Genesys spine™

Apache™ Cervical Interbody Fusion Device Surgical Technique

LC-005 Rev F

INDICATIONS:

When used as an intervertebral body fusion device, the Genesys Spine Interbody Fusion 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:

- Active systemic infection or infection 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, osteomaacia, 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.

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.

- Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
- 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. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.
  B. 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 device.
  C. 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.
  D. 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, orthopaedic devices can only be considered a delaying technique or temporary relief.
  E. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
  F. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
- 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:

- 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.
- 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.
- 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.
- 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.
- 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.
- 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.

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

Apache™ Cervical Interbody Fusion Device

The Genesys Spine Apache™ Cervical Interbody System is comprised of precision instruments and implants to aid in cervical fusion.

The combination of Invibio PEEK Optima® LT1 and tantalum markers allow for radiographic identification of implant placement and fusion.

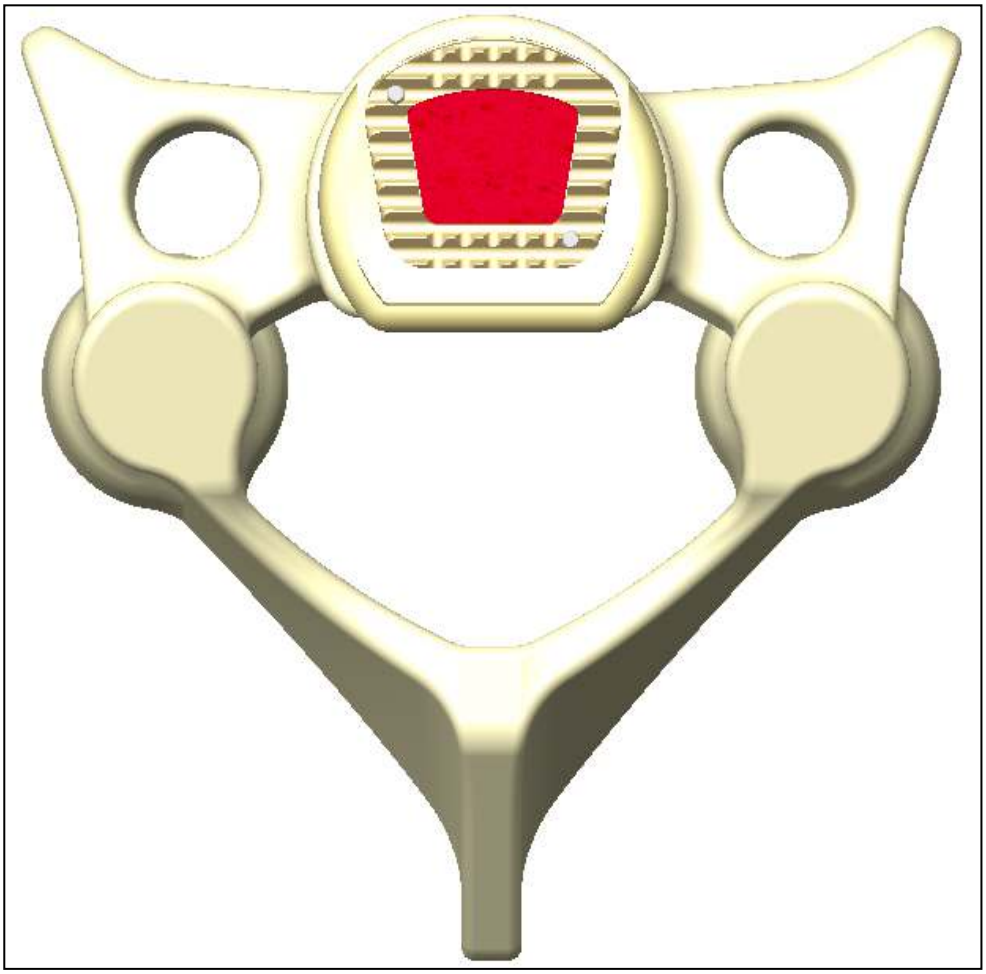
PEEK Optima® LT1 polymer is a high-performance biomaterial for long term use in the human body.

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.

