

Surgical Technique

Zyston™ Straight Spacer System

Designed to enable simple insertion and accurate placement

Simple Insertion

- Secure tactile control
- Clear visualization

Accurate Placement

- Robust implant/insert interface
- Assertive tapered leading edge
- Markers provide confidence and confirmation



BIOMET[®]
SPINE

Contents

Introduction	Page 1
Features and Benefits	Page 2
Implants	Page 3
Instruments	Page 4
Approaches	Page 6
Surgical Technique	Page 7
Implant Removal	Page 14
Indications for Use	Page 15
Sterilization Recommendations	Page 16
Ordering Information	Page 17
Further Information	Page 19



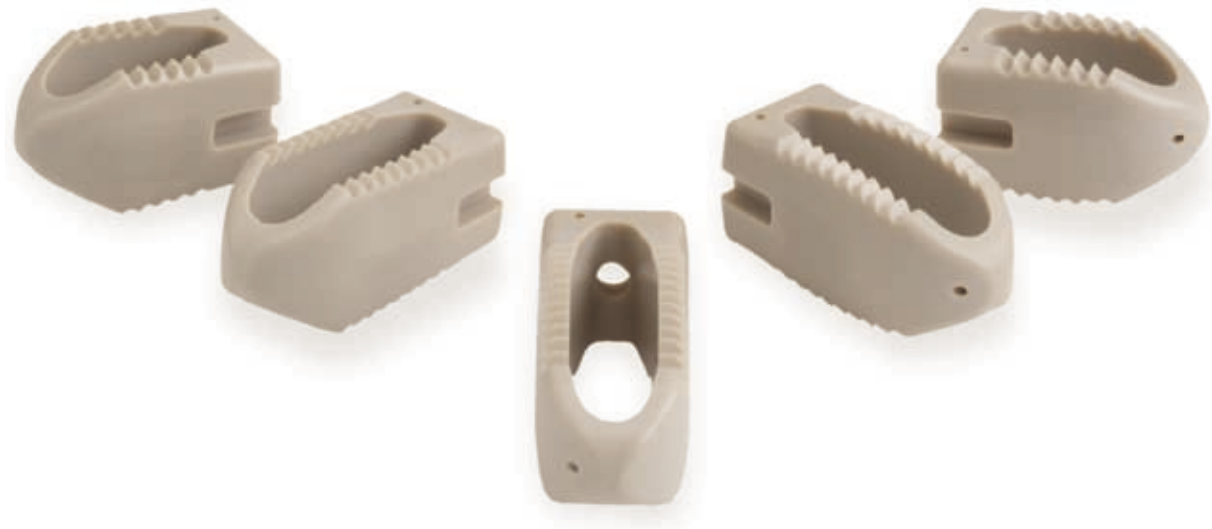
Introduction

Biomet Spine is turning a new edge in spine care, with the introduction of the Zyston™ Straight Interbody Spacer System. The corresponding 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, 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 and implantation of the supporting instrumentation and implants.

Features and Benefits



Features	Benefits
Tapered leading edge	Self distracting, aids in implant insertion due to limited anatomical space
Large graft cavity	Provides increased volume for autograft packing
Low profile implant/instrument interface	Allows for added visualization during implant insertion, particularly in the medial plane
Multiple footprint options	Facilitates a more precise anatomical fit
Line-to-line trials	Reduces intra-operative questions regarding final implant size

Implants



Footprint: 20mm Long

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

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

Shapes: - Convex
- Lordotic (8°)



Footprint: 30mm Long

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

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

Shapes: - Convex Only



Footprint: 25mm Long

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

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

Shapes: - Convex End Plates
- Lordotic (8°)

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

Instruments – Zyston™ Straight Spacer System



20mm Trials 6mm – 18mm (1mm increments)



25mm Trials 6mm – 18mm (1mm increments)



30mm Trials 6mm – 18mm (1mm increments)



Straight Tamp



Corner Tamp



T-Handle Inserter



Inline Inserter



MIS Implant Inserter



“V” Tamp

Instruments – Zyston™ Universal Instrument System



Paddle Scrapers 6mm – 18mm (1mm increments)



