AnyPlus®
Cervical PEEK Cage

Global Standard Medical

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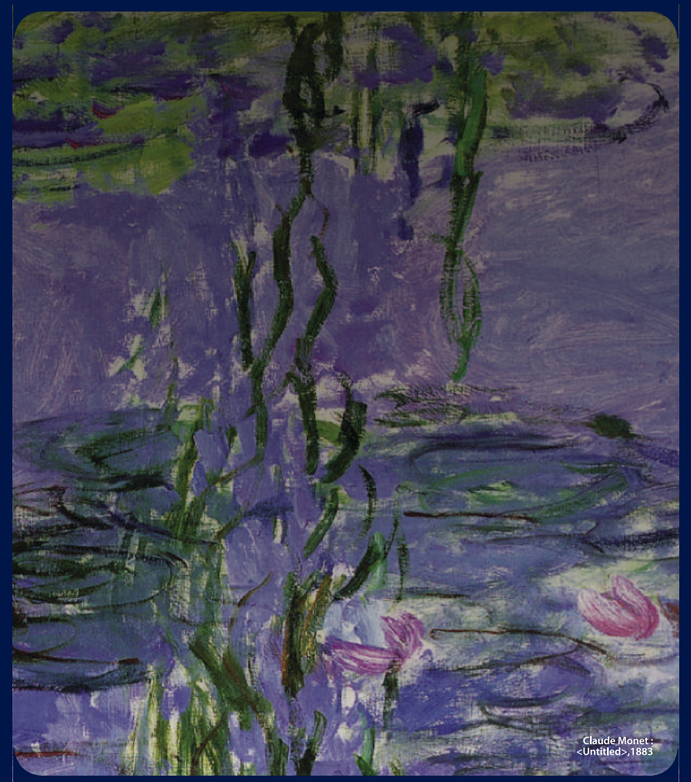
GSCG-0703-1003(3)

AnyPlus®
ACIF PEEK Cage

Anterior Cervical Interbody Fusion cage
Surgical Technique


Claude Monet : <Untitled>,1883

Global Standard Medical

Contents

Material : PEEK-OPTIMA

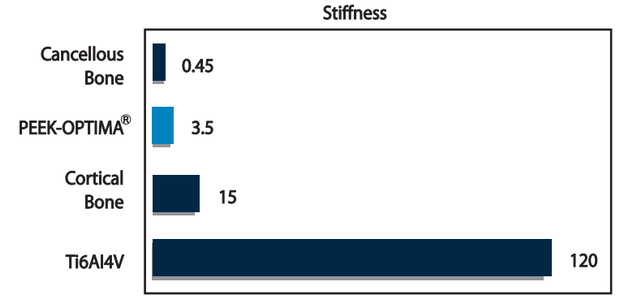
PEEK(Poly-Ether-Ether-Ketone), a semicrystalline aromatic polymer with a modulus of elasticity resembling bone, has been used to create structural spinal implants. PEEK implants elicit minimal inflammatory, or cytotoxic response in-vivo and in-vitro models.

[PEEK-OPTIMA polymer performance]
PEEK-OPTIMA polymer from Invivio Biomaterial Solutions, is a high-performance biomaterial widely accepted and proven in spinal fusion. Formulated to meet exacting in-vivo criteria, PEEK- OPTIMA is a safe, biocompatible and stable polymer that provides both spine surgeons and patients with a variety of distinct advantages and benefits over others accepted implant materials such as bone, metals and other polymers.

[Proven safety and biocompatibility]
PEEK-OPTIMA polymer is classified as cage and is fit for use in medical applications which requie long -term contact. of implant with human bone, blood or tissues.

[Superior mechanical properties]
PEEK-OPTIMA polymer offers a unique combination of mechanical properties that make it especially well suited for applications requiring spinal fusion.

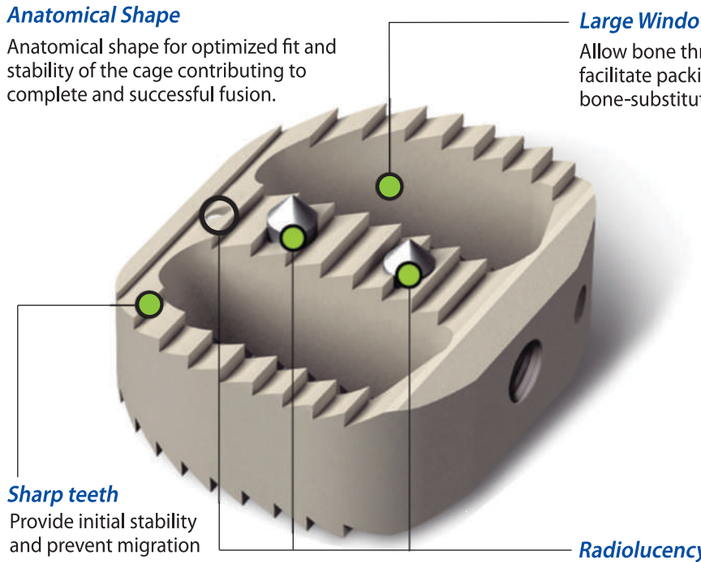
[Elastic Modulus]
PEEK-OPTIMA encourages load sharing between implant and natural bone, thereby minimizing stress shielding and stimulating bone healing activity.



source for metals data : *An introduction to Material in Medicine* ,ed. Ratner et al, Elsevier Academic Press.

