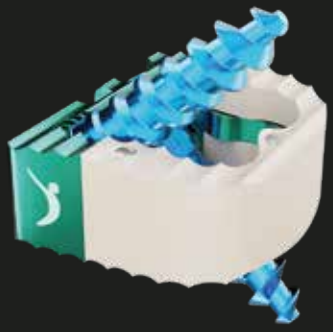
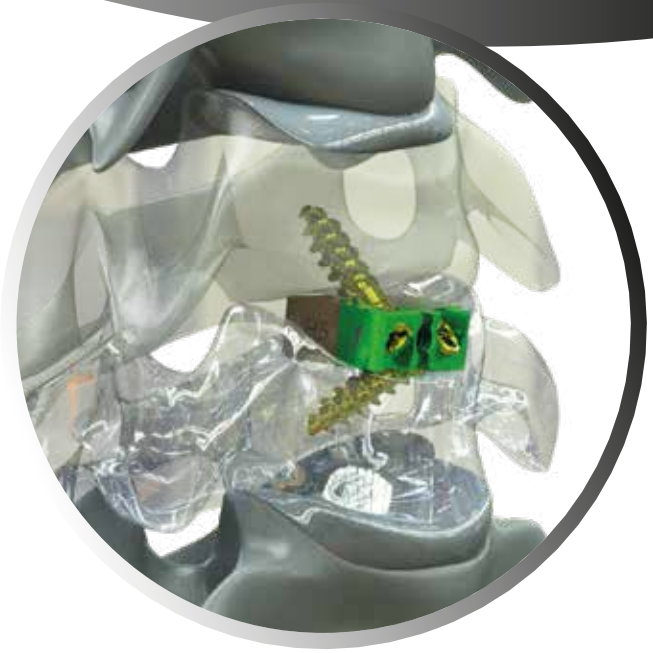
PRODORTH



PRORAY™



Surgical Technique Guide
Anterior Cervical
PEEK Cage with Screws

www.prodorth.com

contents

SURGICAL TECHNIQUE OF PRODORTH CERVICAL PEEK CAGE WITH SCREWS

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

The PRORAY™ Anterior Cervical PEEK Cage with Screws (Stand-Alone Cage) is an intervertebral body fusion device with internal screw fixation. The system is comprised of an interbody cage and bone screws. These implants are for single use only. Prodorth spinal cages are implants for long term in order to relieve the patients' complaints which have raised because of the pain arising from the herniation at discs, traumas or any disorders on spine. Prodorth Cages are composed of specially machined PEEK and Titanium parts. It's aimed to inserted into the intervertebral area. PRORAY is introduced using the anterior approach by its special instruments.

Fusion can be made between both vertebral endplates with or without using bone grafts previously introduced into the cages. The raw material used for the production of the Prodorth spinal cages is PEEK (ASTM F 2026 as indicated by the symbol TM), as well as Titanium alloys (ASTM F 136 parts as supplementery items.).

Prodorth Cervical Peek Cage with Screws is a long term implant, however it's 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.

Cervical Peek Cage with Screws GMDN No: Cages GMDN code 60762 and Cages Screws GMDN code 46651

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 Cervical PEEK Cage with Screws 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

This device is used in the treatment of the anatomical abnormalities of vertebrae typically due to degenerative intervertebral discs. The device can be of several different geometric forms and is implanted between the vertebrae and providing mechanical stability and sufficient space for therapeutic spinal bone fusion to occur. This process helps to relieve pressure on pinched nerves and prevents vertebral slipping. The device is made of a special polymer material.

- 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
- Cervical pseudarthrosis

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

CONTRAINDICATIONS

Prodorth Cervical PEEK Cage with Screws should never be used in 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
- Pregnancy
- Infection
- Recognized allergies to titanium or titanium alloys and PEEK material
- Damaged 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 vertebrae at the level of the surgery
- Low bone mineral density, such as osteoporosis or osteopenia
- Fever or leukocytosis
- Mental disability
- Obesity
- Open wounds
- 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:

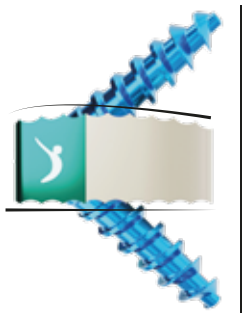
- Pseudarthrosis
- Implant penetration, migration or implant failure
- Infection
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments
- Paralysis
- Allergy to materials used
- Dysphagia
- Loosening
- Increased neck pain
- Instability
- Hematoma
- c7palsy
- Wound infection
- Hoarseness
- Pain or illness
- Anterior displacement of the disc adjacent segment degeneration
- 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
- Death

WARNINGS

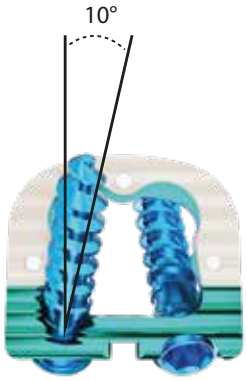
- Never re-use an implant even in a perfect state. Any implant which has been used, twisted, bent, implanted and then removed even if it appears intact, it must be discarded
- Use new implants routinely
- Similar products of competitors shall not be combined with the components of the Prodorth Cervical Peek Cage with Screws. Prodorth implants and instruments should only be used with Prodorth instruments. Incase of using other company's instruments, this might result in galvanic corrosion, incompatibility between the products as well
- No component of the Prodorth Cervical Peek Cage with Screws 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 CERVICAL PEEK CAGE WITH SCREWS DESCRIPTION

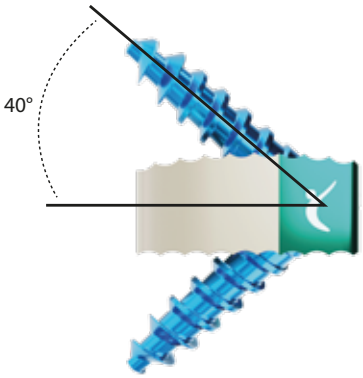
Cervical PEEK Cage with Screws comprises a PEEK body with anterior titanium-alloy bone-anchoring screws. The Cervical PEEK Cage with Screws is anatomically-shaped to fit the cervical disc space optimally, with three footprint sizes and multiple heights to restore disc height. A large bone graft window accommodates bone grafts or synthetic bone inserts. Screw retention is achieved by means of an integrated locking design.

