PRODORTH

Surgical Technique Guide

TLIF PEEK CAGE

PRODOLPHIN™

INTRODUCTION TO SURGICAL TECHNIQUE

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 unexperienced 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 best treatment for the patient and the results will be different according to the patient's physical and mental situation.

DEVICE DESCRIPTION

PRODORTH TLIF CAGE is an implantation system used for disposing the complaints of the patients which are risen from the due to the herniation at discs, traumas or any disorders on lumbar spine.

Prodorth TLIF Cage Implants are long-term implants, however they are not able to withstand the forces like healthy bone structures.

- **Current Status of the Device:** Device is already CE marked (since 2013) and has been on the market.
- **TLIF Cage GMDN No:** 38161
- **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 Assesment:**

Biological Assessment of Device According to TS EN ISO 10993-1 : 2011	
Category	**Implant Device**
Contact Level	**Bone/ Tissue**
Contact Duration	**C (Permanent - > 30days)**

- **Sterilization:**

Prodorth TLIF Cage is released to market as non-sterile.

They must be sterilized prior to surgical use. The validated sterilization method for PRODORTH implants is steam sterilization in autoclave. The implants which are intended to be sterilized should remain in autoclave at 134 C degree for 18 minutes. There is no other sterilization method PRODORTH recommends.

- **Intended Use of the Device:**

PRODORTH TLIF Cage is a long-term implant in order to dispose the complaints of the patients which raised because of the pain arising from the herniation at lumbar discs, traumas on lumbar spine.

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

- **Population:** Skelatally 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

CONTRAINDICATIONS :
Fracture, tumor
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.
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

SECONDARY AND POSSIBLE SIDE EFFECTS:
Pseudarthrosis
Implant penetration, migration or Implant failure
Infection
Allergy to materials used
Dysphagia
Loosening
Increased neck pain
Instability
Hematoma
c7 palsy
Wound infection
Hoarseness
HO (heterotopic ossification)
Displacement of the disc adjacent segment degeneration

WARNINGS:
Never re-use an implant even in 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 TLIF Cage. PRODORTH implants and instruments should only be used with PRODORTH instruments. Instruments developed by PRODORTH to be used in spinal surgeries of its spinal products. Incase of using other company's instruments, this might result in galvanic corrosion, incompatibility between the products as well. No component of the Prodorth lumbar Disc implants shall be reused.

The restricted shelf life of the device is 10 years. It should never be used after its expiration date.

Prodorth TLIF Cage Description

Prodorth TLIF Cage is intended for single use only and restore the degenerative disc pathologies.

When a disc degenerates, the disc:

• Loses liquid. Less liquid content results in a thinner disc which has less padding. The disc might become less flexible.

• May have mini tears or cracks in the annulus fibrosus. Disc degeneration might cause the:

- Inner disc (nucleus pulposus) to squeeze through the outer disc (disc bulge or disc herniation).
- Spinal canal to narrow and pinch the cord and nerves (spinal canal stenosis).
- Spinal cord to be irritated causing a loss of feeling or movement (myelopathy).
- Nerve roots to be irritated or pinched causing pain, weakness, or tingling down the arm and possibly into the hands (radiculopathy).

After discectomy operation, Prodorth TLIF Cage is put through vertebras in order to maintain these problems.

If the lumbar disc is herniated or bulged to the nerves at lumbar area, the patient feels pain at his neck with an accompanying tingling at legs. After discectomy, TLIF PEEK Cage is positioned at intervertebral area. Hence two vertebras work as one vertebra due to bone fusion, in result the pressure on nerves is disposed and patient has a relief.

Prodorth TLIF Cage is made of PEEK (Polyether-ether-kethon/ ASTM F2026) which is a polymer based composite material and Ti6Al4V (grade 5) material.

PRODOLPHIN® TLIF Cages provides an uninterrupted guidance during operation. Circular toothed surface feature for holding the inferior and superior areas.

Made of PEEK material, originated from EVONIK Industries Germany. X-ray marker pins for the visibility.

