ROMEO® 2

SEMI-POLYAXIAL PEDICLE SCREWS

C O N T E N T

CONCEPT AND DESIGN

Since 2005 Spineart has been true to the philosophy: quality, innovation, simplicity, by developing highly performing systems for the treatment of spinal pathologies.
ROMEO®2 is a complete posterior fixation system that incorporates smart technologies and simplified instrumentation.

The ROMEO®2 MIS 25S and ROMEO®2 25D semi-polyaxial screws provide the benefits of monoaxial screw for controlled powerful correction maneuvers and the versatility of the polyaxial screw for ease of rod connection.

The combination of the ROMEO®2 25D screw with the powerful QR Reducer allows multi-segmental vertebral derotation and ‘en bloc’ apical derotation maneuvers.

ROMEO®2 25S

ROMEO®2 25D

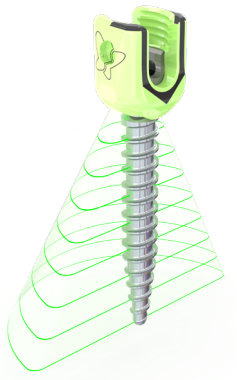
INDICATIONS

ROMEO®2 system implants are designed to treat those dorsal and thoracic pathologies:

- Spondylolisthesis
- Degenerative disc disease
- Thoracic and lumbar fractures
- Thoracic and lumbar vertebra tumors
- Pseudarthrosis
- Stenosis
- Spine deformities: scoliosis, cyphosis

TECHNICAL FEATURES

ROMEO®2 MIS 25S SAGITTAL SCREW



SEMI-POLYAXIAL CANNULATED SCREWS

25S screws restrict motion to half polyaxial range, combining benefits of polyaxial screws and monoaxial screws.

SAGITTAL PLANE CORRECTION

The 25S screws are designed to provide polyaxial freedom in the medial/lateral plane, but restrict motion in the cephalad/caudal plane to facilitate sagittal plane correction maneuvers.

DIRECT COMPRESSION/DISTRACTION MANEUVERS

Restricted motion of the 25S screws can be directed cranially or caudally, enabling direct parallel distraction and compression of vertebra.

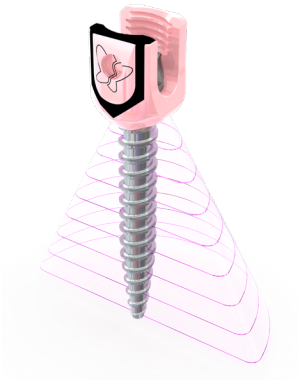
IDENTIFICATION OF THE FIXED AREA

The restricted motion side is indicated by a laser etch on the screw head.

LENGTH / DIAMETER	Ø5 MM	Ø6 MM	Ø7 MM
L30 mm	MIS-TS 05 30-S	MIS-TS 06 30-S	MIS-TS 07 30-S
L35 mm	MIS-TS 05 35-S	MIS-TS 06 35-S	MIS-TS 07 35-S
L40 mm	MIS-TS 05 40-S	MIS-TS 06 40-S	MIS-TS 07 40-S
L45 mm	MIS-TS 05 45-S	MIS-TS 06 45-S	MIS-TS 07 45-S
L50 mm	MIS-TS 05 50-S	MIS-TS 06 50-S	MIS-TS 07 50-S
L55 mm		MIS-TS 06 55-S	MIS-TS 07 55-S
L60 mm		MIS-TS 06 60-S	MIS-TS 07 60-S

TECHNICAL FEATURES

ROMEO®2 25D DEFORMITY SCREW



SEMI-POLYAXIAL SCREWS

25D screws restrict motion to half polyaxial range, combining benefits of polyaxial screws (ease of rod insertion) and monoaxial screws.

CORONAL & AXIAL CORRECTION

The 25D screws are designed to provide polyaxial freedom in the cranial/caudal plane, but restrict motion in the medial/lateral plane to enable more control of the vertebra during reduction maneuvres.

APICAL VERTEBRA DEROTATION

Restricted motion of the 25D screws can be directed medially or laterally, enabling direct rotation of vertebra and allowing a safe and efficient direct or “en bloc” vertebra rotation.

IDENTIFICATION OF THE FIXED AREA

The restricted motion side is indicated by a laser etch on the screw head.

LENGTH / DIAMETER	Ø4 MM	Ø5 MM	Ø6 MM	Ø7 MM
L25 mm	ELL-DS 04 25-S			
L30 mm	ELL-DS 04 30-S	ELL-DS 05 30-S	ELL-DS 06 30-S	ELL-DS 07 30-S
L35 mm	ELL-DS 04 35-S	ELL-DS 05 35-S	ELL-DS 06 35-S	ELL-DS 07 35-S
L40 mm	ELL-DS 04 40-S	ELL-DS 05 40-S	ELL-DS 06 40-S	ELL-DS 07 40-S
L45 mm	ELL-DS 04 45-S	ELL-DS 05 45-S	ELL-DS 06 45-S	ELL-DS 07 45-S
L50 mm		ELL-DS 05 50-S	ELL-DS 06 50-S	ELL-DS 07 50-S
L55 mm			ELL-DS 06 55-S	ELL-DS 07 55-S
L60 mm			ELL-DS 06 60-S	ELL-DS 07 60-S

CLINICAL CASE

Dr Tanguy Vendeuvre
Spine Unit
Orthopedic - Traumatology service
CHU Poitiers - France

HISTORY OF PRESENT ILLNESS AND RADIOGRAPHS

- 19 years-old female presented with an adolescent idiopathic scoliosis, with an apex at the disc between T12 and L1.
- The patient was 16 years-old at the first surgical consultation with a T9-L3 Cobb angle of 39° at a French Risser stage 3. Medical and orthopedic treatment was prescribed until reaching the Risser stage 4 or 5.
- The scoliosis worsened until a 40° Cobb angle between T9 and L1 at a French Risser stage 4, and more than 1cm offset between C7 and S1. Surgery then is planned, especially to restore frontal and sagittal balance. Moderate ventilatory disorder is also reported (CPT 79% th).

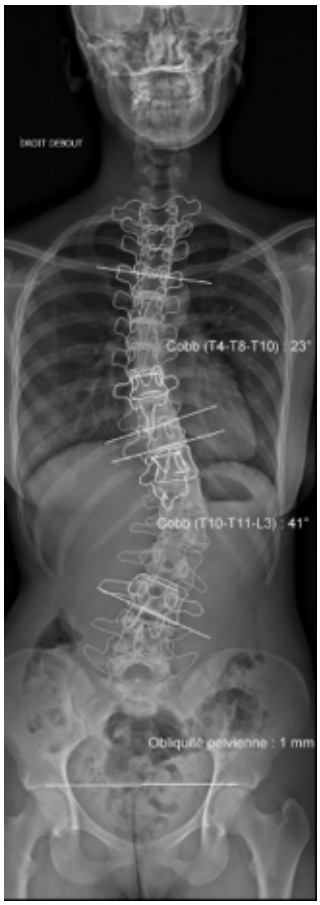


Figure 1:
EOS Frontal X-ray

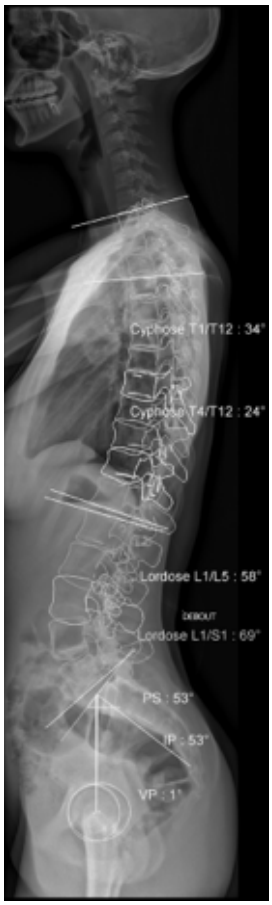
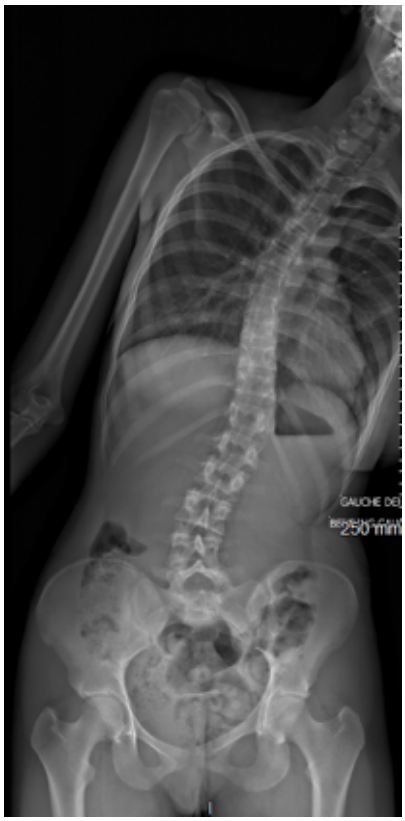
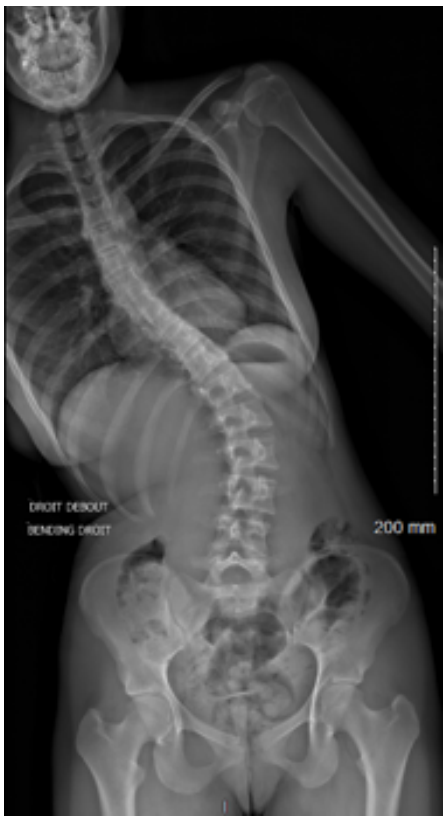


