Surgical technique

Proven French innovation in orthopaedics

NEMOST

Spinal growth osteosynthesis implant

SPINE - RACHIS

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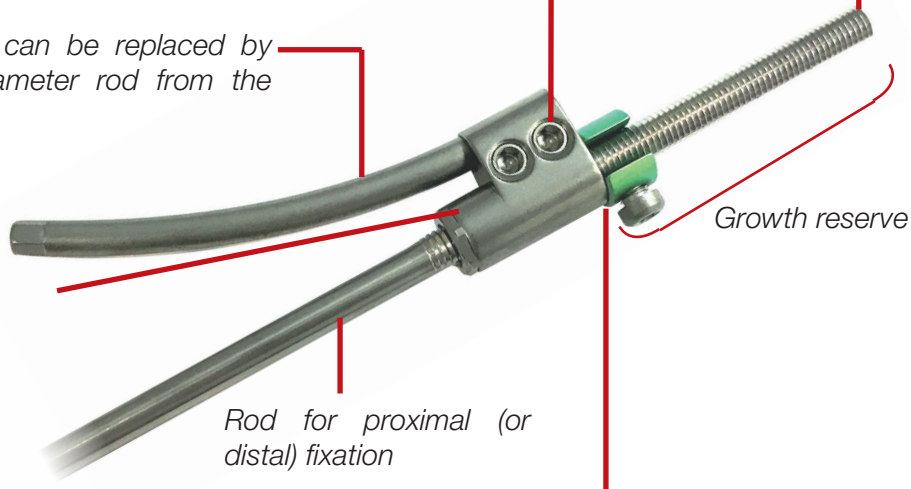
1. DESCRIPTION AND OPERATION OF THE DEVICE

The NEMOST implant is a sterile, single-use device intended for posterior surgical implantation. Its function is to correct spinal deformation and to maintain the correction during growth.

The NEMOST growth domino is intended for paediatric use.

The desired effect is a regular lengthening of the device in order to obtain a progressive correction of spinal deformation over time.

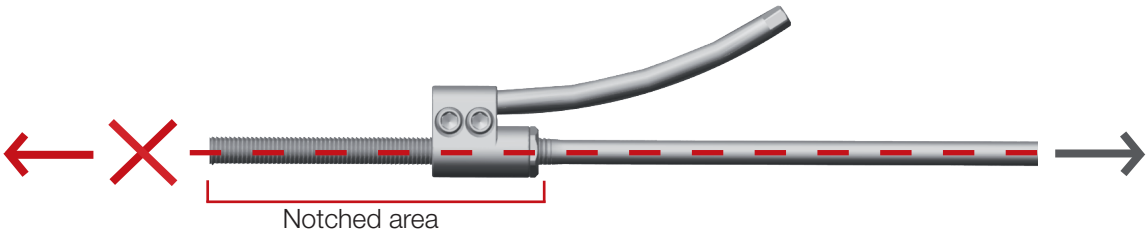
The NEMOST device consists of two longitudinal rods, connected by a domino. The rods connect the cranial anchor to the caudal anchor. The irreversible internal mechanism elongates as a result of bone growth.



A locking ring maintains the relative position of the parts during surgery (factory setting). It is intended to be removed and then disposed of at the end of surgery.

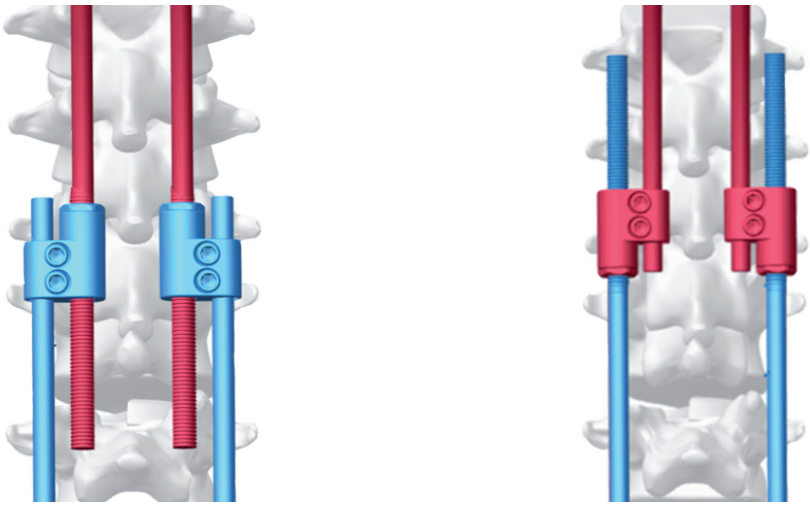
The product is delivered sterile and supplied with a specific wrench to ensure optimal tightening of locking screws.