Footed Tamp



Quick Connect T-Handle



Small Slide Hammer Adapter



Slotted Mallet



Large Slide Hammer Adapter

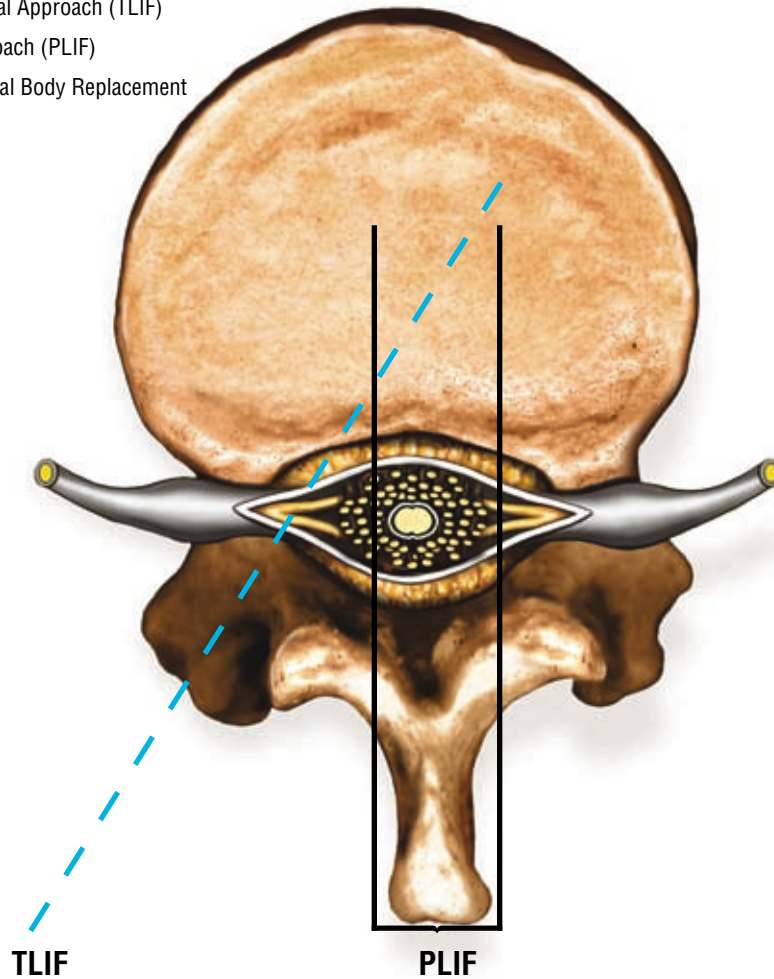


Slide Hammer

Approaches

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



Surgical Technique

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™ Straight Spacer System can be implanted using a traditional open approach, or a minimally invasive approach using the AccuVision® System.*

Refer to the AccuVision® System surgical technique guide for proper implementation of the AccuVision® System.



Surgical Technique (Continued)

2. Exposure and End Plate 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.

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 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: *The 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.*



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 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 Zyston™ 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 1mm increments from 6mm – 18mm. Assemble the modular T-Handle to the Quick Connect Fitting of the shaft prior to use.*



Surgical Technique (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).



3. Distraction and Implant Selection

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

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

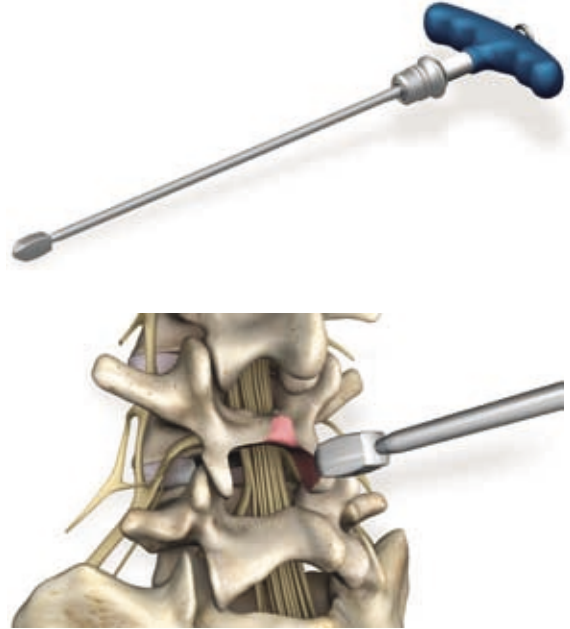
NOTE: The trials of the Zyston™ Straight Spacer System are available in 1mm increments from 6mm – 18mm.

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™ Straight trials match the height of the implant.