AnyPlus® PEEK cervical cages combine superior strength and impact resistance with radiolucency. They do not produce artifacts on plain films, Computed Tomography(CT scans), or magnetic resonance imaging(MRI).
A Titanium bar is inserted into the wall of the PEEK cage for X-ray localization, and fusion can be readily assessed with standard films.

Design Rationale



Anatomical Shape
Anatomical shape for optimized fit and stability of the cage contributing to complete and successful fusion.

Large Windows
Allow bone through-growth and facilitate packing with bone or bone-substitute.

Sharp teeth
Provide initial stability and prevent migration

Radiolucency
2 titanium spikes & 1 pin marker to indicate cage positions on X-ray

Indications

- DDD(Degenerative Disk Disease)
- Herniated disk
- Osteo arthritic foraminal stenosis
- Pseudarthrosis

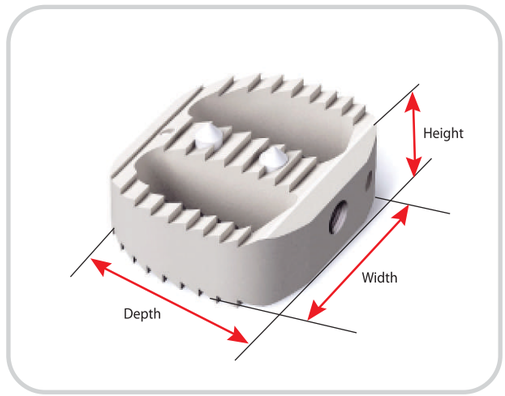
Application Levels

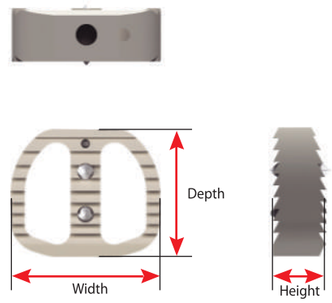
- C2~T1

Approach

- Anterior

Product Range





Depth(mm)	Width(mm)	Height(mm)
12.0~15.0	4.0, 15.0, 17.0, 19.0	5.0~9.0

Introduction

Since it's first description in the early 1950s, the anterior approach to the cervical spine has gained wide acceptance for the treatment of degenerative diseases or fractures.

The AnyPlus Cervical PEEK Cage is designed for interbody stabilization in cervical area in the spine and the instruments with this system as developed easy to use, so it allows to reduce the operation time and result in prompt recovery for patients after surgery.

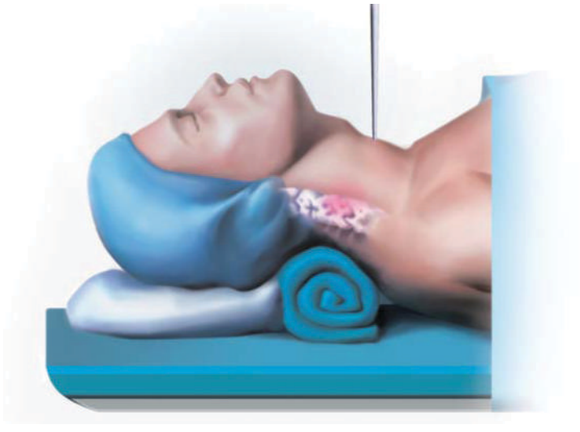
The system is developed to address these issues by maintaining features of successful designs and meeting the following improvement goals.

- Minimize subsidence caused by stand-alone uses.
- Optimal contact with inferior and superior endplates.
- Instrument development for being used simply and with ease.

Positioning

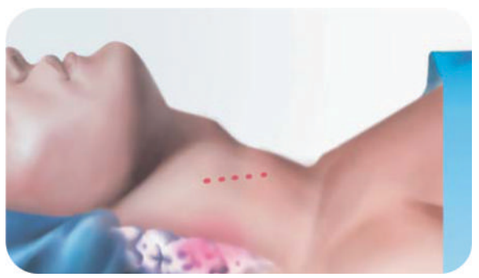
The patient is placed supine on the operating table. After induction of general anesthesia an IV bag wrapped in a green surgical towel is placed under the neck to resotrer lordosis. The shoulders may be pulled down with tape to facilitate radiographic exposure, particularly of the lower cervical levels.

Localization



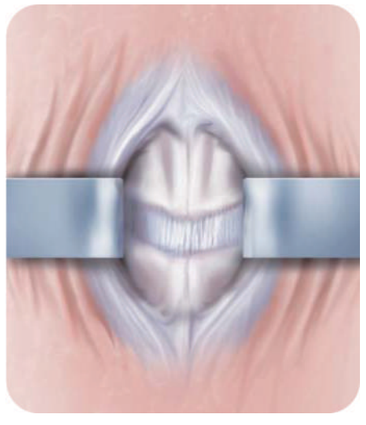
Anatomical landmarks may be palpated to estimate the level of the disk space. In general, the hyoid bone is at C3, the thyroid cartilage is at C5, and the cricoids cartilage is at C6. The carotid tubercle, the most reliable landmark, can ususally be palpated at C6. In the absence of reliable anatomical landmarks a preoperative lateral cervical radiography may be used to determine and place the incision.

