

Neo<sup>+</sup>

BEYOND THE EXPECTED

Pedicle Screw System™



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## MIS SURGICAL TECHNIQUE

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## OPEN SURGICAL TECHNIQUE

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Explanation of symbol:  Caution / Warning

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## MIS SURGICAL TECHNIQUE

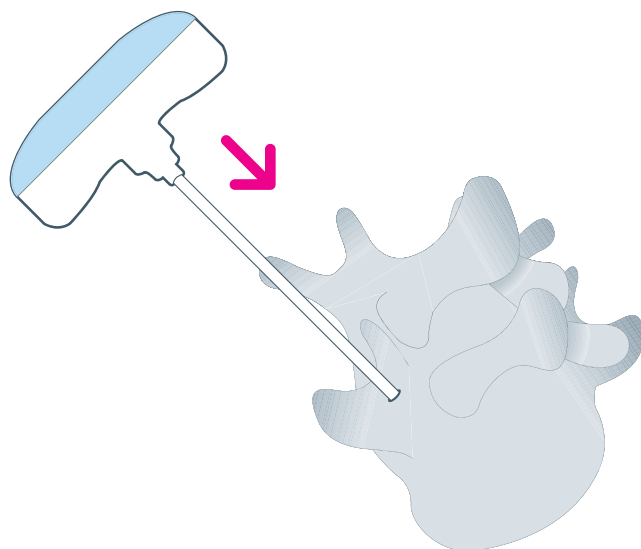
### PRE-OPERATIVE PLANNING

- > Review of preoperative images can be useful to help determine proper entry point, trajectory and potential size of implants to be used. Lateral X-ray or CT-Scan can be used to achieve this goal.
- > DEXA analysis is a useful preoperative information to check the osteoporotic status of the patient.
- > Use an appropriate C-Arm intraoperatively to check implant trajectory, depth and position.

## MIS SURGICAL TECHNIQUE

### PEDICLE TARGETING

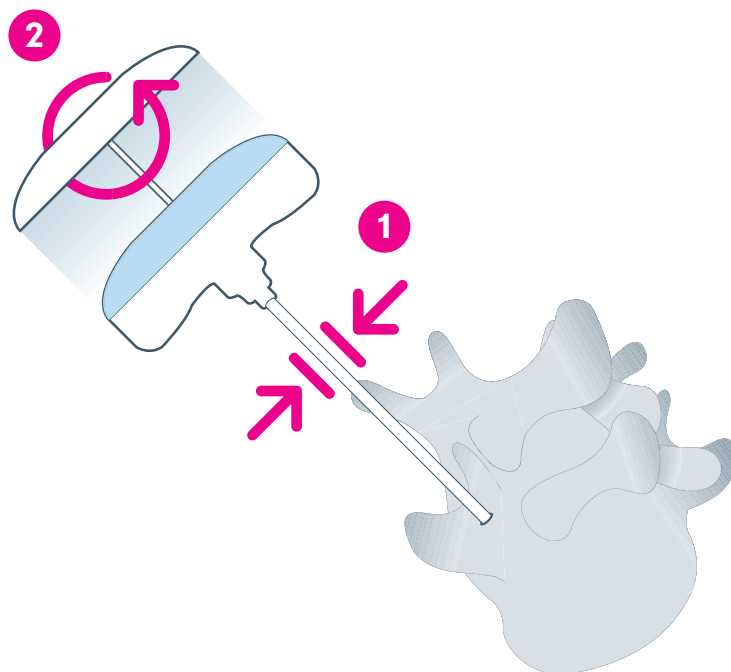
- ⚠ The use of a C-Arm on lateral and AP view is mandatory at every step to monitor the appropriate and safe targeting of the pedicle.
- > Once the skin starting point is correctly defined, an 11 gauge trocar is inserted through the patient skin in the direction of the pedicle. A small skin incision can be performed to limit the potential skin trauma.
- > Use the trocar to perforate the cortical bone at the entry point of the pedicle and push it forward under C-arm AP and lateral controls to navigate through the pedicle.
- > Once the trocar tip has reached the first  $\frac{1}{3}$  of the vertebral body, the needle has reached the right position and the progression is stopped.



## MIS SURGICAL TECHNIQUE

### GUIDEWIRE INSERTION 1/2

- > The inner trocar stylet is removed carefully ensuring the outside cannula is not removed from the pedicle.

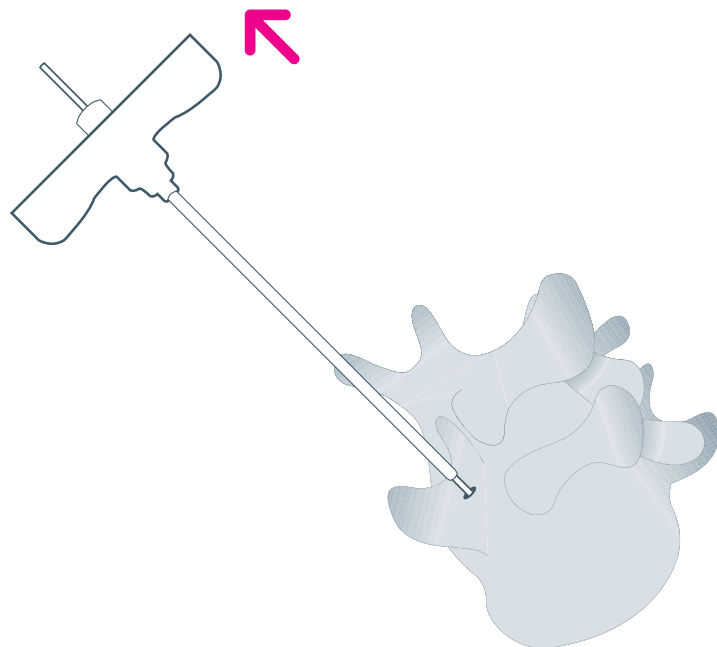


## MIS SURGICAL TECHNIQUE

### GUIDEWIRE INSERTION 2/2

- > The guidewire is then inserted through the cannula into the pedicle and fixed inside the vertebral body by carefully inserting it in the bone. A fluoroscopic control is mandatory to ensure appropriate positioning and to guarantee that the guidewire does not penetrate the anterior wall of the vertebral body. The appropriate positioning of the guidewire should therefore never be deeper than 50% of the A/P length of the vertebral body.
- > The outer shaft of the JamShidi is then removed while securing the guidewire firmly in position to ensure it remains in place.
- > Additional guidewire insertion on the different level to be treated are performed following the same previous steps.

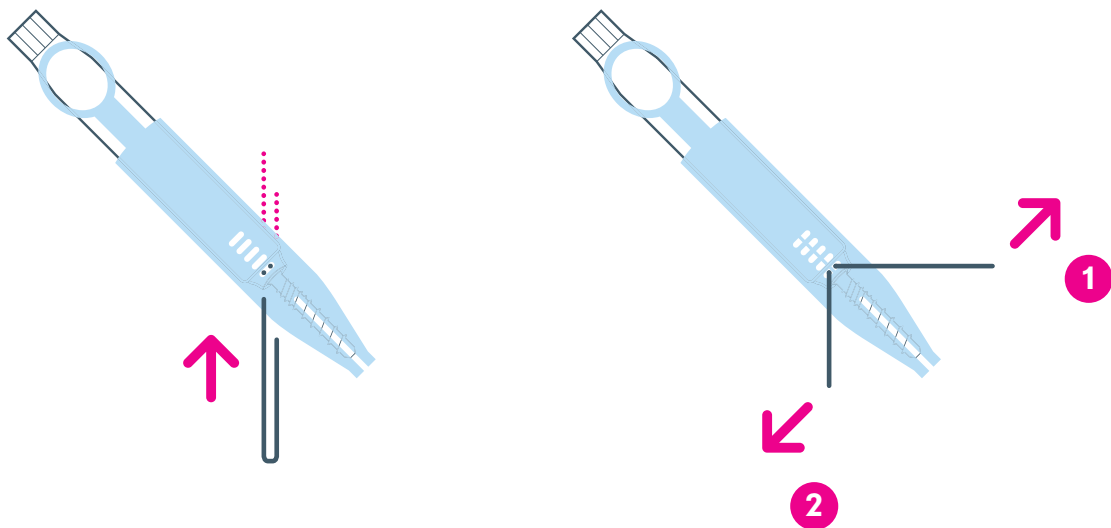
**!** The guidewire should never cross the medial wall of the contralateral pedicle on the AP view.



## MIS SURGICAL TECHNIQUE

### SCREW SELECTION

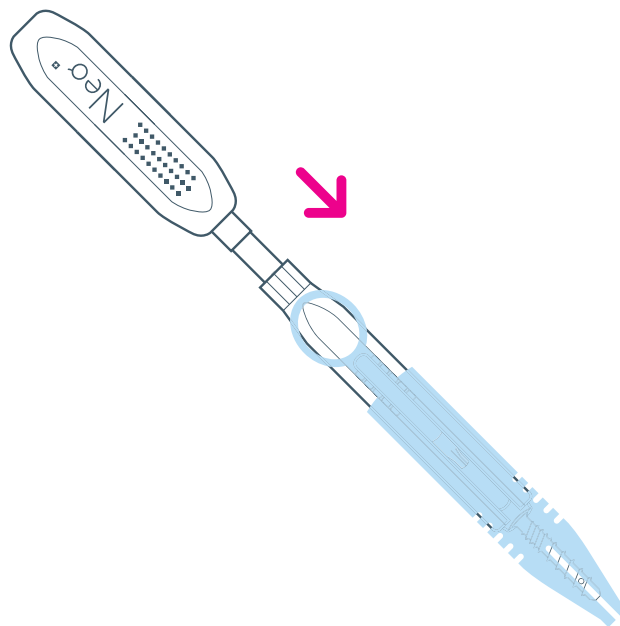
- > Depending on the pedicle size the appropriate screw diameter and length will be selected.
- > Open the appropriate sterile Neo pedicle screw kit.
- > If the surgeon decide to use the monoaxial capability of the Neo screw, the clip should be used and inserted to lock the screw head in a monoaxial position:
  - Insert first the long clip leg through the large insertion window of the tissue dilator and inside one of the small screw head hole.
  - Insert the short clip leg in the second hole
  - Grab the long and small clip leg from the opposite side of insertion and pull it completely to ensure the full insertion of the clip in the screw head.
  - Break the long leg by bending it sideways and proceed in the same way for the short one.
  - Hold onto the legs while breaking them off.



## MIS SURGICAL TECHNIQUE

### SCREW INSERTION 1/5

- > Perform a skin incision of the appropriate length centered around the guidewire. The base plate of the rod measurer can be used to ensure the incision of the right length is achieved. A vertical fascia incision has to be performed to make tissue dilation easier.
- > Insert the screwdriver inside the screw extender and ensure that the tip is well inserted into the screw head.



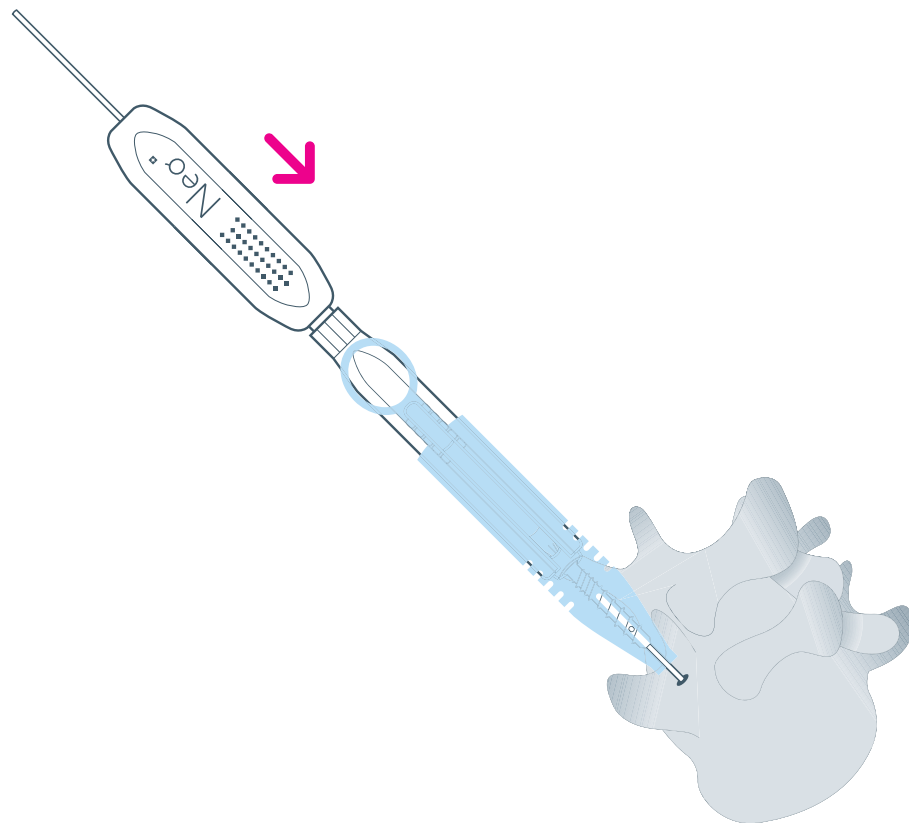


## MIS SURGICAL TECHNIQUE

### SCREW INSERTION 2/5

- > Insert the assembly over the guidewire, through the skin, fascia and the muscle incisions until the bone is reached. The integrated tissue dilator will help progressing through the muscle without damaging them.