Surgical Technique (Continued)

4. Implantation

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

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.

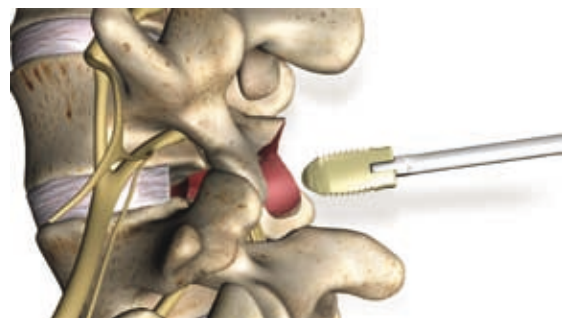
Pack the graft chamber of the Zyston™ Straight implant utilizing the bone graft mold prior to implantation.

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 counter clockwise and remove the inserter from the implant.

Repeat the process as necessary.



Remove the inserter by turning the threaded knob at the proximal end of the inserter counterclockwise until free from the implant.

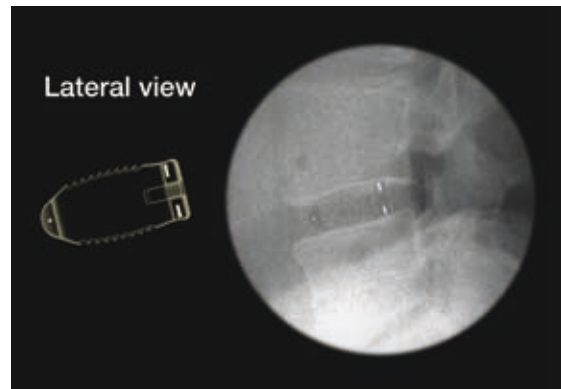
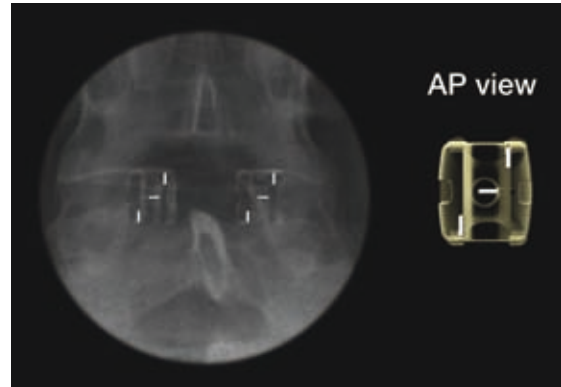
Final positioning of the implant can be achieved by using the Straight, Corner or "V" Tamps with gentle force.

Posterior supplemental fixation is performed.
See the individual surgical technique manuals for specific instructions.

Closure is performed per facility aseptic protocols.

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 Biomet Non-sterile Instrument IFU for further reprocessing instructions.



Implant Removal

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.

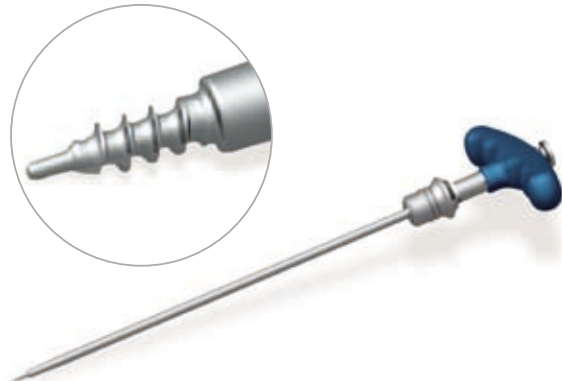
The slide hammer utilizes two types of adapters to connect to the individual instrumentation:

- 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.



Implant Remover



Slide Hammer

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 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 Zyston™ Straight Interbody Spacer System is to be implanted using a posterior approach. The surgeon should only implant the Zyston™ Straight 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™ Straight 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™ Straight 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™ Straight 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

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™ Straight Convex Implants Kit Catalog #14-534002

