DIVA Queen The Lumbar Blocked Cage

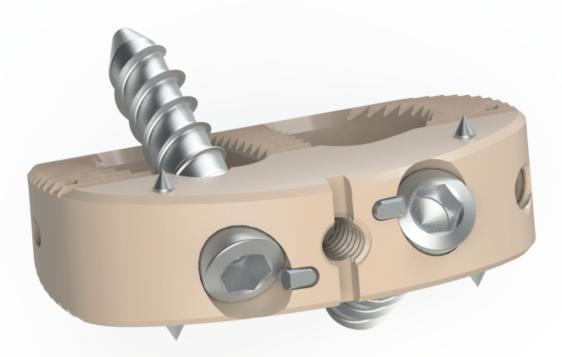






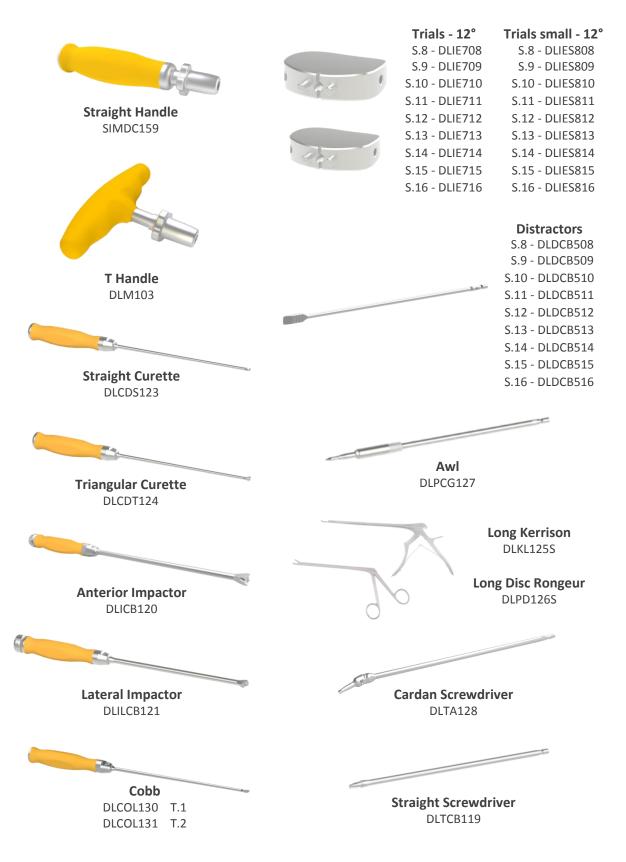
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NovaSpine does not practice medicine. Each physician should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training physicians have received.

The Instructions For Use of the DIVA device must be read carefully before using the device.

INSTRUMENTS RANGE



OVERVIEW

The DIVA Queen is an interbody cage designed to enhance stability and ease the surgical procedure with the following features:

- Large graft holes
- Safe locking mechanism
- Self-tapping titanium bone screws Ø5.5
- Lordotic profile
- Anchoring pins
- Two radiographic markers
- Intuitive and simple instrumentation





INDICATIONS

The DIVA Queen is a lumbar anterior Cage indicated for inter body spinal stabilization procedures in skeletally mature patients with lumbar degenerative disc disease (DDD) at one or two adjacent levels from L2 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 Instruction for Use of DIVA Implants.

PREPARATION

The surgical approach depends on the level to be treated; however, direct anterior access is required for the insertion of the Cage with bone screws.

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.

The DIVA Queen Cage may also be inserted in an Anterolateral approach (See page **Error! Bookmark not defined.**).

Discectomy

Perform a thorough discectomy, centered and wide enough to place the DIVA Queen implant (*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 discal height.