The rod intended to slide freely in the lenghtening direction is partially notched and graduated over a length of 50 mm or 80 mm (2 implant sizes are available), this notched area makes up the «growth reserve».



Generally, 80 mm rods can be used in children under 10 years of age, and primarily when the assembly is extended to the pelvis.

The symmetrical design of the NEMOST growth domino enables its use in all positions, depending on the deformation of the spine: notched rod to the outside or inside of the assembly, and/or notched rod to the proximal or caudal part of the spine.



Note: in red : movable part, in blue : fixed part

2. SURGICAL INDICATIONS

The NEMOST implant is intended for the fusionless surgical treatment of early onset scoliosis in children of RISSER 0 as a first-intent treatment.

Different types of scoliosis concerned:

- Idiopathic scoliosis
- Neuromuscular scoliosis
- Syndromic scoliosis
- Congenital deformities

Precautions:

The NEMOST implant has been designed for use with components of the E.SPINE® posterior fixation system (Refer to the associated surgical technique).

The E.SPINE® rods that can be connected to the NEMOST implant are 5.5 mm in diameter.

The NEMOST implant should not be used in a spine that has already been instrumented or fused.

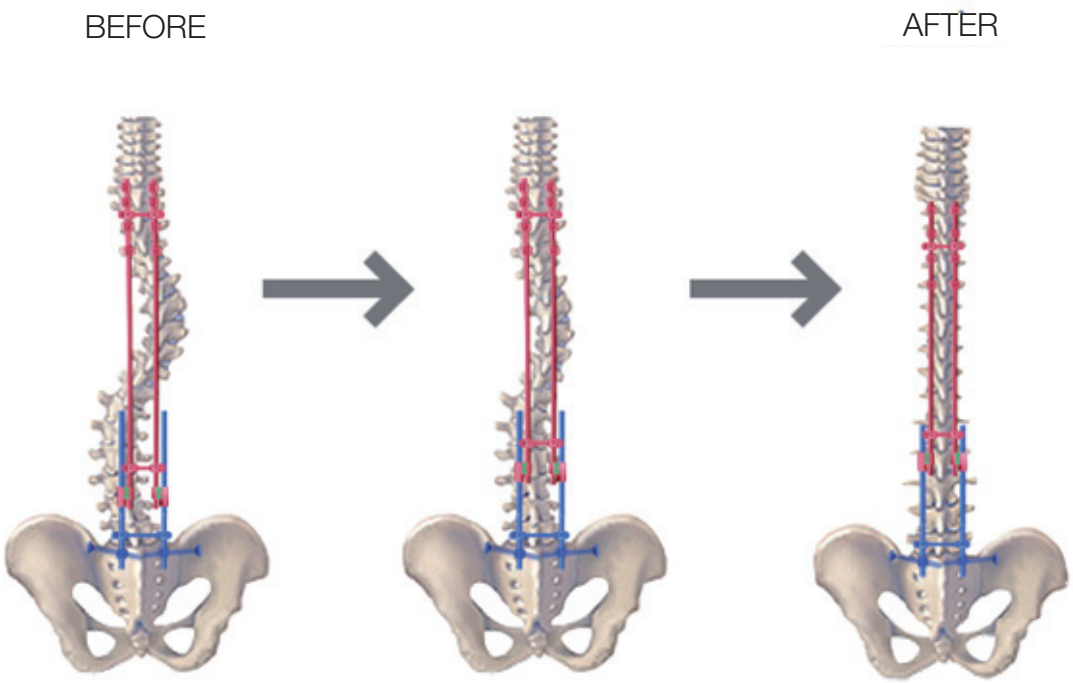
The surgeon is required to assess the patient's growth potential and specific pathological, behavioural or other conditions that could compromise the proper functioning of the NEMOST device.

The NEMOST growth domino must be implanted bilaterally.

