

Surgical Technique

## Zyston® Curve Interbody Spacer System

Designed to enable simple  
insertion and accurate placement



### Simple Insertion

- Secure tactile control
- Clear visualization

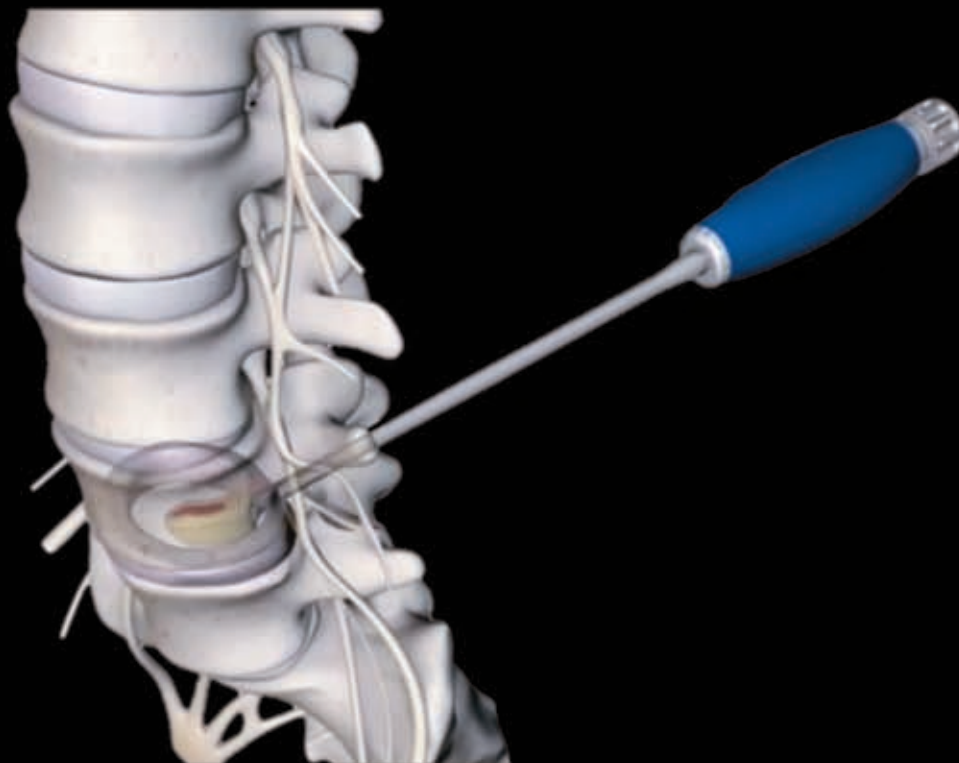
### Accurate Placement

- Controlled Articulating Mechanism provides variable and fixed angulation
- Markers provide confidence and confirmation

**BIOMET**®  
SPINE

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## *Introduction*

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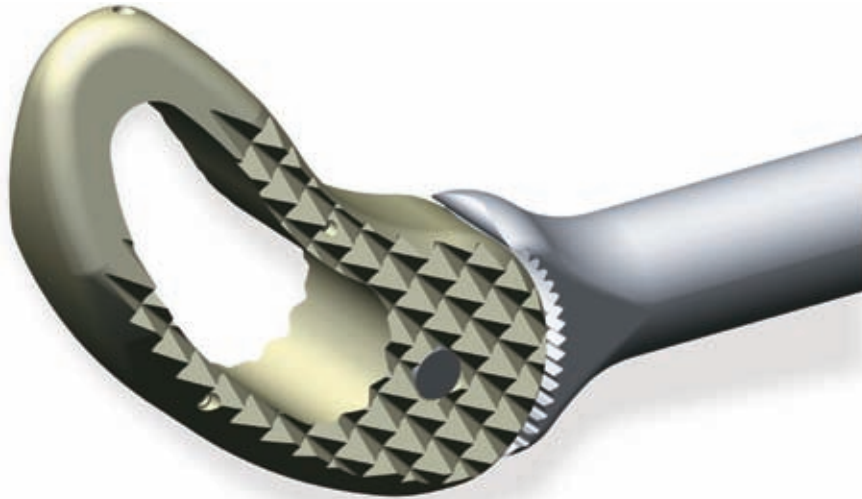
Biomet Spine is turning a new edge in Spine Care, with the introduction of the Zyston® Curve Interbody Spacer System. The implants and supporting instrumentation were designed to help improve the clinical experience of placing TLIF interbody cages in the correct anatomical location.

