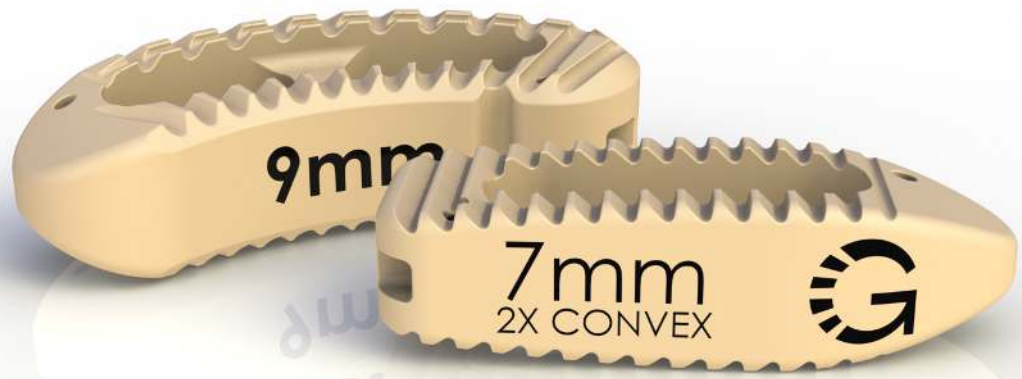
Genesys spine®

Surgical Technique



Apache® Posterior Lumbar Interbody Fusion
Apache® Transforaminal Lumbar Interbody Fusion

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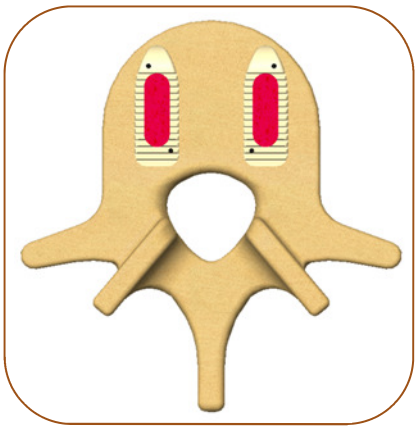
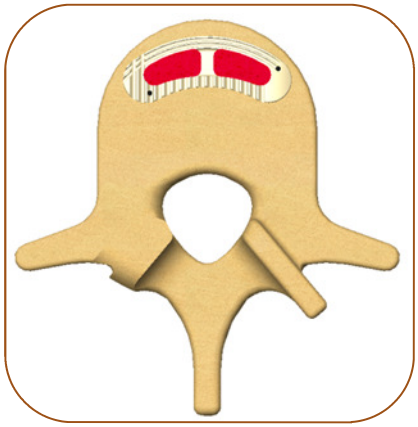
Apache® Posterior Lumbar Interbody Fusion (PLIF)
Apache® Transforaminal Lumbar Interbody Fusion (TLIF)

The Genesys Spine Apache® Lumbar Interbody Fusion System is comprised of precision instruments and implants to aid in lumbar fusion using an anterior approach. The combination of Invibio PEEK Optima® LT1 and tantalum markers allow for radiographic identification of implant placement and fusion.

PEEK Optima® LT1 polymer is a high-performance biomaterial for long term use in the human body. It is a safe and stable polymer that provides spine surgeons and patients distinct advantages and benefits when compared to other accepted implant materials such as bone, metals and other polymers. PEEK Optima® LT1 is radiolucent and compatible with X-ray and CT technology. It allows for clear visualization of surrounding structures and gives the surgeon a clear view of surgery outcome and the healing process.



The Apache® PLIF instruments are utilized for the placement of the PLIF Interbody Fusion Device (IBFD) used for Posterior Lumbar Interbody Fusion (PLIF) to restore disc height, open the neural foramen, stabilize the spinal segment, and provide anterior column support.



The Apache® TLIF instruments are utilized for the placement of the Genesys Spine TLIF IBFD used in transforaminal posterior lumbar interbody fusion procedures to restore disc height, open the neural foramen, stabilize the spinal segment, and provide anterior column support.

Preoperative Planning

Preoperative planning is recommended for the correct selection of the Lumbar IBFD. Determine implant height by comparing a lateral view on the radiographic image with that of the instrument trials/sizers measurements.

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. Due to variability in degrees of magnification, the templates are only an estimate and may not always provide an exact implant measurement.

Patient Positioning

Place patient in a Trendelenburg position on a lumbar frame that promotes suitable exposure and restores sagittal alignment. Radiographic equipment can assist in confirming the precise intraoperative position of the implant.

Disc Exposure

For a PLIF approach, incise and dissect the skin from the midline laterally and locate the spinous process, lamina, dura, and nerve roots of the appropriate level(s). Preserve as much of the facets as possible because they provide stability to the intervertebral segment. Perform a laminotomy to the medial aspect of the facet and retract the dura to expose an approximately 13 mm window to the disc space.

