SPINAL POSTERIOR FIXATION SYSTEM

THORACO-LUMBAR FIXATION

Ulis

SURGICAL TECHNIQUE

SPINEVISION

INNOVATION THAT MATTERS

SpineVision® Ulis

Introduction
The Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) instrumentations are designed for correction and surgical stabilization of the spine during development of solid bone fusion. It is recommended to remove the device as soon as effective solid bone fusion has been achieved.

Description
The Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) instrumentations are composed of pedicle screws and Titanium fusion rods from the UNI-Thread® System.
Their components can be rigidly assembled in a variety of constructs, each corresponding to the needs and anatomy of a specific patient. These constructs are assembled using specific instruments.
The components of the U.L.I.S.™ system are made of titanium alloy (Ti-6Al-4V ELI) complying with ASTM F136 (ISO 5832-3) or ASTM F1537 Cobalt Chromium.
The components of the LUMIS™ system are made of titanium alloy (Ti-6Al-4V ELI) complying with ASTM F136 (ISO 5832-3).
Implants must never be reused.
Components of the U.L.I.S.™ and LUMIS™ systems must not be used with components derived from another manufacturer.

Indications
When used for anterior screw fixation or as a posterior, non-pedicle system of the non-cervical spine, the U.L.I.S.™ and LUMIS™ systems are indicated for:
- degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- fracture
- curvatures (i.e. scoliosis, kyphosis, and/or lordosis)
- spinal stenosis
- tumors
- failed previous fusion (pseudoarthrosis)

The U.L.I.S.™ and LUMIS™ systems are pedicle screw systems indicated for skeletally mature patients who:
- have severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra;
- receive fusions using autogenous bone graft only;
- have the device fixed or attached to the lumbar and sacral spine (L3 to sacrum); and
- have the device removed after the development of a solid fusion.

In addition, the U.L.I.S.™ and LUMIS™ systems are pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T10-S1):
- degenerative spondylolisthesis with objective evidence of neurologic impairment
- fracture
- curvatures (i.e. scoliosis, kyphosis, and/or lordosis)
- spinal tumor
- failed previous fusion (pseudoarthrosis)

This device can only be implanted by a surgeon with a good working knowledge of the device, its applications, the instruments and the required surgical technique.

Contraindications
Contraindications include, but are not limited to:
- Allergy to the implanted material, mainly to metal (e.g. cobalt, chromium, nickel, etc.)
- Any other medical or surgical condition likely to compromise the success of instrumented surgery, such as the presence of a malignant tumour or serious congenital abnormalities, raised erythrocyte sedimentation rate not explained by other diseases, high white blood cell count or a tendency to low white blood cell count.
- All cases not described in the indications.
- Localized infection of the operative site.
- All patients with insufficient tissue cover of the operative site.
- Local signs of inflammation.
- Fever or leukocytosis.
- Pathological obesity.
- Pregnancy.
- Mental illness.
- Rapidly evolving joint diseases, bone absorption, osteopenia and/or osteoporosis. Osteoporosis is a relative contraindication, as this medical condition can limit the expected correction gain and stability of mechanical fixation.
- All cases not requiring bone graft or bone fusion.
- All cases requiring a combination of different metals.
- All patients not agreeing to comply with postoperative instructions.

The contraindications of these devices are similar to those of other spinal rod instrumentations. This spinal instrumentation is not designed, or intended or sold for uses other than those indicated.

Potential Adverse Events
In addition to the risks associated with spinal surgery without instrumentation, the following potential adverse events can occur (non-exhaustive list):
- Early or delayed hardware removal.
- Implant migration.
- Dismantling, deformity, sliding and/or rupture of one or all components or instruments.
- Foreign body reaction due to the presence of implants, such as a mass, auto-immune disease, metallosis and/or impaired healing.
- Subcutaneous pressure by the components, possibly causing alteration of the skin in places in which the tissue cover is insufficient. Skin complications, including perforation of the skin by the implant or the graft.
- Loss of curvature or correction of the spine, loss of height.
- Infection.
- Fracture of the vertebral body due to transfer of loads above and below the instrumented zone.
- Lack of bone consolidation (or non-union).
- Loss of neurological functions, appearance of radiculopathies, dural injuries and/or pain. Neurovascular insufficiency, including paralysis or other serious lesions. Cerebrospinal fluid leak.
- Gastrointestinal, urological and/or reproductive tract disorders, including sterility, impotence.
- Haemorrhage and/or haematoma.
- Disk inflammation, arachnoiditis and/or other types of inflammation.
- Deep vein thrombosis, thrombophlebitis and/or pulmonary embolism.
- Bone graft donor site complications.
- Incapacity to resume the activities of normal everyday life.
- Soft tissue damage.
- Death.

Note: Some potential adverse events may require an additional surgical revision procedure.

Placement of the device
The U.L.I.S.™ and LUMIS™ systems are implants designed to be connected by rods 6mm in diameter. They are designed to be used with instruments specifically intended for these devices.
Connections for the U.L.I.S.™ and LUMIS™ systems must be tightened to a value of 8,5 N.m whatever the rod material is.

Packaging
The packaging of each component must be intact on reception. The operating room personnel must thoroughly verify, before use, that all devices are complete and that no component presents any signs of damage. Damaged packaging and/or products must not be used, but must be returned to SpineVision®.
All packaging and labelling materials must be removed prior to sterilization. Only sterile implants and instruments must be used in surgery.

Cleaning and Decontamination
The U.L.I.S.™ and LUMIS™ systems instruments and implants are supplied not sterile. They must be sterilized before use. Surface decontamination and cleaning of reusable instruments must be completed prior to sterilization.
For the initial and any subsequent cleaning, the recommended general protocol for the pre-disinfection, decontamination and cleaning of the implants and instruments is:
Disassemble necessary implants and instruments. Articulated instruments must be opened.
In a pre-disinfecting bath, immerse and soak (minimum of 15 minutes) implants and instruments in a quaternary ammonia detergent. Transfer implants and instruments to an ultrasound bath, immerse and soak (15 minutes) implants and instruments under ultrasound action, in a quaternary ammonia detergent. SpineVision recommends the use of Hexanios G+R for this process with Ultrasonic vibrations, deionized or distilled warm (room temperature) water for soaking, cleaning and rinsing.
After soaking, scrub all surfaces with a soft appropriate brush, paying close attention to threads, cannulas, hinges and hard to reach areas. Rinse immediately and thoroughly after washing.
Inspect each device and repeat the washing in the presence of any residual debris.
Immediately dry products.
Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices, and should not be used, except in the case of aluminium instruments used on high risk patients (see Note below).

Lubrication specification
SpineVision® recommends the lubrication of instruments that are mechanical or contain articulating surfaces. The lubricant used for the lubrication process of surgical instruments must be available in spray and is recommended to bear the CE marking according to the 93/42/EEC Directive modified by 2007/47/EEC Directive. The instruments must be lubricated after each pre-disinfection/ decontamination and before each steam sterilization.

