MINIMALLY INVASIVE THORACOLUMBAR SYSTEM

THORACO-LUMBAR FIXATION

Lumis

SURGICAL TECHNIQUE

SPINE VISION

INNOVATION THAT MATTERS

Lumis

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
Mini 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.
Note:
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®.

FOR ALL INFORMATION OR COMPLAINTS, CONTACT:

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CE 0123

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

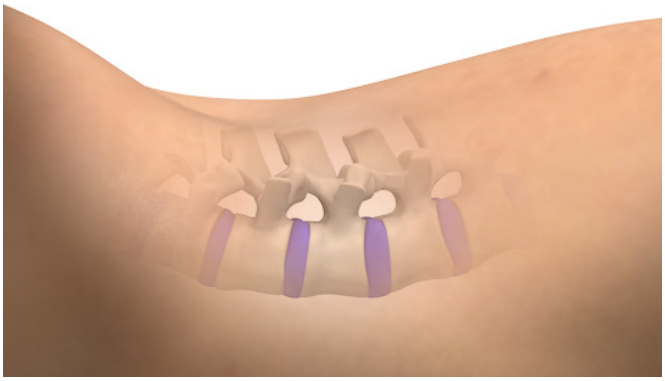
SURGICAL STEPS

REFERENCES

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 implants and the final assembly.



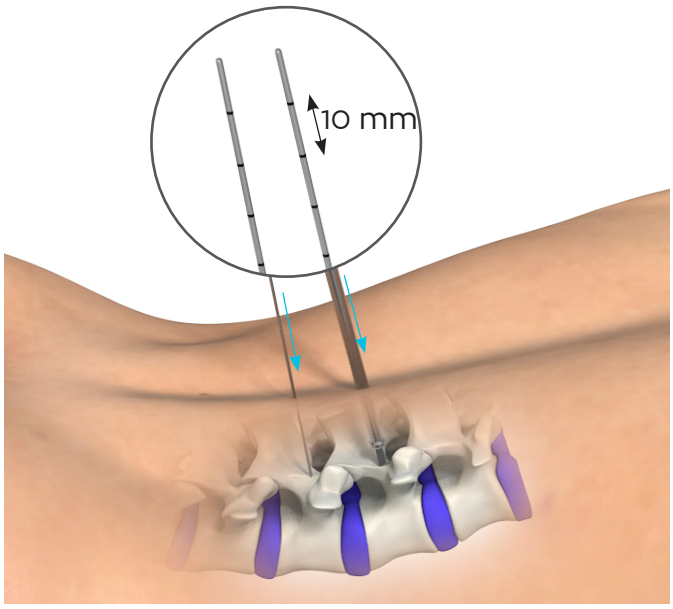
PEDICLE PREPARATION

Guide wire
MS1-WB1450

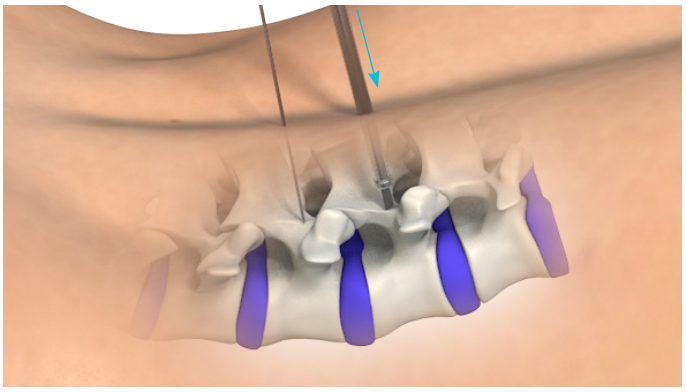
Cannulated square Awl
MS1-A121

After performing a skin incision, use Jamshidi needles (11 gauges) to prepare the trans-pedicular trajectory using radioscopic control (c-arm). Once the wanted trajectory obtained, place the **guide wires** *MS1-WB1450* inside the Jamshidi needles. Remove Jamshidi needles while maintaining the wires.

CAUTION: Guide wires must not be reused.

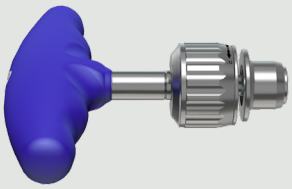


Drag the **cannulated square awl** *MS1-A121* on the guidewire and perforate the cortical.



TAPPING

Cannulated ratcheting cylindrical handle
SD-A411LSH



Cannulated ratcheting T-handle
SD-A411TSH

Cannulated taps
MS1-A11X

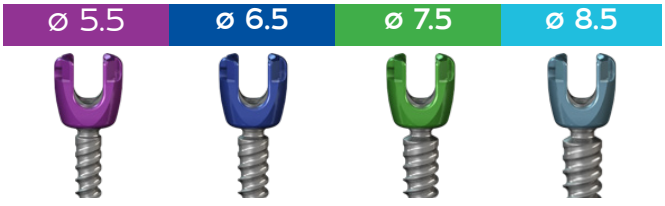
Expander 1
MS1-A110

Protection sleeve for taps
MS1-A111

If needed, and according to the bone condition, it is possible to use taps to facilitate screw insertion or optimize screw anchoring.