3. BIPOLAR ASSEMBLY WITH THE NEMOST IMPLANT

During implantation surgery, the correction of the spine is obtained by a distraction performed between the thoracic and lumbar or pelvic anchor blocks.

Thanks to the free unidirectional sliding, the NEMOST growth domino will be lengthened by the patient's natural movements and growth. The device should keep the spine as straight as possible without repeated lengthening surgery.



3.1. Preparation and installation of patients

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IMPORTANT : The NEMOST implant surgery should not be performed as if it were a definitive arthrodesis surgery, which requires the surgeon to obtain the maximum correction in a single stage.

The surgeon should first seek to obtain a maximum correction on the table:

- Preparation by preoperative traction may be considered in some patients with a particularly rigid spine.
- Intraoperative traction is strongly recommended.
- Patient positioning must be used to decrease the deformation.

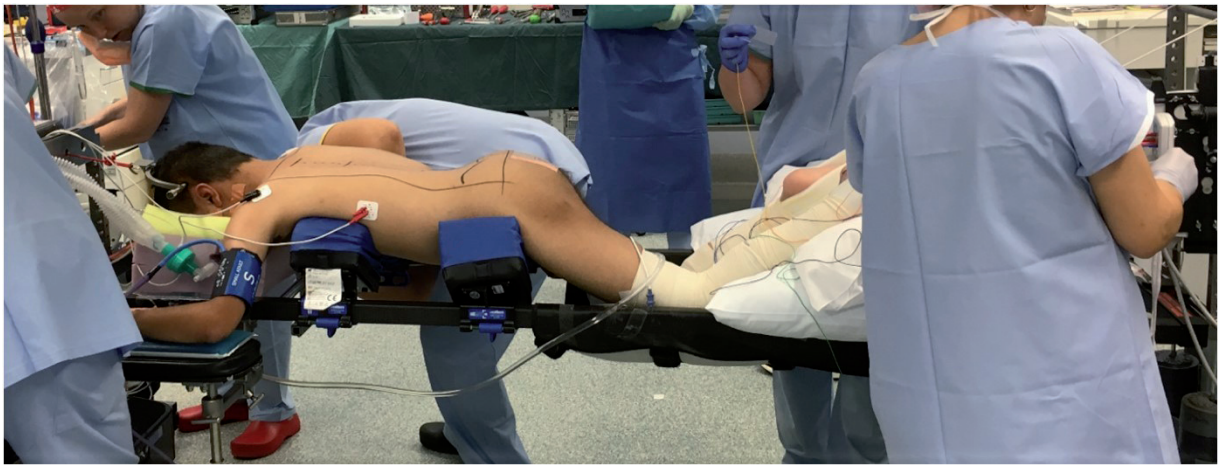
These precautions may reduce the effort required to correct the deformation by using compression / distraction manoeuvres performed directly on the implants. They also protect the anchorages and prevent excessive pretensioning on the NEMOST device thus delaying / preventing its lengthening.

Intraoperative traction is applied when the patient is lying on their back.

- Fixation to the skull can be made using Gardner-Wells tongs, or a cranial halo
- Lower limb traction can be achieved by using boots or adhesive strips

The patient is then returned to the prone position for implantation of the equipment. Traction is applied under control of the sensory evoked potentials (SEP) and motor evoked potentials (MEP).

Traction may be asymmetrical or even unilateral in the case of pronounced pelvic obliquity.



All traction procedures on the spine should be performed under strict neurological control. One of the advantages of preoperative traction is the prevention of possible neurological disorders that could result from a significant intraoperative correction.