Figure 2:
EOS Lateral X-ray

CLINICAL CASE





Figures 3 & 4:
EOS Lateral Bending X-ray

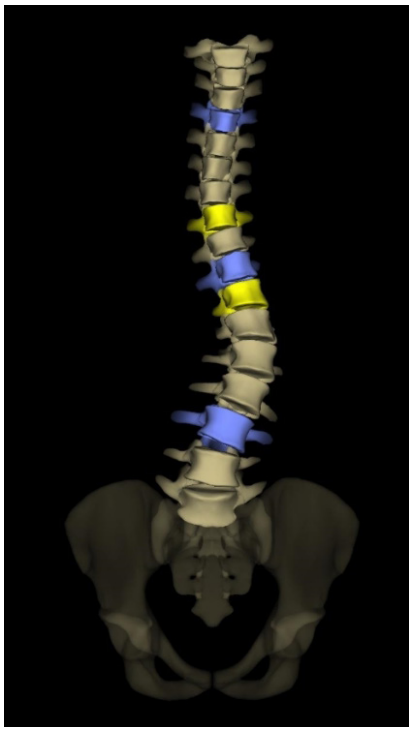


Figure 5:
3D Frontal Reconstruction

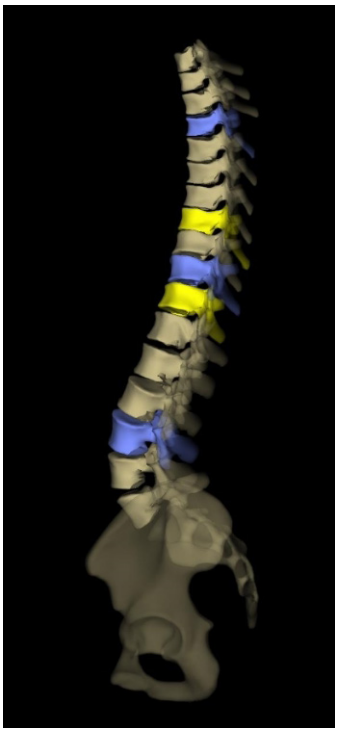


Figure 6:
3D Lateral reconstruction

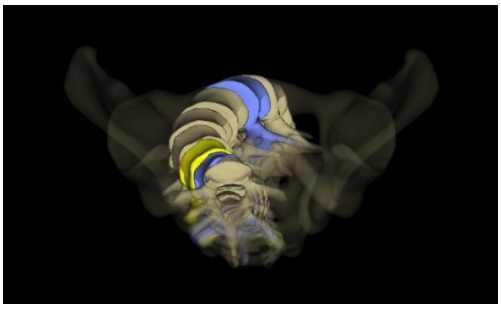


Figure 7:
3D Transverse Reconstruction

Apical vertebrae

Junctional vertebrae

CLINICAL CASE

TREATMENT METHOD AND MATERIAL

- Patient was placed in prone position
- Arthrodesis was performed between T4 and L3 levels, using ROMEO®2 25D and 25S pedicle screws and under O-Arm navigation with nerve monitoring.
- 25D screws were used for apex derotation. 25S screws were used at curves transition to restore sagittal balance (kyphosis, lordosis).

  On frontal plane, 25S screws optimize shoulder balance and avoid flat back syndrome.
- Cobalt Cromium rods were used to ensure resistance of the construct.
- Total anesthesia time was 4 hours and the blood loss was about 700 cc.

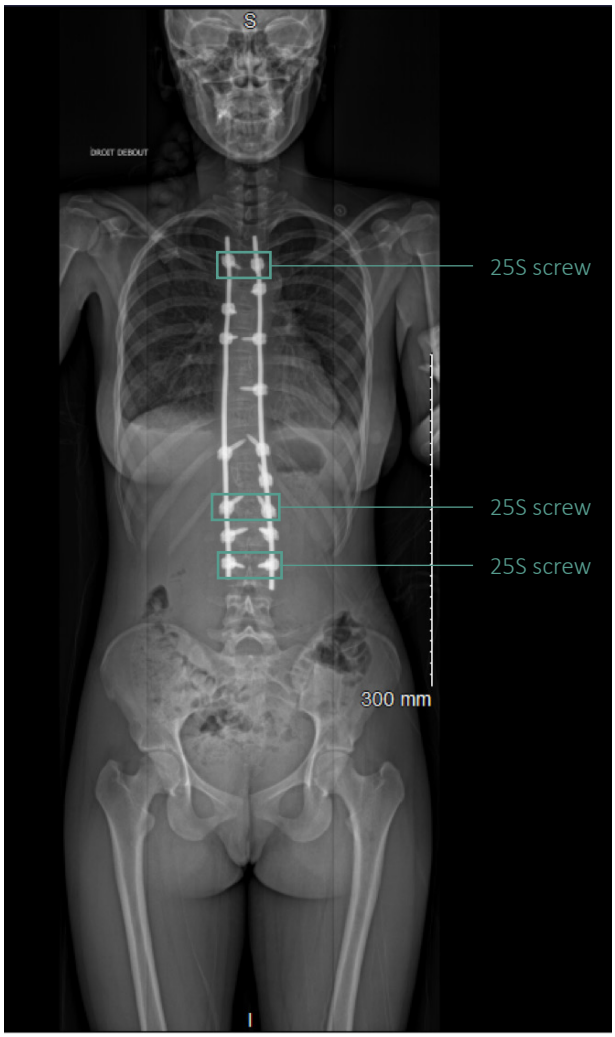


Figure 1:
4 days post-op Frontal X-ray

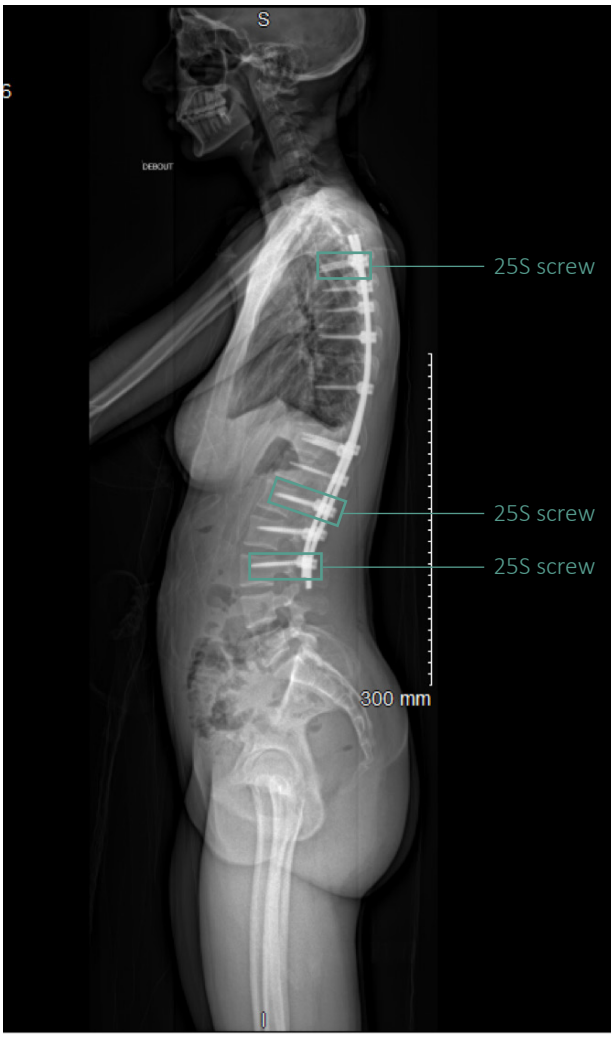


Figure 2:
4 days post-op Lateral X-ray

CLINICAL CASE

FOLLOW-UP RESULTS

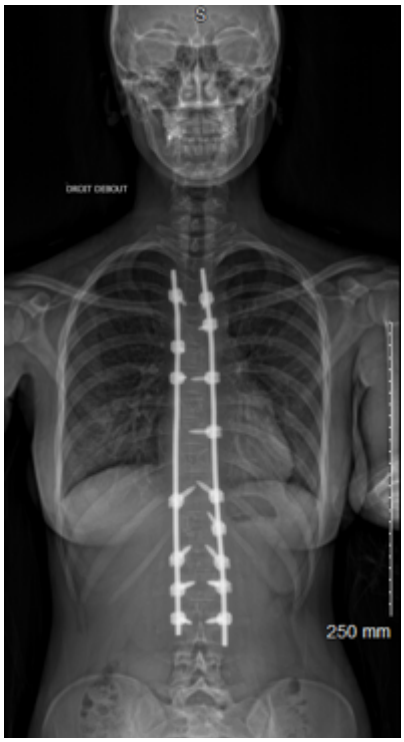


Figure 1:
3 months post-op Frontal X-ray

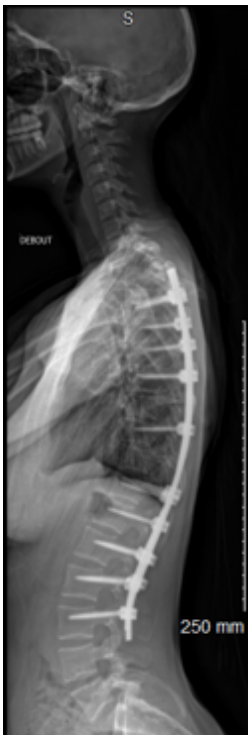


Figure 2:
3 months post-op
Lateral X-ray

- Patient was mobilized 4 days after the surgery and progressive restart of the march was recommended.
- At 3 months post-operative, radiographs demonstrate good sagittal and frontal alignment. A moderate pain remains at the insertion of the trapezius muscle. Scarf is clean and non-inflammatory.
- At 6 months post-operative, Owestry Disability Index (ODI) was 6/100 and EQ-5D (Quality of life measure) is normal. Patient had stopped gymnastics but intend to start fitness for now.