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 and Benefits

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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 intra-operative questions regarding final implant size
Unique placement of Tantalum Markers	Produces clear radiographic visualization during implant insertion

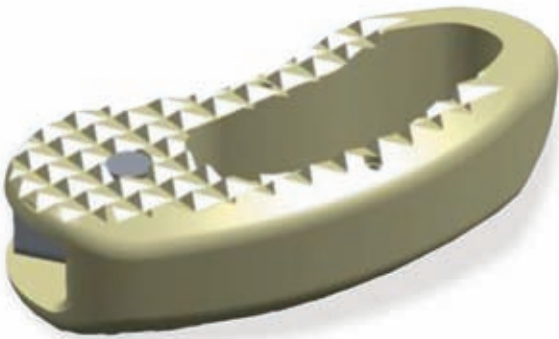
## Implants



**Footprint:** 27mm Long x 10mm Wide  
**Available Heights:** 7mm – 16mm (1mm Increments) 17mm and 18mm (Available as special order)  
**Lordosis:** 0° and 6°



**Footprint:** 32mm Long x 10mm Wide  
**Available Heights:** 7mm – 16mm (1mm Increments) 17mm and 18mm (Available as special order)  
**Lordosis:** 0° and 6°



### Available Graft Volume By Implant Size:

		Length			
		27mm		32mm	
		Parallel	Lordotic	Parallel	Lordotic
Height	7mm	0.55	0.51	0.75	0.70
	8mm	0.63	0.59	0.85	0.81
	9mm	0.71	0.67	0.96	0.91
	10mm	0.79	0.75	1.06	1.02
	11mm	0.86	0.83	1.17	1.12
	12mm	0.94	0.90	1.28	1.23
	13mm	1.02	0.98	1.38	1.34
	14mm	1.10	1.06	1.49	1.44
	15mm	1.18	1.14	1.60	1.55
	16mm	1.26	1.22	1.70	1.66
17mm	1.34	1.30	1.81	1.76	
18mm	1.41	1.37	1.91	1.87	
*Graft Volume depicted in cc's					

*Instruments – Zyston® Curve Spacer System*



**27mm Trials 6mm – 18mm (1mm increments)**  
**Catalog Numbers 14-533006 – 14-533018**



**32mm Trials 6mm – 18mm (1mm increments)**  
**Catalog Numbers 14-533026 – 14-533038**



**MIS Variable Angle Inserter**  
**Catalog Number 14-533072**



**MIS Trial Holder**  
**Catalog Number 14-533074**



**Variable Angle Inserter**  
**Catalog Number 14-533021**



**Trial Holder**  
**Catalog Number 14-533025**



**Bone Graft Mold**

**Catalog Number 14-533044**



**Angled Tamp**

**Catalog Number 14-533024**



**Implant Remover**

**Catalog Number 14-533019**



**Starter Tamp**

**Catalog Number 14-533046**



**Straight Tamp**

**Catalog Number 14-533023**



**Paddle Scrapers** 6mm – 18mm (1mm increments)  
**Catalog Numbers** 14-533206 – 14-533218



**Quick Connect T-Handle**  
**Catalog Number** 14-533202



**Slotted Mallet**  
**Catalog Number** 14-533203



**Slide Hammer**  
**Catalog Number** 14-533204



**Small Slide Hammer Adapter**  
**Catalog Number** 14-533221



**Large Slide Hammer Adapter**  
**Catalog Number** 14-533222



**Footed Tamp**  
**Catalog Number** 14-533205



## *Surgical Technique*

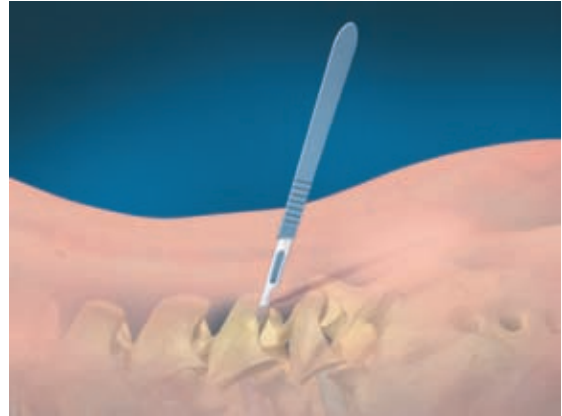
### **Step 1: Patient Positioning and Pre-operative Planning**

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.



