SF00027 P-LIFT

Surgical Technique

DORADO P-LIFT™ Lumbar IBC Surgical Technique

Description

The DORADO™ P-LIFT™ Intervertebral Body Fusion Device is part of the SpineFrontier Lumbar IBC System. The DORADO™ P-LIFT™ Intervertebral Body Fusion Device is intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolithesis at the involved level(s). The SpineFrontier P-LIFT™ Intervertebral Body Cage is intended to be used with supplemental spinal fixation system(s) (Example: Posterior Pedicle Screw).

The implants are provided in two configurations: straight and lordotic (8°). Implants sizes for both configurations are offered with fixed lengths of 22mm, 24mm, 27mm and 30mm, a fixed width of 8mm, 9mm and vary in height from 8mm – 14mm, in 1mm increments. The devices have features on the superior and inferior surfaces to resist device expulsion.

Degenerative Disc Disease is defined as discogenic pain with degeneration of the disc confirmed by a history of radiographic studies. These patients should be skeletally mature and have had six (6) months of non-operative treatment prior to the treatment with an intervertebral cage.

The SpineFrontier Lumbar IBF System components are supplied non-sterile, are single use, and are fabricated from PEEK-OPTIMA® LT1® with tantalum markers for radiographic visualization.

Indications for Use

The SpineFrontier Lumbar Interbody Fusion Device System (Dorado IBC, Dorado P-LIFT, Dorado ELIFT, Dorado ALIFT, Dorado TILT, Dorado TLIFT, Dorado Wide, and URSA S-LIFT) is intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolithesis at the involved level(s).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The SpineFrontier Lumbar Intervertebral Body Fusion Device System is intended to be used with supplemental spinal fixation system(s) cleared for use in the lumbar spine.
Technique

1. **Preoperative Planning**
   All necessary imaging studies should be available to visualize patient anatomy and plan implant placement. Prior to surgery, determine the desired surgical approach and estimate the appropriate P-LIFT™ size. Assess that the quality of the patient's bone is appropriate for this procedure.

   - It is recommended to select the appropriate sized implant that, in the surgeon's judgment, best stabilizes the segments by creating tension on the annulus fibrosis and longitudinal ligaments.
   - Within the P-LIFT™ System there are certain instruments designed to allow striking while others are not. Avoid striking instruments without a strike plate. Striking instruments that do not have a strike plate may damage the instruments and it will affect the performance of those instruments.
   - Caution: Care must be taken throughout the procedure to ensure that no damage is caused to the nerve roots.
   - Care should be exercised when using any articulating instrument or combination of instruments to avoid pinching or damage to gloves or other personal protection equipment.

2. **Patient Positioning**
   The patient is placed in the prone position. Use fluoroscopic images to verify the position of the vertebral levels to be operated on.

3. **Prepare the Site**
   Carefully clean the operative area and make an incision at the appropriate fusion level.

4. **Creating Access to the Disc**
   At the appropriate fusion level, use Kerrison or preferred tool (not provided by SpineFrontier) to remove portions of both the inferior and superior lamina to create the laminal window. This provides access to the disc. Use the appropriate tools (not provided by SpineFrontier) to retract the nerve roots and Dura when performing this procedure.

   - Caution: Care must be taken during this step of the procedure to ensure that no damage is caused to the Dura and the nerve roots.

5. **Discectomy**
   Perform Discectomy using standard surgical techniques. Disc material is removed from the intervertebral disc space using the Curettes. To provide additional support for the Implant,
the anterior and lateral walls of the annulus should be preserved. Additional distraction may be necessary during this procedure. Use the appropriate tools (not provided by SpineFrontier) to retract the nerve roots and Dura when performing this procedure.

⚠️ Caution: Care must be taken during this step of the procedure to ensure that no damage is caused to the Dura and the nerve roots.

⚠️ After evacuation of disc material, ensure residual material is removed from around the disc site.

6. **Prepare the endplates**
After the discectomy is complete, start with the smallest Shaver and increase sequentially until all of the cartilaginous endplate material is removed. This will expose bleeding bone surface. Be careful to minimize the amount of the subchondral bone removed so that the vertebral endplate is not weakened. Use the appropriate tools (not provided by SpineFrontier) to retract the nerve roots and Dura when performing this procedure.

Bone graft material should be placed in the anterior and lateral aspects of the intervertebral disc space prior to placement of the implant. A Bone Funnel and Graft Pusher can be used for this purpose.

⚠️ Caution: Care must be taken during this step of the procedure to ensure that no damage is caused to the Dura and the nerve roots.

7. **Placing Bone Graft Material**
It is recommended to use the Bone Funnel and Graft Pusher to place bone grafting material into the disc space prior to inserting the implant. Place bone grafting material in the cup of the Bone Funnel assembly then use the Graft Pusher to advance the bone grafting material down the shaft of the assembly to the desired location in the disc space.

⚠️ Caution: Be sure not to place too much bone grafting material in the disc space. Sufficient space for the Implant is required.

⚠️ Caution: When using a Bone Funnel check your position to be sure that the tip is in the position of intent before striking. The tip of the Bone Funnel may core or damage soft tissue if placed incorrectly.
8. Determine Implant Size

The height of the Implant should match or at least approximate the heights of the adjacent discs. This can be achieved by using the appropriate size Trial Spacer or Paddle Distractor. Using the Trail Spacer, insert the assembly into the disc space using gentle impaction. Fluoroscopy can now be used to confirm the geometry and fit of the Trial Spacer or Paddle Distractor. When removing the Trial Spacer, be sure that it does not slide out too easily or become stuck because of too tight a fit. If either of these conditions is encountered, repeat the process with an appropriately larger or smaller Trial Spacer until the most secure fit is achieved.

