101M2112
26 x 10 x 12 mm	101M2612
31 x 10 x 12 mm	101M3112
21 x 11 x 13 mm	101M2113
26 x 11 x 13 mm	101M2613
31 x 11 x 13 mm	101M3113
21 x 11 x 14 mm	101M2114
26 x 11 x 14 mm	101M2614
31 x 11 x 14 mm	101M3114
21 x 11 x 15 mm	101M2115
26 x 11x 15 mm	101M2615
31 x 11 x 15 mm	101M3115
21 x 11 x 16 mm	101M2116
26 x 11 x 16 mm	101M2616
31 x 11 x 16 mm	101M3116

Zyston Strut Straight Lordotic 10° Implant Kit
Kit Number: PCR1000M0211

SIZE (L X W X H)	PART NUMBER
21 x 10 x 07 mm	103M2107
21 x 10 x 08 mm	103M2108
26 x 10 x 08 mm	103M2608
21 x 10 x 09 mm	103M2109
26 x 10 x 09 mm	103M2609
21 x 10 x 10 mm	103M2110
26 x 10 x 10 mm	103M2610
21 x 10 x 11 mm	103M2111
26 x 10 x 11 mm	103M2611

SIZE (L X W X H)	PART NUMBER
21 x 10 x 12 mm	103M2112
26 x 10 x 12 mm	103M2612
21 x 11 x 13 mm	103M2113
26 x 11 x 13 mm	103M2613
21 x 11 x 14 mm	103M2114
26 x 11 x 14 mm	103M2614

Zyston Strut Curve Parallel Implant Kit
Kit Number: PCR1000M0311

SIZE (L X W X H)	PART NUMBER
28 x 10 x 07 mm	102M2807
33 x 10 x 07 mm	102M3307
28 x 10 x 08 mm	102M2808
33 x 10 x 08 mm	102M3308
28 x 10 x 09 mm	102M2809
33 x 10 x 09 mm	102M3309
28 x 10 x 10 mm	102M2810
33 x 10 x 10 mm	102M3310
28 x 10 x 11 mm	102M2811
33 x 10 x 11 mm	102M3311

SIZE (L X W X H)	PART NUMBER
28 x 10 x 12 mm	102M2812
33 x 10 x 12 mm	102M3312
28 x 11 x 13 mm	102M2813
33 x 11 x 13 mm	102M3313
28 x 11 x 14 mm	102M2814
33 x 11 x 14 mm	102M3314
28 x 11 x 15 mm	102M2815
33 x 11 x 15 mm	102M3315

Zyston Strut Curve Lordotic 10° Implant Kit
Kit Number: PCR1000M0411

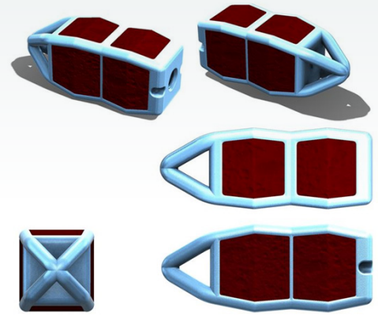
SIZE (L X W X H)	PART NUMBER
33 x 10 x 07 mm	104M3307
28 x 10 x 08 mm	104M2808
33 x 10 x 08 mm	104M3308
28 x 10 x 09 mm	104M2809
33 x 10 x 09 mm	104M3309
28 x 10 x 10 mm	104M2810
33 x 10 x 10 mm	104M3310
28 x 10 x 11 mm	104M2811
33 x 10 x 11 mm	104M3311

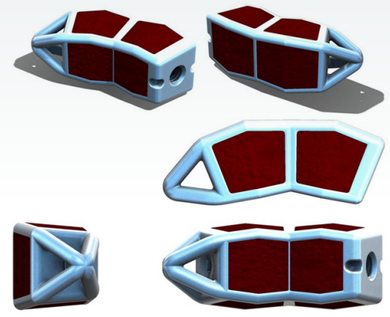
SIZE (L X W X H)	PART NUMBER
28 x 10 x 12 mm	104M2812
33 x 10 x 12 mm	104M3312
28 x 11 x 13 mm	104M2813
33 x 11 x 13 mm	104M3313
28 x 11 x 14 mm	104M2814
33 x 11 x 14 mm	104M3314
28 x 11 x 15 mm	104M2815
33 x 11 x 15 mm	104M3315

Implant Sizes And Graft Volumes

All volumes do not include graft in the nose portion of the cage.

All volumes reported in cubic centimeters (cc).





