Neo

BEYOND THE EXPECTED

Cage System™

CAGE SURGICAL TECHNIQUE

Explanation of symbol : ⚠ Caution / Warning

1. ACCESS

- The Patient is placed in a frame or table that allows the abdomen to hang freely taking care to protect patient pressure points. Positioning should provide for maintenance of lordosis by appropriate pelvis positioning.

- The use of AP and lateral fluoroscopic control to verify the appropriate spinal level, and one should ensure that clear intra-operative imaging can be obtained.

- Routine posterior approach is made by preserving facet capsules above and below the operative level.

- K-Wires are inserted before bone removal and exposure of neural structures are done. This is to minimize the risk of inadvertent injury to the dura and to use the intact anatomical structures to perform the pedicle targeting.

- **PLIF Approach**
  1. A symmetric partial bilateral laminectomy of the cranial and caudal level is made to expose the medial wall of the pedicles and the origin and insertion of the ligamentum flavum. The ligamentum flavum must be completely removed during decompression while carefully protecting the dura.
  2. The laminectomy can be performed with a small osteotome, chisel, or Kerrison type rongeur.

- **TLIF Approach**
  1. In order to gain transforaminal access to the disc space, a unilateral facetectomy is performed. The side chosen for the approach is often determined by the location of the pathology or the presence of scar tissue. Resect the ligamentum flavum from the anterior surface of the lamina with a curette.
  2. The facetectomy can be performed with a small osteotome, chisel, or Kerrison type rongeur.

- Excised bone can be carefully cleaned and saved as graft material later in the procedure.

- An annulotomy is then done with a scalpel in the Kambin's triangle. The disc material is then removed using rongeur and curettes. This step is carried until sufficient decompression is achieved and until appropriate room is made for the cage(s) to be positioned in the interbody space.

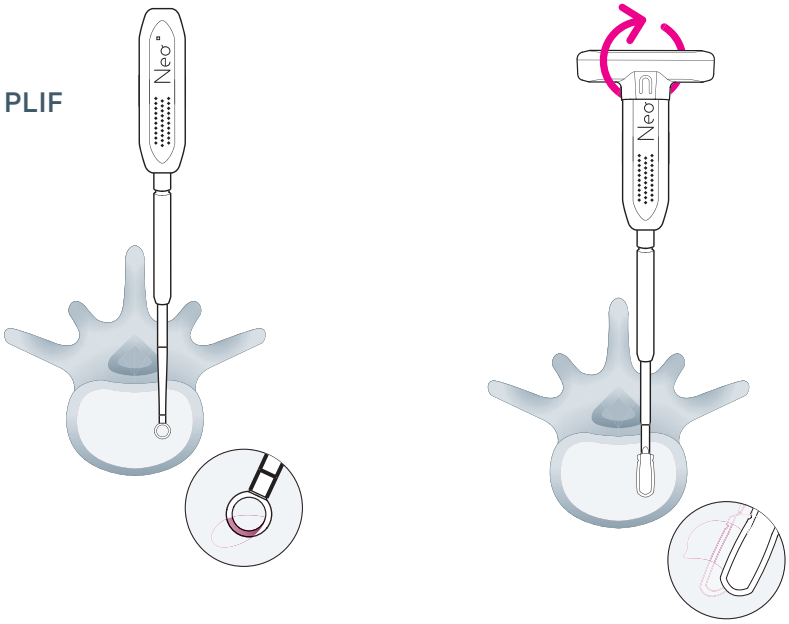
2. DISC SPACE PREPARATION

> Once appropriate amount of disc material is removed, the disc space preparation can be performed. The scrapers / distractors can be used and rotated clockwise to ensure proper disc resection and end-plate preparation.