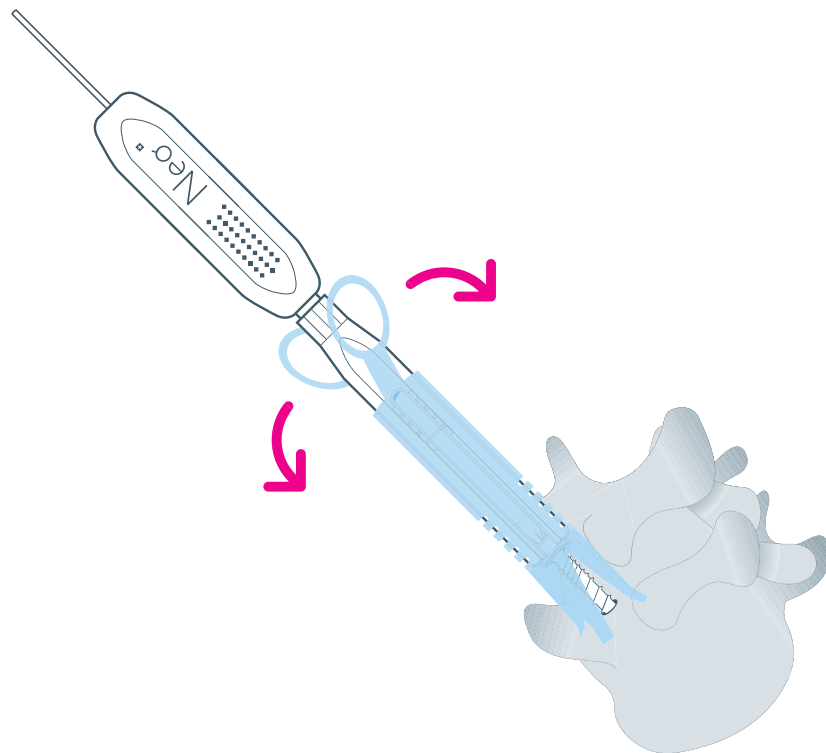
**!** Always ensure the guidewire does not bent or move forward during this step.



## MIS SURGICAL TECHNIQUE

### SCREW INSERTION 3/5

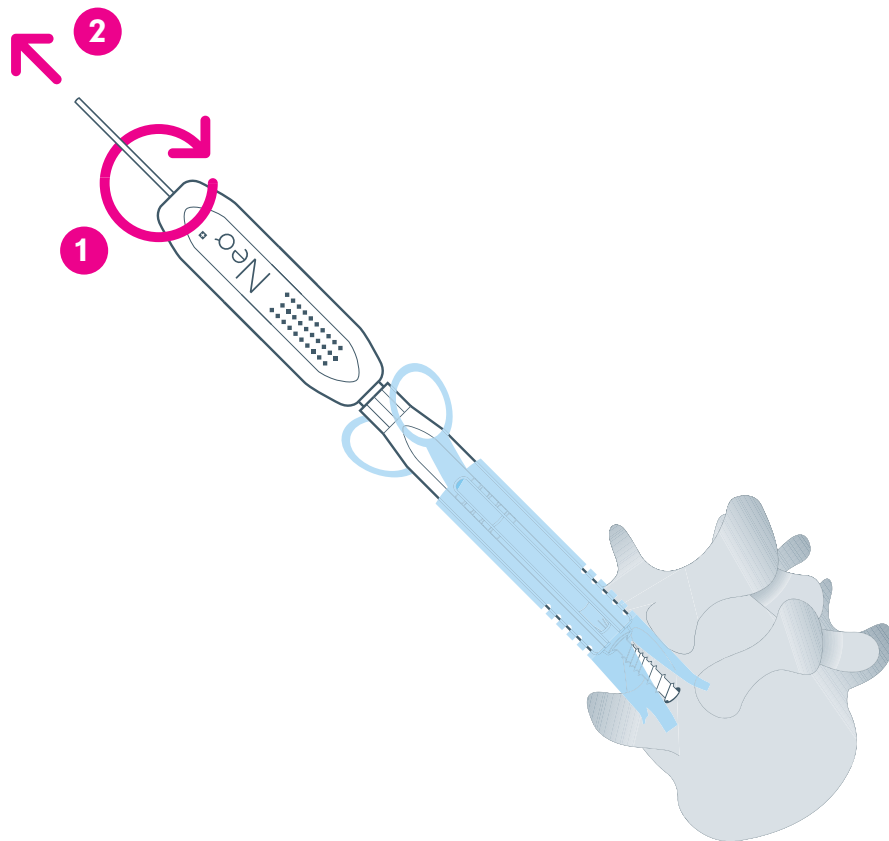
- > Once the bone is reached, the 2 eyelets of the tissue dilators have to be pulled sideways to unlock it.



## MIS SURGICAL TECHNIQUE

### SCREW INSERTION 4/5

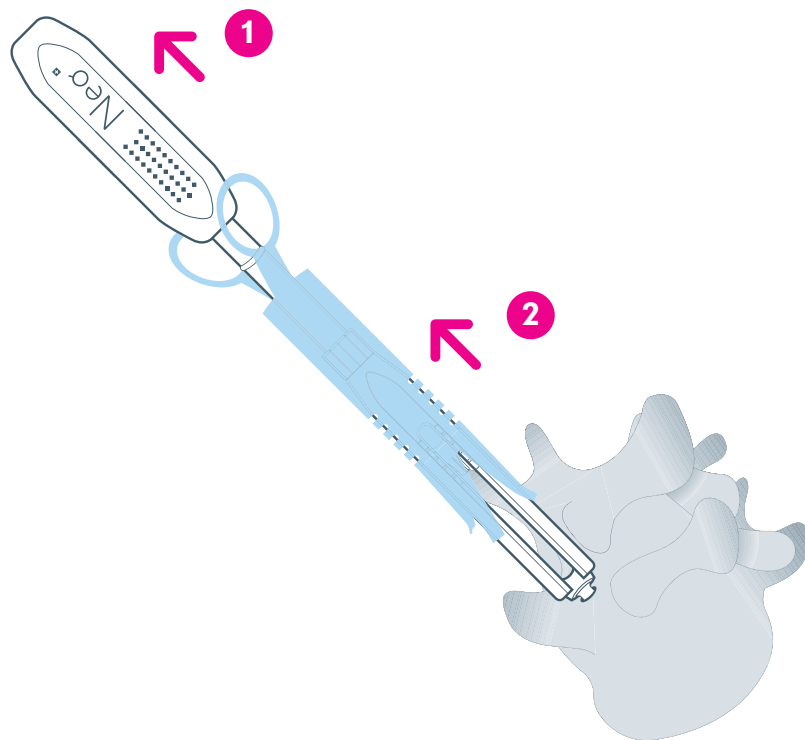
- > Using the screwdriver, the screw is then inserted in the pedicle under fluoroscopic controls to ensure its right positioning while controlling that the guidewire is not being pushed forward.
- > Once the tip of the screw has passed the posterior wall of the pedicle, remove the guidewire to prevent it from advancing and then finalize the screw insertion.



## MIS SURGICAL TECHNIQUE

### SCREW INSERTION 5/5

- > Once the appropriate depth has been achieved the screwdriver should be taken away and the tissue dilator should then pulled out and discarded.
- > When used in polyaxial mode it is important to not drive the screw head too forcefully against the bone in order to prevent the loss of its polyaxial capabilities.
- > Repeat to implant the screws at each additional level as needed.

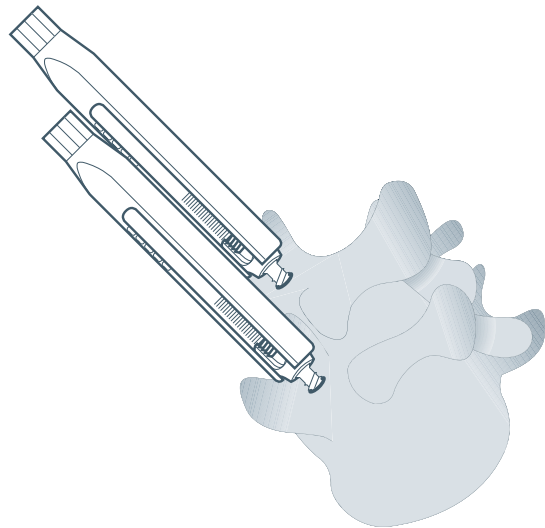


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## MIS SURGICAL TECHNIQUE

### ROD INSERTION 1/5

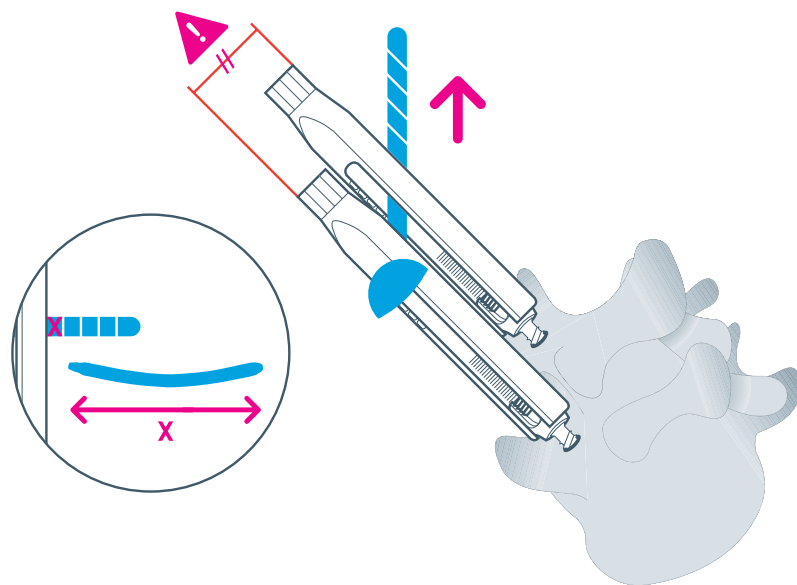
- > Under fluoroscopy, visualize the screw heads to ensure they line up coronally and sagittaly as much as possible: adjust them as needed.
- > Once all the screw extender are in place, rotate the screw extenders to align the tube slots to prepare for rod insertion.



## MIS SURGICAL TECHNIQUE

### ROD INSERTION 2/5

- > Insert the rod measurer through all the screws until the proximal stopper is in contact with the first screw extender. Position the last opposite screw extender in parallel with the first one and read the rod length on the rod measurer: the first readable number is the length of the rod to be selected.
- > The screw depth can be monitored easily by checking on the screw extender height. This will give important information in order to choose the right rod profile as well as understanding how much reduction is needed in case of spondylolisthesis treatment.



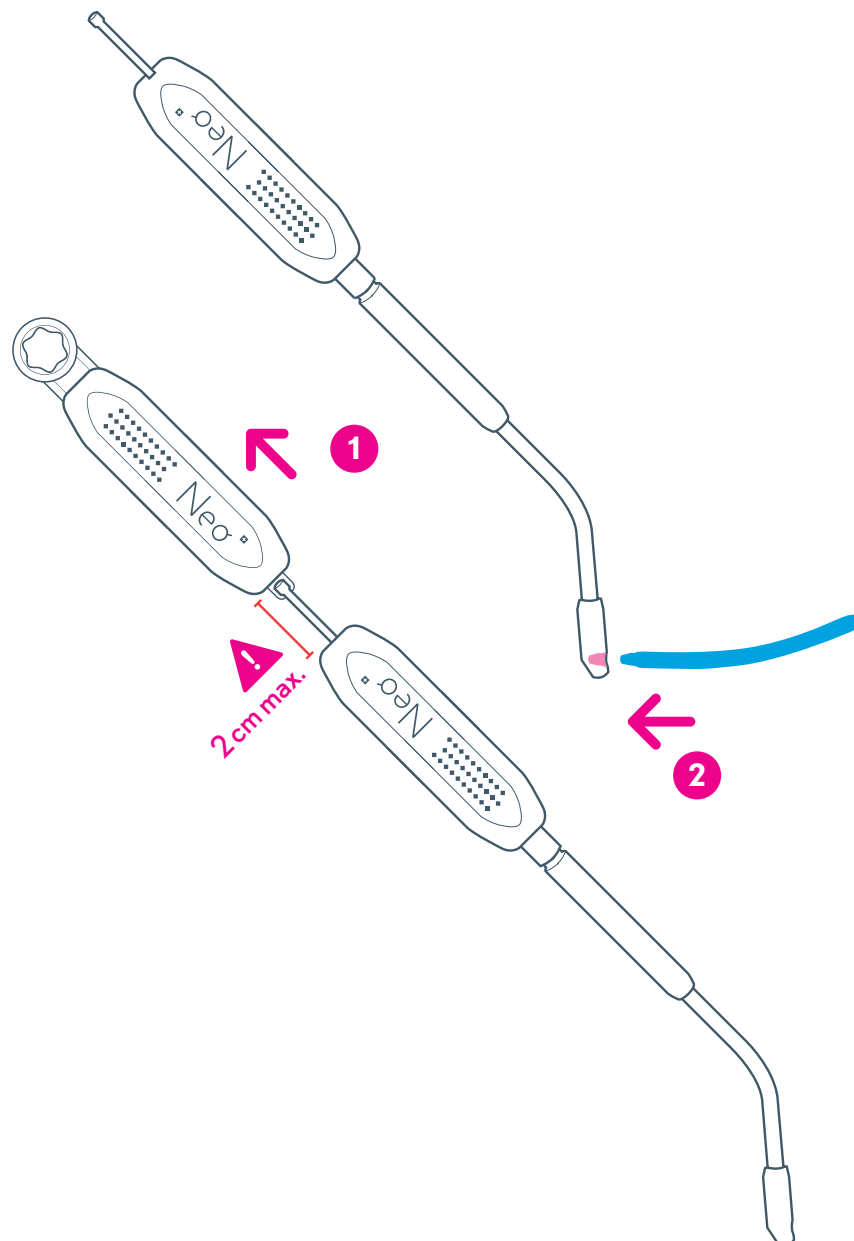
## MIS SURGICAL TECHNIQUE

### ROD INSERTION 3/5

- > Open the appropriate Neo sterile rod kit. Pull the locking notch on the top of the handle of the rod holder by 2 cm in order to ensure the right insertion of the windowed tip of the rod inside the rod holder.

**!** The 400 mm rod is only to be used in open surgery.

- > Position the rod in the rod holder.
- > The notch grabber of the counter-torque handle can be used to ease the process.