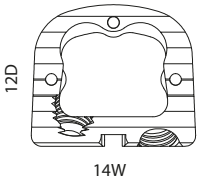


Zero Profile



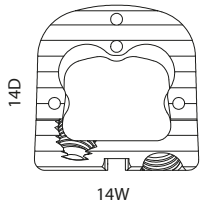
Anatomical fit between endplates
Optimized Screw Angulation





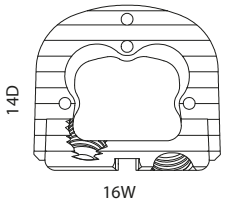
12D x 14W Interbodies
+2 Screws

SIZE	REF.CODE
5x12x14 mm	102.06 051205
6x12x14 mm	102.06 051206
7x12x14 mm	102.06 051207
8x12x14 mm	102.06 051208



14D x 14W Interbodies
+2 Screws

SIZE	REF.CODE
5x14x14 mm	102.06 051405
6x14x14 mm	102.06 051406
7x14x14 mm	102.06 051407
8x14x14 mm	102.06 051408



14D x 16W Interbodies
+2 Screws

SIZE	REF.CODE
5x14x16 mm	102.06 051605
6x14x16 mm	102.06 051606
7x14x16 mm	102.06 051607
8x14x16 mm	102.06 051608

Screws

Ø3,0 Screws	REF.CODE
Ø3,0x10 mm	102.07.3010
Ø3,0x12 mm	102.07.3012
Ø3,0x14 mm	102.07.3014
Ø3,0x16 mm	102.07.3016

Ø3,5 Screws	REF.CODE
Ø3,5x10 mm	102.07.3510
Ø3,5x12 mm	102.07.3512
Ø3,5x14 mm	102.07.3514
Ø3,5x16 mm	102.07.3516

PRODORTH

INSTRUMENTS IN CERVICAL COMBINED INSTRUMENTATION SET

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.

Cervical AWL PC 300.30.003

Caspar Pin Driver PC 300.30.004

Trial Inserter PC 300.30.005

Mallet (Small) PC 300.30.006

Caspar Distractor PC 300.30.007

Caspar Pin (Distraction Screws) PC 300.30.008

Stand-Alone Cage Inserter Type -1 PC 300.30.015

Stand-Alone Cage Inserter Type -2 PC 300.30.016

Stand-Alone Cage Angled Guide PC 300.30.020

Stand-Alone Cage Fixed AWL PC 300.30.017

Stand-Alone Cage Adjustable Angled Screw Driver PC 300.30.030

Stand-Alone Cage Adjustable Angled AWL PC 300.30.019

Stand-Alone Cage Fixed Screw Driver PC 300.30.031

Stand-Alone Cage Fixed Drill PC 300.30.021

Stand-Alone Cage Fixed Angled Driver PC 300.30.032

Stand-Alone Cage AWL Bit PC 300.30.033

Stand-Alone Cage Adjustable Angled Drill PC 300.30.022

Stand-Alone Cage Drill Bit PC 300.30.034

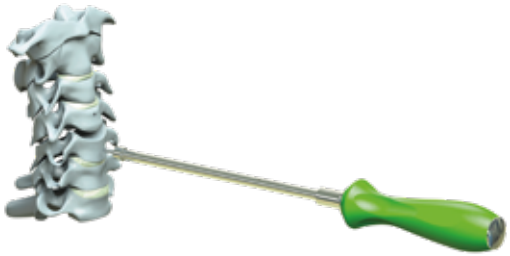
Stand-Alone Cage Torque Limiting I-Handle 1,5 Nm PC 300.30.023

Stand-Alone Cage Screw Bit PC 300.30.035

Step 1
Patient Positioning and Exposure

The patient is positioned in the supine position with the neck supported posteriorly to achieve normal segmental lordosis. In a standard anterior approach, it is recommended to open the vertebrae using Caspar Distractor when using Cervical PEEK Cage with Screws. (Figure 1)

(Figure 1)



(Figure 2)

Step 2
Preparation of The Vertebrae

It is recommended that PRORAY™ be placed under distraction.

After discectomy, insert the Cervical AWL (PC 300.30.003) to create pilot holes for the caspar pins. (Figure 2)

Step 3
Assembly of Distractor Screws

Insert the Caspar Pin (Distraction Screws, PC 300.30.008) into the tip of the Caspar Pin Driver (PC 300.30.004) and push it until assuring it's fully connected. (Figure 3)

(Figure 3)

Step 4
Completing the Distraction

The previous action in the Step-2 is repeated for the adjacent vertebra. (Figure 4)

Figure 4

Step 5
Use of Caspar Distractor

After the distraction screws are inserted properly, the Caspar Distractor's tips are connected to the screws. And the latch of the Caspar Distractor is rotated gradually until the required distance between vertebrae is obtained. (Figure 5)

(Figure 5)

Step 6
Size Selection

Several sizes of Trial implants are available in the set to determine the appropriate size of the cage. They can be introduced by the Trial Inserter (PC 300.30.005) (Figure 6)

(Figure 6)

(Figure 7)

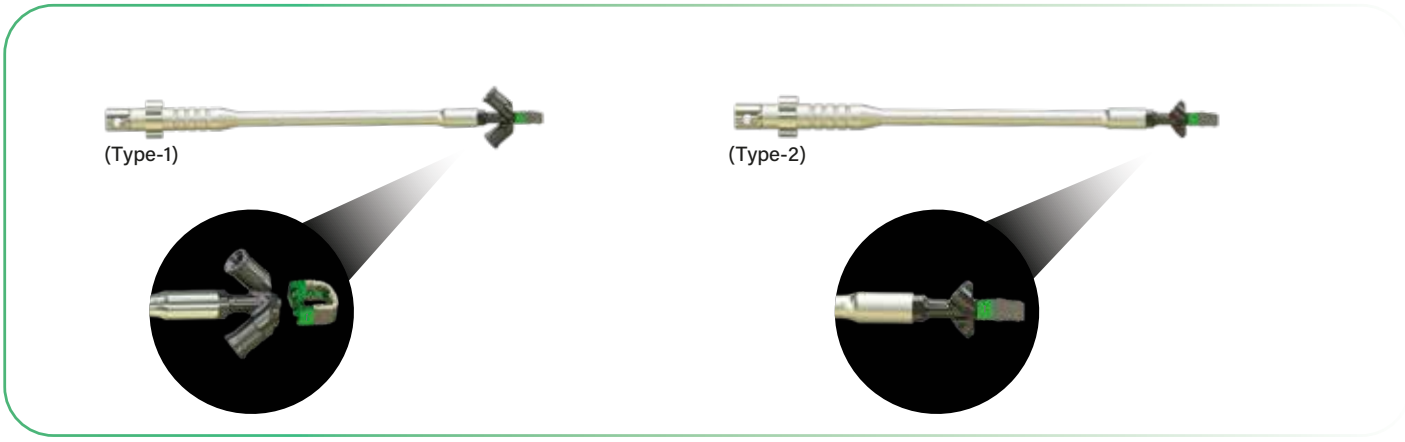
Connect the appropriate trial with the trial inserter and carefully place it into the disc space.
A Mallet (Small) PC 300.30.006 can be used to assist with the insertion of the trial. Care should be taken not to apply excessive force during these operations. (Figure 7)