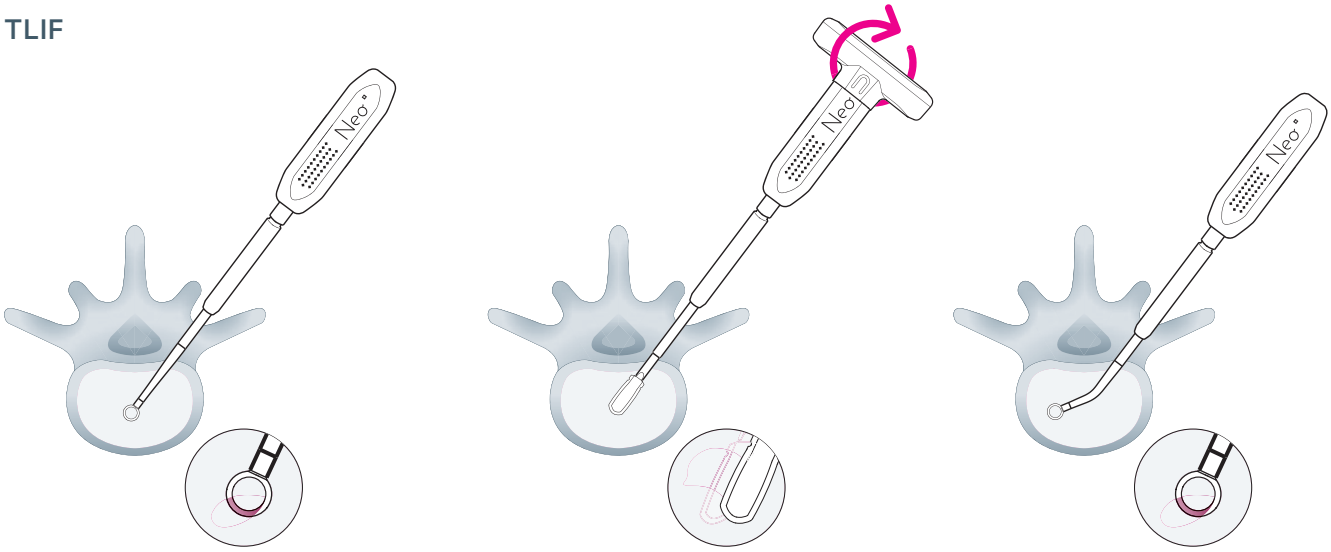
> The straight and curved curettes can be used to ensure perfect end-plate preparation.

> The T-Handle available in the cage instrument kit can be used to facilitate the rotation of the instrument. It is clipped and un-clipped every time a different size of scraper / distractor needs to be used.

PLIF



TLIF



3. TRIAL INSERTION

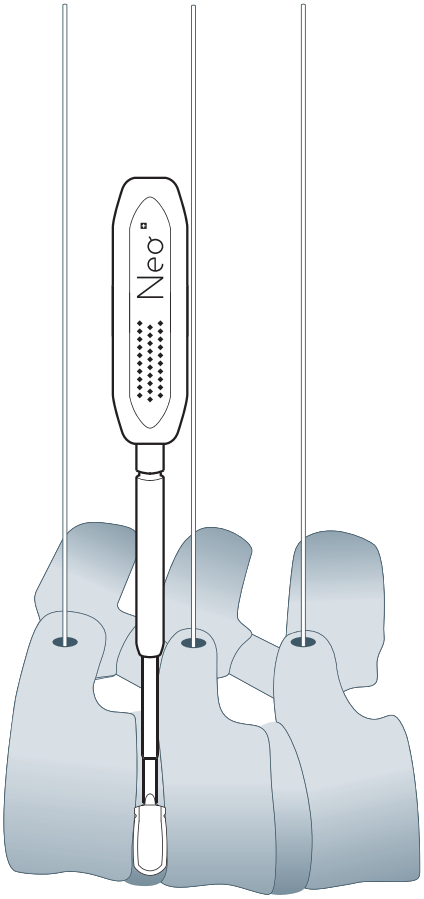
> The insertion of the scraper / distractor in a parallel position to the endplate then rotating it 90° counter-clockwise in the disc space will enable the surgeon to distract the disk space and to verify the optimal final position, height and length of the cage to be inserted. The removable T-handle can be positioned onto each of the scraper / distractor.

> Insert the scraper / distractor by increasing in size until the desired disc height is achieved.

