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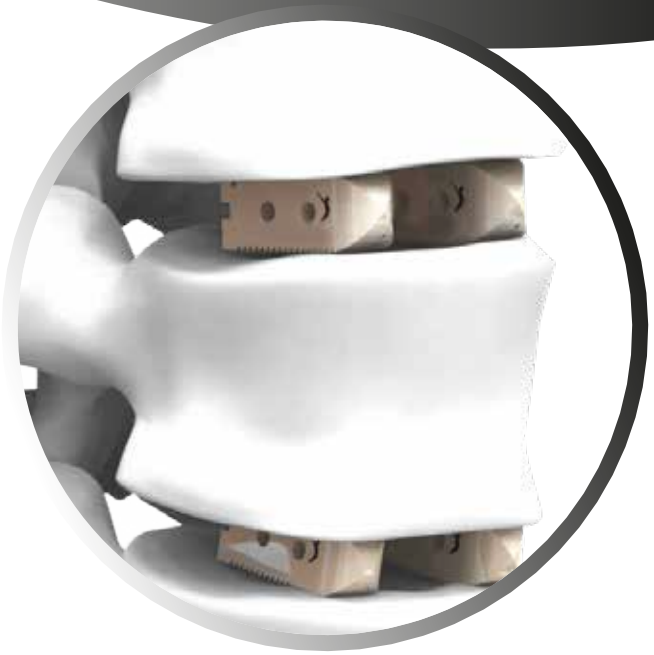

Surgical Technique Guide
PLIF PEEK CAGE

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contents

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SURGICAL TECHNIQUE OF PRODORTH PLIF PEEK CAGE

Prodorth has developed this surgical technique document for surgeons and healthcare professionals but not for unauthorized persons. This document is a supportive source but not a complete instruction for an inexperienced surgeon to perform the entire surgery, therefore the information within this surgical technique should be considered with the previous medical experiences and education of the surgeon. Surgeon's medical judgement and decisions will be the best treatment for the patient and the results will be different according to the patient's physical and mental situation.

DEVICE DESCRIPTION

Prodorth PLIF PEEK Cage is a long-term implant in order to dispose of the patients' complaints which are raised because of the pain arising from the herniation at the lumbar discs, and traumas on the lumbar spine.

Prodorth PLIF PEEK Cages are long-term implants, however, they are not able to withstand the forces like healthy bone structures.

Current Status of the Device: The device is already CE marked (since 2013) and has been on the market.

PLIF PEEK Cage GMDN No: 60762

Product Class: (Annex II of Directive 93/42/EEC) Class IIb

Raw Materials: Ti6Al4V-ELI (ASTM F 136 / ISO 5832-3) and PEEK (ASTM F 2026)

Biological Assessment:

Biological Assessment of Device According to TS EN ISO 10993-1 : 2021	
Category	Implant Device
Contact Level	Bone / Tissue
Contact Duration	C (Permanent - > 30 days)

STERILIZATION

Prodorth PLIF PEEK Cage is released to market as non-sterile. They must be sterilized prior to surgical use. All packaging materials are removed prior to sterilization. The recommended sterilization method for Prodorth cages is steam sterilization in an autoclave. The products which are intended to be sterilized should remain in an autoclave at 134 °C for 18 minutes. There is no other sterilization method Prodorth recommends.

INTENDED PURPOSE OF THE DEVICE

Prodorth PLIF PEEK Cage is a long-term implant in order to dispose of the patients' complaints which are raised because of the pain arising from the herniation at the lumbar discs, and traumas on the lumbar spine.

- It is a single-use device
- Does not include human or animal tissue and phthalate
- Does not include any software or accessory
- The product is supplied as non-sterile
- Product does not cause any radioactive source or beam diffusing

Population: Skeletally mature male / female patients
Intended User(s): Healthcare professionals (Surgeons trained and experienced in the related field.)

INDICATIONS

General criteria and principles related to instrumented spinal surgery are applied here:

- Degenerative disc pathologies
- Herniated nucleus pulposus
- Grade 1 degenerative or isthmic spondylosis
- Visible loss of disc height compared to adjacent levels
- Lumbar pseudarthrosis

Note: Patients should be skeletally mature and have had six months of non-operative treatment.