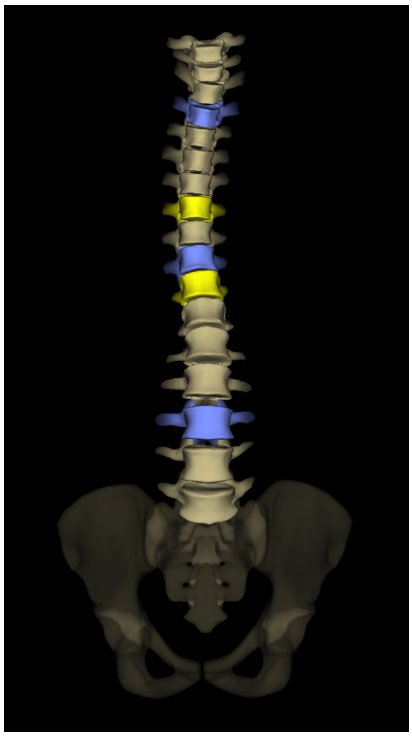


Figure 4:
3D Frontal reconstruction

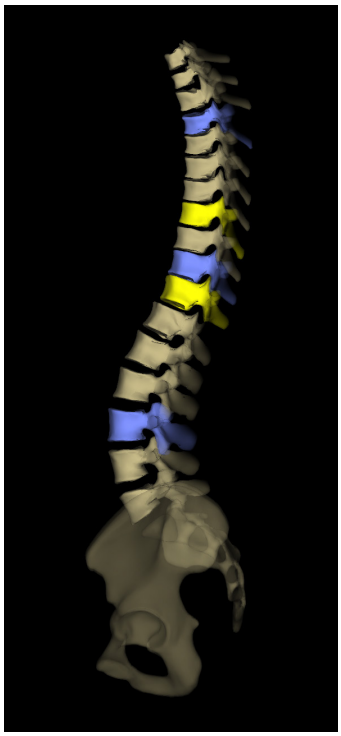


Figure 5:
3D Lateral reconstruction

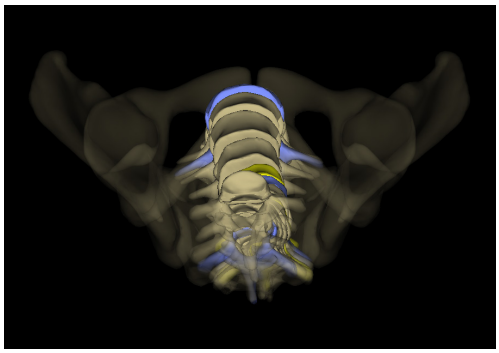


Figure 6:
3D Transverse reconsruction

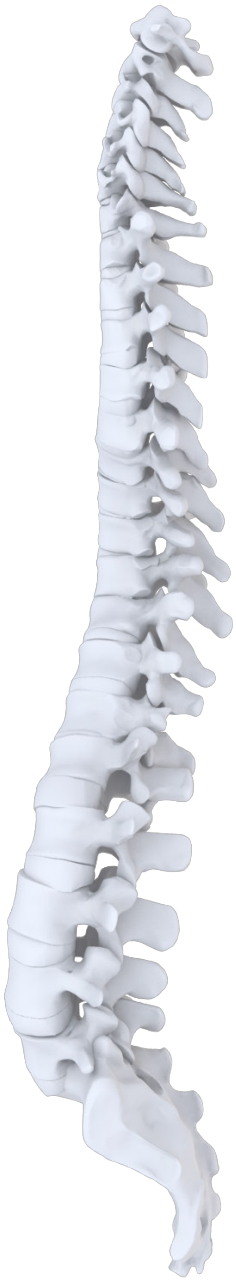
Apical vertebrae

Junctional vertebrae

SURGICAL TECHNIQUE

This surgical technique presents a scoliosis case where 25S and 25D screws are used to correct deformities on the 3 planes. Placement and orientation of the screws are critical to optimize the correction maneuvers.

