RSB SPINE

InterPlate® L-PS
PEEK –OPTIMA®
Lumbar Interbody Spacer

Surgical Technique

Developed by Robert S. Bray, Jr., M.D.

InterPlate is a registered trademark of RSB Spine LLC
PEEK –OPTIMA is a trademark of Invibio Ltd.

MKBR 1030-1.0

Set Contents

Part	# in Set	Part Number
12mm SPACER (30mm WIDE 8°)	2	RSB081230S
14mm SPACER (30mm WIDE 8°)	2	RSB081430S
16mm SPACER (30mm WIDE 8°)	2	RSB081630S
12mm SPACER (30mm WIDE 12°)	2	RSB121230S
14mm SPACER (30mm WIDE 12°)	2	RSB121430S
16mm SPACER (30mm WIDE 12°)	2	RSB121630S
12mm SPACER (35mm WIDE 8°)	2	RSB081235S
14mm SPACER (35mm WIDE 8°)	2	RSB081435S
16mm SPACER (35mm WIDE 8°)	2	RSB081635S
12mm SPACER (35mm WIDE 12°)	2	RSB121235S
14mm SPACER (35mm WIDE 12°)	2	RSB121435S
16mm SPACER (35mm WIDE 12°)	2	RSB121635S
SIZER END 12 x 30 x 8	1	RSB646S
SIZER END 14 x 30 x 8	1	RSB648S
SIZER END 16 x 30 x 8	1	RSB650S
SIZER END 12 x 30 x 12	1	RSB674S
SIZER END 14 x 30 x 12	1	RSB675S
SIZER END 16 x 30 x 12	1	RSB676S
SIZER END 12 x 35 x 8	1	RSB671S
SIZER END 14 x 35 x 8	1	RSB672S
SIZER END 16 x 35 x 8	1	RSB673S
SIZER END 12 x 35 x 12	1	RSB677S
SIZER END 14 x 35 x 12	1	RSB678S
SIZER END 16 x 35 x 12	1	RSB679S
SIZER SHAFT	1	RSB651S
SPACER INSERTER	1	RSB660S
PLATE INSERTER	1	RSB670S
RASP	1	RSB541
DISTRACTOR 5 X 8	1	RSB547
DISTRACTOR 7 X 10	1	RSB548
DISTRACTOR 9 X 12	1	RSB549
GUIDE INSERTER	1	RSB552
T - HANDLE	1	RSB631

Indications and Features

Indications:

The L-PS PEEK lumbar interbody spacer is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space.

The L-PS PEEK lumbar interbody spacer is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to SI, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is to be used in patients who have had six months of nonoperative treatment. The L-PS is intended to be used with a supplemental internal fixation system.

Features:

RANGE OF SIZES

The L-PS is available in heights of 12, 14, and 16mm and widths of 30 and 35mm. The spacers are lordosed 8 and 12º. Specific dimensions are listed in the Appendix.

PERIPHERAL SUPPORT

The L-PS is designed to seat around the perimeter of the endplate facilitating load transfer through the cortical shell.

PEEK OPTIMA POLYMER

The L-PS is constructed of PEEK polymer to facilitate fusion visualization. A radiodense tantalum marker rod is embedded in the posterior wall of the spacer.

EASE OF USE

The set is easy to use with very few instruments required for implantation. The set includes *Sizers*, which help insure correct implant fit. The set also includes an *Inserter* for removing the spacer from the caddy and implanting it between the vertebrae. The set is compact and lightweight.

Surgical Approach

Use the appropriate surgical approach for anterior lumbar interbody fusion. Direct anterior access must be provided. Make provision for the distraction method of choice.

Surgical Technique

Surface Preparation:

The disc should be opened to provide full access to the disc space. Curettes and rongeurs are then used to remove the disc and cartilaginous cephalad and caudal endplates. Anterior osteophytes may need to be removed to improve visualization and access. Distraction may be adjusted during discectomy and decompression. A set of *Distractors* in heights of 5, 7, and 9mm is available to assist in widening the disc space. The endplates should be flattened to maximize the spacer contact area. A *Rasp* is provided for this purpose.

It is important that the discectomy extend far enough laterally. In order to achieve fusion the cartilaginous endplates must be removed and contact between the spacer and endplates must be maximized. Gaps between the endplates and the spacer and central spacer graft chamber must be eliminated.

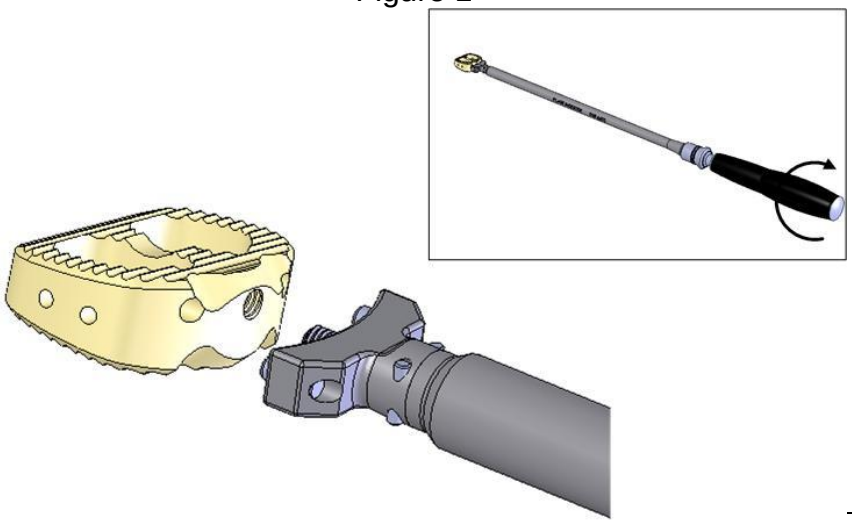
L-PS Selection:

Using the sizers, first determine the width required. Then sequentially increase the sizer height until a snug fit is achieved. The *Sizer* should fit snuggly, but not tightly. **Only gentle impaction should be required to insert the *Sizer*.** In the medial-lateral direction, the width of the L-PS should fit within the available exposure. Fluoroscopy can be used to evaluate fit and position. The Sizer handle is removable to facilitate imaging but **the Sizer head is not suitable for implantation and must be replaced with an L-PS implant.**

L-PS Implantation:

The spacer is docked to the *Inserter* by rotating the handle at the end of the handle clockwise (Figure 1). Once engaged two pins prevent rotation of the *Inserter* relative to the spacer.

