ESL®
Elliptical Shaped Lumbar Spine System

Elliptical Shape
Creates a Natural Fit

Available in
PEEK-OPTIMA®

• Unique, Elliptical Design
• Interbody Fusion Device
• Comprehensive Range of Sizes
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Introduction

The ESL® Spine System is designed to restore the biomechanical integrity of the anterior, middle and posterior column even in the absence of fusion for a prolonged period of time when used as a VBR device. When used as a fusion device, the ESL® Spinal System is designed for use with autograft to facilitate fusion and intended for use with supplemental fixation systems cleared for use in the lumbar spine. The ESL® Spinal System may also be implanted using the AccuVision® System to provide the surgeon with a minimally invasive approach for posterior or posterolateral spinal surgery.

Product Overview

The ESL® Spacer’s anatomically correct shape and open design, coupled with subsidence and retropulsion resistant features, accommodates fusions and can restore sagittal plane alignment. The ESL® Spacer has been designed with an elliptical form that matches the contour shape of the vertebral body. By matching the elliptical curves of the vertebral space in 1.0mm height increments, the ESL® Spacer provides an easy insertion, improved fit, and stability within the vertebral space.

The ESL® Spacer design enables endplates to be preserved, since they do not need to be cut or reamed. By sparing the endplates, subsidence is inherently reduced. The implant’s serrated teeth and elliptical shape engage the bony endplates, resisting sheer and rotational forces. The ESL® Spacer accommodates fusion with large caudal and cranial openings, and is readily filled utilizing a bone mold contained in the instrumentation kit.

In addition to the bone mold, the ESL® Spine System offers an array of instruments that are simple and intuitive to use.

The modular T-Handles are designed to quickly connect and disconnect to the ESL® Trials for ease of use. The color-coded ESL® Trials provide easy identification when determining the appropriate implant size intraoperatively.

The ESL® Implants are available in 8-14mm heights in PEEK-OPTIMA® (Polyetheretherketone) for radiolucency. ESL® Implants in PEEK-OPTIMA® are available in lengths of 21mm, 25mm and 29mm, providing additional sizing options to suit patient anatomy. Tantalum markers help visualize implant orientation within the spine when conducting intraoperative and postoperative radiographic assessment.

The ESL® spacers in PEEK-OPTIMA® can be used unilaterally or bilaterally. This surgical technique illustrates their use with either approach.

The ESL® Spinal System is indicated for vertebral body replacement and intervertebral fusion. When used for vertebral body replacement, the ESL® Spinal 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 ESL® Spinal System is also indicated for treating fractures of the thoracic and lumbar spine. The ESL® Spinal 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.

As an intervertebral body fusion device, the ESL® Spinal 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.
**Design Features**

**Available in a Wide Range of Sizes**
- Implant heights available from 8mm to 14mm in 1mm increments

**Unique, Elliptical Design**
- Conforms to concave shape of the vertebral bodies
- Provides appropriate lordosis with single design
- Easy insertion shape with bulleted nose

**Self Distracting Tips**
- Eases insertion past posterior lip
- Reduces a surgical step by eliminating box chiseling

**Endplate Sparing**
- Preserving endplate resists subsidence
- Reduces a surgical step by eliminating endplate cutting and reaming

**Serrated Teeth**
- Provides stability by engaging bony endplates

**Open Design**
- Accommodates the fusion process with large superior/inferior openings
- Subsidence resistance

**Radiolucent material offers an accurate visualization and assessment of the fusion**
- Provides ideal modulus of elasticity and load sharing attributes
Instruments

Various instruments are available with the ESL® Spine System for use by the surgeon to facilitate implantation of the device.

- Mallet
- Trial Spreader
- 8mm Bone Rasp
- Elliptical Paddle Scraper
- T-Handle
- Two-Piece Inserter Disassembled
- Bone Mold
- Two-Piece Inserter assembled and attached to the ESL® Spacer
1. Distraction/Trialing

A Lamina Spreader is designed to provide distraction to accommodate endplate preparation and confirm the appropriate size ESL® Spacer in PEEK-OPTIMA® prior to implantation. The Lamina Spreader is inserted into the disc space with the teeth coming into direct contact with the superior and inferior lamina. The Lamina Spreader is then squeezed, providing distraction.

The Trial Spreaders are also designed to provide distraction as well as to confirm the appropriate size ESL® Spacer in PEEK-OPTIMA® prior to implantation. The tips of the Trial Spreaders are etched to indicate their height size in millimeters (See Figure 1). The Trial Spreader is inserted into the disc space with the flat surface coming into direct contact with the vertebral body as shown in Figure 2. The Trial Spreader is then rotated 90° orienting the flats of the tip perpendicular to the vertebral body (See Figure 3). Fluoroscopy can be used to verify the position and orientation of the Trial Spreader tip prior to insertion of the ESL® Spacer in PEEK-OPTIMA®.

All of the Trial Spreaders match the elliptical shape of the ESL® Spacer as shown in Figure 4. The height of the Trial Spreaders matches the tip of the serrated teeth of the corresponding ESL® Spacer in PEEK-OPTIMA®. Greater stability after implantation can be achieved by implanting a larger sized ESL® Spacer (See Figure 4).
2. Disc Space Preparation

The Paddle Scrapers are used to facilitate the removal of disc material. The Scrapers feature cutting flutes that allow the instrument to cut in two directions by rotating the Quick Connect T-Handle clockwise and counterclockwise as shown in Figures 5 and 6.

IMPORTANT! Be sure that the Paddle Scraper is always securely attached to the Quick Connect T-Handle prior to insertion.