Trial Options

FOOTPRINTS :
12x14 mm , 14x14 mm , 14x16 mm
HEIGHTS :
5-8 mm (by 1 mm increments)

Step 7
Preparation of the Cage and Insertion

There are 2 types of inserters Prodorth offers: The Stand-Alone Cage Inserter Type -1 (PC 300.30.015)/long guided inserter or the Stand-Alone Cage Inserter Type -2 (PC 300.30.016)/short guided inserter can be used for cage insertion.
After selecting the proper guided inserter, connect the cage to the tip of the guided inserter.
Place the internal bar inside the inserter then attach the cage to the distal tip of the inserter by turning the internal bar knob at the back. Fully thread the cage to the inserter. If some resistance is felt while attaching the cage, verify that it is not cross-threaded. The cage is introduced as the marked arrow on the implant is upside position. (Figure 8)



(Figure 8)

Note: Please make sure the cage is fully engaged with the inserter.

Once the implant is securely attached to the inserter, it should be carefully introduced into the disc space by small impacts with a mallet. The inserters have stoppers that lean on the anterior profile of the vertebral bodies to place the implant safely.

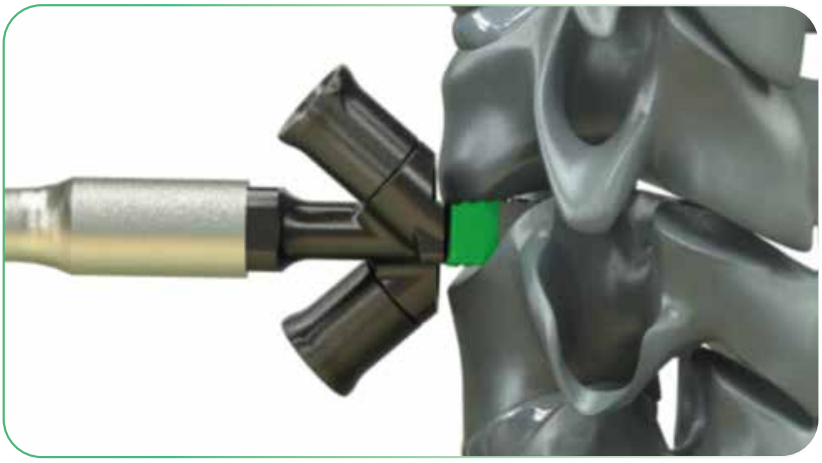
(Figure 9)

After introducing the cage between vertebral bodies, removal of the distractor is recommended. Before proceeding to the next step, please confirm visually that the implant is placed appropriately and leave the guided inserter in its place. (Figure 9)

A titanium marker is embedded in the cage to make a visual verification of the posterior position under fluoroscopy.

Step 8.A (Processing With Fixed Angled Driver) Preparation Of Screw Hole

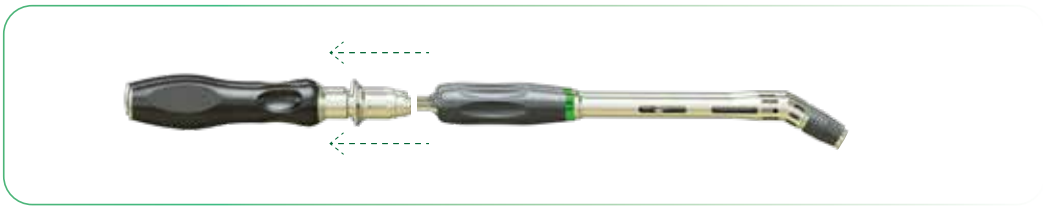
The Stand-Alone Cage Inserter Type -1 (PC 300.30.015) / Long guided inserter should be left in place when preparing the screw hole and for the following processes. (Figure 10)



(Figure 10)

8.a.1 Processing with Awl

Connect the Stand-Alone Cage Torque Limiting I-Handle 1,5 Nm (PC 300.30.023) with the Stand-Alone Cage Fixed Angled Driver (PC 300.30.032) by pulling up the latch as represented below in Figure 11 and then engage the Stand-Alone Cage AWL Bit (PC 300.30.033) by pulling up the black ring (in the direction of arrows) as represented below. (Figure 12)



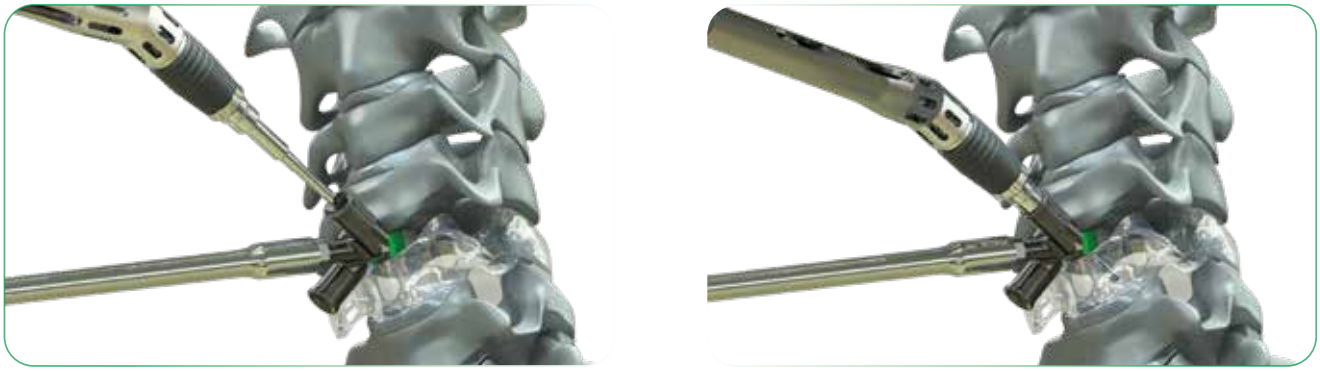
(Figure 11)

