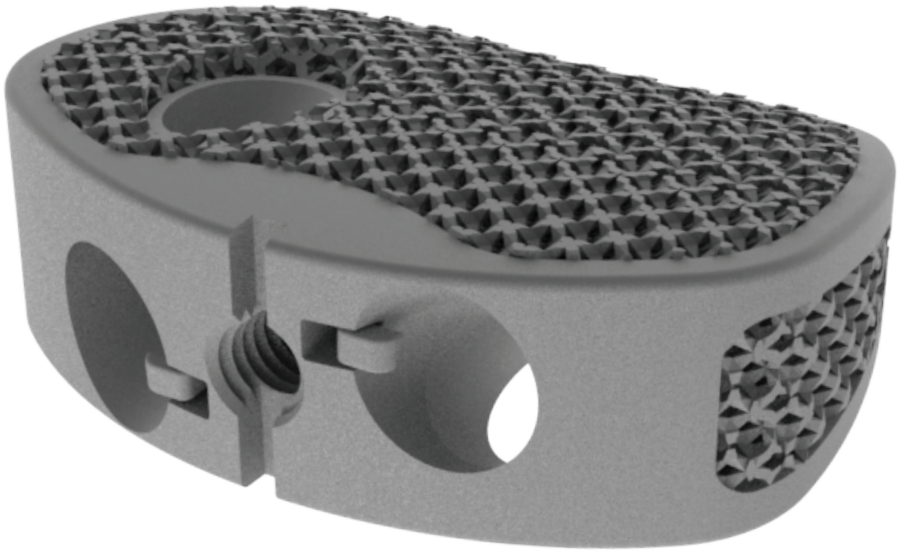
DIVA 3D

ALIF



SURGICAL PROCEDURE

NovaSpine

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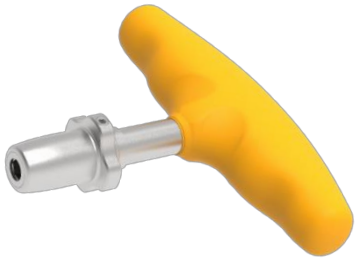
NovaSpine does not practice medicine. Each physician should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training physicians have received.
The Instructions For Use of the DIVA 3D device must be read carefully before using the device.

INSTRUMENTS RANGE

STRAIGHT HANDLE
SIMDC159

T HANDLE
DLM103



STRAIGHT CURETTE
DLCDS123

TRANGULAR CURETTE
DLCDT124

IMPACTOR
DLICB120

COBB
Standard or Large
DLCOD015
DLCODL016

DISTRACTORS
S.8-16
DLDCB508-516

AWL
DLPCG127

CARDAN AWL
DLPCC347

STRAIGHT SCREWDRIVER
DLTCB119

CARDAN SCREWDRIVER
DLTA128

REMOVAL SCREWDRIVER
DLTD055

LONG KERRISON
DLKL125S

LONG DISC PITUITARY
DLPD126S

TRIAL IMPLANTS

8° Lordosis – S.8-18
DLIE908-18
8° Lordosis SMALL – S.8-18
DLIES1008-18

12° Lordosis – S.8-18
DLIE708-18
12° Lordosis SMALL – S.8-18
DLIES808-18

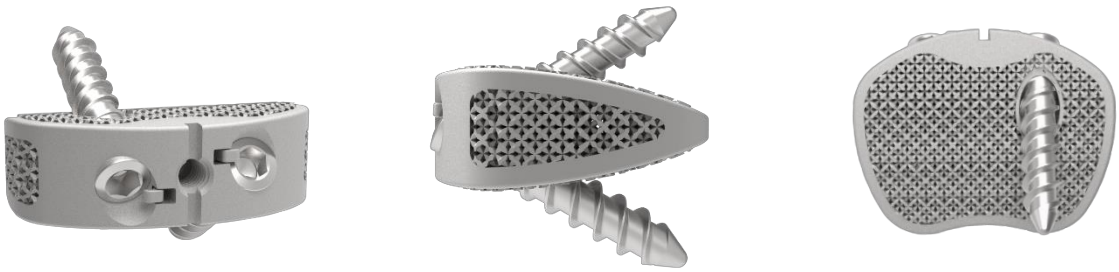
18° Lordosis – S.8-18
DLIE1108-18
18° Lordosis SMALL – S.8-18
DLIE1208-18

OVERVIEW

The DIVA 3D ALIF cage is an interbody cage indicated for the surgical treatment of lumbar disc pathologies in skeletally mature patients.

The design enhances stability and integrates the following features:

- Lordotic profile
- Titanium Alloy Porous mesh
- Two radiographic markers
- Intuitive and simple instrumentation
- Safe Self-locking mechanism
- Self-tapping titanium bone screws Ø5.5



The DIVA 3D blocked cages may be used without additional stabilization system.

