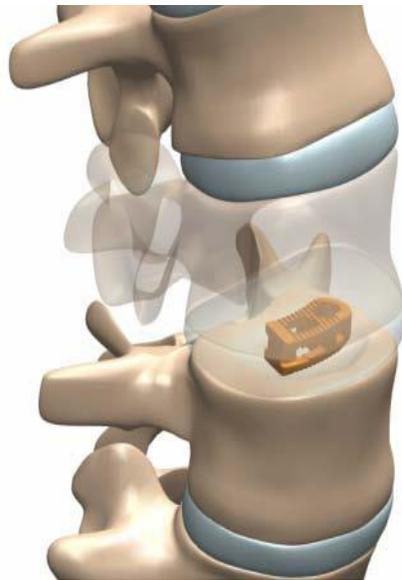


ROMD

Royal Oak IBFD System
Surgical Technique
Transforaminal Lumbar Interbody Fusion (TLIF)



Preoperative Planning

Preoperative planning is necessary for the correct selection of lumbar interbody fusion devices. The implant must be seated firmly with a tight fit between the endplates when the segment is fully distracted. It is essential to use the tallest possible implant to maximize segmental stability.

Device Description

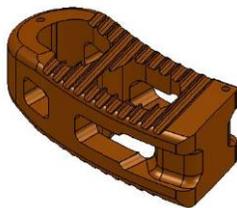
The Royal Oak IBFD System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

The TLIF implant consists of banana shaped blocks in a parallel configuration of various heights (8mm – 16mm, in 2mm increments). The TLIF implant is available in a 25mm length x 10mm width footprint, and is provided with and without lateral windows. Large bone graft windows are located through the body of the device to allow for placement of autograft and facilitate fusion.

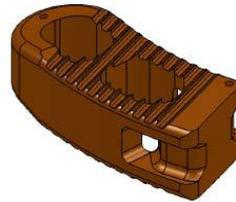
The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the implants. A cross-bar is provided to minimize buckling during insertion.

The TLIF implants contain three (3) tantalum markers to assist the surgeon with proper placement of the device. The nose of the implant is tapered to facilitate insertion.

The figure below provides illustrations of the TLIF implants.



With Lateral Windows



Without Lateral Windows

Position Patient

Place patient in a prone position on a lumbar frame that promotes suitable exposure and restores anatomical lordotic alignment. Radiographic equipment may be used to assist in confirming the affected disc level for intra-operative positioning of the implant.



Spinal Frame Table



Expose and Incise Disc

Incise and dissect the skin and muscle from the midline laterally and locate the spinous process. Confirm location of affected disc using fluoroscopy. After the appropriate level is confirmed via fluoroscopy, begin dissection by performing the medial laminotomy, assuring preservation of as much of the facets as possible to maintain integrity and stability of the intervertebral segments. Once the laminotomy has been performed, retract the nerve roots and dura to expose the disc space. Assure that you have at least a 13 mm window exposure to the disc space.

Prepare Disc and Endplates

Using the instruments in the Royal Oak IBFD System Case 1 and Case 2, remove the disc through the window until only the anterior and lateral annuli remain. Shavers, rasps, and curettes, handles & screws (listed below) are provided in the surgical kit to assist in the removal of the nucleus pulposus and the superficial layers of the cartilaginous endplates.

Note: The superficial layers of the entire cartilaginous endplates are removed to expose bleeding bone.

Adequate preparation of the endplates is important to facilitate vascular supply to the bone graft. Excessive cleaning and/or removal of the entire endplate may result in subsidence and loss of segmental stability.

- #1 Serrated (2401027)
- #1 Oval Gouge (2401030)
- 45° Double Sided Rasp (2401023)
- 30° Left Serrated (2401028)
- 30° Left Fenestrated (2401025)
- 19mm (2401032)
- 25mm (2401033)
- 30° Right Serrated (2401029)
- 30° Right Fenestrated (2401026)
- Straight Fenestrated (2401024)
- 9mm x 10mm (2401031)
- 9mm x 11mm (2401034)



- 10" Handle (2401135)
- 10" Handle Screw (2401036)
- 6" Handle (2133000)
- 6" Handle Screw (2132001)

Distraction of the Disc Space

If the surgeon is utilizing pedicle screws for increased stabilization and correction of spinal alignment, the Lateral Distraction Technique can be used.

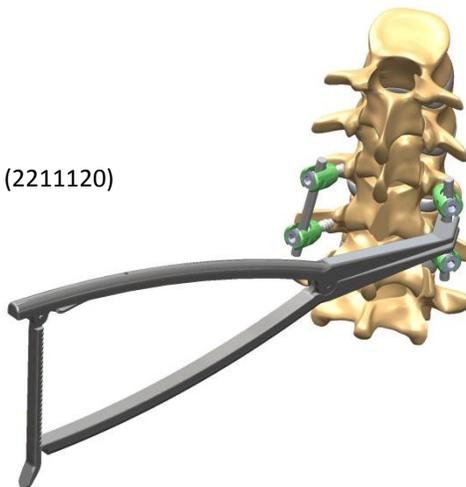
Lateral Distraction (to be used with pedicle screw fixation)

Engage the Lateral Distractor (2211120) to the tulip head of the screws and between the heads of the pedicle screws previously inserted. Once inserted, grasp the ratchet handle and close the handle to distract the disc space. This method prevents potential for fracturing spinous process or endplates.