## ***Surgical Technique (Continued)***

### **Step 2: Exposure and Endplate Preparation**

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:** *The Biomet Spine 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 1mm increments from 6mm – 18mm. Assemble the modular T-Handle to the quick connect fitting of the shaft prior to use.*



## 1. Distraction and Implant Selection

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 1mm increments from 6mm – 18mm.

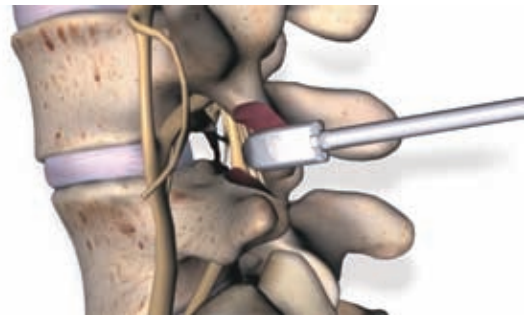
Insert the trial into the annulotomy window and position within the intervertebral space. Confirm positioning with A/P and lateral fluoroscopy.

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 System trials match the total height of the implant.

**O.R. TIP:** Do Not Disconnect Trials From Trial Holder.



## *Surgical Technique (Continued)*

### **2. Implantation**

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.





10°



65°

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

## ***Surgical Technique (Continued)***

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.

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 Biomet Non-sterile Instrument IFU for further reprocessing instructions.



Straight Tamp



Footed Tamp



Angled Tamp



Starter Tamp

## *Implant Removal*

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

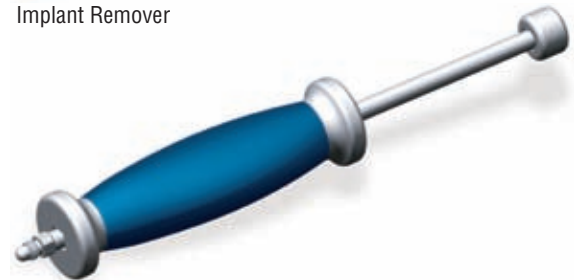
Assemble the appropriate adapter to the slide hammer by threading the adapter onto the distal end of the instrument until tight.

**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.



Implant Remover



Slide Hammer

## 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.

Please refer to the AccuVision® System instructions for use and surgical technique for using the minimally invasive instrumentation.

### 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 Zyston® Curve Interbody Spacer System is to be implanted using a posterior approach. The surgeon should only implant the Zyston® Curve device after adequate training and familiarity with the information provided in the Surgical Technique Manual. Never re-implant an explanted metal device, under any circumstances. Although the device appears to be undamaged, it may have small defects and internal stress patterns. The potential risks associated with the use of the Zyston® Curve Device are similar to those reported for “implantable spinal fusion devices”. See the Warnings, Precautions, and Possible Adverse Effects sections of the package insert for a complete list of potential risks.



## ***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.

The following steam sterilization parameters are recommended:

Cycle: High Vacuum

Temperature: 270°F (132°C)

Time: 4 minutes

Drying time: 20 minutes

**NOTE:** Allow For Cooling

Refer to the 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.