_PRE-OPERATIVE IMAGES

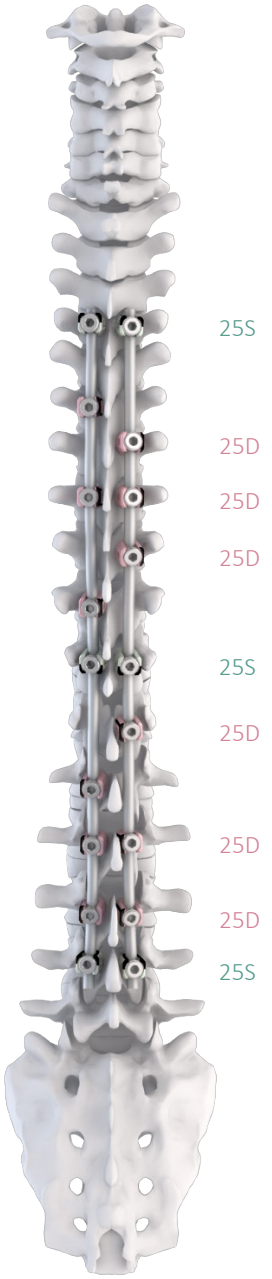


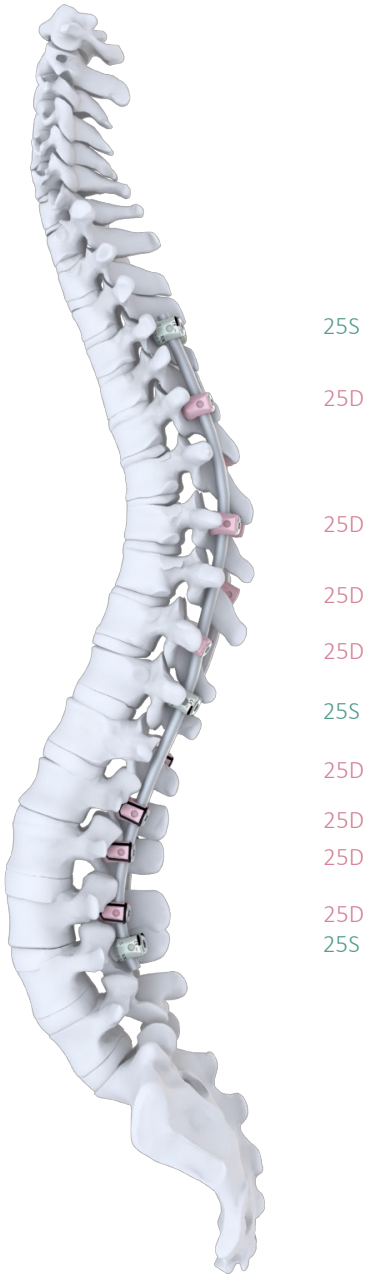
T1-T12
Kyphosis : 34°

L1 - L5
Lordosis : 58°

SURGICAL TECHNIQUE

_POST OPERATIVE IMAGES



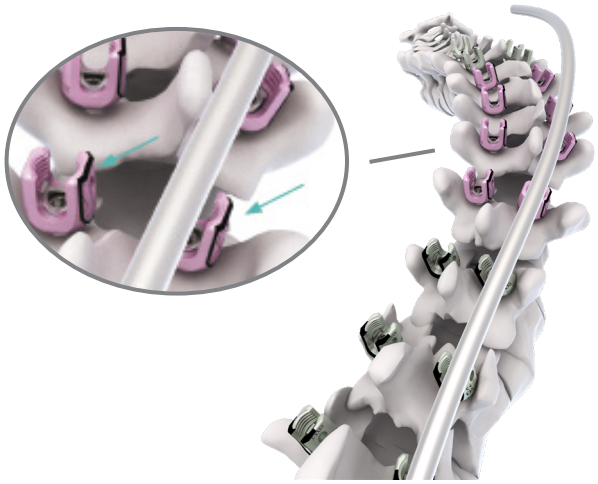


T1-T12
Kyphosis : 47°

L1 - L5
Lordosis : 65°

SURGICAL TECHNIQUE

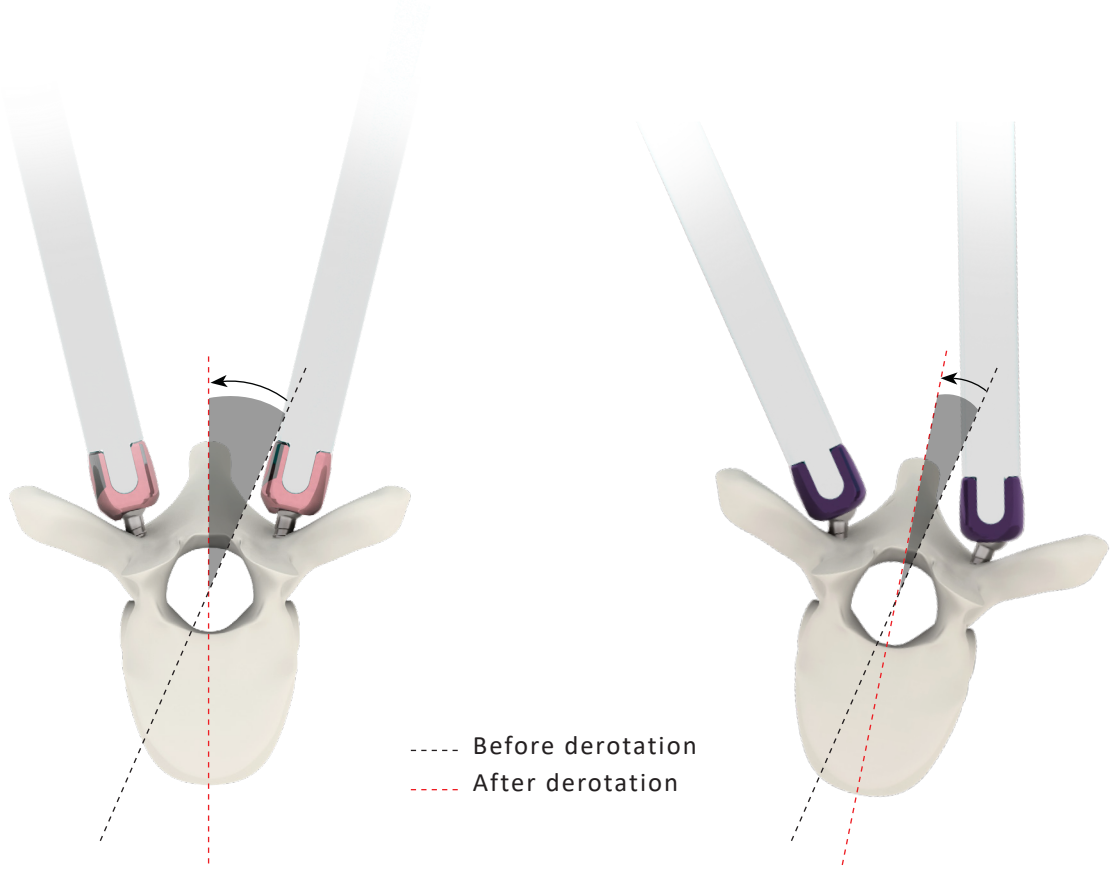
_CORONAL & AXIAL CORRECTION



The Rod Template L500, can be used to determine appropriate rod contour and length.

25D screws are used at the apex of the deformity for coronal and axial correction. The laser mark must be positioned medially for screws located on the concave side and laterally for screws located on the convex side.

Orientation of the laser mark is toward the convexity.



Derotation with ROMEO®2 25D screws

Derotation with standard polyaxial screws

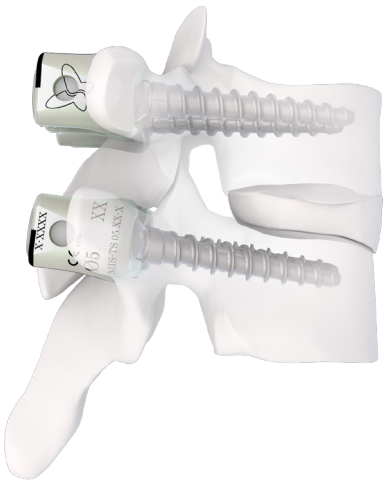
The monoaxial side of the ROMEO®2 25D screw (black laser mark) allows a direct mobilization of the vertebra during derotation maneuvers. With polyaxial screws, a part of the mobilization is lost because of the mobility of the screw head, reducing the amplitude of the correction.

Please refer to ROMEO®2 DEFORMITY Surgical Technique for further details.

SURGICAL TECHNIQUE

_SAGITTAL CORRECTION

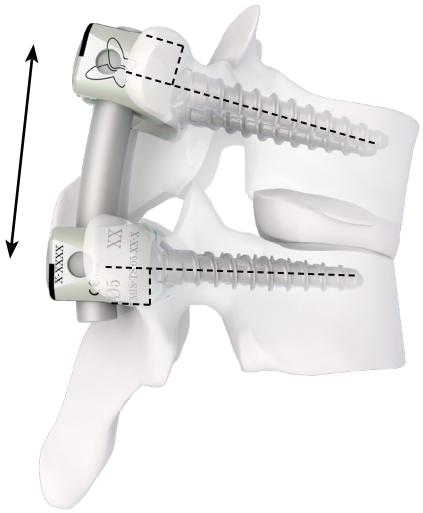
25S screws are used at the transition of each curve to restore sagittal alignment.
Laser marking orientation will depend if lordosis or kyphosis is needed.



THORACIC KYPHOSIS RESTORATION

Insert screws through the pedicle and as parallel to superior endplate as possible. Laser mark are placed facing outside of the segment.

Distraction maneuver



When distraction is performed on screw head, screw will act as monoaxial to restore kyphosis.

When screw reaches 90° angulation on laser mark side, a mechanical stop holds the screw, to enable direct maneuver action on the vertebra.

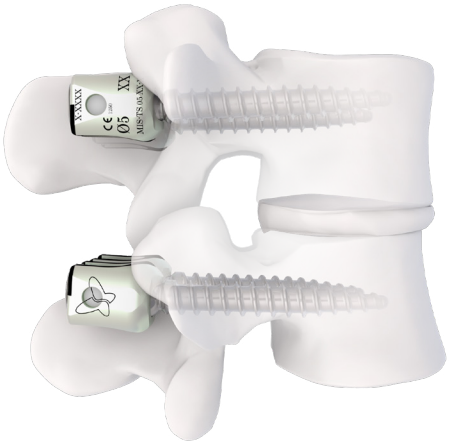
Screws are gradually locked, starting with the rod in the convexity of the scoliosis curve.

INSTRUMENT	REFERENCE
SCREWDRIVER TUBE	ELL-IN 21 03-N
SCREWDRIVER SHAFT PS	ELL-IN 05 03-N
SCREWDRIVER SLEEVE	ELL-IN 20 03-N
STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N
DISTRACTION FORCEPS	ELL-IN 00 07-N

SURGICAL TECHNIQUE

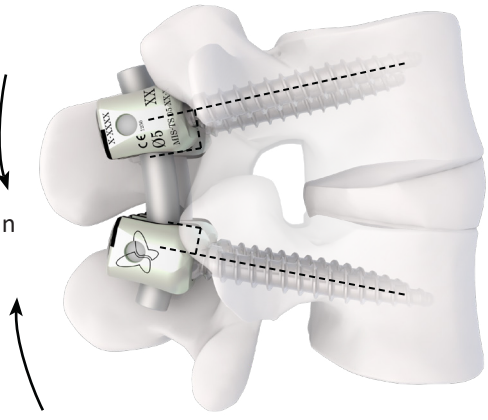
_SAGITTAL CORRECTION

25S screws are used at the transition of each curve to restore sagittal alignment.
Laser marking will depend if lordosis or kyphosis is needed.



LUMBAR LORDOSIS RESTORATION

Insert screws through the pedicle and as parallel to superior endplate as possible. Laser mark are placed facing inside the segment.



Compression maneuver

When compression is performed on screw head, screw will act as monoaxial to restore lordosis.
When screw reaches 90° angulation on laser mark side, a mechanical stop holds the screw, to enable direct maneuver action on the vertebra.

Screws are gradually locked, starting with the rod in the convexity of the scoliosis curve.

INSTRUMENT	REFERENCE
SCREWDRIVER TUBE	ELL-IN 21 03-N
SCREWDRIVER SHAFT PS	ELL-IN 05 03-N
SCREWDRIVER SLEEVE	ELL-IN 20 03-N
STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N
COMPRESSION FORCEPS	ELL-IN 00 08-N

CLINICAL CASE

Dr. Luis Alejandro Esparragoza Cabrera
Spine Specialist
Spine Pathologies Unit
Hospital General Universitario Gregorio Marañon – Madrid – Spain