Incision



The incision for a single-or two-level diskectomy generally follows one of the neck creases. The incision should extend from midline to the medical border of the sternocleidomastoid. Oblique incisions along the medial border of the sternocleidomastoid may be used if access to three or more levels is desired. A right-side approach is generally preferred for a right-handed surgeon.

Exposition



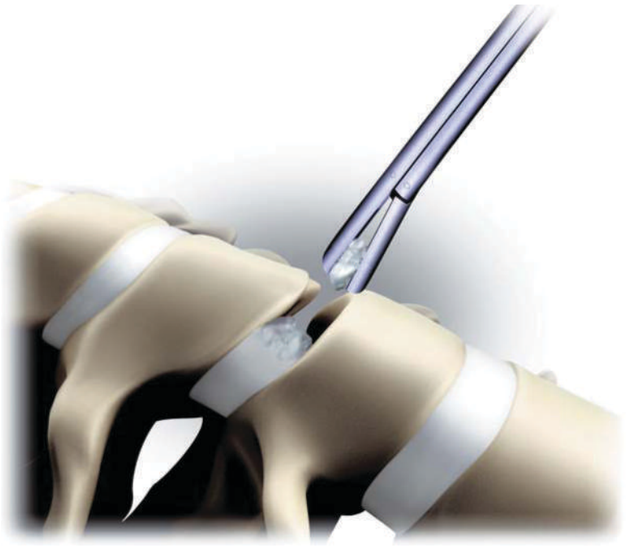
After making the incision, scissors can be used to traverse the subcutaneous tissues and expose the playma muscle. Undermining the platysma is critical to aid in retraction.

Following division of the platysma, the medical border of the sternocleidomastoid is identified. The plane along the medial sternocleidomastoid border is gently developed using superficial sharp dissection. The carotid sheath is identified and its contents pulled laterally with a suction tip as the spine is bluntly palpated.

A localizing X-ray is obtained to confirm the operative disk space level by placement of spinal needle in the disk space.

The longus coli can subsequently be released with bovie and bipolar cautery to gain access to the uncovertebral joints. This creates optimal exposure and aids in middle identification. Then, retractor are placed with small teeth under the medical longus coli. Prior to diskectomy, a Cushing rongeur may be used to remove anterior osteophyes.

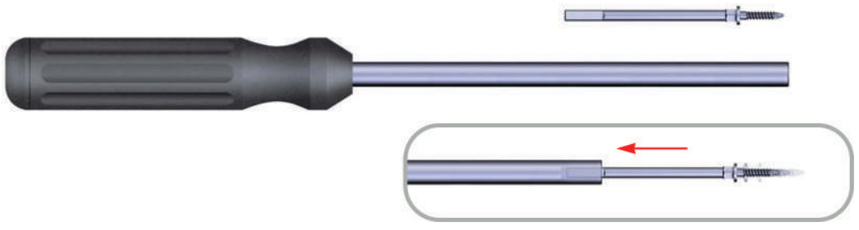
Diskectomy



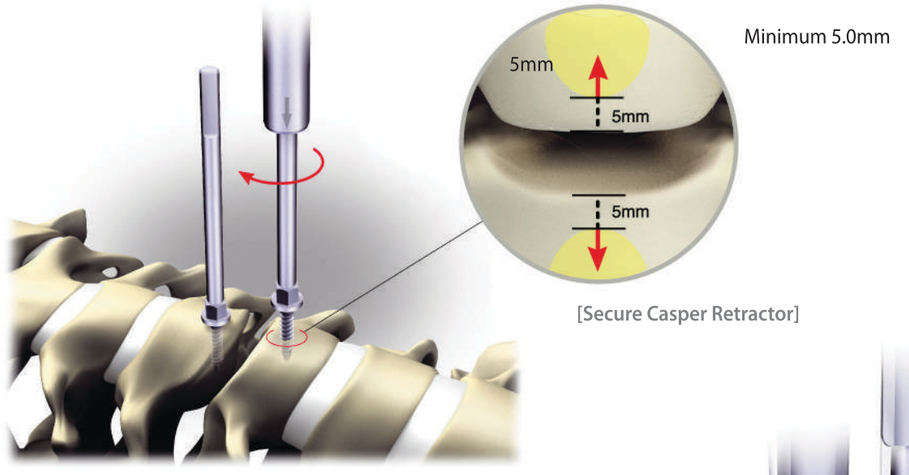
A No. 15 or 11 blade is used to incise the annulus and anterior disk. Diskectomy is performed using curettes. The disk space may be widened by applying distraction across the disk space as the disk removed. The posterior longitudinal ligament(PLL) and disk space are usually obscured by anterior and posterior osteophytes. The anterior lip of the superior vertebral body is frequently drilled to improve visualization of the disk space and prepare for graft insertion. Osteophytes and end plates should be drilled to increase access to the PLL. Further drilling of the posterior vertebral body of the caudal vertebra and undercutting with a 3mm thin-lipped cervical rongeur may be performed to remove osteophytes and further widen the interspace.

