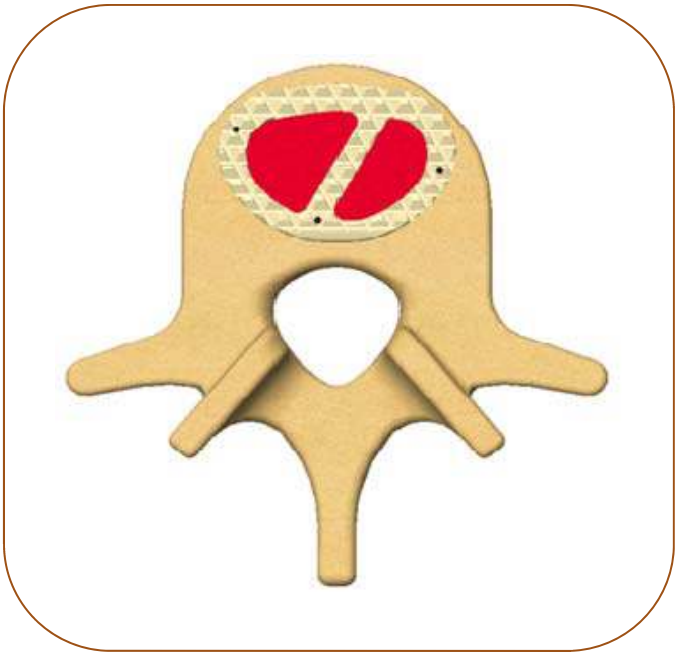
Genesys spine™

Apache™ Interbody Surgical Technique

LC004 Rev F

Genesys spine™



Apache™ Anterior Lumbar Interbody Fusion Surgical Technique

INDICATIONS:

When used as an intervertebral body fusion device, the Genesys Spine Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, 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 deivce system is designed for use with supplemental fixation and with autograft to facilitate fusion.

When used as a vertebral body replacement device, the Genesys Spine System is indicated for use to replace a vertebral body that has been resected to excised (i.e. partial or total vertebrectomy) due to tumor or trauma/ fracture. The device system is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. These devices are designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. The device system is intended to be used with autograft or allograft bone.

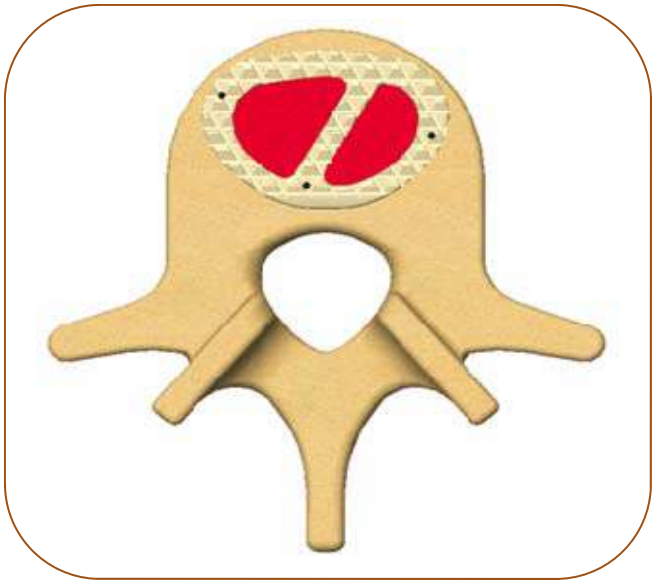
CONTRAINDICATIONS:

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.

Apache™ Anterior Lumbar Interbody Fusion (ALIF)

The Genesys Spine Apache™ Lumbar Interbody 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.



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 end-plates 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 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.

Surgical Technique

1. Expose/ Prepare disc and endplates

Surgeon exposes the midline of the intervertebral disc to position the center of the implant on the vertebral midline. A sufficient amount of the disc and anterior longitudinal ligament are removed to allow for the implant to fit properly. The supplied instruments assists in the removal of the superficial layers of the cartilaginous endplates.

NOTE: Removing the superficial layers of the cartilaginous endplates exposes bleeding bone. Adequate preparation of the endplates is important to facilitate vascular supply to the bone graft. However, excessive scraping may weaken the endplates and cause the implant to subside.

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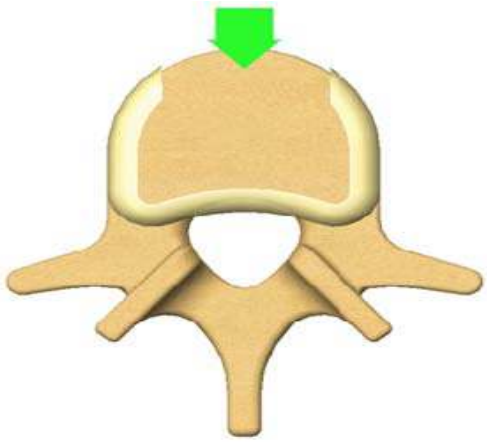


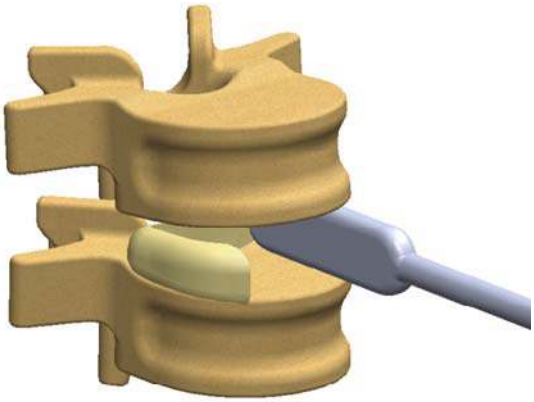
Remove Disc

2. Distraction of the Disc Space/ Size Selection

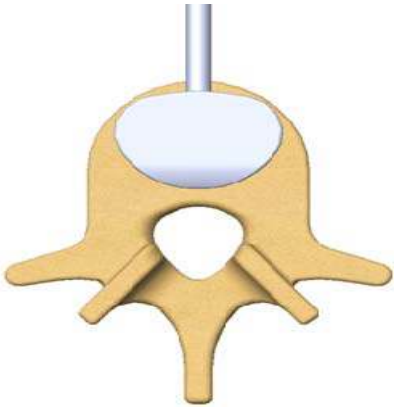
The ALIF distractor is used to distract the vertebral segment to restore the disc height, open the neural foramen, and stabilize the implant. Distract the space using the appropriate elevator blades. Place the blades of the elevator into the disc space and align the blades with the anterior midline of the vertebral bodies. Once the desired level of distraction is achieved, determine the implant size using the ALIF Trial Sizers. Select the ALIF Trial Sizer that corresponds to the desired implant size and attach to the quick release handle.

