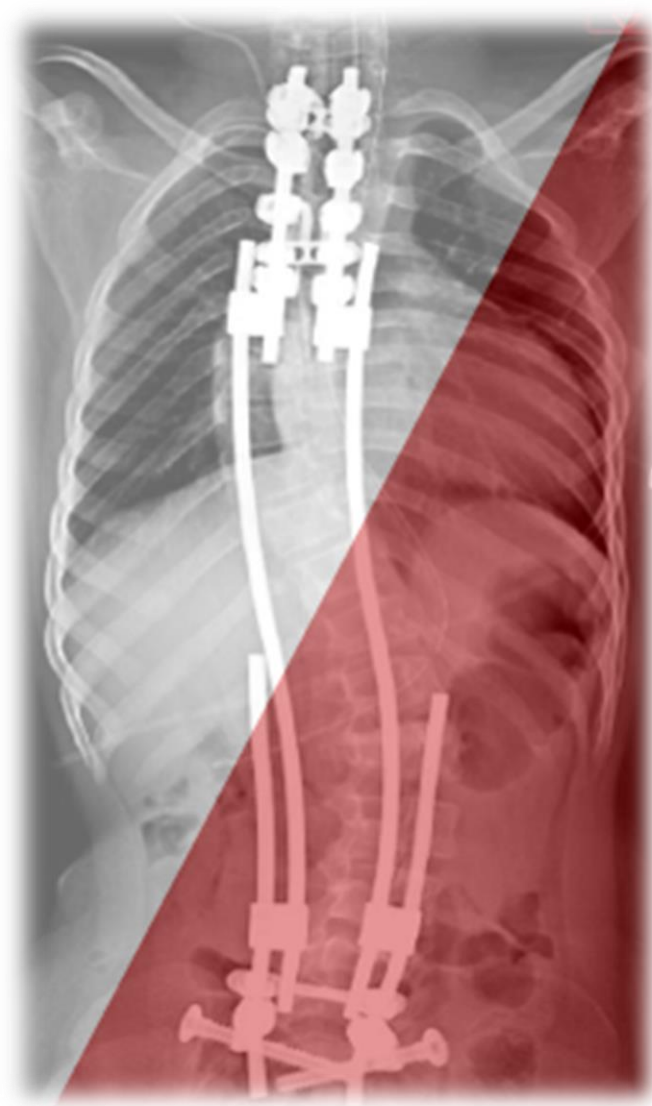


MINIMALLY INVASIVE BIPOLAR TECHNIQUE FOR THE TREATMENT OF SPINAL DEFORMITIES IN CHILDREN AND ADOLESCENTS





Introduction

Whatever the etiology, some forms of early onset scoliosis in young children are progressive and resistant to conservative treatment, requiring surgery. Surgery is also indicated in cases of neglected and complex spinal deformities in adolescents and young adults.

Nowadays, posterior vertebral arthrodesis is the “Gold Standard” technique. These traditional techniques provide vertebral detorsion and translation by a full segmental instrumentation, leading to an immediate and definitive correction of the deformity. However, these methods may expose the patient to neurological and hemorrhagic risks.

For severe and rigid curves, anterior release, vertebral osteotomies, or even vertebrectomies may be indicated in order to obtain maximum mobility and the best possible immediate correction of the deformity, since vertebral arthrodesis is a final operation.

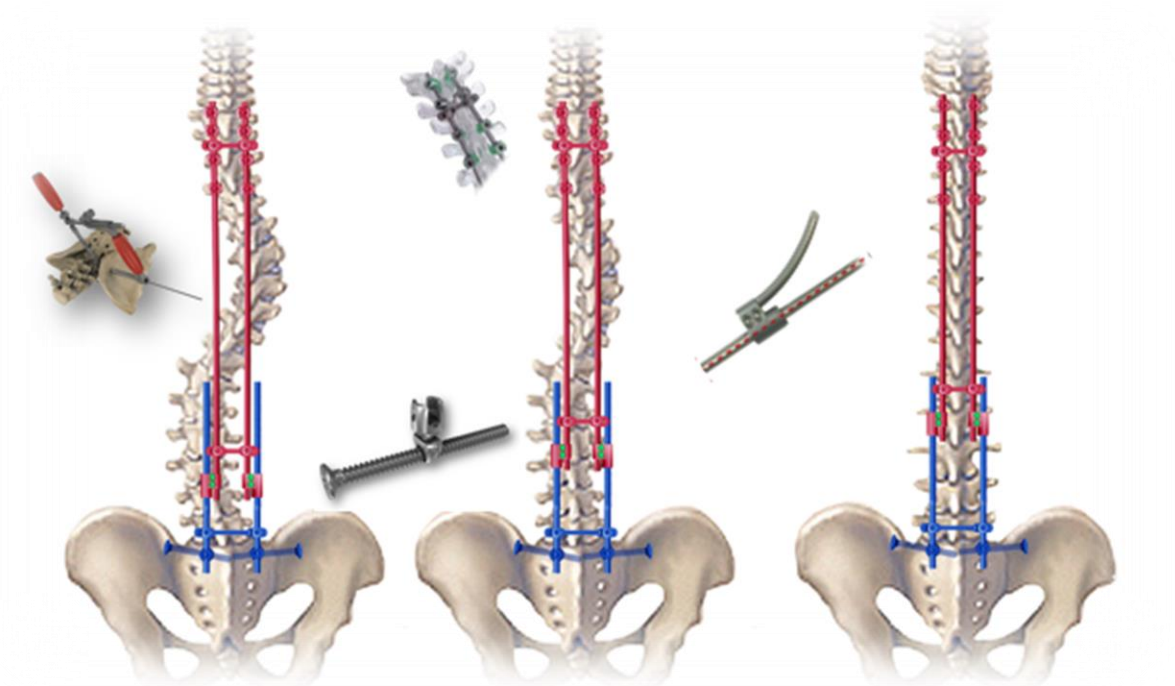
The increase in implant density and the invasiveness of the osteotomies may result in higher surgical risks, particularly hemorrhagic and neurological ones.

In contrast to these risky methods, and in order to reduce the surgical risks for complex spinal deformities, the minimally invasive bipolar technique has been developed starting in 2010.

The minimally invasive bipolar technique achieves global and progressive detorsion of the whole spine, leading to recovery of its initial shape secondary to the correction of the trunk collapse, due to the constant tension maintained by the rods between the two ends of the construct.