Distraction

[Assembling Pin and Pin Driver]

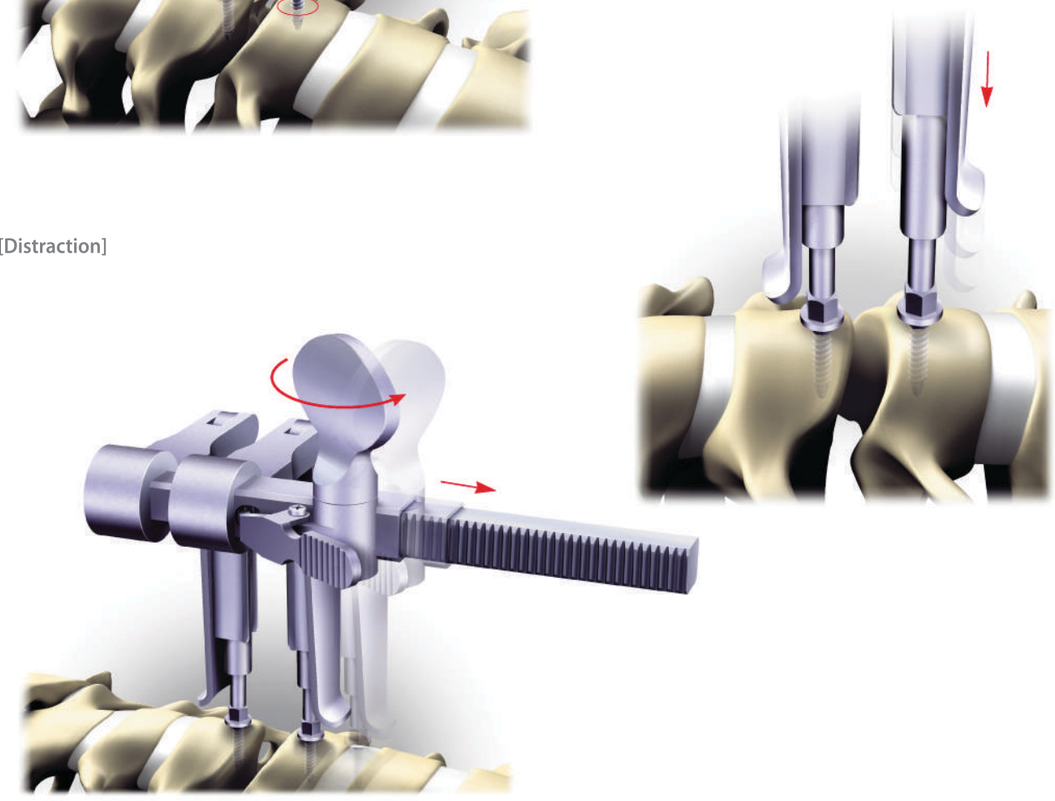


[Driving Pins into the body]



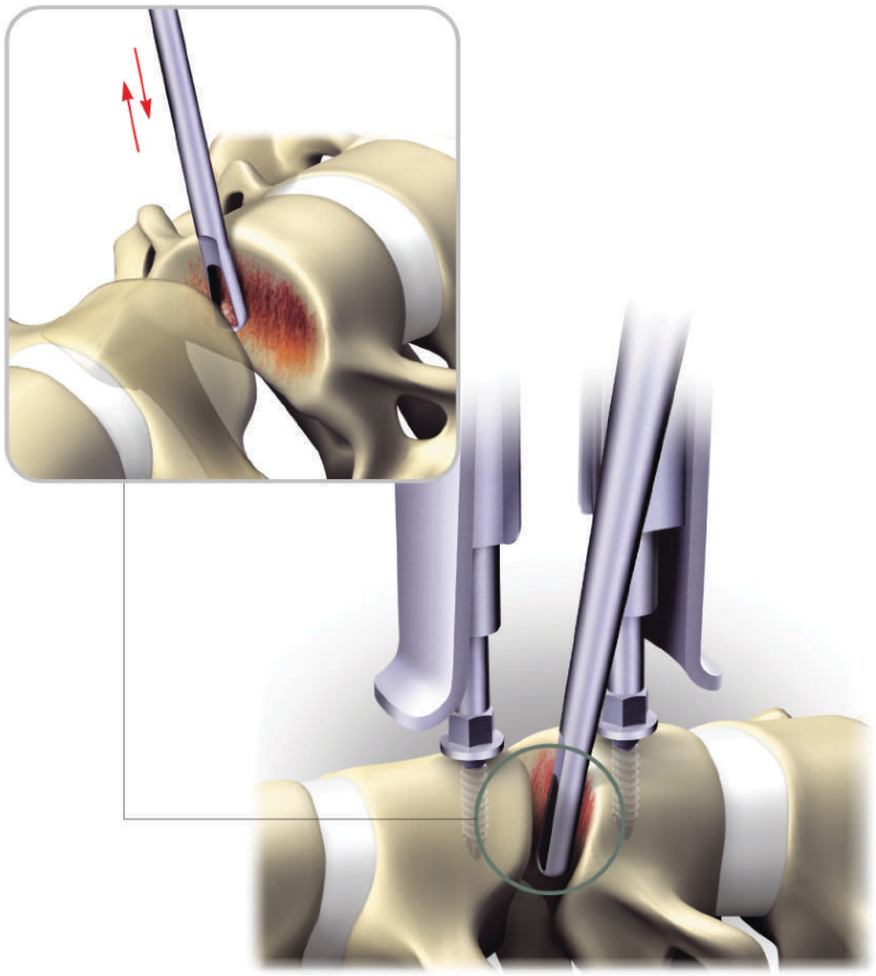
[Secure Casper Retractor]