Straight Convex

(CC)	21 mm	26 mm	31 mm
7 mm	0.36	0.58	0.80
8 mm	0.44	0.71	0.97
9 mm	0.52	0.83	1.14
10 mm	0.60	0.96	1.31
11 mm	0.68	1.08	1.49
12 mm	0.76	1.21	1.66
13 mm	0.94	1.52	2.06
14 mm	1.02	1.64	2.23
15 mm	1.04	1.71	2.37
16 mm	1.06	1.77	2.49

Straight Lordotic

(CC)	21 mm	26 mm
7 mm	0.33	N/A
8 mm	0.41	0.63
9 mm	0.49	0.76
10 mm	0.59	0.88
11 mm	0.65	1.01
12 mm	0.72	1.13
13 mm	0.90	1.41
14 mm	0.99	1.55

Curve Parallel

(CC)	28 mm	33 mm
7 mm	0.70	0.95
8 mm	0.84	1.14
9 mm	0.99	1.34
10 mm	1.13	1.53
11 mm	1.27	1.73
12 mm	1.42	1.92
13 mm	1.71	2.32
14 mm	1.87	2.53
15 mm	1.96	2.68

Curve Lordotic

(CC)	28 mm	33 mm
7 mm	N/A	0.94
8 mm	0.80	1.01
9 mm	0.89	1.21
10 mm	1.04	1.40
11 mm	1.09	1.60
12 mm	1.32	1.79
13 mm	1.61	2.17
14 mm	1.76	2.38
15 mm	1.86	2.54

Important Information On The Zyston Strut Open Titanium Interbody System

Device Description

The Zyston Strut Open Titanium Interbody Spacer System implants are intervertebral body fusion devices consisting of a rectangular or semi-rectangular shape in various heights and footprints. The devices have an open central area to accommodate bone graft. The implants are available in a variety of sizes and configurations to approximate anatomical variation in different vertebral levels and/or patient anatomy. The implants are made of titanium alloy (Ti-6Al-4V). The Zyston Strut Interbody System instruments are provided non-sterile.

Indications for Use

When used as a lumbar intervertebral body fusion device, the Zyston Strut Interbody Spacer System is intended for spinal fusion procedures to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Zyston Strut Interbody Spacer System is to be implanted via a posterior approach and is to be combined with supplemental fixation. The titanium fusion devices are not indicated for vertebral body replacement.

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome.

Contraindications include, but are not limited to:

- Presence of fever or infection (systemic, spinal, or localized)
- Pregnancy
- Sever osteopenia
- Prior fusion at the level to be treated
- Any condition not described in the Indications for Use
- Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as patients with metal sensitivity or allergies to the implant materials, and patients unwilling or unable to cooperate with postoperative care instructions.

Warnings and Precautions

- Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with no previous surgery.
- The risk of a device expulsion and migration is higher without the use of supplemental fixation.
- Mixing of dissimilar metals can accelerate or initiate the corrosion process. Titanium components must NOT be used together in building a construct that involves other metal implant materials except for cobalt chrome.
- The Zyston Strut Interbody System device is intended to be used by surgeons specialized in spinal surgery with thorough knowledge of vertebral anatomy, regional vertebral morphology, and biomechanical principles of the spine. The surgical procedure is technically demanding and presents a risk of serious injury to the patient. It is advised that the surgeon also be thoroughly familiar with the surgical techniques, equipment, and instruments related to the use of the device. The surgical technique guide may be obtained by contacting ZimVie Spine customer service (contact information is provided below).
- Risks associated with neurosurgery, general surgery, orthopedic surgery, and the use of general anesthesia should be explained to the patient prior to surgery. It is recommended that the advantages and disadvantages of using implants, as well as alternative treatment methods, are explained to the patient.
- Correct selection and placement of the implants is extremely important. Implant selection must be based upon the bone defect and/or the levels to be treated as well as the patient's weight, height, occupation, or degree of physical activity.
- The Zyston Strut Interbody System must only be used with appropriate secondary stabilization instrumentation. The Zyston Strut Interbody System must not be used with vertebral components or instruments from other manufacturers and instrument components should not be used with instrument components from any other system or manufacturer. Specialized instruments are designed for ZimVie implant systems to aid in proper implantation. The use of instruments or implant components from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure.
- Perform a careful preoperative review to be sure that all necessary implant components are available and that the instrument set is complete and in working order prior to initiating surgery.
- Surgical instruments are subject to wear with normal usage. Instruments with cutting functions or points may become dull with normal use and no longer perform as intended. Instruments that have experienced extensive use are susceptible to fracture.
- Before use, inspect all instrumentation for possible damage, wear, or non-function. Damaged or defective instruments should not be used or processed. Contact your local ZimVie Spine representative or distributor for repair or replacement.
- Proper handling of the implant before and during the operation is crucial. Do not modify instruments. Do not notch, bend, or reshape instruments. Notches, scratches or other damage and/or wear in the instrument occurring during surgery may contribute to breakage. Do not use an instrument that has become bent from its original shape as this will affect the performance of the instrument. Bent instruments should be disposed of.
- The use of an instrument for tasks other than those for which they are indicated may result in damaged or broken instruments.
- Proper handling of the implant before and during the operation is crucial. Do not apply excessive force; misuse can damage instruments or implants.
- The Zyston Strut Interbody System has not been tested for safety and compatibility in the magnetic resonance (MR) environment. The Zyston Strut Interbody System device has not been tested for heating or migration in the MR environment.
- Do not reuse single use devices such as implants. While a single use device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the single use device. Do not treat patients with single use devices that have been, even momentarily, placed in or used on a different patient.
- Zyston Strut Interbody Spacers are not intended for rotation within the disc space.
- Federal Law (USA) restricts this device to sale by or on the order of a licensed physician only.
- All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.
- Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use.
- Instruments must be thoroughly cleaned prior to sterilization. Instruments that are not clean may not be effectively sterilized.
- Automated cleaning using a washer/disinfector alone may not be effective for complex orthopaedic instruments with lumens, cannulations, blind holes, mated surfaces and other features.
- Do not clean soiled instruments while in polymer or metal trays.