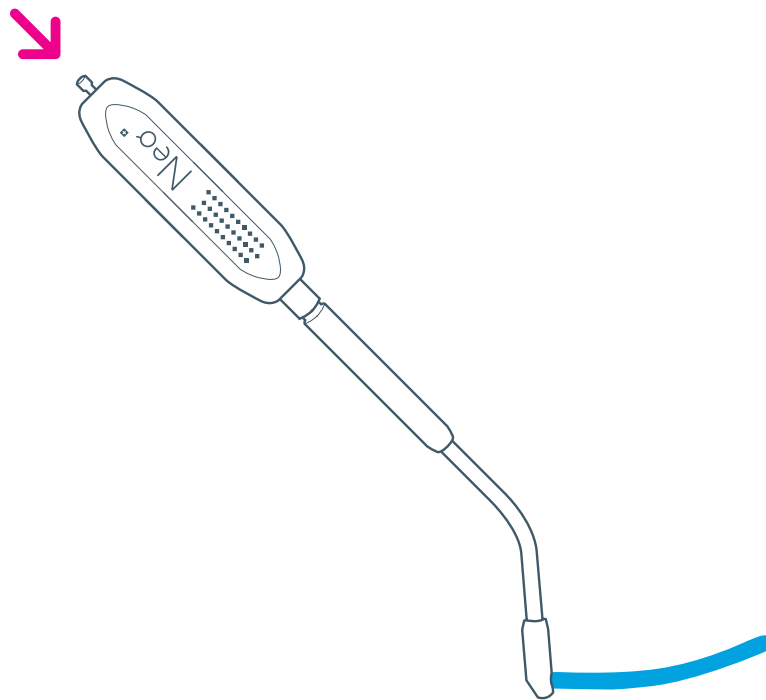


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## MIS SURGICAL TECHNIQUE

### ROD INSERTION 4/5

- > Once the rod is completely inserted in the rod holder slot, lock it by pushing on the locking notch until it is flush with the rod holder handle. The notch grabber of the counter-torque handle can be used to ease the process. Always ensure the right locking of the rod in the rod holder before starting the insertion.



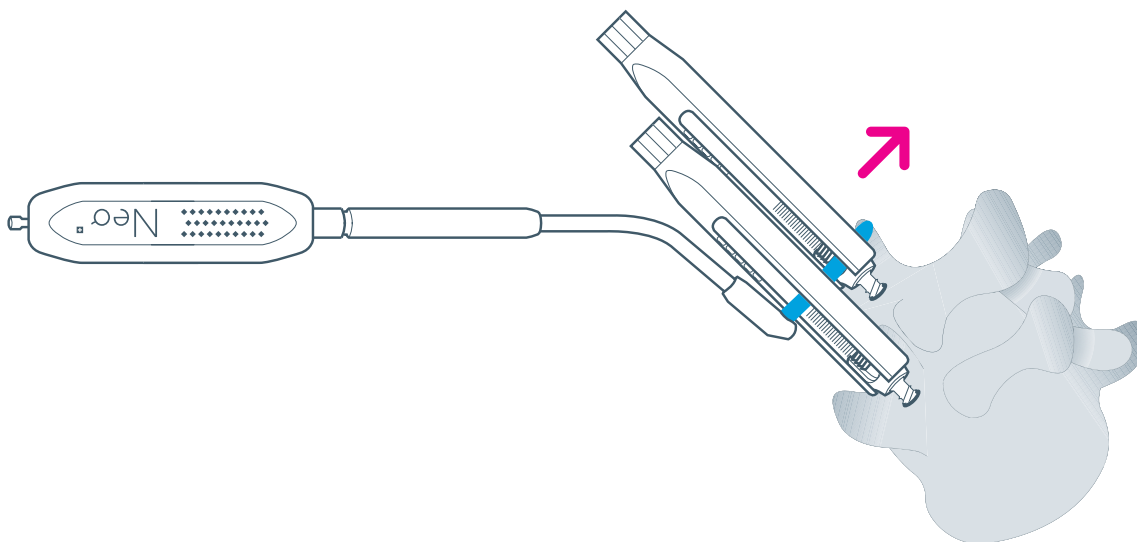


## MIS SURGICAL TECHNIQUE

### ROD INSERTION 5/5

- > Start inserting the rod's bullet tip through the window of the first screw extender under the fascia, and carefully push it through the windows of each screw extender: check that none of the screw extender can rotate anymore to ensure that the rod is properly seated. Push the rod holder until its tip is in contact with the first screw extender. Insertion should always be cranio-caudal when sacral segment is involved.
- > Push the rod holder until the rod sits inside the most distal screw's head.

**!** Confirm the rod position fluoroscopically. The rod should always overhang the most distal screw by a few mm.



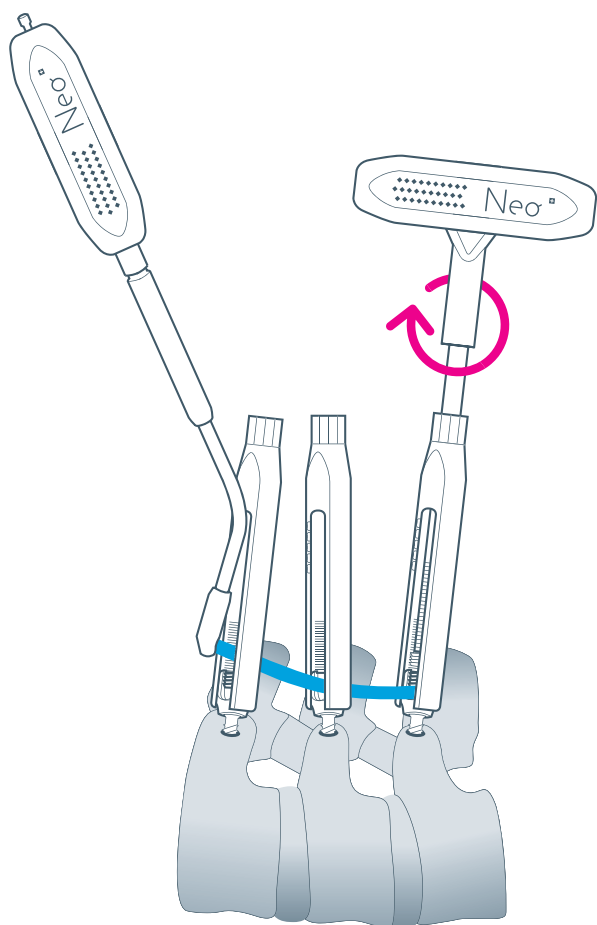
## MIS SURGICAL TECHNIQUE

### ROD FIXATION 1/4 (ROD PRE-FIXATION)

- > Insert in the most distal screw extender (where the bullet tip of the rod is located) a set screw driver.

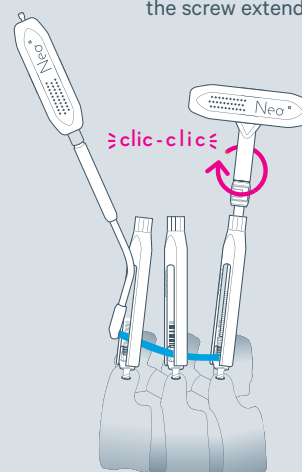
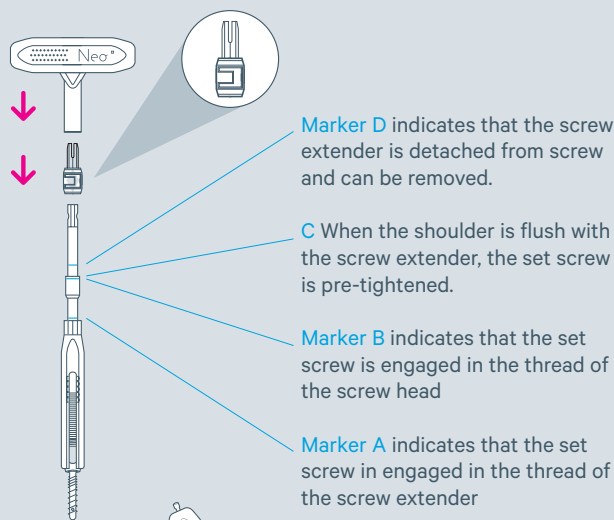
**!** Don't drop the set screw driver inside the screw extender but bring it down by holding and pushing it down with the hand until it reaches the inside thread of the screw extender (marker A).

- > Turn clock-wise the T-handle to bring down and pre-tighten the set screw. Insure while doing so that the polyaxiality of the screw is always insured. The polyaxiality check can be done by checking that nothing is blocking the screw extender to move freely and to self-adjust to a 90° angle relative to the rod.



#### OPTION

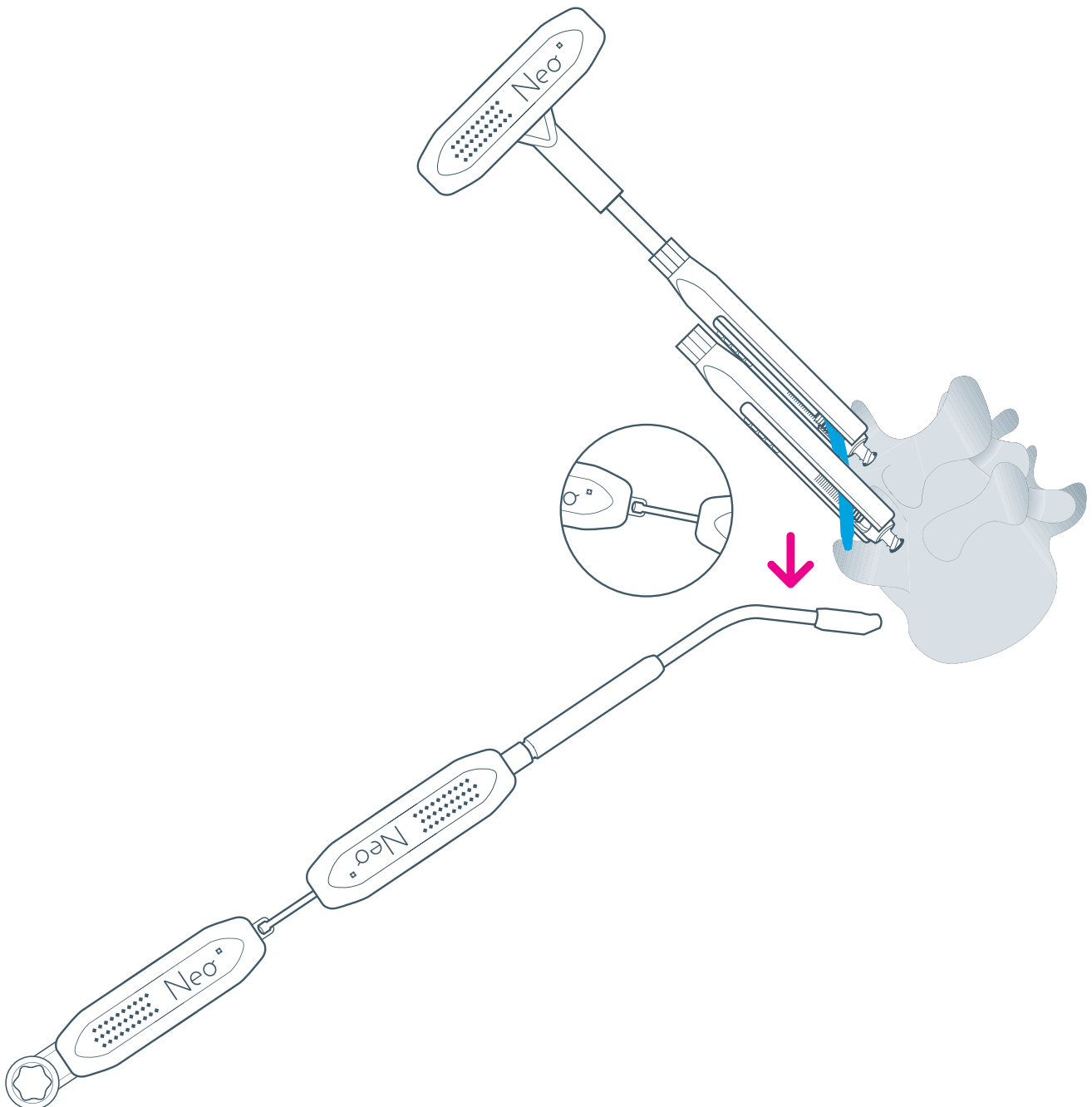
Insert the torque limiter between the T-handle and the set screw driver. Pre-tightening is achieved when the torque limiter is reached with an audible «click – click» and remove torque limiter.



## MIS SURGICAL TECHNIQUE

### ROD FIXATION 2/4 (ROD HOLDER RELEASE)

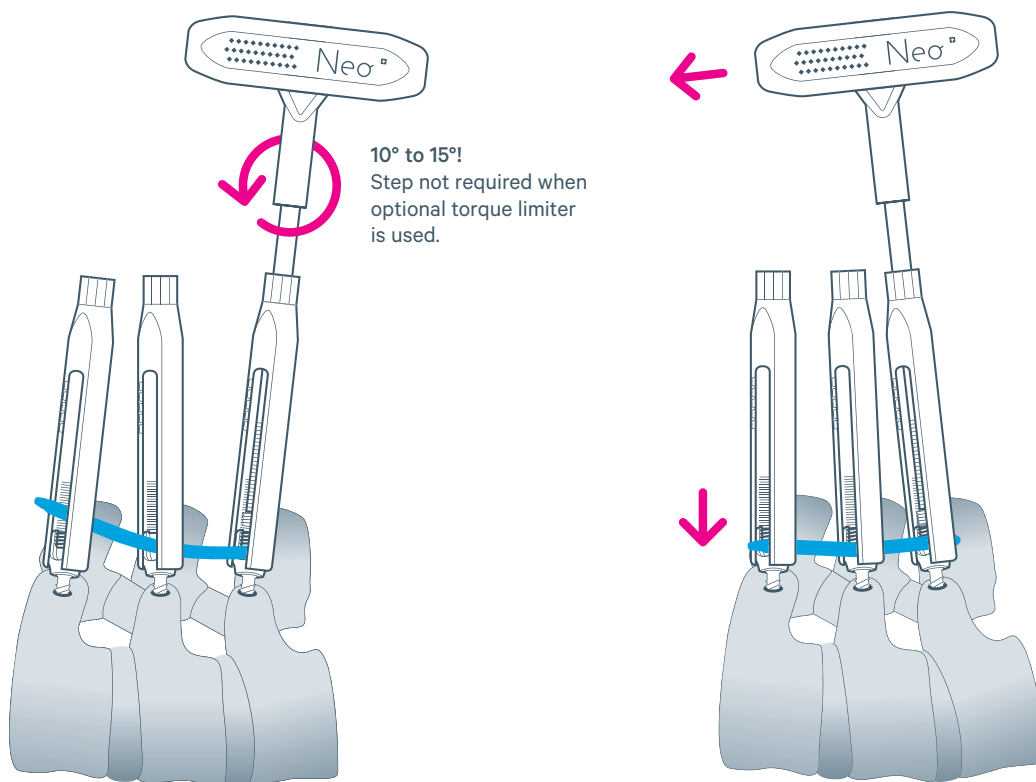
- > After a check of the correct positioning of the rod in the most distal screw head and in all other screw extenders with fluoroscopy and when the rod is pre-fixed, disengage the rod holder by pulling the locking notch of the rod holder by approximately 1,5 cm. The notch grabber from the counter-torque handle can be used to ease the process.