⚠ AP and lateral fluoroscopy is mandatory to confirm adequate placement

> Each straight cage has two sizes in one. Choose the cage with the appropriate height and length according to the size of the last scraper / distractor used.

> **TLIF Approach**
Pre-op planning is required to define which length of cage is most appropriate.



4. CAGE PREPARATION

> Open the single use package of the appropriately sized cage determined in the previous step. The Neo Cage is then filled with prepared bone graft material through the only opening available in the cage protection sleeve. The bone graft is molded inside the cage and through the sleeve by inserting the fingers under the sleeves and using one of the scraper / distractors on the top openings.

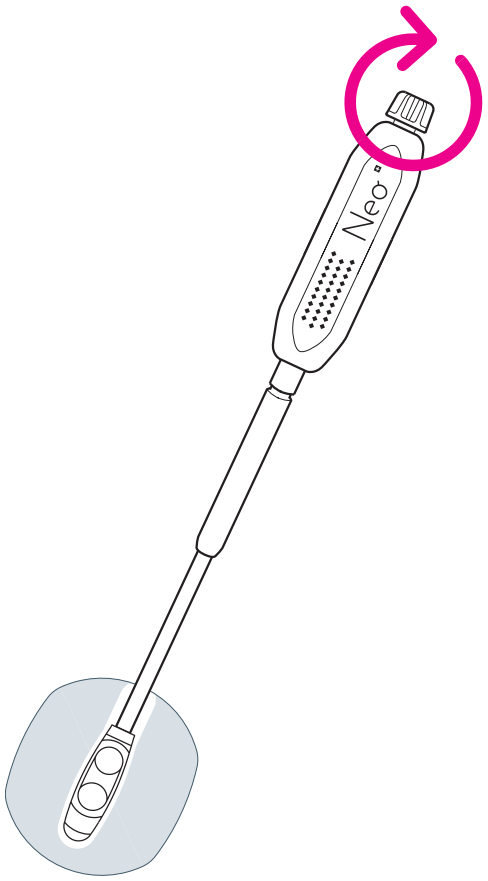
5. CAGE FIXATION

> Once the cage is ready, it is then aligned to the cage holder in the same plane : the cage handle mimics the cage identically, such that the large face of the handle (with the Neo print) is in the same plane as the large face of the cage and the narrow side of the handle is the same plane as the narrower side of the cage.

> Next, the cage is screwed on the cage holder by positioning it in the proximal opening of the protection sleeve and rotating the button situated on the top of the cage holder's handle.

> It is important to check that the cage is appropriately fixed onto the cage holder before implanting it.

⚠ Remove the sleeve from the cage before implanting it.

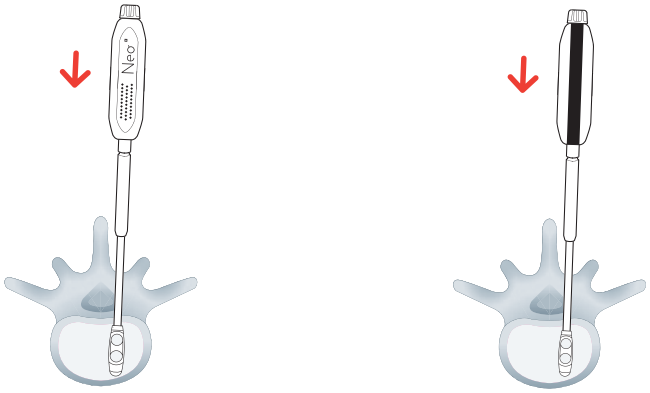


6. CAGE INSERTION

> **PLIF Approach**

1. Before implanting the cage, insert appropriate amount of graft material in the disc space anteriorly and in the mid-space.

⚠ As the Neo straight cages have 2 sizes in one, it is important to check the orientation of the cage before inserting it to ensure proper height selection has been made.
The smaller size when flat side of handle is in cranio-caudal direction.
Bigger size when the handle is turned 90°.