## Ordering Information

### Zyston® Curve Parallel Implant Kit Catalog # 14-533105

Catalog #	Description	Qty
14-533107	Zyston® Curve Spacer - 0° 27mm x 7mm	1
14-533108	Zyston® Curve Spacer - 0° 27mm x 8mm	2
14-533109	Zyston® Curve Spacer - 0° 27mm x 9mm	2
14-533110	Zyston® Curve Spacer - 0° 27mm x 10mm	2
14-533111	Zyston® Curve Spacer - 0° 27mm x 11mm	2
14-533112	Zyston® Curve Spacer - 0° 27mm x 12mm	2
14-533113	Zyston® Curve Spacer - 0° 27mm x 13mm	2
14-533114	Zyston® Curve Spacer - 0° 27mm x 14mm	2
14-533115	Zyston® Curve Spacer - 0° 27mm x 15mm	1
14-533116	Zyston® Curve Spacer - 0° 27mm x 16mm	1
14-533117	Zyston® Curve Spacer - 0° 27mm x 17mm	0
14-533118	Zyston® Curve Spacer - 0° 27mm x 18mm	0
14-533147	Zyston® Curve Spacer - 0° 32mm x 7mm	1
14-533148	Zyston® Curve Spacer - 0° 32mm x 8mm	2
14-533149	Zyston® Curve Spacer - 0° 32mm x 9mm	2
14-533150	Zyston® Curve Spacer - 0° 32mm x 10mm	2
14-533151	Zyston® Curve Spacer - 0° 32mm x 11mm	2
14-533152	Zyston® Curve Spacer - 0° 32mm x 12mm	2
14-533153	Zyston® Curve Spacer - 0° 32mm x 13mm	2
14-533154	Zyston® Curve Spacer - 0° 32mm x 14mm	2
14-533155	Zyston® Curve Spacer - 0° 32mm x 15mm	1
14-533156	Zyston® Curve Spacer - 0° 32mm x 16mm	1
14-533157	Zyston® Curve Spacer - 0° 32mm x 17mm	0
14-533158	Zyston® Curve Spacer - 0° 32mm x 18mm	0

### Zyston® Curve Lordotic Implant Kit Catalog # 14-533125

Catalog #	Description	Qty
14-533127	Zyston® Curve Spacer - 6° 27mm x 7mm	1
14-533128	Zyston® Curve Spacer - 6° 27mm x 8mm	2
14-533129	Zyston® Curve Spacer - 6° 27mm x 9mm	2
14-533130	Zyston® Curve Spacer - 6° 27mm x 10mm	2
14-533131	Zyston® Curve Spacer - 6° 27mm x 11mm	2
14-533132	Zyston® Curve Spacer - 6° 27mm x 12mm	2
14-533133	Zyston® Curve Spacer - 6° 27mm x 13mm	2
14-533134	Zyston® Curve Spacer - 6° 27mm x 14mm	2
14-533135	Zyston® Curve Spacer - 6° 27mm x 15mm	1
14-533136	Zyston® Curve Spacer - 6° 27mm x 16mm	1
14-533137	Zyston® Curve Spacer - 6° 27mm x 17mm	0
14-533138	Zyston® Curve Spacer - 6° 27mm x 18mm	0
14-533167	Zyston® Curve Spacer - 6° 32mm x 7mm	1
14-533168	Zyston® Curve Spacer - 6° 32mm x 8mm	2
14-533169	Zyston® Curve Spacer - 6° 32mm x 9mm	2
14-533170	Zyston® Curve Spacer - 6° 32mm x 10mm	2
14-533171	Zyston® Curve Spacer - 6° 32mm x 11mm	2
14-533172	Zyston® Curve Spacer - 6° 32mm x 12mm	2
14-533173	Zyston® Curve Spacer - 6° 32mm x 13mm	2
14-533174	Zyston® Curve Spacer - 6° 32mm x 14mm	2
14-533175	Zyston® Curve Spacer - 6° 32mm x 15mm	1
14-533176	Zyston® Curve Spacer - 6° 32mm x 16mm	1
14-533177	Zyston® Curve Spacer - 6° 32mm x 17mm	0
14-533178	Zyston® Curve Spacer - 6° 32mm x 18mm	0

Shaded Implants are available by special order.