Steam Sterilisation
Prior to use, the U.L.I.S.™ and LUMIS™ systems components should be steam sterilised with according to the following parameters:

Method	Steam	Steam
Cycle	Prevacuum	Prevacuum
Temperature	134° (273°F) See note 1	132° (270°F) See note 2
Minimum exposure time	18 minutes	4 minutes
Minimum drying time	30 minutes	30 minutes

Validations were performed with dynamic-air-removal steam sterilisation process.

Note 1: This sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Note 2: Remove all the handles from the trays for this cycle and sterilize them separately in a double wrap.
The instruments and implants must be completely dried before use.

Verification
Devices must always be verified before use: any devices presenting signs of weakness or surface scratches must not be used.

New requirements related to high risk patients
In the case of high risk patients, i.e. being suspected of contact with Non-Conventional Transmissible Agents (e.g. prions), decontamination should be performed according to requirements of the World Health Organization. In this case, SpineVision® instruments can be decontaminated with sodium hydroxide, with the strict exception of instruments made out of aluminium, where bleach should be used.

WARNINGS
This instrumentation is not designed to be the only means of long-term support of the spine. The use of this product cannot be successful without a mechanically solid bone graft. In the absence of a solid bone graft, the implanted devices can become deformed, loose, dismantled and/or may break.
The LUMIS™ and U.L.I.S.™ systems have not been evaluated for safety and compatibility in the MR environment. The LUMIS™ and U.L.I.S.™ systems have not been tested for heating or migration in the MR environment.
The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
Compliance with preoperative and intraoperative procedures and recommendations, a good knowledge of surgical techniques, correct selection and positioning of implants as well as the quality of the reduction obtained are important factors determining success of the operation. Appropriate patient selection and patient cooperation also have a major influence on the results. High non-fusion rates have been demonstrated in smokers, obese subjects, alcoholics, patients with poor quality bone or muscle and/or suffering from paralysis. These patients must be informed of this risk and its consequences.
In the case of a major bone defect of the anterior vertebral column, the surgeon must consider the use of additional support devices.

Patient selection
- Particular attention must be paid to patient selection criteria, correct placement of the implant and postoperative care in order to minimize the stresses to which the implants are submitted.
- Only patients satisfying the criteria described in the indications must be selected.
- Patients corresponding to criteria described in the contraindications must not be selected.

Implant Use
- Adequate selection of the type, shape and size of the implant for each patient is crucial to the success of the operation. After implantation, implants are subjected to repeated stresses and their resistance is limited by adaptation of their dimensions to bone anatomy. When these dimensions are not adapted, repeated stresses can induce excessive loading of the hardware, resulting in deformity, rupture or dismantling of the device before bone consolidation has been achieved, which may cause damage or require premature removal of the instrumentation.
- Implants must be handled and stored very carefully. They must not be scratched or damaged. Implants and instruments must be protected during storage, especially from corrosive environments.
- As this is a mechanical assembly, the surgeon must be familiar with all components before using this instrumentation and must personally manipulate the components to ensure that all implants and instruments are available before starting surgery.
- The type of construct to be performed for each case must be determined before starting the surgical operation. An adequate range of implant sizes must be available at the time of the operation, including smaller sizes and larger sizes than those initially planned.
- All components must be sterilized before use. Supplementary sterile components must be available if required unexpectedly.
- Mixing of dissimilar metals can accelerate the corrosion process. The components of this system are not to be used with implants of other material in building a construct. Components of this system should NOT be used with components from any other system or manufacturer.
- SpineVision ASTM F136 Titanium Alloy (Ti-6Al-4V ELI) and ASTM F1537 Cobalt Chromium rods can be used with the U.L.I.S.™ system.
- LUMIS™ and UNI-Thread® ASTM F136 Titanium Alloy (Ti-6Al-4V ELI) can be used with the LUMIS™ system

PRECAUTIONS
Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
SURGICAL IMPLANTS MUST NEVER BE REUSED; An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

PREOPERATIVE
- Implants must be handled and stored very carefully. They must not be scratched or damaged. Implants and instruments must be protected during storage, especially from corrosive environments.
- The surgeon must be familiar with all components before using this instrumentation and must personally manipulate the components to ensure that all implants and instruments are available before starting surgery.
- The type of construct to be performed for each case must be determined before starting the surgical operation. An adequate range of implant sizes must be available at the time of the operation, including smaller sizes and larger sizes than those initially planned.
- All components must be sterilized before use. Supplementary sterile components must be available if required unexpectedly.

INTRAOPERATIVE
The surgeon must strictly comply with the instructions for use of the spinal instrumentation.
- The surgeon must always exert extreme caution in relation to the spinal cord and nerve roots. This warning is particularly important during insertion of screws. All nerve lesions can induce loss of neurological function.
- Rupture, sliding or incorrect use of the instruments or components of the implant can injure the patient or operating room personnel.
- Rods must not be repeatedly or excessively bent beyond that which is absolutely necessary. Very thoroughly verify that the surfaces of the implant are neither scratched nor damaged. If the rods must be cut to a certain length, they must be cut to obtain a flat, blunt surface, perpendicular to the axis of the rod. Cut the rod outside of the surgical field.
- Do not to use screws of inappropriate dimensions (length, diameter) due to the risk of damage to the nerve roots or causing haemorrhage and/or avulsion.
- Bone graft must be performed to ensure satisfactory fusion. Autologous bone grafts are essentially used with this instrumentation.
- Before closure, all tightening screws must be tightened according to the instructions.

POSTOPERATIVE
- The postoperative advice given by the surgeon to the patient and the patient's compliance with this advice are extremely important.
- The patient must be informed about the limits of use of the device. If premature and/or excessive loading of the spine occurs prior to complete bone consolidation, the patient must be informed that complications such as deformity, dismantling and/ or rupture of the device can occur.
- The patient or the device must not be exposed to mechanical vibrations which could induce dismantling of the device. The patient must be informed about this risk and must be advised to limit his or her physical activities, particularly lifting and torsion movements, as well as any sports activities. The patient must be advised to refrain from smoking and drinking alcohol during the process of consolidation of the bone graft.
- Patients must be informed that they will be unable to laterally flex their spine at the level of fusion and must be trained to compensate for this permanent physical limitation of their body's movements.
- Persistent absence of bone consolidation that cannot be immobilized places repeated and excessive stresses on the implant. Due to the mechanism of fatigue, these stresses can finally result in dismantling, deformity or rupture of the device. It is important to immobilize the zone of fusion and confirm this consolidation by radiological examination. If an abnormal absence of consolidation is observed or if the components become dismantled, deformed and/or broken, the device must be removed immediately, before it causes a serious lesion.
- Spinal implants are internal fixation devices designed to stabilize the operative zone during the normal consolidation process. Once consolidation has been achieved, these devices no longer have any useful function and can be removed by the surgeon. If the device is not removed after having completed its role, one of the following complications can occur :
  - corrosion, with a tissue reaction or localized pain,
  - migration of the implant resulting in a lesion,
  - risk of additional lesions due to postoperative trauma,
  - deformity, dismantling and/or rupture may make hardware removal difficult or impossible,
  - pain or abnormal feelings due to the presence of the device,
  - high risk of infection and
  - osteolysis due to transfer of mechanical loads.