Apache™ Cervical Interbody Fusion Device



The Genesys Spine Apache™ Cervical Interbody instruments are utilized for the placement of the Genesys Spine Apache™ Cervical Interbody Fusion Device (IBFD) used for Cervical Interbody Fusion 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 Cervical IBFD. Determine implant height 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

Position patient

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

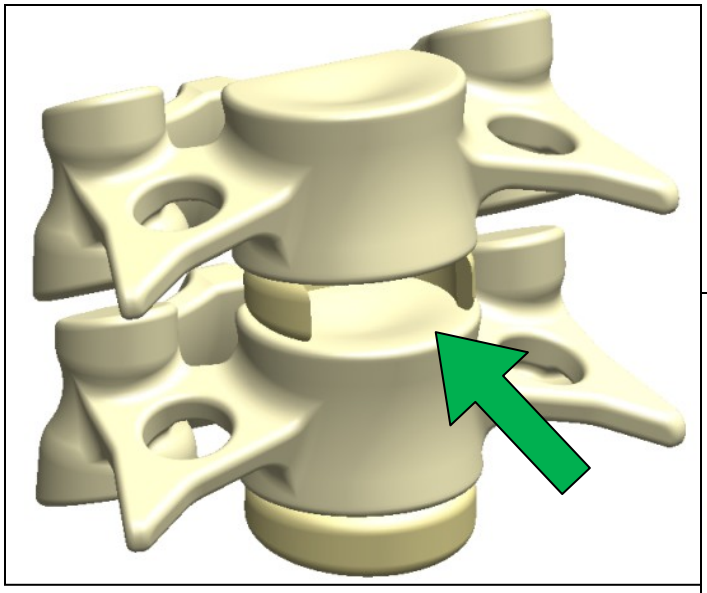
The vertebra to be fused should be identified and approached using a standard anterior exposure. Care should be taken to avoid vascular gastro enteric structures. Such structures should be identified and retracted safely for the procedure.

