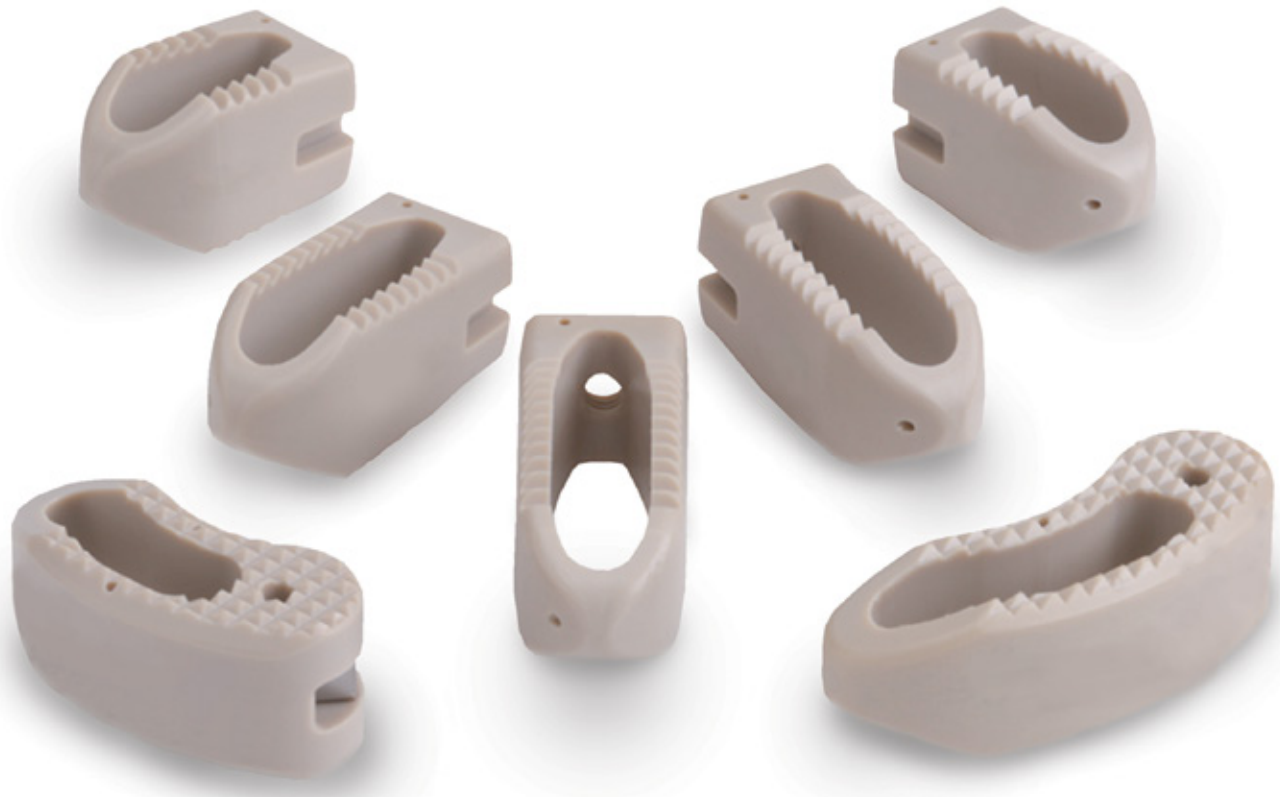
ZIMMER BIOMET
Your progress. Our promise.™



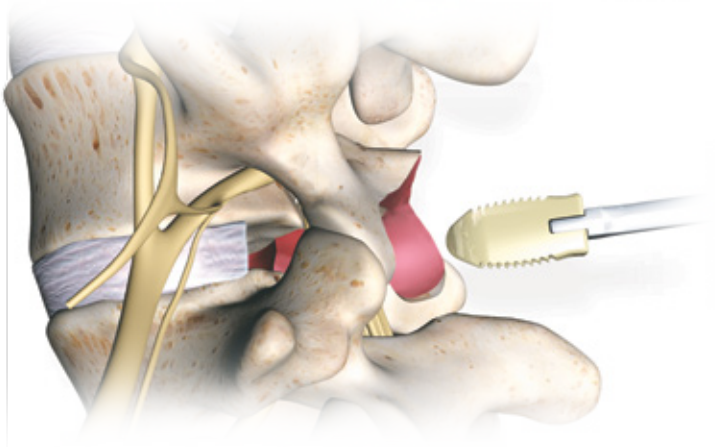
Thoracolumbar Solutions

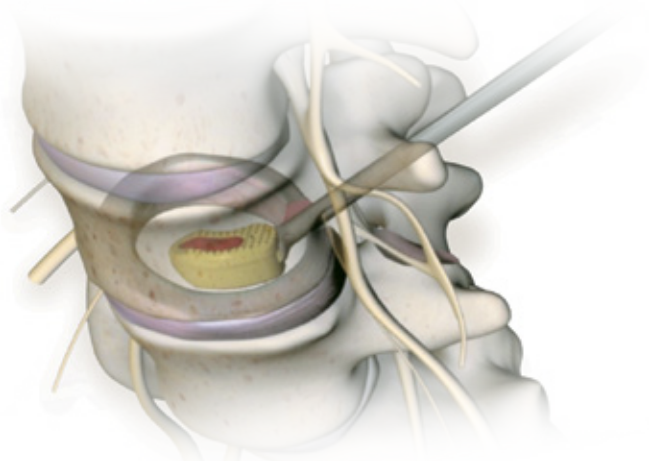
Zyston®
Interbody Spacer System

Featuring both straight and curved spacers, the Zyston System is designed to optimize your procedures through simplified insertion and accurate placement.