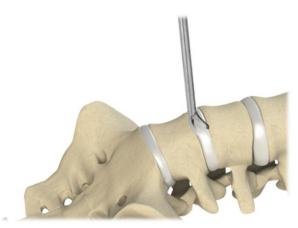


Figure 1

IMPLANT SIZE SELECTION

A distraction clamp may be used to initiate the opening of the discal space. The initial distractors are used to distract the vertebrae and to give primary information on the optimal size of DIVA Queen implant to use. Sizes from 8 to 16 are available. Assemble the smallest distractor (S.8) to the T handle and insert it in the discal 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 adequate size is reached.

Use only The T handle with the distractors in this technique.

When suitable size is defined, select the adapted trial implant and firmly attach it to the Anterior Impactor by screwing the inner threaded shaft (

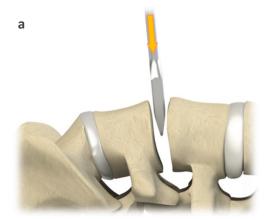
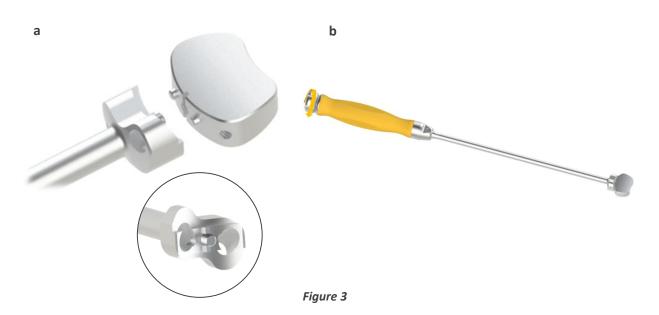




Figure 2

Figure 3*a*&*b*).



Insert the trial implant in the prepared discal space. A controlled and light hammering on the Impactor may be required to insert the trial into the discal space (*Figure 4a*). The anterior side of the trial must be 1 or 2mm behind the anterior wall of adjacent vertebrae. The two guiding holes of the Impactor contribute to limit the impaction.

The trial implant must fit firmly and accurately in the disc space, concerning the height, the depth and the width. A radiographic control will help to check.

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.



b

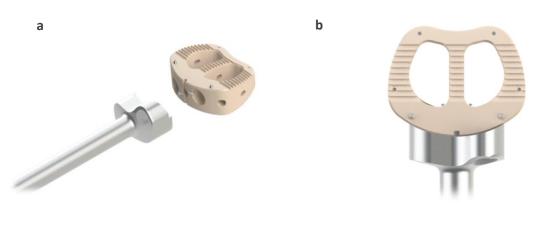


Figure 4

IMPLANT SETTING AND PLACEMENT

Select the appropriate size of DIVA Queen Cage corresponding to the suitable trial implant, 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 impactor must fit in the sagittal groove of the Cage** (*Figure 5a&b*).

Wrong fixation may result in the damage of the Cage or of the Impactor.

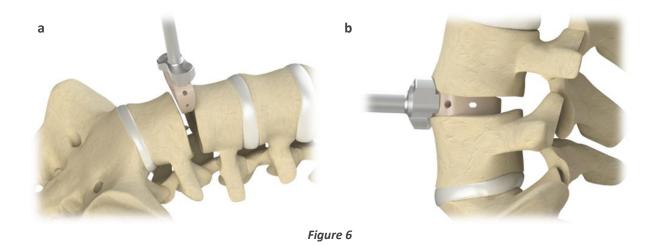




The central implant holes can be filled with autograft or bone substitute before impaction.

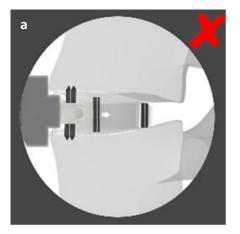
Insert the Cage into the disc space until reaching the desired depth (*Figure 6a*) obtained by the contact between the impactor and the vertebral bodies. A controlled and light hammering on the Impactor may be required to achieve complete insertion of the Cage. For an easy insertion of screws, the anterior side of the Cage should be placed 1 or 2mm behind the anterior walls of upper and lower vertebrae (*Figure 6*b). The implant must fit tightly into the discal space, to maximize segment stability by creating a ligamentous tension.