(Figure 12)

Insert the Stand-Alone Cage AWL Bit (PC 300.30.033) through the guided inserter in order to make the initial holes for the drill. (Figure 13)

(Figure 13)

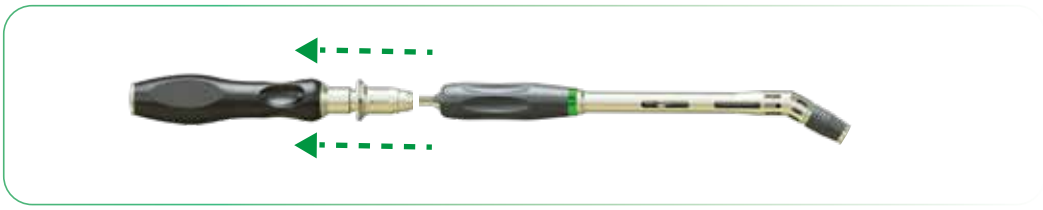
There is a stopper on the Stand-Alone Cage AWL Bit to make a safe advance. (Figure 14)



(Figure 14)

8.a.2 Drilling

Connect the Stand-Alone Cage Fixed Angled Driver (PC 300.30.032) to the Stand-Alone Cage Torque Limiting I-Handle 1,5 Nm (PC 300.30.023)) by pulling up the latch as represented below in Figure 15 and then engage the Stand-Alone Cage Drill Bit (PC 300.30.034) by pulling up the black ring (in the direction of arrows) as represented below. (Figure 16)



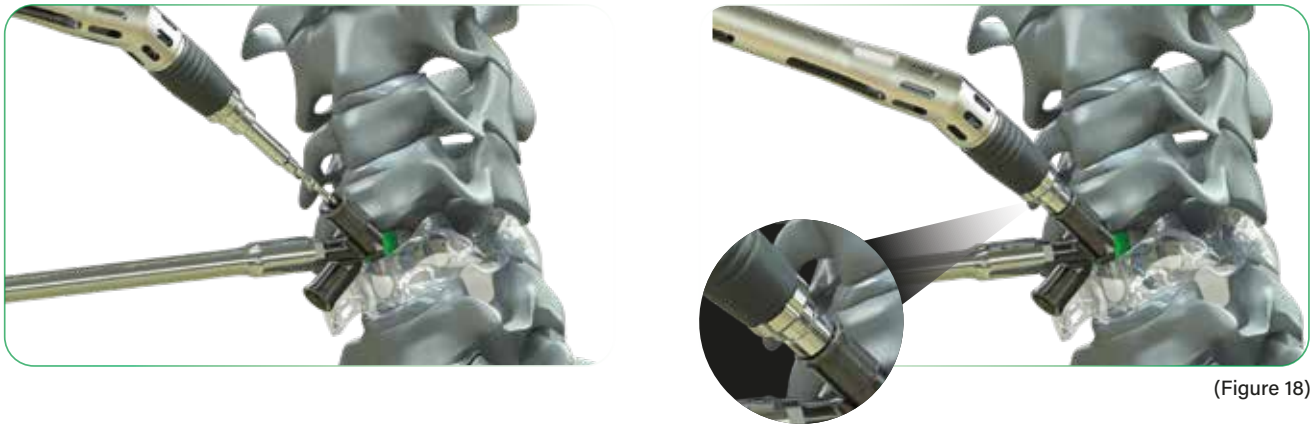
(Figure 15)

(Figure 16)

Insert the Stand-Alone Cage Drill Bit (PC 300.30.034) through the guided inserter to prepare the holes for screws. (Figure 17)

(Figure 17)

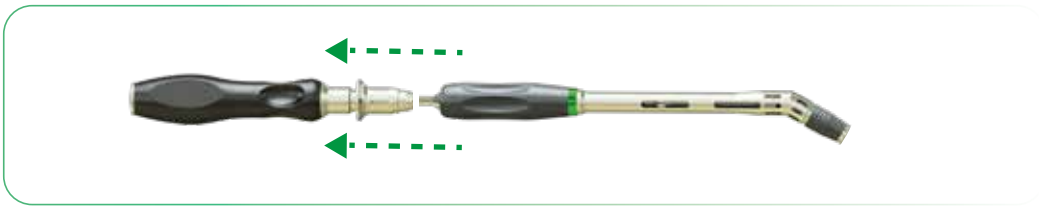
There is a stopper on the Stand-Alone Cage Drill Bit to limit its advance. (Figure 18)



(Figure 18)

8.a.3 Insertion of Screw

Connect the Stand-Alone Cage Fixed Angled Driver (PC 300.30.032) to the Stand-Alone Cage Torque Limiting I-Handle (PC 300.30.023) by pulling up the latch as represented below in Figure 19 and then engage the screw bit (PC 300.30.035) by pulling up the black ring (in the direction of arrows) as represented below. (Figure 20)



(Figure 19)

(Figure 20)

Note: All stand-alone cage screwdriver types have a distal tip to securely hold the screw. You can safely connect the screw to the Fixed Screwdriver, Fixed Angled Screwdriver or Adjustable Angled Screw Driver.

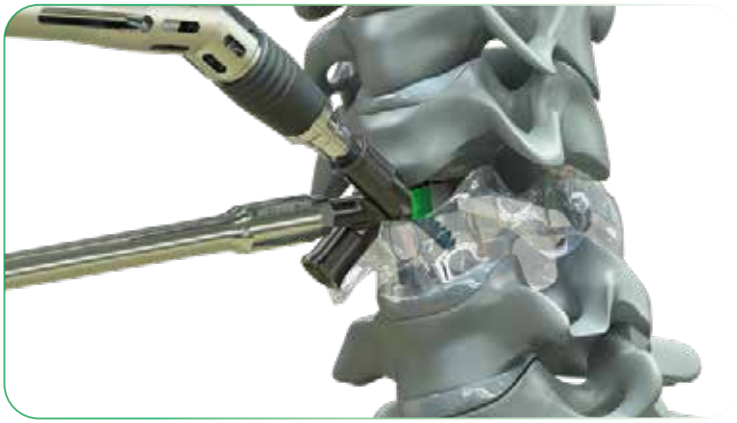
Select the appropriate screw and attach it to the screw bit (PC 300.30.035). (Figure 21)

(Figure 21)

Then, introduce the screw through the guided inserter and advance the screw by rotating the I-Handle clockwise. (Figure 22)

(Figure 22)

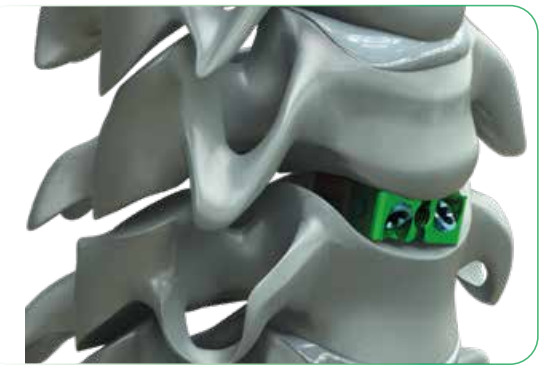
Although the screw bit (PC 300.30.035) seems to have a stopper like the drill or awl bit, it can be advanced to the required depth. So that, after selecting the appropriate size screw, it should be introduced until the torque limiting handle reaches the limit and the "click" sound is heard which means the screw is fully secured.