Catalog #	Description	Qty
14-534007	Str. Spacer 7H x 20L x 10W Convex	2
14-534008	Str. Spacer 8H x 20L x 10W Convex	4
14-534009	Str. Spacer 9H x 20L x 10W Convex	4
14-534010	Str. Spacer 10H x 20L x 10W Convex	4
14-534011	Str. Spacer 11H x 20L x 10W Convex	4
14-534012	Str. Spacer 12H x 20L x 10W Convex	4
14-534033	Str. Spacer 13H x 20L x 11W Convex	4
14-534034	Str. Spacer 14H x 20L x 11W Convex	4
14-534035	Str. Spacer 15H x 20L x 11W Convex	2
14-534036	Str. Spacer 16H x 20L x 11W Convex	2
14-534037	Str. Spacer 17H x 20L x 11W Convex	0
14-534038	Str. Spacer 18H x 20L x 11W Convex	0
14-534067	Str. Spacer 7H x 25L x 10W Convex	2
14-534068	Str. Spacer 8H x 25L x 10W Convex	4
14-534069	Str. Spacer 9H x 25L x 10W Convex	4
14-534070	Str. Spacer 10H x 25L x 10W Convex	4
14-534071	Str. Spacer 11H x 25L x 10W Convex	4
14-534072	Str. Spacer 12H x 25L x 10W Convex	4
14-534093	Str. Spacer 13H x 25L x 11W Convex	4
14-534094	Str. Spacer 14H x 25L x 11W Convex	4
14-534095	Str. Spacer 15H x 25L x 11W Convex	2
14-534096	Str. Spacer 16H x 25L x 11W Convex	2
14-534097	Str. Spacer 17H x 25L x 11W Convex	0
14-534098	Str. Spacer 18H x 25L x 11W Convex	0
14-534127	Str. Spacer 7H x 30L x 10W Convex	2
14-534128	Str. Spacer 8H x 30L x 10W Convex	2
14-534129	Str. Spacer 9H x 30L x 10W Convex	2
14-534130	Str. Spacer 10H x 30L x 10W Convex	2
14-534131	Str. Spacer 11H x 30L x 10W Convex	2
14-534132	Str. Spacer 12H x 30L x 10W Convex	2
14-534153	Str. Spacer 13H x 30L x 11W Convex	2
14-534154	Str. Spacer 14H x 30L x 11W Convex	2
14-534155	Str. Spacer 15H x 30L x 11W Convex	2
14-534156	Str. Spacer 16H x 30L x 11W Convex	2
14-534157	Str. Spacer 17H x 30L x 11W Convex	0
14-534158	Str. Spacer 18H x 30L x 11W Convex	0

Zyston™ Straight Lordotic Implants Kit Catalog #14-534181

Catalog #	Description	Qty
14-534187	Str. Spacer 7H x 20L x 10W 8°	2
14-534188	Str. Spacer 8H x 20L x 10W 8°	4
14-534189	Str. Spacer 9H x 20L x 10W 8°	4
14-534190	Str. Spacer 10H x 20L x 10W 8°	4
14-534191	Str. Spacer 11H x 20L x 10W 8°	4
14-534192	Str. Spacer 12H x 20L x 10W 8°	4
14-534213	Str. Spacer 13H x 20L x 11W 8°	4
14-534214	Str. Spacer 14H x 20L x 11W 8°	4
14-534215	Str. Spacer 15H x 20L x 11W 8°	2
14-534216	Str. Spacer 16H x 20L x 11W 8°	2
14-534217	Str. Spacer 17H x 20L x 11W 8°	0
14-534218	Str. Spacer 18H x 20L x 11W 8°	0
14-534247	Str. Spacer 7H x 25L x 10W 8°	2
14-534248	Str. Spacer 8H x 25L x 10W 8°	4
14-534249	Str. Spacer 9H x 25L x 10W 8°	4
14-534250	Str. Spacer 10H x 25L x 10W 8°	4
14-534251	Str. Spacer 11H x 25L x 10W 8°	4
14-534252	Str. Spacer 12H x 25L x 10W 8°	4
14-534273	Str. Spacer 13H x 25L x 11W 8°	4
14-534274	Str. Spacer 14H x 25L x 11W 8°	4
14-534275	Str. Spacer 15H x 25L x 11W 8°	2
14-534276	Str. Spacer 16H x 25L x 11W 8°	2
14-534277	Str. Spacer 17H x 25L x 11W 8°	0
14-534278	Str. Spacer 18H x 25L x 11W 8°	0

Shaded Implants are available by special order.