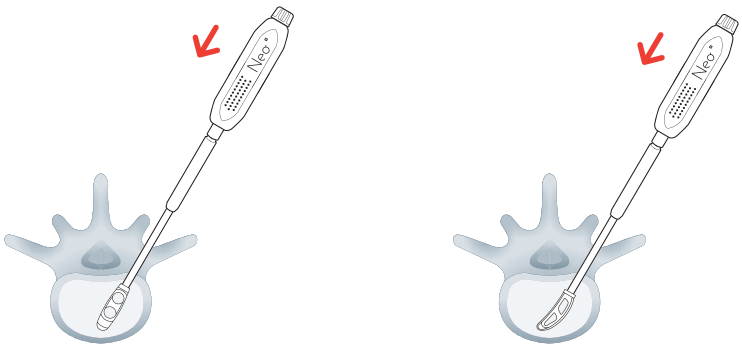
> **TLIF Approach**

1. Before implanting the cage, insert appropriate amount of graft material in the disc space contralaterally.

⚠ As the Neo straight cages have 2 sizes in one, it is important to check the orientation of the cage before inserting it to ensure proper height selection has been made.
The smaller size when flat side of handle is in cranio-caudal direction.
Bigger size when the handle is turned 90°.

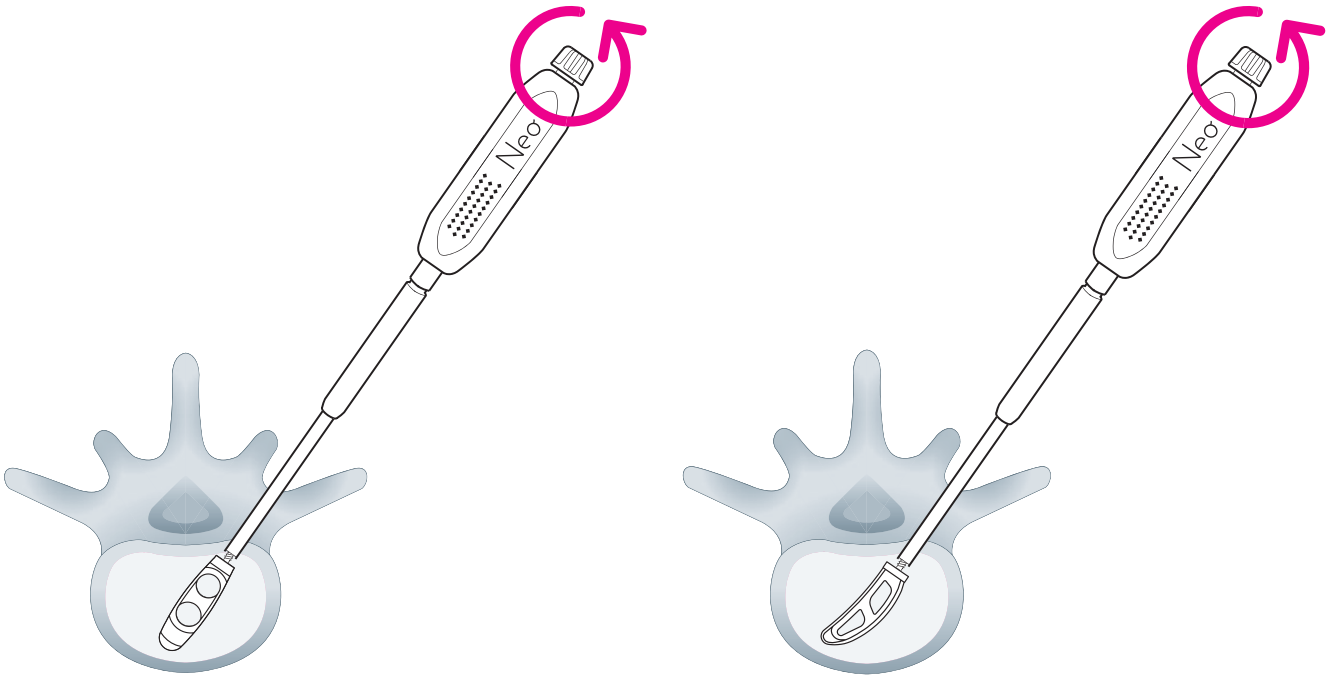
> Gently impact the Neo cage until the optimal position is achieved.