(Figure 23)

After the screw is introduced through the guide, it advances and when its head leans on the socket of the cage, it's secured automatically. The second screw is introduced and secured likewise. (Figure 23)

When the cage is in the correct position and the screws are locked, the surgical area is closed normally and the operation is ended. (Figure 24)

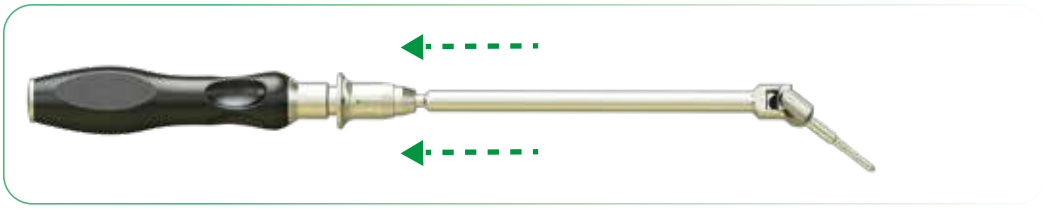


(Figure 24)

Step 8.B (Alternative Method / Processing with Adjustable Angled Drivers)

8.b.1 Processing with Adjustable Angled AWL

Connect the Stand-Alone Cage Torque Limiting I-Handle (PC 300.30.023) with Stand-Alone Cage Adjustable Angled Awl (PC 300.30.019) by pulling up the latch as represented below in Figure 25.



(Figure 25)

Insert the Stand-Alone Cage Adjustable Angled AWL (PC 300.30.019) through the guided inserter in order to make the initial holes for drill. (Figure 26)

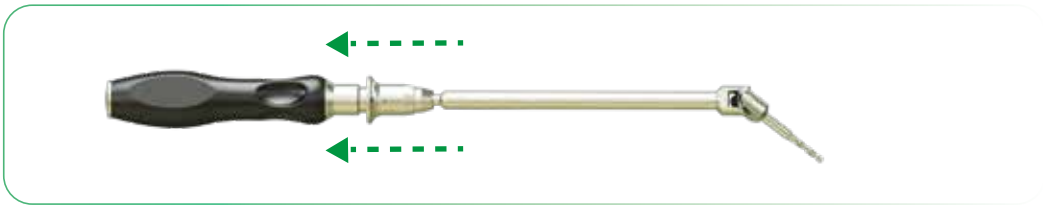
(Figure 26)

There is a stopper on the AWL Bit to make a safe advance. (Figure 27)

(Figure 27)

8.b.2 Drilling with Adjustable Angled Drill

Connect the Stand-Alone Cage Adjustable Angled Drill (PC 300.30.022) to the Stand-Alone Cage Torque Limiting I-Handle (PC 300.30.023) by pulling up the latch as represented below in Figure 28.



(Figure 28)

Insert the Adjustable Angled Drill (PC 300.30.022) through the guided inserter to prepare the holes for screws. (Figure 29)

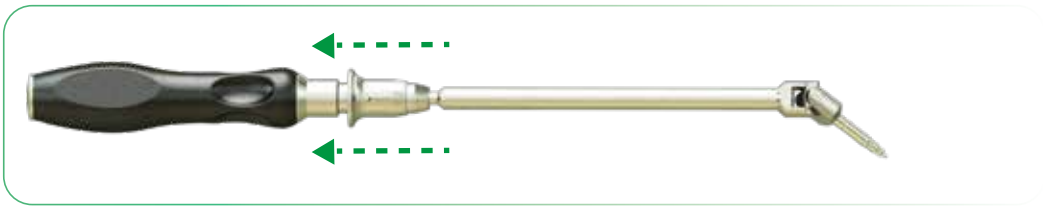
(Figure 29)

There is a stopper on the Adjustable Angled Drill to limit its advance. (Figure 30)

(Figure 30)

8.b.3 Insertion of Screw with Adjustable Angled Screw Driver

Connect the Stand-Alone Cage Adjustable Angled Screw Driver (PC 300.30.030) to the Stand-Alone Cage Torque Limiting I-Handle (PC 300.30.023) by pulling up the latch as represented below in Figure 31 to introduce the screw.