Surgical Technique

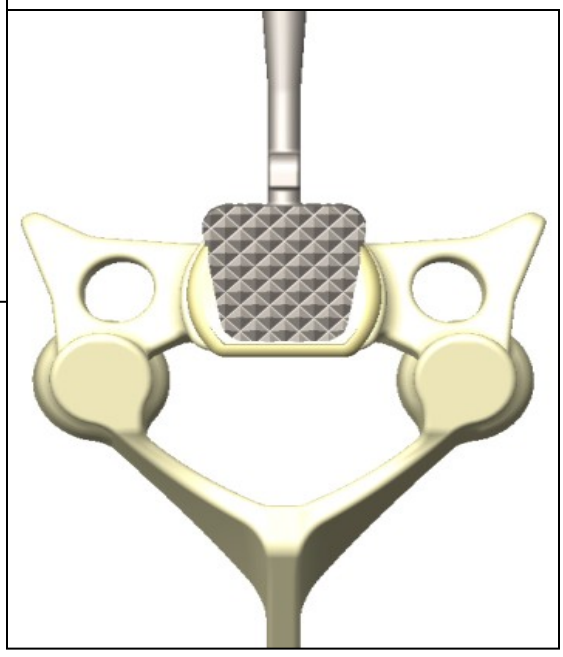
1. Prepare disc and endplates

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



Remove Disc



Rasp

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

2. Distraction of the Disc Space

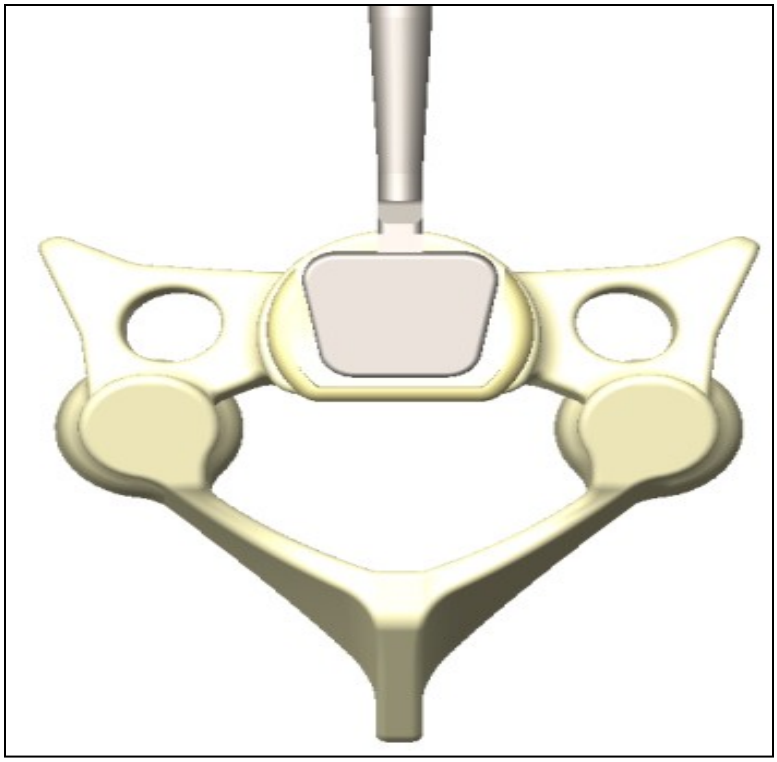
It is recommended that intervertebral distraction be implemented prior to implant placement to facilitate the use of the correct size implant and to secure implantation. Implants which are undersized carry an increased risk of pseudarthrosis and implant expulsion.

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

3. Size

After distraction, insert a 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.

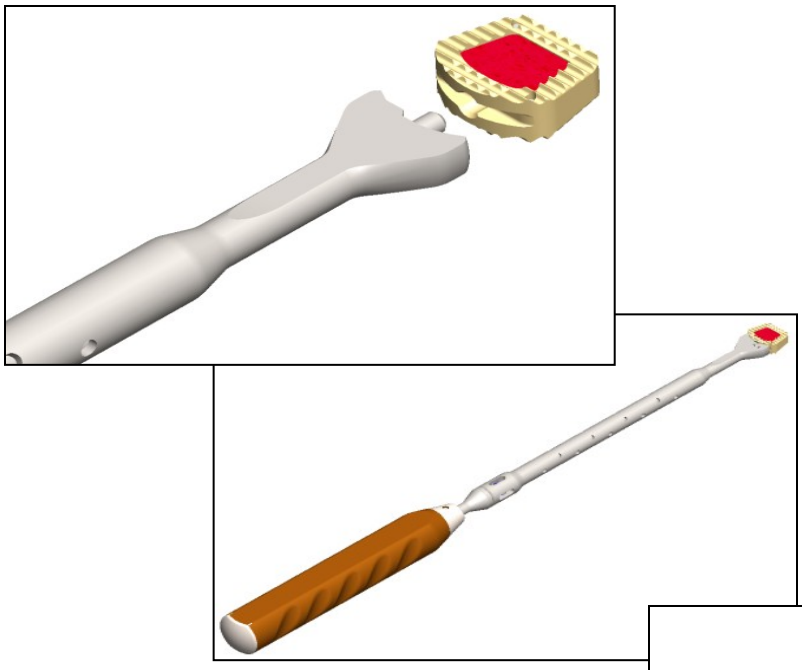
Select the implant corresponding to the correct trial IBFD. Remove the assembly.



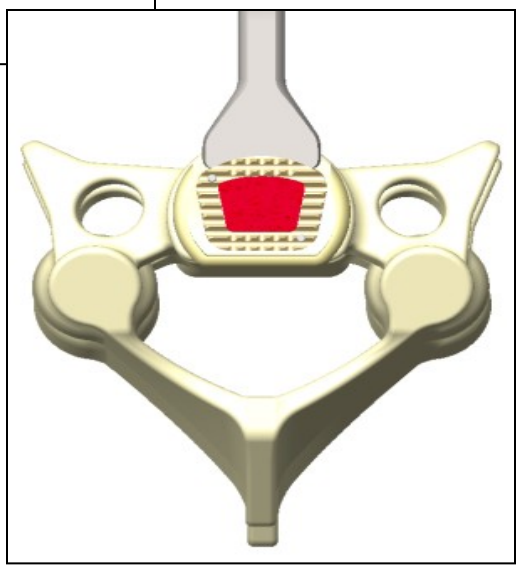
Trial

4. Insert Implant

Once the correct size implant has been determined using the trials, the implant may be packed with autograft bone to facilitate fusion. 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. Under fluoroscopy, the implant should be gently impacted into the vertebral/intervertebral space at the midline.