All explanted devices must be treated in order to prevent reuse in another surgical procedure.

Product complaints
Any health care professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, reliability, durability, safety, effectiveness and/or performance should notify SpineVision®. Further, If any of the implanted spinal instrumentation components does not meet any of its performance specifications or otherwise does not perform as intended, or is suspected of doing so, SpineVision® should be notified immediately. If any SpineVision® product may have caused or contributed to the death or serious injury of a patient, SpineVision® should be notified as soon as possible by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report is requested from SpineVision®.

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IMPORTANT INFORMATION CONCERNING U.L.I.S.™ System, and LUMIS™ System INSTRUMENTATION

SURGICAL STEPS

I . . Patient preparation. 02
II . . Pedicle preparation & screw selection. 02
III . . Tapping. 04
IV . . Screw insertion. 05
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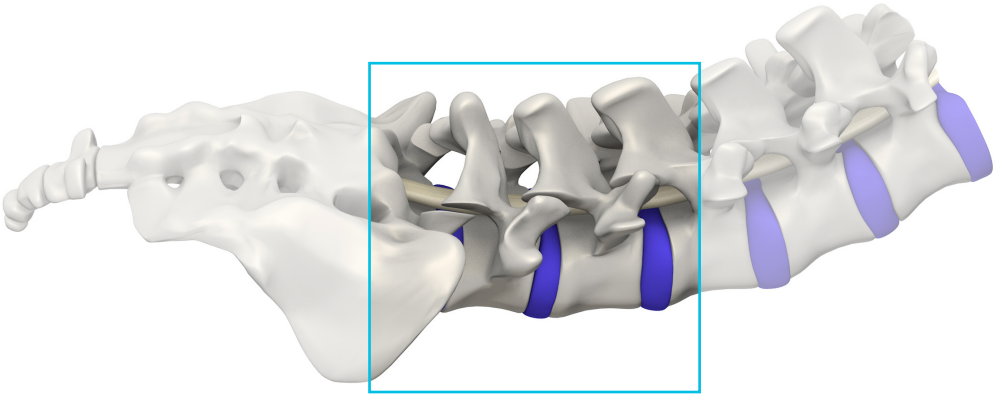
PATIENT PREPARATION

The patient is placed on the operating room table using the standard position indicated for posterior fixation placement.

X-ray shall be used during the entire procedure: to confirm identification of the affected disc, good positioning of the screws and the final position of the whole assembly.

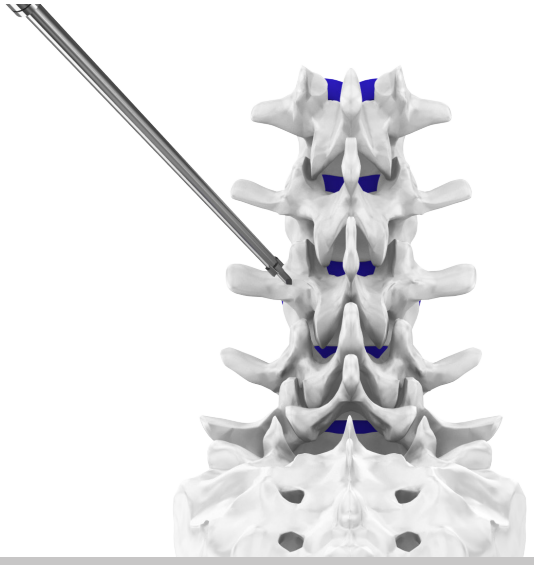


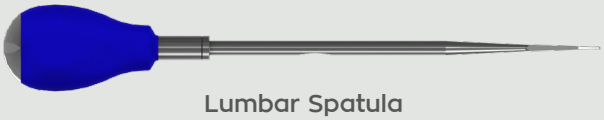
PEDICLE PREPARATION & SCREW SELECTION

Square Awl
U1-A121N1

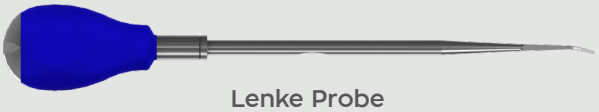
Mark the affected segment after C-arm control. Perform the incision over the levels on which the screws must be inserted.

Once the different structures (facets, pedicles and processes) have been exposed, locate the entry point for screws on the pedicle and perforate the cortical bone using the **square awl** *U1-A121N1*.



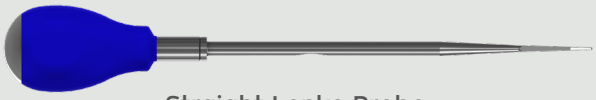


Lumbar Spatula
U1-A127



Lenke Probe
U1-A128

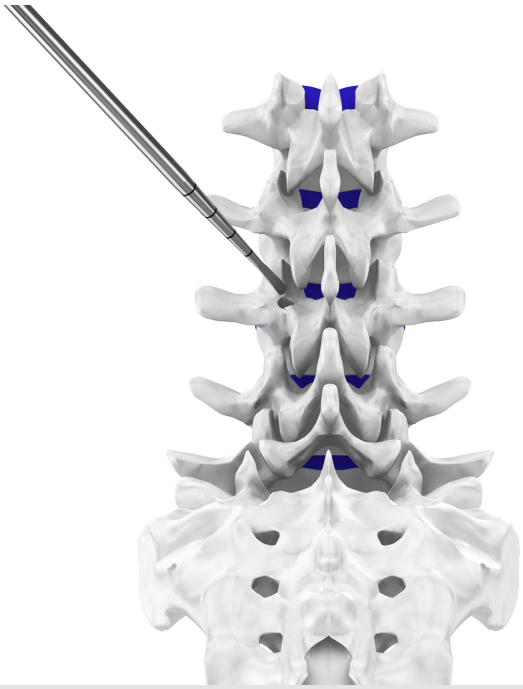
Curved Lumbar Spatula
U1-A127C



Straight Lenke Probe
U1-A128S

To create a pathway for screws in the pedicle, use the different pedicle probes available depending on surgeon's practice: **lumbar spatula** *U1-A127*, **lenke probe** *U1-A128*, **curved lumbar spatula** *U1-A127C* or the **straight lenke probe** *U1-A128S*.

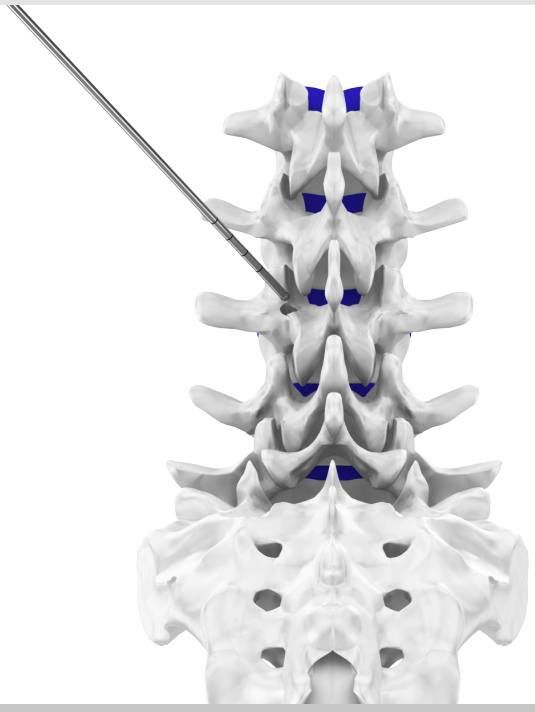
The appropriate depth for each vertebra is estimated by the surgeon.