[Distraction]



The pins(GS136-2300) may be selected to widen interbody disk space. If possible, drive 2 pins into the middle of superior and inferior vertebrae in each using pin driver(GS136-2400), it is recommended that pins should be driven at least 5.0mm aparted from the endplates. Then put the 2 holes of Casper retractor (GS136-2200) into the pins driven into the vertebrae. The disk space can be prepared by tuming a knob prior to diskectomy.

Endplate Preparation

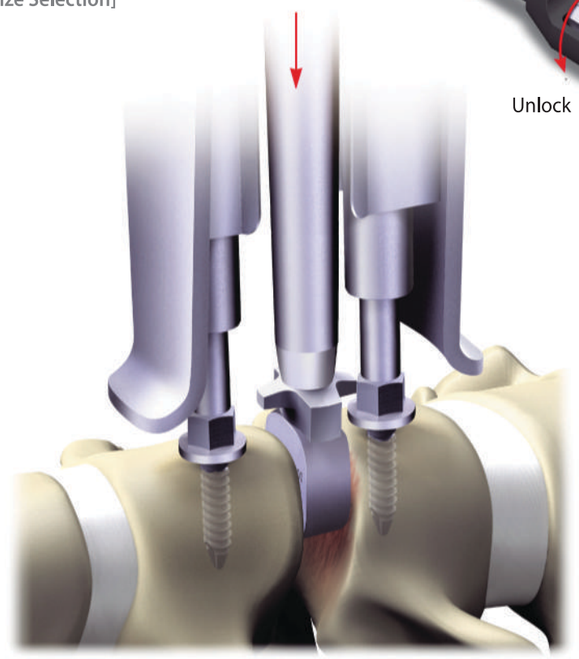


Following decompression of the disk space and neural elements, a freehand technique can be used to prepare the end plates for space inertion. The goal of end plate preparation when using free hand technique is to create a combination of cancellous bone and cortical bone by drilling the anterior inferior edge of the rostral vertebral body and posterior superior edge of the caudal vertebral body. Cortical bone prevents graft subsidence, whereas the exposed cancellous bone enhances fusion.

Cage Size Selection

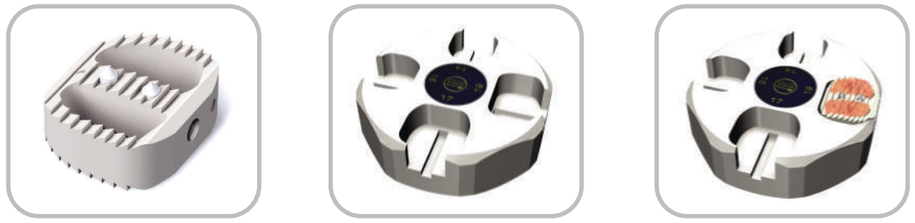
[Assembling Trial Cage and Cage Holder]

[Size Selection]



The trial cage is designed for use with cage holder(GS136-1800) in Anyplus cervical instrument. Starting with the smallest trial, sequentially larger trials are completely into the disk space. The trial that produces the most satisfactory fit in the disk space is selected. Successful trial selection confirms parallel end plate preparation. The trial should fit flush and produce a tight fit in the disk space. If theis is not possible, a larger trial should be attempted, or the end plates should be more adequately prepared, or both.

Cage Preparation

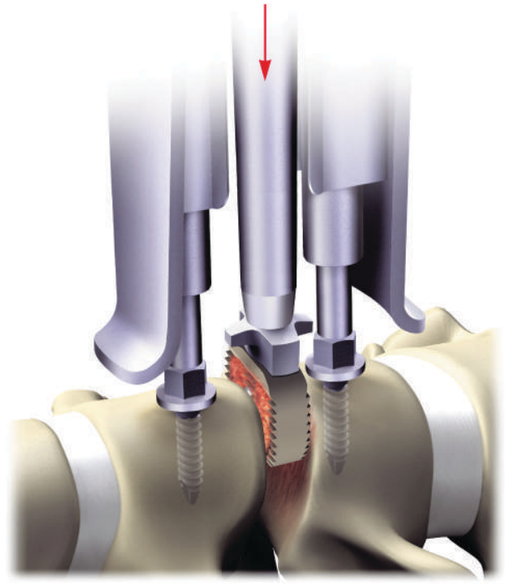


[Assembling Cage and Cage Holder]

The Anyplus PEEK implant in supplied that corresponds to the final trial chosen and gently place into the disk space using cage holder(GS136-1800). The implant taped into the disk space using a mallet.
The 2 windows of implant may be filled with bone dust from the end plate drilling or with the surgeon's choice of osteoinductive material by using Bone impactor(GS136-1410) and Graft holder GS(136-1320).

Note : In case of non-sterile implants, they must be sterilized prior to use.
Please see the reference of IFU(Instruction For Use) at the end of this catalogue.