HISTORY OF PRESENT ILLNESS AND RADIOGRAPHS

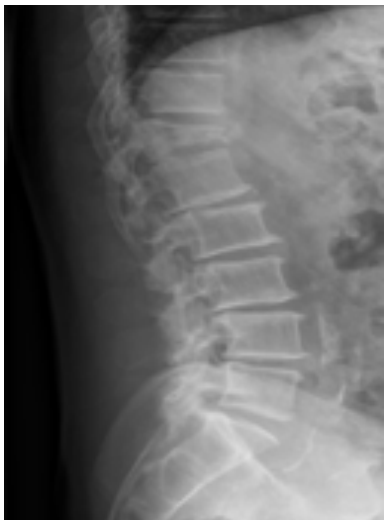


Figure 1 : Lateral X-ray view

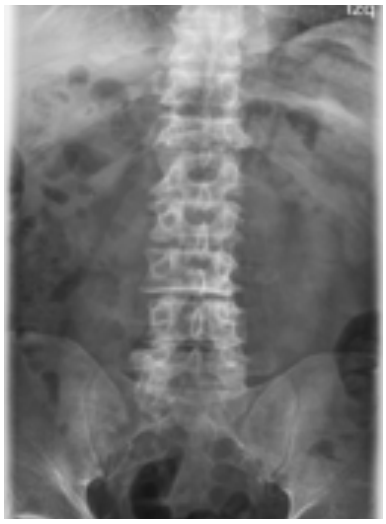


Figure 2 : Frontal X-ray view

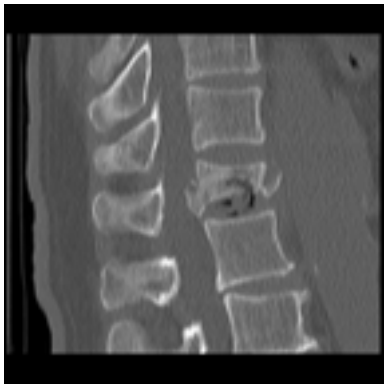


Figure 3 : Lateral CT-Scan

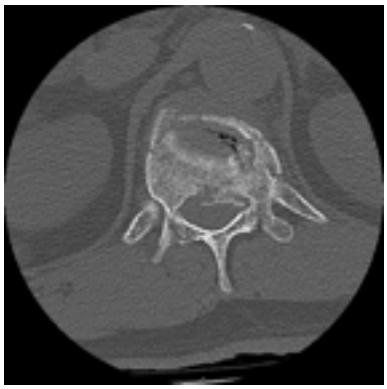


Figure 4 : Transverse CT-Scan

- 62 years old male with intense dorsal and lumbar pain after a fall on the stairs. Pain occurs when standing, and the patient demonstrates a limitation of lumbar mobility.
- Patient had no previous surgery and reports a VAS of 9/10. Orthopedic immobilization is set-up until surgery.
- Images reveal a T12 fracture type A3 (following AO classification), with more than 50% of the vertebral body collapsed and less than 30% impingement of medullary canal.

CLINICAL CASE

TREATMENT METHOD AND MATERIAL

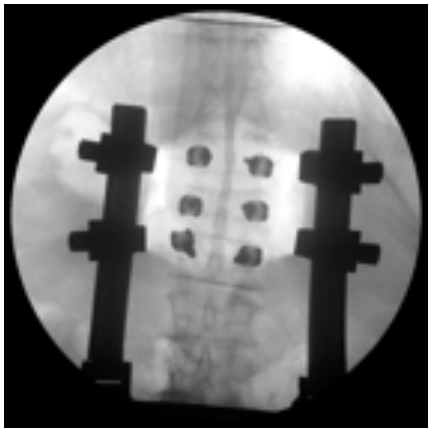


Figure 1: Screws insertion

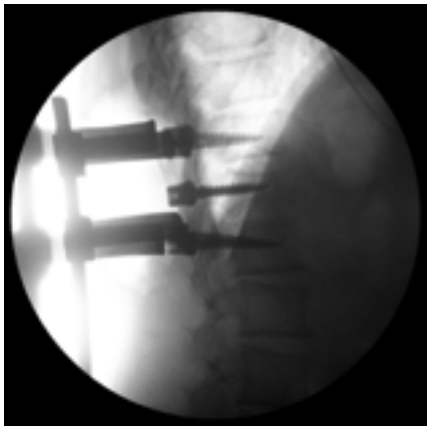


Figure 2: Screws insertion

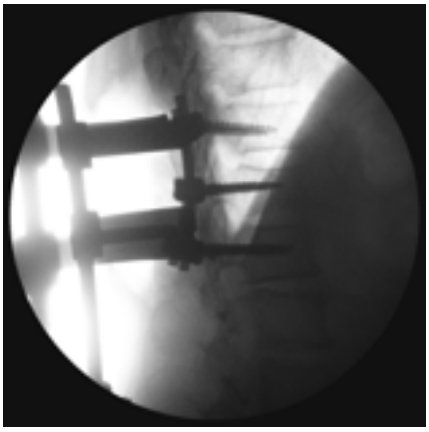


Figure 3: Rod placement

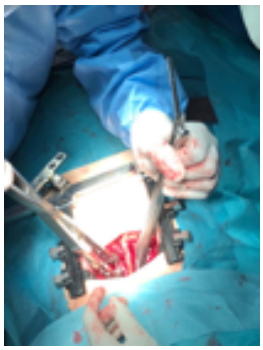


Figure 4: Distraction maneuvers

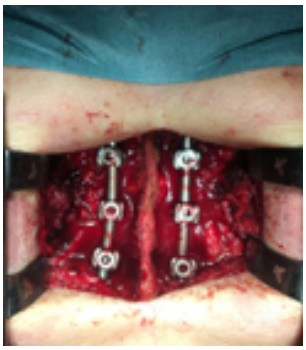


Figure 5: Final construct

- 3 levels were fused (T11-T12-L1) from a posterior approach, to reduce and stabilize the fracture but also to prevent neurological injuries. Local and regional kyphosis were corrected also thanks to the patient positionning.
- The patient was placed in prone position, with attention paid to the lordotic curve.
- Two 25S screws were inserted in adjacent superior and inferior vertebrae (T11 and L1) to enable direct vertebrae maneuvers and fracture reduction. Two polyaxial screws were placed in the fractured vertebra (T12) to stabilize the contruct . At last, two titanium lordotic rods were placed before using reduction instruments to perform fracture reduction.
- Fracture reduction is achieved by distraction between the 25S screws on superior and inferior vertebrae, and the polyaxial screw on fractured vertebra. Patient positionning is also critical for fracture reduction and kyphosis correction.
- Total anesthesia time was 55 minutes and the blood loss was inferior to 100cc.
- Rehabilitation and mobilization are key for an early patient ambulation.

CLINICAL CASE

FOLLOW-UP RESULTS

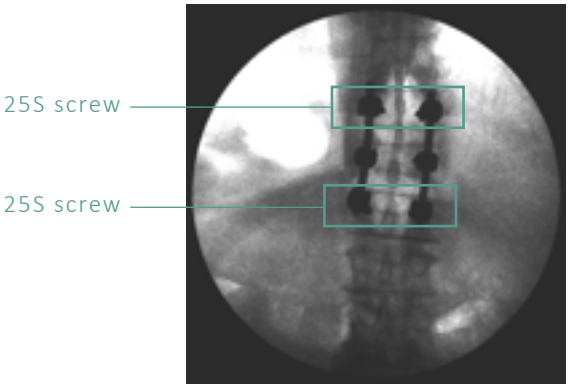


Figure 1 : Frontal immediate post-operative X-ray

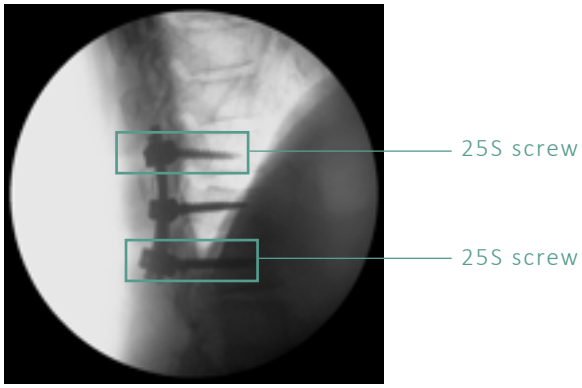


Figure 2 : Lateral immediate post-operative X-ray

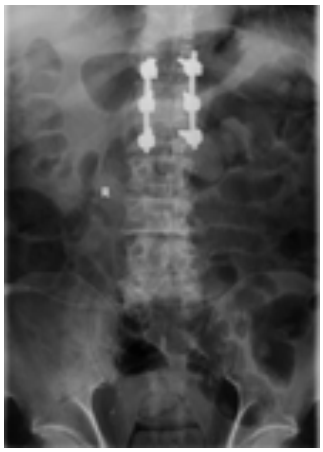


Figure 3 : Frontal 48h post-operative X-ray

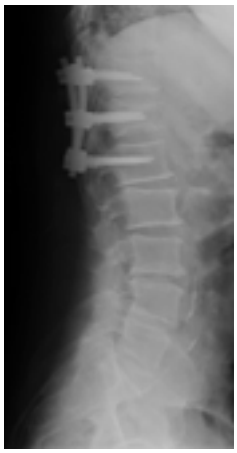


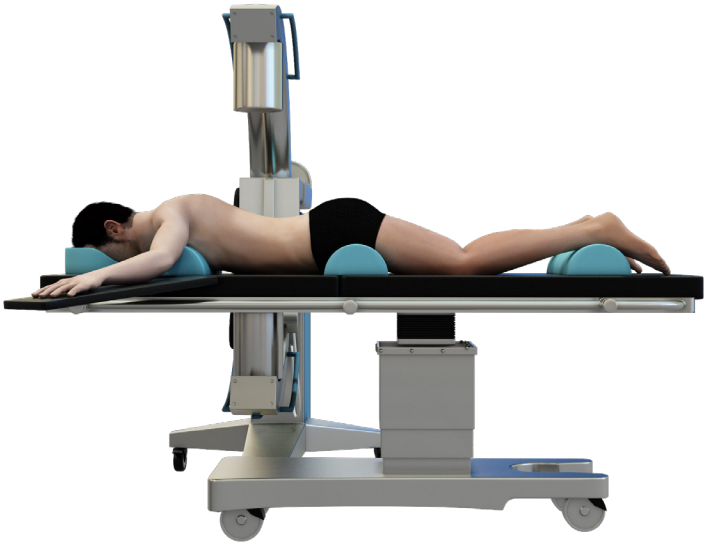
Figure 4 : Lateral 48h post-operative X-ray

- Patient was mobilized after 24 and 36 hours and could start an early ambulation.
- By immediate post-op, the patient reported a good mobilization, an EVA score of 2/10 and fully recovered his functions.

SURGICAL TECHNIQUE

25S screws enable powerful fracture reduction thanks to the restrited motion side of the screw.
This procedure can be performed in open or MIS technique.