The spine is composed of different components acting all together as bony structures (vertebrae) and soft tissues (discs, ligaments) providing a viscoelastic behavior to the spine when submitted to traction forces. The progressive relaxation under permanent traction results in a gradual detorsion of the spinal deformity.

The bipolar method consists in performing a telescopic construct, bridging the curve and maintaining a constant tension between the two extremities (cephalad in red and caudal in blue) allowing when required a relative elongation in between the two “poles”.





Main requirements

However, to successfully obtain a progressive bipolar detorsion and stable elongation of the spine, four main conditions need to be addressed :

- The construct must provide strong and stable anchorages at the extremities
 - Double supra-laminar pedicle hook claws on each side of four or five adjacent vertebrae for the thoracic area assembled as an independent solid frame
 - Ilio-sacral fixation or group of 2 to 3 levels pedicular lumbar screws for the caudal anchorage
- The link between fixation points must create a solid but flexible bridge
 - Single rods or dual rods constructs
 - Different rod material and diameter options
 - Construct strategy being determined by the patient's pathology, severity, symptoms and comorbidities
- The intermediate zone (apex of the deformation) must not be exposed and instrumented
 - Preservation of biologic tissues
 - Auto fusion risk reduction
 - No risky maneuvers or osteotomies in the most deformed area of the spine
- The tension between the two extremities of the construct must be maintained permanently
 - Construct Re-tensioning surgeries could be planned every 12 to 18 months with standard E.SPINE® dominos are used
 - Self-expandable NEMOST device will capture the available mobility to automatically maintain the traction in the spine





Patient preparation and installation

The intervention should preferably be carried out under intraoperative traction
Load should not exceed 20% of the body weight.

Traction is realized when the patient is still lying on his back

- The attachment to the skull being carried out using a Gardner frame, a cranial halo or a Mayfield frame
- The attachment to the inferior limbs will be performed using boots or adhesive tapes

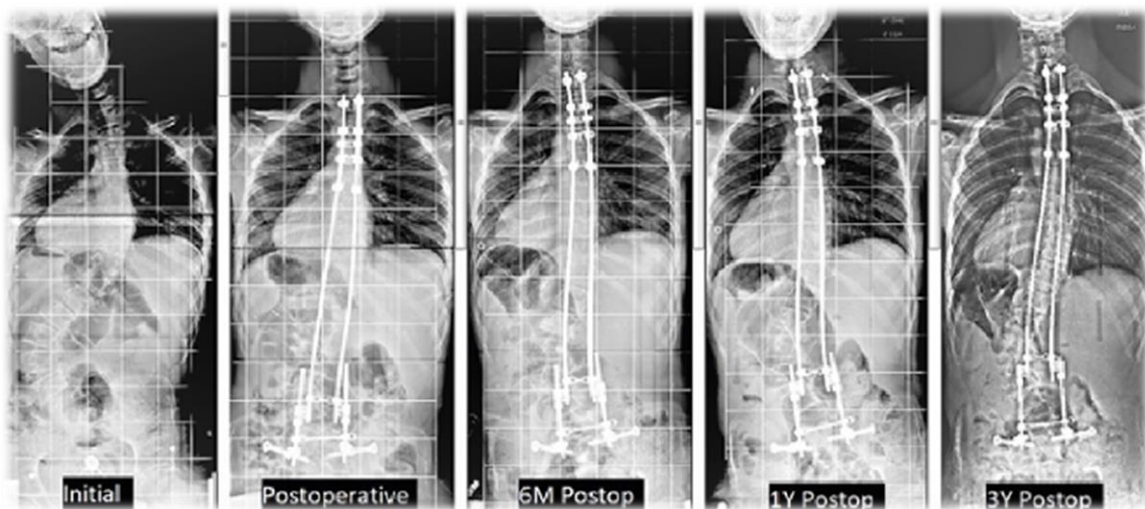
The traction is implemented under the control of the somesthetic (PES) and motor (PEM) evoked potentials.

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

The patient is then positioned on the back, taking care to leave the abdomen free from any point of support.



Example : Consecutive X-Rays of a neuromuscular scoliosis case in a 17-year-old operated with self-expanding device NEMOST, showing spontaneous expansion of the device over time combined with the minimally invasive bipolar technique





Step 1 : Caudal anchorage

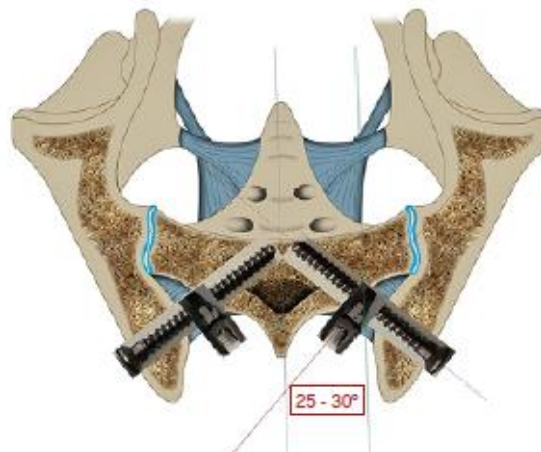
In neuromuscular scoliosis, pelvic fixation is performed using ilio-sacral screws, which provide great stability and high resistance to dislodgement.

In idiopathic and syndromic scoliosis, distal fixation is performed using pedicle screws in two or three levels on each side.

Option 1 : Implantation of the ilio-sacral fixation E.SPINE® TANIT

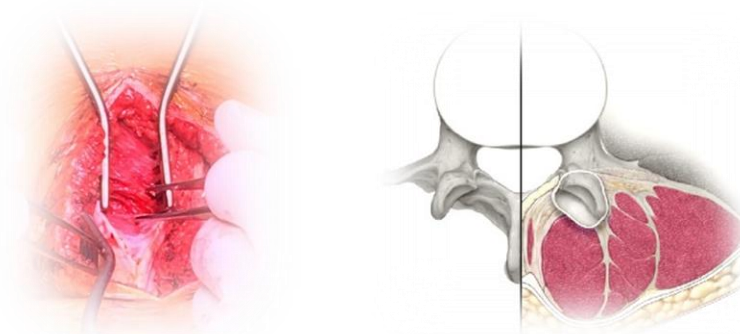
It is important to refer to the E.SPINE® TANIT surgical technique to obtain the precise description of the instrument sequence usage and details.

