

**AnyPlus®**  
PLIF PEEK Cage

## Posterior Lumbar Interbody Fusion cage Surgical Technique

**AnyPlus®**  
PLIF PEEK Cage



Global Standard  
**GS Medical**

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Global Standard  
**GS Medical**



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**Material : PEEK-OPTIMA**

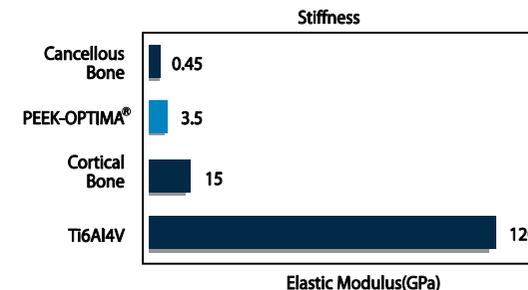
PEEK (Poly-Ether-Ether-Ketone), a semicrystalline aromatic polymer, with a modulus of elasticity resembling bone, has been used to create structural spinal implants. PEEK implants elicit minimal inflammatory or cytotoxic response in in-vivo and in-vitro models.

[ PEEK-OPTIMA polymer performance ]  
 PEEK-OPTIMA polymer from Invibio Biomaterial Solution 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 both spine surgeons and patients with a variety of distinct advantages and benefits over other accepted implant material 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 require 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 applications.

[ 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® PLIF PEEK 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 plain films.

## Introduction

### 2.2 pirkimo dalis pagamintas iš PEEK

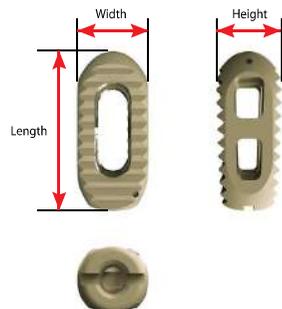
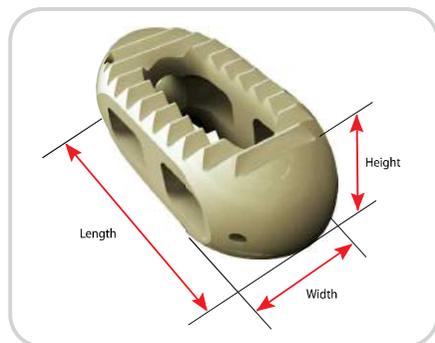
The AnyPlus® PLIF PEEK Cage is designed for interbody stabilization of the lumbar spine. The instruments developed with this system are easy to use, thereby leading to reduction in operative time and resulting in prompt recovery of the patient after surgery.

The successful features developed in the system address numerous design issues to meet the following improvement goals.

- Optimal contact with inferior and superior endplates.
- Simple instruments developed for ease of use.

## Product Range

### 2.3 Vienas implanto galas smailėjantis, kulkos formos lengvesniam implantavimui



### 2.7 lordozės kampas 0-8 laipsniai

Length(mm)	Height(mm)	Width(mm)	Angle(°)
25,28	8 - 16(mm)	11	0,4,8

2.6 Ilgis 25 ir 28 mm. Užpakalinio paviršiaus aukštis ne mažesnė kaip 8-16 mm ribose, didėja kas 1 mm, ne mažiau kaip 6-ų dydžių.

## Design Rationale

### Anatomical Shape

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

### Large Windows

Aids packing of bone or bone substitutes and facilitates bone in-growth.

2.5 Viršutiniai ir apatiniai paviršiai platūs, šiukštūs, geresniam implanto fiksavimui tarp slankstelių

### Sharp Teeth

Provide initial stability and prevent migration

### Radiolucency

2 titanium markers to indicate cage positions on X-ray

2.4 Rentgenkontrastiniai markeriai implanto pozicionavimui ir pooperacinei kontrolei, 2 vnt.

2.1 Skirtas gydyti potrauminius stuburkaulių pasislinkimus, degeneracines stuburo ligas.

### Indications ✓

- Discogenic back pain
- Disc herniation with radicular pain and major back pain component
- Facet syndrome
- Spondylolysis
- Spondylolisthesis (grade I and II)
- Failed posterior intertransverse fusion

### Application Levels

L2 ~ S1

2.1 pirkimo dalis Tarpslankstelinio tarpo implantas skirtas naudoti juosmeninėje-kryžkaulinėje dalyse.