Slide the ALIF trial sizer into the disc space. If the chosen trial sizer is too small, use incrementally larger trial sizers until a tight fit is achieved. It is recommended that the tallest implant is used to maximize segment stability.

Select the implant that corresponds to the correct trial sizer.



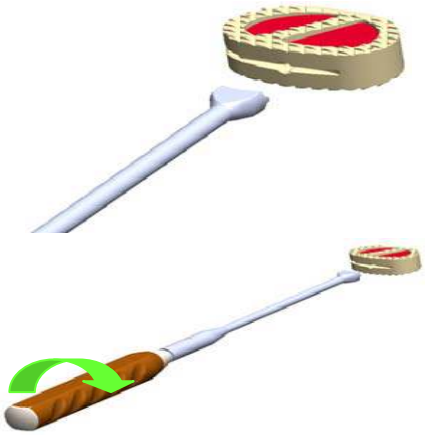
Distraction (Elevator)



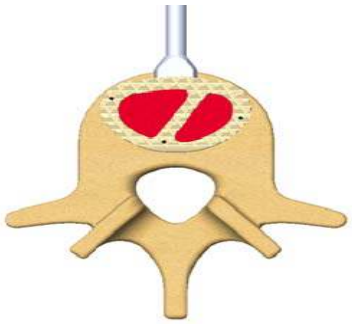
Trial

3. Insert Implant

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, autograft bone may be packed into the graft windows of the implant. Introduce the correctly oriented implant into the disc space.
Slight impaction may be necessary.



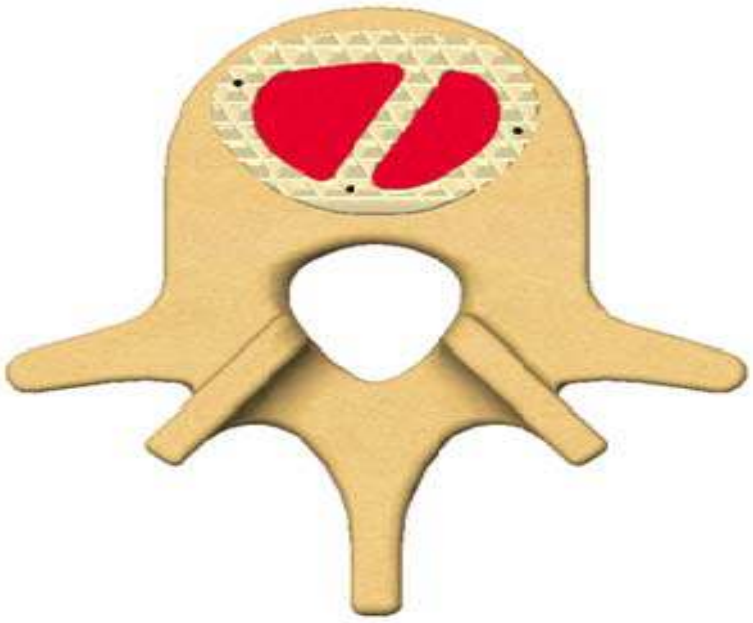
Thread on



Insert

4. Final seating and fluoroscopy verification step

Supplemental fixation, such as the Genesys TiLock™ 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.



Anterior Approach

5. 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.

6. 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.

Apache™ Anterior Lumbar Interbody Fusion

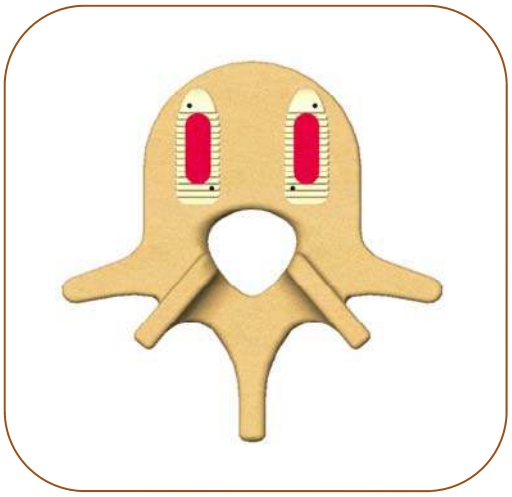
Implants

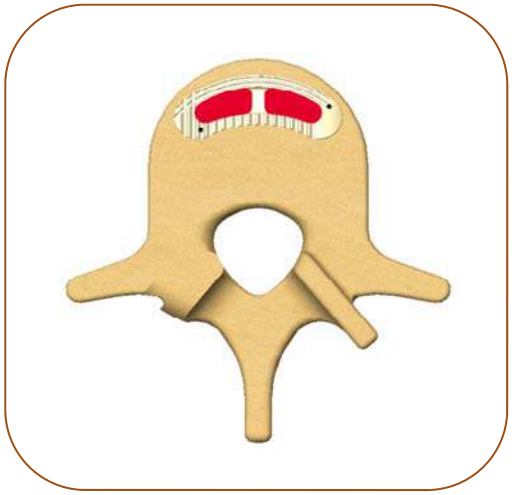
NUMBER	DESCRIPTION
GA-08-06	8mm 6deg ALIF PEEK
GA-10-12	10mm 12deg ALIF PEEK
GA-10-06	10mm 6deg ALIF PEEK
GA-12-12	12mm 12deg ALIF PEEK
GA-12-06	12mm 6deg ALIF PEEK
GA-14-12	14mm 12deg ALIF PEEK
GA-14-06	14mm 6deg ALIF PEEK
GA-16-12	16mm 12deg ALIF PEEK
GA-16-06	16mm 6deg ALIF PEEK
GA-18-12	18mm 12deg ALIF PEEK
GA-18-06	18mm 6deg ALIF PEEK
GA-20-12	20mm 12deg ALIF PEEK
GA-20-06	20mm 6deg ALIF PEEK