Using the Paddle Distractor, insert the assembly into the disc space, and then rotate 90 degrees to push the sides of the Paddle Distractor against the endplates to determine the size of the disc space. Pull back slightly on the Paddle Distractor assembly to feel the resistance of the vertebrae against the Paddle Distractor. Fluoroscopy can now be used to confirm the geometry and fit of the Paddle Distractor. To remove the Paddle Distractor, rotate back 90 degrees and remove.

⚠️ Caution: If using the Shavers to determine the disc space the aggressive bone removal feature may create a large disc space than intended.

⚠️ Caution: It is important to select the correct size implant. If the Implant is too small expulsion may occur. If the Implant is too large subsidence may occur.

9. Insert Implant

Select the Implant that corresponds to the Trial Spacer or Paddle Distractor height. The groove in the Implant is engaged in the Inserter to provide stability and proper alignment of the Implant when inserting into the vertebral space. Refer to the images below for proper orientation of the Implant in the Inserter. Fully tighten down the rear knob of the inserter to secure the Implant in place.

Fig 9.1
10. Insert Implant-Continued

Introduce the **DORADO™ P-LIFT** Intervertebral Body Cage through the Laminal window into the intervertebral disc space, ensuring that the orientation of the Implant is correct. Check anterior positioning using fluoroscopy. Slightly impact the Inserter until the Implant reaches the optimal anterior position. Using fluoroscopy, verify Implant location and position in the vertebral space. Once correctly positioned, release the Implant by unscrewing the knob on the Inserter until the implant is free, and then remove the Inserter.

![Fig 10.1](image)

11. Check Position of Cage

If further adjustment is needed, use Impactor to engage Implant. When engaging the Impactor with the implant, make sure that the Impactor seats with Implant. Strike gently with mallet to achieve adjustment of the implant anteriorly in the intervertebral space or across the midline.

After insertion check position and orientation of Implant using AP and Lateral fluoroscopy.

In the AP view, if the Implant is placed correctly the Implant markers (white dots) should create a triangulated pattern. In the Lateral view Implant markers will appear as two white dots. The dots if placed correctly will create a line that is 20 degrees from a horizontal line.

If the Implant has crossed the midline, adjust the Implant position by re-engaging the inserter to the Implant and pull the Implant back into the optimal position as illustrated in the
AP and Lateral fluoroscopy images shown. Additional graft material should be inserted posterior to the cage after correct Implant position is confirmed.

![Lateral Fluoro](image1.png) ![AP Fluoro](image2.png)

**Fig 11.1 Lateral Fluoro**  **Fig 11.2 AP Fluoro**

**Implant Removal**

Revision could be necessary under the following situations:

**A. Intra-operative Revision**
1. Larger implant preferred after initial implant inserted
2. Misplaced implant; too anterior or not straight
3. Implant placed too far into disc space
4. Implant fracture during impaction/insertion
5. Wrong level surgery
6. Loss of neurologic function of unknown cause

**B. Post-Operative Revision**
1. Non-Union
2. Infection
3. Subsidence into endplates
4. Psychological patient fear of having a device in forever
5. Painful hardware irritating soft tissues or nerves
6. Cage migration causing neural compression
7. Vertebral body fracture around cage leading to cage malposition

The following steps are taken to remove the implant:

1. Approach the level through the original anterior incision and locate the implant.
2. Using surgical tools clean off any scar tissue or bone that is impeding access to the implant.
3. Attach the inserter to the implant using the threaded shaft of the inserter.

If the inserter cannot be attached to the implant, a Kocher or similar instrument can be used to remove the implant.

Surgical Technique Symbols

⚠️ Warning

CONTRAINDICATIONS

Use of implants is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.

Severe osteoporosis may prevent adequate fixation and thus precludes the use of this or any other orthopaedic implants. Patients with severe obesity, osteopenia, or degenerative diseases may place excessive stresses on bone and implants and may be at higher risk of implant failure.

Conditions that reduce the likelihood of successful fusion, such as radio- or chemotherapy for cancer, kidney dialysis, or osteopenia are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.

Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow post operative restrictions and who may place undue stresses on the implant during bony healing and may be of higher risk of implant failure.

WARNINGS AND PRECAUTIONS CONCERNING SPINAL IMPLANTS

WARNINGS

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

a. Previous Spinal Surgery: Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

b. The patient’s weight. An overweight or obese patient can produce loads on the device which can lead to failure of the appliance and the operation.

c. The patient’s occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing the patient may not be able to return to these activities successfully.

d. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

e. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.

f. Foreign body sensitivity. Where material allergy or sensitivity is suspected, appropriate tests (such as skin sensitivity testing) should be made prior to implant selection or use. The surgeon is advised that no pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

g. Smoking. Smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

4. MAGNETIC RESONANCE (MR). The Dorado™ PLIF Intervertebral Body Fusion Device has not been evaluated for safety and compatibility in the MR environment. The Dorado™ PLIF Intervertebral Body Fusion Device has not been tested for heating or migration in the MR environment.
PRECAUTIONS

1. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

2. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient’s ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implant fixation is not as strong as normal healthy bone and may loosen, bend and/or break if excessive demands are placed in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration of the devices and damage to nerves or blood vessels.