Ilio-sacral screws have a full bony path, from the iliac ala to the S1 body, crossing three or even four cortices. Their position is perpendicular to the rods into which they are fixed, at the middle of the rods, by locked connectors. The bilateral ilio-sacral screws realize with the crosslink a triangular construct that represents a very resistant fixation against pullout forces, even in very fragile bone.



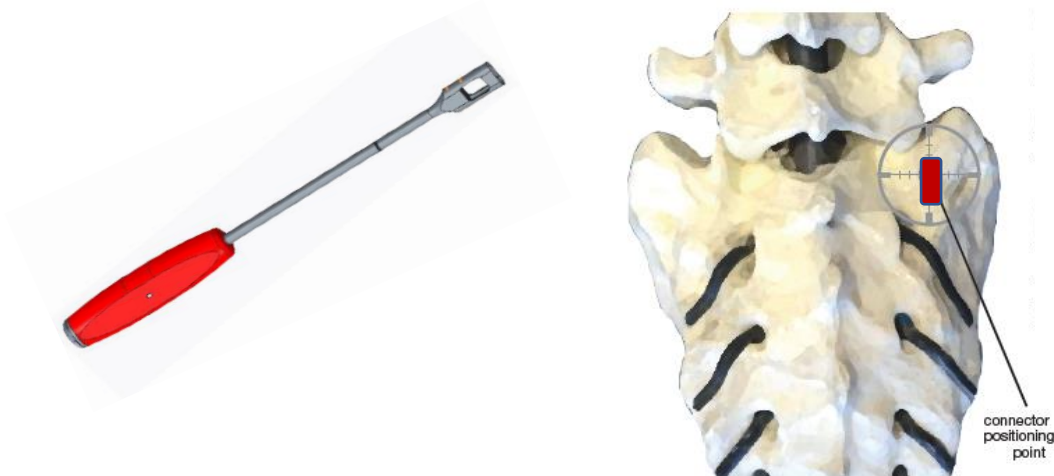
The site of the incision is localized by the horizontal line passing through the top of the iliac crests. This median incision will extend 4-5 cm above and below this line.

After bilateral detachment under fascia, a paramedian trans muscular approach (according to the Wiltse pathway) is performed by passing between the longissimus and the multifidus.

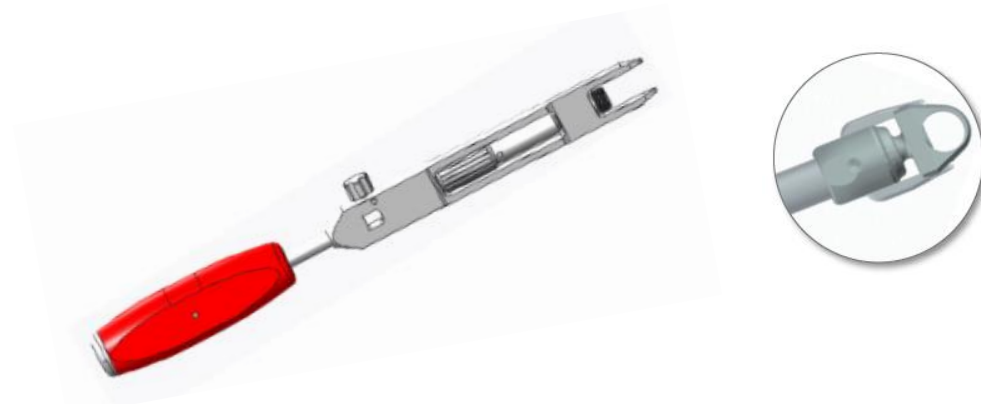


The lateral part of the posterior arch of L5 must be cleared to the transverse as well as the posterior face of S1 to locate the L5/S1 articular facet and the first sacral foramen.

To find the entry point of the connector, an hole is made using an osteotome placed halfway between the lower edge of the articular facet of L5 and the upper edge of the sacral foramen. Slightly offset by 2 to 3 mm towards the iliac wings.



The connector is attached to the implant holder. Thanks to a square guiding device attached to the implant holder, the orientation of the ilio-sacral is given by the angulation of the implant holder of an angle between 25 to 30° towards the midline.



A complete range of ilio-sacral connectors is available to best fit with the anatomy conditions of the patient, the physiological loads and the correction technique.

The transverse position of the ilio-sacral screw towards the flexion / extension forces makes it possible to resist to high pulling out forces to which the assembly is submitted due to the large lever arms.

The lateral anchoring of the ilio-sacral screws inside the pelvis allows a good control of coronal plane, particularly in the case of pelvic obliquity.

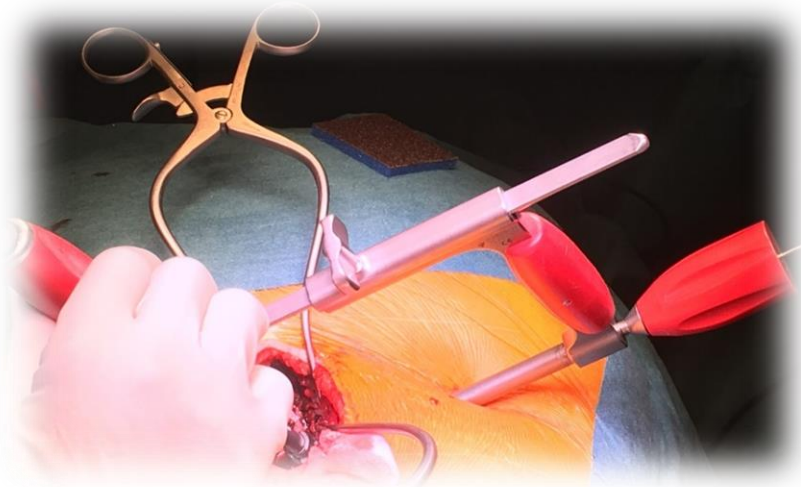
Finally the stability of the ilio-sacral fixation allows the assembly to be used as a fulcrum for reduction maneuvers without compromising the anchorage in the bone.



The construction of the external guiding frame will help locate the future entry point of the ilio-sacral screw. The tube placed in contact with the skin gives the position of the 11 to 12mm horizontal incision to be realized. The trocar tip being pushed in contact with the surface of the iliac wing to dilate the muscles.