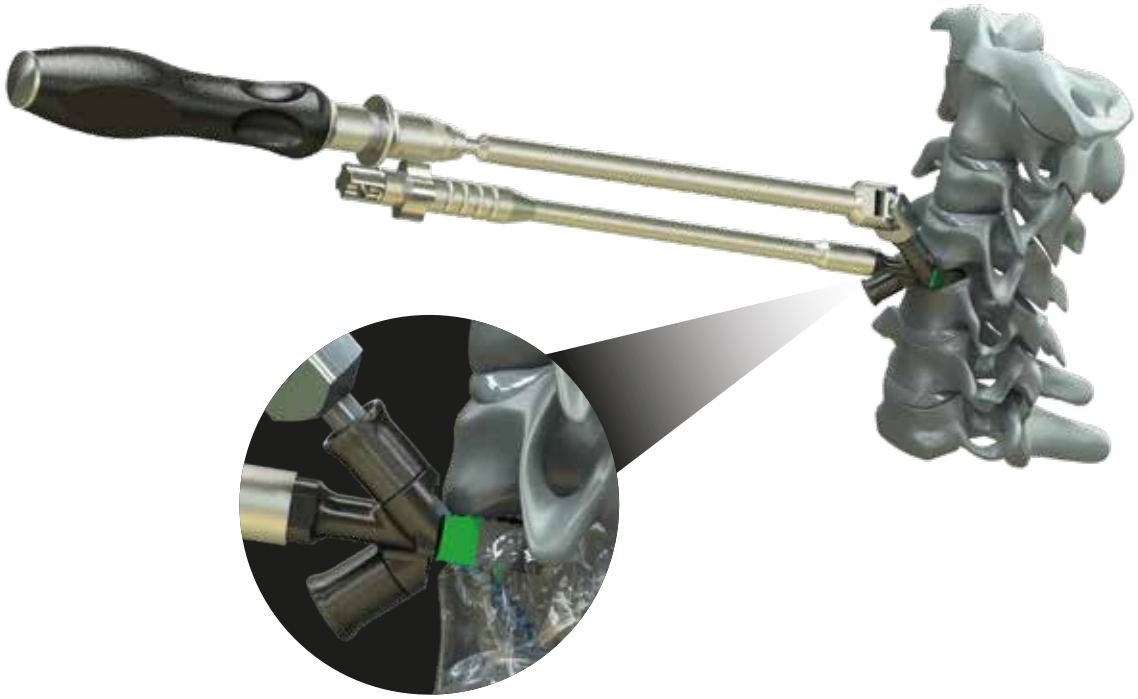


(Figure 31)

Select the appropriate screw and attach it to Adjustable Angled Screw Driver (PC 300.30.030). Then, introduce the screw through the guided inserter and advance the screw by rotating the I-Handle clockwise (Figure 32)

(Figure 32)

Adjustable Angled Screw Driver (PC 300.30.030) can be advanced to the required depth. So that, after selecting the appropriate size screw, it should be introduced until the torque limitting handle reaches the limit and the "click" sound is heard which means the screw is fully secured.

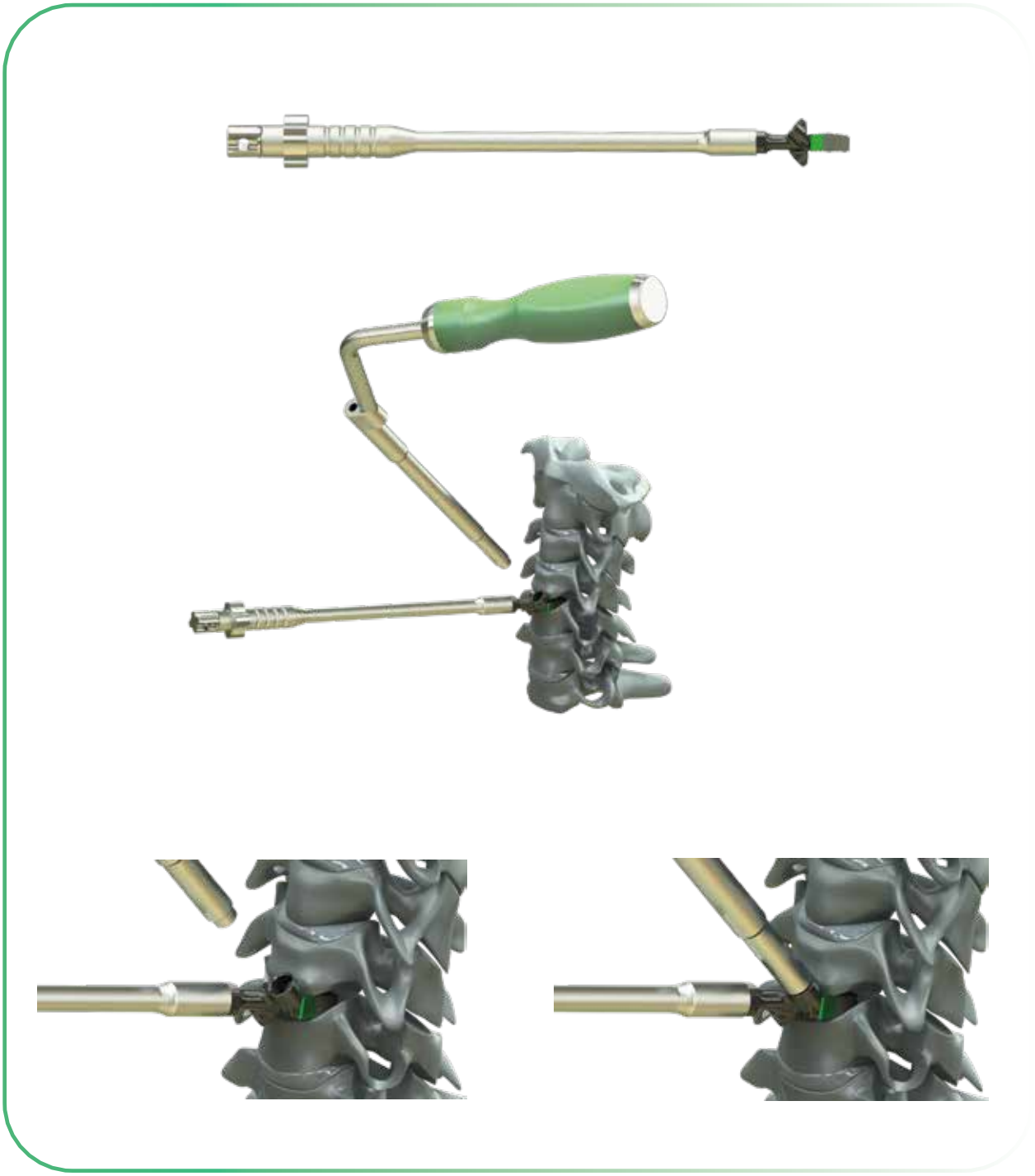


(Figure 33)

When the cage is in the correct position and the screws are locked, the surgical area is closed normally and the operation is ended. (Figure 33)

Step 8.C (Alternative Method / Processing with Fixed Drivers & Short Guided Inserter) Preparation Of Screw Hole

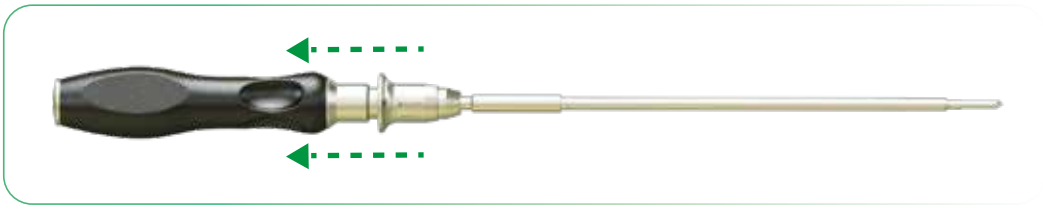
Stand-Alone Cage Inserter Type -2 (PC 300.30.016) / Short guided inserter should be left in the place when preparing the screw hole and for the following processes. This is an alternative method when a more free procedure is needed. It's recommended to use the Stand-Alone Cage Angled Guide (PC 300.30.020) (Figure 34)



(Figure 34)

8.c.1 Processing with Fixed Awl

Connect the Stand-Alone Cage Torque Limiting I-Handle (PC 300.30.023) with Stand-Alone Cage Fixed AWL (PC 300.30.017) by pulling up the latch as represented below in the Figure 35.