This maneuver temporarily opens the posterior disc space and promotes increased exposure for both decompression and delivery of the implant. To avoid inducing a kyphotic curve, care should be taken to ensure proper longitudinal distraction.

Note: Proper distraction is essential to restore the disc height and to decompress the neural elements.

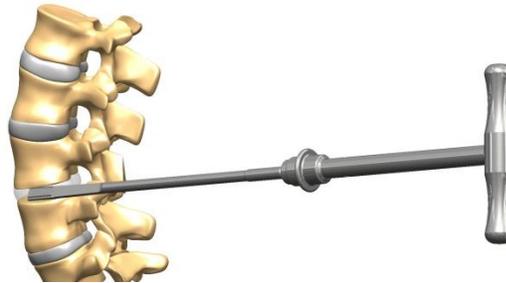
- Distractor (2211120)



Sizing

After distraction, load the spacer/shaver instrument (listed below) into the T-Handle (2501032), and insert into the disc space to determine the appropriate size and length. Use fluoroscopy and tactile feedback to confirm the fit. Select the implant corresponding to the correct size. The spacer/shaver should move in and out of the disc space with a slight give, but should not need significant force or move freely within the disc space.

- Disk Shaver 6mm (2501026)
- Disk Shaver 8mm (2501027)
- Disk Shaver 10mm (2501028)
- Disk Shaver 12mm (2501029)
- Disk Shaver 14mm (2501030)
- Disk Shaver 16mm (2501031)
- T-Handle (2501032)

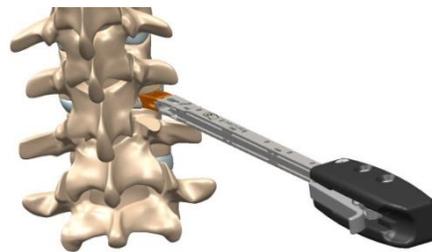


Insert Implant

Choose the correct size implant, place the implant in the jaws of the TLIF inserter, (SP20023) orient the implant as shown on the inserter. Clamp handle to the lock position to secure implant. Pack the window(s) of the implant with autograft bone.



- TLIF Inserter (SP20023)



Introduce the correctly oriented implant into the disc space.

When implant articulation is desired, release the handle from the locked position. (The implant will be free to rotate but will not be released from the clamping jaws.) Slight impaction may be necessary.

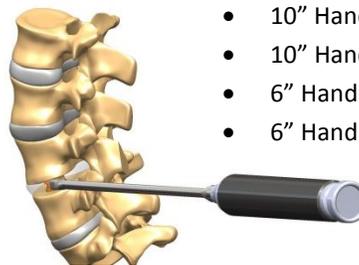


When position is achieved pull the lock handle away from the inserter and hold to release and remove the inserter instrument.

Final Seating and Fluoroscopy Verification Step

Using an impactor assembled with a handle and screw (listed below), gently tap the implant into final position. Confirm positioning of the implant using fluoroscopy.

- Straight Impactor (SP20010)
- Curved Impactor (SP20011)



- 10" Handle (2401135)
- 10" Handle Screw (2401036)
- 6" Handle (2133000)
- 6" Handle Screw (2132001)

Supplemental Fixation

Supplemental fixation cleared for use in the thoracolumbar spine should be used in addition to the implant. Failure to provide supplemental fixation may result in failure to fuse, loosening, displacement or expulsion of the implant.

Revision/Removal Step

No specific instruments are provided with the Royal Oak IBFD System relative to revision surgery. Use standard procedure for exposure of the lumbar spine as during initial insertion of the Royal Oak IBFD System to get down to the appropriate level for removal of the device. Debridement of scar tissue and osteophytes can be performed with rongeurs and other instrumentation within the Standard Orthopedic Instrument Kit. Once exposure has been obtained, the implant may be loosened from the endplates with the use of a Cobb Elevator or Osteotome. Care should be given to prevent fracture of the implant and vertebral endplates.

Postoperative Management Step

The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient to limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

Indications

When used as an intervertebral body fusion device, the Royal Oak IBFD System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

Contraindications

Active systemic infection or infections localized to the site of the proposed implantation are contraindications to implantation. Known sensitivity to PEEK material.

Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation. Any condition that significantly affects the likelihood of fusion may be relative contraindication (e.g. cancer, diabetes, osteomalacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.

Other relative contraindications may include mental illness, drug abuse or alcoholism as these may cause the patient to be non-compliant with post-operative guidance (e.g. bracing and physical therapy).

Prior fusions at the levels to be treated.

Any condition not described in the indications for use.

This product is NOT provided sterile and is for single use only.

See also the Warnings, Precautions and Possible Adverse Effects sections of the Royal Oak IBFD System product insert.

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

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