_STEP 1



Patient must be positioned in prone position with attention paid to lordotic position of the spine.
Cushion pads are positionned under the patient's chest and iliac crest, with free abdomen.

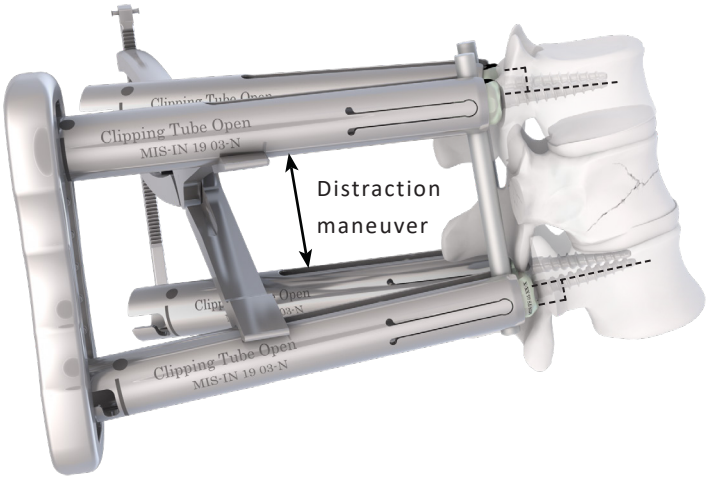
_STEP 2

Connect screws to clipping tubes and screwdriver.
Insert screws through the pedicle and as parallel to superior endplate as possible.
Laser mark are placed facing outside the segment.
A polyaxial screw can be inserted, when possible, in the fractured vertebra to stabilize the construct.

INSTRUMENT	REFERENCE
STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N
SCREWDRIVER TUBE	ELL-IN 21 03-N
SCREWDRIVER SHAFT PS CANNULATED	MIS-IN 33 01-N
CLIPPING TUBE	MIS-IN 17 01-N

SURGICAL TECHNIQUE

_STEP 3



The rod is bent according to the patient sagittal profile, and inseted with the rod holder.

One of the set screw is locked before performing the maneuver.

Place the stabilizer on the top of the clipping tubes and use the distraction forceps to perform ligamentotaxis. This maneuver allows to restore height of the fractured vertebral body, to correct post-traumatic kyphosis and to reduce the bone fragments.

When screw reaches 90° angulation on laser mark side, a mechanical stop holds the screw, to enable direct maneuver action on the vertebra.

INSTRUMENT	REFERENCE
CLIPPING TUBE	MIS-IN 17 01-N
STABILIZER	MIS-IN 29 00-N
DISTRACTION FORCEPS	MIS-IN 42 00-N
UNIVERSAL TUBE	MIS-IN 28 01-N

CLINICAL CASE

Dr Fethi Laouissat
Spine- Orthopedic Surgeon
Hôpital Privé de l'Est Lyonnais
Lyon - France

HISTORY OF PRESENT ILLNESS AND RADIOGRAPHS

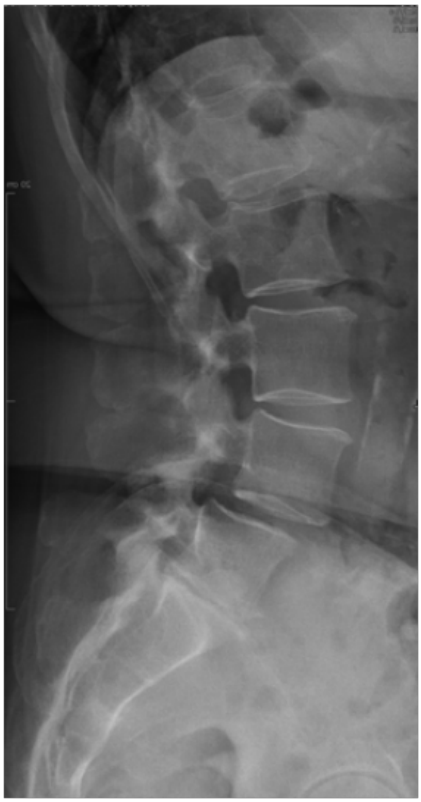


Figure 1 : Lateral x-ray view

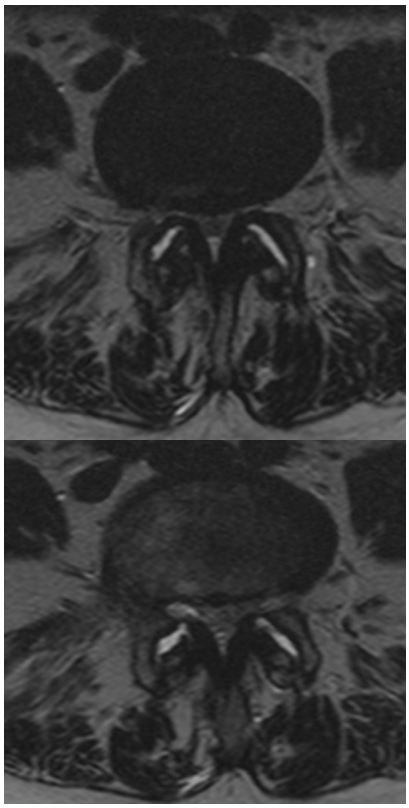


Figure 2 : Axial MRI view

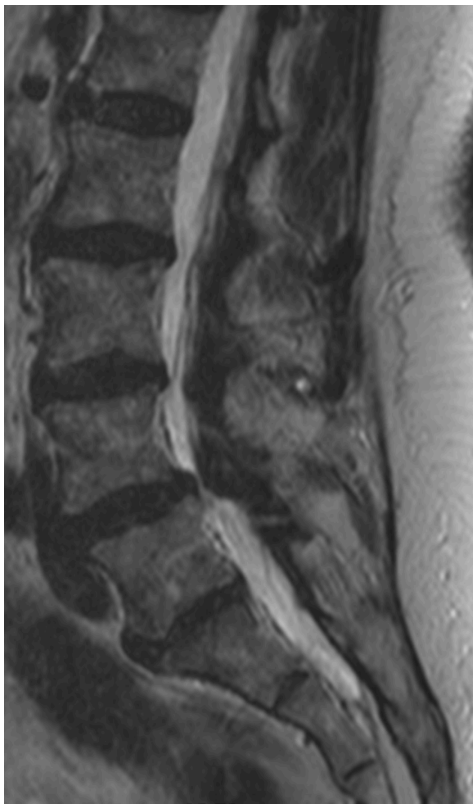


Figure 3 : Midsagittal MRI view

- 74 years old female with severe lumbar pain (VAS = 7/10) and bilateral leg pain due to L5 radiculopathy (VAS = 9/10). Presented because of a conservative treatment failure.
- The patient disability was evaluated by ODI score: 59%. No previous surgery was reported.
- Figure 1 shows a L4-L5 Grade 1 degenerative spondylolisthesis. L4-S1 lordosis angle equals 24°. Figures 2 & 3 show a spinal stenosis at L4-L5 Level (Schizas Grade C) and a hyperintense T2 signal at the facets articular space underlying the local instability. Also, L4-L5 and L5-S1 Discopathies were documented.

CLINICAL CASE

TREATMENT METHOD AND MATERIAL

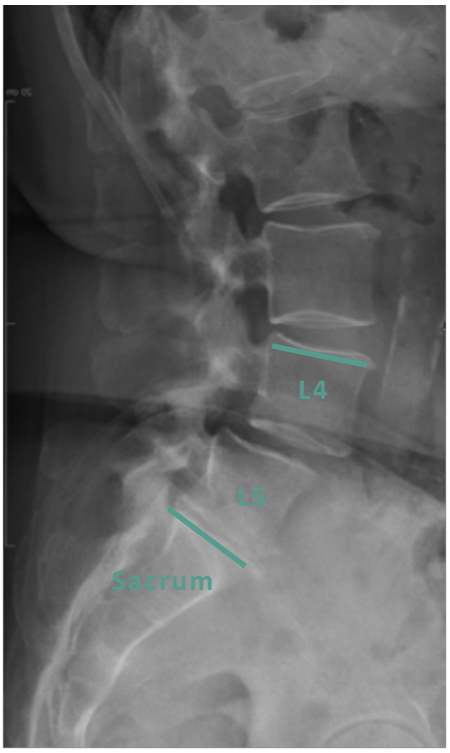


Figure 1 : Pre-op lateral view
L4-S1 = 26°

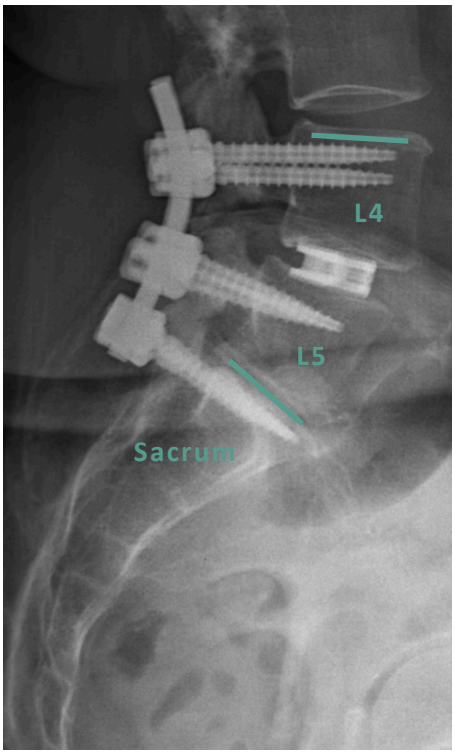


Figure 2 : Post-op lateral view
L4-S1 = 40°

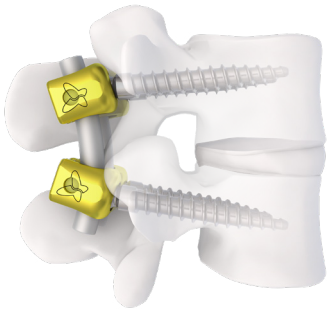
- Besides the decompression of the neural elements, the aim of surgery was to stabilize the spine and to reduce the local and regional kyphosis induced by the slipped vertebra through an open posterior approach.
- The patient was placed prone on a jackson table with an extended hips and knees, in order to optimize the lordotic curve of the lumbar spine during the surgery. After a posterior approach and a meticulous hemostasis, facetectomies are performed at the L5-S1 and L4-L5 levels. Fusion to the Sacrum was choosen to provide a solid fixation.
- Bilateral 25S Screws are placed at each level. An interbody cage could be placed at the L4-L5 level via a TLIF technique, to enhance interbody fusion and maintain post-op disc height.
- After decompression of the Cauda Equina, reduction is performed by means of two titanium rods bent according to the lumbar shape of the patient. Lumbo-pelvic parameters helps the surgeons to achieve the adequate bending of the rods. Closure is achieved layer by layer after bony grafting.
- Duration of surgery was 95 minutes,and blood loss was 280 cc.