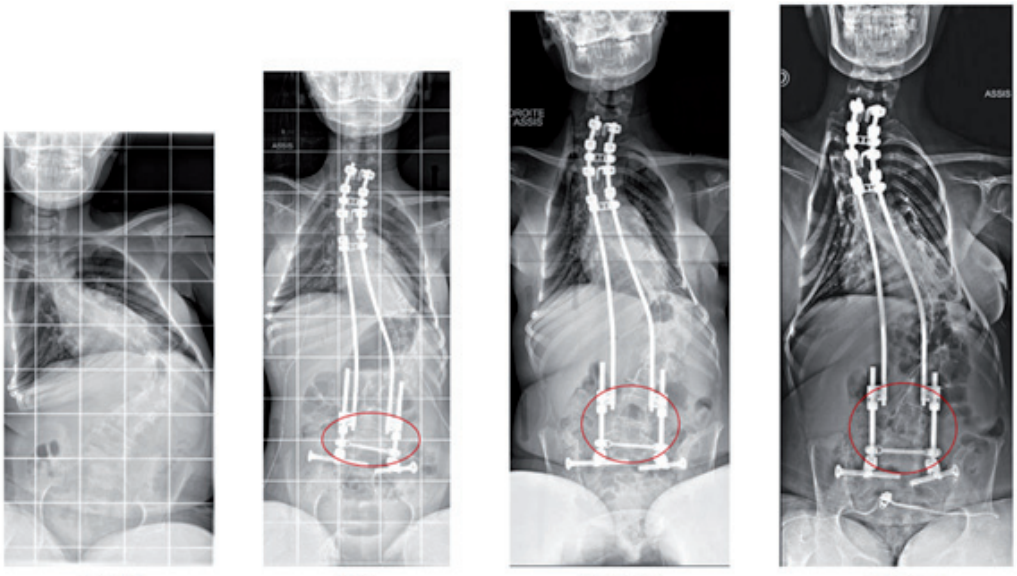
3.2. Bipolar assembly

The bipolar assembly, carried out using the NEMOST implant, must bridge the deformation by restoring the spinal balance in its entirety, in the frontal plane as well as in the sagittal plane. The spinal part, not included in the assembly, must remain properly oriented.

Cranial anchors are placed in the thoracic region, at the vertebral levels which will prevent the development of a junctional kyphosis. It takes four or five vertebrae: two groups of two adjacent vertebrae are fixed by bilateral pedicle-lamina (or transverse) clamps. Between these two pairs of vertebrae, a floor can be left free.

Caudal anchoring can be lumbar or pelvic. Lumbar anchoring is ensured by pedicle screwing on two adjacent vertebrae. In the situation of pelvic obliquity, pelvic anchoring is ensured by ilio-sacral screws.

The NEMOST implant should be implanted bilaterally and symmetrically, paying particular attention to the best possible parallelism of the rods, oriented along the growth axis and in a plane as close as possible to the spine. The two rods of the construct are connected by at least two transverse links devices to prevent twisting of the assembly which could interfere with the sliding of the rods.



Initial PO 2 years PO 4 years PO

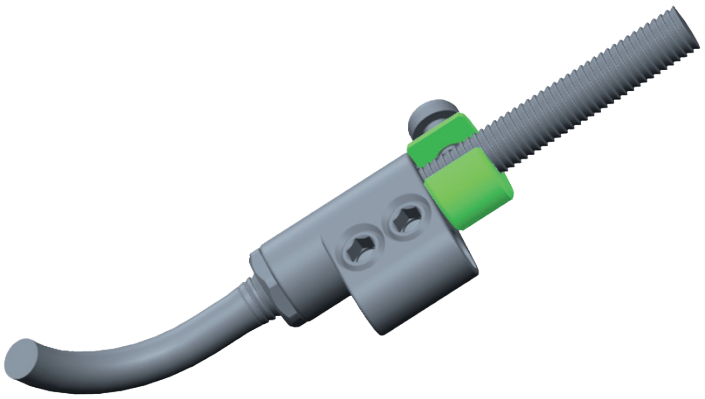
An example of infantile-onset spinal muscular atrophy in a 10-year-old child

Note: The transverse traction devices must not interfere with the sliding of the NEMOST systems.

3.2.1. Assembly with pelvic caudal fixation

When an assembly is to extend to the pelvis, the notched part of the NEMOST rod must point towards the top of the assembly (thoracic) in the lateral position.

In this assembly configuration, the long rod is cut with a standard rod cutter to the desired length to connect to the pelvic anchor. It is bent according to the desired local lordosis.



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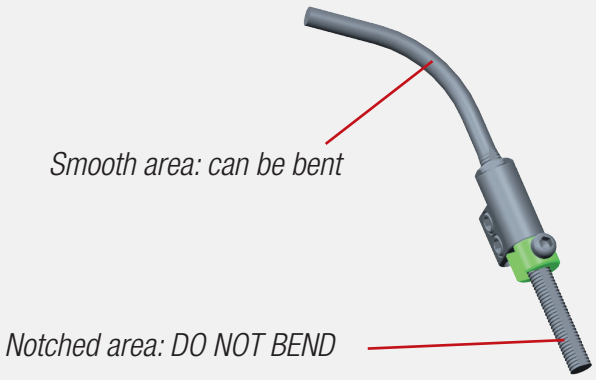
IMPORTANT :
Bending the rods

Only the smooth portions of the rods can be bent.

