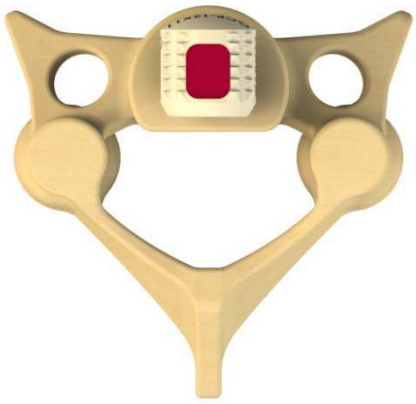
Apache™ Interbody Fusion Device Star Cervical System

The Genesys Spine IBFD Star Cervical System is comprised of precision instruments and implants to aid in cervical fusion. The combination of Invibio PEEK Optima LT-1 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 Genesys Spine IBFD Star Cervical System instruments are utilized for the placement of the Genesys Spine IBFD Star Cervical System implants used 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 IBFD Star Cervical System implant. Determine implant size by comparing a lateral view on the radiographic image with that of the instrument trials /sizers.

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.

Surgical Approach

1. Position patient

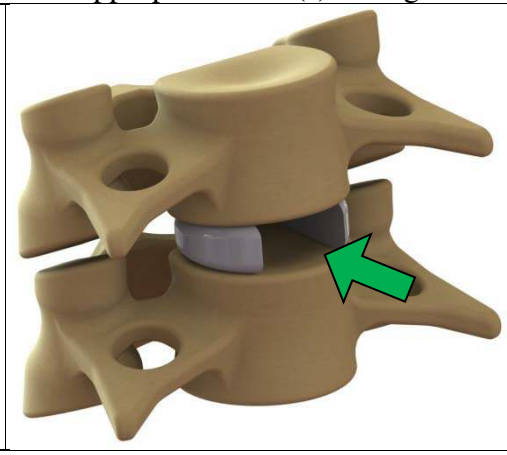
Place patient in a reverse Trendelenburg position to promote suitable exposure and restores sagittal alignment. Radiographic equipment can assist in confirming the precise intraoperative position of the implant.

The vertebra to be fused should be identified and approached using a standard anterior exposure. Care should be taken to avoid vascular or gastroenteric structures. Such structures should be identified and retracted safely for the procedure.

Surgical Technique

1. Prepare disc space

Remove the disc of the appropriate level(s) through the window.



Remove Disc

2. Distraction of the Disc Space

It is recommended that intervertebral distraction be implemented prior to implant placement to facilitate the use of the correct size implant and to secure implantation. Implants which are undersized carry an increased risk of psuedarthrosis and implant expulsion.

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

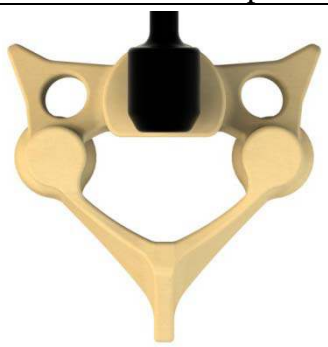
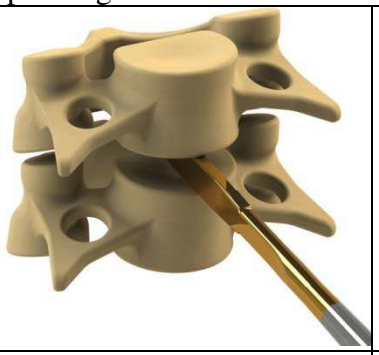
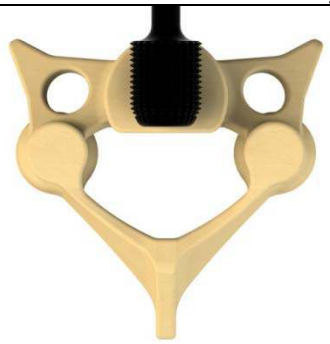
3. Size and Endplate Preparation

After distraction, insert a trial into the disc space to determine the appropriate size and length. The Intervertebral Disc Shavers and Rasps are provided to assist in the removal of the nucleus pulposus and the superficial layers of the cartilaginous endplates. Great care should be taken to avoid plunging the rasp instrument into any neurological structures.

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

Use fluoroscopy and tactile feedback to confirm the fit of the trial IBFD.

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

		
Trial	*Shaver*	*Rasp*

4. Insert Implant

Once the correct size implant has been determined, pack autograft into the graft windows of the implant.

The implant inserter is used to engage the implant via a threaded insert and stabilization planes. The inserter is screwed into the implant with the stabilization planes aligned laterally until the thread is fully seated. Care should be taken to not over tighten the inserter which could result in stripping of the implant threads. Be sure that the implant's graft windows face the vertebral endplates while inserting the implant.