Pedicle probe with ball tip
U1-A124N1

The integrity of the intrapedicular cancellous bone can be checked with the **pedicle probe with ball tip** *U1-A124N1* by letting it slide on the pilot hole's wall.

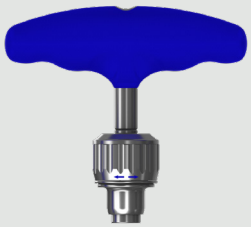
The length of the screw to be inserted can be determined by putting the tip of the pedicle probe at the bottom of the hole and then marking the length of the inserted intrapedicular part by a forceps at the external pedicle's surface.



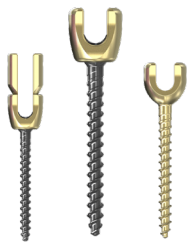
TAPPING

Cannulated ratcheting cylindrical handle
SD-A411ALSH

Sharp Taps
U1-A13XS



Cannulated ratcheting T-handle
SD-A411ATSH

				
Ø 4.5 mm	Ø 5.5 mm	Ø 6.5 mm	Ø 7.5 mm	Ø 8.5 mm
U1-A134S	U1-A135S	U1-A136S	U1-A137S	U1-A138S

IS2-MXXXT: Multiaxial screw
IS2-MRXXXT: Reduction screw
IS2-SXXXT: Monoaxial screw

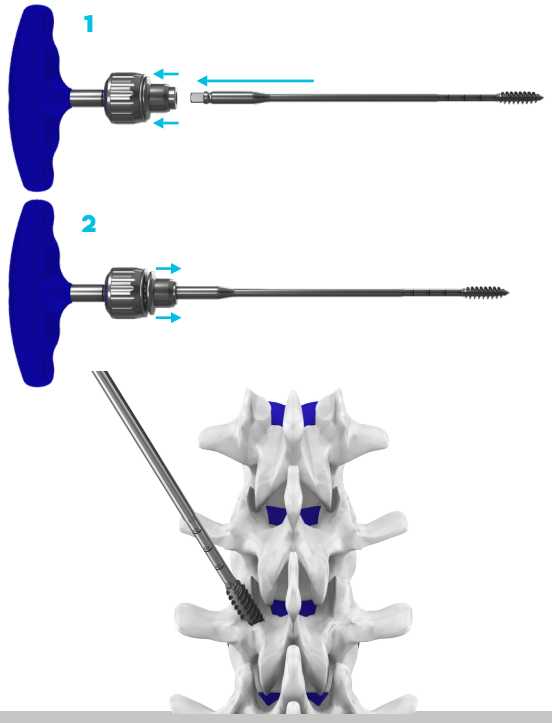
X= Diameter
XX= Length
Ex: IS2-M645T Ø6.5 & 45 mm

! WARNING !
The Ulis screws are color coded according their diameters. It is mandatory to use the tap corresponding to the screw diameter.

1 To connect a **sharp tap** *U1-A13XS* to the **ratcheting cylindrical handle** *SD-A411ALSH* or **T-handle** *SD-A411ATSH*, pull the ring of the handle towards the silicon part.

2 While maintaining this position, insert the square tip of the sharp tap into the handle and release the ring to secure the connection between the two instruments.

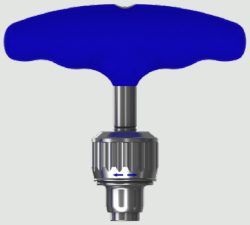
Always double check the connection of the two pieces before giving it to the surgeon.



IV SCREW INSERTION

Cannulated ratcheting cylindrical handle
SD-A411ALSH

Universal Screwdriver
MS2-A221

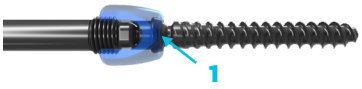


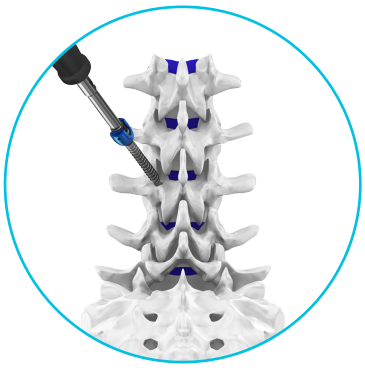
Cannulated ratcheting T-handle
SD-A411ATSH

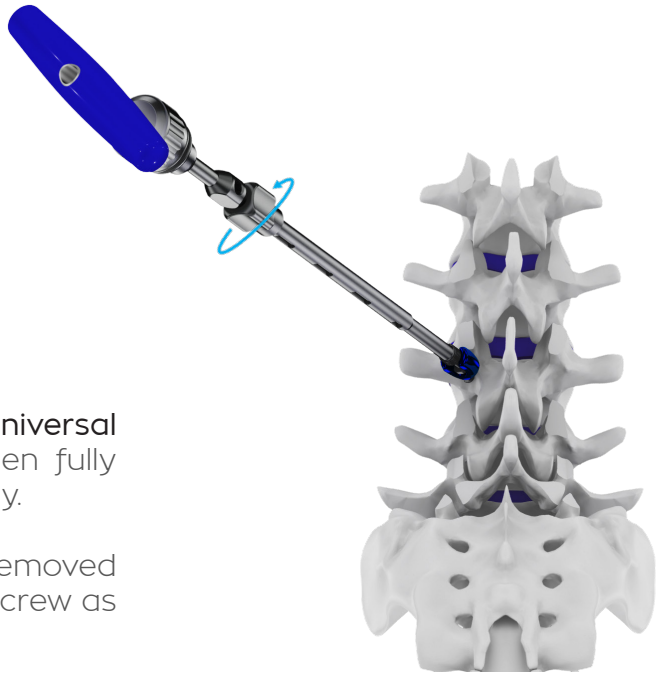
To connect a **Universal screwdriver** *MS2-A221* to the **cannulated ratcheting cylindrical handle** *SD-A411ALSH* or **T-handle** *SD-A411ATSH*, repeat the maneuver described in the previous step.

1 The screwdriver is the same for monoaxial, polyaxial and reduction screws. To connect it to a screw, position the implant on the screwdriver and make sure that the distal tip of the inner part of the screwdriver is entirely inserted into the screw head.

2 Then block the screw's multiaxiality by turning clockwisely the square part of the ULIS Universal Screwdriver until it is not possible anymore. You can then insert the screw in the pedicle.





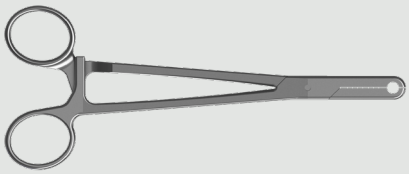


To disconnect a **Universal screwdriver** *MS2-A221* from the screw when fully inserted, turn the square part unclockwisely.