**Zyston® Curve Instrument Kit Catalog # 14-533000**

Catalog #	Description	Qty
14-533006	Trial Head - 70° 27mm x 6mm	1
14-533007	Trial Head - 70° 27mm x 7mm	1
14-533008	Trial Head - 70° 27mm x 8mm	1
14-533009	Trial Head - 70° 27mm x 9mm	1
14-533010	Trial Head - 70° 27mm x 10mm	1
14-533011	Trial Head - 70° 27mm x 11mm	1
14-533012	Trial Head - 70° 27mm x 12mm	1
14-533013	Trial Head - 70° 27mm x 13mm	1
14-533014	Trial Head - 70° 27mm x 14mm	1
14-533015	Trial Head - 70° 27mm x 15mm	1
14-533016	Trial Head - 70° 27mm x 16mm	1
14-533017	Trial Head - 70° 27mm x 17mm	1
14-533018	Trial Head - 70° 27mm x 18mm	1
14-533026	Trial Head - 70° 32mm x 6mm	1
14-533027	Trial Head - 70° 32mm x 7mm	1
14-533028	Trial Head - 70° 32mm x 8mm	1
14-533029	Trial Head - 70° 32mm x 9mm	1
14-533030	Trial Head - 70° 32mm x 10mm	1
14-533031	Trial Head - 70° 32mm x 11mm	1
14-533032	Trial Head - 70° 32mm x 12mm	1
14-533033	Trial Head - 70° 32mm x 13mm	1
14-533034	Trial Head - 70° 32mm x 14mm	1
14-533035	Trial Head - 70° 32mm x 15mm	1
14-533036	Trial Head - 70° 32mm x 16mm	1
14-533037	Trial Head - 70° 32mm x 17mm	1
14-533038	Trial Head - 70° 32mm x 18mm	1
14-533019	Zyston® Curve Implant Remover	1
14-533021	Zyston® Curve Variable Inserter	1
14-533023	Zyston® Curve Straight Tamp	1
14-533024	Zyston® Curve Angled Tamp	1
14-533025	Zyston® Curve Trial Holder	3
14-533044	Zyston® Curve Bone Mold	1
14-533046	Zyston® Curve Starter Tamp	1
14-533072	Zyston® Curve MIS Variable Inserter	1
14-533074	Zyston® Curve MIS Trial Holder	1
14-533001	Zyston® Curve Instrument Case	1

**Zyston® Universal Instrument Kit Catalog # 14-533200**

Catalog #	Description	Qty
14-533202	Zyston® T-Handle	2
14-533203	Zyston® Slotted Mallet	1
14-533204	Zyston® Slide Hammer	1
14-533205	Zyston® Footed Tamp	1
14-533206	Zyston® Paddle Scraper - 6mm	1
14-533207	Zyston® Paddle Scraper - 7mm	1
14-533208	Zyston® Paddle Scraper - 8mm	1
14-533209	Zyston® Paddle Scraper - 9mm	1
14-533210	Zyston® Paddle Scraper - 10mm	1
14-533211	Zyston® Paddle Scraper - 11mm	1
14-533212	Zyston® Paddle Scraper - 12mm	1
14-533213	Zyston® Paddle Scraper - 13mm	1
14-533214	Zyston® Paddle Scraper - 14mm	1
14-533215	Zyston® Paddle Scraper - 15mm	1
14-533216	Zyston® Paddle Scraper - 16mm	1
14-533217	Zyston® Paddle Scraper - 17mm	1
14-533218	Zyston® Paddle Scraper - 18mm	1
14-533221	Zyston® Small Slide Hammer Adapter	1
14-533222	Zyston® Large Slide Hammer Adapter	1
14-533201	Zyston® Universal Instrument Case	1

## ***Further Information***

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This brochure describes a surgical technique used by:

- Nitin Bhatia, M.D.
- Stephane Lavoie, M.D.
- Alan McGee, M.D.
- Joseph Riina, M.D.
- Paul Suh, M.D.

The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

**CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

For further information, please contact the Customer Service Department at:

Biomet Spine  
100 Interpace Parkway  
Parsippany, NJ 07054  
973.299.9300 • 800.526.2579  
[www.biomet.com](http://www.biomet.com)







At Biomet, engineering excellence is our heritage and our passion. For over 25 years, through various divisions worldwide, we have applied the most advanced engineering and manufacturing technology to the development of highly durable systems for a wide variety of surgical applications.

### **Zyston® Curve Interbody Spacer System**

Designed to enable simple insertion and accurate placement

To learn more about this product,  
contact your local Biomet Sales Representative today.



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