The notched area must remain straight to ensure it freely slides in one direction inside the tunnel provided.

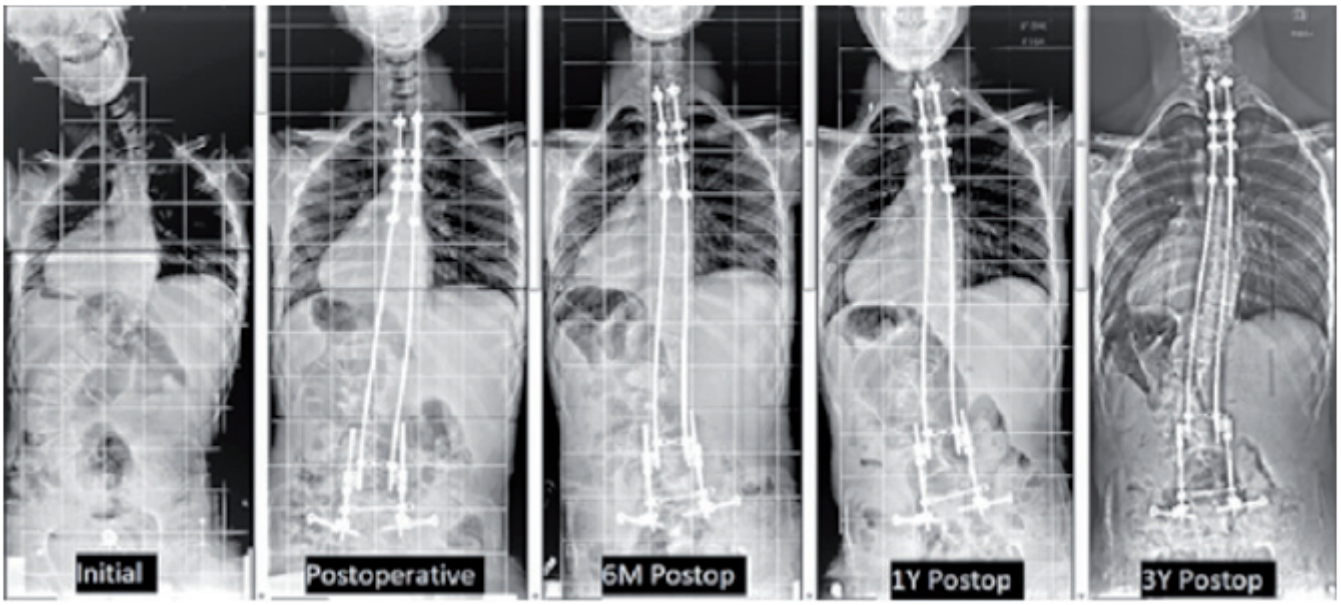


Preserving the rods

The notched portion of the implant must not be bent, or come into contact with the clamps or other instruments that can damage it in any way.

It must not be cut as the burrs may prevent its sliding in the body of the domino.

Clinical case example:



A consecutive series of X-rays in a neuromuscular patient showing spontaneous lengthening over time with a follow up at 3 years.

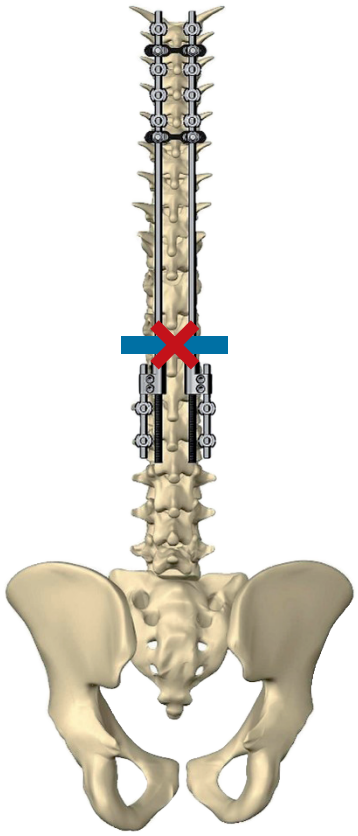
3.2.2. Assembly with lumbar caudal fixation

When an assembly must not extend to the pelvis, the notched part of the rods must point towards the bottom of the assembly in the medial position.