Do not hammer strongly on the cage impactor (especially small sizes) and do not make forced lateral movements to avoid breakage of the cage



When the implant is in place, use fluoroscopy to confirm appropriate placement of the Cage. In the lateral view, the two anterior stabilization pins and the two posterior 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 migration of the Cage.



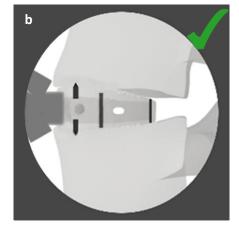
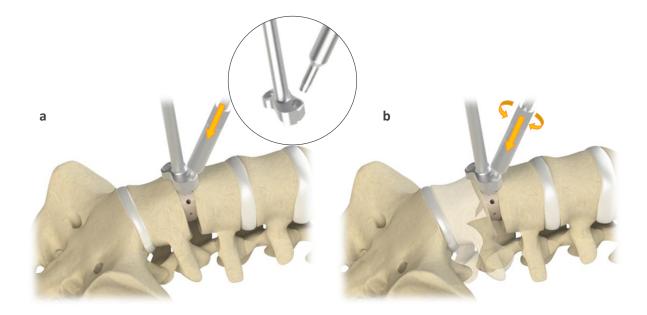


Figure 7

IMPLANT FIXATION

Screw path preparation

Attach the Awl to the **straight handle** to prepare the path of the bone screws. Slide the Awl through the Impactor's guide and through the cage. The awl's direction is guided by the impactor preoriented holes (*Figure 8*).





Adapt carefully the tip of the awl guide into the hole of the cage and push it firmly along its axis while making rotational movements to perforate the vertebral endplates (

Figure 8a&b). Use the awl in the direction of the effort and avoid lateral forces.

The perforation depth is limited by the stop inside the guide of the Awl.

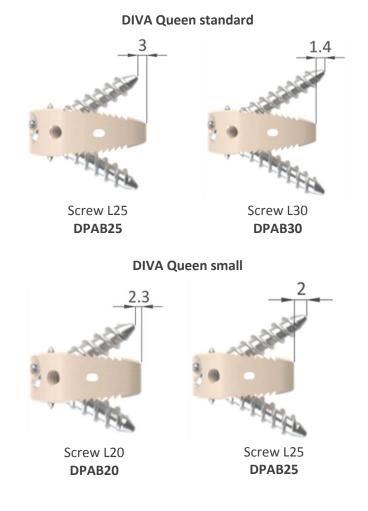
Screw placement

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.

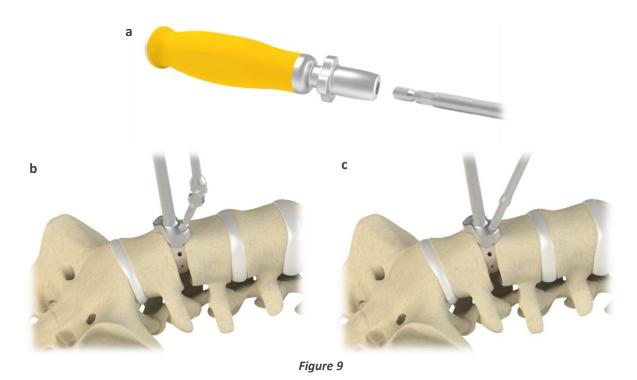
The choice of the screw size must be done with thorough analysis of patient anatomy to avoid any damage of surrounding tissues.



Assemble the screwdriver, straight or cardan, to the **straight handle**.

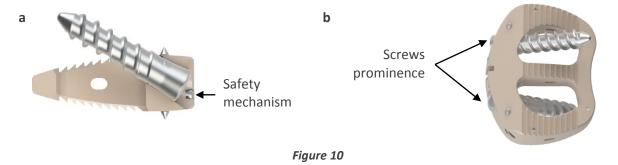
The T handle must NOT be used for screw insertion (*Figure 9a*).