Instruments

NUMBER	DESCRIPTION
GP500	ALIF Inserter
GP501	Pituitary Rongeur
GP502	Double Action Rongeur
GP503	O'Brien Curette
GP504	Cobb Elevator
GP505	Large Cobb Elevator
GP506	#3 Angled Cup Curette
GP507	#6 Angled Cup Curette
GP0608	8mm 6deg ALIF Trial
GP0610	10mm 6deg ALIF Trial
GP0612	12mm 6deg ALIF Trial
GP0614	14mm 6deg ALIF Trial
GP0616	16mm 6deg ALIF Trial
GP0618	18mm 6deg ALIF Trial
GP0620	20mm 6deg ALIF Trial
GP1208	8mm 12deg ALIF Trial
GP1210	10mm 12deg ALIF Trial
GP1212	12mm 12deg ALIF Trial
GP1214	14mm 12deg ALIF Trial
GP1216	16mm 12deg ALIF Trial
GP1218	18mm 12deg ALIF Trial
GP1220	20mm 12deg ALIF Trial
GP120	1/4” Driver

Genesys spine™





Apache™ Posterior Lumbar Interbody Fusion
Apache™ Transforaminal Lumbar Interbody Fusion
Surgical Technique

INDICATIONS:

When used as an intervertebral body fusion device, the Genesys Spine Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, 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.

When used as a vertebral body replacement device, the Genesys Spine System is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/ fracture. The device system is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. These devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The device system is intended to be used with autograft or allograft bone.

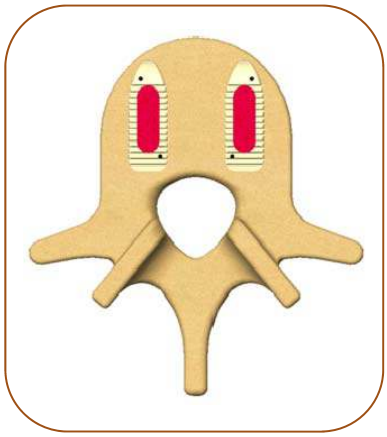
CONTRAINDICATIONS:

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.

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

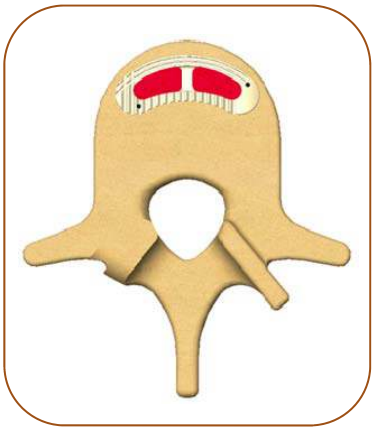
The Genesys Spine Apache™ Lumbar Interbody System is comprised of precision instruments and implants to aid in lumbar fusion. The combination of Invibio PEEK Optima® LT1 and tantalum markers allow for radiographic identification of implant placement and fusion.

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.



The Genesys Spine PLIF instruments are utilized for the placement of the Genesys Spine 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 Genesys Spine 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.



Genesys Spine recommends the use of intraoperative neurophysiologic monitoring (IONM) during spine surgery to minimize the risk of postoperative neural deficit.

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.

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 prone 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.

Expose the disc

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 13mm 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.

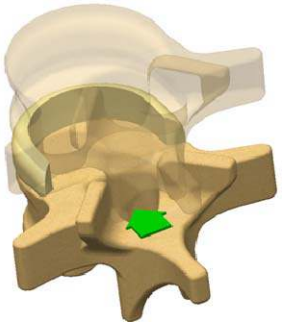
Surgical Technique

1. Prepare disc and endplates

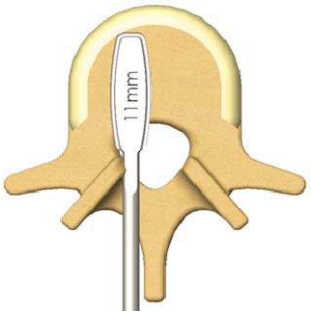
Remove the disc through the window until only the anterior and lateral annuli remain.

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.

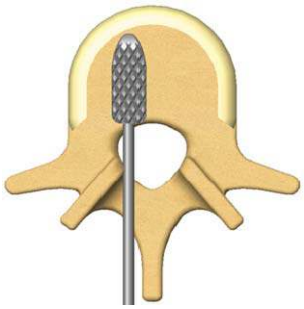
Note: The superficial layers of the entire cartilaginous endplates are removed to expose bleeding bone.



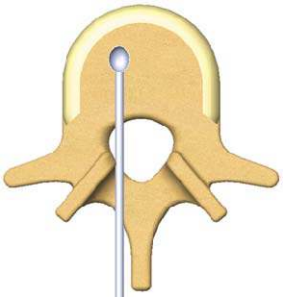
Remove Disc



Shavers



Rasp



Curettes

NOTE: (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)

2. Distraction of the Disc Space

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.

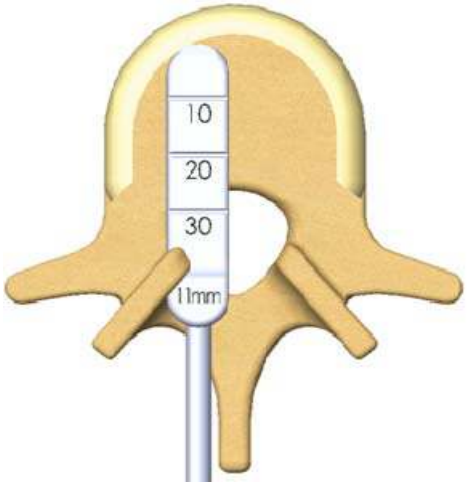
This maneuver temporarily opens the posterior disc space and promotes increased exposure for both decompression and delivery of the implant. To avoid inducing a kyphotic curve, care should be taken to ensure proper longitudinal distraction.