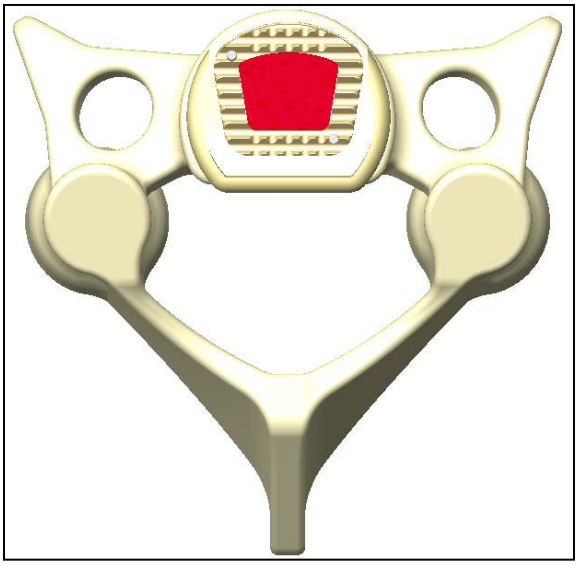
Thread on



Insert

5. Final seating and fluoroscopy verification step

Radiographic markers 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. The tamp may be used for final implant positioning. Implant position should be confirmed by AP and lateral radiography. It is recommended that supplemental fixation, such as an anterior cervical plate, should be used in addition to the Genesys 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	NUMBER	DESCRIPTION
GCL-05-S	7˚ Lordotic - 5mm Cervical PEEK – Small	GCL-05-L	7˚ Lordotic—5mm Cervical PEEK—Large
GCL-06-S	7˚ Lordotic - 6mm Cervical PEEK – Small	GCL-06-L	7˚ Lordotic - 6mm Cervical PEEK – Large
GCL-07-S	7˚ Lordotic - 7mm Cervical PEEK – Small	GCL-07-L	7˚ Lordotic - 7mm Cervical PEEK – Large
GCL-08-S	7˚ Lordotic - 8mm Cervical PEEK – Small	GCL-08-L	7˚ Lordotic - 8mm Cervical PEEK – Large
GCL-09-S	7˚ Lordotic - 9mm Cervical PEEK – Small	GCL-09-L	7˚ Lordotic - 9mm Cervical PEEK – Large
GCL-10-S	7˚ Lordotic - 10mm Cervical PEEK – Small	GCL-10-L	7˚ Lordotic - 10mm Cervical PEEK – Large
GCL-11-S	7˚ Lordotic - 11mm Cervical PEEK – Small	GCL-11-L	7˚ Lordotic - 11mm Cervical PEEK – Large
GCL-12-S	7˚ Lordotic - 12mm Cervical PEEK – Small	GCL-12-L	7˚ Lordotic - 12mm Cervical PEEK – Large
GCLC-05S	5˚ Lordotic - 5mm Cervical PEEK – Small	GCLC-09M	5˚ Lordotic - 9mm Cervical PEEK – Medium
GCLC-06S	5˚ Lordotic - 6mm Cervical PEEK – Small	GCLC-10M	5˚ Lordotic - 10mm Cervical PEEK – Medium
GCLC-07S	5˚ Lordotic - 7mm Cervical PEEK – Small	GCLC-11M	5˚ Lordotic - 11mm Cervical PEEK – Medium
GCLC-08S	5˚ Lordotic - 8mm Cervical PEEK – Small	GCLC-12M	5˚ Lordotic - 12mm Cervical PEEK – Medium
GCLC-09S	5˚ Lordotic - 9mm Cervical PEEK – Small	GCLC-05L	5˚ Lordotic - 5mm Cervical PEEK – Large
GCLC-10S	5˚ Lordotic - 10mm Cervical PEEK – Small	GCLC-06L	5˚ Lordotic - 6mm Cervical PEEK – Large
GCLC-11S	5˚ Lordotic - 11mm Cervical PEEK – Small	GCLC-07L	5˚ Lordotic - 7mm Cervical PEEK – Large
GCLC-12S	5˚ Lordotic - 12mm Cervical PEEK – Small	GCLC-08L	5˚ Lordotic - 8mm Cervical PEEK – Large
GCLC-05M	5˚ Lordotic - 5mm Cervical PEEK – Medium	GCLC-09L	5˚ Lordotic - 9mm Cervical PEEK – Large
GCLC-06M	5˚ Lordotic - 6mm Cervical PEEK – Medium	GCLC-10L	5˚ Lordotic - 10mm Cervical PEEK – Large
GCLC-07M	5˚ Lordotic - 7mm Cervical PEEK – Medium	GCLC-11L	5˚ Lordotic - 11mm Cervical PEEK – Large
GCLC-08M	5˚ Lordotic - 8mm Cervical PEEK – Medium	GCLC-12L	5˚ Lordotic - 12mm Cervical PEEK – Large
GCP-05-S	Parallel - 5mm Cervical PEEK – Small	GCP-05-L	Parallel—5mm Cervical PEEK—Large
GCP-06-S	Parallel - 6mm Cervical PEEK – Small	GCP-06-L	Parallel - 6mm Cervical PEEK – Large
GCP-07-S	Parallel - 7mm Cervical PEEK – Small	GCP-07-L	Parallel - 7mm Cervical PEEK – Large
GCP-08-S	Parallel - 8mm Cervical PEEK – Small	GCP-08-L	Parallel - 8mm Cervical PEEK – Large
GCP-09-S	Parallel - 9mm Cervical PEEK – Small	GCP-09-L	Parallel - 9mm Cervical PEEK – Large
GCP-10-S	Parallel - 10mm Cervical PEEK – Small	GCP-10-L	Parallel - 10mm Cervical PEEK – Large
GCP-11-S	Parallel - 11mm Cervical PEEK – Small	GCP-11-L	Parallel - 11mm Cervical PEEK – Large
GCP-12-S	Parallel - 12mm Cervical PEEK – Small	GCP-12-L	Parallel - 12mm Cervical PEEK – Large
GCX-05-S	Convex - 5mm Cervical PEEK – Small	GCX-05-L	Convex—5mm Cervical PEEK—Large
GCX-06-S	Convex - 6mm Cervical PEEK – Small	GCX-06-L	Convex - 6mm Cervical PEEK – Large
GCX-07-S	Convex - 7mm Cervical PEEK – Small	GCX-07-L	Convex - 7mm Cervical PEEK – Large
GCX-08-S	Convex - 8mm Cervical PEEK – Small	GCX-08-L	Convex - 8mm Cervical PEEK – Large
GCX-09-S	Convex - 9mm Cervical PEEK – Small	GCX-09-L	Convex - 9mm Cervical PEEK – Large
GCX-10-S	Convex - 10mm Cervical PEEK – Small	GCX-10-L	Convex - 10mm Cervical PEEK – Large
GCX-11-S	Convex - 11mm Cervical PEEK – Small	GCX-11-L	Convex - 11mm Cervical PEEK – Large
GCX-12-S	Convex - 12mm Cervical PEEK – Small	GCX-12-L	Convex - 12mm Cervical PEEK – Large