It easily adapts to the required position

Prodorth TLIF CAGES

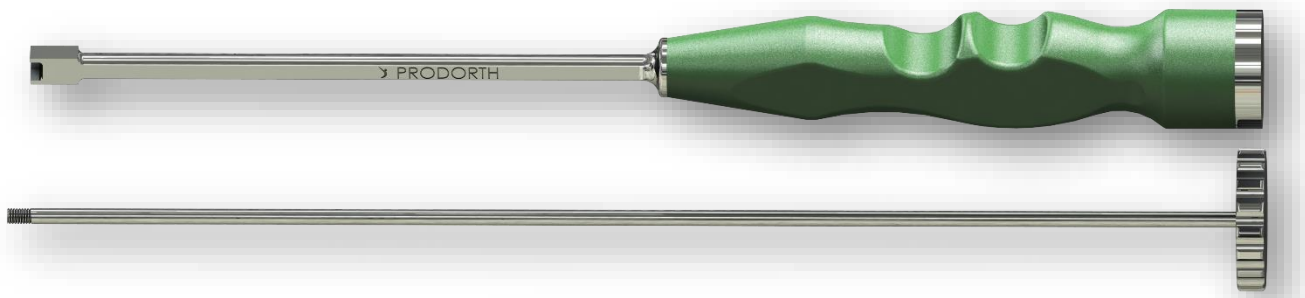
Sizes & Ref. Codes

Product Name / Sizes	Ref. Code
PRODORTH TLIF PEEK CAGE 25x7 mm	102.05 002507
PRODORTH TLIF PEEK CAGE 25x8 mm	102.05 002508
PRODORTH TLIF PEEK CAGE 25x9 mm	102.05 002509
PRODORTH TLIF PEEK CAGE 25x10 mm	102.05 002510
PRODORTH TLIF PEEK CAGE 25x11 mm	102.05 002511
PRODORTH TLIF PEEK CAGE 25x12 mm	102.05 002512
PRODORTH TLIF PEEK CAGE 25x13 mm	102.05 002513
PRODORTH TLIF PEEK CAGE 25x14 mm	102.05 002514
PRODORTH TLIF PEEK CAGE 25x15 mm	102.05 002515
PRODORTH TLIF PEEK CAGE 28x7 mm	102.05 002807
PRODORTH TLIF PEEK CAGE 28x8 mm	102.05 002808
PRODORTH TLIF PEEK CAGE 28x9 mm	102.05 002809
PRODORTH TLIF PEEK CAGE 28x10 mm	102.05 002810
PRODORTH TLIF PEEK CAGE 28x11 mm	102.05 002811
PRODORTH TLIF PEEK CAGE 28x12 mm	102.05 002812
PRODORTH TLIF PEEK CAGE 28x13 mm	102.05 002813
PRODORTH TLIF PEEK CAGE 28x14 mm	102.05 002814
PRODORTH TLIF PEEK CAGE 28x15 mm	102.05 002815

PRODOLPHIN™

Prodorth offers different designs of instruments for each step of the surgical procedure. They have been designed as simple as possible and user-friendly in order to provide ease of use.

Stainless chrome nickel steel, aluminum, and silicone raw materials are used for Prodorth instruments.



PL 200.20.001 ***Tlif Cage Insertion***

PL 200.20.006 ***Cup Curette Left***

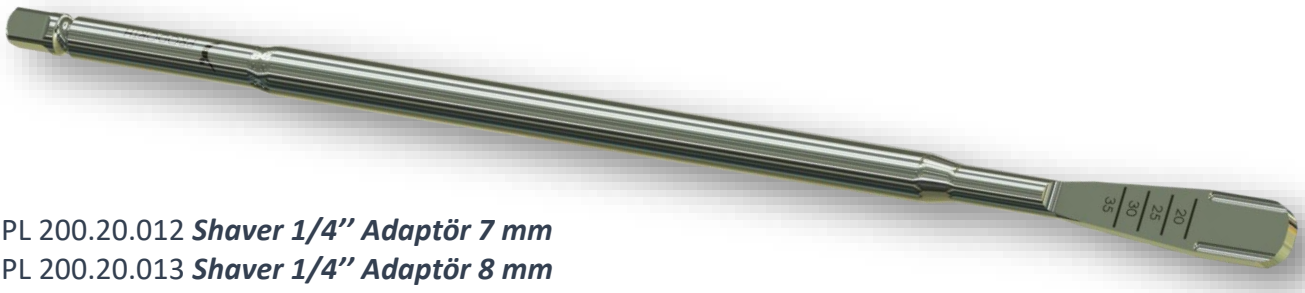
PL 200.20.007 ***Cup Curette Straigth***