### Approach

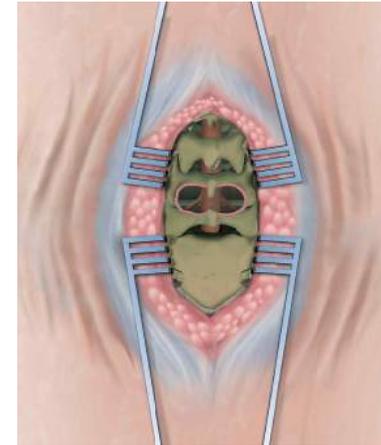
Posterior

### Positioning



The patient is positioned on the operating table in a Prone or Knee-Chest position. This frame is used to maintain a lumbar lordosis and to avoid abdominal pressure which reduces the bleeding.

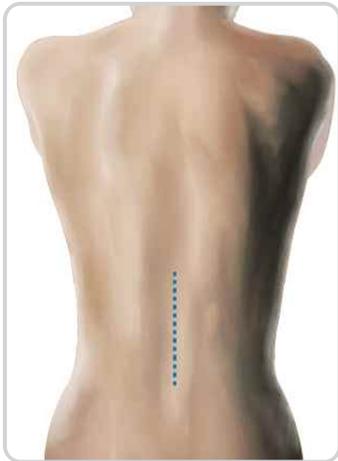
### Exposure



The paravertebral muscles are retracted laterally, beyond the edge of the facet joints. The muscle exposure should also include the pedicle entry zone.

The dura and annulus lateral to the dura are exposed by performing a complete laminectomy and partial medial facetectomy.

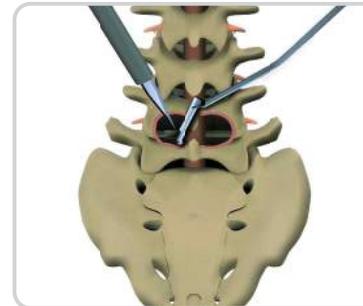
### Incision



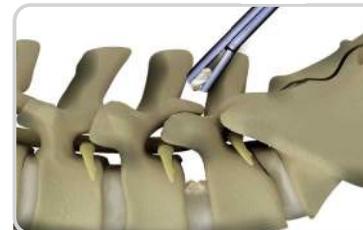
The skin and fascia are incised in the midline at the affected level.

**AnyPlus® Pedicle Screw System** and **GSS™ Pedicle Screw System** are recommended for use with **AnyPlus® PLIF PEEK Cage System**.

### Discectomy



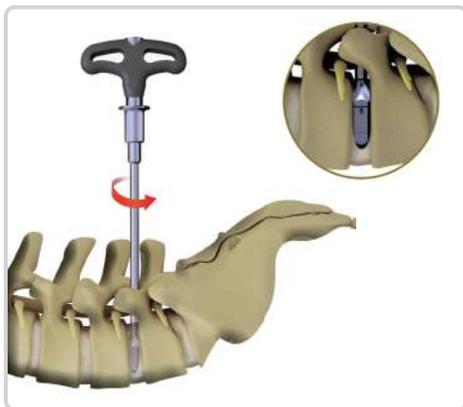
To gain access into the disc space, an opening is created in the annulus with a scalpel on both sides of the dural sac. The disc space is prepared by excising the remaining annulus and nucleus pulposus with pituitary rongeurs, disc punches and curettes. Avoid damage to the bony end plate while using the curette. Gentle distraction of the disc space aids in disc space preparation.



### Distraction

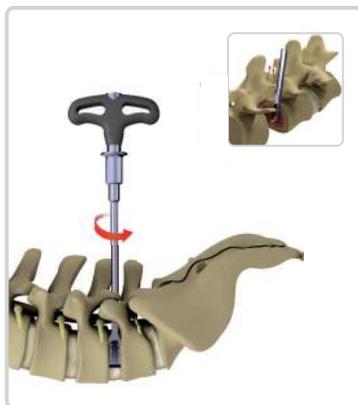
The intervertebral disc space is distracted by using a **Distractor**, up to the desired height. The **Distractor**, coupled with the **T-handle**, is introduced flat into the intervertebral disc space and rotated by 90° to distract the space. The **T-handle** is then removed and the same step is carried out on the other side using a 1 mm larger **Distractor**. This procedure is carried out alternatively on both sides, with progressively larger distractors, till the required height is achieved.