## MIS SURGICAL TECHNIQUE

### ROD FIXATION 3/4 (NON CONSTRAINT ROD REDUCTION)

- > When the set screw is pre-tightened in the most distal screw, mobility of the polyaxial screw head while maintaining the rod in place should be gained back by turning the T-Handle counterclockwise approx. 10° to 15°. *This step does not apply when using the optional torque limiter (as the polyaxiality of the screw has been maintained).*
  - > In case the rod is not completely sitting in all screw head(s), no spondylolysis or fracture reduction is planned and no posterior compression is desired, push the T-handle cranially until the rod is well positioned in all screw head(s).
  - > When satisfied with the rod positioning, remove the T-handle from the distal set screw driver, *as well as the optional torque limiter if used.*
- !** Retrieval of the screw head mobility with the counter-clockwise turn of the T-handle or with the optional use of the torque limiter should only be used for the most distal screw on each sides of the construct. For all other screw, the T-handle should be directly connected to the screw extender.
- > Proceed the same way on the contra-lateral side.



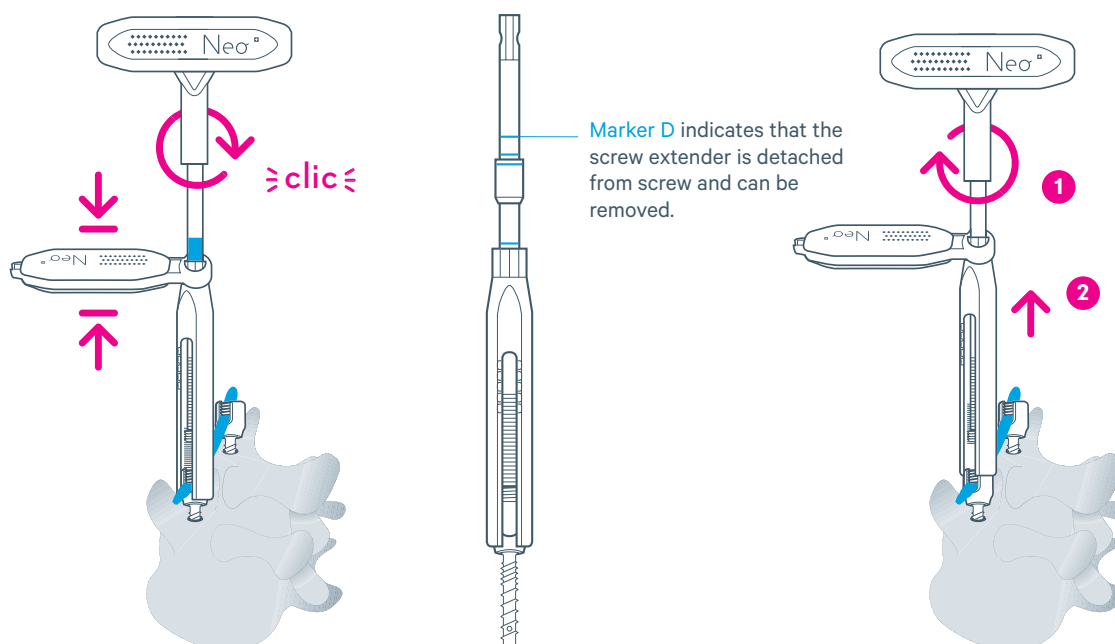
## MIS SURGICAL TECHNIQUE

### ROD FIXATION 4/4 (FINAL TIGHTENING)

**!** Only place the counter-torque handle on the top of the screw extender after the set screw head has been pre-tightened.

- > Always place the counter-torque handle on the top of the screw extender before doing the final tightening. Position the T-Handle on the top of the set-screw driver. If more than two levels are involved, always tighten the most distal level first and then sequentially toward the most proximal level.
- > Tighten the set screw by turning the T-Handle while firmly holding the counter-torque handle until the integrated torque limiting mechanism is reaching the right torque.
- > The pre-set optimal torque is reached when an audible « clic » is heard and the force accumulated tactilely released. Continue turning clockwise the T-handle until the screw extender is fully released from the screw head and can be discarded.
- > When both rods are reduced in the head(s) of the screws and are fixed in the most distal screws, work your way sequentially up (from the most caudal screw to the most cranial screw) level by level by introducing the set screw drivers, pre-fixing them and doing the final tightening and removing the screw extenders (as explained in Step 3/4). These steps should be done symmetrically (on both both sides simultaneously).

**!** While pre-fixing the rod into the head of each screw with the set screw, leave the screw extender completely free and do not try to align them to each others. This would lead to the built up of unwanted increased biomechanical forces in the final construct. The screw head need to self align toward the rod meaning that the screw extender will during the final tightening, self align at 90° angle to the rod.



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## OPEN SURGICAL TECHNIQUE

### PRE-OPERATIVE PLANNING

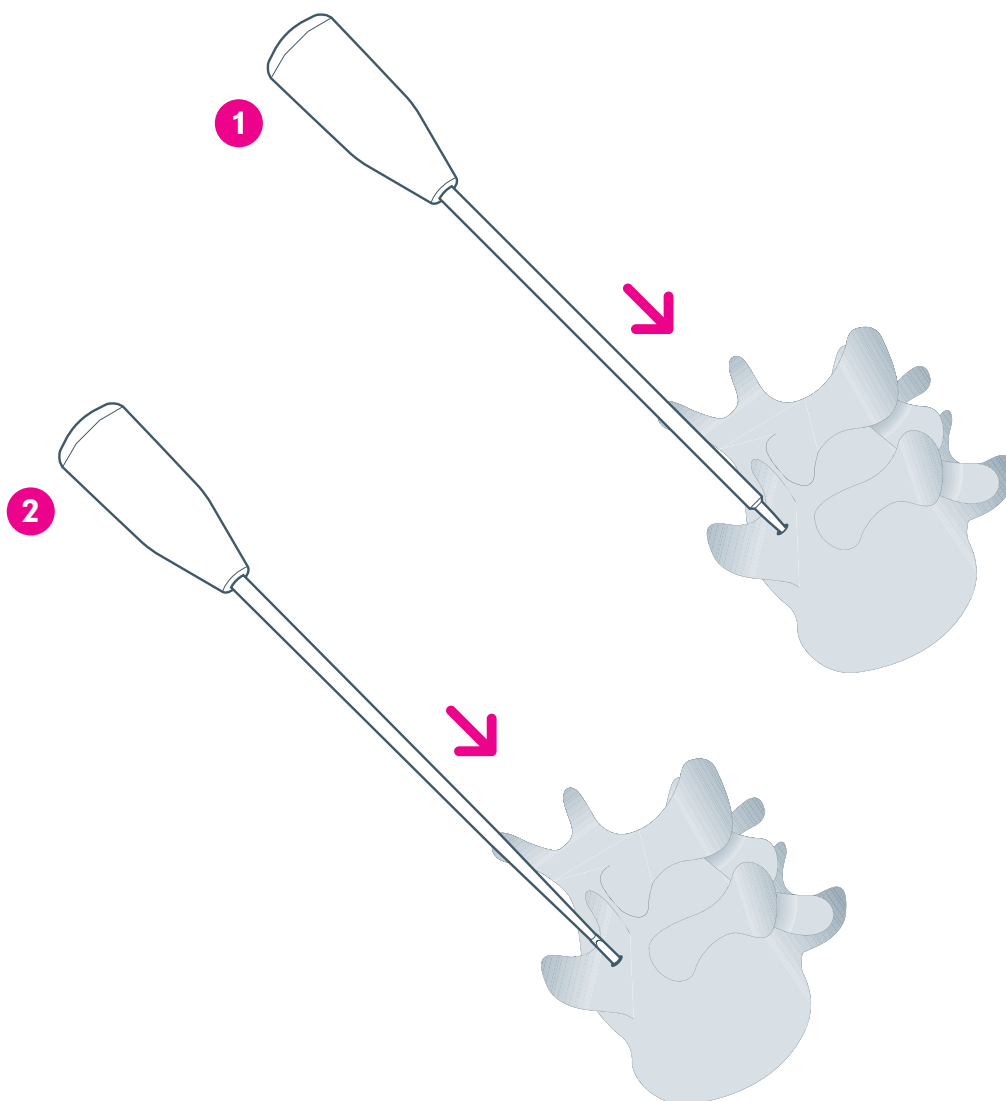
- > Preoperative planning can be useful to determine the entry point, trajectory and potential size of implants to be used. Lateral X-ray or CT-Scan can be used to achieve this goal.
- > DEXA analysis is a useful preoperative information to check the osteoporotic status of the patient.
- > Use an appropriate C-Arm intraoperatively to check implant trajectory, depth and position.

## OPEN SURGICAL TECHNIQUE

### PEDICLE PREPARATION 1/2

- > Identify the appropriate anatomical landmarks for creating the entry points of the pilot holes for the screw insertion.
- > Pilot holes are created using the round awl and followed by the use of the Steffee probe.

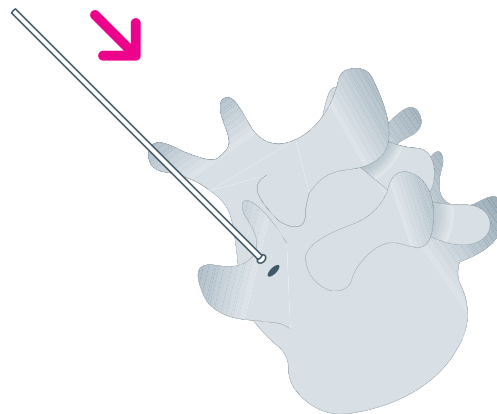
**!** For 4,5 mm diameter screws, the 3,5 mm Steffee (packed separately) should be used to create pilot hole.



## OPEN SURGICAL TECHNIQUE

### PEDICLE PREPARATION 2/2

- > The pedicle probe can be used to palpate for any imperfection in the pedicle walls.
- > Whenever tapping is necessary, use the tap to prepare the screw placement. The tap has been in fact designed to have a smaller diameter (4,3 mm) of the 5 mm screw to ensure perfect fixation.

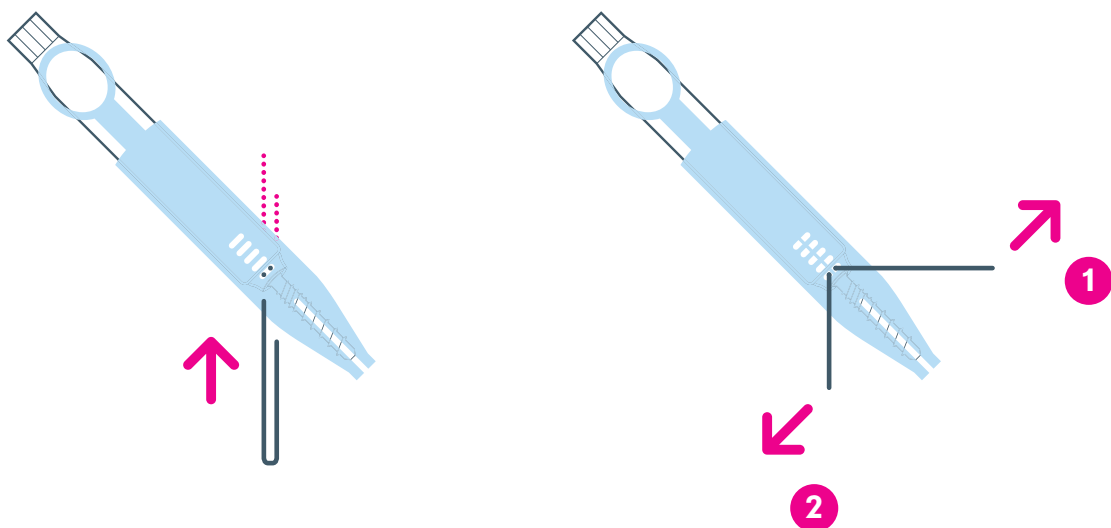




## OPEN SURGICAL TECHNIQUE

### SCREW SELECTION

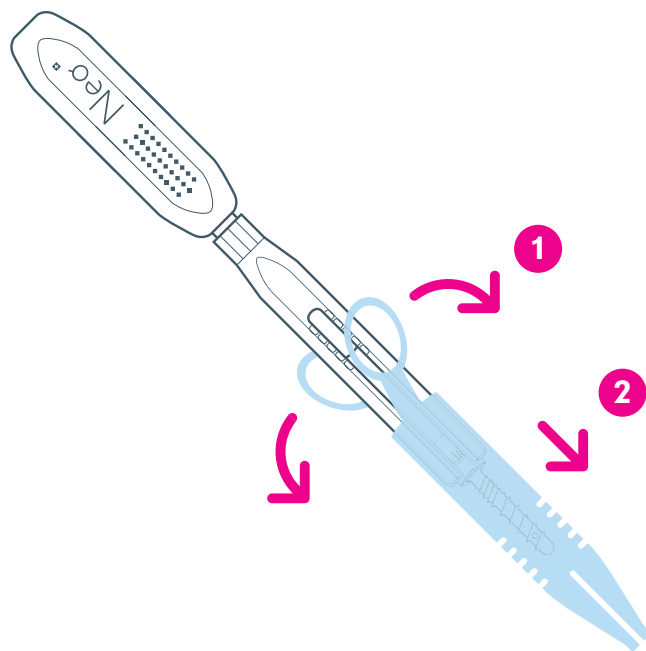
- > Depending on the pedicle size the appropriate screw diameter and length will be selected.
- > Open the appropriate sterile Neo pedicle screw kit.
- > If the surgeon decide to use the monoaxial capability of the Neo screw, the clip should be used and inserted to lock the screw head in a monoaxial position:
  - Insert first the long clip leg through the large opening of the tissue dilator and inside one of the small screw head hole.
  - Insert the short clip leg in the second hole.
  - Grab the long and small clip leg from the other side and pull it completely to ensure the full insertion of the clip in the screw head.
  - Break the long leg by bending it sideways and proceed in the same way for the short one.
  - Hold onto the legs while breaking them off.