INDICATIONS

The DIVA 3D ALIF cages are lumbar anterior cages indicated for interbody spinal stabilization procedures in skeletally mature patients with lumbar degenerative disc disease (DDD) at one or two adjacent levels from L4 to S1. It may be supplemented with NovaSpine's SOCORE posterior fixation system.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

For complete indications, please see the Instructions for Use of DIVA 3D Implants.

PREPARATION

Anterior access and approach

Locate the correct operative disc level and incision location by taking a lateral fluoroscopy while holding a straight metal wire at the side of the patient.

Expose the operative disc level through a retroperitoneal approach. **This step must be achieved giving a particular care to the pre-vertebral vascular structures.**

Discectomy

Perform a thorough discectomy, centered and wide enough to place the DIVA 3D ALIF cage (*Figure 1*). A trial spacer may be used as a template to indicate the width and depth of the space required.

Remove the cartilaginous endplates until bleeding bone using curettes and Cobb. Give special care when scratching the bone in order to preserve the integrity of endplates.

Excessive removal of subchondral bone may weaken the vertebral endplates and result in a subsidence and a loss of segmental stability and disc height.

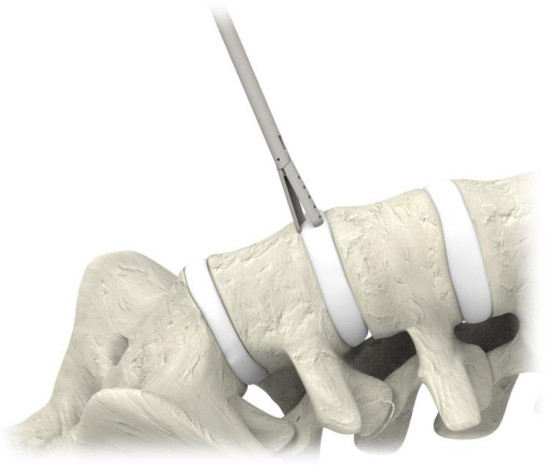


Figure 1

IMPLANT SIZE SELECTION

The initial distractors are used to distract the vertebrae and to give primary information on the optimal size of DIVA 3D ALIF cage to use. Sizes from 8 to 18 are available. Assemble the smallest distractor (S.8) to the T handle and insert it in the disc space with the thin edge parallel to endplates (*Figure 2a*). Rotate the distractor 90° to distract the vertebrae, and test the stability (*Figure 2b*). Sequentially test bigger distractors until an appropriate size is reached.

Use only The T handle with the distractors.

When suitable size is defined, select the corresponding trial implant and firmly attach it to the anterior impactor by screwing the inner threaded shaft into the central hole (*Figure* 3a *& b*).