> AP and lateral fluoroscopyis mandatory to confirm adequate placement.



7. CAGE RELEASE

> Once appropriate positioning is achieved, release the cage in position by unscrewing it from the implant holder using its posterior button.

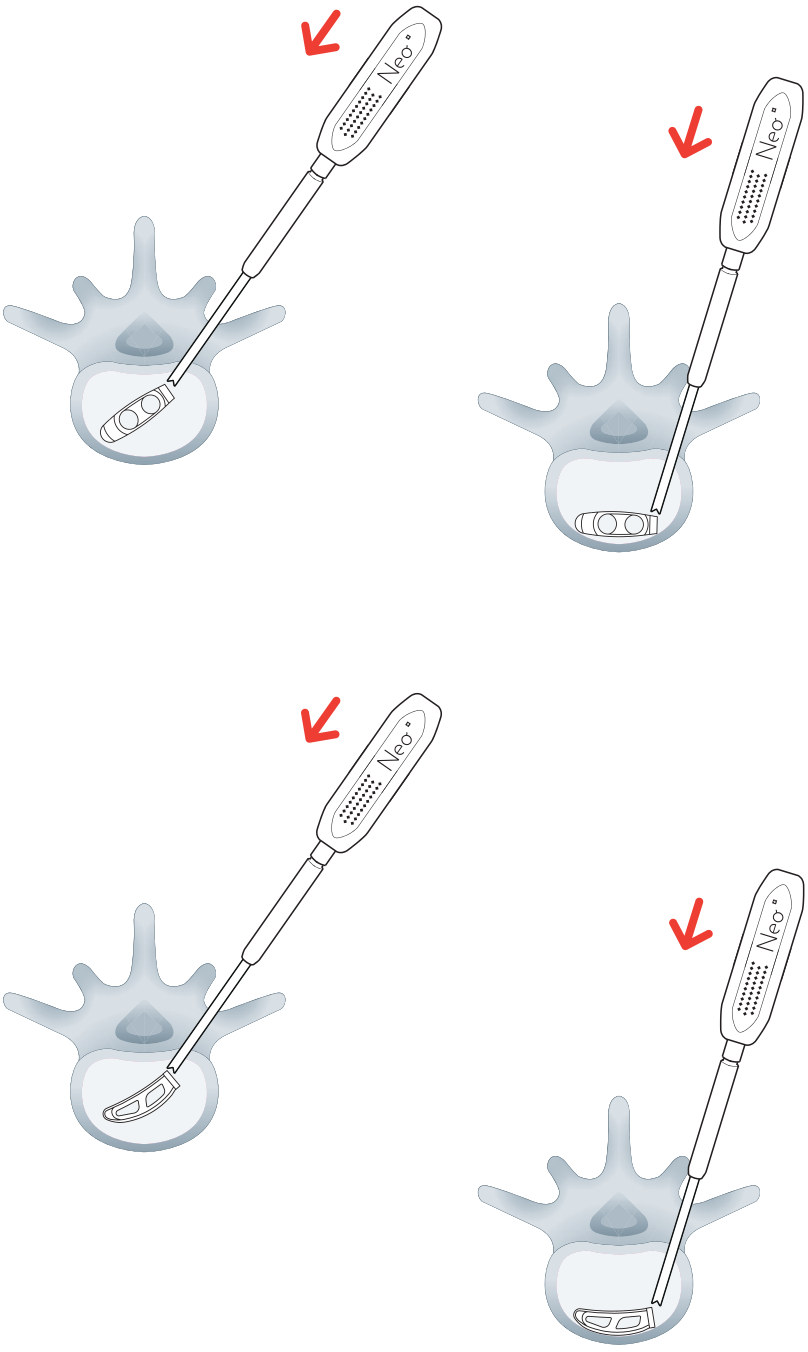


8. CAGE ROTATION (TLIF ONLY)

> **TLIF Approach**

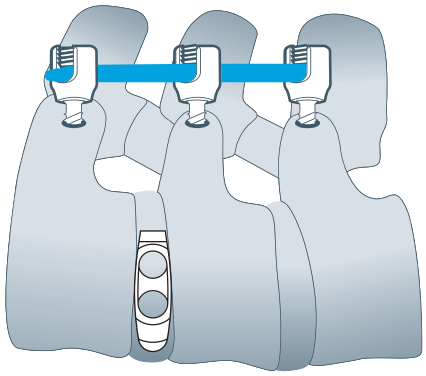
1. The Neo cage can be positioned anteriorly by rotating it using the cage pusher until the right position is reached.
2. Alternatively the straignt cages can be placed in an oblique TLIF position without rotation.

⚠ AP and lateral fluoroscopyis mandatory to confirm adequate placement.



9. POSTERIOR FIXATION

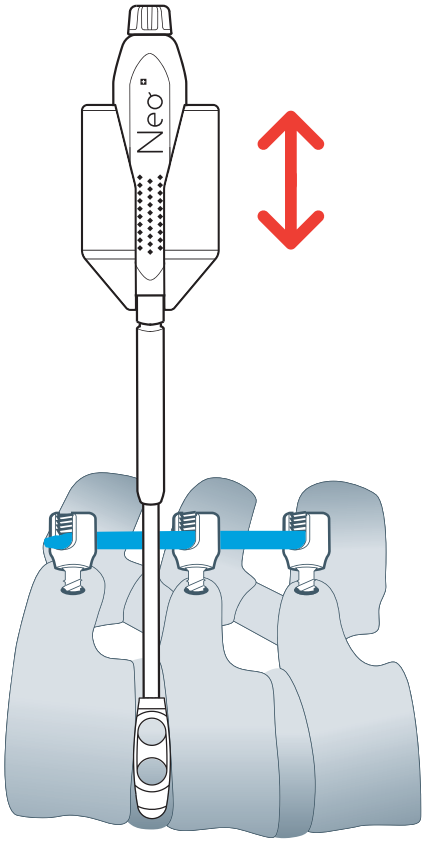
To ensure satisfactory stabilization of the grafted interspace is achieved, segmental posterior fixation follows using standard techniques.



CAGE REVISION

> The Neo cage may be removed by using the cage holder and cage puller instruments. Attach the threaded part to the cage and ensure a strong cage to cage holder connection. Slide the cage puller below the handle of the cage holder and gently pull out the cage by sliding back and forth the cage puller.

> Additional distraction and bone removal may be required before the cage can be safely removed.



INDICATIONS EUROPE AND OTHER COUNTRIES EXCEPT U.S.A. AND CANADA

Neo Cage System™ is intended to be used with bone graft material packaged within the implant to facilitate interbody fusion and to be used with supplemental spinal fixation systems that have been cleared for the use in the lumbosacral spine. The indication for use is Degenerative Disc Disease (DDD) at one or multiple levels from L2 to S1. These DDD patients may also have grade 1 and potentially grade 2 or 3 Spondylolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The Instruments are to be used for the implantation of the above mentioned medical devices.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- This device is not intended for cervical spine use.
- Infection local to the operative site
- Signs of local inflammation
- An overweight or obese patient can produce loads on the spinal system, which can lead to failure of the fixation of the device or to failure of the device itself.
- Pregnancy
- Open wounds
- Any mental or neuromuscular disorder, which would create an unacceptable risk of fixation failure or complications in postoperative care
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis
- Patients with a known hereditary or acquired bone friability or calcification problem
- Suspected or documented allergy or intolerance to the materials used
- Any case not described in the indications
- Any condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Spondylolisthesis unable to be reduced to Grade 1
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any case that requires the mixing of metals from two different components or systems
- Any patient having inadequate tissue coverage over the operative
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Prior fusion at the level to be treated
- Any neuromuscular deficit, which places an unsafe load level on the device during the healing period

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- Severe bone resorption
- Osteomalacia
- Severe osteoporosis

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