## OPEN SURGICAL TECHNIQUE

### SCREW INSERTION 1/3

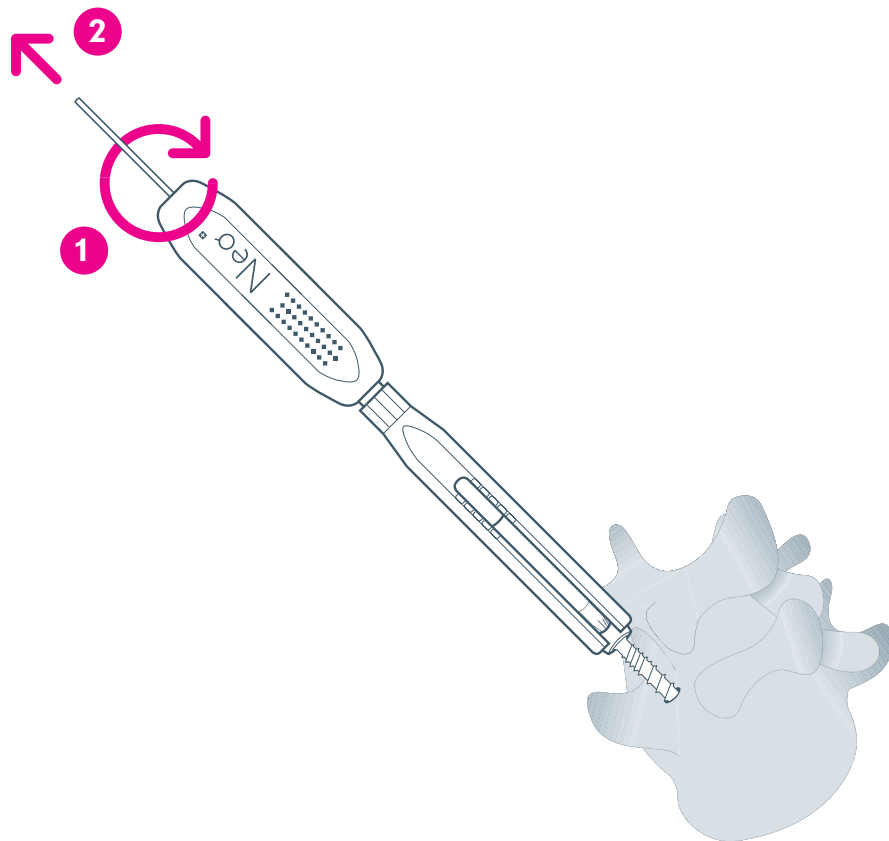
- > Insert the screwdriver inside the screw extender and ensure that the tip is well inserted into the screw head.
- > Remove the tissue dilator from the screw assembly by opening sideways the two lateral eyelets and pulling it away.



## OPEN SURGICAL TECHNIQUE

### SCREW INSERTION 2/3

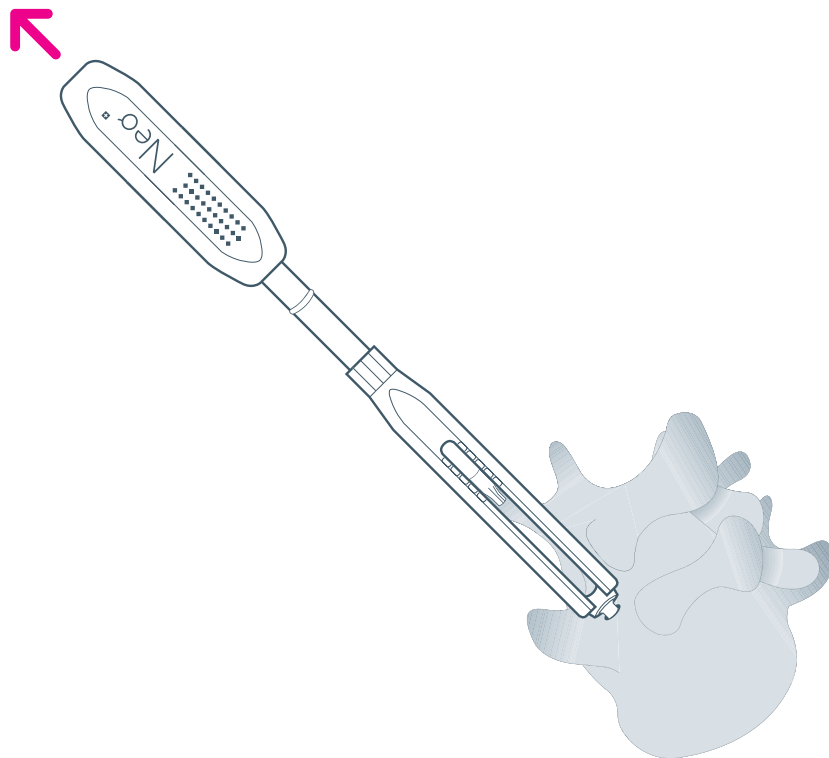
- > Insert the screw assembly inside the pilot hole previously created.



## OPEN SURGICAL TECHNIQUE

### SCREW INSERTION 3/3

- > Once the appropriate screw position has been achieved, the screwdriver can be taken away. Fluoroscopic controls are recommended to ensure an appropriate positioning of the screws.
- > When used in polyaxial mode it is important to not push the screw head flush too forcefully against the bone in order to prevent the loss of its multiaxial property.

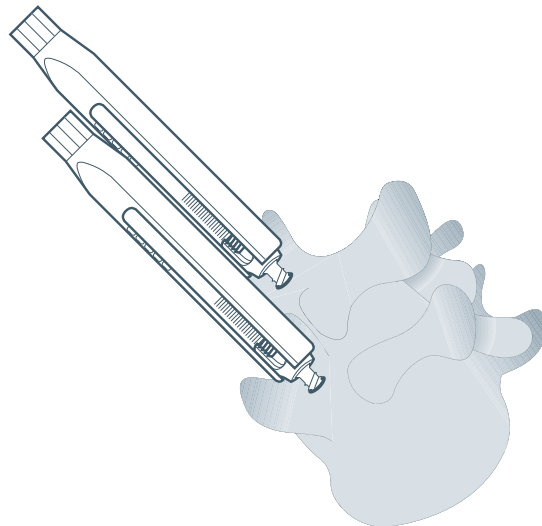


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## OPEN SURGICAL TECHNIQUE

### ROD INSERTION 1/5

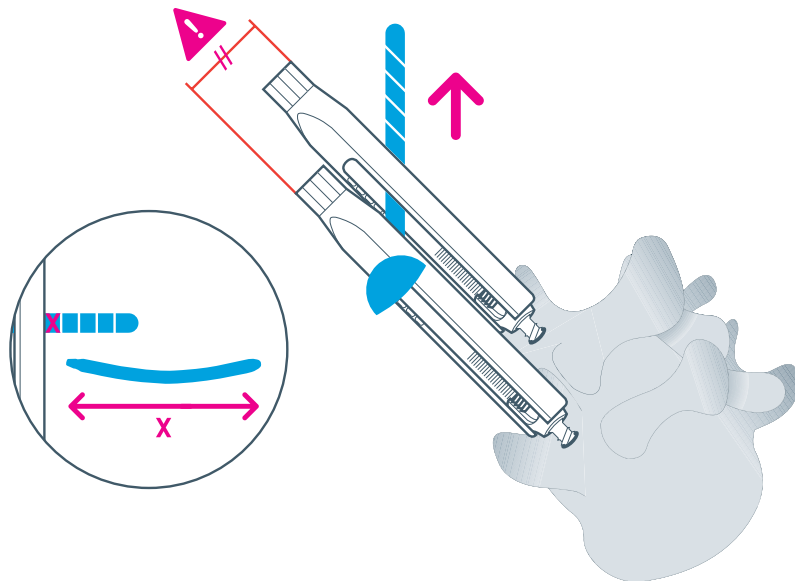
- > Repeat the previous step for each screw to be placed. Under fluoroscopy, visualize the screws to ensure they line up coronally as much as possible.
- > Once all the screws are in place, rotate the screw extenders to ensure the alignment of all the windows in a position that will allow the rod to be passed.



## OPEN SURGICAL TECHNIQUE

### ROD INSERTION 2/5

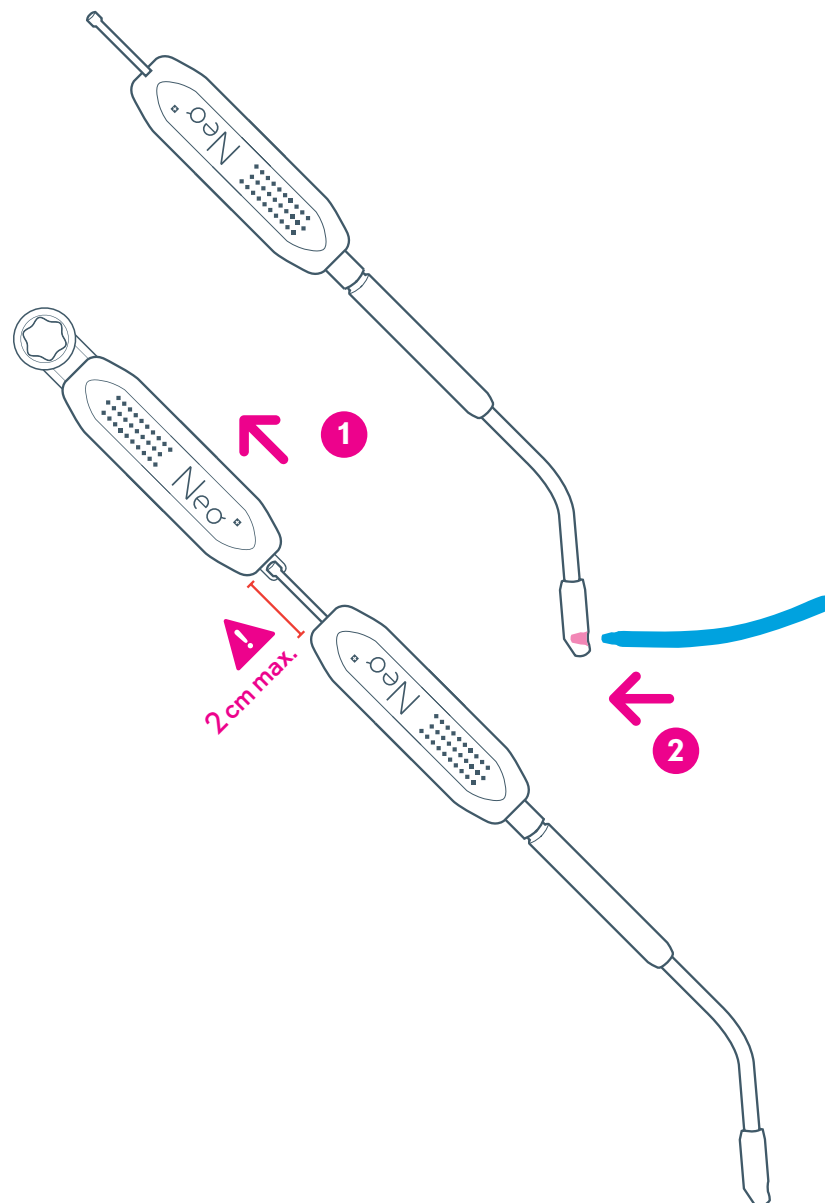
- > Insert the rod measurer through all the screws until the proximal stopper is in contact with the first screw extender. Position the last opposite screw extender in parallel with the first one and read the rod length on the rod measurer: the first readable number is the length of the rod to be selected.
- > The screw depth can be monitored easily by checking on the screw extender height. This will give important information in order to choose the right rod profile as well as understanding how much reduction is needed in case of spondylolisthesis treatment.



## OPEN SURGICAL TECHNIQUE

### ROD INSERTION 3/5

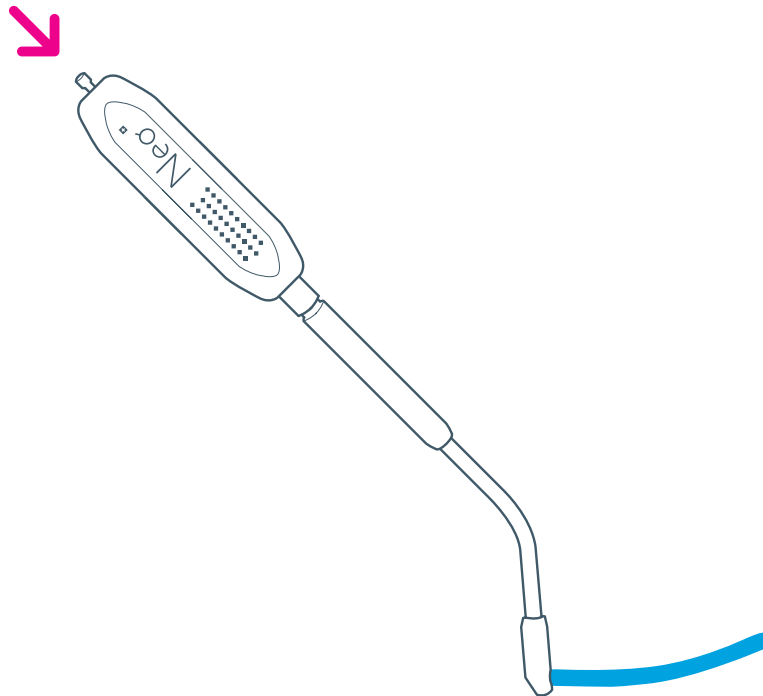
- > Open the appropriate Neo sterile rod kit. Pull the locking notch on the top of the handle of the rod holder to the maximum in order to ensure the right insertion of the windowed tip of the rod inside the rod holder. The notch grabber of the counter-torque handle can be used to ease the process.
- > Position the rod in the rod holder.