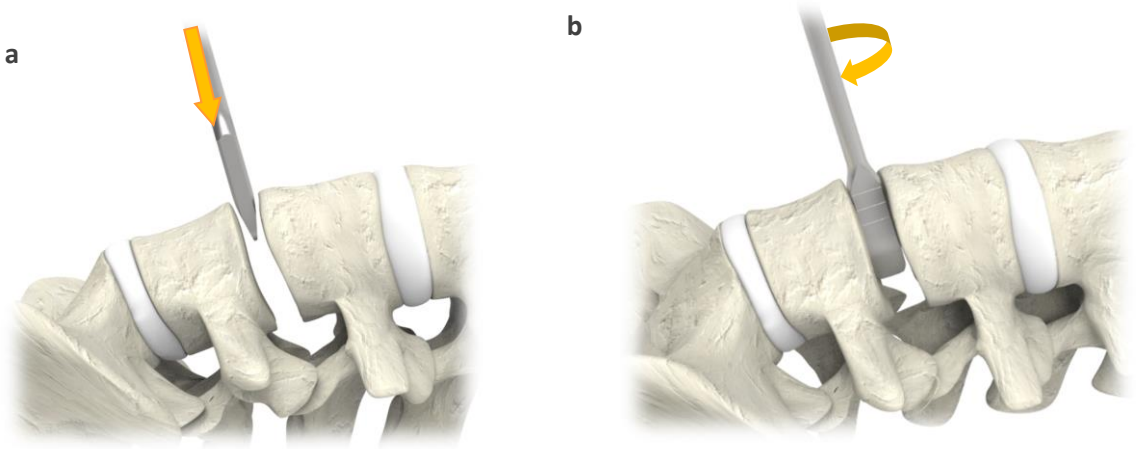


Figure 2

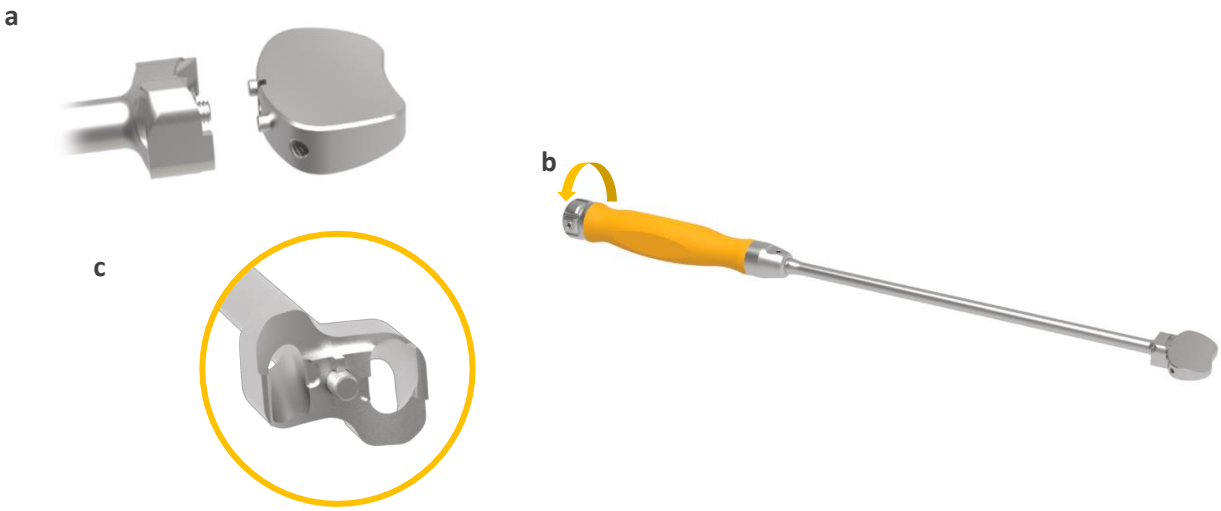


Figure 3

Insert the trial implant in the prepared disc space. A controlled and light hammering on the impactor may be required to insert the trial into the disc space (*Figure 4a*). The impactor, through its guiding holes, must come into contact with the anterior part of the vertebral bodies, which limits the impaction depth. The anterior side of the trial will be slightly (2mm) behind the anterior wall of adjacent vertebrae.

The trial implant must fit firmly and accurately in the disc space, concerning the height, the depth and the width. A radiographic control may help in checking the adequate choice of trial implant.

Test the stability by making a cephalad-caudal movement with the holder. (*Figure 4b*)

If the stability and size are not satisfactory, try more suitable trial implants until the optimal size is obtained.