Enhance Control and Precision in Each Procedure

The Zyston System is purposefully engineered to address two of your most important clinical needs: **insertion and placement.**





Zyston® Straight Interbody Spacer

Simplified Insertion

- Secure tactile control
- Clear visualization
- Assertive tapered leading edge

Accurate Placement

- Robust implant/inserter interface
- Markers that provide confidence and confirmation

Zyston® Curved Interbody Spacer

While a clinically efficient procedure, placement of the TLIF interbody cage poses a challenge to surgeons due to anatomical anomalies and instrumentation that does not permit the proper orientation of the spacer. To optimize this approach, the interbody cage needs to be placed in the anterior third of the disc space to support the biomechanical loads of the anterior column.

The Zyston Curved System is designed to address this challenge through simplified insertion and accurate placement.

Simplified Insertion

- Secure tactile control
- Clear visualization

Accurate Placement

- Controlled articulating mechanism that provides variable and fixed angulation
- Markers that provide confidence and confirmation

Zyston Straight System: Simplified Insertion

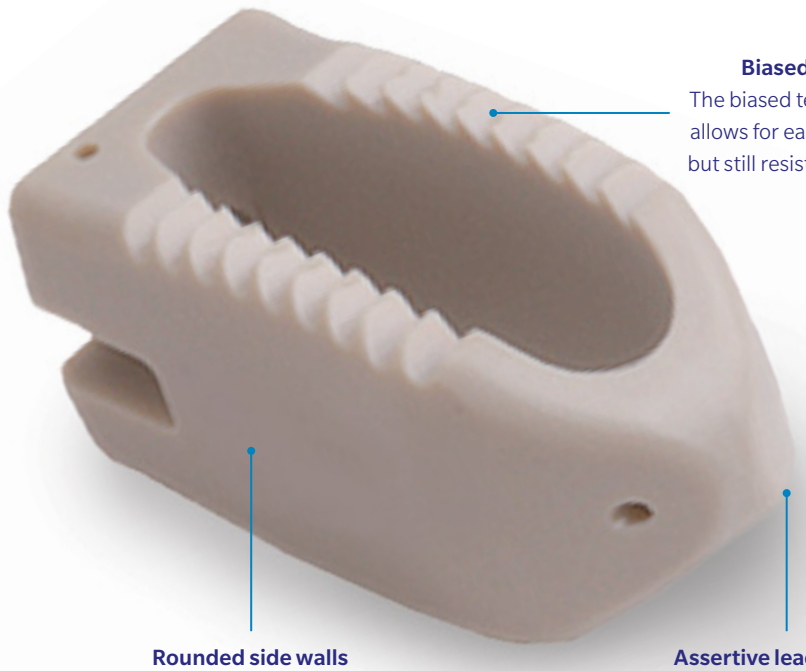
Secure Tactile Control

By providing a strong bond between the Zyston Straight System inserter and implant, the system promotes secure tactile control throughout the insertion process. This can minimize the number of passes through the annulotomy window.

Clear Visualization

Offering a 8mm × 5mm inserter with a low profile, the Zyston Straight System delivers clear visualization during the entire insertion process.

IMPLANT DESIGN

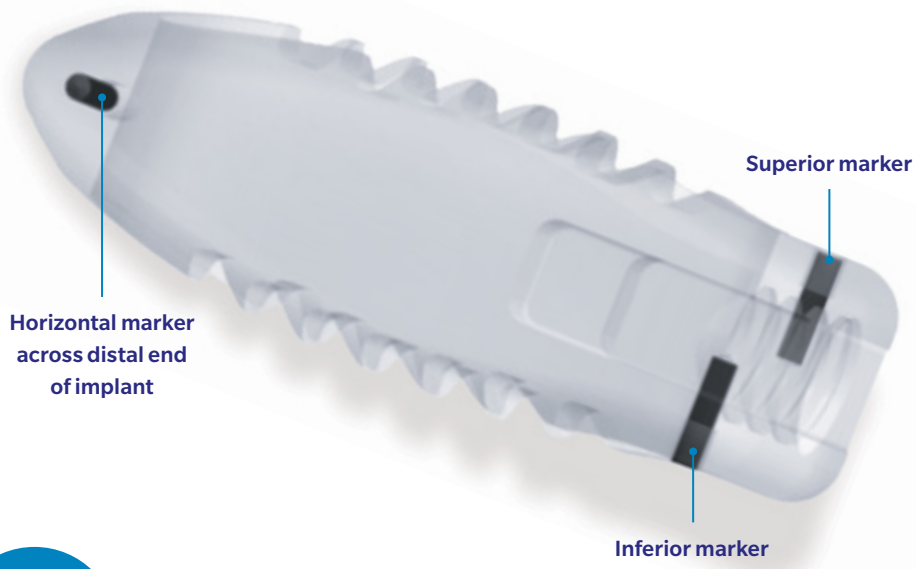


Biased teeth
The biased teeth pattern allows for easy insertion, but still resists expulsion.

