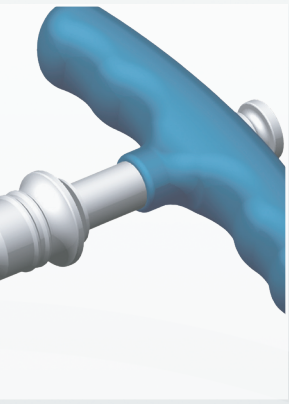
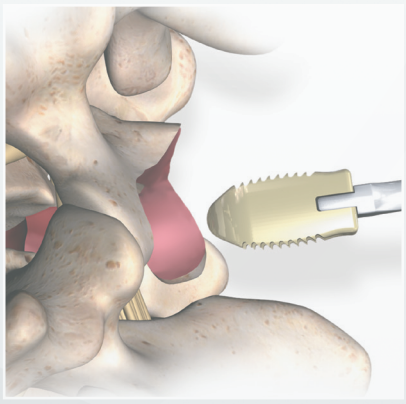
Zyston® Straight

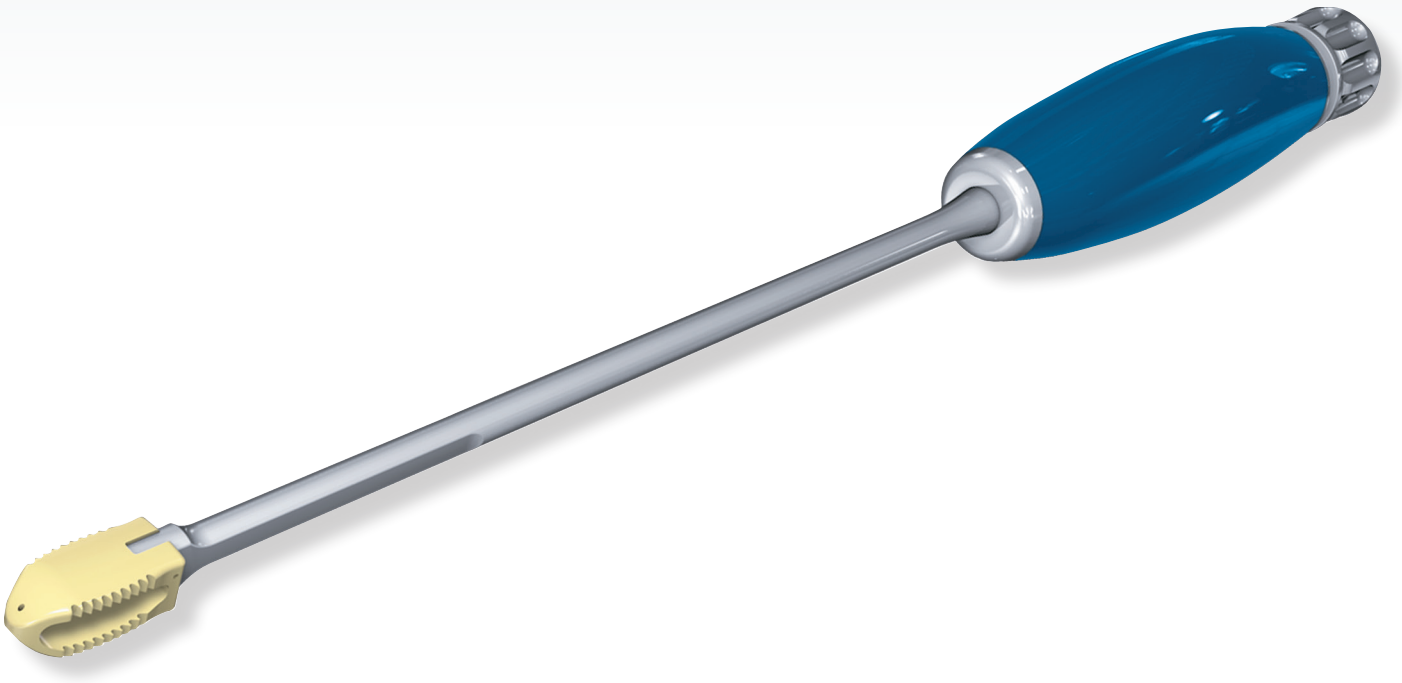
Interbody Spacer System

Surgical Technique Guide





ZimVie



The Zyston Straight Spacer System is designed
to enable simple insertion and accurate placement.

Table of Contents

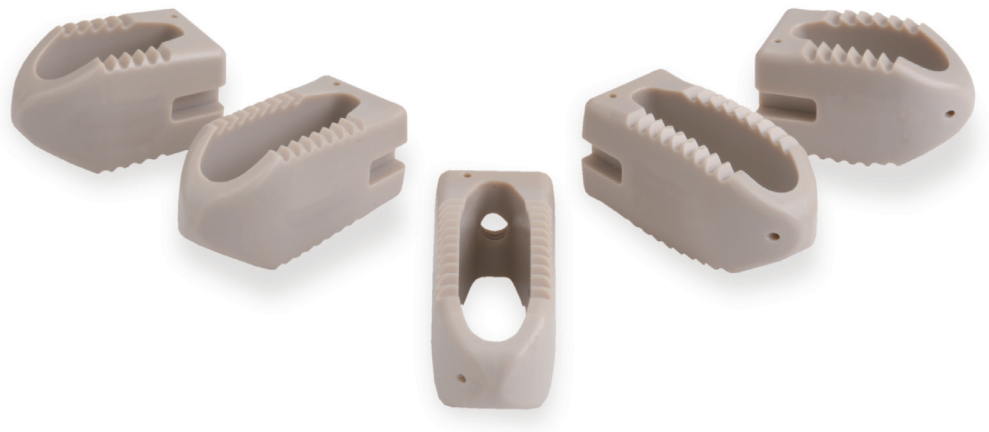
ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual 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.