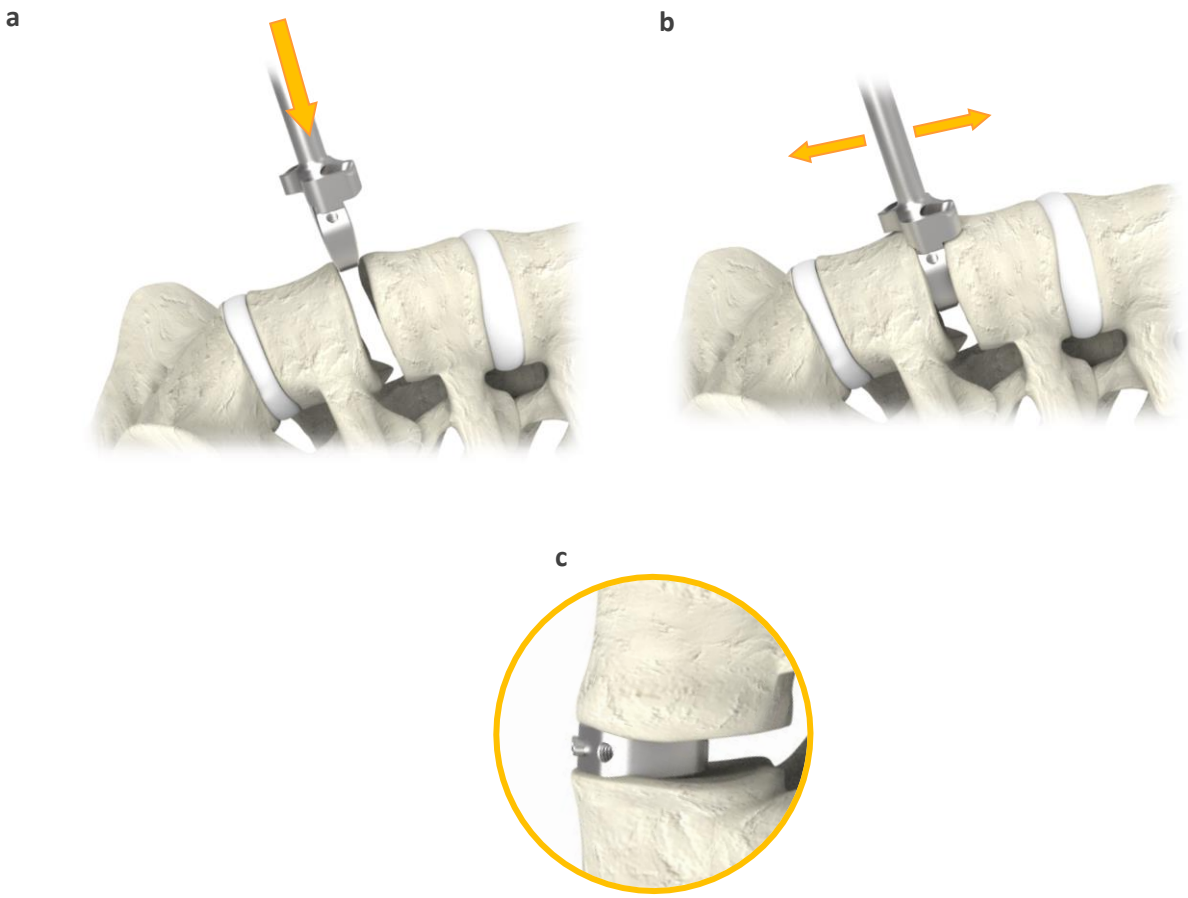


Figure 4

IMPLANT SETTING AND PLACEMENT

Select the appropriate size of DIVA 3D ALIF cage corresponding to the suitable trial implant determined, and attach it to the anterior impactor. The assembly is made by tightening the inner shaft in the anterior threaded hole of the Cage. **The central blade of the impactor must fit in the sagittal groove of the Cage** (Figure 5*a & b)*.

Wrong fixation may result in the damage of the cage or of the impactor.

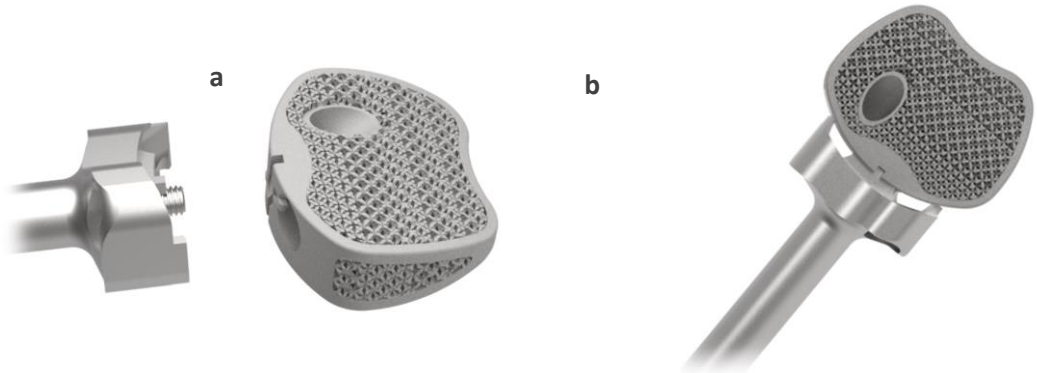


Figure 5

Insert the cage into the disc space until reaching the desired depth (*Figure 6a*) obtained by the contact of the impactor with the vertebral bodies. A controlled and light hammering on the Impactor may be required to achieve complete insertion of the cage. The implant must fit tightly into the disc space, to maximize segment stability by creating a ligamentous tension.

Do not hammer strongly on the cage impactor (especially for small sizes of cages) and do not make forced lateral movements to avoid breakage of the cage or damaging surrounding tissues.

Figure 6

When the implant is in place, use fluoroscopy to confirm appropriate placement of the cage. In the lateral view, the two radio markers must be aligned to confirm the correct orientation of the cage (

*Figure **7***).

Keep holding the Impactor firmly until the final tightening of the screws to avoid posterior migration of the Cage.

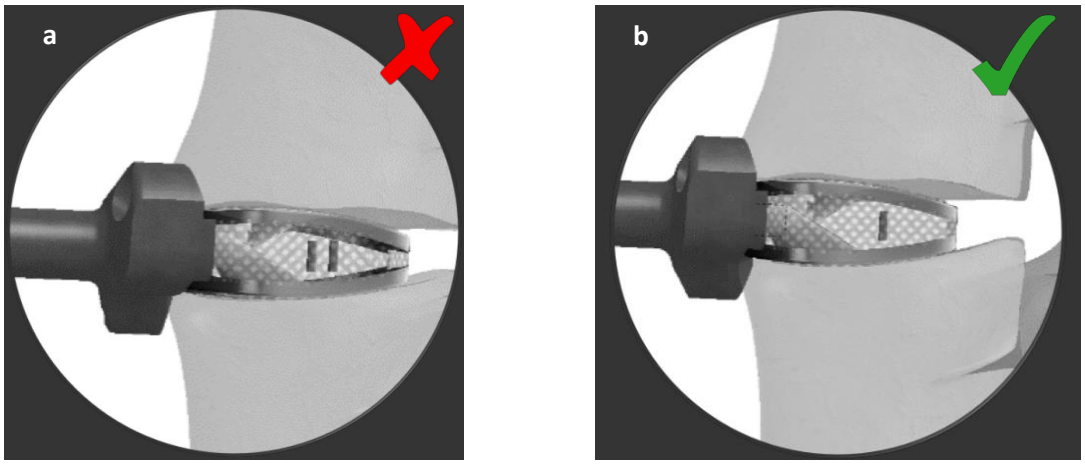


Figure 7

CAGE FIXATION

Screw path preparation

Attach the **cardan awl**, rather than the straight awl, to the **straight handle** to prepare the path of the bone screws (Figure 8).