Rounded side walls
Rounded side walls provide a smooth edge during the insertion process.

Assertive leading edge
The bi-directional leading edge of the implant is approximately ⅓ the height of the implant, which allows the implant to be placed in the tightest anatomical locations.

Zyston Straight System: Accurate Placement



Robust Implant/Inserter Interface

The Zyston Straight System is designed with an enhanced connection between the implant and the inserter. This enhanced connection delivers both tensional stability and rotational guidance, which allows you to accurately guide the implant into the desired position within the intervertebral space.

Confidence and Confirmation

A series of strategically placed vertical and horizontal radio-opaque markers assist with the visualization of the correct anatomic placement.

Lateral view

Anterior/Posterior view

Zyston Curved System: Simplified Insertion

Secure Tactile Control

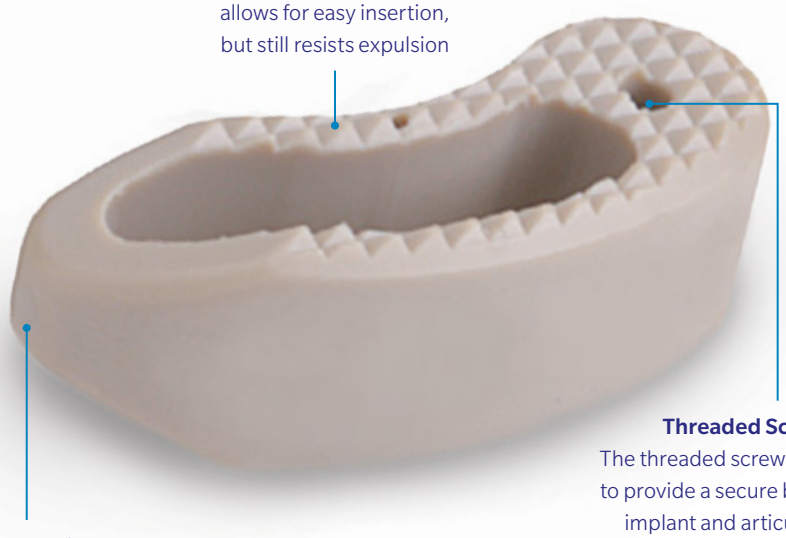
By providing a strong bond between the Zyston Curved System inserter and implant, this system is designed to ensure secure tactile control throughout the insertion process, which can minimize the number of passes through the annulotomy window.

Clear Visualization

With a 5.25mm diameter, the low profile inserter shaft provides clear medial visualization during the entire insertion process.

IMPLANT DESIGN

Biased teeth
The biased teeth pattern allows for easy insertion, but still resists expulsion

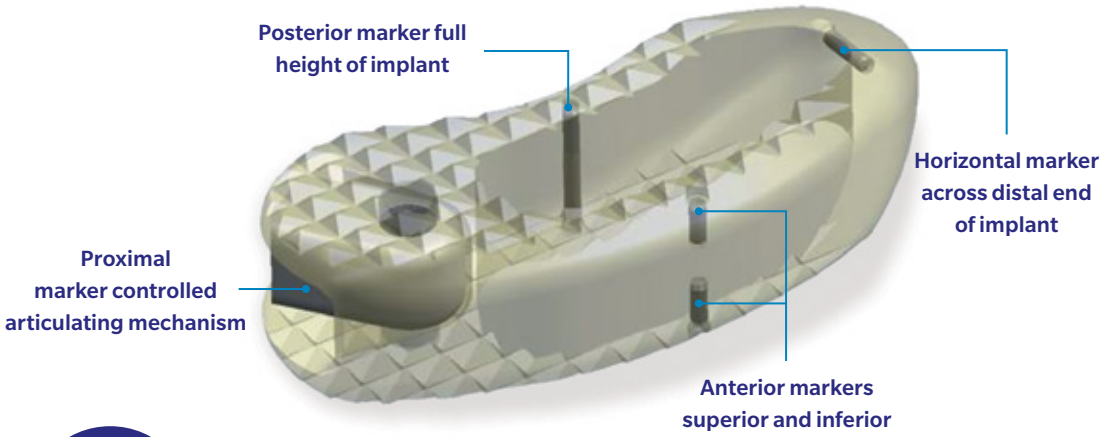


Threaded Screw Insert
The threaded screw insert is designed to provide a secure bond between the implant and articulating inserter.

Assertive leading edge
The bi-directional leading edge of the implant is approximately 1/3 the height of the implant, which allows the implant to be placed in the tightest anatomical locations.

Zyston Curved System: Accurate Placement

The Zyston Curved System incorporates an articulating threaded titanium insert. When connected to the low profile inserter, the spacer's controlled articulating mechanism allows the implant to articulate relative to the shaft, which allows you to guide the implant into the desired position within the intervertebral space.