PL 200.20.008 ***Cup Curette Right***

PL 200.20.009 ***Mallet***

PL 200.20.010 ***Trial Insertion***

PL 200.20.011 ***T Handle Locking ¼"***



PL 200.20.012 ***Shaver 1/4'' Adaptör 7 mm***
PL 200.20.013 ***Shaver 1/4'' Adaptör 8 mm***
PL 200.20.014 ***Shaver 1/4'' Adaptör 9 mm***
PL 200.20.015 ***Shaver 1/4'' Adaptör 10 mm***
PL 200.20.016 ***Shaver 1/4'' Adaptör 11 mm***

SURGICAL PROCEDURE

Step 1

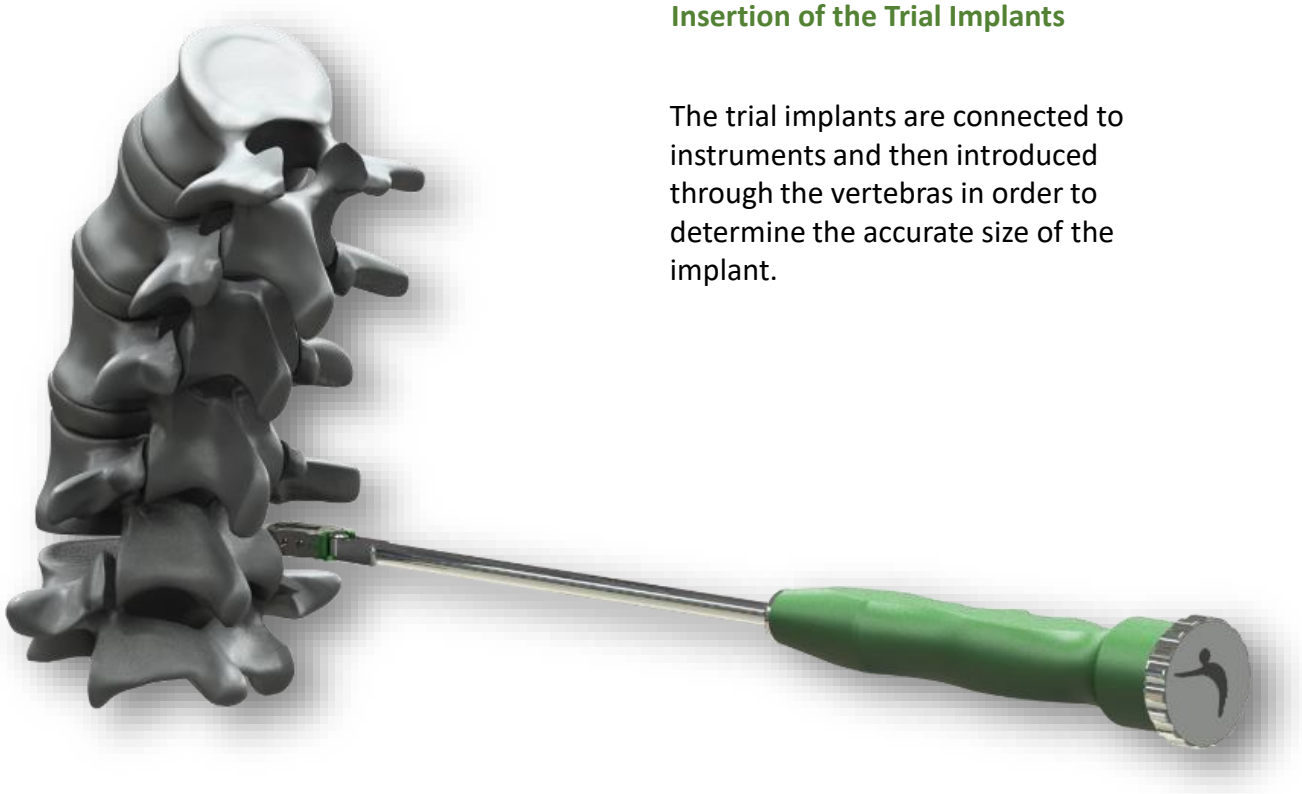
The patient is positioned properly in the adequate position. The general essentials of lumbar surgery is applied.

Step 2
Preparation of the Disc Spaces

Use Prodorth Curettes in order to actualize the discectomy process. Remove the disc as required.