Figure 8

Slide the awl (cardan version or straight version) through the impactor's guide and through the cage. The awl's direction is guided by the impactor pre-oriented holes (*Figure 9*).

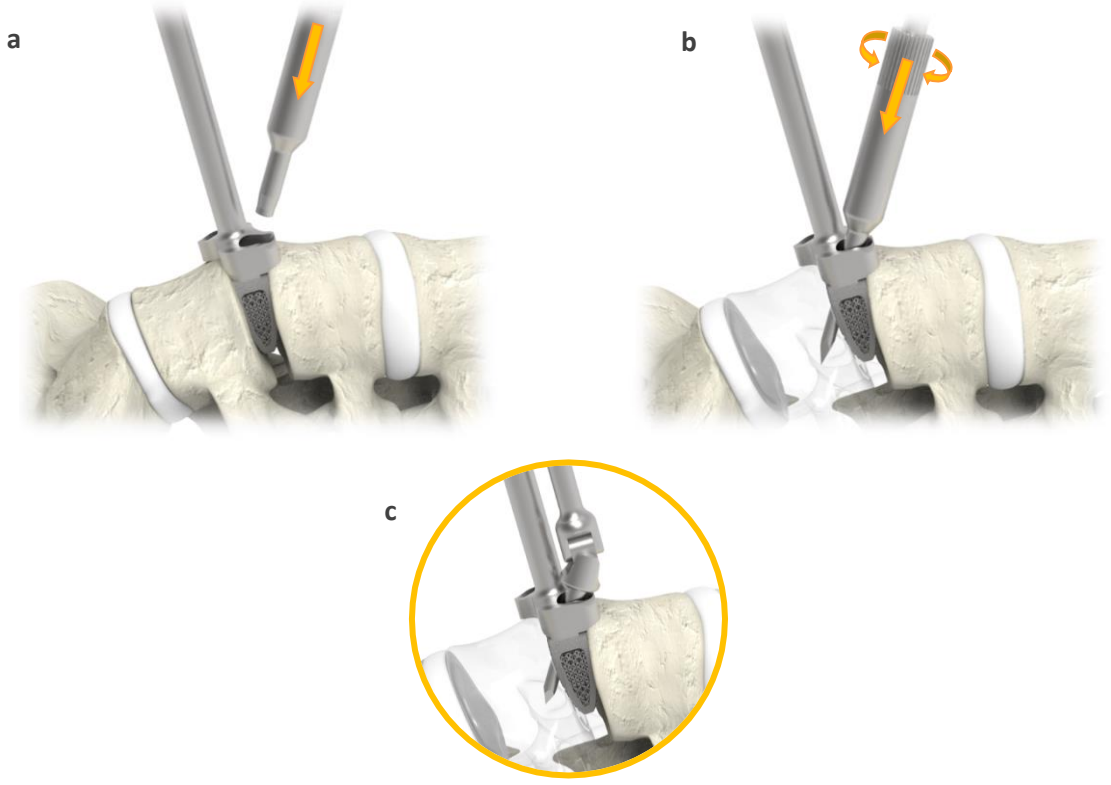


Figure 9

Push it firmly while making back and forth movements to perforate the vertebral endplates and initiate the path for the screw (*Figure 9a & b & c*). Use the awl in the direction of the effort and avoid lateral forces.

The perforation depth is limited by the integrated stop of the awl guide.

Screw placement

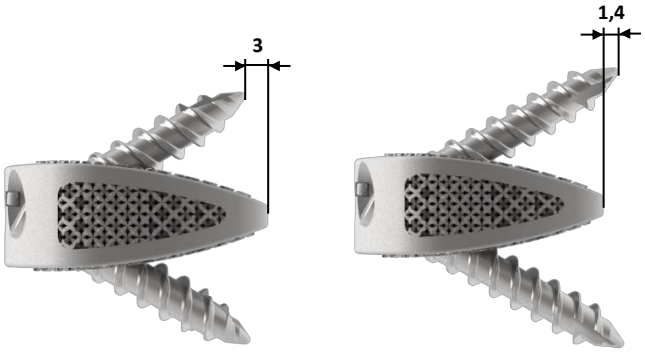
Select the appropriate screw length. The screw length may be defined with radiographic measures.