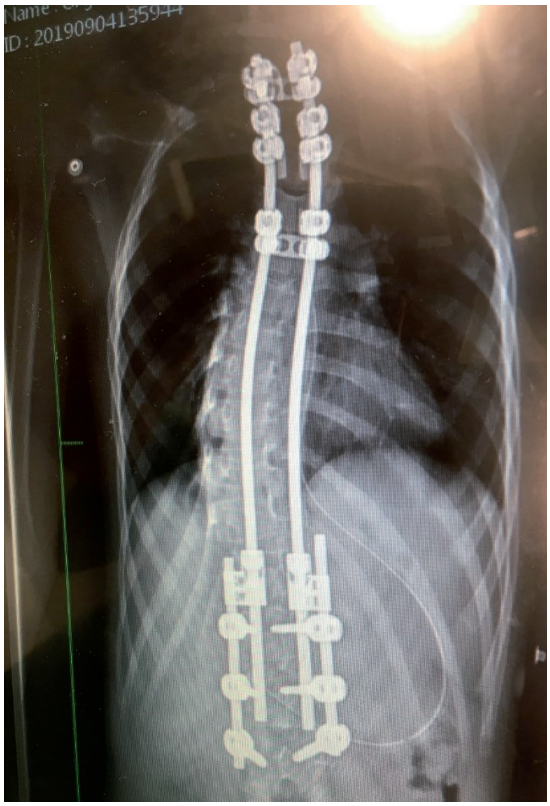
Fixation with bilateral pedicle screws can be performed on a block of two adjacent vertebrae where the bone quality permits it. Otherwise, where there is a lumbar curvature, an anchor on a block of three adjacent vertebrae is recommended.

In this type of assembly, using 80 mm rods are not recommended due to the lower potential for natural growth in the thoracolumbar region.

In order to reinforce the effect of the assembly, two cross-link devices must be added in the proximal fixation area around the hooks. It should never be positioned on the smooth distal portion of the middle rods of the NEMOST device as it may conflict with the spinous processes.



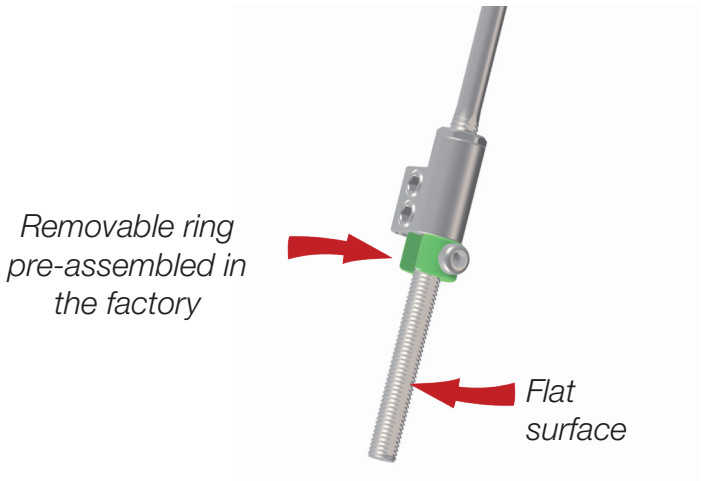
Clinical case example



4. PRECAUTIONS WHEN HANDLING IMPLANTS

4.1. Removable locking ring

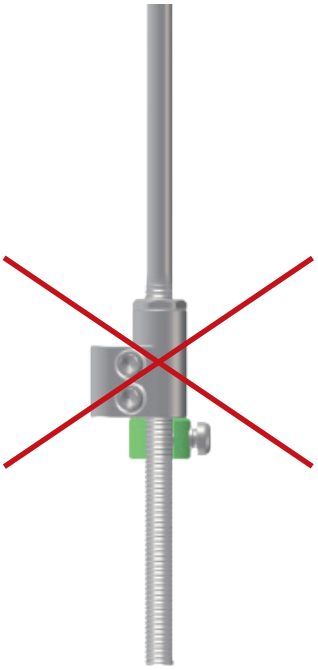
The NEMOST implant is supplied with a locking ring to maintain the factory settings during handling and thus avoid unwanted sliding of the domino along the notched rod before implantation.