System Overview

The Zyston Straight Interbody Spacer System implants and supporting instrumentation were designed to improve the clinical experience of placing PLIF and TLIF cages in the correct anatomical location.

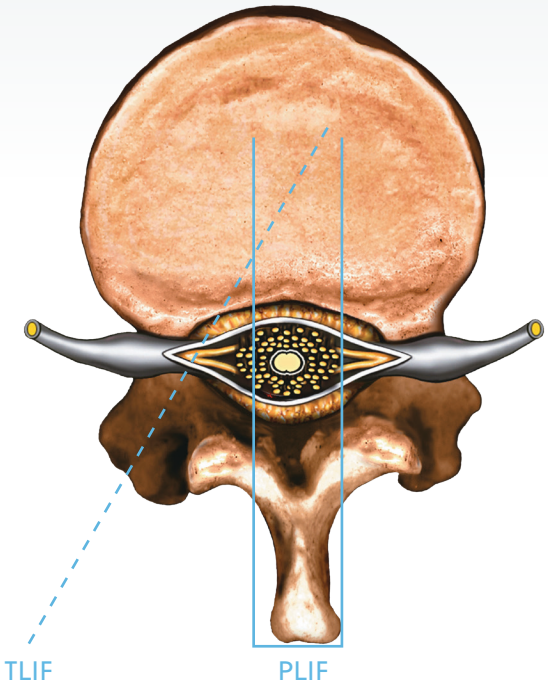
The system provides a full array of implant options featuring a bi-directional tapered leading edge, a large graft cavity and a streamlined instrumentation set to facilitate the insertion process.

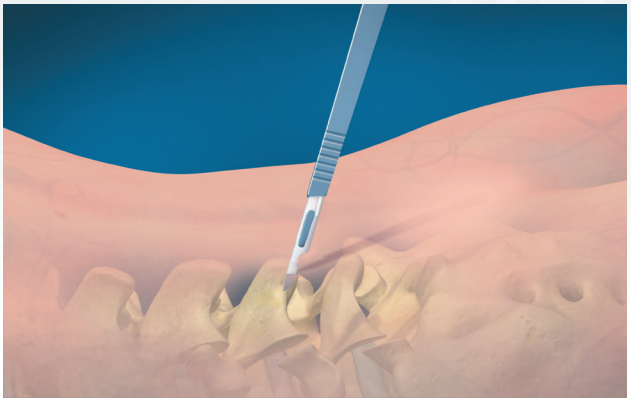
This surgical technique guide will provide guidance to the approach-related aspects of the PLIF and TLIF procedure, as well as describe the functionality of the implants and supporting instrumentation.



FEATURES	BENEFITS
Tapered leading edge	Self-distracting, aids in implant insertion and distraction
Large graft cavity	Provides increased volume for autograft packing to help aid in the fusion process
Low profile implant/instrument interface	Allows for added visualization during implant insertion, particularly in the medial plane
Multiple footprint options	Facilitates a precise anatomical fit
Line-to-line trials	Reduces intraoperative questions regarding final implant size

Preoperative Planning and Patient Positioning





Based on the individual patient and pathology, the Zyston Straight System can be utilized in a variety of approaches, which include:

- Transforaminal Approach (TLIF)
- Bilateral Approach (PLIF)
- Partial Vertebral Body Replacement

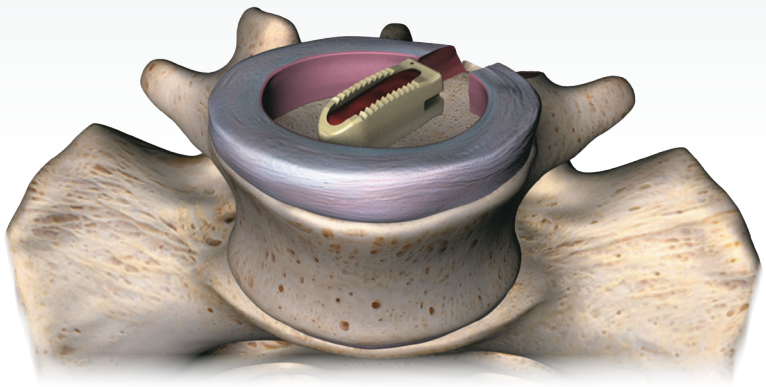
STEP 1

- The patient should be placed prone, in the appropriate
  position for a posterior approach, and shall be prepared and draped in a manner consistent with surgical facility protocol.
- Utilizing anterior and posterior fluoroscopic imaging and palpation of the patient anatomy, the affected level is identified and marked appropriately for incisions.

  Note: The Zyston Straight Spacer System can be implanted using a traditional open approach or a minimally invasive approach with the AccuVision System.

Refer to the AccuVision System surgical technique to learn about proper use of the AccuVision System.