Figure 1



Pack the interior chamber of the L-PS with autograft. The autograft material should extend beyond the spacer by no more than 1mm.

Do not release distraction until after the spacer has been inserted. Only gentle impaction should be required to insert the L-PS. NEVER use the L-PS attached to the *Inserter* as a sizer, distractor, or to pry apart or otherwise spread the vertebrae. Only apply force along the axis of the inserter. Check the spacer for damage after insertion.

Confirming Proper Installation:

An x-ray or fluoroscopy should be used to confirm that the spacer is in the desired location. If misalignment is apparent, consideration should be given to repositioning the spacer.

Refer to the package insert for a complete list of warnings, precautions, indications, and contraindications.

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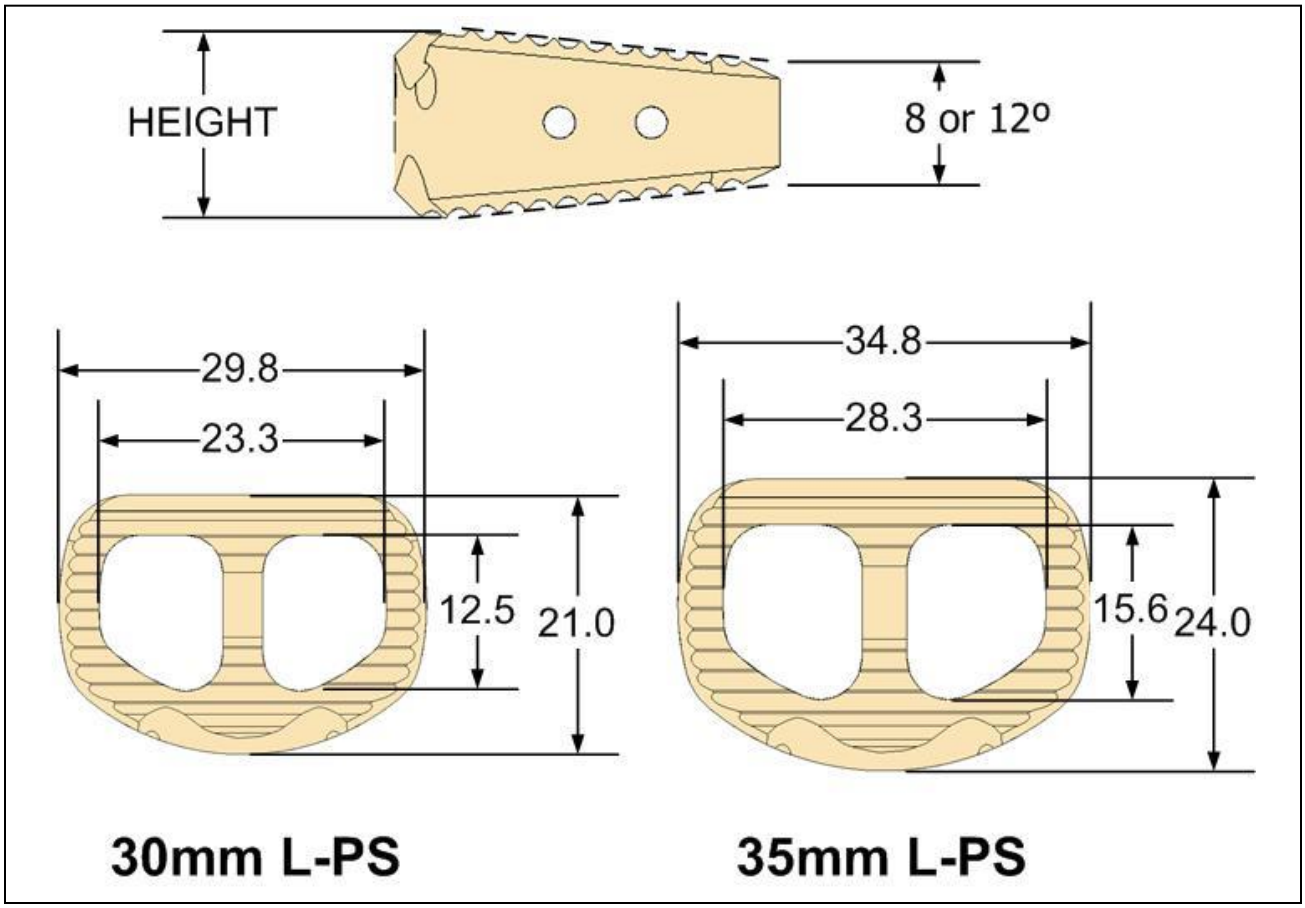
Appendix

InterPlate L-PS Dimensions



	12mm	14mm	16mm
30mm, 8º	2.09	2.52	2.95
35mm, 8º	2.78	3.44	4.11
30mm, 12º	1.58	2.01	2.44
35mm, 12º	2.35	3.02	3.68

Autograft Volume (cc)