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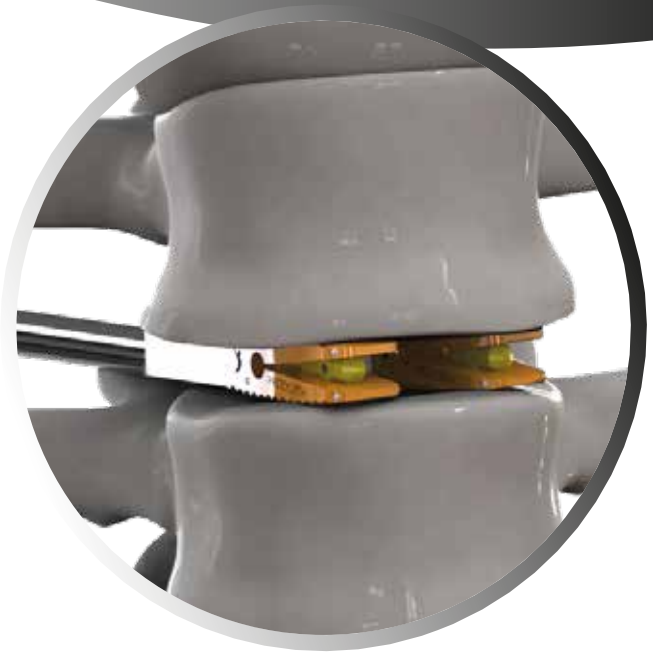

Surgical Technique Guide
Expandable
PLIF PEEK Cage

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contents

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SURGICAL TECHNIQUE OF PRODORTH EXPANDABLE 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 Expandable PLIF 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 Expandable PLIF PEEK Cage implants 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.

Expandable 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 Expandable 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 Expandable 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 Expandable 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 and PEEK material
- 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 Expandable 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 Expandable 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 EXPANDABLE PLIF PEEK CAGE DESCRIPTION

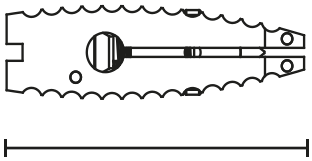
Prodorth Expandable PLIF PEEK Cage is intended for single use only and restores degenerative disc pathologies.

The unstable situation of the lumbar spine causes herniation of discs and this makes pressure on nerves. In order to solve this problem, Expandable 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 Expandable PLIF PEEK Cage is made of PEEK (Polyether-ether-ketone/ ASTM F2026) which is a polymer-based composite material and Ti6Al4V –ELI (Grade23) material.

X-ray marker pins for visibility.

The Expandable 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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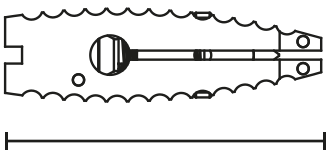

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28x11mm	102.01 002811
28x12 mm	102.01 002812
28x13 mm	102.01 002813
28x14 mm	102.01 002814
28x15 mm	102.01 002815

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PRODORTH EXPANDABLE 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

Mallet PL 200.20.008

Left Angled Hole Curette PL 200.20.003

Trial Implant Inserter PL 200.20.009

Straight Hole Curette PL 200.20.004

T Handle Locking ¼" PL 200.20.011

Right Angled Hole Curette PL 200.20.005

Shaver ¼" 7 mm PL 200.20.012
Shaver ¼" 8 mm PL 200.20.013
Shaver ¼" 9 mm PL 200.20.014
Shaver ¼" 10 mm PL 200.20.015
Shaver ¼" 11 mm PL 200.20.016
Shaver ¼" 12 mm PL 200.20.017

Reverse Cup Curette PL 200.20.006

Straight Cup Curette PL 200.20.007

SURGICAL PROCEDURE

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 1

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)

Figure 2

Step 3
Insertion of the Trial Implants

The trial implants are connected to the Trial Implant Inserter (PL 200.20.009) 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 Expandable PLIF PEEK Cage with its inserter

After selecting the appropriate size of the Expandable PLIF PEEK Cage, it is connected to the inserter (PL 200.20.002). In order to fix it accurately, the knob behind the inserter is rotated clockwise until assuring the implant is completely connected. (Figure 4) Then the steel T-Handle with bar is inserted through the inserter which is used for expanding the cage. (Figure 5)

After a successful connection, the cage is able to be introduced into the intervertebral area by small impacts with a mallet (PL 200.20.008).

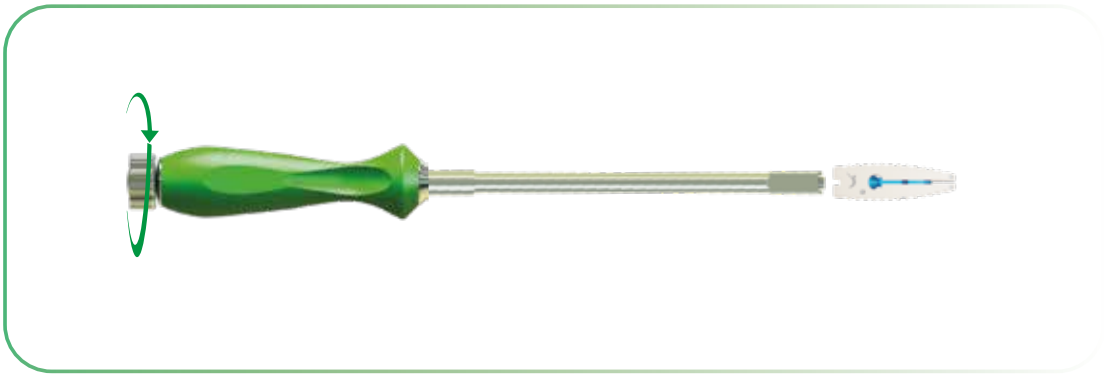

Figure 4

Figure 5

Step 5
Expanding the Expandable PLIF PEEK Cage

When the Expandable PLIF PEEK Cage is positioned accurately, the T-Handle behind the inserter is rotated clockwise. Thus the Expandable PLIF PEEK Cage will be expanded. Surgeon can stop expansion at the required level and leave it so on, or it can be fully expanded until the expansion will stop at its limit. (Figure 6)