Depending on which direction the NEMOST device is used, it may be necessary to reposition the ring to ensure that the ring opening is oriented toward the column to facilitate its removal at the end of surgery and then release the mechanism.

The ring can be removed from the top

The ring is locked under the rod



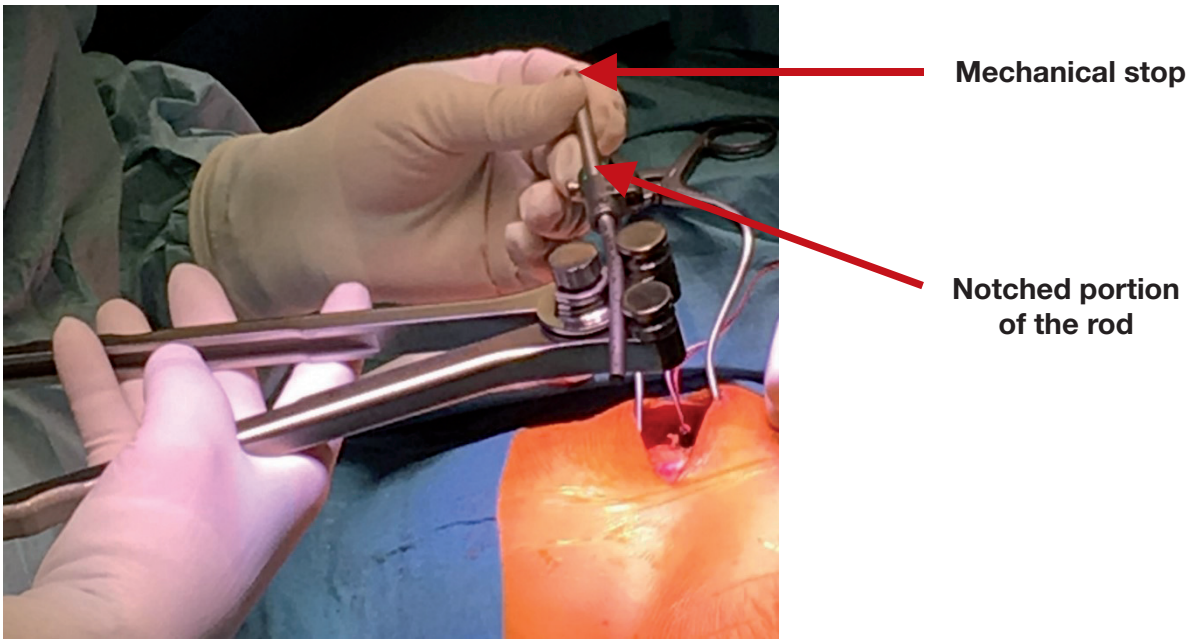
IMPORTANT
This ring must be removed at the end of surgery to release the sliding mechanism.

4.2. **Bending rods**

Only the smooth portions of the rods can be bent.

IMPORTANT
The notched area must never be bent or twisted. The notches must be preserved intact during handling and implantation of the NEMOST rod (otherwise the rod will not slide). The use of a clamp or any other instrument which may damage this notched area should be avoided.