Push firmly the screw to attach it to the screwdriver and activate the gripping mechanism. The hexagon of the screwdriver must be completed 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 9b&c*).



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 10a*). **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 (*Figure 10b*). **On lateral fluoroscopy, the head of the screw is at the same level than the safety mechanism** (*Figure 11b*).



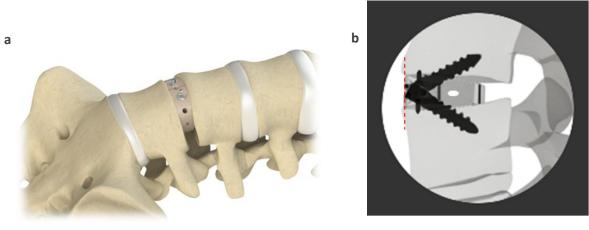


Figure 11

After insertion of the two screws, unscrew the inner shaft of the Impactor to release the Cage and remove the Impactor (*Figure 11a*).

The DIVA Queen Cage is designed to restore the physiological lordosis (Figure).

Even if the DIVA Lumbar Anterior Blocked cage is a standalone implant, it is highly recommended to add a posterior fixation with transpedicular screws (SOCORE) to enhance the biomechanical stability of the segment and the stability of the DIVA Queen Cage. A firm compression of the screws is recommended before the final tightening to avoid the mobility and migration of the Cage.



Figure 13

ANTEROLATERAL APPROACH

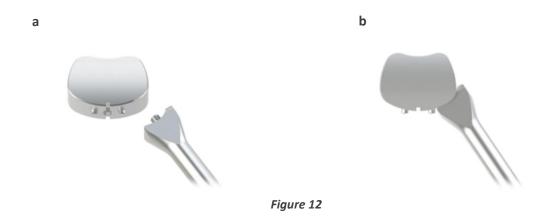
Locate the correct operative disc level and incision location by taking a lateral fluoroscopy while holding a straight metal wire at the side of the patient.

Expose the operative disc level through a retroperitoneal approach.

The discectomy and distraction operations are identical for anterior and anterolateral approach.

The implant size selection step must be performed with the anterolateral impactor.

When suitable size is defined, select the adapted trial implant and firmly attach it to the Anterolateral Impactor by screwing the inner threaded shaft of the Impactor into the anterolateral hole of the trial (*Figure 12*). Insert it in the prepared discal space. A controlled and light hammering on the Impactor may be required to insert the trial into the discal space. The anterior side of the trial must be 1 or 2mm behind the anterior wall of adjacent vertebrae.



Similarly to anterior approach, find the appropriate size of trial implant and select the associated size of DIVA Queen Cage.

Insert the Cage into the disc space until reaching the desired depth (*Figure 13a*). The anterior side of the Cage should be placed 1 or 2mm behind the anterior walls of upper and lower vertebrae (*Figure 13b*).

Do not hammer strongly on the cage impactor (especially small sizes) and do not make forced lateral movements to avoid breakage of the cage

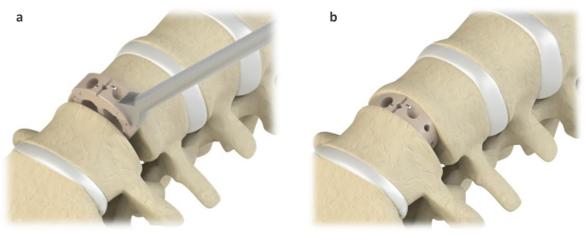


Figure 13

When the Cage is in final position, unscrew the inner shaft of the Impactor to release it and remove the Impactor.

In an anterolateral approach, no screws can be inserted in association with the DIVA Queen Cage. In this case it is imperative to add a posterior fixation with transpedicular screws (SOCORE) to enhance the biomechanical stability of the segment and the stability of the DIVA Queen Cage. A firm compression of the screws is recommended before the final tightening to avoid the mobility and migration of the Cage.

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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