3. End Plate Preparation

In addition to the Paddle Scrapers, the ESL® Spine System also has a Rasp instrument that can be used to remove the disc material and help prepare the endplate as shown in Figure 7.
4. Autograft Placement

The ESL® Bone Mold is specifically designed for the impaction of autograft or allograft material into the cavity of the ESL® Implant in PEEK-OPTIMA® depending on the indication. After the ESL® Implant has been selected, attach the Inserter, then place it into the corresponding cavity size in the ESL® Bone Mold (Figure 8). Autograft is impacted into the ESL® Implant using a bone tamp instrument for an interbody indication; allograft may be used in VBR procedures.
5. Implant Insertion

The ESL® Inserter is a two-piece instrument (See Figure 9). The Inserter securely attaches to the ESL® Spacer in PEEK-OPTIMA® by placing the inner shaft into the outer shaft and turning the knurled knob clockwise engaging the ESL® Implant (See Figure 10).

When the Inserter is attached to the ESL® Implant, the black T-Handle will be parallel to the open top and bottom of the ESL® Implant. The black T-Handle will help to determine the orientation of the ESL® Spacer during implantation. Impact the ESL® Implant to the desired position. (See Figure 11).

**IMPORTANT! Do Not Twist or Rotate** the two-piece implant inserter instrument during or after implant insertion. When implanting the PEEK-OPTIMA® Implant it is recommended to avoid excessive impaction force during implantation.

If being used bilaterally, repeat the same steps for the contralateral side (See Figure 12).
5. Implant Insertion (Continued)

Additional graft material is then placed between and beside the implants (See Figure 13).

If being used unilaterally, a single implant is utilized (See Figure 14).

Imaging can be used to confirm the desired position of the ESL® Spacer in PEEK-OPTIMA® prior to disconnecting the Implant Inserter from the spacer. See Figure 15 for locations of anterior/posterior tantalum markers used for locating the PEEK-OPTIMA® Spacer.
**Closure and Postoperative Care**

A routine wound closure is then performed.

- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient
- Pain medication
- NG tubes and/or Foley catheters should be discontinued within 24 - 48 hours
- Diet is restricted to small amounts of liquids until return of bowel function is completed
- The patient is encouraged to ambulate as soon as possible. The individual surgeon determines activity level
- Braces are to be used as per each surgeon’s discretion

**Indications for Use**

The ESL® Spinal System is indicated for vertebral body replacement and intervertebral fusion. When used for vertebral body replacement, the ESL® Spinal 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 ESL® Spinal System is also indicated for treating fractures of the thoracic and lumbar spine. The ESL® Spinal 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.

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Please refer to the AccuVision® Surgical Technique for instructions on using the minimally invasive instrumentation.
Description of Device

The ESL® PEEK implant has convex top and bottom surfaces to match the anatomical shape of the vertebral endplates within the vertebral space. The top and bottom surfaces also have teeth to resist shear and rotational forces by engaging the bony endplates. The PEEK implant also has an open design to promote bone growth between the endplates of the adjacent vertebral bodies. The ESL® PEEK implant is available in height sizes from 8mm-14mm and in three lengths, 21mm, 25mm, and 29mm. The ESL® PEEK implant is made from PEEK-OPTIMA® (a registered trademark of Invibio Limited) as described by ASTM F-2026, titanium alloy (Ti-6Al-4V ELI), conforming to ASTM Standard F136, with tantalum radio-opaque markers made to the standard ASTM F-560. Instruments for the ESL® Spinal System are made from stainless steel conforming to ASTM Standards A276, A564, A582, or F899, aluminum conforming to ASTM Standard B221 or B209, or are components of the AccuVision® System.

Instructions for Use

**CAUTION:** The ESL® Spinal System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Refer to the ESL® Spinal System Surgical Technique Manual for complete Instructions-for-Use. Refer to the AccuVision® System Surgical Technique for complete Instructions-for-Use for 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 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.
Warnings

The surgeon should be aware of the following:

1. 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.

2. 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.

3. All instruments must be cleaned and sterilized prior to surgery.

4. As with all orthopaedic implants, the ESL® Spinal System should never be reused under any circumstances.

5. 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.

6. 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.

7. The ESL® Spinal System has not been evaluated for safety and compatibility in the MR environment. The ESL® Spinal System has not been tested for heating or migration in the MR environment.

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.
**Indications for Use (Continued)**

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.

**Potential Adverse Effects and Complications**

Possible adverse effects include, but are not limited to, bending, loosening or fracture of the implants or instruments; loss of fixation; sensitivity to a metallic foreign body, including possible tumor formation; skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications; nonunion or delayed union; infection; nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage; gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium; pain or discomfort; bone loss due to resorption or stress shielding, or bone fracture at, above or below the level or surgery (fracture of the vertebra); hemorrhage of blood vessels and/or hematomas; malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height; bursitis; bone graft donor site pain; inability to resume activities of normal daily living; reoperation or death.

**Sterilization**

The ESL® PEEK 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 resterilize.

**Caution**

Federal (USA) law restricts these devices to sale by or on the order of a licensed physician.
# Product Information

## PEEK-OPTIMA® Implant Loaner Tray Short
(Catalog No. 80982)

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*Products highlighted are available as special order.*
Further Information

This brochure describes the surgical technique used by Paul S. Lin, 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. The contents of this brochure are intended to be only a guide and are not intended to set a standard of care.

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

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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.

ESL® Elliptical Shaped Lumbar Spine System
Elliptical Shape Creates a Natural Fit

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