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

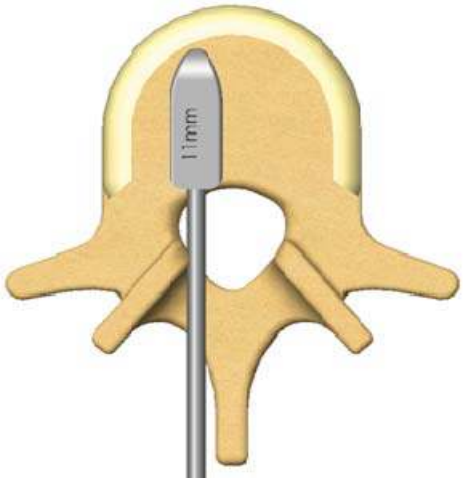
3. Size

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



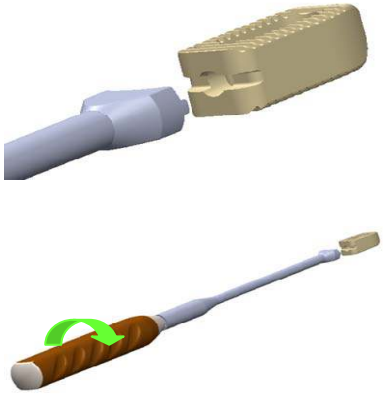
Trial

4. Insert Implant

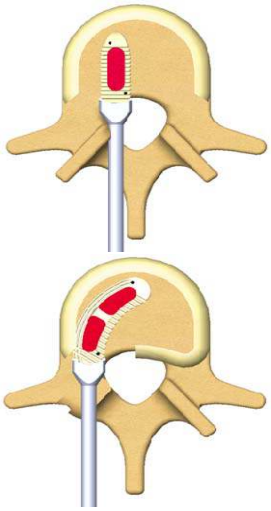
Using the inserter, grasp the chosen size of implant by threading the implant on to the inserter, which will hold the implant firmly and allow for control during insertion.

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
Note: PLIF Shown, same process

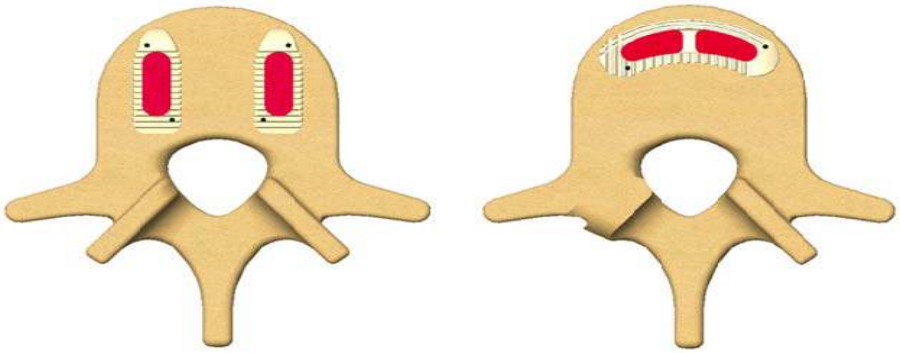


Insert

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

5. Final seating and fluoroscopy verification step

Supplemental fixation, such as the Genesys TiLock™ 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.



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.

Apache™ Posterior Interbody Fusion
Apache™ Transforaminal Lumbar Interbody Fusion

TLIF - Implants

NUMBER	DESCRIPTION
GT-06-P	6mm TLIF Parallel
GT-07-P	7mm TLIF Parallel
GT-08-P	8mm TLIF Parallel
GT-09-P	9mm TLIF Parallel
GT-10-P	10mm TLIF Parallel
GT-11-P	11mm TLIF Parallel
GT-12-P	12mm TLIF Parallel
GT-13-P	13mm TLIF Parallel
GT-14-P	14mm TLIF Parallel
GT-15-P	15mm TLIF Parallel
GT-07-L	7mm TLIF Lordotic
GT-08-L	8mm TLIF Lordotic
GT-09-L	9mm TLIF Lordotic
GT-10-L	10mm TLIF Lordotic
GT-11-L	11mm TLIF Lordotic
GT-12-L	12mm TLIF Lordotic
GT-13-L	13mm TLIF Lordotic
GT-14-L	14mm TLIF Lordotic
GT-15-L	15mm TLIF Lordotic

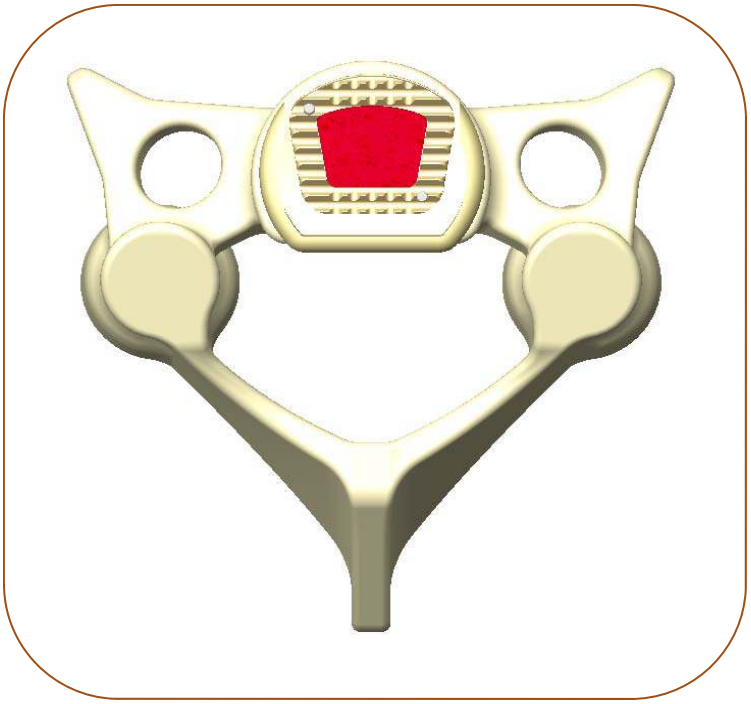
PLIF - Implants

NUMBER	DESCRIPTION
GP-06	6mm PLIF STD
GP-07	7mm PLIF STD
GP-08	8mm PLIF STD
GP-09	9mm PLIF STD
GP-10	10mm PLIF STD
GP-11	11mm PLIF STD
GP-12	12mm PLIF STD
GP-13	13mm PLIF STD
GP-14	14mm PLIF STD
GP-15	15mm PLIF STD
GP-06-30	6mm PLIF 30
GP-07-30	7mm PLIF 30
GP-08-30	8mm PLIF 30
GP-09-30	9mm PLIF 30
GP-10-30	10mm PLIF 30
GP-11-30	11mm PLIF 30
GP-12-30	12mm PLIF 30
GP-13-30	13mm PLIF 30
GP-14-30	14mm PLIF 30
GP-15-30	15mm PLIF 30