The Universal Screwdriver can then be removed and this step repeated to insert as many screw as needed.

ROD PREPARATION & HANDLING

French Bender
U1-A321



Rod Holder
U1-A214S

The ULIS system offers a large range of **prebent rods** from 30 mm up to 120 mm *MS1-R6XXXCT*.

The system can also be used with **straight rigid rod** *L2-R6XXHT* or **Co-Cr rigid rod** *U1-R625HC* which can be contoured at the desired curvature with the **french bender** *U1-A321*.

The prepared rod can then be handled and inserted using the **rod holder** *U1-A214S*.

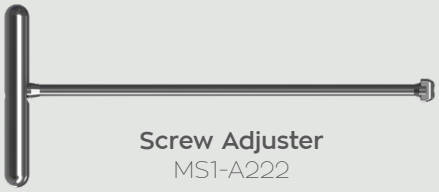
! WARNING !
Rods must not be repeatedly or excessively bent beyond that which is absolutely necessary.

! WARNING !
If using the Flex+2 rods for dynamic stabilization or topping-off, it is mandatory not to bend it on the flexible part.

Never bend the Flex+2 rods above the transversal laser mark

VI ROD REDUCTION & SETSCREW INSERTION

Setscrew Holder
MS1-A231



Screw Adjuster
MS1-A222

To align the screw head, or to to adjust the screw depth for monobloc screws, use the **screw adjuster** *MS1-A222*.

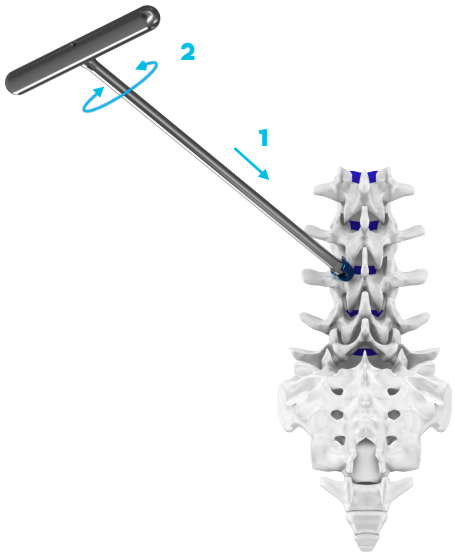
When the screw heads are aligned, insert the rod in the implant saddles using the **rod holder** *U1-A214S*. Then place the setscrew using the **setscrew holder** *MS1-A231*.

To load a **setscrew** *MS1-L100T* on the setscrew holder :

1 Pull up the trigger of the setscrew holder

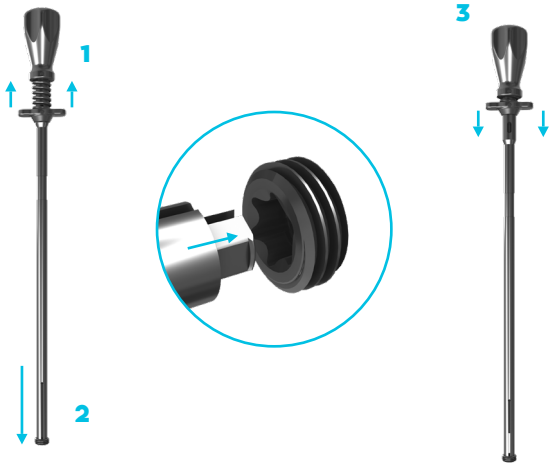
2 While maintaining this position, slide the tip of the instruments in the «star» footprint of the setscrew.

3 Finally release the trigger of the setscrew holder.



! WARNING !
Never use the setscrew holder MS1-A231 for the final tightening.

The Ulis system offers three options to persuade the rod :
- Rod pusher
- Persuader
- Reduction screws



OPTION A

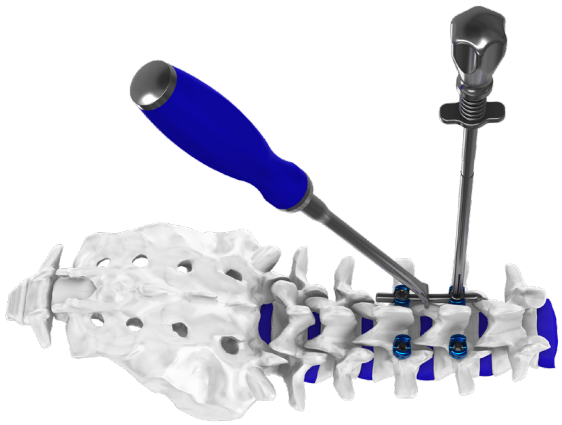
Rod Pusher
U1-A224

Use the **rod pusher** *U1-A224* to push the rod in the screw head prior to the setscrew insertion.

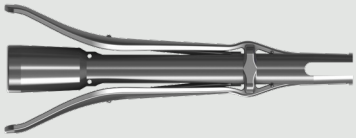
1 While maintaining the rod in the implant saddle with the rod pusher, engage partially the setscrew in the screw head and turn clockwisely to thread it

2 Once the setscrew is in position, pull up the wing of the setscrew holder to release the connection and remove the setscrew holder.

Repeat this step on all screws prior to apply correction maneuvers.



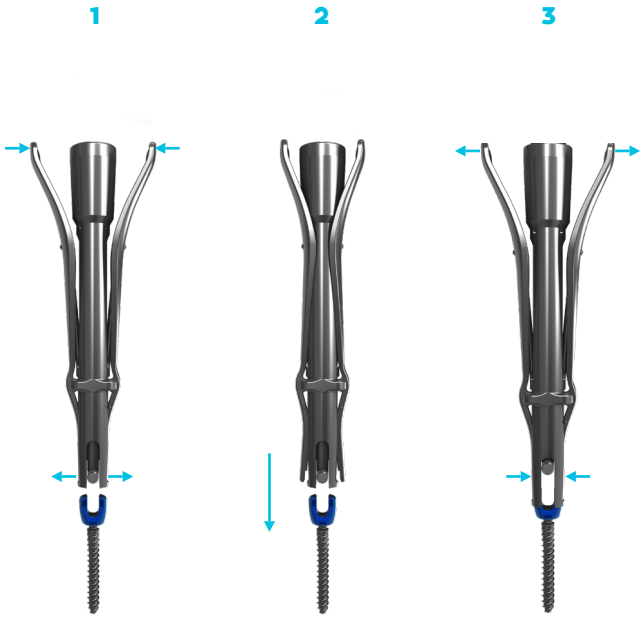
OPTION B



Persuader
IS1-A317

Inner Tube for Persuader
IS1-A316

If a more powerful reduction is needed, use the **persuader** *IS1-A317* and the **inner tube for persuader** *IS1-A316*.