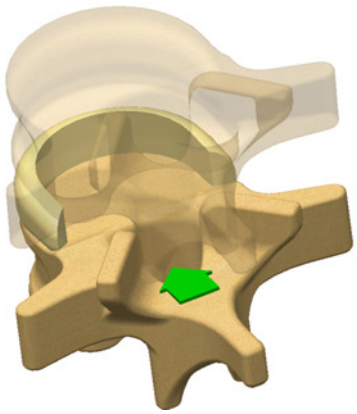
For a TLIF approach, use standard surgical instruments to remove the inferior facet of the cranial vertebra and the superior facet of the caudal vertebra of the appropriate levels to create a transforaminal window.

Disc and Endplate Preparation

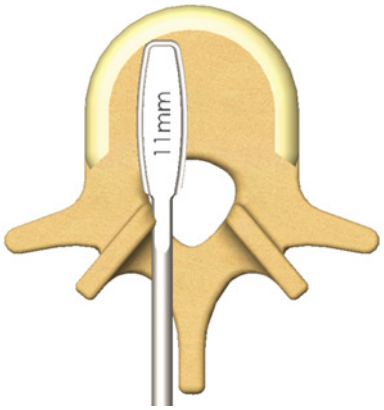
Remove the disc through the window until only the anterior and lateral annuli remain.

The Intervertebral Disc Shavers, Rasps, and preferred curettes are provided to assist in the removal of the nucleus pulposus and the superficial layers of the cartilaginous endplates.

NOTE: Removing the superficial layers of the cartilaginous endplates exposes bleeding bone.

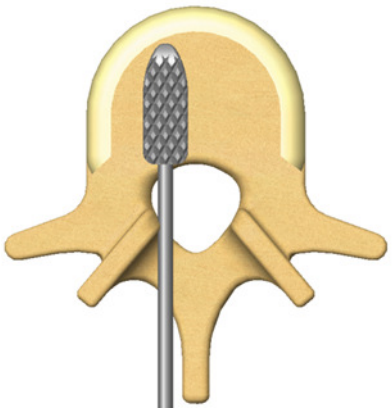


Remove Disc

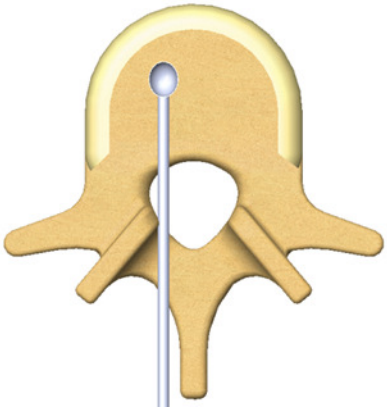


Shavers

Disc and Endplate Preparation Continued



Rasp



Curettes

NOTE: Adequate preparation of the endplates is important to facilitate vascular supply to the bone graft. However, excessive cleaning may weaken the endplates and cause the implant to subside.

Distraction

Use one of the following options for distraction:

Lamina Spreader – place the lamina spreader at the base of the spinous processes of the appropriate levels and apply distraction. This temporarily opens the disc space and promotes increased exposure for both decompression and the delivery of the implant.

Lateral Distraction – Distraction can be applied between the heads of the inserted screws. Use the Lateral Distractor engaged to the tulips of the screws to apply distraction. This temporarily opens the posterior disc space and allows for increased exposure for both decompression and the delivery of the implant.

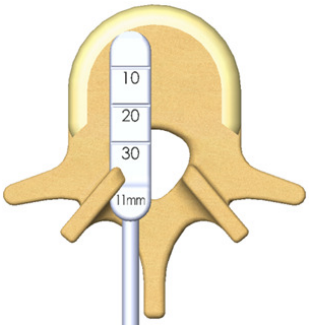
This maneuver temporarily opens the posterior disc space and promotes increased exposure for both decompression and delivery of the implant. To avoid inducing a kyphotic curve, care should be taken to ensure proper longitudinal distraction.

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

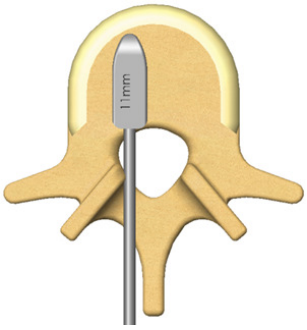
Sizing

After distraction, insert either the paddle assembly or the trial IBFD assembly into the disc space to determine the appropriate size and length. Use fluoroscopy and tactile feedback to confirm the fit of the trial IBFD. If the trial IBFD appears too loose or too tight, try the next larger or smaller size until a secure fit is achieved.

Select the implant corresponding to the correct paddle or trial IBFD. Remove the assembly.