CONTRAINDICATIONS

Prodorth PLIF PEEK Cages should never be used at any condition not described in the indications for use. Contraindications include, but are not limited to:

- Fracture, tumor
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia
- Marked local inflammation
- Osteoporosis, calcium metabolism disorder
- Pregnancy
- Infection
- Recognized allergies to titanium or titanium alloys
- Damaged lumbar vertebrae from an accident (trauma) at the level of the surgery
- Prior fusion at the level(s) to be treated
- An unhealthy shape (deformity) of the lumbar vertebrae at the level of the surgery
- Low bone mineral density, such as osteoporosis or osteopenia
- Mental disability
- Obesity
- Open wounds
- Fever or leukocytosis
- Alcohol or drug addiction
- Uncooperative patient or patient with neurologic disorders rendering the patient incapable of following instructions

These contraindications can be relative or absolute and should be considered when physician makes a decision. The above list does not include all possibilities. Surgeons should discuss relative contraindications with the patient.

SECONDARY AND POSSIBLE SIDE EFFECTS

The patient shall be notified regarding the below mentioned adverse events pre-operatively. A second surgical treatment may be required:

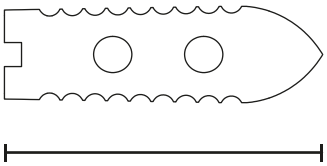
- Pseudarthrosis
- Implant penetration, migration or implant failure
- Infection
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments
- Paralysis
- Allergy to materials used
- Loosening
- Increased pain
- Instability
- Hematoma
- Pain or illness
- Nonunion or delayed union of the bone
- Bleeding blood vessels
- Bursitis
- Inability to perform daily activities
- Dura leak requiring a repeating surgery
- Intervertebral cages can be fractured postoperatively above or below segments of the surgical level due to trauma, the presence of any defect or weak bone structure. Re-operation may be required
- Wound infection
- Displacement of the disc adjacent segment degeneration
- Death

WARNINGS

- Never re-use an implant even in a perfect state. Any implant which has been used, twisted, bent, implanted and then removed even if it appears intact, it must be discarded
- Use new implants routinely
- Similar products of competitors shall not be combined with the components of the Prodorth PLIF PEEK Cage. Prodorth implants and instruments should only be used with Prodorth instruments. In case of using other company's instruments, this might result in galvanic corrosion, incompatibility between the products as well
- No component of the Prodorth PLIF PEEK Cage shall be reused
- The restricted shelf life of the device is 10 years. It should never be used after its expiration date
- Correct selection of the implant is highly important!
- Use of provided trials is recommended

PRODORTH PLIF PEEK CAGE DESCRIPTION

The unstable situation of the lumbar spine causes herniation of discs and this makes pressure on nerves. In order to solve this problem, PLIF PEEK Cage is positioned at the intervertebral area after discectomy, so that 2 vertebrae work as one vertebra as a result of bone fusion. In this way, the pressure on nerves is disposed and the patient has relief.
Prodorth PLIF Cage is made of PEEK (Polyether-ether-ketone/ ASTM F2026) which is a polymer-based composite material and Ti6Al4V-ELI (grade 23) material.
X-ray marker pins for visibility.
The PLIF PEEK Cage is anatomically-shaped to fit the lumbar disc space optimally, with two footprint sizes and multiple heights to restore disc height. A large bone graft window accommodates bone grafts or synthetic bone inserts.



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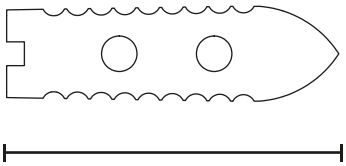

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28x11mm	102.03 002811
28x12 mm	102.03 002812
28x13 mm	102.03 002813
28x14 mm	102.03 002814
28x15 mm	102.03 002815

PRODORTH PLIF PEEK CAGE INSTRUMENTS

Prodorth offers different designs of instruments for each step of the surgical procedure. They have been designed as simply as possible and user-friendly in order to provide ease of use.
Prodorth instruments are made of stainless chrome nickel steel, aluminum, and silicone.