Controlled Articulating Mechanism Provides Variable and Fixed Angulation

The Zyston Curved System inserter features a unique controlled articulating mechanism that allows the spacer to act with variable angulation at all times or to be fixed at a desired angle. **It's designed to achieve up to 55° of angulation.**

Confidence and Confirmation

A series of strategically placed vertical and horizontal radiopaque markers assist with visualization of correct anatomic placement by indicating a plus sign when the spacer is placed in the correct plane.

Lateral view (plus sign example)

Anterior/Posterior view (plus sign example)

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Thoracolumbar Solutions

Zyston® Curve
Interbody Spacer System

Surgical Technique Guide

The Zyston Curve Interbody System is designed to optimize your procedures through simplified insertion and accurate placement.

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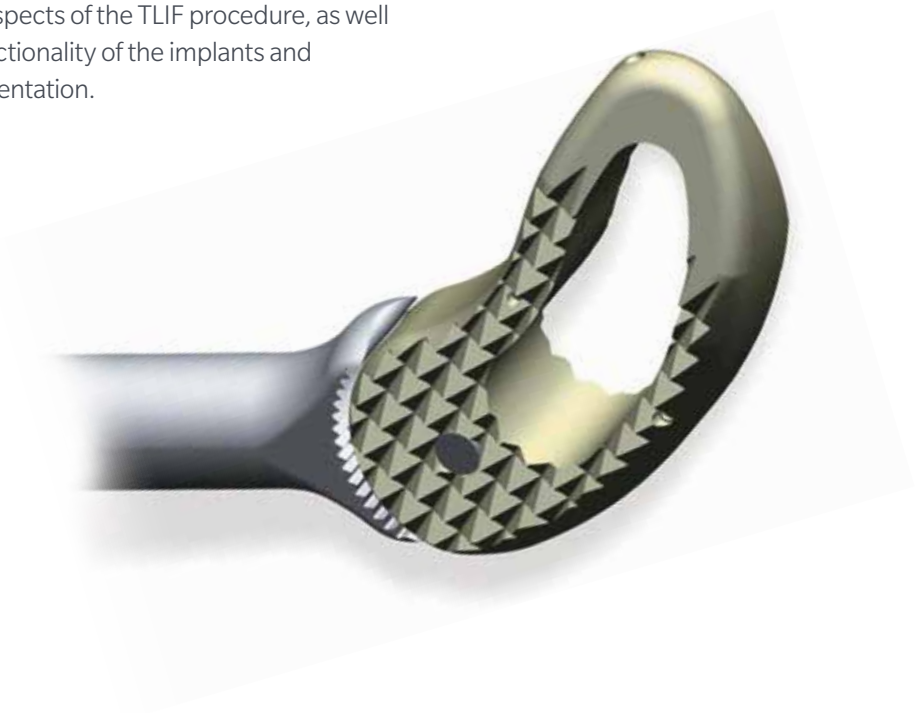
Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an 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 Curve Interbody Spacer System implants and supporting instrumentation were designed to help improve the clinical experience of placing TLIF interbody cages in the correct anatomical location.

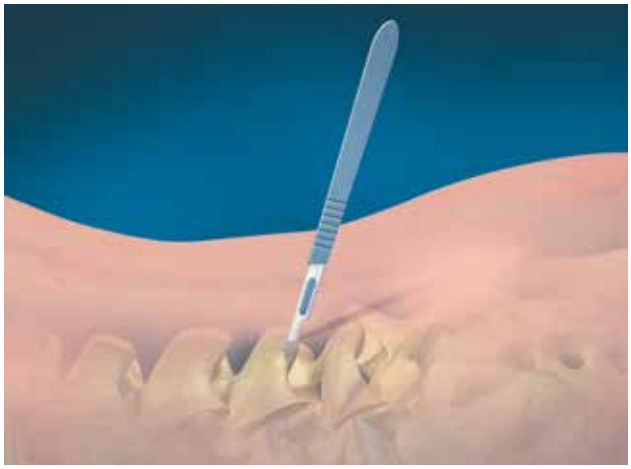
The system provides a full array of implant options, featuring a bi-directional tapered leading edge, a large autograft cavity and a uniquely designed controlled articulating mechanism to aid in the placement of the implant.

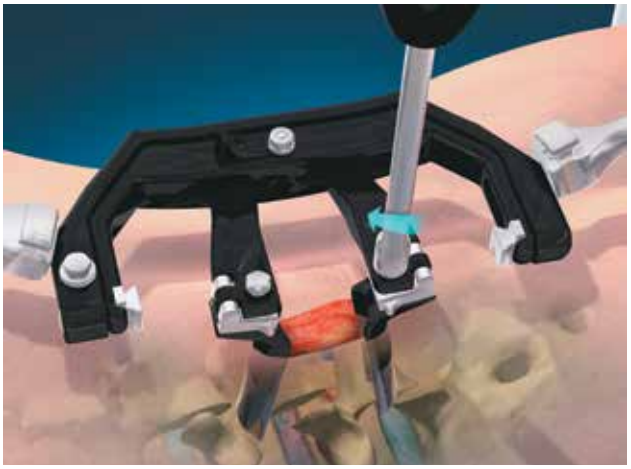
This surgical technique will provide guidance to the approach-related aspects of the TLIF procedure, as well as describe the functionality of the implants and supporting instrumentation.