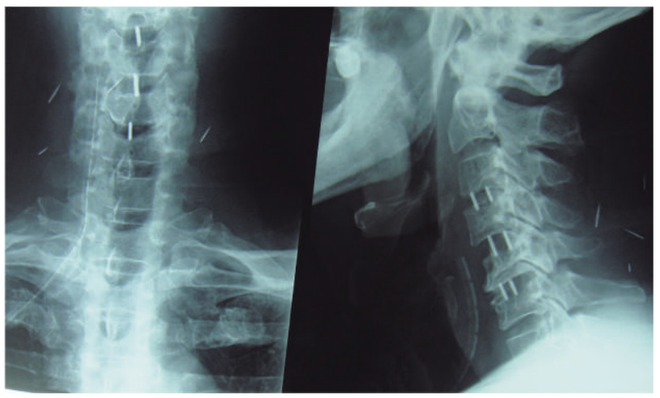
Cage Insertion

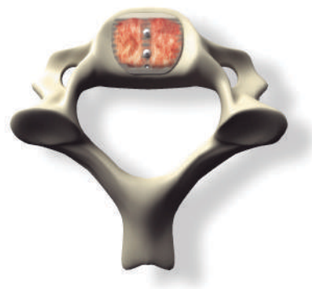


Position the implant and holder in the correct cranial/caudal alignment and carefully insert them into the distracted segment. The PEEK cage is impacted using the mallet or hammer while distraction of the interbody space is maintained.

Release the Casper retractor(GS136-2200) and remove all instruments.

Verifying Cage position





The optimal position of the cage is centered within periphery of the vertebral endplates. Depending on the size of the vertebrae, the anterior edge of the cage will be approximately 2mm behind the anterior edge of the adjacent vertebrae.
A cross-table lateral X-ray is obtained after implantation to confirm adequate placement. Bleeding from epidural vessels generally responds to Gelfoam and slight pressure.

Implant Specification

No.	Cat,No (Non- Sterile)	Cat,No (Sterile)	Range		
			Depth(mm)	Width(mm)	Heigth(mm)
1	1102-1205	1112-1205	12.0	14.0	5.0
2	1102-1206	1112-1206	12.0	14.0	6.0
3	1102-1207	1112-1207	12.0	14.0	7.0
4	1102-1208	1112-1208	12.0	14.0	8.0
5	1102-1209	1112-1209	12.0	14.0	9.0
6	1102-1405	1112-1405	14.0	14.0	5.0
7	1102-1406	1112-1406	14.0	14.0	6.0
8	1102-1407	1112-1407	14.0	14.0	7.0
9	1102-1408	1112-1408	14.0	14.0	8.0
10	1102-1409	1112-1409	14.0	14.0	9.0
11	1122-1305	1132-1305	13.0	15.0	5.0
12	1122-1306	1132-1306	13.0	15.0	6.0
13	1122-1307	1132-1307	13.0	15.0	7.0
14	1122-1308	1132-1308	13.0	15.0	8.0
15	1122-1309	1132-1309	13.0	15.0	9.0
16	1142-1205	1152-1205	12.0	17.0	5.0
17	1142-1206	1152-1206	12.0	17.0	6.0
18	1142-1207	1152-1207	12.0	17.0	7.0
19	1142-1208	1152-1208	12.0	17.0	8.0
20	1142-1209	1152-1209	12.0	17.0	9.0
21	1142-1305	1152-1305	13.0	17.0	5.0
22	1142-1306	1152-1306	13.0	17.0	6.0
23	1142-1307	1152-1307	13.0	17.0	7.0
24	1142-1308	1152-1308	13.0	17.0	8.0
25	1142-1309	1152-1309	13.0	17.0	9.0
26	1142-1405	1152-1405	14.0	17.0	5.0
27	1142-1406	1152-1406	14.0	17.0	6.0
28	1142-1407	1152-1407	14.0	17.0	7.0
29	1142-1408	1152-1408	14.0	17.0	8.0
30	1142-1409	1152-1409	14.0	17.0	9.0
31	1142-1505	1152-1505	15.0	17.0	5.0
32	1142-1506	1152-1506	15.0	17.0	6.0
33	1142-1507	1152-1507	15.0	17.0	7.0
34	1142-1508	1152-1508	15.0	17.0	8.0
35	1142-1509	1152-1509	15.0	17.0	9.0
36	1162-1405	1172-1405	14.0	19.0	5.0
37	1162-1406	1172-1406	14.0	19.0	6.0
38	1162-1407	1172-1407	14.0	19.0	7.0
39	1162-1408	1172-1408	14.0	19.0	8.0
40	1162-1409	1172-1409	14.0	19.0	9.0

Implant Specification

Implant Trial(Depth-Width-Height)

12.0mm(D)×14.0mm(W)
GS136-1015(5H) GS136-1018(8H)
GS136-1016(6H) GS136-1019(9H)
GS136-1017(7H)

14.0mm(D)×14.0mm(W)
GS136-1025(5H) GS136-1028(8H)
GS136-1026(6H) GS136-1029(9H)
GS136-1027(7H)

13.0mm(D)×15.0mm(W)
GS136-0915(5H) GS136-0918(8H)
GS136-0916(6H) GS136-0919(9H)
GS136-0917(7H)