To position the persuader on the screw head:

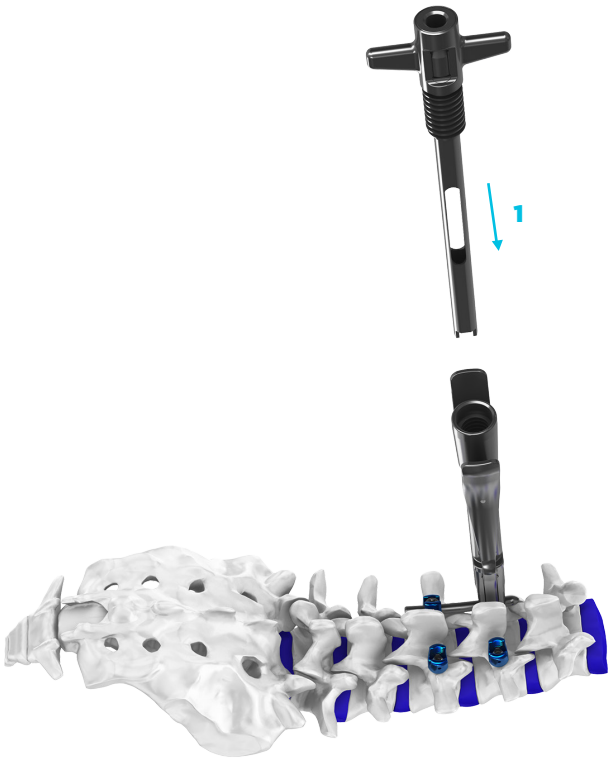
1 Squeeze the flanges toward the tube to open the persuader at its distal end.

2 Slide down the persuader on the screw head. Repeat this step on all screws prior to apply correction maneuvers.

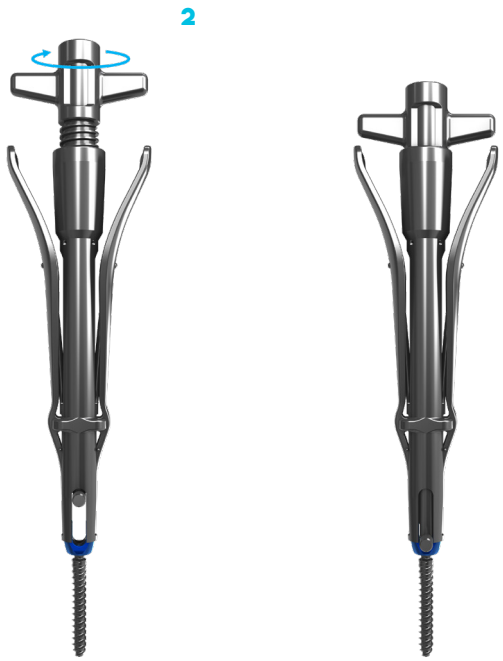
3 Release the flanges to connect the persuader to the screw.

Once the persuader is positionned on the screw head, persuade the rod thanks to the **inner tube for persuader** *IS1-A316*:

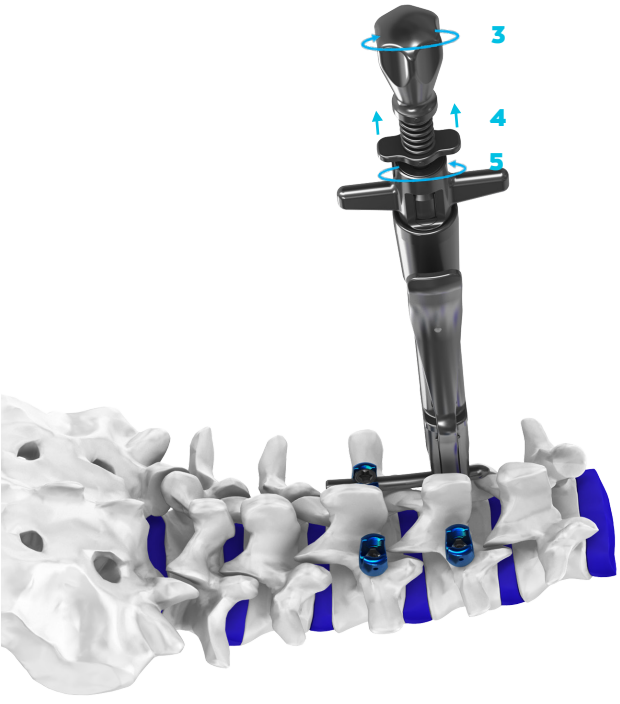
1 Slide the inner tube into the persuader in place.



2 Once the threaded part of the inner tube comes in contact with the superior edge of the persuader, begin screwing to reduce the rod in the implant saddle.



To insert the setscrew when the rod is completely seated in the implant saddle, load a setscrew on the setscrew holder as described above and slide down the assembly through the inner shaft for persuader.



3 Once the setscrew reaches the top of the screw head, turn Clockwisely to load it on the screw and secure the rod.

4 With the setscrew in position, pull up the wing of the setscrew holder to release the connection and remove the setscrew holder.

5 Remove the inner shaft for persuader by unscrewing it and sliding it up from the persuader. Then squeeze the persuader's flanges to disconnect it from the screw head.

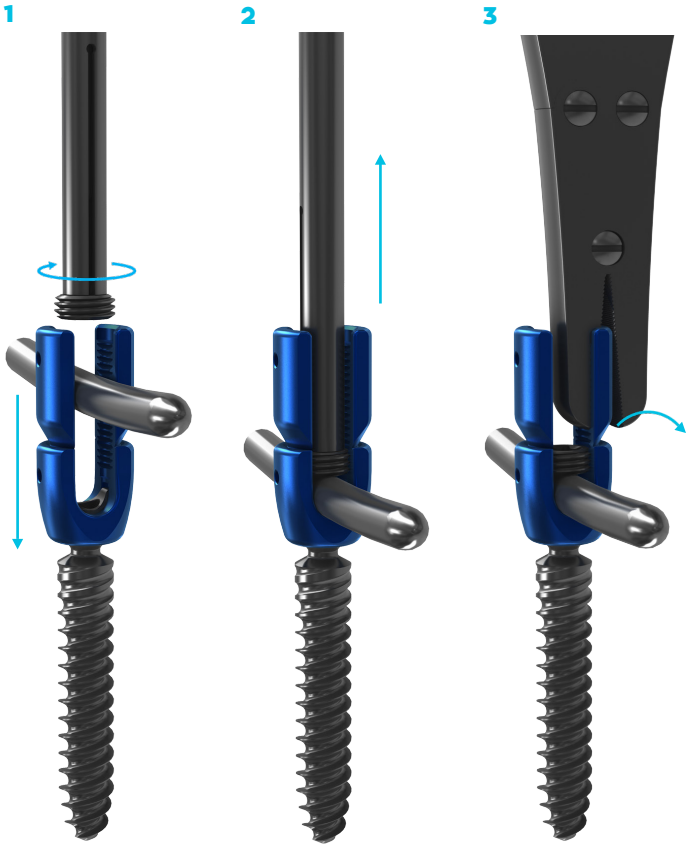
Repeat these steps on all screws prior to apply correction maneuvers.

OPTION C

Tab Remover
IS2-A421

Setscrew Holder
MS1-A231

T30 Shaft
MS1-A411



Reduction screws *IS2-MRXXXT* can also be used to help in rod reduction. The most convenient is to place reduction screws in the middle of the construct where spondylolisthesis reduction is often needed.