Step 3
Insertion of the Trial Implants

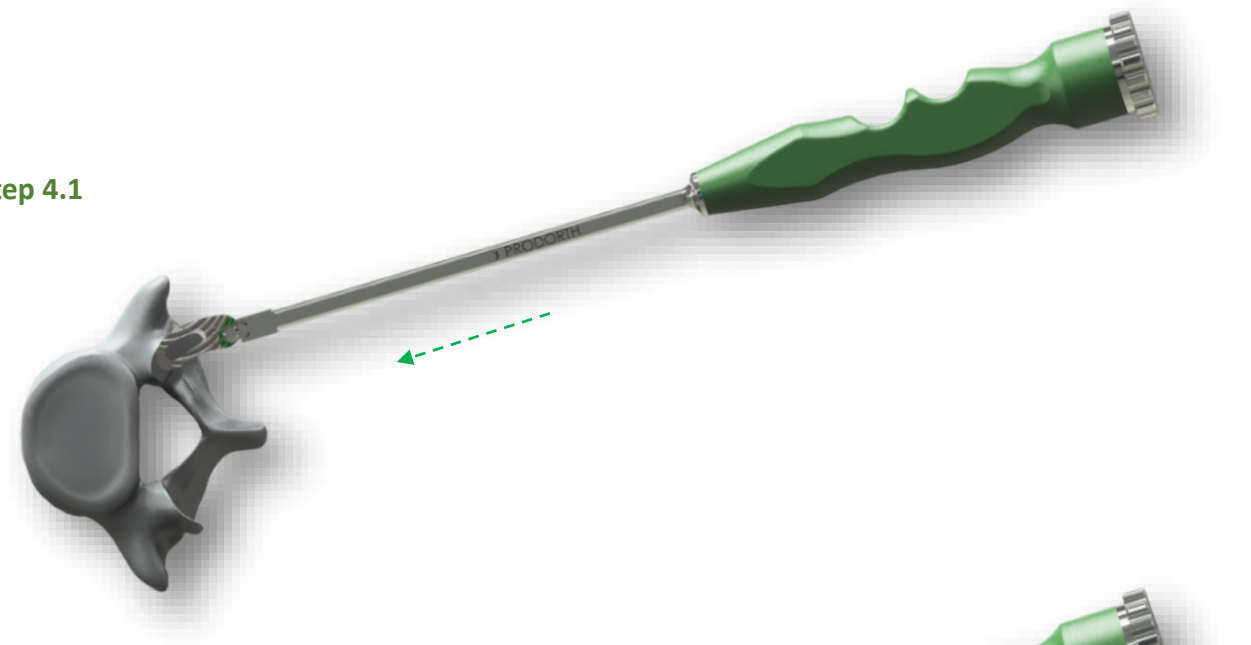
The trial implants are connected to instruments and then introduced through the vertebras in order to determine the accurate size of the implant.



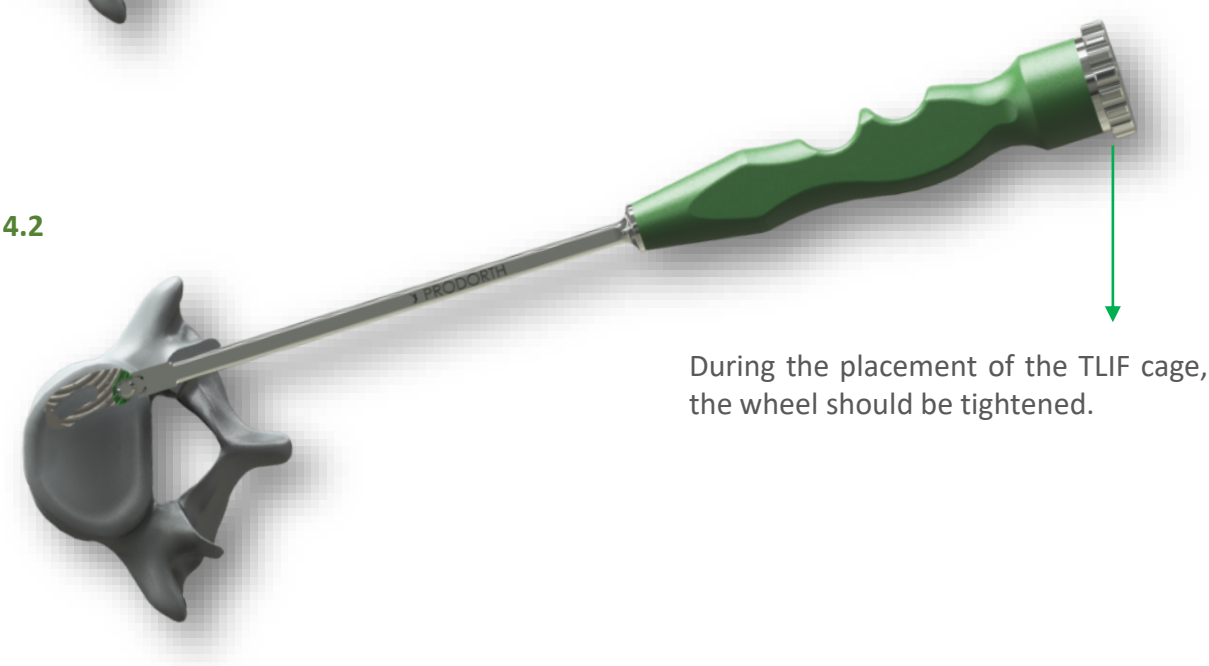
Step 4
Connection of the TLIF Cage with its inserter