Exposure and Endplate Preparation



STEP 2

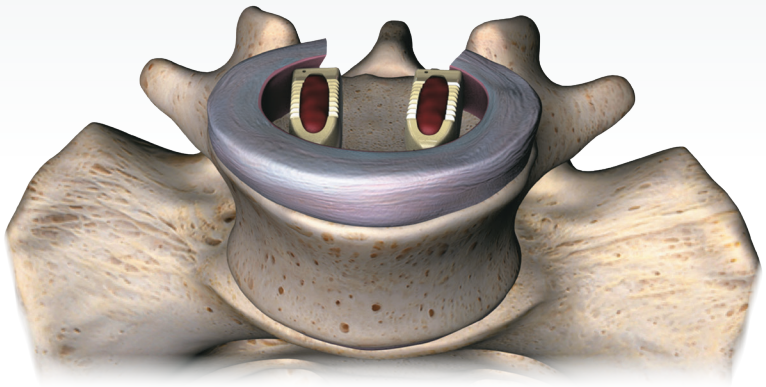
- Upon proper targeting of the affected level(s) a skin incision is made. The soft tissues are dissected and retracted providing the desired visualization of the bony anatomy.

TLIF 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.
- The neural foramen and central spinal 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.

  Note: A posterior discectomy instrument set can be utilized for decompressive and discectomy procedures.
- The cartilaginous endplates are removed utilizing the paddle scrapers.

  Note: The paddle scrapers are available in 1 mm increments from 6 mm to 18 mm. Assemble the modular T-handle to the quick connect fitting of the shaft prior to use.



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.

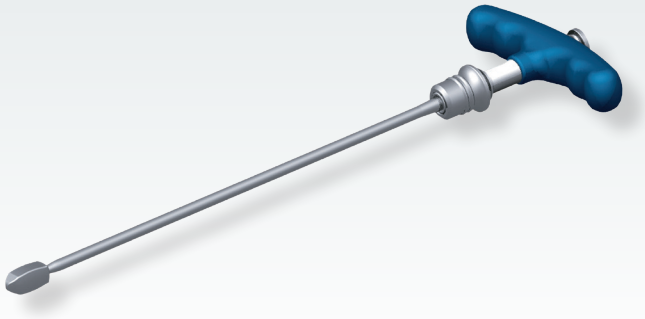
- Repeat the process on the contralateral side.
- The neural foramen and central spinal canal are decompressed as necessary.
- The posterolateral portion of the annulus fibrosus is exposed, and an annular window is created to gain access to the intervertebral space.
- A discectomy is performed.

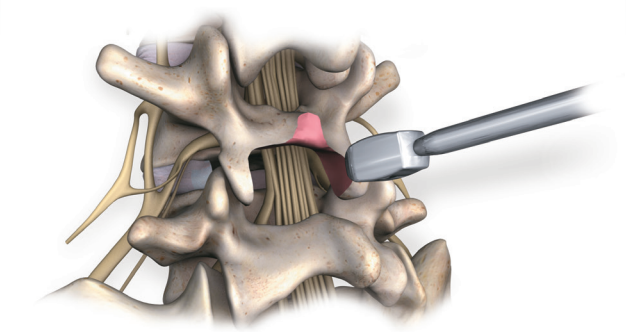
Note: A posterior discectomy instrument set can be utilized for decompressive and discectomy procedures.

- The cartilaginous endplates are removed utilizing the paddle scrapers.

Note: The paddle scrapers are available in 1 mm increments from 6 mm to 18 mm. Assemble the modular T-handle to the quick connect fitting of the shaft prior to use.

Trialing and Implant Selection





STEP 2 (CONTINUED)

Vertebral Body Replacement Technique

- The Zyston Straight Spacer System may also be utilized during vertebral body replacement procedures.
- The patient is positioned appropriately for the desired approach to the anatomical landmarks.
- A partial corpectomy is performed at the affected level(s).

STEP 3

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

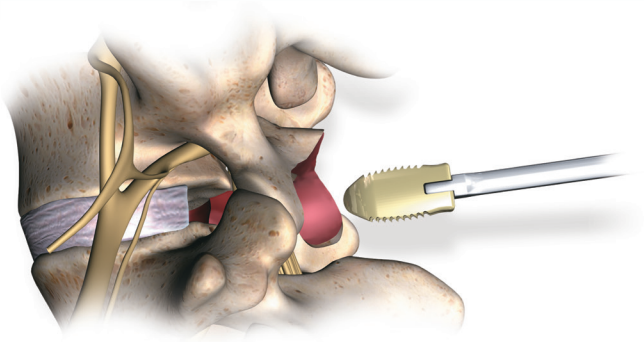
- Attach the appropriate size trial to the modular T-handle.

  Note: The trials of the Zyston Straight Spacer System are available in 1 mm increments from 6 mm to 18 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 Straight trials match the height of the implant.

Implantation



STEP 4

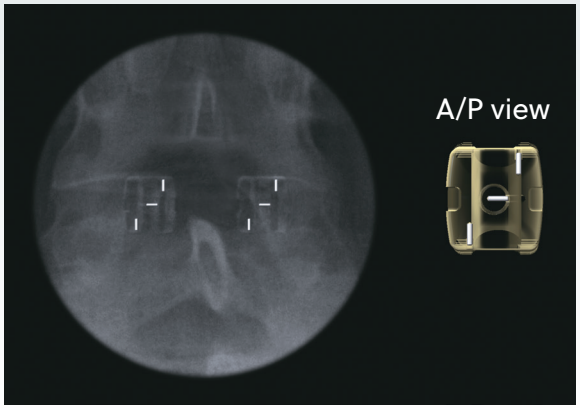
It is recommended to pack the anterior portion of the disc space with autograft prior to placement of the Zyston Straight implant.