12.0mm(D)×17.0mm(W)
GS136-0815(5H) GS136-0818(8H)
GS136-0816(6H) GS136-0819(9H)
GS136-0817(7H)

13.0mm(D)×17.0mm(W)
GS136-0825(5H) GS136-0828(8H)
GS136-0826(6H) GS136-0829(9H)
GS136-0827(7H)

14.0mm(D)×17.0mm(W)
GS136-0835(5H) GS136-0838(8H)
GS136-0836(6H) GS136-0839(9H)
GS136-0837(7H)

15.0mm(D)×17.0mm(W)
GS136-0845(5H) GS136-0848(8H)
GS136-0846(6H) GS136-0849(9H)
GS136-0847(7H)

14.0mm(D)×19.0mm(W)
GS136-0715(5H) GS136-0718(8H)
GS136-0716(6H) GS136-0719(9H)
GS136-0717(7H)

Graft Holder
GS136-1320

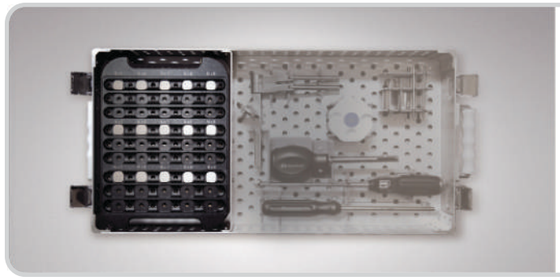
Bone Impactor
GS136-1410

Cage Holder
GS136-1800

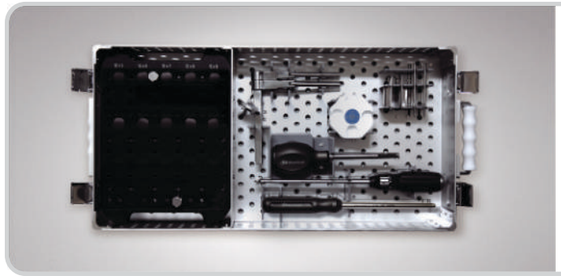
Casper Retractor
GS136-2200

Pin(14mm)
GS136-2300

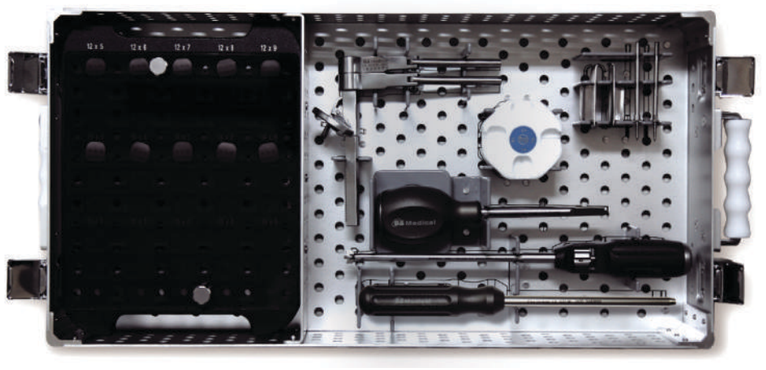
Pin Dirver
GS136-2400

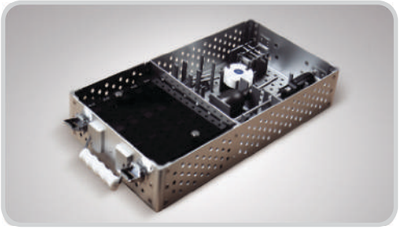


Implant Tray



Instrument Tray





Instruction For Use

(AnyPlus® PEEK Cage System (Sterilized/Non-sterilized))

1. General Prerequisites for Use

Any decision on possible use has to consider the non-operative and surgical indications, possible risks and benefits of this type of surgery, indications, cautions and adverse events specified in these instructions for use, type of materials, and mechanical characteristics of the implants employed according to the surgical technique recommended by GS Medical.
Detailed instructions on the correct use of the AnyPlus PEEK Cage System by GS Medical are found in the manual on surgical technique.
Precise preoperative planning of the implant position, based on plain radiographs, CT scans, etc., is absolutely mandatory. Normally, selection of the proper size device cannot be realized before the procedure but must be performed during surgery. All instruments are designed so as to help the surgeon determine the correct size of the implant. Implant size is clearly marked on each packaging.

2. Application

The AnyPlus PEEK implants are designed primarily for restoring the height of the intervertebral space after resection of the disc.

3. Description

The intervertebral AnyPlus PEEK cages by GS Medical are designed for implantation between the endplates of adjacent vertebral bodies. Their size and shape have been adapted to the intervertebral spaces and to the specified surgical techniques. They comprise one or more cavities for bone grafts, as well as superior, inferior, and lateral openings. The cages are available in different shapes and sizes.