The frame is now firmly locked and will serve as a guide for the rest of the ilio-sacral screw placement.

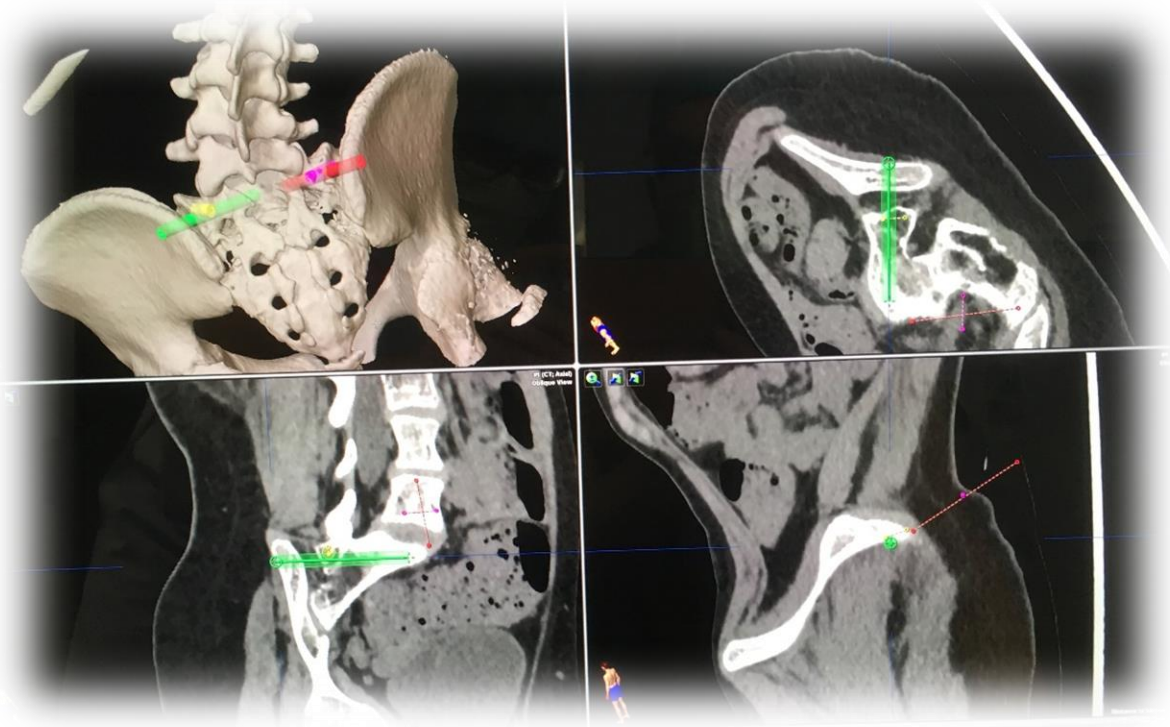
A sequence of instruments is used through this guiding tube to prepare the entry point of the screw with a cannulated awl followed by a cannulated tap to prepare the first threads inside the iliac wing and the first centime inside the sacrum.



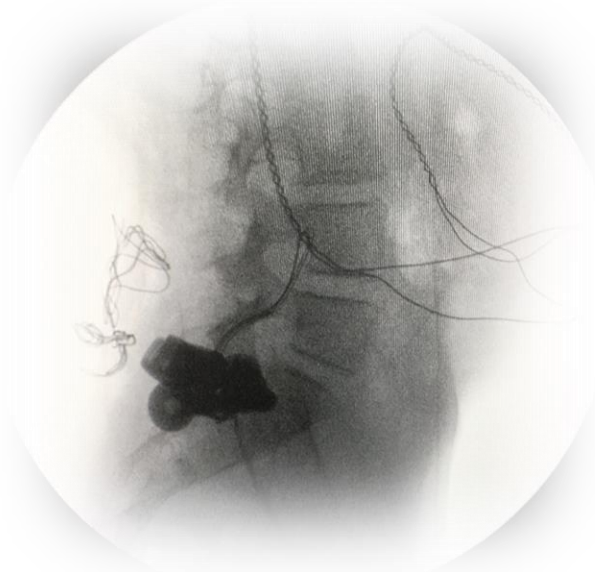
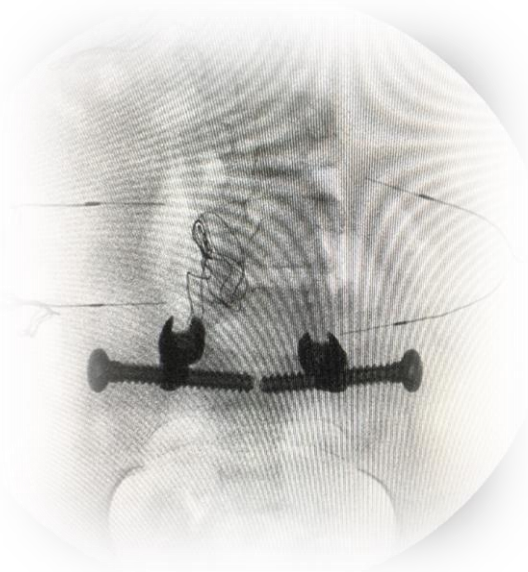
A “diapason” hammer is used to detect the contact of the smooth and round tip of the guide wire with the anterior cortical wall of the sacral vertebral body.



Alternatively, intra operative navigation can be used to plan, guide and check the position of the screw.



When the entire guiding device has been dismantled, an X-ray control can be carried out to check both sides of implantation.