FEATURES	BENEFITS
Bi-directional tapered leading edge	Self-distracting, aids in implant insertion and distraction
Controlled articulating mechanism	Access multiple insertion angles; allows implant to pivot *in situ* (up to 55°); facilitates final positioning with minimal passes through the annulotomy window; makes a robust connection to inserter
Large graft cavity	Provides increased volume for autograft packing to help aid in the fusion process
Low profile implant/instrument interface	Allows for increased 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
Unique placement of tantalum markers	Produces clear radiographic visualization during implant insertion

PREOPERATIVE PLANNING AND PATIENT POSITIONING





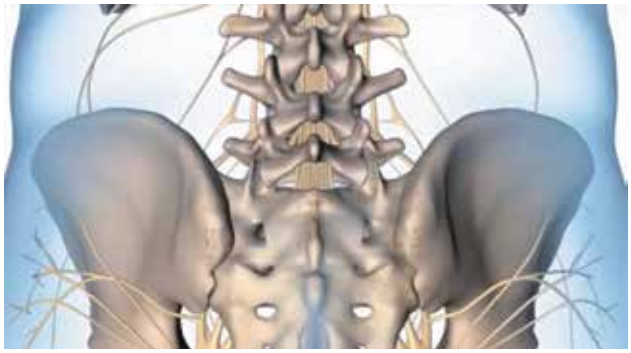
STEP 1

- 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 Curve Spacer System can be implanted using a traditional open approach or implanted using 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



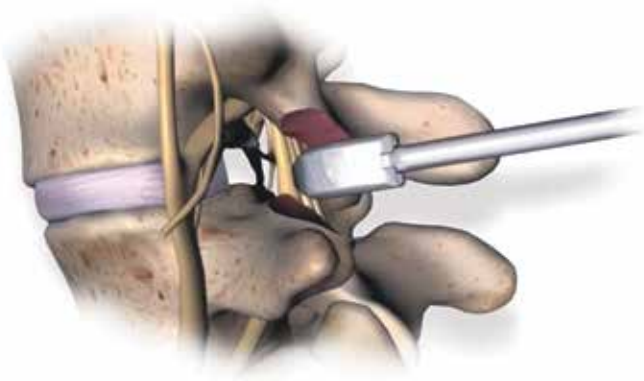
STEP 2

- 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.
- 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 annular 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: *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 3

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

Assembly of Trial Holder

- Insert the threaded inner shaft into the proximal end of the trial holder; turn the inner shaft clockwise to engage the retainer feature of the inner shaft to the trial holder.
- Guide the appropriate size trial head to the distal end of the trial holder ensuring that the concave side of the trial head is in-line with the finger grips of the trial holder.
- Turn the inner shaft clockwise to engage the threads of the trial head until tight.

  Note: *The trials of the Zyston Curve Spacer System have a fixed insertion angle of 20° and 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.

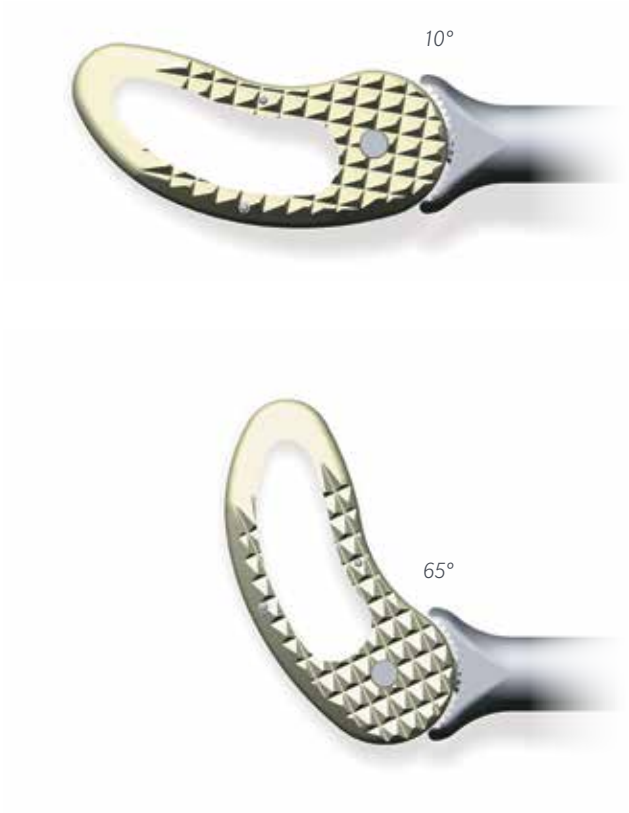
Note: *The Zyston Curve trials match the total height of the implant.*

O.R. Tip: *Do not disconnect trials from trial holder.*

IMPLANTATION

MIS variable angle inserter

Variable angle inserter



STEP 4

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

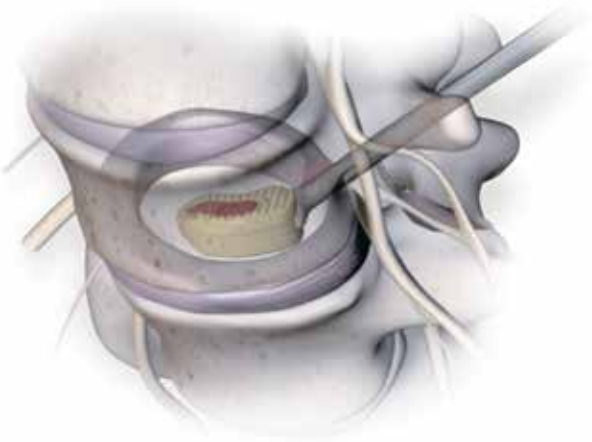
The Zyston Curve System comes complete with two inserters specific to the needs of the individual procedure.