After complete distraction is achieved, the **Distractor** can also be used as a trial cage to determine the size of the final cage that is to be implanted.



### Endplate Preparation

Following decompression of the disc space and neural elements, a freehand technique can be used to prepare the end plates for cage insertion. The goal of end plate preparation is to remove the cartilaginous end plate and provide a healthy bed for the bone graft to stimulate fusion. The disc space preparation is performed by using **Curette** and **Reamer distractor**.



### Cage Preparation

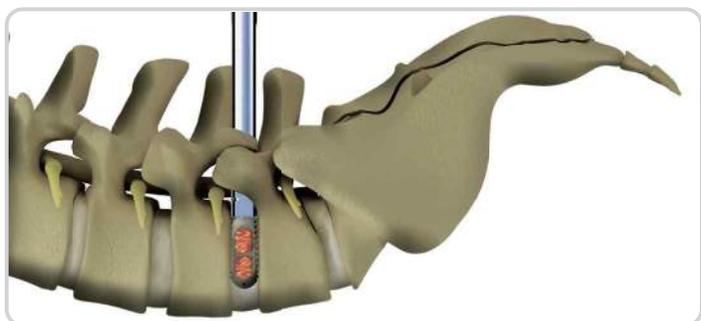


The supplied **AnyPlus® PLIF PEEK Cage** corresponds to the chosen final trial. It is gently advanced into the disc space using the **PLIF Cage holder**. Before insertion the window of the graft may be filled with autologous bone obtained by laminectomy and facetectomy, or any other synthetic osteoinductive material. The **Bone impactor** and **Graft holder** may be used for this purpose.

### Cage Insertion

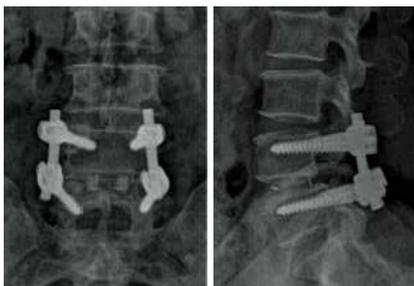
The cage is tapped into the disc space using a mallet. Before inserting the cage in the dural tube, the nerve roots and vessels are identified and protected by the Root Retractor. After implanting the cage, the **PLIF Cage holder** is removed carefully.

Tip : To ensure that the intervertebral space is freely accessible to the cage, the contralateral distractor is left in place during the cage placement.



### Verifying Cage Position

The optimally positioned cage is centered within periphery of the vertebral endplates. Depending on the size of the vertebrae, the posterior edge of the cage should be approximately 5mm anterior to the posterior margin of the adjacent vertebrae. Fluoroscopy can also be performed to verify the position of the cage.



### IMPLANTS

Standard Range  
Optional Range

No.	Cat.No (Non- Sterile)	Cat.No (Sterile)	Range			
			Length(mm)	Height(mm)	Width(mm)	Angle(°)
1	✓ 1101-0008	1111-0008	25	8	11	0
2	✓ 1101-0009	1111-0009	25	9	11	0
3	✓ 1101-0010	1111-0010	25	10	11	0
4	✓ 1101-0011	1111-0011	25	11	11	0
5	✓ 1101-0012	1111-0012	25	12	11	0
6	✓ 1101-0013	1111-0013	25	13	11	0
7	✓ 1101-0014	1111-0014	25	14	11	0
8	✓ 1101-0015	1111-0015	25	15	11	0
9	✓ 1101-0409	1111-0409	25	9	11	4
10	✓ 1101-0410	1111-0410	25	10	11	4
11	✓ 1101-0411	1111-0411	25	11	11	4
12	✓ 1101-0412	1111-0412	25	12	11	4
13	✓ 1101-0413	1111-0413	25	13	11	4
14	✓ 1101-0414	1111-0414	25	14	11	4
15	✓ 1101-0415	1111-0415	25	15	11	4
16	✓ 1101-0416	1111-0416	25	16	11	4
17	✓ 1101-0810	1111-0810	25	10	11	8
18	✓ 1101-0811	1111-0811	25	11	11	8
19	✓ 1101-0812	1111-0812	25	12	11	8
20	✓ 1101-0813	1111-0813	25	13	11	8
21	✓ 1101-0814	1111-0814	25	14	11	8
22	✓ 1101-0815	1111-0815	25	15	11	8
23	✓ 1101-0816	1111-0816	25	16	11	8
24	✓ 1141-0008	1151-0008	28	8	11	0
25	✓ 1141-0009	1151-0009	28	9	11	0
26	✓ 1141-0010	1151-0010	28	10	11	0
27	✓ 1141-0011	1151-0011	28	11	11	0
28	✓ 1141-0012	1151-0012	28	12	11	0
29	✓ 1141-0013	1151-0013	28	13	11	0
30	✓ 1141-0014	1151-0014	28	14	11	0
31	✓ 1141-0015	1151-0015	28	15	11	0
32	✓ 1141-0409	1151-0409	28	9	11	4
33	✓ 1141-0410	1151-0410	28	10	11	4
34	✓ 1141-0411	1151-0411	28	11	11	4
35	✓ 1141-0412	1151-0412	28	12	11	4
36	✓ 1141-0413	1151-0413	28	13	11	4
37	✓ 1141-0414	1151-0414	28	14	11	4
38	✓ 1141-0415	1151-0415	28	15	11	4
39	✓ 1141-0416	1151-0416	28	16	11	4
40	✓ 1141-0810	1151-0810	28	10	11	8
41	✓ 1141-0811	1151-0811	28	11	11	8
42	✓ 1141-0812	1151-0812	28	12	11	8
43	✓ 1141-0813	1151-0813	28	13	11	8
44	✓ 1141-0814	1151-0814	28	14	11	8
45	✓ 1141-0815	1151-0815	28	15	11	8
46	✓ 1141-0816	1151-0816	28	16	11	8