TLIF Cage is connected to the inserter. In order to fix it accurately, the wheel behind the inserter is rotated clock-wise until assuring the implant is completely connected. After a succesful connection, Prodorth TLIF cage is able to be moved to both directions. This provides an easy guidance as required. After discectomy, the wheel is rotated while the TLIF cage is upright position and it's placed intervertebral area so on.

Step 4.1



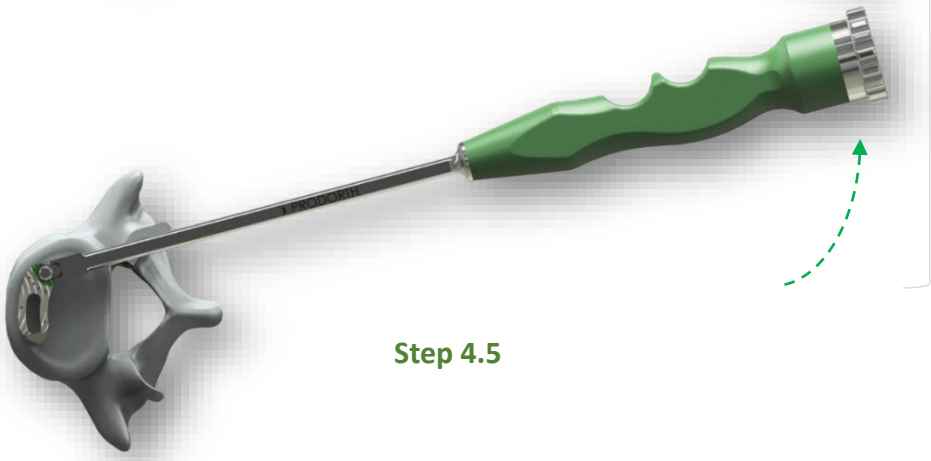
Step 4.2



During the placement of the TLIF cage, the wheel should be tightened.

Step 4.3

Step 4.4

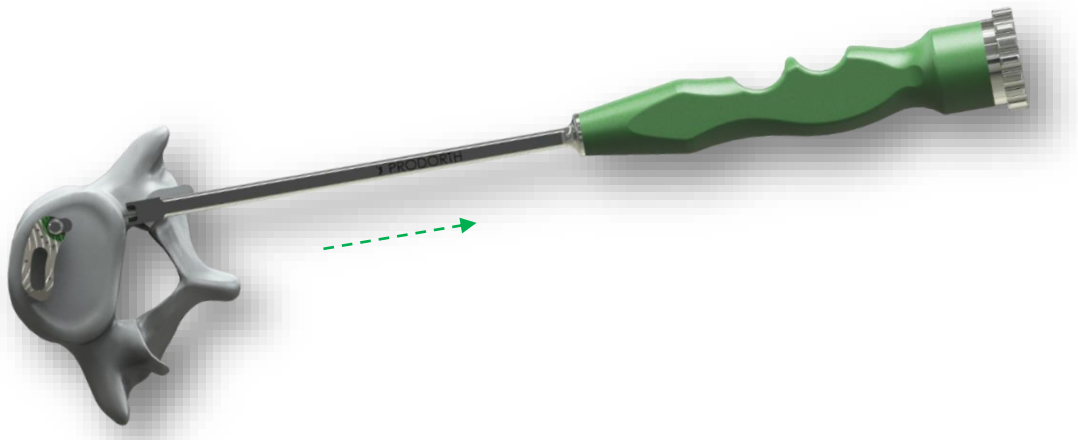


Step 4.5

As it's represented at the figure 4.3, 4.4 and 4.5 the implant is positioned as required by the wheel is tightened and loosened.

Step 5
Taking off the TLIF Cage from inserter

Finally the wheel is loosened and the TLIF is released at the required position.



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See the IFU prior to use for additional information.

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