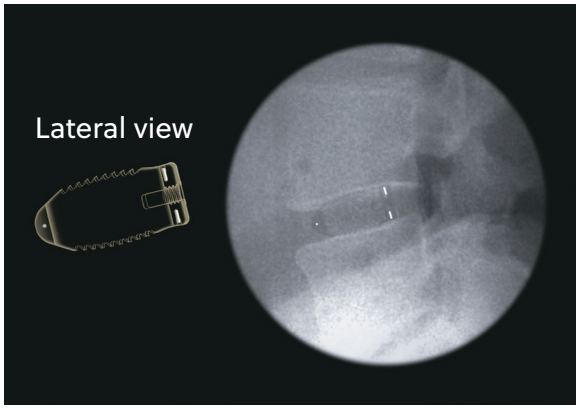
The Zyston Straight System comes complete with three inserters specific to the needs of the individual procedure and surgeon preference.

- Inline inserter
- T-handle inserter
- MIS inserter
- All instruments assemble to the implant and function in the same manner.

Assembly of Implant Inserter:

- Insert the threaded inner shaft into the proximal end of the desired inserter, turn the inner shaft clockwise to engage the retainer feature of the inner shaft to the inserter.
- Guide the appropriate size Zyston Straight implant to the inserter, ensuring that the prongs at the distal end of the inserter mate with the channels along the medial/lateral walls of the implant. Turn the proximal knob of the inserter clockwise until tight.
- Pack the graft chamber of the Zyston Straight implant utilizing the bone graft mold prior to implantation.
- Insert the Zyston Straight 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 counterclockwise and remove the inserter from the implant.
- Repeat the process as necessary.





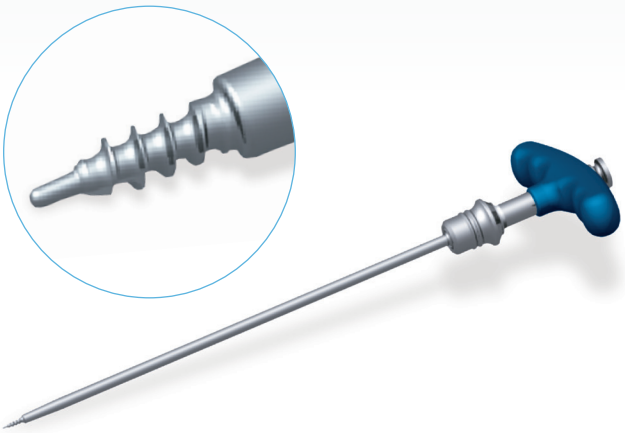
STEP 4 (CONTINUED)

- Final positioning of the implant can be achieved by using the straight, corner or "V" tamps with gentle force.
- Posterior supplemental fixation is performed. See the individual surgical technique manuals for specific instructions.
- Closure is performed per facility aseptic protocols.

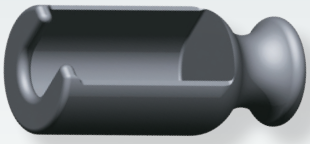
Cleaning

- Prior to cleaning and sterilization, remove the inner shafts from the implant inserters by turning the inner shaft counterclockwise until the retainer feature is free from the instrument and fully remove the inner shaft.
- Please refer to the Zimmer Biomet non-sterile instrument IFU for further reprocessing instructions.

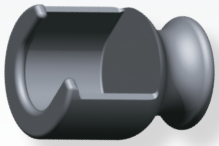
Implant Removal



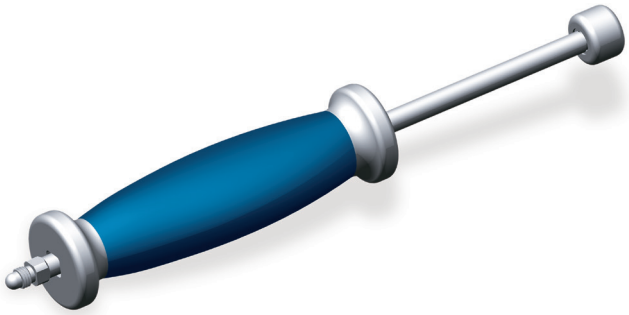
IMPLANT REMOVER



LARGE SLIDE HAMMER ADAPTER



SMALL SLIDE HAMMER ADAPTER



SLIDE HAMMER

- Assemble the quick connect T-handle to the implant remover.
- Locate the threaded portion of the implant.
- Thread the implant remover into the threaded PEEK hole.
- Using gentle force, slowly back out implant from the disc space by using the slotted mallet or the slide hammer.

The slide hammer utilizes two types of adapters to connect to the individual instrumentation:

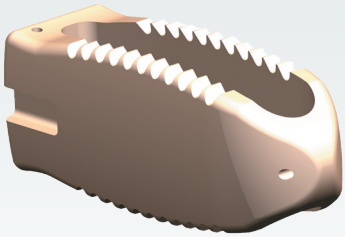
- MIS inserters "small adapter".
- Straight inserters "large adapter".

Assemble the appropriate adapter to the slide hammer by threading the adapter onto the distal end of the instrument 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 slide hammer proximal as necessary to remove the implant.