## INSTRUMENTS

Distractor		Reamer Distractor	
Cat. No	Length	Cat. No	Length
GS133-1108	8mm	GS133-1208	8mm
GS133-1109	9mm	GS133-1209	9mm
GS133-1110	10mm	GS133-1210	10mm
GS133-1111	11mm	GS133-1211	11mm
GS133-1112	12mm	GS133-1212	12mm
GS133-1113	13mm	GS133-1213	13mm
GS133-1114	14mm	GS133-1214	14mm

	<b>Root Retractor</b> GS133-1500
	<b>Curette 5mm</b> GS133-2610
	<b>Curette 8mm</b> GS133-2620
	<b>Graft Holder</b> GS133-1300
	<b>T-Handle</b> GS133-1900
	<b>Bone Impactor</b> GS133-1400
	<b>PLIF Cage Holder</b> GS133-1800
	<b>Final Impactor</b> GS133-2100

## 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 the 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 TLIF PEEK Cage**

(Transforaminal Lumbar Interbody Fusion Cage) The AnyPlus lumbar 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 Ti6Al4V ELI (ISO 5832-3).

## 5. Indications

Uni- or multilevel interbody fusion in case of: degenerative instabilities, 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 procedure.

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. Sterilization

### 10-1. AnyPlus 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 process parameters below:

No.	Method	Cycle	Temperature	Exposure Time
1	Steam	Gravity	250°F (121°C)	20 minutes
2	Steam	Gravity	273°F (134°C)	15 minutes

### 10-2. Anyplus PEEK Cage System (Sterile)

#### 10-2-1 Sterilization for medical devices supplied sterile(implants)

Sterilization for medical devices supplied sterile(implants) The expiration date of the sterile packaging should be checked before use .GS Medical dose not assume liability for products used beyond their expiration date. The integrity of the sterile packaging should be checked before use .The sterility of the implant can only be guaranteed if the packaging is not damaged in any way. The implant cannot be re-sterilized once the packaging has been damaged or opened.

#### 10-2-2 Sterilization for medical devices supplied non-sterile(Instruments)

The instruments are supplied in non-sterile packaging .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 (121°C)	20 minutes
2	Steam	Gravity	273°F (134°C)	15 minutes

## 11. Cautions

In case of sterilization boxes with paper filters the integrity of the filters must be checked before autoclaving.

The user assumes responsibility for any other type of sterilization and relieves GS Medical of any liability.

The user should contact GS Medical for full details.

## 12. Storage

Store the product in a dry place (< 25°C).

## 13. 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

## 14. Additional information

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

## 15. Complaints and claims

Any professional (customer or user) with complaints or claims regarding the services and/or quality, identification, resistance, reliability, safety, 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 complaint or claim in a written report as quickly as possible. Should a malfunction or 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 claim 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

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