Introduce the rod in all screw heads and load a setscrew on the setscrew holder:

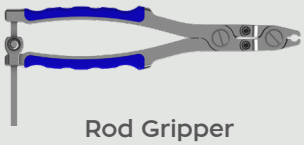
1 Engage the setscrew in the reduction screw's extended tabs using the setscrew holder or the **T30 shaft** *MS1-A411* and turn clockwisely to screw it and reduce the rod.

2 Once the rod reaches the bottom of the implant saddle, disconnect the setscrew holder by pulling the wing up and removing it.

3 To break the extended tabs after the rod persuasion and setscrew tightening, use the **tab remover** *IS2-A421*. Close the jaw on the extension and break it.

VII CORRECTION MANEUVERS

ROTATION OF THE ROD



Rod Gripper
U1-A216

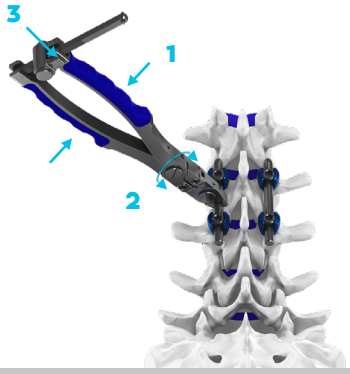
Open Rod Rotation Wrench
U1-A344N1

After all setscrew's placement, the rod can be rotated with the **rod gripper** *U1-A216*.

1 Strongly grip the rod in the instrument's jaw

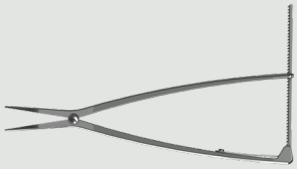
2 Rotate the rod to give a normal curvature in the sagittal plan.

3 Release the grip by pushing the button on the rack and pinion.

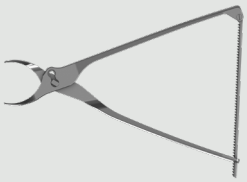


When using the **straight rigid rod** *L2-R6XXHT* or **Co-Cr rigid rod** *U1-R625HC*, grab the hexagonal end of the rod thanks to one or the other side of the **open rod rotation wrench** *U1-A344N1* and use it to rotate the rod.

DISTRACTION & COMPRESSION

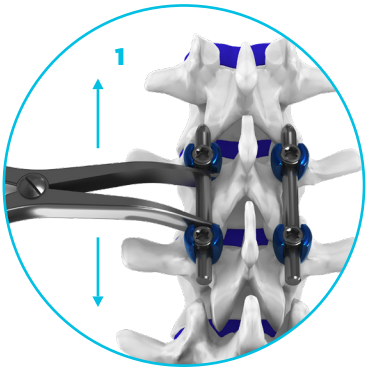


Distractor
U1-A342

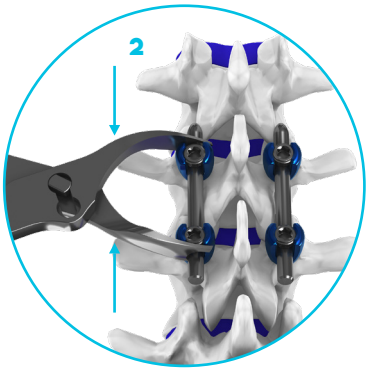


Dual Axis Compressor
U1-A343

To adjust the restored disc height or the curvature of the spine, a **distractor** *U1-A342* and a **dual axis compressor** *U1-A343* are available.



1 **To distract**: lock the setscrew on the screw used as « reference », place the jaw of the distractor as shown on the picture and distract by squeezing the handles. Lock the untightened setscrew when the desired distraction is obtained



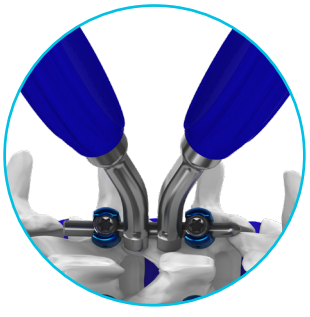
2 **To compress**: lock the setscrew on the screw used as « reference », place the jaw of the compressor as shown on the picture and compress by squeezing the handles. Lock the untightened setscrew when the desired compression is obtained.

IN SITU BENDING

Left Sagittal Bender
U1-A329

Right Sagittal Bender
U1-A328

If additional correction of the curvature in the sagittal plane is needed, use the **right/left sagittal bender** *U1-A328*/*U1-A329* as shown besides.

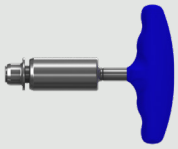


! WARNING !
Rods must not be repeatedly or excessively bent beyond that which is absolutely necessary.

VIII FINAL TIGHTENING

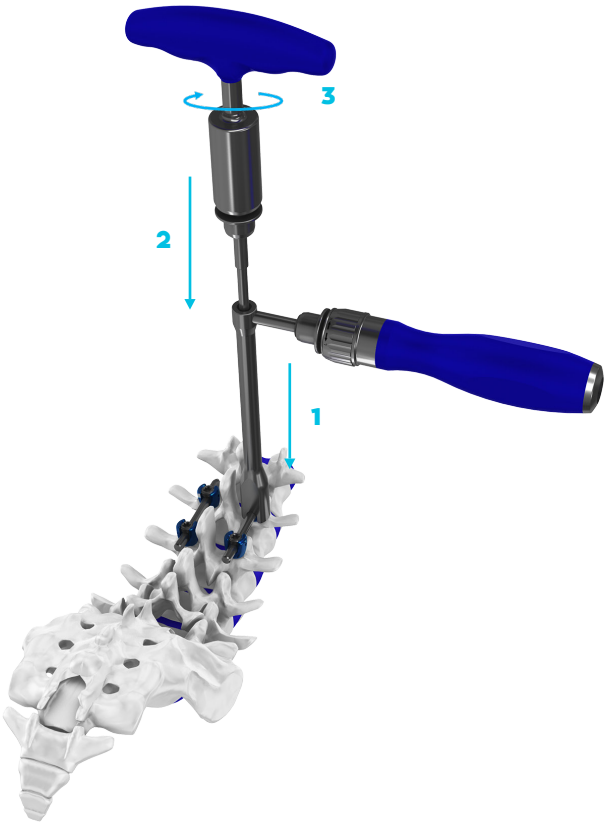
Counter Torque
IS1-A431

T30 Shaft
MS1-A411



Torque Limiting Handle
MS1-A421

Cannulated ratcheting cylindrical handle
SD-A411ALSH



Connect the **T30 shaft** *MS1-A411* to the **torque limiting handle** *MS1-A421*.

1 Position the **counter torque** *IS1-A431* on the screw head as shown besides.

2 Slide the **T30 shaft** *MS1-A411* into the counter torque until the distal tip of the shaft engages in the setscrew's footprint.