Instruments

NUMBER	DESCRIPTION	NUMBER	DESCRIPTION
GP600	Cervical PEEK Inserter	GP601	Cervical PEEK Tamp
GP605	5mm Cervical PEEK Trial	GP615	5mm Cervical PEEK Rasp
GP606	6mm Cervical PEEK Trial	GP616	6mm Cervical PEEK Rasp
GP607	7mm Cervical PEEK Trial	GP617	7mm Cervical PEEK Rasp
GP608	8mm Cervical PEEK Trial	GP618	8mm Cervical PEEK Rasp
GP609	9mm Cervical PEEK Trial	GP619	9mm Cervical PEEK Rasp
GP610	10mm Cervical PEEK Trial	GP620	10mm Cervical PEEK Rasp
GP611	11mm Cervical PEEK Trial	GP621	11mm Cervical PEEK Rasp
GP612	12mm Cervical PEEK Trial	GP622	12mm Cervical PEEK Rasp
GP704	Fixed AO Straight Handle	GP636-S05 thru GP636-S12	5mm thru 12mm Small Cervical Rasp with Handle
GP636-L05 thru GP636-L12	5mm thru 12mm Large Cervical Rasp with Handle	GP637-S05 thru GP637-S12	5mm thru 12mm Small Cervical Trial with Handle
GP637-L05 thru GP637-L12	5mm thru 12mm Large Cervical Trial with Handle	N/A	N/A

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