## OPEN SURGICAL TECHNIQUE

### ROD INSERTION 4/5

- > Once the rod is completely inserted in the rod holder slot, lock it by pushing on the locking notch until it is flush with the rod holder handle. The notch grabber of the counter-torque handle can be used to ease the process. Always ensure the right locking of the rod in the rod holder before starting the insertion.



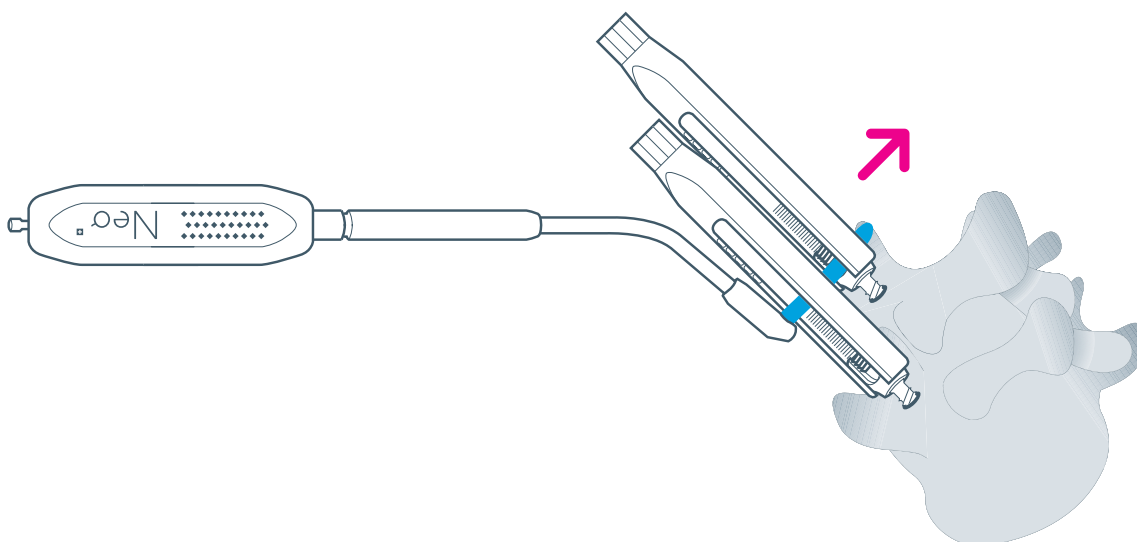


## OPEN SURGICAL TECHNIQUE

### ROD INSERTION 5/5

- > Start inserting the rod's bullet tip through the window of the first screw extender under the fascia, and carefully push it through the windows of each screw extender: check that none of the screw extender can rotate anymore to ensure that the rod is properly seated. Push the rod holder until its tip is in contact with the first screw extender. Insertion should always be cranio-caudal when sacral segment is involved.
- > Push the rod holder until the rod sits inside the most distal screw's head.

**!** Confirm the rod position fluoroscopically. The rod should always overhang the most distal screw by a few mm.



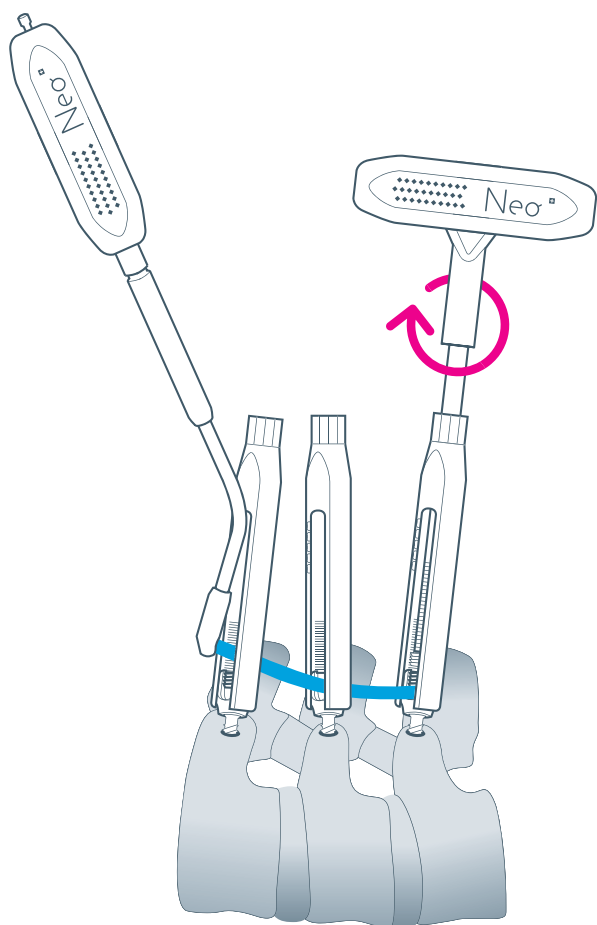
## OPEN SURGICAL TECHNIQUE

### ROD FIXATION 1/4 (ROD PRE-FIXATION)

- > Insert in the most distal screw extender (where the bullet tip of the rod is located) a set screw driver.

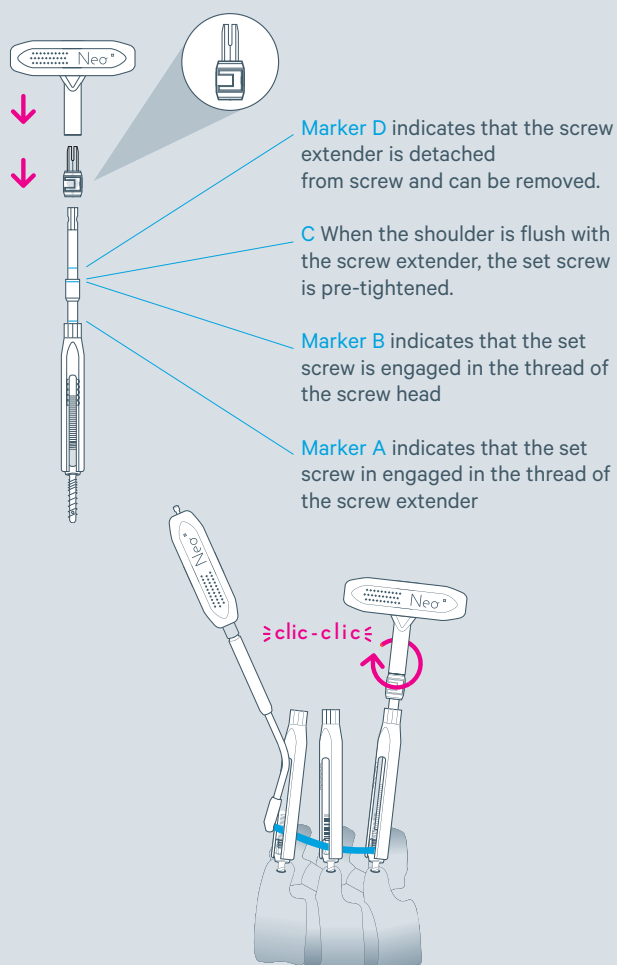
**!** Don't drop the set screw driver inside the screw extender but bring it down by holding and pushing it down with the hand until it reaches the inside thread of the screw extender (marker A).

- > Turn clock-wise the T-handle to bring down and pre-tighten the set screw. Insure while doing so that the polyaxiality of the screw is always insured. The polyaxiality check can be done by checking that nothing is blocking the screw extender to move freely and to self-adjust to a 90° angle relative to the rod.



#### OPTION

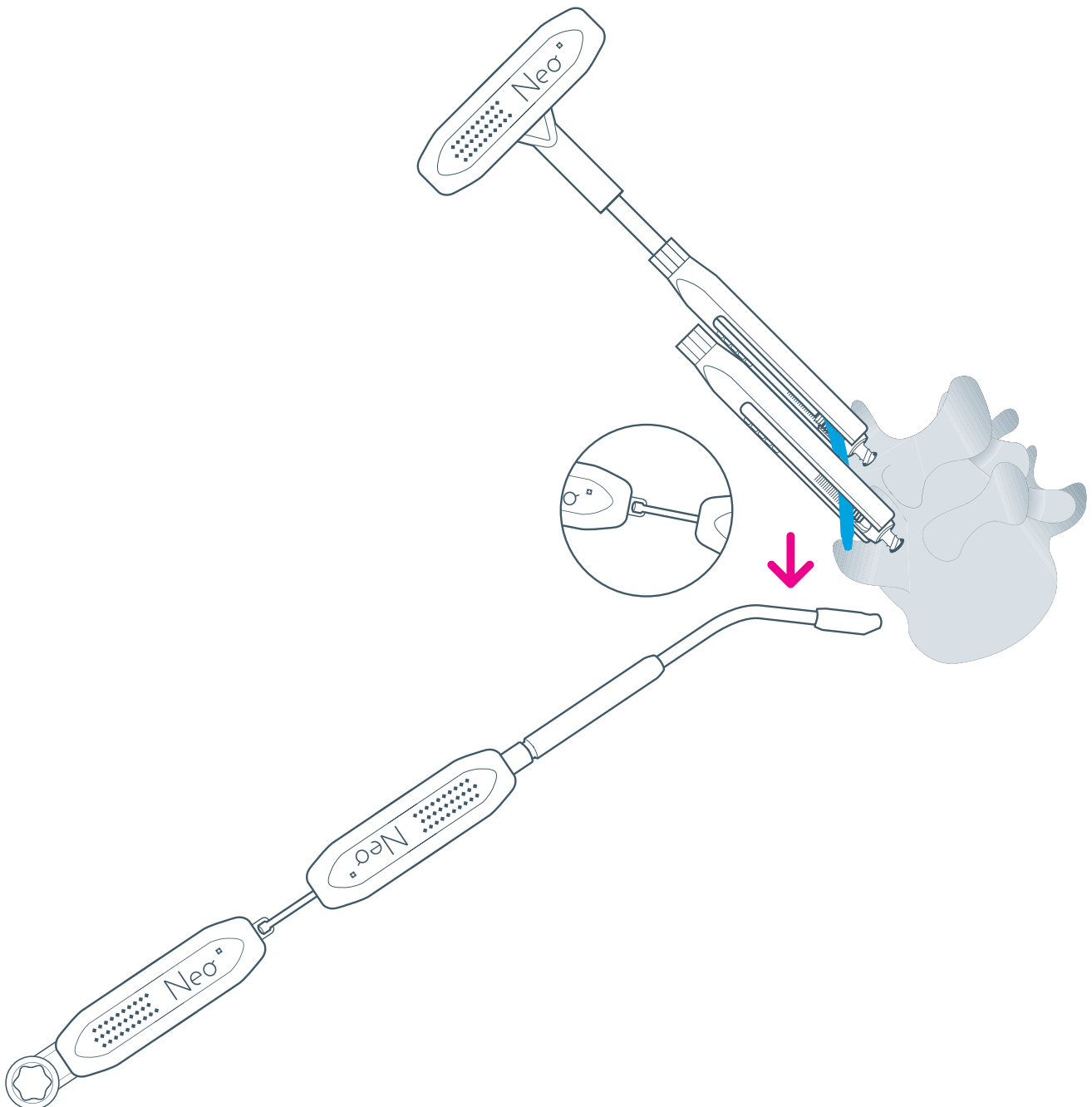
Insert the torque limiter between the T-handle and the set screw driver. Pre-tightening is achieved when the torque limiter is reached with an audible «click – click» and remove torque limiter.



## OPEN SURGICAL TECHNIQUE

### ROD FIXATION 2/4 (ROD HOLDER RELEASE)

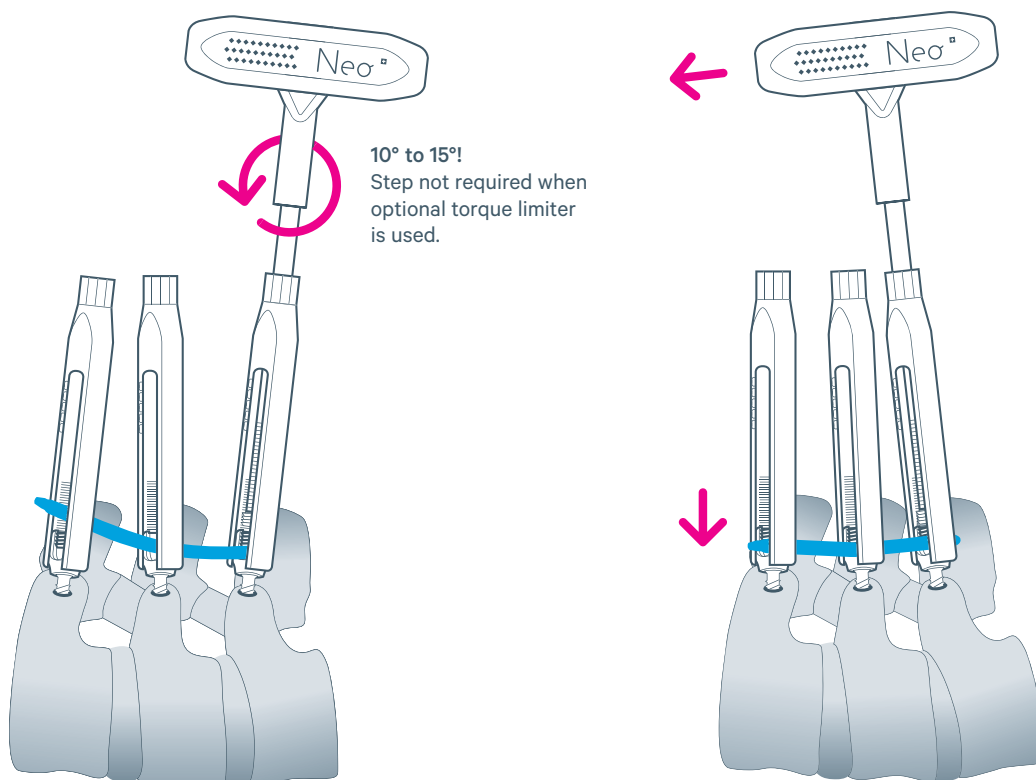
- > After a check of the correct positioning of the rod in the most distal screw head and in all other screw extenders with fluoroscopy and when the rod is pre-fixed, disengage the rod holder by pulling the locking notch of the rod holder by approximately 1,5 cm. The notch grabber from the counter-torque handle can be used to ease the process.