(Figure 35)

Insert the Stand-Alone Cage Fixed AWL (PC 300.30.017) through the Angled Guide (PC 300.30.020) in order to make the initial holes for drill. (Figure 36)

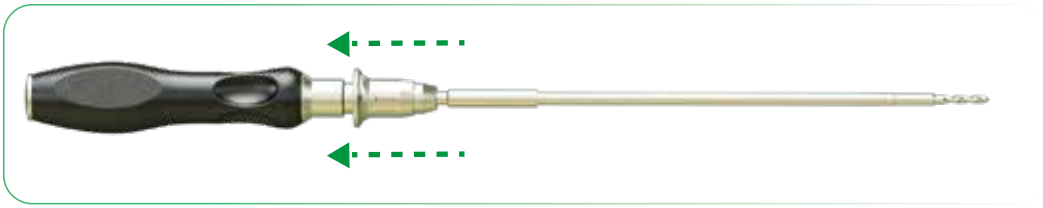
(Figure 36)

(Figure 37)

There is a stopper on the Fixed AWL (PC 300.30.017) to make a safe advance. (Figure 37)

8.c.2 Drilling with Fixed Drill

Connect the Stand-Alone Cage Fixed Drill (PC 300.30.021) to the Stand-Alone Cage Torque Limiting I-Handle (PC 300.30.023) by pulling up the latch as represented below in Figure 38.



(Figure 38)

Insert the Fixed Drill (PC 300.30.021) through the Angled Guide (PC 300.30.020) to prepare the holes for screws. (Figure 39)

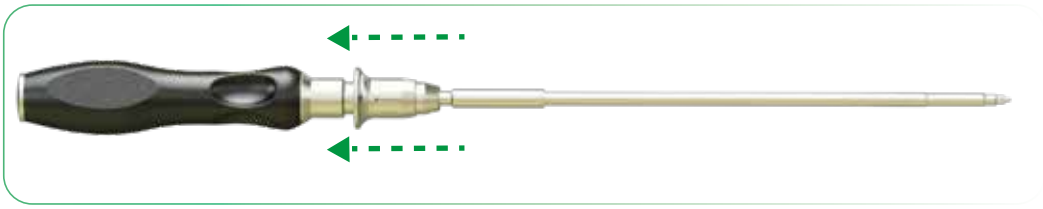
(Figure 39)

(Figure 40)

There is a stopper on the Fixed Drill (PC 300.30.021) to limit its advance. (Figure 40)

8.c.3 Insertion of Screw with Fixed Screw Driver

Connect the Stand-Alone Cage Fixed Screw Driver (PC 300.30.031) to the Stand-Alone Cage Torque Limiting I-Handle (PC 300.30.023) by pulling up the latch as represented below in Figure 41.



(Figure 41)

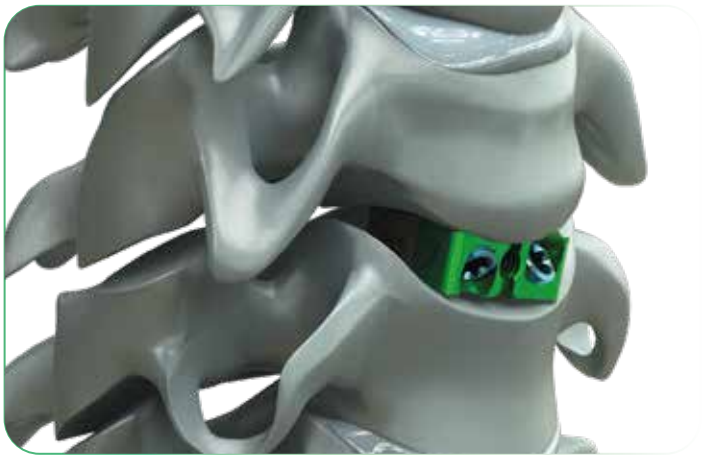
Select the appropriate screw and attach it to Stand-Alone Cage Fixed Screw Driver (PC 300.30.031). Then, introduce the screw through the Angled Guide (PC 300.30.020) and advance the screw by rotating the I-Handle clockwise (Figure 42)

(Figure 42)

(Figure 43)

Fixed Screw Driver (PC 300.30.031) can advance to the required depth. So that, after selecting the appropriate size of the screw, it should be introduced until the torque limitting handle reaches the limit and the "click" sound is heard which means the screw is fully secured. (Figure 43)

After the screw is introduced through the Angled Guide (PC 300.30.020), it advances and when its head leans on the socket of the cage, it's secured automatically. The second screw is introduced and secured likewise. (Figure 44)



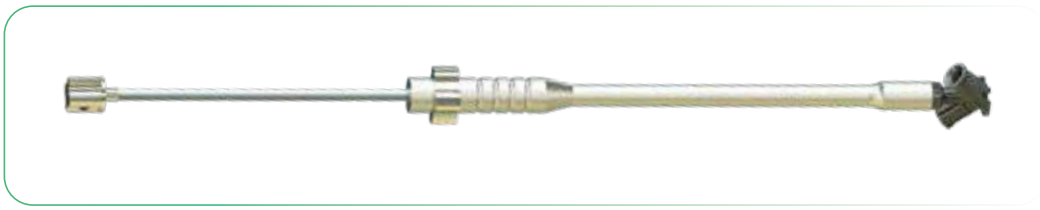
(Figure 44)

When the cage is in the correct position and the screws are locked, the surgical area is closed normally and the operation is ended.