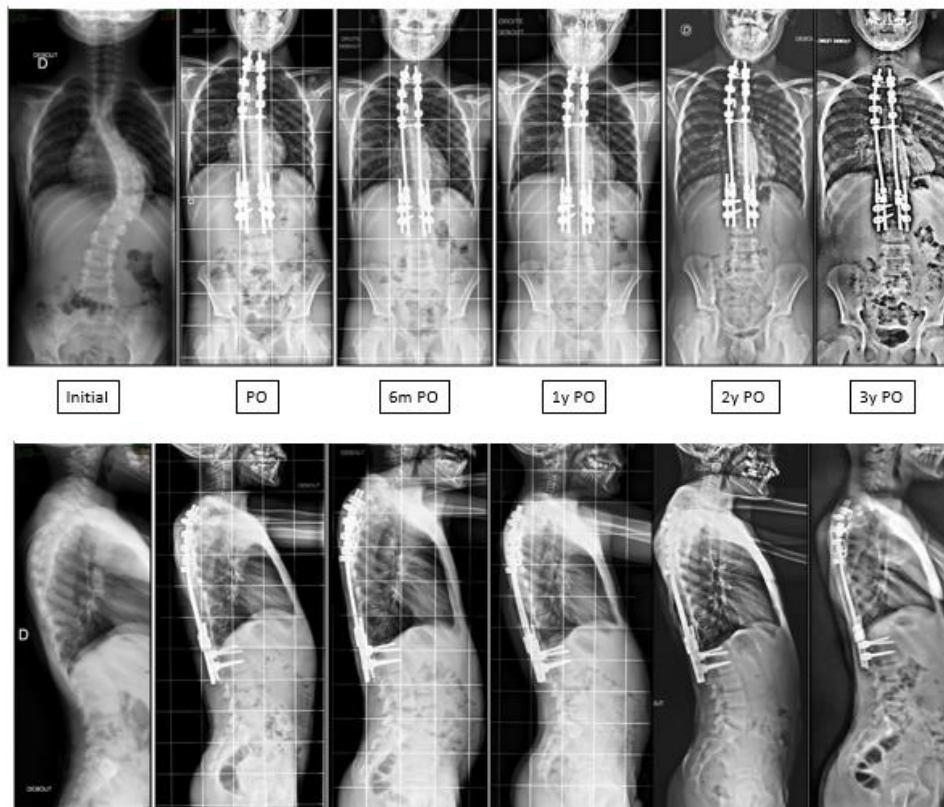


Last but not least, a last very important step consists in tightening the locking screw located at the bottom of the connector to permanently secure it with the ilio-sacral screw while maintaining the polyaxiality of the connector.



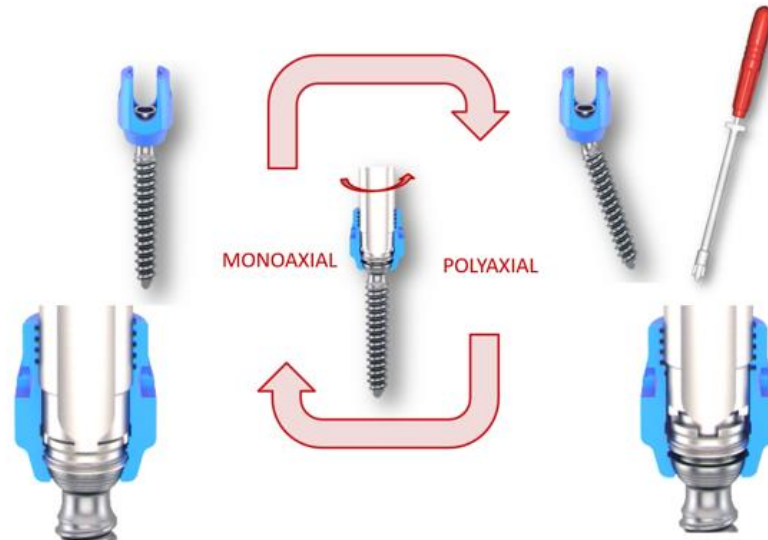
Option 2 : Implantation of lumbar pedicle screws

In idiopathic and syndromic scoliosis, distal fixation can stop in the lumbar area. The fixation is then realized using pedicle screws in two or three levels on each side.



Example of a neglected infantile scoliosis in a 14Y old boy operated after 4 weeks halo-traction

The E.SPINE® pedicular screw offers a dual function with the same implant. Screw can be converted in situ as MONOAXIAL or POLYAXIAL one as per surgeon preference or strategic choice.



With a mono axial screw, the corrective forces are transmitted directly to the vertebra using the long lever arm offered by the thread of the screw passing through the pedicle into the anterior vertebral body. The surgeon can then better control the position of the vertebra in the three planes.

Poly axial screws have the advantage of better accommodating misalignments or bending defects of the rods in complex situations.

It is important to refer to the E.SPINE® surgical technique to obtain the precise description of surgical sequences and instruments usage details.



Step 2 : Cephalad anchorage

It is important to refer to the E.SPINE® surgical technique to obtain the precise description of sequences and instruments usage details.

Proximally, a midline incision is made at the level of the first thoracic vertebrae. The posterior arches from T1 to T5 are exposed subperiosteally while preserving the interspinous ligament.

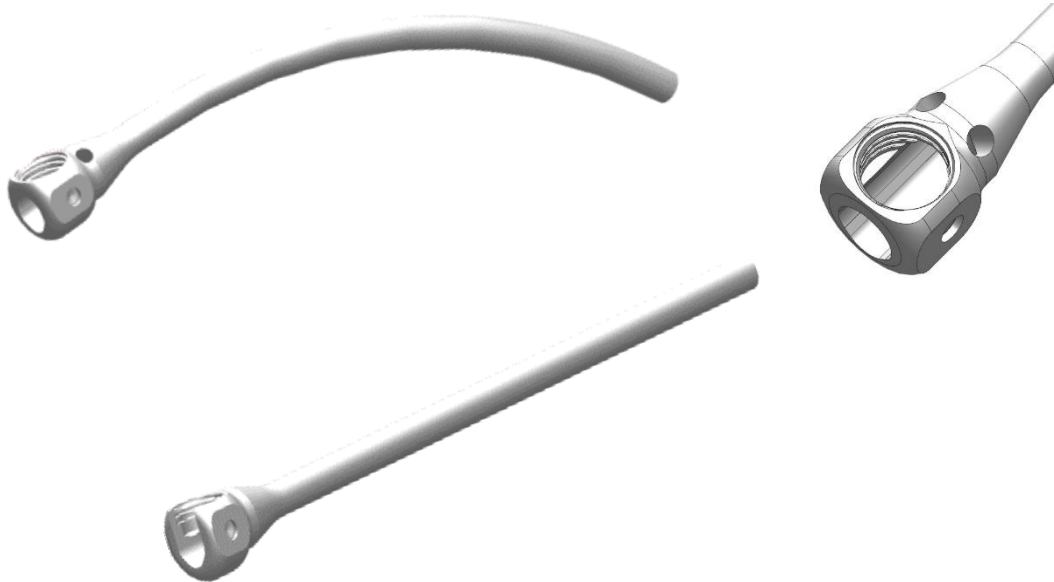
Bi-vertebral pediculo-laminar claws are performed in T1-T2 and T4-T5 leaving the T3 vertebra free.