## OPEN SURGICAL TECHNIQUE

### ROD FIXATION 3/4 (NON CONSTRAINT ROD REDUCTION)

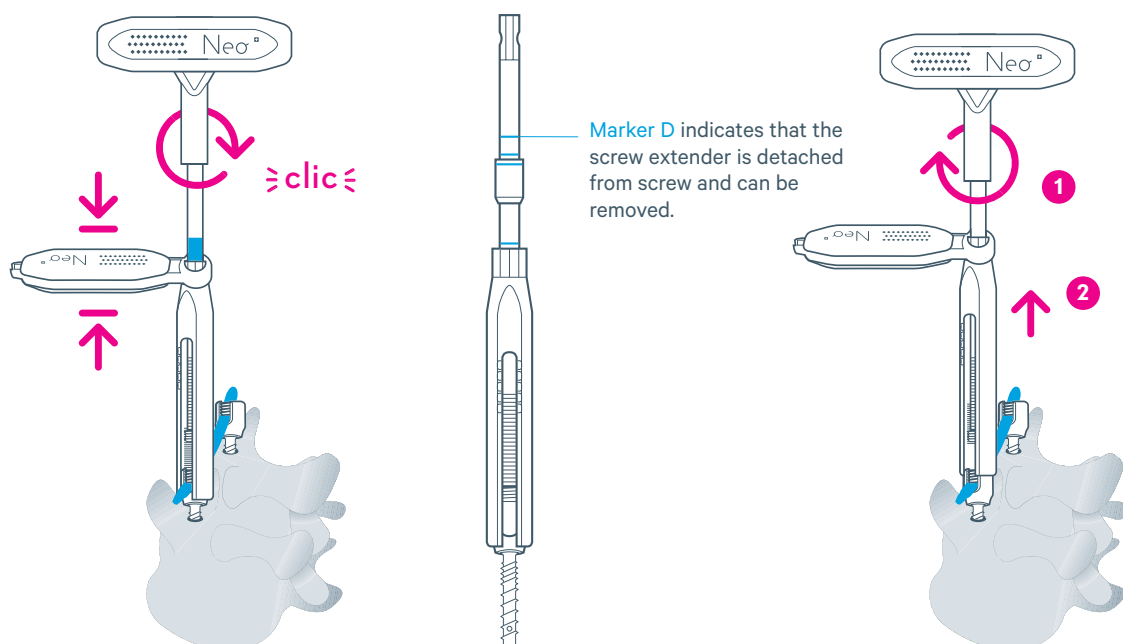
- > When the set screw is pre-tightened in the most distal screw, mobility of the polyaxial screw head while maintaining the rod in place should be gained back by turning the T-Handle counterclockwise approx. 10° to 15°. *This step does not apply when using the optional torque limiter (as the polyaxiality of the screw has been maintained).*
  - > In case the rod is not completely sitting in all screw head(s), no spondylolysis or fracture reduction is planned and no posterior compression is desired, push the T-handle cranially until the rod is well positioned in all screw head(s).
  - > When satisfied with the rod positioning, remove the T-handle from the distal set screw driver, *as well as the optional torque limiter if used.*
- !** Retrieval of the screw head mobility with the counter-clockwise turn of the T-handle or with the optional use of the torque limiter should only be used for the most distal screw on each sides of the construct. For all other screw, the T-handle should be directly connected to the screw extender.
- > Proceed the same way on the contra-lateral side.



## OPEN SURGICAL TECHNIQUE

### ROD FIXATION 4/4 (FINAL TIGHTENING)

- !** Only place the counter-torque handle on the top of the screw extender after the set screw head has been pre-tightened.
- > Always place the counter-torque handle on the top of the screw extender before doing the final tightening. Position the T-Handle on the top of the set-screw driver. If more than two levels are involved, always tighten the most distal level first and then sequentially toward the most proximal level.
- > Tighten the set screw by turning the T-Handle while firmly holding the counter-torque handle until the integrated torque limiting mechanism is reaching the right torque.
- > The pre-set optimal torque is reached when an audible « clic » is heard and the force accumulated tactilely released. Continue turning clockwise the T-handle until the screw extender is fully released from the screw head and can be discarded.
- > When both rods are reduced in the head(s) of the screws and are fixed in the most distal screws, work your way sequentially up (from the most caudal screw to the most cranial screw) level by level by introducing the set screw drivers, pre-fixing them and doing the final tightening and removing the screw extenders (as explained in Step 3/4). These steps should be done symmetrically (on both both sides simultaneously).
- !** While pre-fixing the rod into the head of each screw with the set screw, leave the screw extender completely free and do not try to align them to each others. This would lead to the built up of unwanted increased biomechanical forces in the final construct. The screw head need to self align toward the rod meaning that the screw extender will during the final tightening, self align at 90° angle to the rod.



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## SURGICAL TECHNIQUE OPTIONS

### SCREW CEMENTATION 1/3

- > In case of an insufficient screw anchorage into the bone due to reduced bone mass, a pedicle screw augmentation might be required.
- > The use of high viscosity cement is highly recommended when use in combination with Neo pedicle screws system. Carefully check the IFU of the cement used in order to ensure an appropriate use with Neo pedicle screw system.
- > Use the Neo cement pushers and pre-fill them with the high viscosity bone cement. The volume of cement contained in each cement filler is of 1ml. The appropriate cement volume will be decided according the surgeon experience and appreciation.
- > Manually ensure the alignment of the screw extender with the axis of the screw thread in order to facilitate the insertion of the cement pusher in the appropriate axial position.

## SURGICAL TECHNIQUE OPTIONS

### SCREW CEMENTATION 2/3

- > Insert the cement pusher inside the screw extender and screw it down when it has reached the inside thread of the screw extender.
- > The self centering capability of the cement pusher will ensure the final locking of the cement filler inside the screw head.

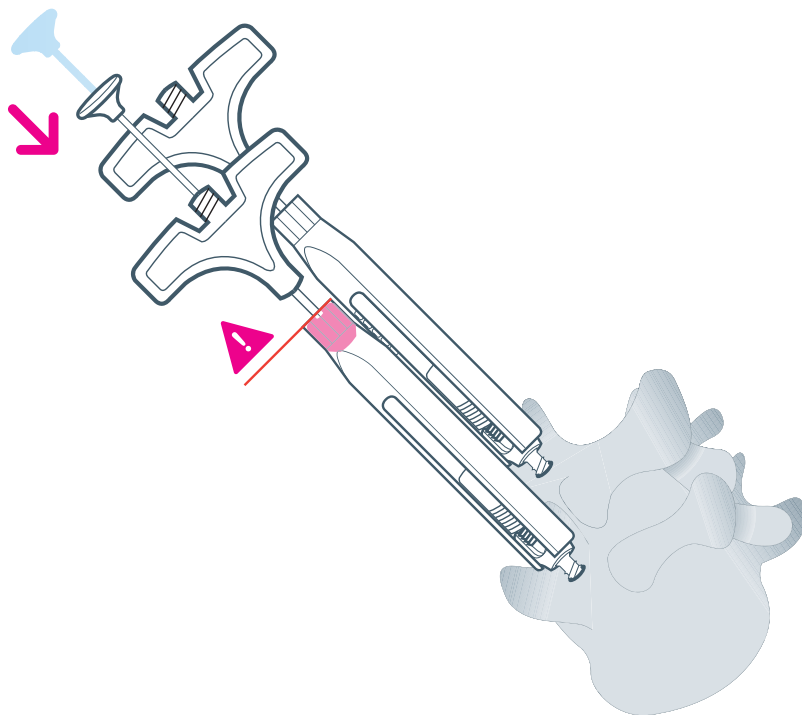


## SURGICAL TECHNIQUE OPTIONS

### SCREW CEMENTATION 3/3

- > Carefully check that the cement pusher is perfectly placed and locked into the screw head by making sure the posterior marker of the cement pusher is perfectly flush with the screw extender. An inappropriate positioning might result in cement leaking in the head of the screw those resulting in a need to replace the screw before the final tightening of the whole construct.

- ⚠ Always check with C-arm control the injection of cement to prevent leakage and to ensure adequate distribution around the screw head.





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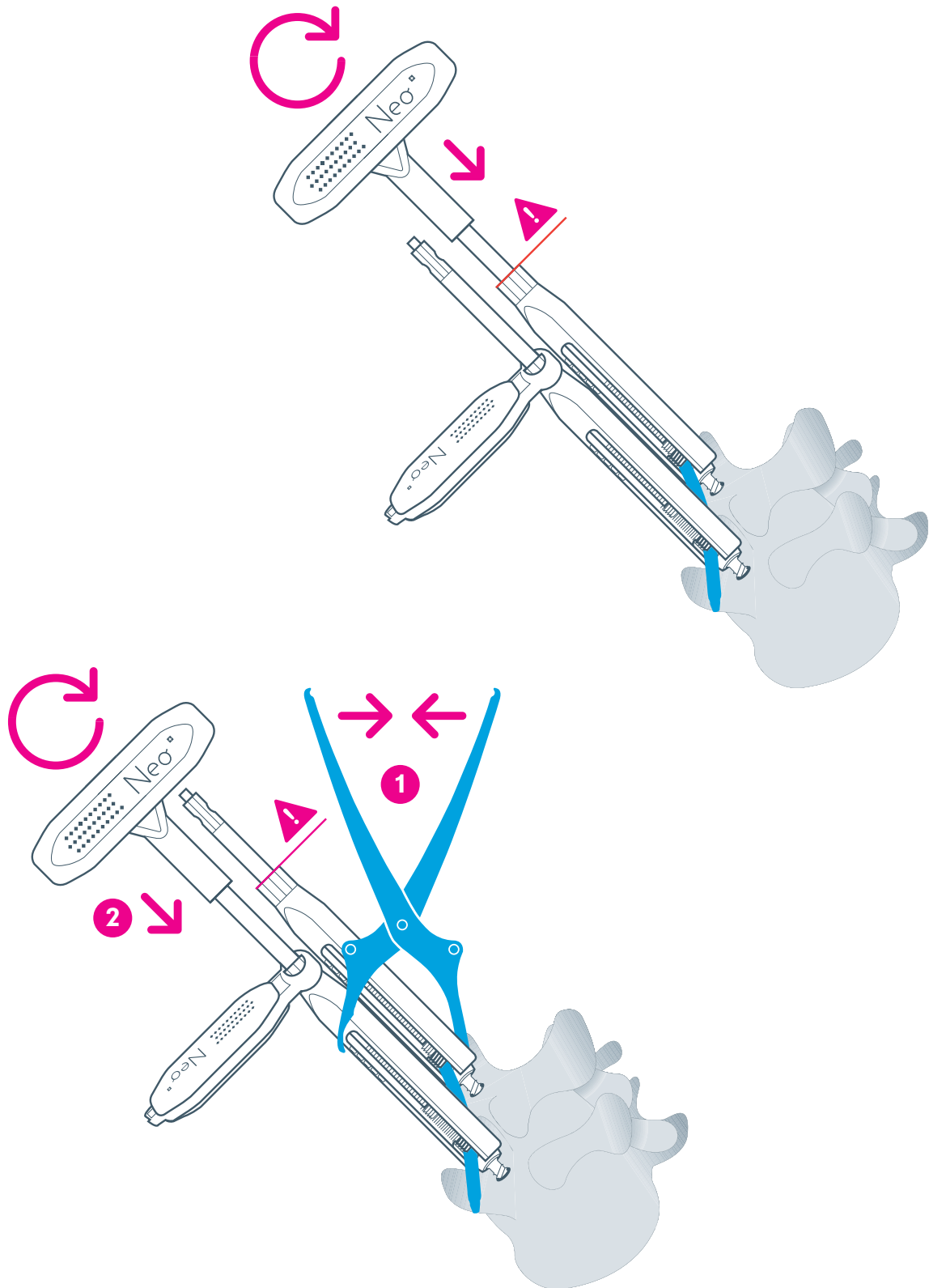
## SURGICAL TECHNIQUE OPTIONS

### COMPRESSION / DISTRACTION

- > It is recommended to do a mobility test with bending and extension under X-Ray before doing compression / distraction.
- > When such maneuver are needed, open a Neo compressor / distractor kit. It is a 2 in 1 instrument.
- > If either compression or distraction is needed, it should be performed at this time. In either maneuver, the set screw on one side of the motion segment should be provisionally tightened, with the set screw loose in the implant to be compressed or distracted.
- > Compression or distraction will occur against the provisionally tightened implant. The set screw driver may be used to temporarily lock and secure the rod and implant construct. Usually, temporary fixation of the implant may be performed numerous times without damage to either the set screw or the implant threads.
- > Care should be taken to ensure that the feet of either the compressor or the distractor are placed securely against the implant body or screw extender.
- > Care should be taken to not proceed to the final tightening until the compression or distraction maneuvers are performed.
- > Once satisfactory compression or distraction has been achieved, final tightening may be performed.
- > The chain ball can be used to lock in position the distraction or compression when required.