Recommended screw sizes:

The dimensions in millimeters are only indicative as it corresponds to theoretical values.

The choice of the screw size must be done with thorough analysis of patient anatomy to avoid any damage of surrounding tissues.

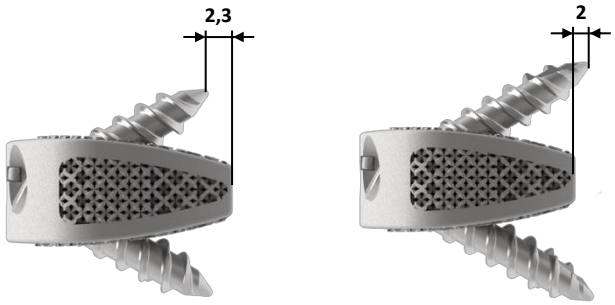
DIVA 3D ALIF blocked cage – Standard footprint



Screw L25
DPAB25

Screw L30
DPAB30

DIVA 3D ALIF blocked cage – Small footprint



Screw L20
DPAB20

Screw L25
DPAB25

Assemble the screwdriver, cardan rather than the straight, to the **straight handle** as explained in Figure 8**.**

Push firmly the screw to attach it to the screwdriver and activate the gripping mechanism. The hexagon of the screwdriver must be completely inserted into the female hexagon of the screw.
Slide the self-tapping screws through the impactor's guiding holes and into the pilot path created by the awl (*Figure 10a & b*).

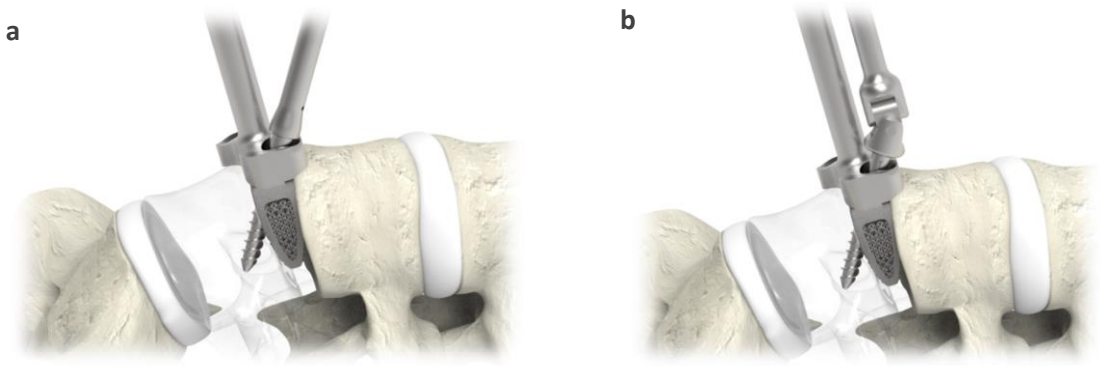


Figure 10

Proceed to screw insertion until overtaking the migration safety mechanism. Continue **slightly** the insertion until the conical heads of the screw grip in the conical hole of the cage (*Figure 11a & b*). **Make firm but not strong tightening**. The integrated stop of screwdrivers ensures that an adequate depth is reached, when they touch the guiding holes of the impactor.

At the end of screw insertion, the head of the screw is **at the same level** than the anterior limit of the cage. **On lateral fluoroscopy, the head of the screw is at the same level than the safety mechanism** (*Figure 12a*).