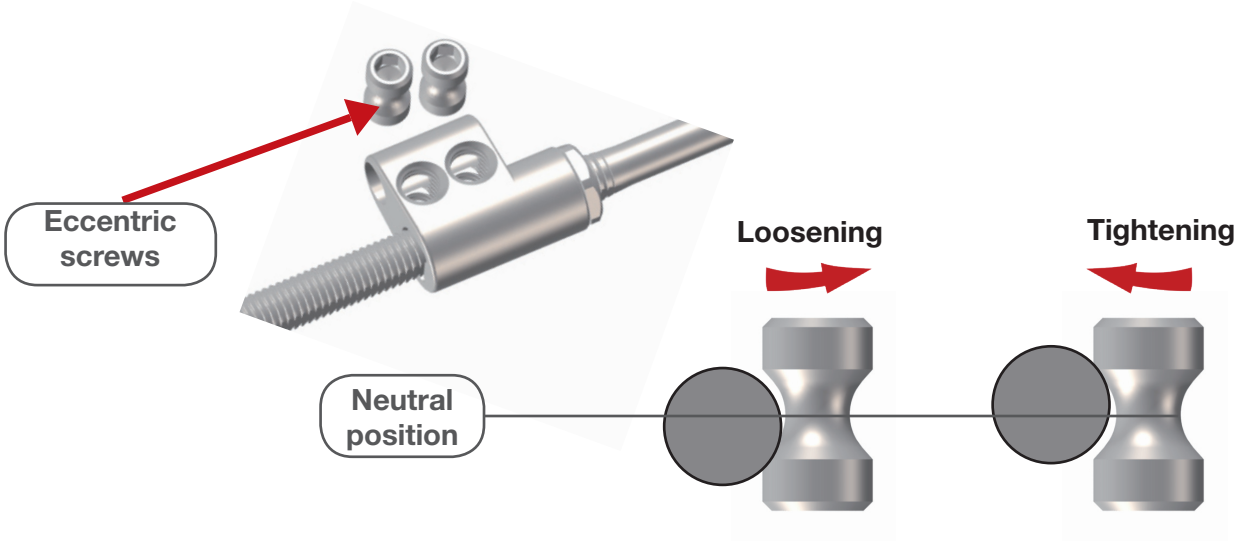
The notched rod portion must not be cut as the end has a mechanical stop preventing the domino from coming out of the rod when the maximum lengthening of the implant has been reached.



Note the presence of the locking ring, which must remain mounted on the implant throughout handling.

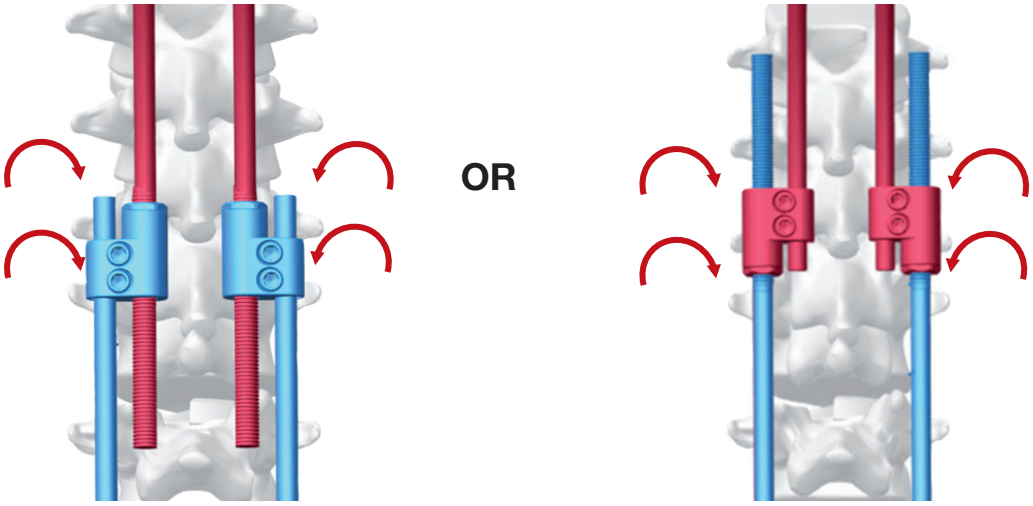
4.3. Tightening locking screws

The locking principle of the domino is based on the use of two eccentric screws.



In order to release the conditioning rod, the neutral position of the eccentrics screws (without tightening on the rod) must be found.

In order to permanently lock the connection at the end of the assembly, these two set screws must be tightened in the same direction to resist the translational of the smooth rod inside the domino.



When the mobile parts of the construct (red) are medical then all excentric screws must be tightened towards the inside of the construct.

Eccentric screws must be tightened using the specific wrench provided (sterile).

4.4. Presence of a flat surface

Due to the presence of a flat surface on the notched rod, it is important not to attempt to reposition the body of the NEMOST implant after locking the eccentric screws (e.g., to reduce the prominence of the implant). This final position of the domino body in the plane with the smallest footprint in the frontal plane must be obtained by means of appropriate rod bending and adjustment of various assembly components.

5. POST-OPERATIVE CARE

The NEMOST rods do not require the wearing of a post-operative corset. However, it is important to train/inform the health care provider and any person who is required to handle the patient regarding good practices and appropriate precautions (including not to make significant asymmetric movements).

CAUTION !

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