PLIF Inserter | PL 200.20.002

Left Angled Hole Curette | PL 200.20.003

Straight Hole Curette | PL 200.20.004

Right Angled Hole Curette | PL 200.20.005

Reverse Cup Curette | PL 200.20.006

Straight Cup Curette | PL 200.20.007

Mallet | PL 200.20.009

Trial Implant Inserter | PL 200.20.010

T-Handle Locking ¼" | PL 200.20.011

Shaver 7 mm | PL 200.20.012
Shaver 8 mm | PL 200.20.013
Shaver 9 mm | PL 200.20.014
Shaver 10 mm | PL 200.20.015
Shaver 11 mm | PL 200.20.016
Shaver 12 mm | PL 200.20.017
Shaver 13 mm (Upon Request) | PL 200.20.016A
Shaver 14 mm (Upon Request) | PL 200.20.016B
Shaver 15 mm (Upon Request) | PL 200.20.016C
Shaver 3 mm (Upon Request) | PL 200.20.016D
Shaver 4 mm (Upon Request) | PL 200.20.016E
Shaver 5 mm (Upon Request) | PL 200.20.016F
Shaver 6 mm (Upon Request) | PL 200.20.016G

Reamer 7 mm (Upon Request) | PL 200.20.028
Reamer 8 mm (Upon Request) | PL 200.20.029
Reamer 9 mm (Upon Request) | PL 200.20.030
Reamer 10 mm (Upon Request) | PL 200.20.031
Reamer 11 mm (Upon Request) | PL 200.20.032
Reamer 12 mm (Upon Request) | PL 200.20.033

SURGICAL PROCEDURE

Figure 1

Step 1
Patient Positioning and Exposure

The patient is positioned properly in the prone position. The general essentials of lumbar surgery are applied. (Figure 1)

Figure 2

Step 2
Preparation of the Disc Spaces

Use Prodorth Curettes for removing the disc from disc spaces. A proper discectomy is essential for the success of the surgery. (Figure 2)

Step 3
Insertion of the Trial Implants

The trial implants are connected to the Trial Implant Inserter (PL 200.20.010) and then introduced through the vertebrae in order to determine the accurate size of the implant. (Figure 3)

Figure 3

Step 4
Connection of the PLIF PEEK Cage with its Inserter

After selecting the appropriate size of PLIF PEEK Cage, it is firmly attached to the PLIF Inserter (PL 200.20.002). In order to connect it properly, the knob behind the inserter is rotated clockwise until assuring the implant is completely connected. And it's introduced into the intervertebral area. Care should be taken to ensure the PLIF PEEK Cage is aligned properly. (Figure 4)

Figure 4

Step 5
Releasing the PLIF PEEK Cage from its Inserter

After the PLIF PEEK Cage is placed, the extradural space and foramina are probed to ensure adequate decompression of the neural elements. And once it's decided the cage is positioned accurately, it's released by rotating the knob of the inserter anti-clockwise. (Figure 5)

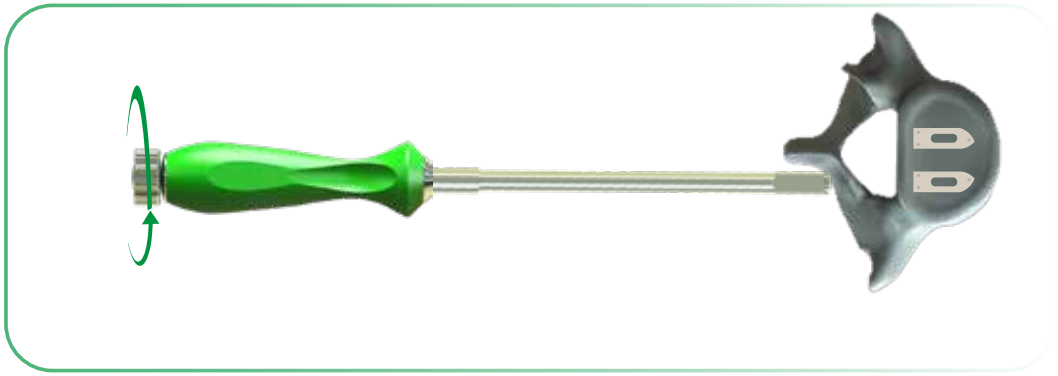

Figure 5

Surgical Technique Guide

PLIF PEEK CAGE

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See the IFU prior to use for additional information.

Please check our website for the latest version of this Surgical Technique.

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