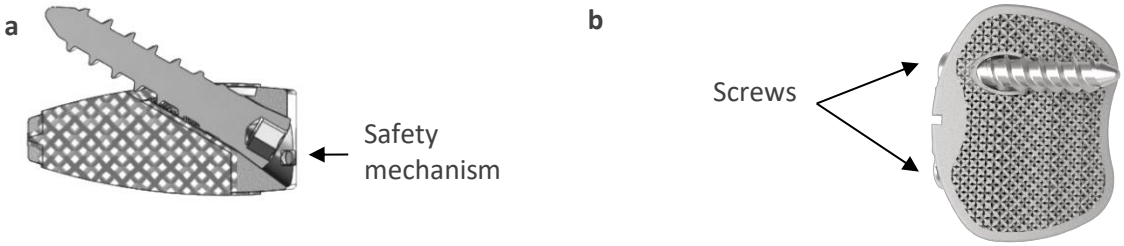


Figure 11

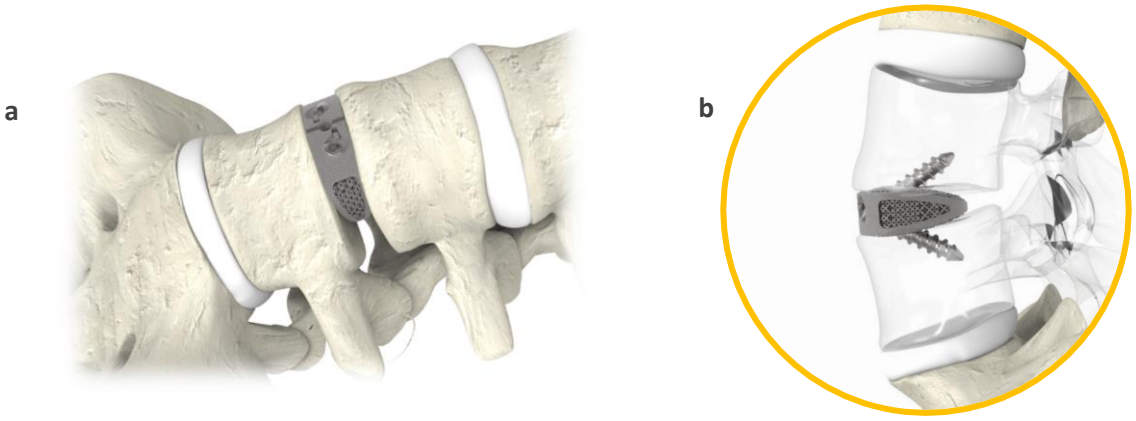


Figure 12

After insertion of the two screws, unscrew the inner shaft of the impactor to release the cage and remove the impactor (*Figure 12a*).

The DIVA 3D ALIF blocked cage is designed to restore the physiological lordosis (*Figure 12*b).

Even if the DIVA 3D lumbar anterior blocked cage is a standalone implant, a posterior fixation with transpedicular screws (SOCORE) may be added to enhance the biomechanical stability of the segment and the stability of the DIVA 3D ALIF blocked Cage. **However, particular care must be paid to material interferences when using several fixation systems.**