A minimally invasive (offset) inserter and straight inserter are provided. Both 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 variable angle inserter; turn the inner shaft clockwise to engage the retainer feature of the inner shaft to the inserter.
- Guide the appropriate size Zyston Curve implant to the variable angle inserter, ensuring that the concave side of the implant is in-line with the finger grips of the variable angle inserter.
- Align the titanium insert of the Zyston Curve implant to the inner shaft of the variable angle inserter, and turn the proximal knob clockwise until tight.

  Note: *The Zyston Curve implant can be positioned at any angle between 10° to 65° from the axis of the inserter shaft.*



Straight tamp

Footed tamp

Angled tamp

Starter tamp

STEP 5

- Using the bone graft mold, place the implant into the corresponding slot and fill the graft cavity with autograft.
- Guide the implant into the intervertebral space, verifying placement via fluoroscopic imaging. The angle of insertion can be customized *in situ* to facilitate final positioning.
- ***Turn the knob at the proximal end of the inserter counterclockwise until three audible clicks are heard, then move the inserter shaft to the desired angle, turn the knob clockwise until tight, and continue to insert the implant.***
- Repeat the steps until the implant has reached the desired position.
- Verify positioning with A/P and lateral fluoroscopy.
- Remove the inserter by turning the threaded knob at the proximal end of the inserter counterclockwise until free from the implant (approximately four full revolutions).
- Final positioning of the implant can be achieved by using the starter, angled, straight or footed 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 variable angle inserters and trial holders 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

Slide hammer

Small slide hammer adapter

- Locate the threaded portion of the implant.
- Thread the implant remover into the threaded insert.
- 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”.
- Implant remover threads into the proximal end of the remover.
- 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: 27 mm long × 10 mm wide
Available Heights: 7 mm–16 mm (1 mm increments)
17 mm and 18 mm (Available as special order)
Lordosis: 0° and 6°

Footprint: 32 mm long × 10 mm wide
Available Heights: 7 mm–16 mm (1 mm increments)
17 mm and 18 mm (Available as special order)
Lordosis: 0° and 6°

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

HEIGHT \ LENGTH	27 mm		32 mm	
	PARALLEL	LORDOTIC	PARALLEL	LORDOTIC
7 mm	0.55	0.51	0.75	0.70
8 mm	0.63	0.59	0.85	0.81
9 mm	0.71	0.67	0.96	0.91
10 mm	0.79	0.75	1.06	1.02
11 mm	0.86	0.83	1.17	1.12
12 mm	0.94	0.90	1.28	1.23
13 mm	1.02	0.98	1.38	1.34
14 mm	1.10	1.06	1.49	1.44
15 mm	1.18	1.14	1.60	1.55
16 mm	1.26	1.22	1.70	1.66
17 mm	1.34	1.30	1.81	1.76
18 mm	1.41	1.37	1.91	1.87

INSTRUMENTS

27 mm Trials 6 mm–18 mm (1 mm increments)

PART NUMBERS

14-533006–14-533018

32 mm Trials 6 mm–18 mm (1 mm increments)

PART NUMBERS

14-533026–14-533038

MIS Variable Angle Inserter

PART NUMBER

14-533072

MIS Trial Holder

PART NUMBER

14-533074

Variable Angle Inserter

PART NUMBER

14-533021

Trial Holder

PART NUMBER

14-533025

Bone Graft Mold

PART NUMBER

14-533044

Implant Remover

PART NUMBER

14-533019

Straight Tamp

PART NUMBER

14-533023

Angled Tamp

PART NUMBER

14-533024

Starter Tamp	PART NUMBER
	14-533046

Paddle Scrapers 6 mm–18 mm (1 mm increments)	PART NUMBERS
	14-533206–14-533218

Quick Connect T-handle	PART NUMBER
	14-533202

Slotted Mallet	PART NUMBER
	14-533203

Large Slide Hammer Adapter	PART NUMBER
	14-533222

Small Slide Hammer Adapter	PART NUMBER
	14-533221

Slide Hammer	PART NUMBER
	14-533204

Footed Tamp	PART NUMBER
	14-533205

KIT CONTENTS

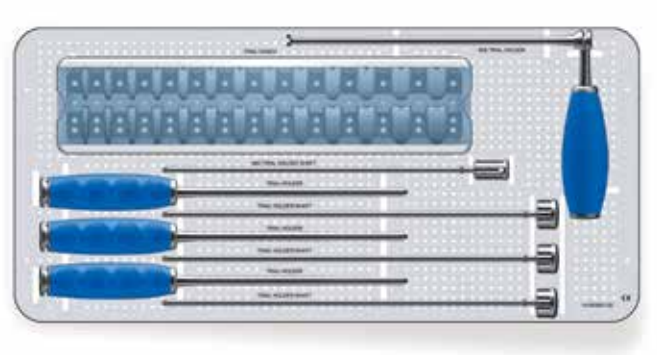
Zyston Curve Parallel Implants 14-533105