-AnyPlus Cervical PEEK Cage
The cages are designed for the cervical segments C2 to C7(T1). Two fixed spikes just out from top and bottom of the implant and acts as an additional stabilizer.
-Anyplus ALIF PEEK Cage(Anterior Lumbar Interbody Fusion Cage)
The AnyPlus anterior, lateral and anterolateral cages are designed for segments L1 to L5(S1)
-AnyPlus PLIF PEEK Cage(Posterior Lumbar Interbody Fusion Cage)
The AnyPlus lumbar cages are designed for segments L1 to L5(S1)
-AnyPlus TLIP PEEK Cage(Transforaminal Lumbar Interbody Fusion Cage)
The AnyPLus luabar cages are designed for segments L1 to L5(S1)
-AnyPLus DLIF PEEK Cage(Direct Lumbar Interbody Fusion Cage)
The AnyPlus lumbar cages are designed for segments L1 to L5(S1)

4. Material

The implants are made of polyether-ether-ketone(PEEK, ISO 527-1&2) body and the X-ray marker are made of titanium alloy Ti5Al4V ELI(ISO 5832-3)

5. Indications

Uni-or multilevel interbody fusion in cafe of :
degenerative instavilities, post-discectomy syndrome, spondylolisthesis, posttraumatic instabilities, previous spinal surgery. These and any other indications are subject to the judgment of the surgeon, taking into account the specific clinical, biological, and biomechanical setting of each patient.

6. Contraindications

6.1 Absolute contraindications
Surgery should not be considered if any of the following contraindications are present : acute and chronic infections or major bone defects in the vertebral bodies, bone tumors close to the fixation sites of the implants, probable excessive stresses placed on implant and bone.
6.2 Relative contraindications
osteoporosis or other bone loss, bone tumors near the implant, poor general health, drug abuse or alcoholism, psychosocial problems or non-compliance of the patient, pregnancy, infections or symptoms/signs of infection.
The surgeon must take these absolute and relative contraindications into account when making his/her decision. This list is by no means complete.

7. Risks

Potential risks associated with this type of procedure are :
- nerve complications due to hyperdistension of or trauma to the nerve roots or the dura,
- disc diminution due to resection of normal bone.

Potential risks associated with spinal surgery are:
- pseudarthrosis,
- bone graft resorption,
- vertebral slippage,
- implant malposition,
- infections.

8. Possible adverse events

- delayed union of the fusion, no visible fusion, and pseudarthrosis,
- neurologic complications, paralysis, tissue lesions,
- pain as sequela to the procedure,
- implant migration,
- superficial and deep infection or signs/symptoms of infection,
- implant material sensitivity or allergic reaction,
- implant creep into the vertebral body,
- decrease in bone density due to stress shielding,
- neurologic and / or dural lesions during the procedure,
- wear/degradation microdebris around the implant.

This list of adverse events is by no means complete. In case of adverse event(s) reoperation may become necessary.

9. Important Notes

The patient must be informed of the risks and benefits of this prodedure.
- Proper implant sizing must also consider the physical activity level and weight of the patient.
- Smoking is detrimental to bone fusion and increases the risk of pseudarthrosis. Patients with a smoking habit must be informed of this risk.
- Implantation should only be undertaken if the surgeon has become thoroughly knowledgeable about spinal stabilization techniques and biomechanics.
- These implants may only be used in conjunction with the dedicated instruments of the AnyPlus PEEK Cage system by GS Medical.
- Preoperative planning by the surgeon for implant sizing and positioning is mandatory.
- In addition, every effort should be made to ensure that all implants needed are available and the instruments complete and in good working order.

10. Packaging(Sterile Only)

The implants are supplied in sterile packaging. At delivery the integrity of the packaging must be checked. All information required by law for this type of implants is listed on the packaging label.

11. Sterilization

11-1. Anyplys PEEK Cage System(Non-Sterile)
These are non-sterile implants. They must be sterilized before use.
Use the storage trays for sterilization and intra-operative storage.

The following recommendations should be followed when autoclaving:
- Only Sterile products should be placed in the operative field. For a 10 Sterility Assurance Level, these products are recommended to be steam sterilized by the hospital using one of the two sets of process parameters below :

No.	Method	Cycle	Temperature	Exposure Time
1	Steam	Gravity	250°F(120°C)	20 minutes
2	Steam	Gravity	273°F(134°C)	15 minutes

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12. Cautions

In case of sterilization boxes with paper filters the integrity of the filters must be checked before autoclaving. The user assumers responsibility for any other type of sterilization and relieves GS Medical of any liability. The user should contact GS Medical for full details.

13. Storage

Store the product in a dry place(<25℃)

14. Warranty

The warranty is only valid if the product has been used and implanted according to the specified surgical technique and the normal conditions set down in these instructions.

15. Additional information

For a brochure and manual of the surgical technique, please inquire at your GS Medical representative or at GS Medical directly.

16. Complaints and claims

Any professional (customer or user) with complaints or claims regarding the services and / or quality, identification, resistance, reliability, safely, effectiveness and /or performance of products by GS Medical must inform his/her GS Medical representative or authorized supplier. The supplier will inform GS Medical about this complant or claim in a written report as quickly as possible.
Should a malfunction of impairment of the device or any error in the Instructions for Use have or could have resulted in death or a severely impaired state of health of a patient or user, this adverse event must be reported immediately by phone or fax. Any report of such an event should include as many details as possible (product designation, order no., serial no., charge no., etc.), the type of laim or a precise description of the event, any consequences, as well as any technical element which could aid a future expert opinion (implant component, radiographs, etc.) For additional information and claim reports, please contact us.