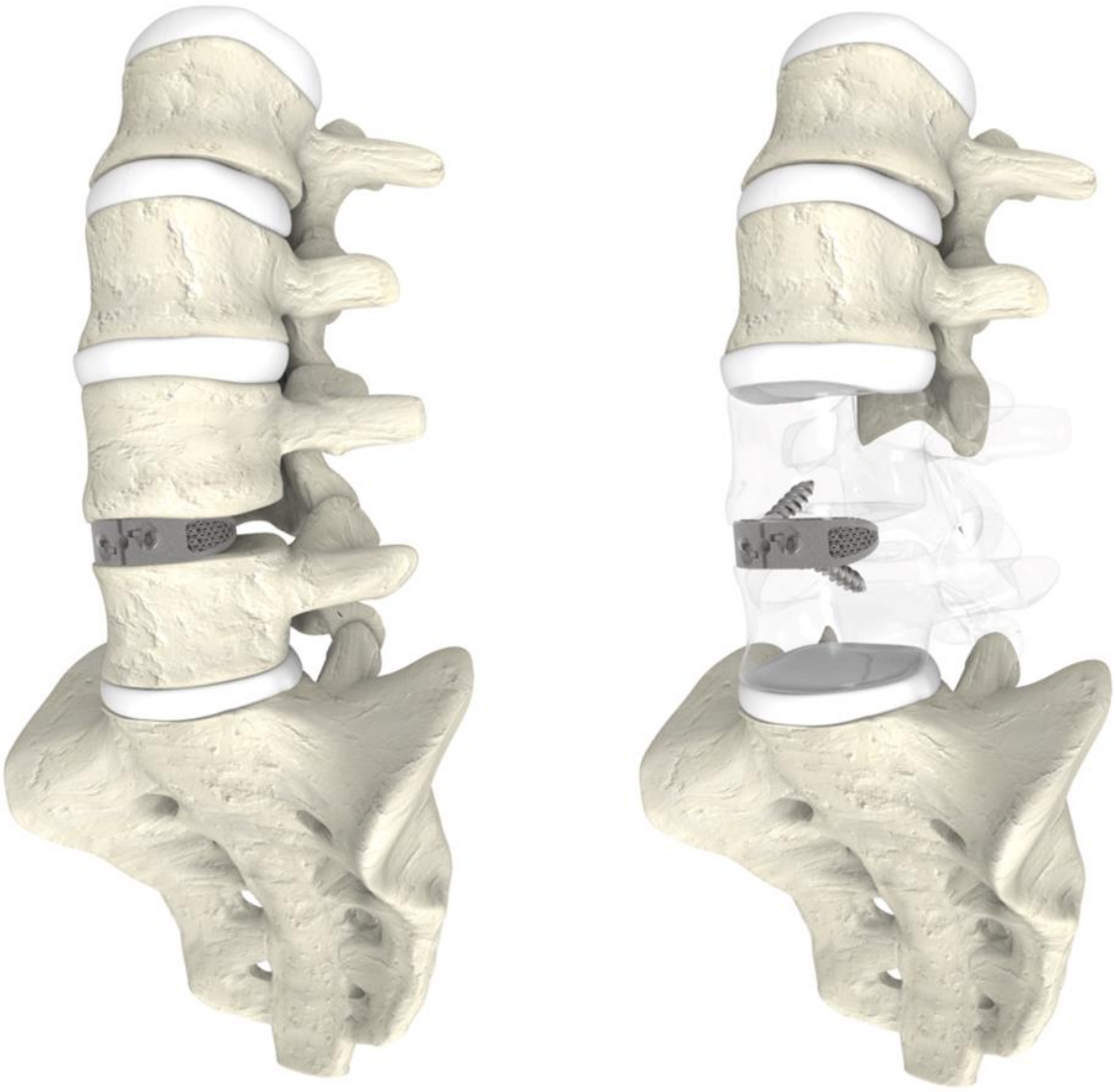


Figure 13

CAGE REMOVAL

Should the cage be removed after screw placement, a special screwdriver should be used to push the locking mechanisms to the side and remove the screws (*Figure 14*).

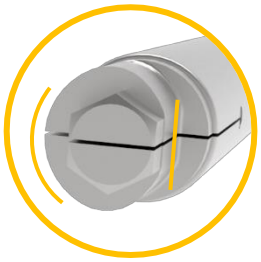


Figure 14

Fully engage the tip of the removal screwdriver into the first screw to be removed. The **flat face** of the screwdriver should be **oriented medially** to allow the insertion of the screwdriver tip in the screw without interference with the blocking button of the cage (*Figure 15a*). Turn the screwdriver counterclockwise to remove the screw (*Figure 15b & c*). Repeat the same procedure with the other screw.

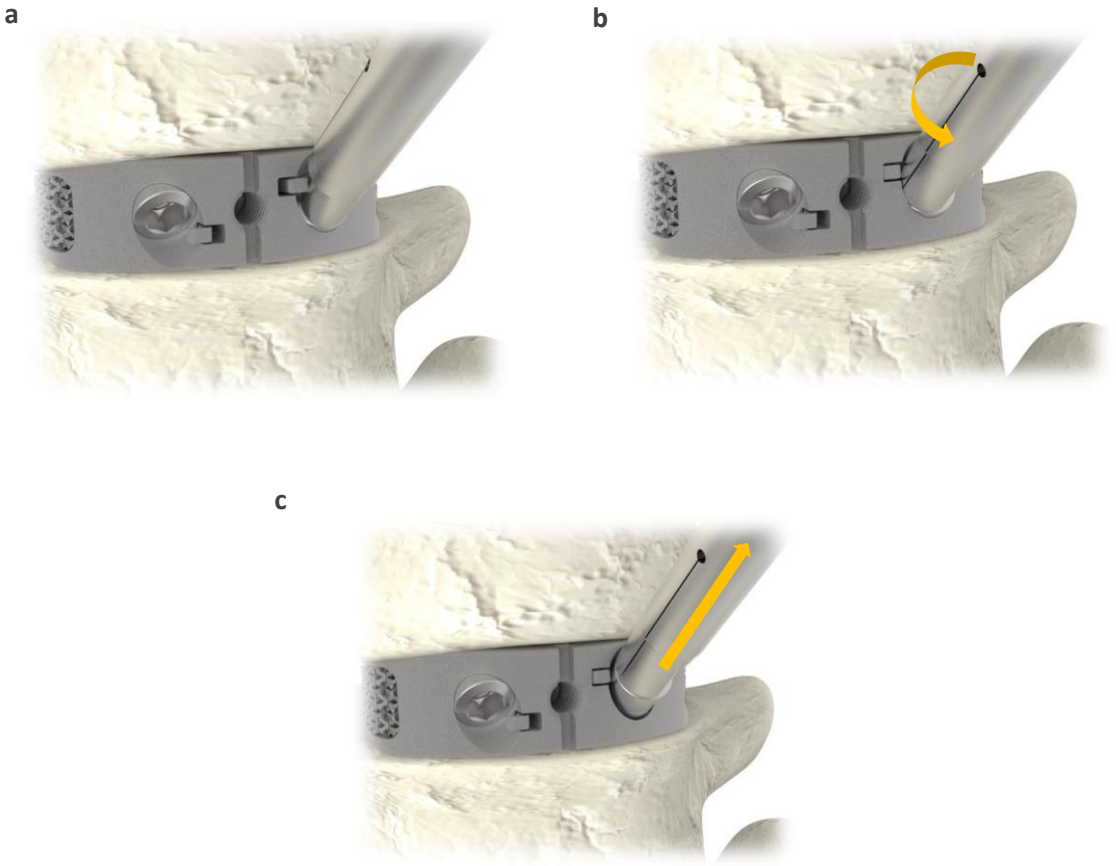


Figure 15

This document is intended exclusively for physician and for illustrative purpose only. The actual techniques employed will always depend on surgeons' medical judgment and can differ from one patient to another. Each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

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