Implants



Footprint: 30 mm long

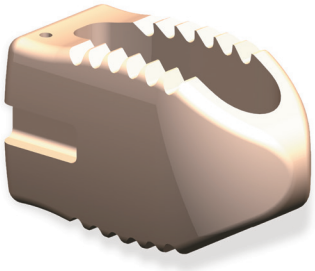
Standard Heights: 7 mm–16 mm (1 mm increments)

17 mm and 18 mm* (Available as special order)

Shapes: Convex only

10 mm × 30 mm, 7 mm to 12 mm H

11 mm × 30 mm, 13 mm to 16 mm H



Footprint: 20 mm long

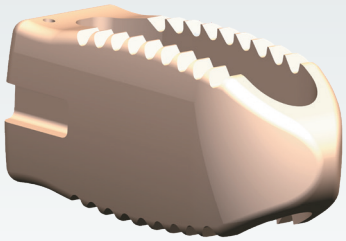
Standard Heights: 7 mm–16 mm (1 mm increments)

17 mm and 18 mm* (Available as special order)

Shapes: Convex and Lordotic 8°

10 mm × 20 mm, 7 mm to 12 mm H

11 mm × 20 mm, 13 mm to 16 mm H



Footprint: 25 mm long

Standard Heights: 7 mm–16 mm (1 mm increments)

17 mm and 18 mm* (Available as special order)

Shapes: Convex endplates and Lordotic 8°

10 mm × 25 mm, 7 mm to 12 mm H

11 mm × 25 mm, 13 mm to 16 mm H

Available Graft Volume By Implant Size (Graft volume depicted in cc's):

HEIGHT	LENGTH		
	20 mm	25 mm	30 mm
7 mm	0.43	0.59	0.73
8 mm	0.5	0.68	0.85
9 mm	0.56	0.77	0.97
10 mm	0.63	0.86	1.09
11 mm	0.69	0.95	1.25
12 mm	0.84	1.19	1.52
13 mm	0.92	1.29	1.66
14 mm	0.99	1.39	1.76
15 mm	1.07	1.51	1.93
16 mm	1.14	1.61	2.06
17 mm	1.2	1.7	2.19
18 mm	1.28	1.81	2.33

Note: The convex and lordotic implants have the same volumetric graft cavity.

*10 mm widths not available in 17 mm and 18 mm heights.

Instruments

20 MM TRIALS 6 MM–18 MM (1 MM INCREMENTS) | PART NUMBERS

14-534606–14-534638

25 MM TRIALS 6 MM–18 MM (1 MM INCREMENTS) | PART NUMBERS

14-534666–14-534698

30 MM TRIALS 6 MM–18 MM (1 MM INCREMENTS) | PART NUMBERS

14-534726–14-534758

STRAIGHT TAMP | PART NUMBER

14-534908

"V" TAMP | PART NUMBER

14-534909

CORNER TAMP | PART NUMBER

14-534910

INLINE INSERTER | PART NUMBER

14-534900

MIS IMPLANT INSERTER | PART NUMBER

14-534901

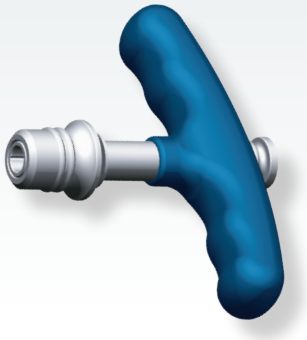
T-HANDLE INSERTER | PART NUMBER

14-534904

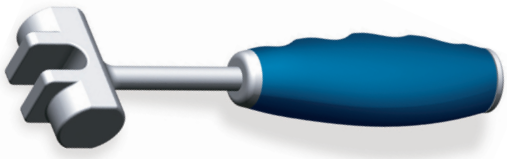
PADDLE SCRAPERS 6 MM–18 MM (1 MM INCREMENTS) | PART NUMBERS

14-533206–14-533218

Instruments (Continued)



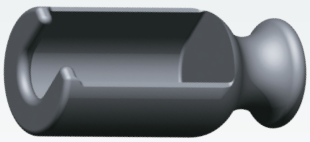
QUICK CONNECT T-HANDLE	PART NUMBER
	14-533202



SLOTTED MALLET	PART NUMBER
	14-533203

SLIDE HAMMER	PART NUMBER
	14-533204

FOOTED TAMP	PART NUMBER
	14-533205



LARGE SLIDE HAMMER ADAPTER	PART NUMBER
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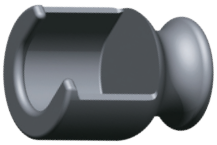

SMALL SLIDE HAMMER ADAPTER	PART NUMBER
	14-533221

Kit Contents

Zyston Straight Convex Implants
Kit Number: 14-534002

DESCRIPTION H × L × W	QTY	PART NUMBER
Straight Spacer, Convex, 7 mm × 20 mm × 10 mm	2	14-534007
Straight Spacer, Convex, 8 mm × 20 mm × 10 mm	2	14-534008
Straight Spacer, Convex, 9 mm × 20 mm × 10 mm	2	14-534009
Straight Spacer, Convex, 10 mm × 20 mm × 10 mm	2	14-534010
Straight Spacer, Convex, 11 mm × 20 mm × 10 mm	2	14-534011
Straight Spacer, Convex, 12 mm × 20 mm × 10 mm	2	14-534012
Straight Spacer, Convex, 13 mm × 20 mm × 11 mm	2	14-534033
Straight Spacer, Convex, 14 mm × 20 mm × 11 mm	2	14-534034
Straight Spacer, Convex, 15 mm × 20 mm × 11 mm	0	14-534035*
Straight Spacer, Convex, 16 mm × 20 mm × 11 mm	0	14-534036*
Straight Spacer, Convex, 17 mm × 20 mm × 11 mm	0	14-534037
Straight Spacer, Convex, 18 mm × 20 mm × 11 mm	0	14-534038
Straight Spacer, Convex, 7 mm × 25 mm × 10 mm	2	14-534067
Straight Spacer, Convex, 8 mm × 25 mm × 10 mm	2	14-534068
Straight Spacer, Convex, 9 mm × 25 mm × 10 mm	2	14-534069
Straight Spacer, Convex, 10 mm × 25 mm × 10 mm	2	14-534070
Straight Spacer, Convex, 11 mm × 25 mm × 10 mm	2	14-534071
Straight Spacer, Convex, 12 mm × 25 mm × 10 mm	2	14-534072
Straight Spacer, Convex, 13 mm × 25 mm × 11 mm	2	14-534093
Straight Spacer, Convex, 14 mm × 25 mm × 11 mm	2	14-534094
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Straight Spacer, Convex, 16 mm × 25 mm × 11 mm	0	14-534096*
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Straight Spacer, Convex, 12 mm × 30 mm × 10 mm	0	14-534132*
Straight Spacer, Convex, 13 mm × 30 mm × 11 mm	0	14-534153*
Straight Spacer, Convex, 14 mm × 30 mm × 11 mm	0	14-534154*
Straight Spacer, Convex, 15 mm × 30 mm × 11 mm	0	14-534155*
Straight Spacer, Convex, 16 mm × 30 mm × 11 mm	0	14-534156*
Straight Spacer, Convex, 17 mm × 30 mm × 11 mm	0	14-534157
Straight Spacer, Convex, 18 mm × 30 mm × 11 mm	0	14-534158