Ordering Information (Continued)

Zyston™ Straight Convex Trials Kit Catalog #14-534601

Catalog #	Description	Qty
14-534606	Str. Fixed Trial 6H x 20L x 10W Convex	1
14-534607	Str. Fixed Trial 7H x 20L x 10W Convex	1
14-534608	Str. Fixed Trial 8H x 20L x 10W Convex	1
14-534609	Str. Fixed Trial 9H x 20L x 10W Convex	1
14-534610	Str. Fixed Trial 10H x 20L x 10W Convex	1
14-534611	Str. Fixed Trial 11H x 20L x 10W Convex	1
14-534612	Str. Fixed Trial 12H x 20L x 10W Convex	1
14-534633	Str. Fixed Trial 13H x 20L x 11W Convex	1
14-534634	Str. Fixed Trial 14H x 20L x 11W Convex	1
14-534635	Str. Fixed Trial 15H x 20L x 11W Convex	1
14-534636	Str. Fixed Trial 16H x 20L x 11W Convex	1
14-534637	Str. Fixed Trial 17H x 20L x 11W Convex	1
14-534638	Str. Fixed Trial 18H x 20L x 11W Convex	1
14-534666	Str. Fixed Trial 6H x 25L x 10W Convex	1
14-534667	Str. Fixed Trial 7H x 25L x 10W Convex	1
14-534668	Str. Fixed Trial 8H x 25L x 10W Convex	1
14-534669	Str. Fixed Trial 9H x 25L x 10W Convex	1
14-534670	Str. Fixed Trial 10H x 25L x 10W Convex	1
14-534671	Str. Fixed Trial 11H x 25L x 10W Convex	1
14-534672	Str. Fixed Trial 12H x 25L x 10W Convex	1
14-534693	Str. Fixed Trial 13H x 25L x 11W Convex	1
14-534694	Str. Fixed Trial 14H x 25L x 11W Convex	1
14-534695	Str. Fixed Trial 15H x 25L x 11W Convex	1
14-534696	Str. Fixed Trial 16H x 25L x 11W Convex	1
14-534697	Str. Fixed Trial 17H x 25L x 11W Convex	1
14-534698	Str. Fixed Trial 18H x 25L x 11W Convex	1
14-534726	Str. Fixed Trial 6H x 30L x 10W Convex	1
14-534727	Str. Fixed Trial 7H x 30L x 10W Convex	1
14-534728	Str. Fixed Trial 8H x 30L x 10W Convex	1
14-534729	Str. Fixed Trial 9H x 30L x 10W Convex	1
14-534730	Str. Fixed Trial 10H x 30L x 10W Convex	1
14-534731	Str. Fixed Trial 11H x 30L x 10W Convex	1
14-534732	Str. Fixed Trial 12H x 30L x 10W Convex	1
14-534753	Str. Fixed Trial 13H x 30L x 11W Convex	1
14-534754	Str. Fixed Trial 14H x 30L x 11W Convex	1
14-534755	Str. Fixed Trial 15H x 30L x 11W Convex	1
14-534756	Str. Fixed Trial 16H x 30L x 11W Convex	1
14-534757	Str. Fixed Trial 17H x 30L x 11W Convex	1
14-534758	Str. Fixed Trial 18H x 30L x 11W Convex	1
14-534600	Zyston™ Str. Fixed Trial Instrument Case	1

Zyston™ Straight Instruments Kit Catalog #14-534921

Catalog #	Description	Qty
14-534900	Str. Inline Inserter	2
14-534901	Str. Inline Inserter Inner Shaft	2
14-534902	Str. Offset Inserter	1
14-534903	Str. Offset Inserter Inner Shaft	1
14-534904	Str. T-Handle Inserter	2
14-534905	Str. T-Handle Inserter Inner Shaft	2
14-534906	Str. Implant Remover	1
14-534907	Str. Bone Graft Mold	1
14-534908	Str. Inline Tamp	1
14-534909	Str. "V" Tamp	1
14-534910	Str. Corner Tamp	1
14-534920	Zyston™ Straight Instruments Case	1

Zyston™ Universal Instruments Kit Catalog #14-533200

Catalog #	Description	Qty
14-533201	Zyston™ Universal Instrument Case	1
14-533202	Zyston™ Quick Connect 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

Further Information

This brochure describes a surgical technique used by:

- Steven Fiore, MD
- Scot Miller, DO
- Philip Schneider, MD
- Steven Zielinsky, MD

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:

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Parsippany, NJ 07054
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www.biometspine.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™ Straight Spacer System

Designed to enable simple insertion and accurate placement

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