DESCRIPTION	QTY	PART NUMBER
Curve Spacer, 27 mm × 7 mm, 0°	1	14-533107
Curve Spacer, 27 mm × 8 mm, 0°	2	14-533108
Curve Spacer, 27 mm × 9 mm, 0°	2	14-533109
Curve Spacer, 27 mm × 10 mm, 0°	2	14-533110
Curve Spacer, 27 mm × 11 mm, 0°	2	14-533111
Curve Spacer, 27 mm × 12 mm, 0°	2	14-533112
Curve Spacer, 27 mm × 13 mm, 0°	2	14-533113
Curve Spacer, 27 mm × 14 mm, 0°	2	14-533114
Curve Spacer, 27 mm × 15 mm, 0°	1	14-533115
Curve Spacer, 27 mm × 16 mm, 0°	1	14-533116
Curve Spacer, 27 mm × 17 mm, 0°	0	14-533117*
Curve Spacer, 27 mm × 18 mm, 0°	0	14-533118*
Curve Spacer, 32 mm × 7 mm, 0°	1	14-533147
Curve Spacer, 32 mm × 8 mm, 0°	2	14-533148
Curve Spacer, 32 mm × 9 mm, 0°	2	14-533149
Curve Spacer, 32 mm × 10 mm, 0°	2	14-533150
Curve Spacer, 32 mm × 11 mm, 0°	2	14-533151
Curve Spacer, 32 mm × 12 mm, 0°	2	14-533152
Curve Spacer, 32 mm × 13 mm, 0°	2	14-533153
Curve Spacer, 32 mm × 14 mm, 0°	2	14-533154
Curve Spacer, 32 mm × 15 mm, 0°	1	14-533155
Curve Spacer, 32 mm × 16 mm, 0°	1	14-533156
Curve Spacer, 32 mm × 17 mm, 0°	0	14-533157*
Curve Spacer, 32 mm × 18 mm, 0°	0	14-533158*

Zyston Curve Lordotic Implants 14-533125

DESCRIPTION	QTY	PART NUMBER
Curve Spacer, 27 mm × 7 mm, 6°	1	14-533127
Curve Spacer, 27 mm × 8 mm, 6°	2	14-533128
Curve Spacer, 27 mm × 9 mm, 6°	2	14-533129
Curve Spacer, 27 mm × 10 mm, 6°	2	14-533130
Curve Spacer, 27 mm × 11 mm, 6°	2	14-533131
Curve Spacer, 27 mm × 12 mm, 6°	2	14-533132
Curve Spacer, 27 mm × 13 mm, 6°	2	14-533133
Curve Spacer, 27 mm × 14 mm, 6°	2	14-533134
Curve Spacer, 27 mm × 15 mm, 6°	1	14-533135
Curve Spacer, 27 mm × 16 mm, 6°	1	14-533136
Curve Spacer, 27 mm × 17 mm, 6°	0	14-533137*
Curve Spacer, 27 mm × 18 mm, 6°	0	14-533138*
Curve Spacer, 32 mm × 7 mm, 6°	1	14-533167
Curve Spacer, 32 mm × 8 mm, 6°	2	14-533168
Curve Spacer, 32 mm × 9 mm, 6°	2	14-533169
Curve Spacer, 32 mm × 10 mm, 6°	2	14-533170
Curve Spacer, 32 mm × 11 mm, 6°	2	14-533171
Curve Spacer, 32 mm × 12 mm, 6°	2	14-533172
Curve Spacer, 32 mm × 13 mm, 6°	2	14-533173
Curve Spacer, 32 mm × 14 mm, 6°	2	14-533174
Curve Spacer, 32 mm × 15 mm, 6°	1	14-533175
Curve Spacer, 32 mm × 16 mm, 6°	1	14-533176
Curve Spacer, 32 mm × 17 mm, 6°	0	14-533177*
Curve Spacer, 32 mm × 18 mm, 6°	0	14-533178*