Zyston Straight Lordotic Implants
Kit Number: 14-534181

DESCRIPTION H × L × W	QTY	PART NUMBER
Straight Spacer, 7 mm × 20 mm × 10 mm, 8°	2	14-534187
Straight Spacer, 8 mm × 20 mm × 10 mm, 8°	4	14-534188
Straight Spacer, 9 mm × 20 mm × 10 mm, 8°	4	14-534189
Straight Spacer, 10 mm × 20 mm × 10 mm, 8°	4	14-534190
Straight Spacer, 11 mm × 20 mm × 10 mm, 8°	4	14-534191
Straight Spacer, 12 mm × 20 mm × 10 mm, 8°	4	14-534192
Straight Spacer, 13 mm × 20 mm × 11 mm, 8°	4	14-534213
Straight Spacer, 14 mm × 20 mm × 11 mm, 8°	4	14-534214
Straight Spacer, 15 mm × 20 mm × 11 mm, 8°	0	14-534215*
Straight Spacer, 16 mm × 20 mm × 11 mm, 8°	0	14-534216*
Straight Spacer, 17 mm × 20 mm × 11 mm, 8°	0	14-534217
Straight Spacer, 18 mm × 20 mm × 11 mm, 8°	0	14-534218
Straight Spacer, 7 mm × 25 mm × 10 mm, 8°	2	14-534247
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Straight Spacer, 9 mm × 25 mm × 10 mm, 8°	4	14-534249
Straight Spacer, 10 mm × 25 mm × 10 mm, 8°	4	14-534250
Straight Spacer, 11 mm × 25 mm × 10 mm, 8°	4	14-534251
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Straight Spacer, 16 mm × 25 mm × 11 mm, 8°	0	14-534276*
Straight Spacer, 17 mm × 25 mm × 11 mm, 8°	0	14-534277
Straight Spacer, 18 mm × 25 mm × 11 mm, 8°	0	14-534278

*Available by special order.

Kit Contents (Continued)

Zyston Straight Convex Trials
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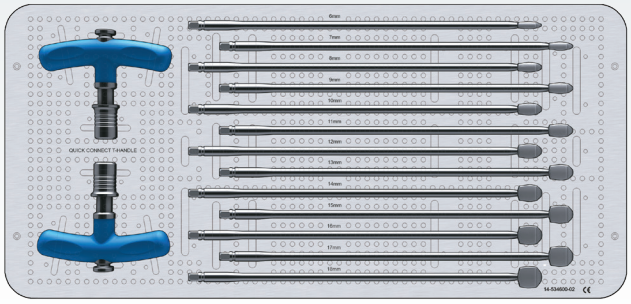
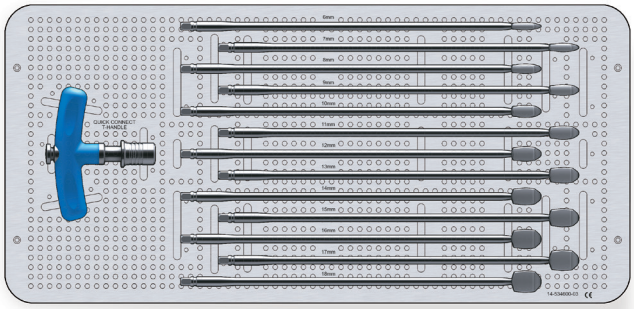
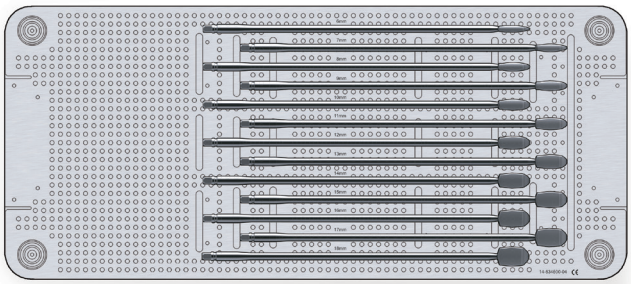