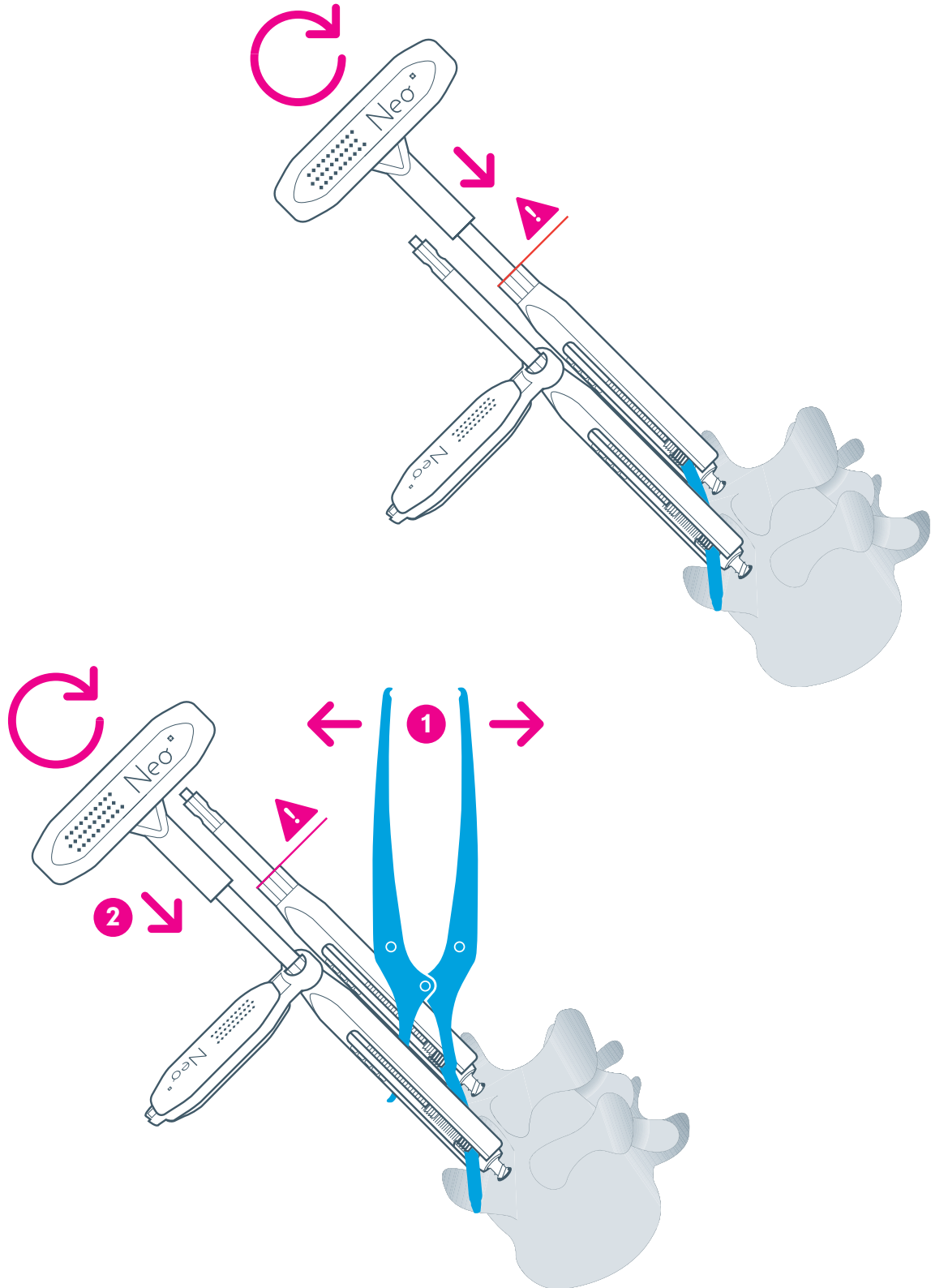
## SURGICAL TECHNIQUE OPTIONS

### COMPRESSION



## SURGICAL TECHNIQUE OPTIONS

### DISTRACTION



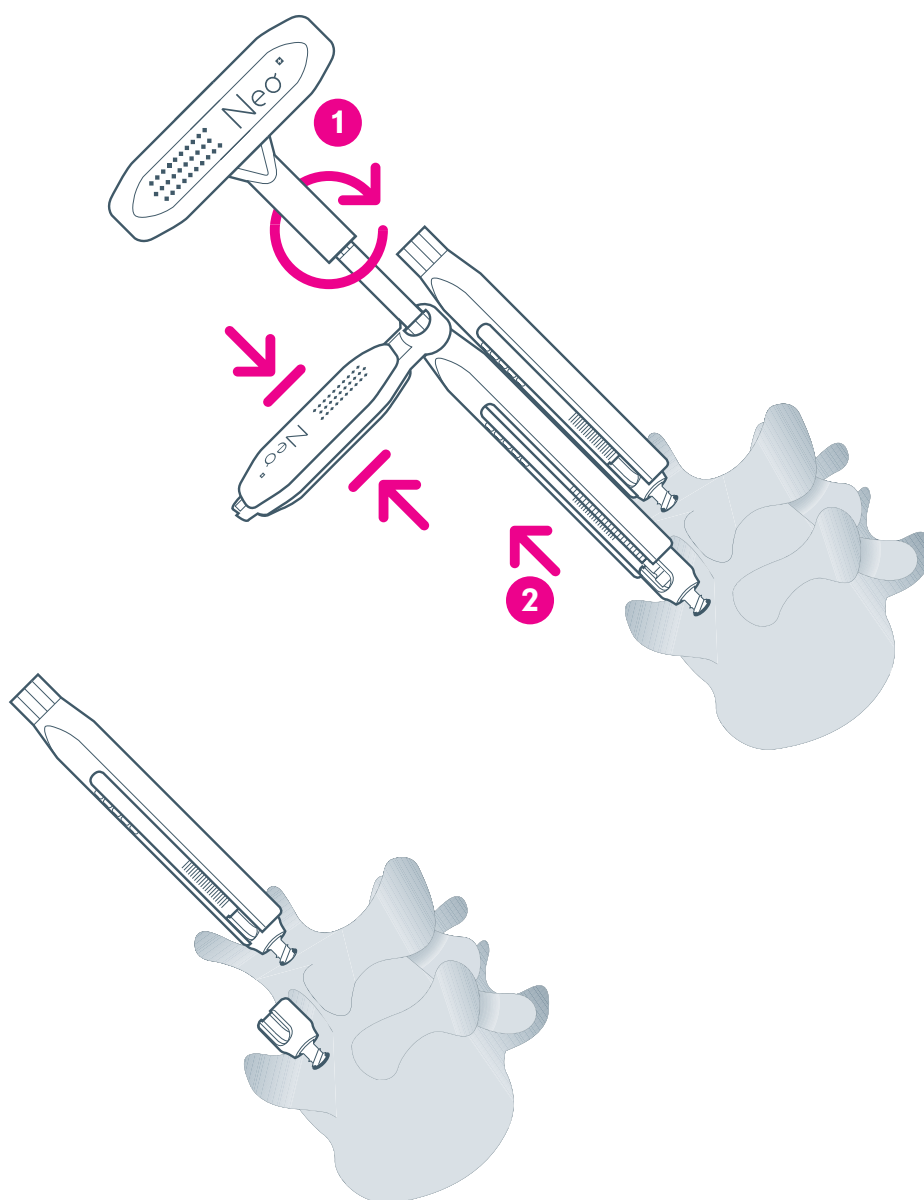
## SURGICAL TECHNIQUE OPTIONS

### SCREW EXTENDER REMOVAL 1/2

- > If the removal of one or more screw extenders are needed, the screw extender remover can be used by inserting it into the screw extender and screwing it until the bottom of the head of the screw is reached. The use of the T-Handle might be then used to continue the screwing of this instrument in order to pull out the screw extender from the screw head.

**!** Once a screw extender is removed, it cannot be reattached.

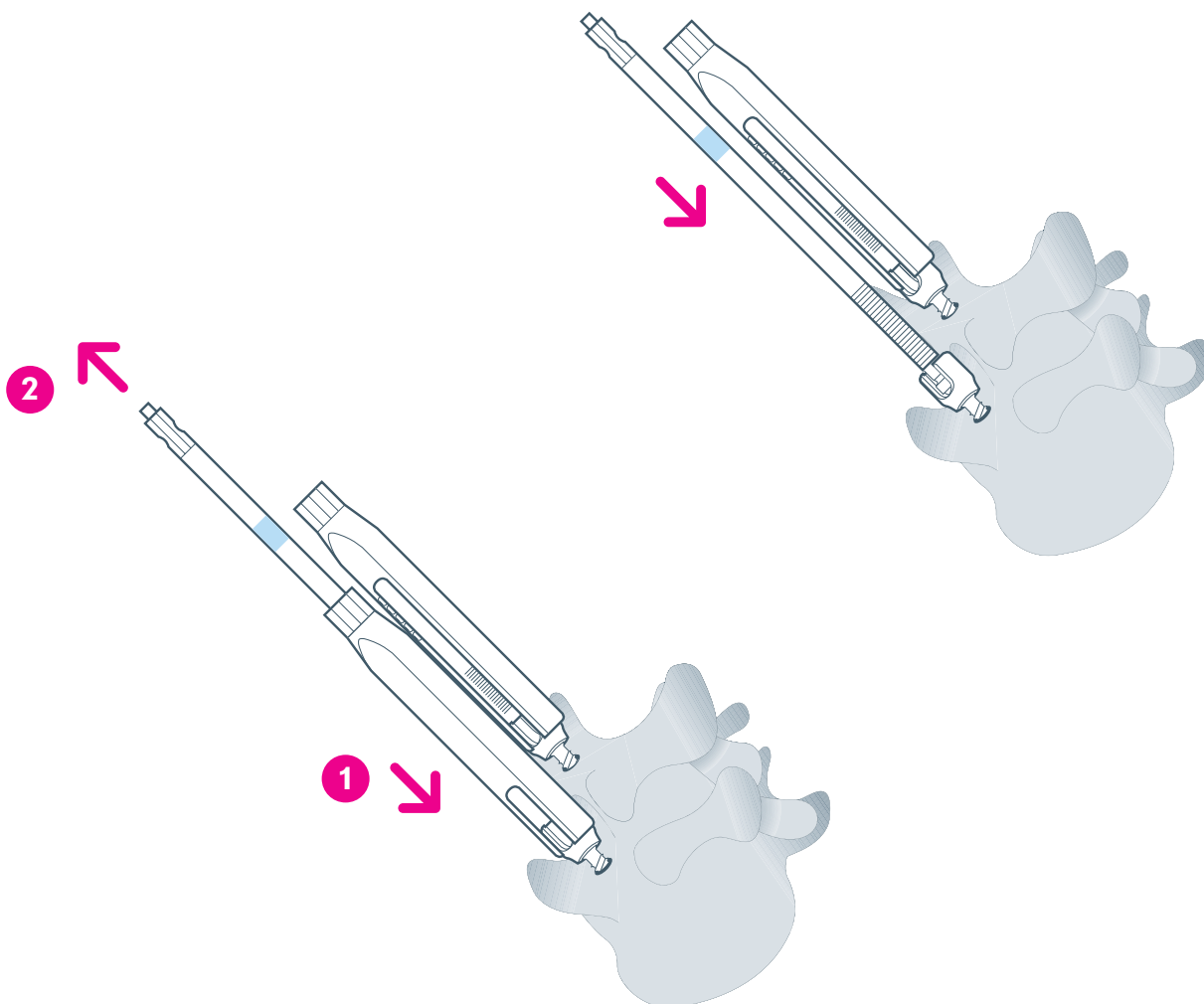
**!** Once a screw extender has been removed, screw cementation is not possible anymore.



## SURGICAL TECHNIQUE OPTIONS

### SCREW EXTENDER REMOVAL 2/2

- > To proceed to the final tightening the removable screw extender have to be used in order to replace the original screw extender along with the necessary instruments as explained into the surgical technique.
- > To facilitate the insertion of the removable screw extender the screw extender remover can be used to find the screw head and the removable screw extender will then be slid over it and down in order to lock in the screw head.



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## SURGICAL TECHNIQUE OPTIONS

### REVISION

- > The revision kit should be used in that case.
- > Use the removable screw extender and the counter-torque on the screw to be retrieved. Use the non cannulated screw driver to loosen the set screw and take it away.
- > Proceed for every screw of the construct in the same way.
- > Once every set screw have been retrieved, the rods can be retrieved as well either by hands or by the use of the clamping side of the compressor / distractor instrument.
- > The screws can then be extracted by the use of the screw driver.
- > If anything is blocking the access for the screw driver in the screw head, the screw locker plug can be used in order to ensure a proper screw extraction. They are inserted and locked in the screw head using the screw driver. The screw can then be extracted by turning the removable screw extender counter-clockwise with the counter-torque on. Insert the removable screw extender prior to the insertion of the screw remover to avoid cross threading.



Never use the cannulated screw driver during revision surgery.

## INDICATIONS

The NEO Pedicle Screw System™ is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. The system is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, tumor, pseudarthrosis, and/or failed previous fusion. The Instruments are to be used for the implantation of the above mentioned medical devices.

## CONTRAINDICATIONS

Contraindications include, but are not limited to:

- > Active infectious process or significant risk of infection (immunocompromise).
- > Signs of local inflammation.
- > Fever or leukocytosis.
- > Morbid obesity.
- > Pregnancy.
- > Mental illness.
- > Grossly distorted anatomy caused by congenital abnormalities.
- > Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- > Suspected or documented metal allergy or intolerance.
- > Any case not needing a bone graft and fusion.
- > Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- > Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- > Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- > Pediatric patients or where the patient still has general skeletal growth.
- > Any patient unwilling to follow postoperative instructions.
- > Any case not described in the indications.


### 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.

**Use the Surgical Technique together with the Instructions for Use for this product for complete warnings, precautions and adverse events.**

[www.neo-medical.com/ifu](http://www.neo-medical.com/ifu)

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