Instruments

NUMBER	DESCRIPTION
GP100	PLIF/TLIF Inserter
GP300	Straight Tamp
GP301	Curved Tamp
GP302	Lamina Spreader
GP106 thru GP115	6mm thru 15mm PLIF Trial
GP206 thru GP215	6mm thru 15mm TLIF Trial
GP306 thru GP315	6mm thru 15mm Paddle Trial
GP406 thru GP415	6mm thru 15mm Paddle Shaver
GP1001	Straight Curette
GP1002	Up Curette
GP1003	Down Curette
GP1004	Left Curette
GP1005	Right Curette
GP1006	Straight Ring Curette
GP1007	Angled Ring Curette
GP1008	Straight Rasp
GP120	1/4" Driver
GP121	Mallet
GP122	Rongeur
GP123	Cobb
GP124	Kocher forceps
GP125	Osteotome

Genesys spine™



Apache™ Cervical Interbody Fusion Device Surgical Technique

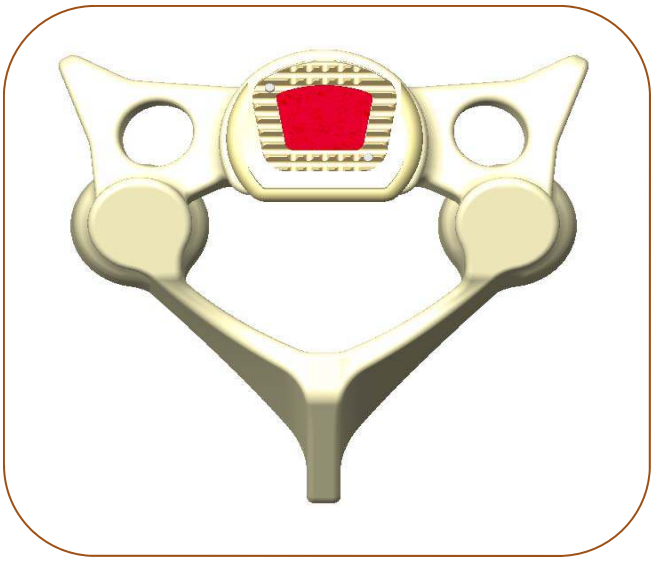
INDICATIONS:
When used as an intervertebral body fusion device, the Genesys Spine Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the 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.

Apache™ Cervical Interbody Fusion Device

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



The Genesys Spine 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.

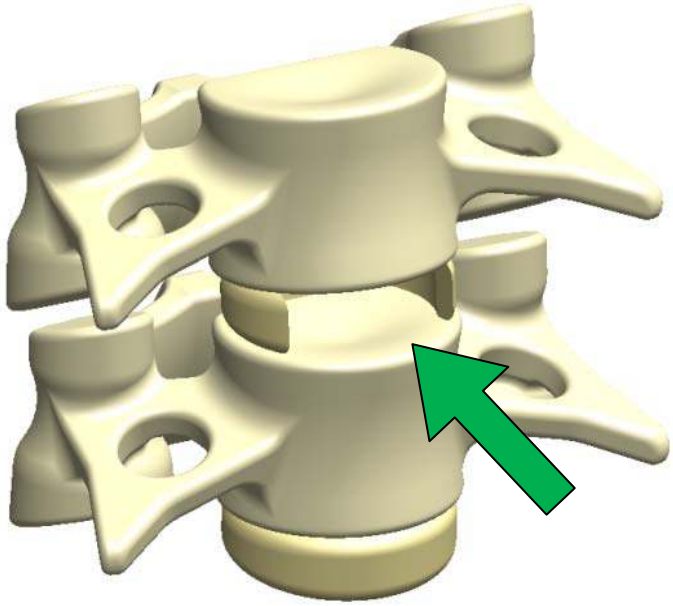
The vertebra to be fused should be indentified and approached using a standard anterior exposure. Care should be taken to avoid vascular gastro enteric structures. Such structures should be identified and retracted safely for the procedure.