Possible Complications

Possible complications specific to the device may include:

- Early or late implant bending, breakage, failure, loosening or movement/migration;
- Bone fracture;
- Allergic reaction to implant material; and
- Nerve damage due to surgical trauma.
- Other general complications associated with any spinal surgical procedure may include: Non-union or delayed union, pseudoarthrosis; pain; second surgery; bleeding; infection, early and late; tissue or nerve damage, including dural tears or other neurological problems; incisional complications; scar formation; damage to blood vessels and cardiovascular system compromise; changes in mental status; damage to internal organs and connective tissue; complications due to the use of bone grafting, including graft donor site complications; respiratory problems; reactions to anesthesia and/or death.

Important Information On The Zyston Strut Open Titanium Interbody System *(continued)*

Sterilization

- The non-sterile Zyston Strut Interbody System instruments must be cleaned and sterilized prior to use. The recommended sterilization process for the instruments is steam autoclave sterilization, using the parameters listed in the table below. Use of an FDA-cleared wrap is recommended to maintain sterility prior to use. The recommended sterilization cycles have been validated to assure a Sterility Assurance Level of at least 10-6 SAL. All packaging materials must be removed prior to sterilization.
- Flash (immediate-use) steam sterilization is not recommended.
- The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be defined by the hospital's internal procedures.
- Steam sterilizer manufacturer recommendations should always be followed. When steam sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.
- Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contract with all surfaces.
- See Table 1 for recommended minimum steam sterilization parameters that have been validated to provide a 10-6 sterility assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table.

Note: *The Sterilizer Manufacturer's instructions for operation and load configuration should be followed explicitly.*

Table 1 – Recommended Steam Sterilization Parameters

Cycle Type	Temperature	Exposure Time	Minimum Dry Time[3]	Minimum Cool Time[4]
Prevacuum	132°C/270°F	4 min.	45 min.	30 min.
U.K. Prevacuum	134°C/273°F	3 min.		
Prevacuum[1,2]	134°C/273°F	18 min.		

1. Steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination.
2. This cycle is not to be used for the inactivation of prions.
3. Drying times vary according to load size and should be increased for larger loads.
4. Cooling times vary according to the type of sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.

These steam autoclave sterilization cycles and associated dry times are not considered by the Food and Drug Administration to be standard sterilization cycles. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature) and drying times. ZimVie does not recommend stacking of trays during the sterilization process. Individuals not using the recommended method, temperature and time are advised to validate any alternative methods or cycles using an approved method or standard. Sterile packaged components are sterilized by exposure to a minimum dose of 25-kGy gamma radiation, according to individual component labeling.

For more information, visit ZimVie.com

ZimVie Spine
10225 Westmoor Drive
Westminster, CO 80021, USA

Mfd. by: ZimVie Spine
10225 Westmoor Drive
Westminster, CO 80021, USA
Phone: +1-303-465-8960
Fax: +1-866-973-9072

EC REP **Zimmer GmbH**
Sulzerallee 8
CH-8404 Winterthur
Switzerland
+41 058.854.80.00

ZimVie
Restoring Daily Life.®