**Available by special order.*



Zyston Curve Instruments 14-533000

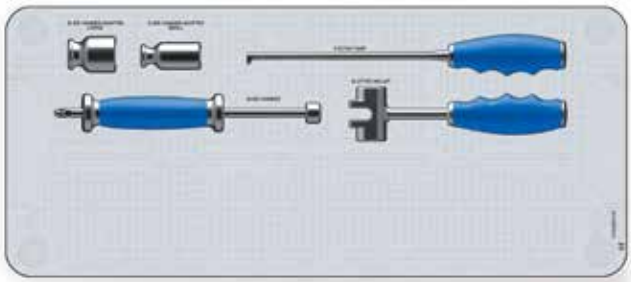
DESCRIPTION	QTY	PART NUMBER
Trial Head, 27 mm × 6 mm, 70°	1	14-533006
Trial Head, 27 mm × 7 mm, 70°	1	14-533007
Trial Head, 27 mm × 8 mm, 70°	1	14-533008
Trial Head, 27 mm × 9 mm, 70°	1	14-533009
Trial Head, 27 mm × 10 mm, 70°	1	14-533010
Trial Head, 27 mm × 11 mm, 70°	1	14-533011
Trial Head, 27 mm × 12 mm, 70°	1	14-533012
Trial Head, 27 mm × 13 mm, 70°	1	14-533013
Trial Head, 27 mm × 14 mm, 70°	1	14-533014
Trial Head, 27 mm × 15 mm, 70°	1	14-533015
Trial Head, 27 mm × 16 mm, 70°	1	14-533016
Trial Head, 27 mm × 17 mm, 70°	1	14-533017
Trial Head, 27 mm × 18 mm, 70°	1	14-533018
Trial Head, 32 mm × 6 mm, 70°	1	14-533026
Trial Head, 32 mm × 7 mm, 70°	1	14-533027
Trial Head, 32 mm × 8 mm, 70°	1	14-533028
Trial Head, 32 mm × 9 mm, 70°	1	14-533029
Trial Head, 32 mm × 10 mm, 70°	1	14-533030

Zyston Curve Instruments *(Continued)* 14-533000

DESCRIPTION	QTY	PART NUMBER
Trial Head, 32 mm × 11 mm, 70°	1	14-533031
Trial Head, 32 mm × 12 mm, 70°	1	14-533032
Trial Head, 32 mm × 13 mm, 70°	1	14-533033
Trial Head, 32 mm × 14 mm, 70°	1	14-533034
Trial Head, 32 mm × 15 mm, 70°	1	14-533035
Trial Head, 32 mm × 16 mm, 70°	1	14-533036
Trial Head, 32 mm × 17 mm, 70°	1	14-533037
Trial Head, 32 mm × 18 mm, 70°	1	14-533038
Curve Implant Remover	1	14-533019
Curve Variable Inserter	1	14-533021
Curve Straight Tamp	1	14-533023
Curve Angled Tamp	1	14-533024
Curve Trial Holder	3	14-533025
Curve Bone Mold	1	14-533044
Curve Starter Tamp	1	14-533046
Curve MIS Variable Inserter	1	14-533072
Curve MIS Trial Holder	1	14-533074

KIT CONTENTS *(Continued)*

Zyston Universal Instruments
14-533200



DESCRIPTION	QTY	PART NUMBER
T-handle	1	14-533202
Slotted Mallet	1	14-533203
Slotted 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 CURVE INTERBODY SYSTEM

Device Description

The Zyston Curve Interbody Spacer System is intended to be inserted into the intervertebral disc space for intervertebral body fusion.

The Zyston Curve Interbody Spacer is designed to restore height and lordotic angle in the spine. The Zyston Curve Interbody Spacer is available in two lengths (27 mm and 32 mm), two lordotic angles (0 and 6 degrees) and in heights from 7 mm to 18 mm in one millimeter increments.

The device is curved (kidney shaped) to match the anatomical shape of the anterior spine with an endplate sparing design to resist subsidence. The spacer has a tapered leading edge to aid in insertion of the implant, and allows the implant to be self-distracting. The spacer has teeth on the endplate-engaging surfaces to provide stability, resist shear and rotational forces, and to help prevent migration of the spacer within the disc space. The open central cavity allows for placement of autograft material allowing for subsequent bone growth through the interior of the device.

The Zyston Curve Spacer is a lumbar spacer with an internal articulating feature to facilitate implant placement. The design incorporates a threaded titanium insert which has the potential to pivot within the body of the spacer. When connected to the inserter, the insert allows the implant to pivot relative to the shaft, enabling the user to guide the implant into the desired position within the intervertebral space.

The PEEK-OPTIMA® material is radiolucent and permits unobstructed radiographic assessment of the fusion mass. However, due to its radiolucency, the Zyston Curve device has tantalum markers within the body of the spacer to help visualize implant orientation within the spine during surgery and postoperatively.

Indications for Use

The Zyston Curve Interbody 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.

The Zyston Curve Interbody 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 Curve Interbody 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 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 Curve Interbody 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.

IMPORTANT INFORMATION *(Continued)*

Warnings *(Continued)*

- 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 Curve Interbody Spacer System has not been evaluated for safety and compatibility in the MR environment. The Zyston Curve Interbody 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.
- Zimmer Biomet 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 intervertebral body fusion 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.

Sterilization Recommendations

The Zyston Curve implant is provided sterile. The product is gamma radiation sterilized. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not re-sterilize. Where specified, do not use the device after expiration date.

The Zyston Curve instrumentation is provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to use.

Refer to the Zimmer Biomet Non-sterile Instrument IFU for full processing instructions.

Individuals not using the recommended method temperature and time are advised to validate any alternative methods or cycles using an approved method or standard.

Disclaimer: *This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.*

Caution: *Federal (USA) law restricts this device to sale by or on the order of a physician. Rx only. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, adverse effects, and patient counseling information.*

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