FOLLOW-UP RESULTS

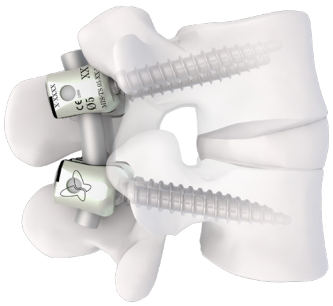
- The patient was mobilized 24h after the surgery and discharged 4 days later.
- At 3 months follow-up visit, the patient reported a significant improvement: Lumbar VAS : 2/10, Radicular VAS : 0/10, ODI : 12%.
- Postop upright lateral X-ray shows a restituo ad integrum slippage reduction, and an adequate L4-S1 lordosis restoration.

SURGICAL TECHNIQUE

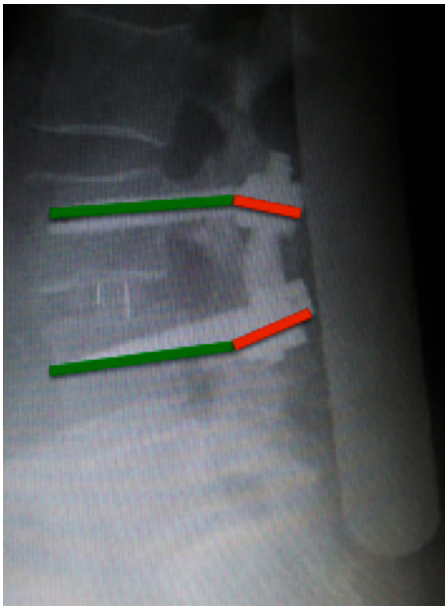
The monoaxial side of the ROMEO®2 25S screw (black laser mark) allows a direct mobilization of the vertebra during maneuvers.
With polyaxial screws, a significant part of the mobilization is lost because of the mobility of the screw head, reducing the amplitude of the correction.

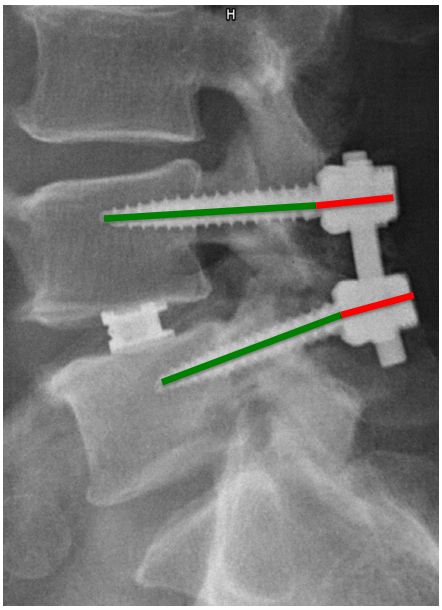


Sagittal alignment with polyaxial screw
Sagittal blind spot effect : unplanned sagittal angulation between the screw head and the screw thread



Sagittal alignment with 25S screw
Note the disc height and segmental lordosis restoration





SURGICAL TECHNIQUE

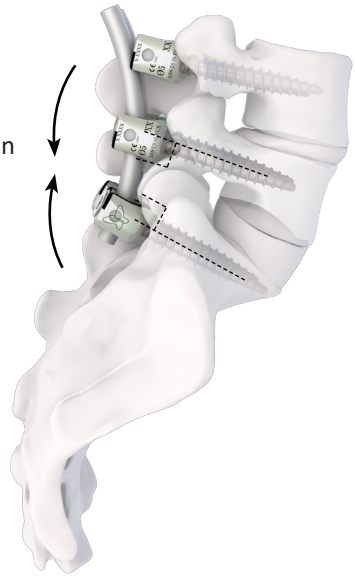
In this configuration, sequential compression is performed segment per segment, in order to create a lever arm effect with the sagittal monoaxial strengh of the 25S screw.
It is advised to use long screws in order to optimize lever arm effect on the whole vertebra.

_STEP 1

Insert screws through the pedicle as parallel to superior endplate as possible.
Laser marks face toward the lower instrumented vertebra.

_STEP 2

Compression maneuver



Segmental compression is performed on the lower level first:

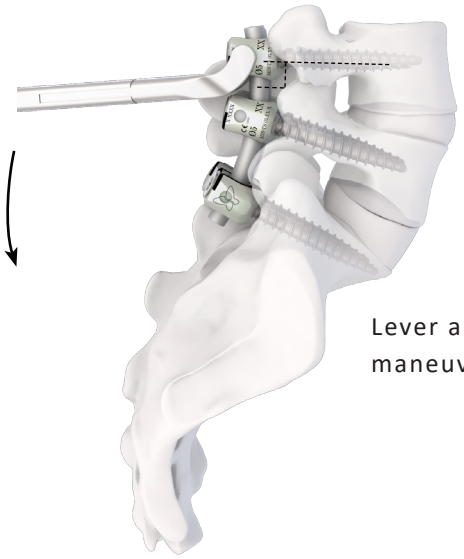
The rod is bent according to the patient sagittal profile and placed, with the set screws, in L5 and S1 levels. S1 set screw is locked in order to get a fixed point for efficient compression. L5 set screw is not locked.

When segmental compression is performed, the 25S screw head acts as monoaxial to restore lordosis.
When screw head reaches 90° sagittal angulation on laser mark side, a mechanical stop holds the screw, to enable direct maneuver action on the vertebra. The Sagittal blind spot effect due to the use of polyaxial screws is disabled.

L5 set screw is then locked.

SURGICAL TECHNIQUE

_STEP 3



Lever arm maneuver

Once S1 and L5 set screws are locked, compression is performed on the upper level. L4 screw will act as monoaxial when reaching 90° angulation on laser mark side.

Rocker instrument or reducers are used to persuade the rod and apply lever arm to restore segmental lordosis of the segment. This enables direct compression maneuver on the vertebra.

The use of 25S screws parralel to the upper vertebral endplate at each level of a lumbo-sacral posterior construct permits to restore a lumbo-sacral curve nearly close to the rod bending, avoiding the sagittal Blind Spot effect of the polyaxial screws and conserving their axial properties.

INSTRUMENT	REFERENCE
SCREWDRIVER TUBE	ELL-IN 21 03-N
SCREWDRIVER SHAFT PS	ELL-IN 05 03-N
SCREWDRIVER SLEEVE	ELL-IN 20 03-N
STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N
COMPRESSION FORCEPS	ELL-IN 08 00-N
ROCKER	ELL-IN 00 05-N
FINAL TIGHTENER	ELL-IN 04 06-N

SELECTED PUBLICATIONS ON SAGITTAL BALANCE RESTORATION

1. Yasuda T, Hasegawa T, Yamato Y, Togawa D, Kobayashi S, Yoshida G, Banno T, Arima H, Oe S, Matsuyama Y (2018) Effect of position on lumbar lordosis in patients with adult spinal deformity. Journal of neurosurgery Spine:1-5. doi:10.3171/2018.3.SPINE1879

2. Kuklo TR, Potter BK, Polly DW, Jr., Lenke LG (2005) Monaxial versus multiaxial thoracic pedicle screws in the correction of adolescent idiopathic scoliosis. Spine 30 (18):2113-2120

3. Lonner BS, Auerbach JD, Boachie-Adjei O, Shah SA, Hosogane N, Newton PO (2009) Treatment of thoracic scoliosis: are monoaxial thoracic pedicle screws the best form of fixation for correction? Spine 34 (8):845-851. doi:10.1097/BRS.0b013e31819e2753

4. Wang H, Li C, Liu T, Zhao WD, Zhou Y (2012) Biomechanical efficacy of monoaxial or polyaxial pedicle screw and additional screw insertion at the level of fracture, in lumbar burst fracture: An experimental study. Indian journal of orthopaedics 46 (4):395-401. doi:10.4103/0019-5413.98827

5. Schroerlucke SR, Steklov N, Mundis GM, Jr., Marino JF, Akbarnia BA, Eastlack RK (2014) How does a novel monoplanar pedicle screw perform biomechanically relative to monoaxial and polyaxial designs? Clinical orthopaedics and related research 472 (9):2826-2832. doi:10.1007/s11999-014-3711-x

6. Roussouly P, Pinheiro-Franco J, Labelle H, Gehrchen M, Sagittal Balance of the Spine, From Normal to Pathology: A Key for Treatment Strategy, 2019, Print.