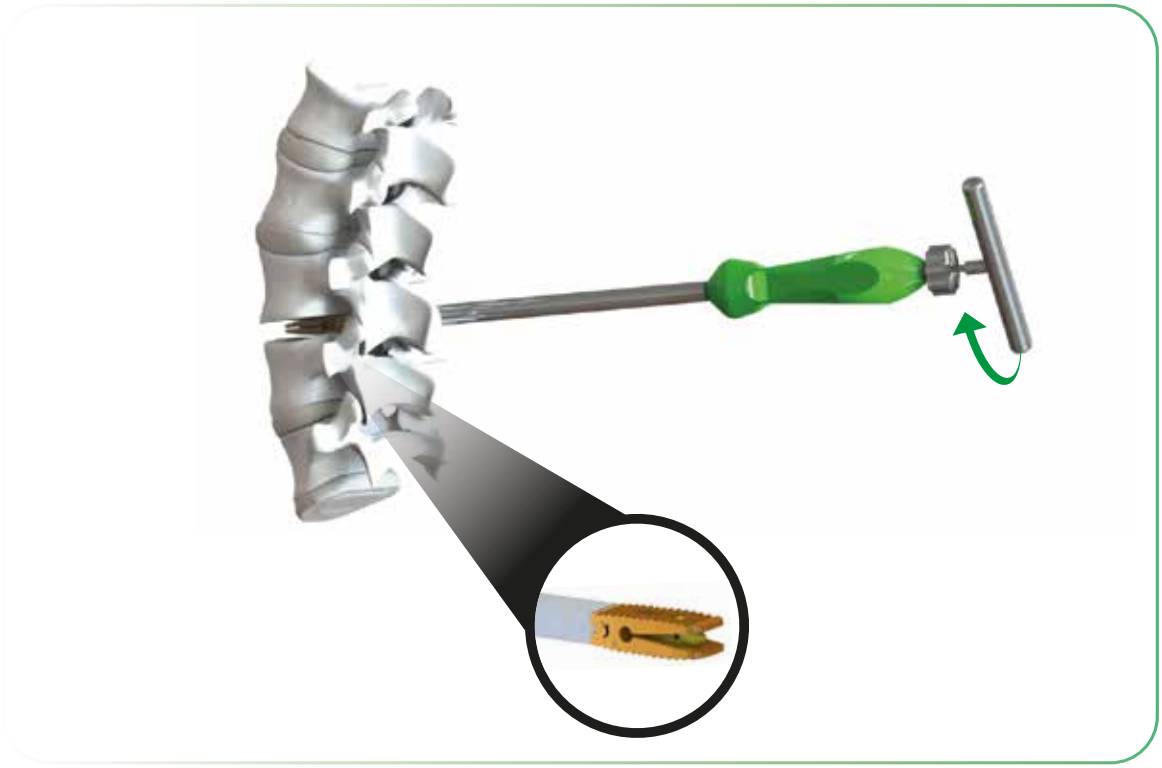

Figure 6

Step 6
Releasing the Expandable PLIF PEEK Cage from its Inserter

After the Expandable PLIF PEEK Cage is placed and expanded 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 anticlockwise. (Figure 7)

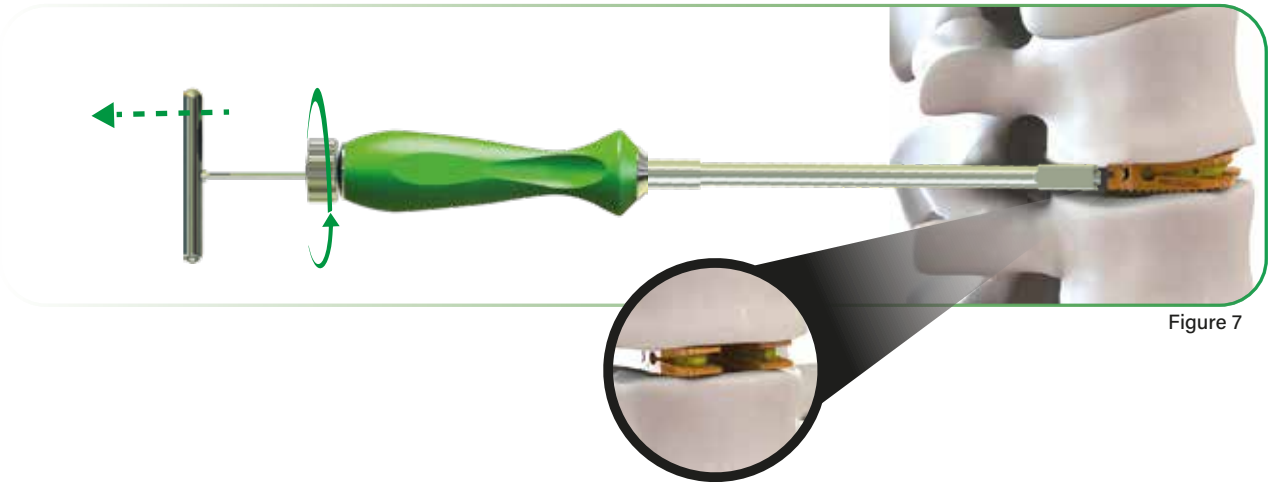

Figure 7

Surgical Technique Guide

EXPANDABLE 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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