The hook claws grip the posterior arch of the vertebrae and tend to reduce the risk of implant dislodgement and proximal junctional kyphosis especially in long constructs, even in hyperkyphotic deformities.

The installation of the hooks is preferably carried out by mounting them directly on the hook pusher, stabilized by the plug, without prior bone preparation, or opening of the spinal canal to preserve the bone capital and ensure a solid fixation.



On both sides, the two hook claws are connected using specific “end to end” prebent or straight connecting rods available in different sizes.

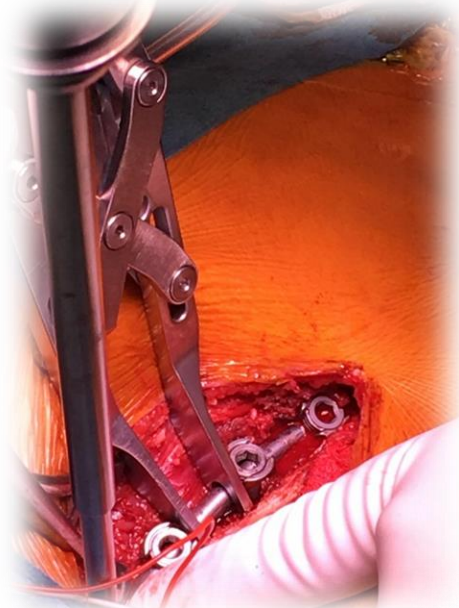


Additional bending to accommodate to the local deformity can be required.

It is necessary to close and preload the hook claws using the distracting and compressing pliers.



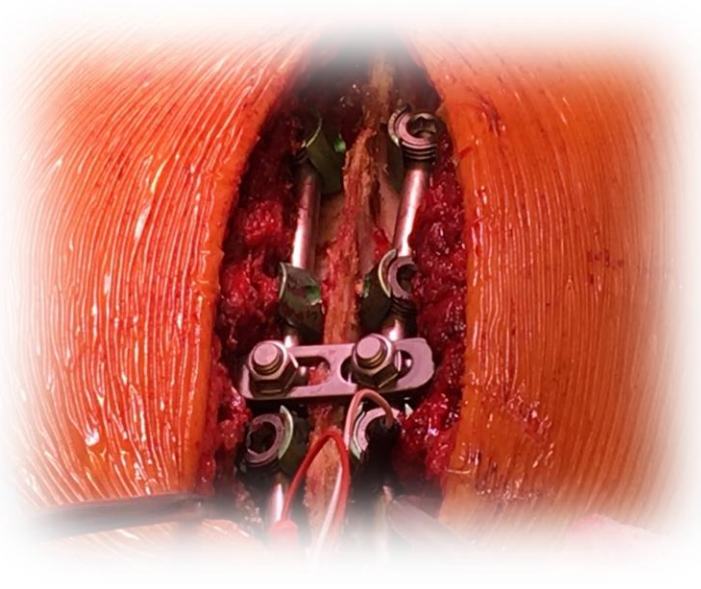
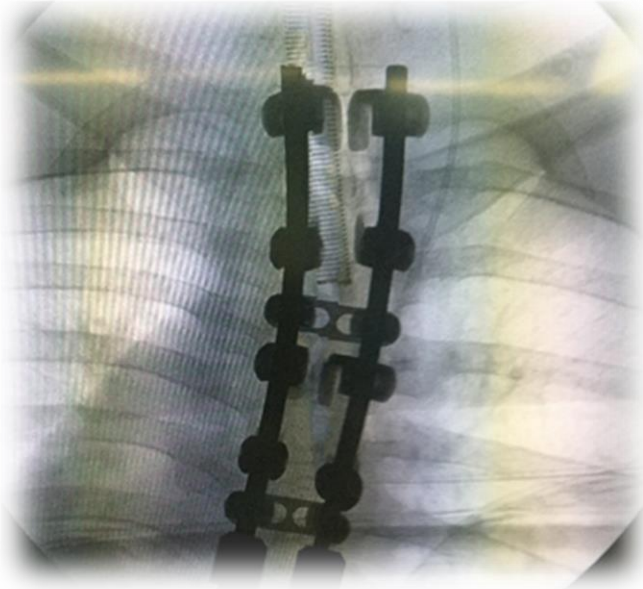
Compressing the pedicle and the laminar hook at T1-T2



Distracting the two pedicle laminar claws in T3 area

The assembly is consolidated by the placement of transverse links. The first proximal, at the site of the T3 vertebra left free and the second under the T5 vertebra.

A very solid frame, independent of the rest of the construct is then obtained. This first thoracic “pole” will help mobilize the trunk by limiting the risks of movement of hooks and will allow to distribute all the correction efforts on all the anchor points.



Example : Patient 8Y old presenting severe sagittal and coronal imbalance

Pre-Op images



Post-Op Images



1 day Post op





Step 3 : Connecting the thoracic “pole” to the pelvic or lumbar “pole”

It is important to refer to the E.SPINE® and E.SPINE® TANIT surgical techniques to obtain the precise description of sequences and instruments usage details.

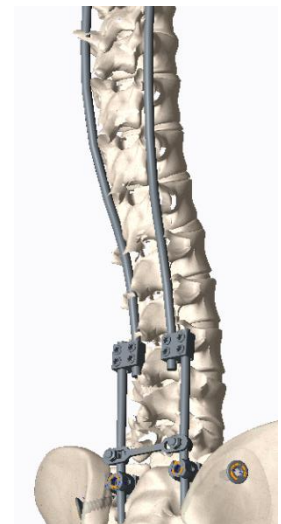
Rods selection and Length

The cephalad and caudal anchors at two ends of the construct must be connected by a solid bridge created by using two pre-bent rods on each side: a long medial rod fixed to the hook block at the top, and a short pre bent lateral rod fixed to the pedicle screws or ilio-sacral connectors at the bottom. The two rods are connected to each other by dominoes.



Long rods, available in diameter 5,5mm and 6 mm are pre-bent in a shape close to physiological angles and manufactured in both TA6V4 and CrCo material. Straight rods remain available if more suitable for the patient case.