GENERAL INFORMATION

REFERENCE OF THE IFU	ROM-IF TL 01-W	REVISION OF THE FINAL IFU	DEC-2018

_STERILITY

The implant is provided sterile or non sterile.

The sterile packed instruments are for single used.

In case of non sterile condition delivery, see § “Decontamination, cleaning and sterilization”.

_CAUTION

If the sterile packed implants and instruments or their packaging do not appear to be intact, if the expiry date is exceeded or if the sterility cannot be guaranteed for any reason, the sterile packed implants and instruments must not be used.

The re-sterilization of the gamma sterilized implant is forbidden.

The re-sterilization of the delivered sterilized instruments is forbidden.

The ROMEO®2 implant must not be used with implant other than ROMEO®2 range. The ROMEO®2 Implant must only be used with the ROMEO®2 instruments.

_DESCRIPTION

ROMEO®2 spine system was designed to ensure the best possible adaptation to patient’s anatomic variations. This system has been designed to correct and stabilize the spine.

ROMEO®2 spine system range consists of pedicle screws of various length and diameters, and hooks receiving longitudinal rods. In order to obtain a maximal stiffness, a transverse rod associated to connectors is also available. All implants of the ROMEO®2 spinal system are either made of titanium or cobalt chromium, corresponding to legal medical requirements.

_INDICATIONS

ROMEO®2 system implants are designed to treat those dorsal and thoracic pathologies:

- Spondylolisthesis
- Degenerative disc disease
- Thoracic and lumbar fractures
- Thoracic and lumbar vertebra tumors
- Pseudarthrosis
- Stenosis
- Spine deformities: scoliosis, cyphosis

_CONTRAINDICATIONS

- Include but not limited to:
- Mental illness.
- Infection.
- Severely damaged bone structures that could prevent stable implantation of the implant.
- Neuromuscular or vascular disorders or illness.
- Inadequate activity.
- Pregnancy
- Bone tumor in the region of implant.

_SIDE EFFECTS

Per operative:

Haemostatic problems, injuries to the nervous system resulting in temporary or permanent weaknesses, pain or functional handicap, fractures.

Post operative:

Venous thrombosis and pulmonary embolism, infection, cardio-vascular disorders, hematoma and late cicatrisation.

Specific to implant:

Implant migration, adhesion and fibrosis, limited range of movement, secondary fractures.

Potential risk identified with the use of this posterior osteosynthesis system, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e non-union), fracture of the vertebra, neurological injury, and vascular or visceral injury.

GENERAL INFORMATION

_CAUTION - PRECAUTIONS FOR USE

An in-depth discussion of all possible complications associated with spine stabilization with implants is beyond the scope of these instructions. Every surgeon who uses these implants must take each patient's clinical state and medical status into consideration, and be fully familiar with procedures involving the use of this type of implant and the potential complications in each case.

Implants are mechanical devices that can be worn, damaged or broken. An implant site can become infected, painful, swollen, or inflamed. Significant weight on the implant, an implant of inadequate size, and patient hyperactivity or a misuse will increase the risk of complications, including wear and tear or rupture.

The soft tissue and the adjacent bones may deteriorate over time, or may not be in an adequate state to support the implant, thus causing instability and/or malformation. The benefits of this posterior osteosynthesis procedure may not meet the patient's expectations, thus requiring more surgery to replace or remove the implant, or other types of procedures. Surgeons should therefore take several factors into consideration, in order to achieve optimal results for each patient. It is therefore essential that each patient who must undergo this type of procedure be informed, with the supporting documentation available, of the potential complications.

_HANDLING

No effort has been spared to ensure that only the highest-quality materials and expertise have been deployed in producing each implant. When handling these implants, blunt instruments should be used in order to avoid scratching, cutting, or nicking the device. Sharp-edged, serrated or toothed instruments should not be used.

Careful preparation of the surgical site and choosing an implant of the right size will increase the chances of a successful reconstruction. Surgeons are advised not to remove the device from its sterile packaging until after the implant site has been properly prepared and precise measurements have been taken.

_SURGERY METHODS

Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced surgeons with specific training in the use of this pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The surgeon is responsible for familiarizing him/herself with the surgical technique used for implanting these devices, by studying the relevant published articles, consulting experienced colleagues, and receiving training in the methods appropriate to the particular implant being used. We strongly recommend that excessive force should not be applied when installing any of the ROMEO®2 implants.

A handbook on surgical techniques, describing the standard implant procedure, is available.

_STORAGE CONDITION

The sterile packed implants and instruments must mandatorily be stored in the original packages in a clean, dry, mild place and under normal atmospheric pressure.

_INSTRUMENTATION

The instruments were specifically designed for use when installing the ROMEO®2 implants.

Specific markings are engraved on each instrument to facilitate identification of the corresponding implant size.

The instrument set equipment is composed of delivered sterile or non sterile instruments for single use.

_DECONTAMINATION, CLEANING, AND STERILIZATION

Point-of-instruction: The instruments must, immediately after use, be decontaminated, cleaned, and sterilized as described below.

Prior to starting the surgical procedure, all non sterile reusable instruments must be properly cleaned, decontaminated and sterilized.

The ROMEO®2 instruments have been designed in order to avoid disassembly manipulation prior decontamination, cleaning and sterilization processes.

These methods and parameters have been validated following the AAMI TIR 30 Technical Report for reusable instruments and not sterile implants.

GENERAL INFORMATION

Manual disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 1 minute, using softbristled brush to assist in the removal of gross soil debris. The devices which can be disassembled must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 5 minutes using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute.
- Use a syringe to flush the devices with cannulation with 2x20 ml of neutral enzymatic cleaner at room temperature (+15/+25°C).
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minutes. Devices with mobile parts will be activated during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 2 minutes using softbristled brush at room temperature (+15/+25°C).
- Use a syringe to flush the devices with cannulation with 2x20 ml of deionized water at room temperature (+15/+25°C).
- Rinse thoroughly the devices with deionized water for 2 minutes. Devices with mobile parts will be activated during rinsing.
- Visually inspect devices
- Dry using a soft, lint free cloth.

Automatic disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 30 seconds, using softbristled brush to assist in the removal of gross soil debris. The devices which can be disassembled must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 1 minute using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 30 seconds. Devices with mobile parts will be activated during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute. Devices with mobile parts will be activated during rinsing.
- Load devices into the washer-disinfector.
- Visually inspect devices.
- Dry using a soft, lint free cloth.

WASHER-DISINFECTOR PARAMETERS

STEP	SOLUTION	TEMPERATURE	TIME
Pre-cleaning	Water	<45°	2 minutes
Cleaning	Water + Neutral enzymatic cleaner (as example NEODISHER Mediclean Forte)	55°C	10 minutes
Neutralizing	Water	<45°	2 minutes
Rinsing	Tap water	<45°	2 minutes
Thermal disinfection	Reversed osmosis water	90°C	5 minutes

GENERAL INFORMATION

Sterilization trays cleaning and disinfection

All the trays must be thoroughly cleaned and disinfected after surgery completion.

Cleaning recommendations

- Remove all the instruments from the trays,
- Large and visible impurities must be removed from the trays,
- Use running water and rinse thoroughly for at least one minute,
- Use freshly prepared cleaning bath of the specified concentration for the period specified by the manufacturer,
- Use soft brush until there is no visible contamination,
- Dry trays with lint-free disposable cloths.

Disinfection recommendations

- Use a freshly disinfectant bath of the specified concentration for the period specified by the manufacturer. Rinse thoroughly three times,
- Rinse trays thoroughly with water as specified by the disinfectant manufacturer,
- Dry trays with lint-free disposable cloths.

Trays must be visually clean, if not, repeat the cleaning and disinfection protocol.

Subsequent sterilization in containers is recommended, using an autoclave and steam, and following a protocol that meets the minimum requirements or more, and is in compliance with current legislation (e.g., 134°C – 18 minutes) to obtain a guaranty of sterility of 10-6.The validation for sterilization have been done according to overkill/half cycle method as described in the ISO 17664, ISO 17665 standards and of AAMI TIR 12 Technical Report. Implants delivered into non sterile condition must follow the same protocol of decontamination, cleaning and sterilization.

Sterilization parameters:

Method: Pre-vacuum cycle of Steam sterilization (moist heat - autoclave)

Cycle 1 (EU):

Minimum exposure time: 18 minutes

Minimum temperature: 134°C

Drying time: 30 minutes

Cycle 2 (USA):

Minimum exposure time: 4 minutes

Minimum temperature: 132°C

Drying time: 30 minutes

“Do not stack trays during sterilization”

The instruments must, immediately after use, be decontaminated, cleaned, and sterilized as described above, particularly before they are returned to Spineart®.

_MAINTENANCE AND REPAIR

Spineart® instruments are guaranteed for at least 150 steam sterilization runs.

Spineart® instruments that need to be repaired must be decontaminated and cleaned, then sent to the address mentioned in this document.

_FURTHER INFORMATION

If further directions for use of this system are needed, please check with the Spineart® Customer Service. If further information is needed or required, please see the addresses on this document.

N O T E

N O T E

N O T E

S P I N E A R T

SPINEART SA
CHEMIN DU PRÉ-FLEURI 3
1228 PLAN-LES-OUATES
SWITZERLAND

SEP-2019 - REF.: ROM-BR 2S 31-E CE 1250