Surgical Technique

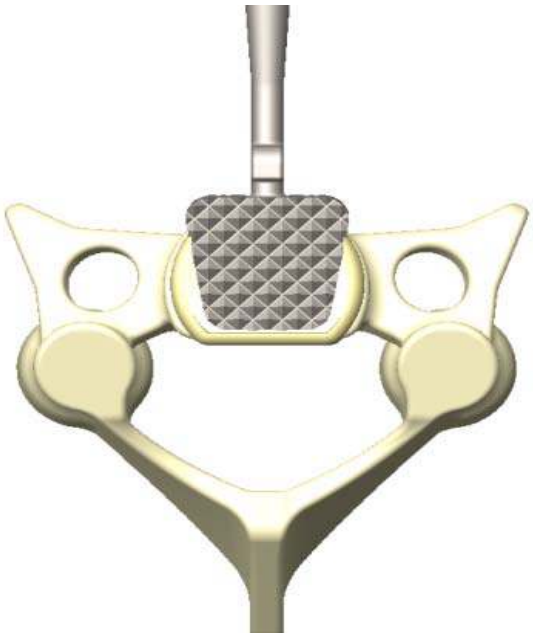
1. Prepare disc and endplates

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

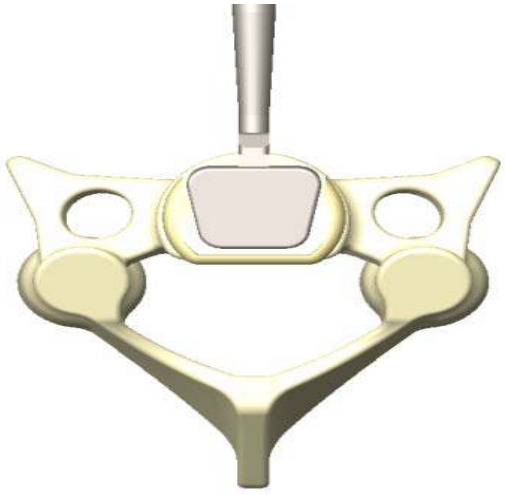
It is recommended that intervertebral distraction be implemented prior to implant placement to facilitate the use of the correct size implant and to secure implantation. Implants which are undersized carry an increased risk of pseudarthrosis and implant expulsion.

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.

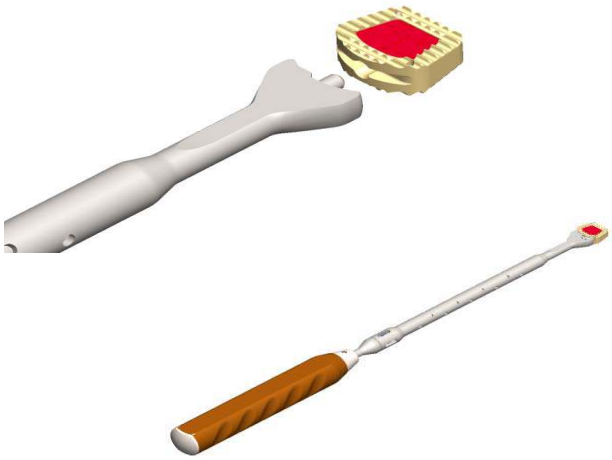
Select the implant corresponding to the correct trial IBFD. Remove the assembly.



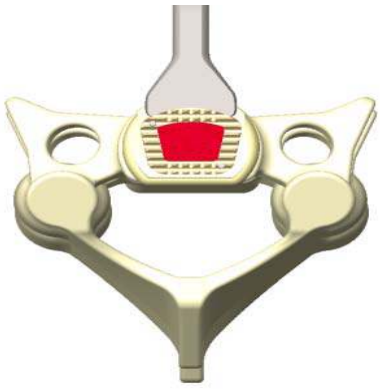
Trial

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.



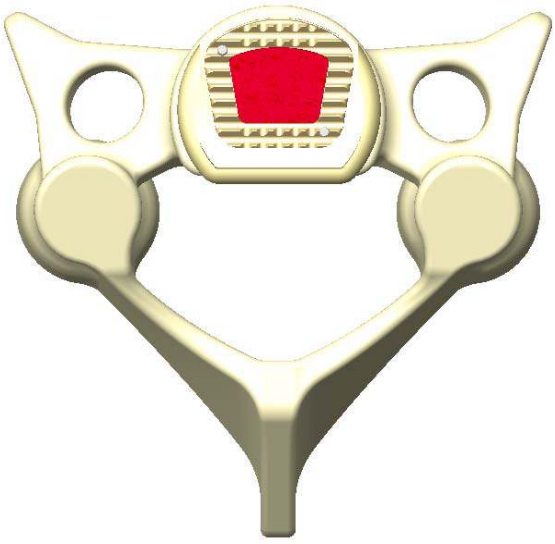
Thread on



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.

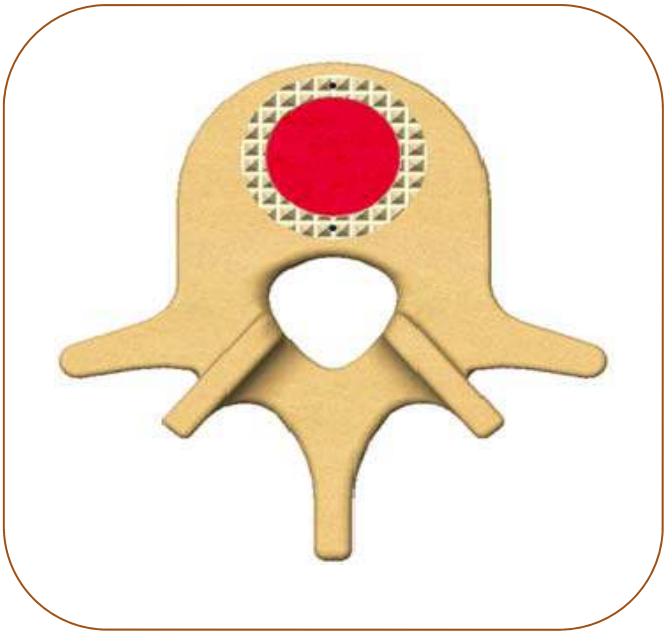
Apache™ Cervical Interbody Fusion Device

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



Apache™ Vertebral Body Replacement Device Surgical Technique

INDICATIONS:

When used as a vertebral body replacement device, the Genesys Spine Apache™ VBR System is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/ fracture. The device system is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. These devices are designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. The device system is intended to be used with autograft or allograft bone.

CONTRAINDICATIONS:

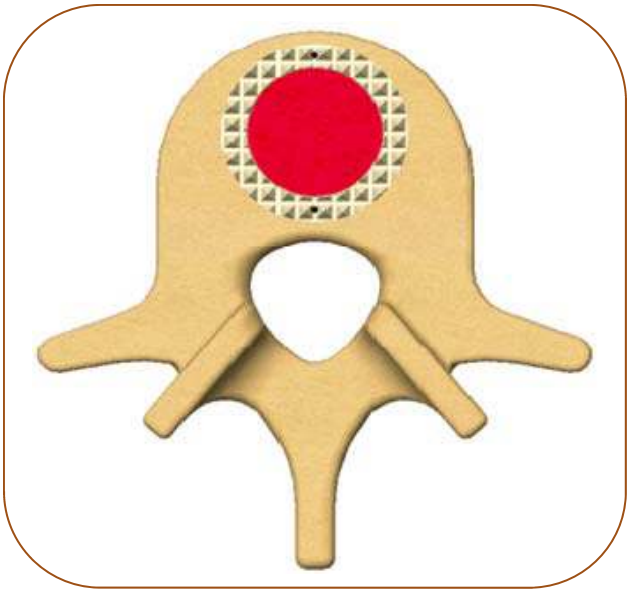
Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
Known sensitivity to PEEK material.
Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.
Any condition that 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.