The small rods (only available in 5.5mm diameter in both TA6V4 and CrCo) are delivered pre-bent as well. They present a lordotic distal part and a straight proximal part to prevent them from protruding under the skin once positioned.



The length of the rods will be selected to allow the connection from the "end to end" rod connector to the ilio-sacral connectors or lumbar screws.

Short rods should be of a length allowing to connect the ilio-sacral connectors or the lumbar screws to the long rods and allowing an overlap of 5 to 8 cm depending on the age of the child as a “reservoir for spine growth”.

The short rod can be chosen even longer if the local lordosis does not allow an optimal position of the dominoes in the lumbar region or a significant kyphotic effect is anticipated during growth or elongation of the construct.

The curvature of the spine may require some adjustment of the bending of the rods. Especially in the frontal plane to obtain a harmonious shape in regards of the deformity itself.

For patients with body weight of more than 40 kg, the use of cobalt chromium rods fixed to the pelvis is recommended to reduce the risk of breakage, especially in walking and hypertonic neuromuscular patients.

A four-rod construct may also be performed in dynamic patients with cobalt chromium rods fixed until the pelvis.



Note the extra short rod length anticipated for construct elongation



Example of a 4 rods construct extending the high thoracic area

Trans-muscular rods insertion

The long rods are passed trans-muscularly from one incision to the other, usually from top to bottom to avoid puncturing the thorax. Their pathway can be prepared using Bengol a forceps.



View of both incisions

The first long rod will be placed in the concavity of the main curvature or the one on the side of the most important pelvic obliquity.

It is important to control the orientation of the rods so that they are positioned in the correct plane thus the laser engraved lines along the pre bent long rods.

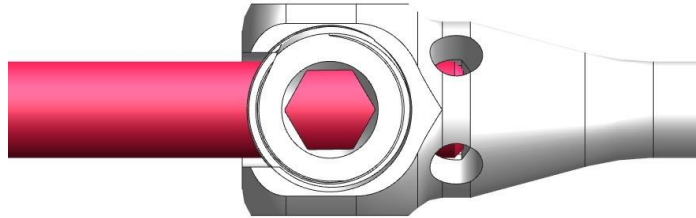
Double barrel dominoes are then assembled on the small rods pre-bent in their straight portion, leaving a reserve of rod from 5 to 8 cm (already anticipated when selecting the lengths of these rods). The short rods should be connected in the external hole of the dominoes (left and right side).

E.SPINE® offers a complete range of closed, Open dominoes as well as cylinders is available to connect 5.5 mm together or 5,5 mm and 6 mm rods.



The short rods equipped with the dominoes are then assembled to the long rods in situ. Set screws of the dominoes should be kept almost free to facilitate the interconnection of the different components. Check once again the proper orientation of all rods in the adequate plan of bending. Dominoes should now be locked in their proper future orientation.

Moving back to the proximal incision, the long rods must be inserted inside the 'end to end' rod connectors. Check that both extremities of rods are deeply inserted inside the connectors. The free end of the rods must be captured in the closed area of the connector. Set screws are then tightened on both 'end to end' connectors.

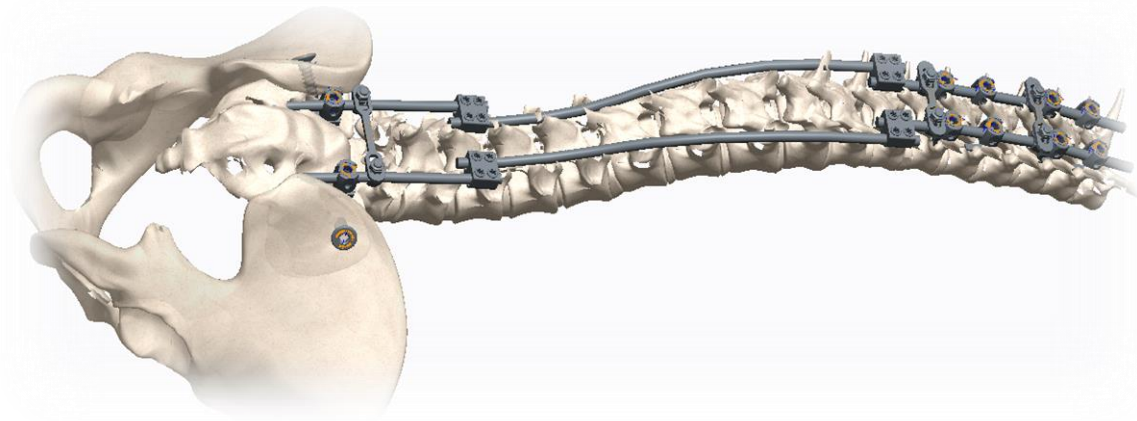


Back again to the distal incision, the short rods are inserted into the ilio-sacral connectors or lumbar screws. Either by sliding from top to bottom for the closed connectors, either using the rod pusher or persuader instruments from E.SPINE® for the open connector or using the threaded portion of the reduction connectors.



IMPORTANT :

In all cases, the construct must be reinforced by two proximal crosslinks in a thoraco-lumbar construct, and at least three crosslinks, two proximal and one distal, as close as possible to the ilio-sacral connectors, in a thoraco-sacral construct.





Step 4 : Correction of the deformity

It is important to refer to the E.SPINE® and E.SPINE® TANIT surgical techniques to obtain the precise description of sequences and instruments usage details.

Once the small lumbar rods are firmly attached to the connectors, corrective maneuvers can be performed.

- ✓ A distraction is made on the side of the concavity between the ilio-sacral connector and the adjacent domino
- ✓ On the other side :
 - A more moderate distraction if there is no pelvic obliquity
 - A compression if pelvic obliquity persists despite distraction on the concave side

Remember that a last transverse connection is put in place on the small lumbar rods, as close as possible to the ilio-sacral connectors to create a triangulation of the pelvic anchorages and significantly reinforce the assembly. Advantageously, this transverse connection will be put in place through and without cutting the interspinous ligament.



Post-operative follow-up

The bipolar construct, performed in this way, is solid and stable enough to avoid the need to wear a cast or brace postoperatively.

Sitting is authorized quickly, as soon as the child's condition allows, without external support.

For children who do not control their head well, a foam or semi-rigid collar can be put on to verticalize the patient. Lengthening operations will be performed later every 12 to 24 months depending on the age of the patients and the extent of the residual deformation.