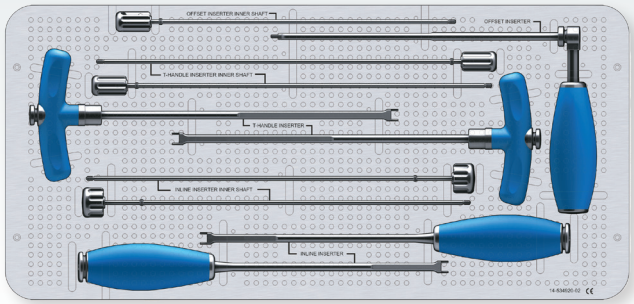


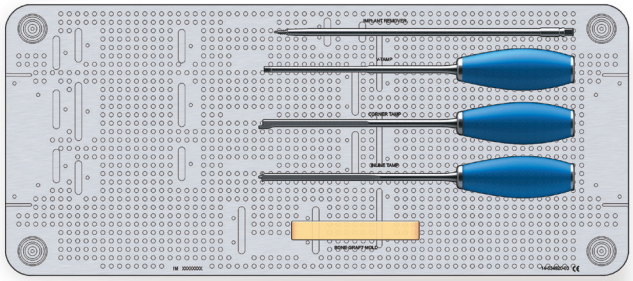


DESCRIPTION H × L × W	QTY	PART NUMBER
Straight Fixed Trial, Convex, 6 mm × 20 mm × 10 mm	1	14-534606
Straight Fixed Trial, Convex, 7 mm × 20 mm × 10 mm	1	14-534607
Straight Fixed Trial, Convex, 8 mm × 20 mm × 10 mm	1	14-534608
Straight Fixed Trial, Convex, 9 mm × 20 mm × 10 mm	1	14-534609
Straight Fixed Trial, Convex, 10 mm × 20 mm × 10 mm	1	14-534610
Straight Fixed Trial, Convex, 11 mm × 20 mm × 10 mm	1	14-534611
Straight Fixed Trial, Convex, 12 mm × 20 mm × 10 mm	1	14-534612
Straight Fixed Trial, Convex, 13 mm × 20 mm × 11 mm	1	14-534633
Straight Fixed Trial, Convex, 14 mm × 20 mm × 11 mm	1	14-534634
Straight Fixed Trial, Convex, 15 mm × 20 mm × 11 mm	1	14-534635
Straight Fixed Trial, Convex, 16 mm × 20 mm × 11 mm	1	14-534636
Straight Fixed Trial, Convex, 17 mm × 20 mm × 11 mm	1	14-534637
Straight Fixed Trial, Convex, 18 mm × 20 mm × 11 mm	1	14-534638
Straight Fixed Trial, Convex, 6 mm × 25 mm × 10 mm	1	14-534666
Straight Fixed Trial, Convex, 7 mm × 25 mm × 10 mm	1	14-534667
Straight Fixed Trial, Convex, 8 mm × 25 mm × 10 mm	1	14-534668
Straight Fixed Trial, Convex, 9 mm × 25 mm × 10 mm	1	14-534669
Straight Fixed Trial, Convex, 10 mm × 25 mm × 10 mm	1	14-534670
Straight Fixed Trial, Convex, 11 mm × 25 mm × 10 mm	1	14-534671
Straight Fixed Trial, Convex, 12 mm × 25 mm × 10 mm	1	14-534672

DESCRIPTION H × L × W	QTY	PART NUMBER
Straight Fixed Trial, Convex, 13 mm × 25 mm × 11 mm	1	14-534693
Straight Fixed Trial, Convex, 14 mm × 25 mm × 11 mm	1	14-534694
Straight Fixed Trial, Convex, 15 mm × 25 mm × 11 mm	1	14-534695
Straight Fixed Trial, Convex, 16 mm × 25 mm × 11 mm	1	14-534696
Straight Fixed Trial, Convex, 17 mm × 25 mm × 11 mm	1	14-534697
Straight Fixed Trial, Convex, 18 mm × 25 mm × 11 mm	1	14-534698
Straight Fixed Trial, Convex, 6 mm × 30 mm × 10 mm	1	14-534726
Straight Fixed Trial, Convex, 7 mm × 30 mm × 10 mm	1	14-534727
Straight Fixed Trial, Convex, 8 mm × 30 mm × 10 mm	1	14-534728
Straight Fixed Trial, Convex, 9 mm × 30 mm × 10 mm	1	14-534729
Straight Fixed Trial, Convex, 10 mm × 30 mm × 10 mm	1	14-534730
Straight Fixed Trial, Convex, 11 mm × 30 mm × 10 mm	1	14-534731
Straight Fixed Trial, Convex, 12 mm × 30 mm × 10 mm	1	14-534732
Straight Fixed Trial, Convex, 13 mm × 30 mm × 11 mm	1	14-534753
Straight Fixed Trial, Convex, 14 mm × 30 mm × 11 mm	1	14-534754
Straight Fixed Trial, Convex, 15 mm × 30 mm × 11 mm	1	14-534755
Straight Fixed Trial, Convex, 16 mm × 30 mm × 11 mm	1	14-534756
Straight Fixed Trial, Convex, 17 mm × 30 mm × 11 mm	1	14-534757
Straight Fixed Trial, Convex, 18 mm × 30 mm × 11 mm	1	14-534758

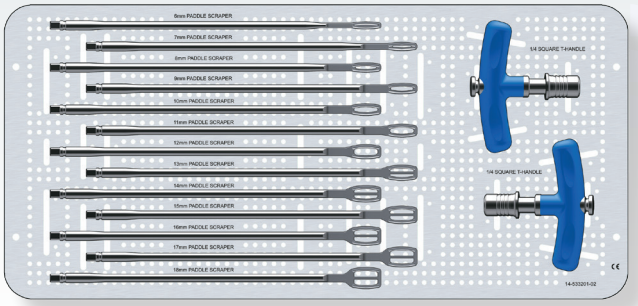
Zyston Straight Instruments
Kit Number: 14-534921