Under fluoroscopy, the implant should be gently impacted into the vertebral/intervertebral space at the midline.

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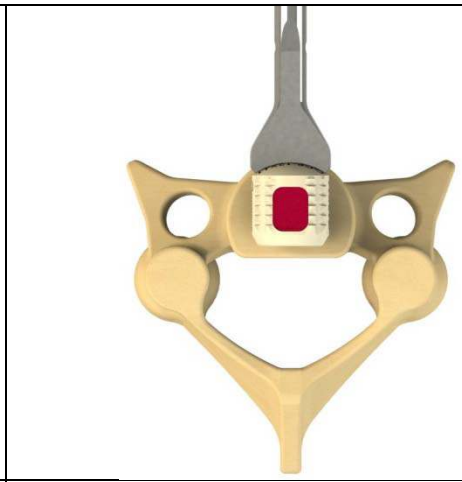
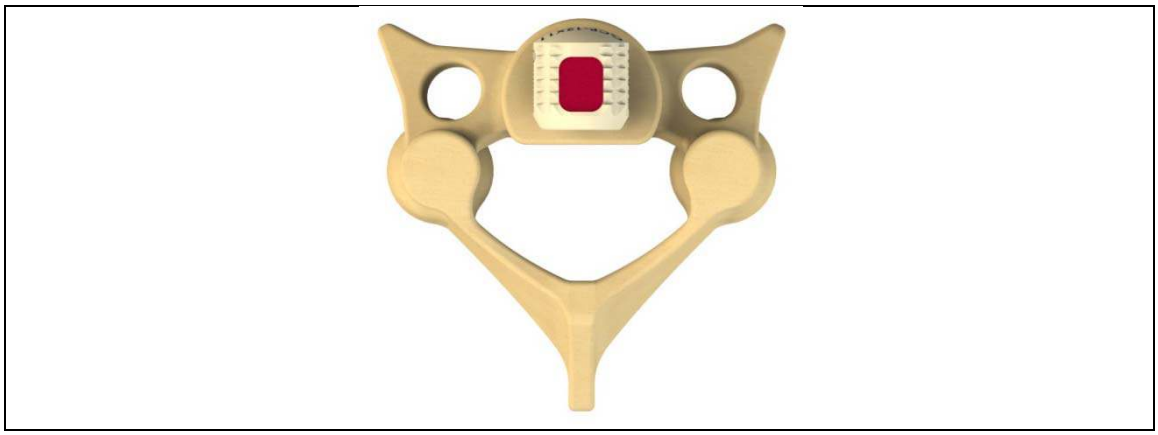
	
Thread on to Inserter	*Insert into Disc Space*

5. Final seating and fluoroscopy verification step

Radiographic markers on the ventral and dorsal portions of the implant can be used to determine correct implant position. Care should be taken to avoid over impaction of the implant.

The inserter is removed by un-threading the instrument. Implant position should be confirmed by AP and lateral radiography.

Supplemental fixation, such as an anterior cervical plate, should be used in addition to the Genesys Spine implant. Failure to provide supplemental fixation may result in loosening, displacement or expulsion of the implant.



6. 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.

7. Post-operative 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.

Implants

NUMBER	DESCRIPTION
GCP-12X11	Star Cervical PEEK - Ø12MM X 11MM
GCP-12X12	Star Cervical PEEK - Ø12MM X 12MM
GCP-12X13	Star Cervical PEEK - Ø12MM X 13MM
GCP-12X14	Star Cervical PEEK - Ø12MM X 14MM
GCP-14X11	Star Cervical PEEK - Ø14MM X 11MM
GCP-14X12	Star Cervical PEEK - Ø14MM X 12MM
GCP-14X13	Star Cervical PEEK - Ø14MM X 13MM
GCP-14X14	Star Cervical PEEK - Ø14MM X 14MM

Instruments

NUMBER	DESCRIPTION	NUMBER	DESCRIPTION
GP600	Cervical PEEK Inserter	GP601	Cervical PEEK Tamp
GP630-12	12mm Cervical Star PEEK Rasp	GP630-14	14mm Cervical Star PEEK Rasp
GP631-12	12mm Cervical Star Trial	GP631-14	14mm Cervical Star Trial
GP632-xx	Star Cervical Shaver - 6 through 14mm	GP704	Fixed AO Straight Handle
GP120	¼" T- Driver		

INDICATIONS

The Genesys Spine Apache™ IBFD Star Cervical System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-TI disc. DDD is defined as discogenic pain 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. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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 relative contraindication (e.g. cancer, diabetes, osteomaacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.
5. 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).
6. Prior fusions 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.

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.
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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