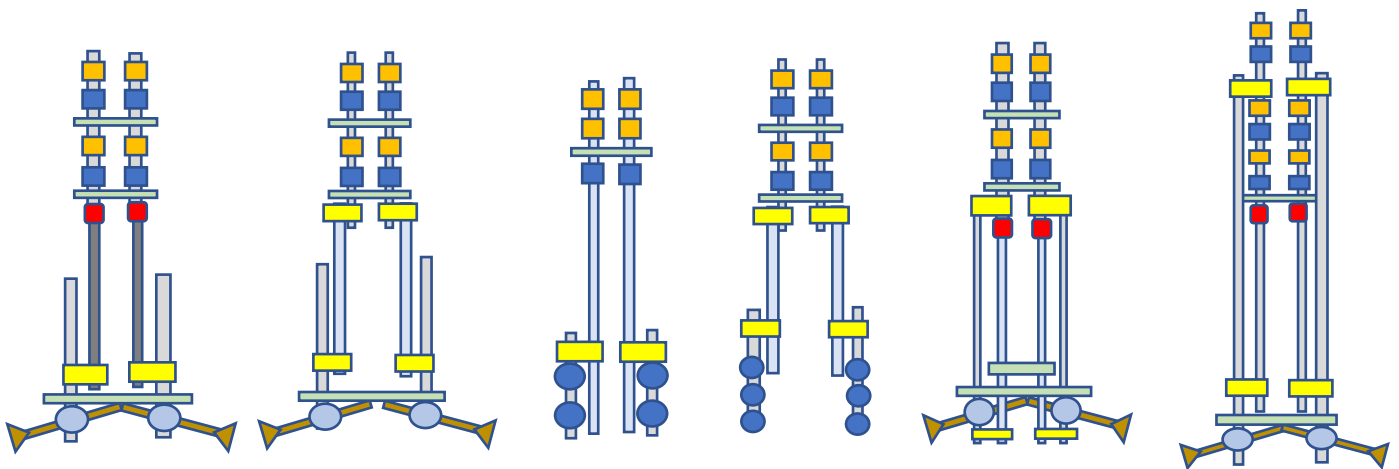




Variations and modularity of the constructs

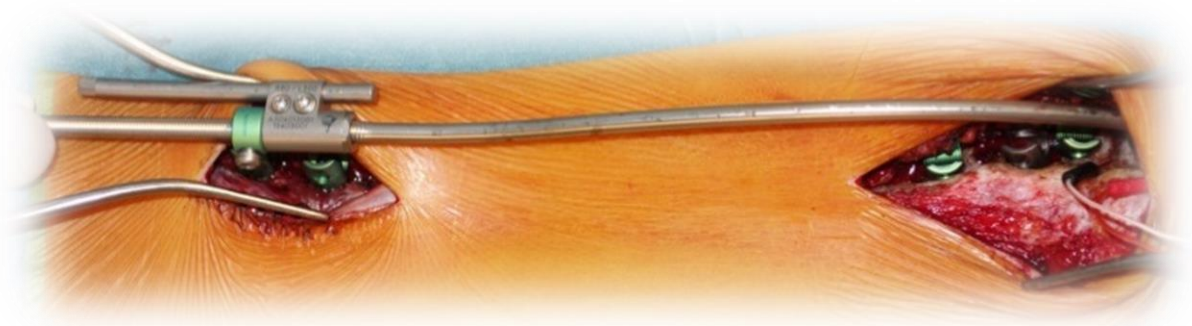
The range of dominos offered, the different rod diameters (5.5 and 6mm) as well as the different materials (TA6V and CrCo) allow to vary the type of assembly as well as its mechanical characteristics depending on the pathology to be treated.

Example of construct variability



NEMOST Self expandable rod

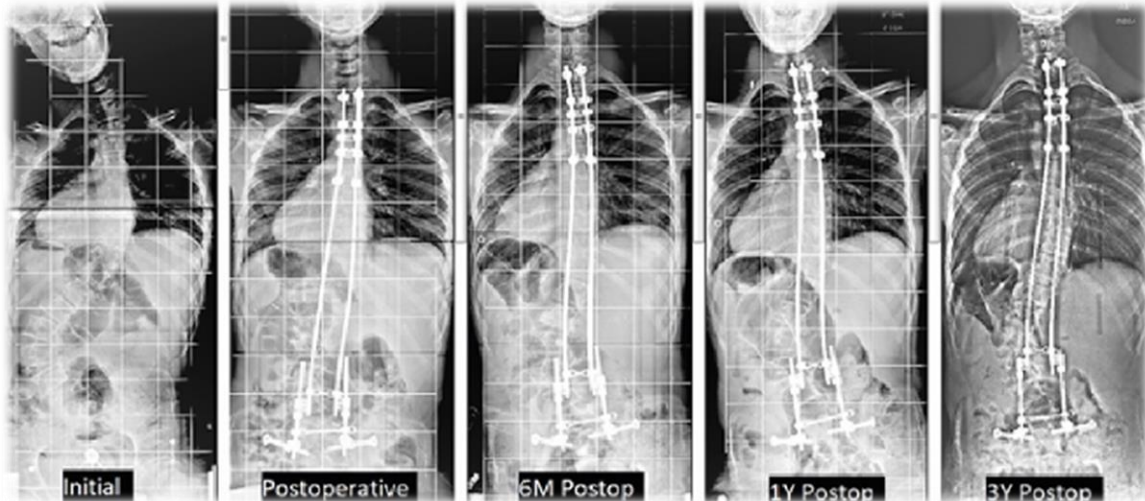
Repeated rod-lengthening procedures represent the main drawback of the method using standard dominoes. A One-Way Self-Expanding Rod NEMOST has been designed to expand spontaneously or by external axial traction maneuvers if required.



The NEMOST device is composed of two rods. A first long smooth section combined with a 50 or 80 mm-long notched area which represents the lengthening reserve of the device.

The domino connector slides gradually along the notched part of the rod in a single direction, in 1-mm steps. A mechanical system prevents the domino from moving backwards. The smooth part of the rod can be bent as needed along its entire length to accommodate to the residual deformity and avoid excessive constraints on the spinal anchors.

Example : Consecutive X-Rays of a neuromuscular scoliosis case in a 17-year-old operated with self-expanding device NEMOST, showing spontaneous expansion of the device over time.



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