Apache™ Vertebral Body Replacement (VBR) Device

The Genesys Spine Apache™ Vertebral Body Replacement (VBR) System is comprised of precision instruments and implants designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. 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 Genesys Spine corpectomy instruments are utilized for the placement of the Genesys Spine Vertebral Body Replacement (VBR) devices during partial or complete corpectomy procedures.

Preoperative Planning

Preoperative planning is recommended for the correct selection of the Vertebral Body Replacement device. Determine implant height and footprint by comparing a lateral view on the radiographic image with that of the instrument trials and calipers.

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

Surgical Technique

1. Discectomy

According to surgeon preference, instruments such as pituitary rongeurs and curettes are used to perform a complete discectomy.

2. Corpectomy

Prepare corpectomy to adequately decompress the spinal cord. Remove bone and retain for graft material if appropriate.

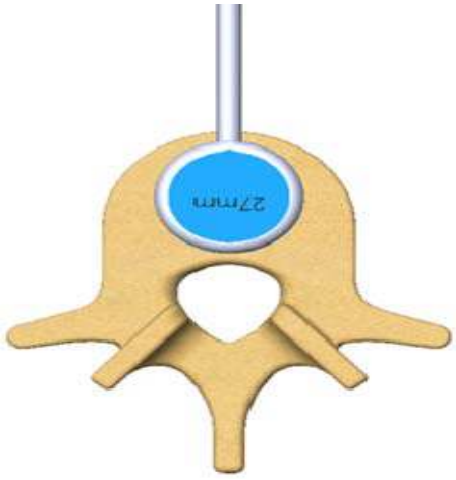
3. Distraction

Assess the patient's bone quality prior to using a Vertebral Distractor. Using the Vertebral Distractor, distract defect to the appropriate height.

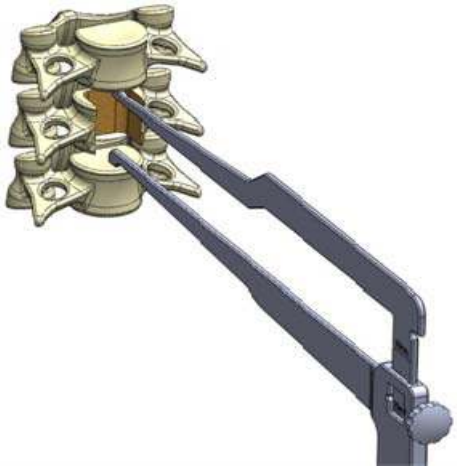
4. Determine Proper Footprint

After distraction, insert a footprint assembly into the disc space to determine the appropriate size. The optimal footprint will be the largest cage that fits within the cortical margins of the superior and inferior vertebral bodies.

Note: *During footprint trialing, use fluoroscopy as needed to determine the proper size and placement of the implant.*



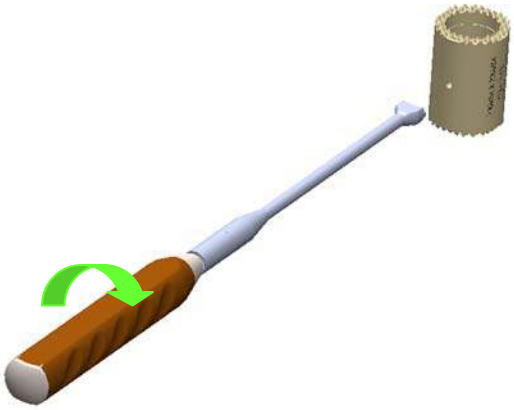
Paddle



Caliper

5. Determine Defect Height

Using the caliper, place the tips so that they contact the anterior lip of the vertebral bodies. Caliper tips should be placed as close as possible to the anterior face of the vertebral body. Extend the caliper to the appropriate defect height. Determine implant height from scale on caliper.

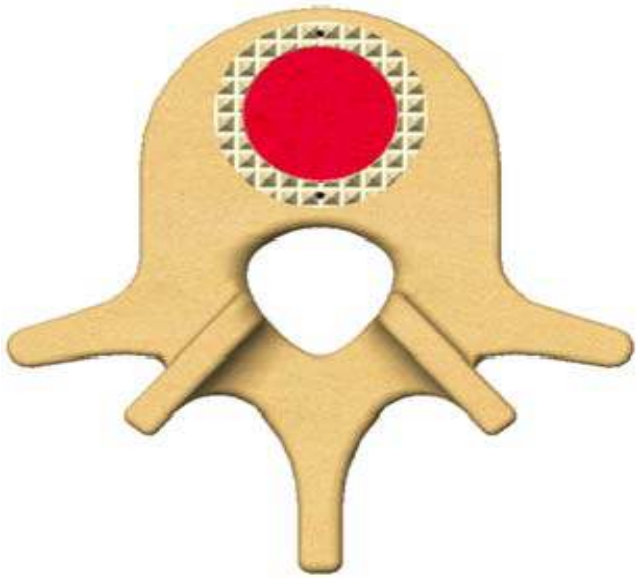


Thread on

Insert

6. Implant Insertion

Once the correct implant size has been determined, engage the implant by threading the inserter tip into the insertion point on the implant. Fully engage by tightening the handle end of the inserter. Take care not to overtighten the inserter as this my lead to stripping the implant threads. Insert the implant into the vertebral space. Light impaction may be used to fully seat the implant.



Prior to releasing the implant from the inserter, remove the Vertebral Distractor and verify that the appropriate compression is applied to the cage. Also, use fluoroscopy to verify proper size and placement of the implant.

7. Revision / Removal Step

No specific instruments are provided with the Genesys Spine VBR 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.