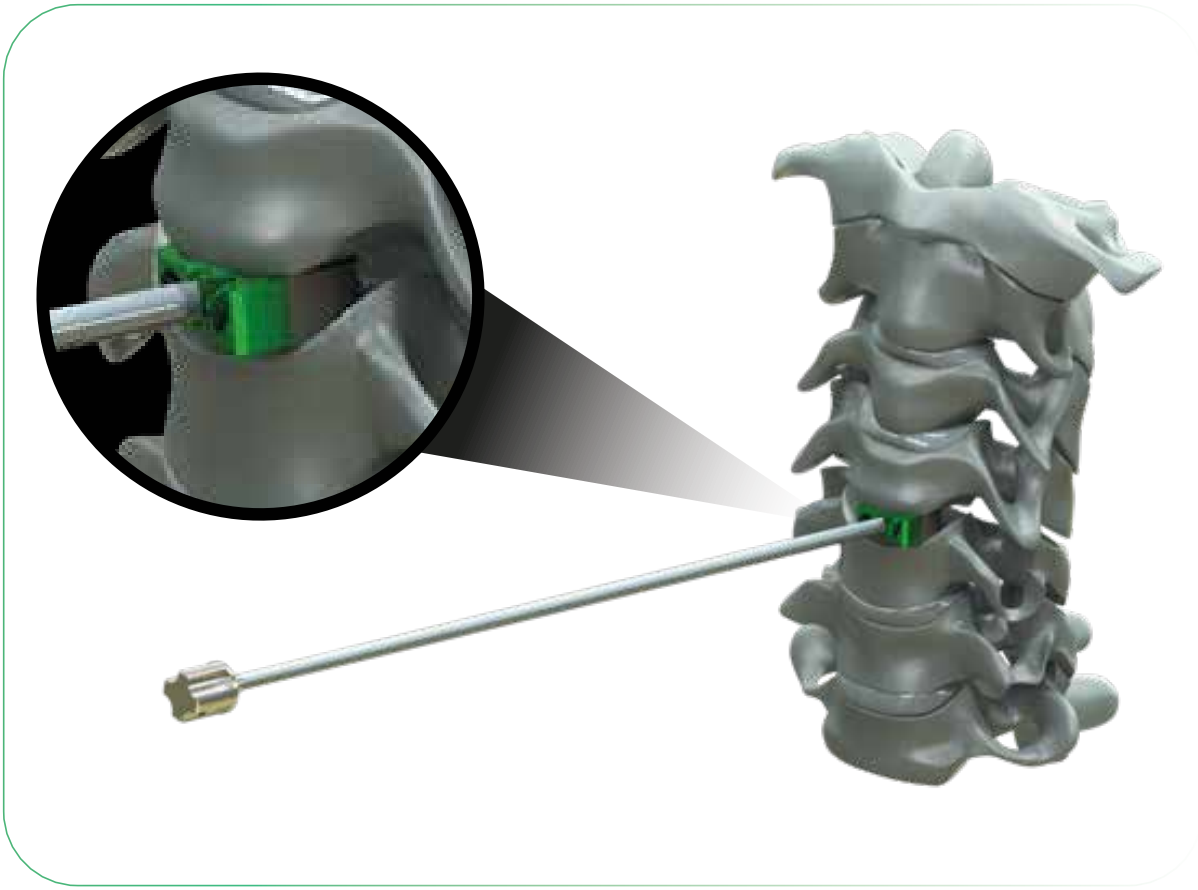
REMOVAL

If removal is required, at first, the screws should be removed by using any type of screwdriver up to your decision and condition of the case.

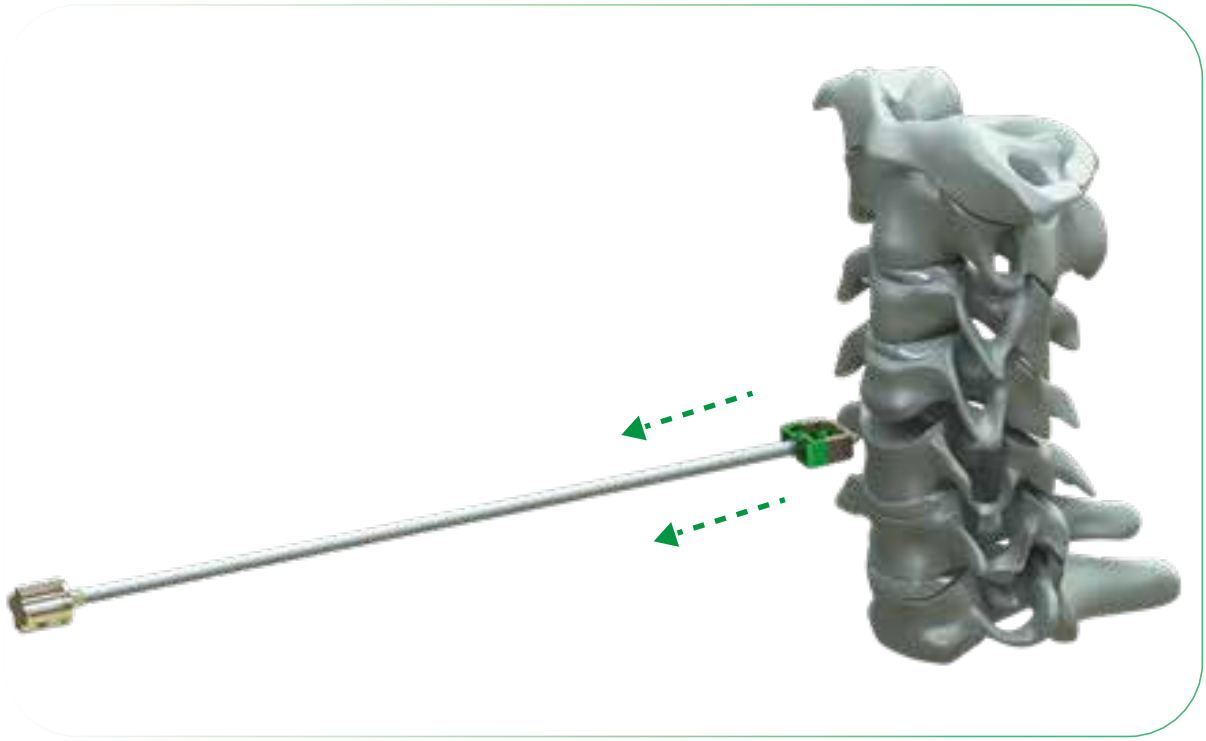
Once the screws are removed, to be more practical, the stand alone cage can be connected with the inner bar of any inserter (STAND-ALONE CAGE INSERTER TYPE-1 / PC 300.30.015 or STAND-ALONE CAGE INSERTER TYPE-2 / PC 300.30.016) and it can be pulled out easily. (Figure 45, Figure 46, Figure 47)



(Figure 45)



(Figure 46)



(Figure 47)

Surgical Technique Guide

Anterior Cervical Peek Cage with Screws

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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