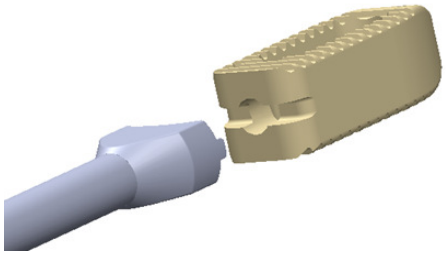
Paddle

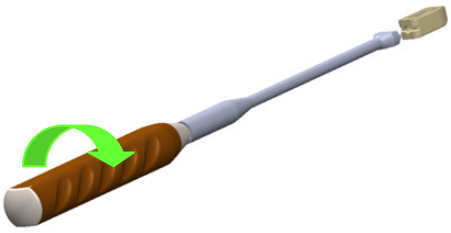


Trial

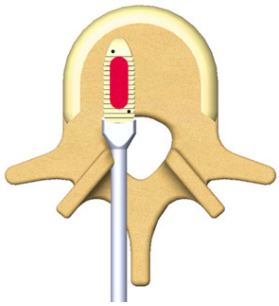
Implant Insertion

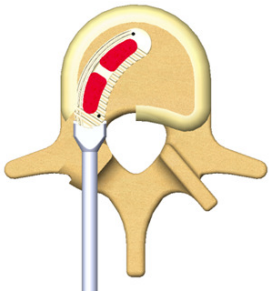
Using the inserter, grasp the chosen size of implant by threading the implant on to the inserter, which will hold the implant firmly and allow for control during insertion. Once the implant is fully engaged on the inserter, allograft bone or a bone graft substitute may be packed into the graft windows of the implant. Introduce the correctly oriented implant into the disc space. Slight impaction may be necessary.





Thread On



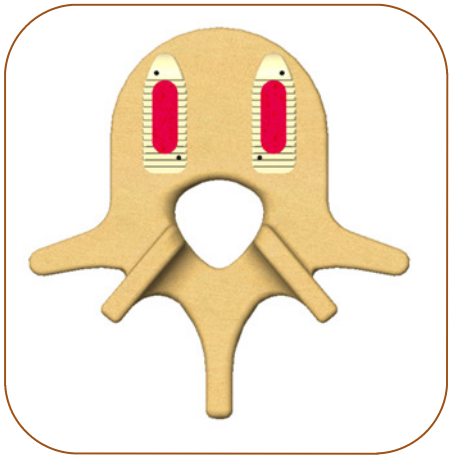


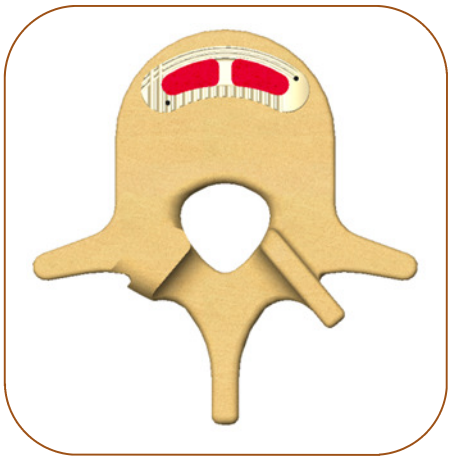
Insert

NOTE: Prior to placement of a second implant, autogenous bone may be placed in the anterior and medial aspect of the vertebral disc space.

Final Seating and Fluoroscopy Verification

Supplemental fixation, such as the Genesys TiLock^{2TM} pedicle screw system, should be used in addition to the Genesys implant. Failure to provide supplemental fixation may result in loosening, displacement or expulsion of the implant.





Revision/Removal Step

No specific instruments are provided with the Genesys Spine System relative to revision surgery. Use a standard operating instrument, such as Kocher forceps, to remove the implant. If the implant cannot be easily removed, a Cobb Elevator or Osteotome should be used to loosen the bone to implant interface.

Post Operative Management

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

The Genesys Spine Apache® Interbody Fusion 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 1 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.

Contraindications

1. Active systemic infection and infection localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to PEEK material.
3. Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.
4. Any condition that significantly affects the likelihood of fusion may be a 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.
5. Other relative contraindication 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).
6. Prior fusion at the levels to be treated.
7. Any condition not described in the indications for use.

Warnings

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
2. 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. A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc, facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record, including radiographic studies and applicable diagnostic tests, should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.
    b. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
    c. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant or subsidence.

d. Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
e. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
f. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

3. MIXING METALS CAN CAUSE CORROSION. Plates, screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
4. REUSE OF IMPLANTS. The risk of reusing implants includes infection and tissue irritation. In addition, exposure to the chemicals used for cleaning can induce physical changes to the materials; the result can be sudden mechanical failure or device malfunction. Genesys Spine accepts no responsibility for a re-used implant
5. Instruments should not be used in any capacity other than their intended use

Precautions

1. THE IMPLANTATION OF SPINAL FIXATION DEVICES SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.
2. PROPER SIZING OF THE IMPLANTS IS IMPORTANT. The surgeon should use trials to determine the appropriate implant to use. The implant should be tall enough to provide segmental distraction and stability. The implant should be wide enough to maintain contact with the cortical rim of the vertebral body else the risk of subsidence may increase.
3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
4. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Visually inspect all implants for damage prior to use.
5. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is non-compliant with post-operative guidance is particularly at risk during the early postoperative period.
6. MAGNETIC RESONANCE (MR) ENVIRONMENT. The Genesys Spine Apache® Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment. The Genesys Spine Apache® Interbody Fusion System has not been tested for heating or migration in the MR environment.

Possible Adverse Effects

1. Non-union, delayed union.
2. Bending or fracture of implant.
3. Anterior or posterior migration of the implant.
4. Allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Loss of proper spinal curvature, correction height and/or reduction.
9. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
10. Paralysis.
11. Death.
12. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

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