8. 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.

Apache™ Vertebral Body Replacement Device

Implants

NUMBER	DESCRIPTION
GCR-012	13.5MM X 12MM VBR
GCR-014	13.5MM X 14MM VBR
GCR-016	13.5MM X 16MM VBR
GCR-018	13.5MM X 18MM VBR
GCR-020	13.5MM X 20MM VBR
GCR-022	13.5MM X 22MM VBR
GCR-024	13.5MM X 24MM VBR
GCR-026	13.5MM X 26MM VBR
GCR-028	13.5MM X 28MM VBR
GCR-030	13.5MM X 30MM VBR
GCR-032	13.5MM X 32MM VBR
GCR-034	13.5MM X 34MM VBR
GCR-036	13.5MM X 36MM VBR
GCR-038	13.5MM X 38MM VBR
GCR-040	13.5MM X 40MM VBR
GCR-042	13.5MM X 42MM VBR
GCR-044	13.5MM X 44MM VBR
GCR-046	13.5MM X 46MM VBR
GCR-048	13.5MM X 48MM VBR
GCR-050	13.5MM X 50MM VBR
GCR-052	13.5MM X 52MM VBR
GCR-054	13.5MM X 54MM VBR
GCR-056	13.5MM X 56MM VBR
GCR-058	13.5MM X 58MM VBR
GCR-060	13.5MM X 60MM VBR
GCR-062	13.5MM X 62MM VBR
GCR-064	13.5MM X 64MM VBR
GCR-066	13.5MM X 66MM VBR
GLR-020	27MM X 20MM VBR
GLR-022	27MM X 22MM VBR
GLR-024	27MM X 24MM VBR
GLR-026	27MM X 26MM VBR
GLR-028	27MM X 28MM VBR
GLR-030	27MM X 30MM VBR
GLR-032	27MM X 32MM VBR
GLR-034	27MM X 34MM VBR
GLR-036	27MM X 36MM VBR
GLR-038	27MM X 38MM VBR

NUMBER	DESCRIPTION
GLR-040	27MM X 40MM VBR
GLR-042	27MM X 42MM VBR
GLR-044	27MM X 44MM VBR
GLR-046	27MM X 46MM VBR
GLR-048	27MM X 48MM VBR
GLR-050	27MM X 50MM VBR
GLR-052	27MM X 52MM VBR
GLR-054	27MM X 54MM VBR
GLR-056	27MM X 56MM VBR
GLR-058	27MM X 58MM VBR
GLR-060	27MM X 60MM VBR
GLR-062	27MM X 62MM VBR
GLR-064	27MM X 64MM VBR
GLR-066	27MM X 66MM VBR
GLR-068	27MM X 68MM VBR
GLR-070	27MM X 70MM VBR
GLR-072	27MM X 72MM VBR
GLR-074	27MM X 74MM VBR
GLR-076	27MM X 76MM VBR
GLR-078	27MM X 78MM VBR
GLR-080	27MM X 80MM VBR
GLR-082	27MM X 82MM VBR
GLR-084	27MM X 84MM VBR
GLR-086	27MM X 86MM VBR
GLR-088	27MM X 88MM VBR
GLR-090	27MM X 90MM VBR
GLR-092	27MM X 92MM VBR
GLR-094	27MM X 94MM VBR
GLR-096	27MM X 96MM VBR
GLR-098	27MM X 98MM VBR
GLR-100	27MM X 100MM VBR
GLR-102	27MM X 102MM VBR
GLR-104	27MM X 104MM VBR
GLR-106	27MM X 106MM VBR
GLR-108	27MM X 108MM VBR
GLR-110	27MM X 110MM VBR

Instruments

NUMBER	DESCRIPTION
GP100	Inserter
GP700	13.5mm Paddle
GP701	27mm Paddle
GP704	AO Connect Handle
GP705	Mallet
GP706	Rongeur
GP707	Cobb

WARNINGS:

1. THIS PRODUCT HAS LABELING LIMITATIONS.
2. THE SAFETY AND EFFECTIVENESS OF INTERBODY FUSION SYSTEMS HAVE BEEN ESTABLISHED ONLY FOR SPINAL CONDITIONS WITH SIGNIFICANT MECHANICAL INSTABILITY OR DEFORMITY REQUIRING FUSION WITH INSTRUMENTATION. These conditions are significant mechanical instability secondary to degenerative spondylolis thesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions is unknown.
3. BENEFIT OF SPINAL FUSIONS UTILIZING ANY INTERBODY FUSION SYSTEM HAS NOT BEEN ADEQUATELY ESTABLISHED IN PATIENTS WITH STABLE SPINES.

   Potential risks identified with the use of this device system, which may require additional surgery, include:

   A. Device component fracture.
   B. Loss of fixation.
   C. Non-union.
   D. Fracture of the vertebra.
   E. Neurological injury.
   F. Vascular or visceral injury.
4. 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. Metallic 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.
5. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NON-UNION. 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 metal 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.
6. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with other metal objects, must be made from like or compatible metals.
7. 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.

PRECAUTIONS:

1. THE IMPLANTATION OF INTERBODY FUSION SYSTEMS SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF THIS INTERBODY FUSION SYSTEM BECAUSE THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.
2. SURGEONS SHOULD HAVE KNOWLEDGE OF HOW TO TARGET PEDICLE SCREWS USING FLUOROSCOPY AND K-WIRE WHEN UTILIZING A MINIMALLY INVASIVE SURGICAL TECHNIQUE.
3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted metal implant should never be re-implanted. Even though the device appears 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. Contouring of the metal implants should only be performed with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease fatigue life and may cause failure.
5. REMOVAL OF THE IMPLANT AFTER HEAING. Metallic implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.
6. 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 limitations of the implant and that physical activity and full weight bearing have been implicated in bending or fracture. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
7. MAGNETIC RESONANCE (MR) ENVIRONMENT. The Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment. The Interbody Fusion System has not been tested for heating or migration in the MR environment.
8. PATIENT SELECTION. Based on fatigue testing results, when using the Genesys Spine Interbody Fusion System, the physician/ surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

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

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