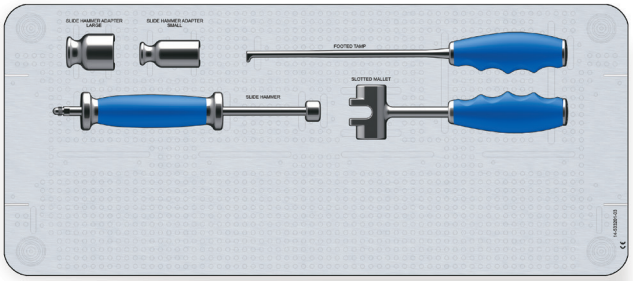




DESCRIPTION	QTY	PART NUMBER
Straight Inline Inserter	2	14-534900
Straight Inline Inserter Inner Shaft	2	14-534901
Straight Offset Inserter	1	14-534902
Straight Offset Inserter Inner Shaft	1	14-534903
Straight T-handle Inserter	2	14-534904
Straight T-handle Inserter Inner Shaft	2	14-534905
Straight Implant Remover	1	14-534906
Straight Bone Graft Mold	1	14-534907
Straight Inline Tamp	1	14-534908
Straight "V" Tamp	1	14-534909
Straight Corner Tamp	1	14-534910

Zyston Universal Instruments
Kit Number: 14-533200





DESCRIPTION	QTY	PART NUMBER
Quick Connect T-handle	2	14-533202
Slotted Mallet	1	14-533203
Slide Hammer	1	14-533204
Footed Tamp	1	14-533205
Paddle Scraper, 6 mm	1	14-533206
Paddle Scraper, 7 mm	1	14-533207
Paddle Scraper, 8 mm	1	14-533208
Paddle Scraper, 9 mm	1	14-533209
Paddle Scraper, 10 mm	1	14-533210
Paddle Scraper, 11 mm	1	14-533211
Paddle Scraper, 12 mm	1	14-533212
Paddle Scraper, 13 mm	1	14-533213
Paddle Scraper, 14 mm	1	14-533214
Paddle Scraper, 15 mm	1	14-533215
Paddle Scraper, 16 mm	1	14-533216
Paddle Scraper, 17 mm	1	14-533217
Paddle Scraper, 18 mm	1	14-533218
Small Slide Hammer Adapter	1	14-533221
Large Slide Hammer Adapter	1	14-533222

Important Information on the Zyston Straight Interbody Spacer System

Device Description

The Zyston Straight Spacer System was designed to restore height and lordotic angle in the spine. The Zyston Straight Spacer System is available in two styles (lordotic and convex), in a variety of lengths, widths and heights to optimize fit.

The convex style is elliptical in shape to match the natural contours of the endplates with an endplate sparing design to resist subsidence. The lordotic style is tapered to aid in the restoration of lordosis in the anterior-posterior plane with an endplate sparing design to resist subsidence. The top and bottom walls of the implant body have serrated teeth to provide stability by engaging the endplates to help resist shear and rotational forces. Curved superior and inferior surfaces provide structural integrity. The central area allows for placement of autograft material allowing for subsequent bone growth through the interior of the device. When used for vertebral body replacement, bone graft material may be used.

The PEEK-OPTIMA® LT1 material is radiolucent and permits unobstructed radiographic assessment of the fusion mass. However, due to its radiolucency, the Zyston Straight device has tantalum markers within the body of the spacer to help visualize implant orientation within the spine during surgery and post-operatively. A threaded insertion feature is machined into the PEEK body to allow use of an inserter.

Indications for Use

The Zyston Straight Spacer System is indicated for vertebral body replacement and intervertebral body fusion. When used for vertebral body replacement, the Zyston Straight Spacer System is indicated for use in the thoracolumbar spine (i.e., T1- L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Zyston Straight Spacer System is also indicated for treating fractures of the thoracic and lumbar spine. The Zyston Straight Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time. When used for vertebral body replacement, the Zyston Straight Spacer System is designed for use with bone graft and is intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine.

As an intervertebral body fusion device, the Zyston Straight Spacer System is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. When used as an intervertebral body fusion device, the Zyston Straight Spacer System is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

The Zyston Straight Spacer System may also be implanted using the AccuVision System to provide the surgeon with a minimally invasive approach for posterior or posterolateral spinal surgery.

Contraindications

Contraindications include, but are not limited to: infection, systemic, spinal or localized; morbid obesity; signs of local inflammation; fever or leukocytosis; metal sensitivity/allergies to the implant materials; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count; grossly distorted anatomy due to congenital abnormalities; rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft); any case not needing a bone graft and fusion or where fracture healing is not required; any case requiring the mixing of metals from different components; any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition; any case not described in the indications; any patient unwilling to cooperate with the postoperative instructions; any time implant utilization would interfere with anatomical structures or expected physiological performance; prior fusion at the level(s) to be treated.

Warnings

The surgeon should be aware of the following:

- The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
- The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be

carefully unpacked and inspected for damage prior to use.

- All instruments must be cleaned and sterilized prior to surgery.
- As with all orthopaedic implants, the Zyston Straight Spacer System should never be reused under any circumstances.
- Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
- Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.
- The Zyston Straight Spacer System has not been evaluated for safety and compatibility in the MR environment. The Zyston Straight Spacer System has not been tested for heating or migration in the MR environment.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- ZimVie spine implants should not be used with implants or instruments from another manufacturer for reasons of metallurgy, mechanics and design.
- Based upon dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, and any other factor which may impact on the performance of the device.

Precautions

Preoperative:

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or pre-dispositions such as those addressed in the Contraindications Section should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
- All instruments should be cleaned and sterilized before use.

Intraoperative:

- Any instruction manuals should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions.

Postoperative:

- The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented, or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
- If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants/devices that have been even momentarily placed in or used on a different patient.

For more information, visit ZimVie.com

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