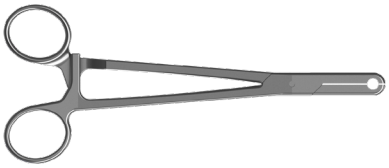
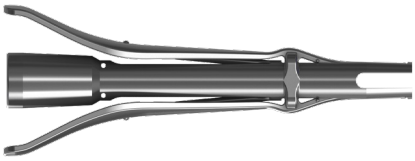
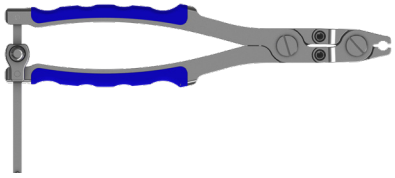
3 While strongly holding the counter torque with the cylindrical handle, turn clockwisely the torque limiting handle until it clicks 3 times. This will ensure a final tightening to a value of 8.5Nm.

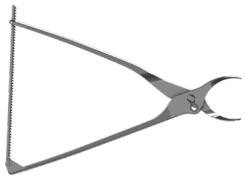
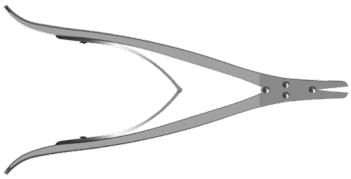
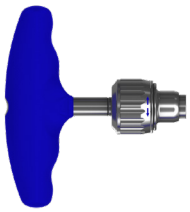
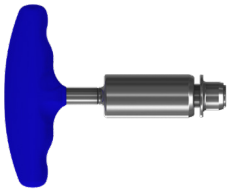
Repeat this step on all setscrews to ensure final tightening of the construct.

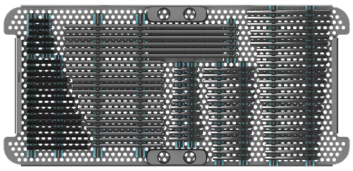
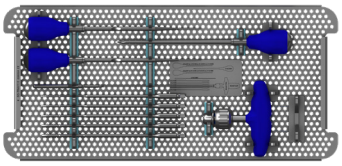
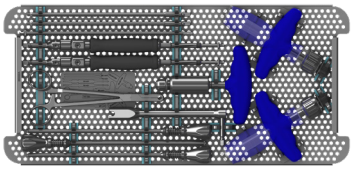
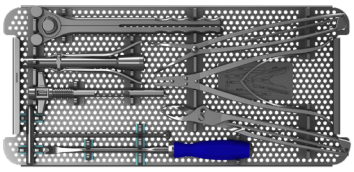
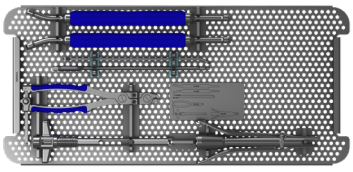
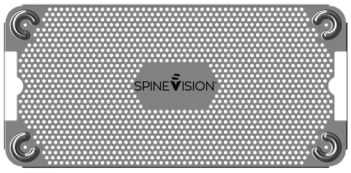
! WARNING !
The proper tightening of the screw is ensured by 3 « clics » produced by the torque limiting handle when performing tightening.
Never use the torque limiting handle to unscrew a setscrew.
Alsways be sure to be on the neutral position of the ratcheting handle when performing tightening.

1 INSTRUMENTS

	Square Awl	U1-A121N1
	Lumbar Spatula	U1-A127
	Curved Lumbar Spatula	U1-A127C
	Lenke Probe	U1-A128
	Straight Lenke Probe	U1-A128S
	Sharp Tap	U1-A13XS
	Pedicle Probe with ball Tip	U1-A124N1
	Universal Screwdriver	MS2-A221
	Screw Adjuster	MS1-A222

	Screw Removal Instrument	IS2-A420
	French Bender	U1-A321
	Open Rod Rotation Wrench	U1-A344N1
	Rod Holder	U1-A214S
	Setscrew Holder	MS1-A231
	T30 Shaft	MS1-A411
	Rod Pusher	U1-A224
	Persuader	IS1-A317
	Inner Tube for Persuader	IS1-A316
	Rod Gripper	U1-A216

	**Dual Axis Compressor**	U1-A343
	**Distractor**	U1-A342
	**Right Sagittal Bender**	U1-A328
	**Left Sagittal Bender**	U1-A329
	**Tab Remover**	IS2-A421
	**Cannulated Ratchteing T-Handle**	SD-A411TSH
	**Cannulated Ratcheting Cylindrical Handle**	SD-A411LSH
	**Torque Limiting Handle**	MS1-A421

	**Ulis Screws Rack**	SD-RACK1
	**Tray 5 ULIS**	IS1-TRAY115
	**Pedicular Preparation Tray**	SD-TRAY111
	**Tray 1 ULIS**	IS1-TRAY111
	**Tray 2 ULIS**	IS1-TRAY112
	**Tray 4 ULIS**	IS1-TRAY114
	**SV Common Base**	SD-BASE1168
	**SV Common Base (2 levels)**	SD-BASE11117
	**SV Common Lid**	SD-LID11

SCREWS RANGE

MULTIAXIAL & MONOAXIAL SCREWS

Ø/L	25	30	35	40	45	50	55	60	70	80	90
4.5	✓	✓	✓	✓	✓						
5.5			✓	✓	✓	✓	✓	✓			
6.5			✓	✓	✓	✓	✓	✓			
7.5			✓	✓	✓	✓	✓	✓			
8.5*			✓	✓	✓	✓	✓	✓	✓	✓	✓

* Only multiaxial

IS2-MXXXT: Multiaxial screw
IS2-SXXXT: Monoaxial screw

X= Diameter
XX= Length
Ex: IS2-M645T: Ø6,5 & 45 mm

REDUCTION SCREWS

Ø/L	25	30	35	40	45	50	55	60
4.5	✓	✓	✓	✓				
5.5		✓	✓	✓	✓	✓	✓	✓
6.5			✓	✓	✓	✓	✓	✓
7.5			✓	✓	✓	✓	✓	

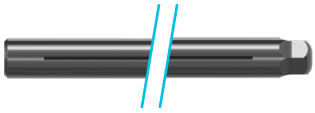
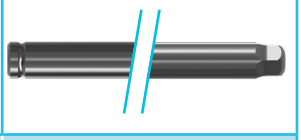
IS2-MRXXXT: Reduction screw

X= Diameter
XX= Length

COLOR CODED DIAMETERS

Ø 4.5 mm	Ø 5.5 mm	Ø 6.5 mm	Ø 7.5 mm	Ø 8.5 mm

ROD RANGE

Length	MS1-R6XXXCT	L2-R6XXCHT	L2-R6XXHT	U1-R6XXHC
	Prebent Percutaneous Rod	Prebent Rod with Hexagonal End	Straight Rod with Hexagonal End	Chromium Cobalt Straight Rod
	TiA6V	TiA6V	TiA6V	Co-Cr
				
30	✓			
35	✓			
40	✓	✓		
45	✓			
50	✓	✓		
55	✓			
60	✓	✓		
65	✓			
70	✓	✓		
75	✓			
80	✓	✓		
85	✓			
90	✓	✓		
95	✓			
100	✓	✓		
110	✓	✓	✓	
120	✓	✓	✓	
130			✓	
140			✓	
250			✓	✓
420			✓	✓

NOTES

NOTES

NOTES

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