! WARNING !
The Lumis screws are color coded according to their diameter. It is mandatory to use the tap corresponding to the screw diameter. Diameter of the taps is 0.5mm lower than corresponding screw diameter.

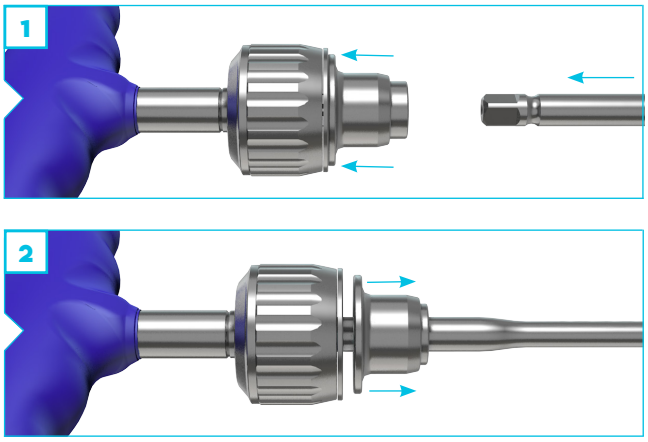
Multiaxial Lumis screws :
MS2-MXXXT (Ex : MS2-M640T)
MS2-MDiameterLengthTitane



Corresponding taps:

1 To connect a **cannulated tap** *MS1-A11X* to the **cannulated ratcheting cylindrical handle** *SD-A411LSH* or **cannulated ratcheting T-handle** *SD-A411TSH*, pull the ring of the handle towards the silicon part.

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

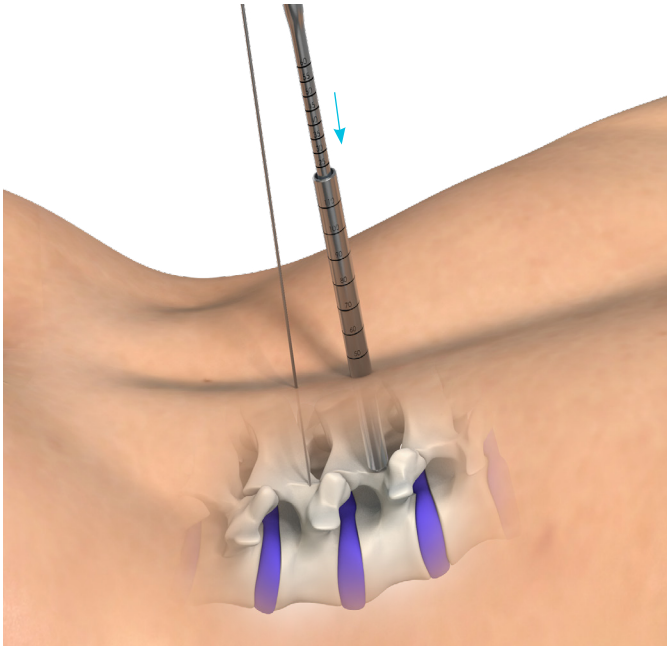


! WARNING !
Always check the connection between the handle and the screwdriver before use.

To protect soft tissue from the sharp edges of the taps, it is recommanded to use **the expander 1** *MS1-A110* and then **the protection sleeve for taps** *MS1-A111* can be inserted onto the guide wire.

Remove the expander 1.

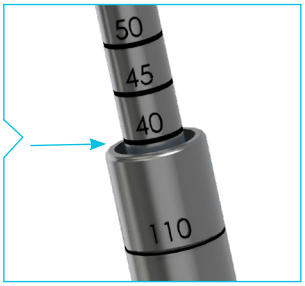
The protection sleeve must be inserted with laser marks on the caudal part to remain visible.



Insert the appropriate tap depending on the inserted screw size over the guide wire.

Forceps can be used to maintain the guide wire during tapping.

The insertion depth of the tap inside the vertebra is indicated by laser markings on the tap shaft. Thus, the appropriate screw length can be precisely determined.



SCREW INSERTION

Enlarged screw extender
MS1-A214

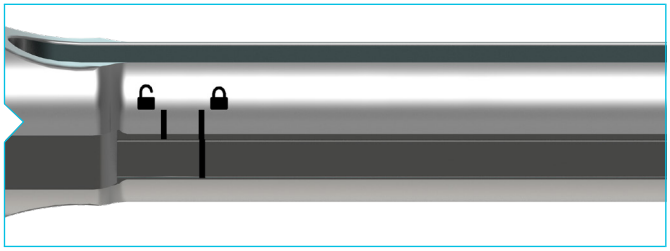
Screw
MS2-MXXXT

Once the screw of the desired diameter and length has been selected, it must be connected to the enlarged screw extender.

To fix the enlarged screw extender to the screw:

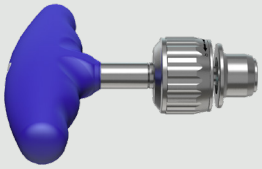
1. Insert the screw onto the enlarged screw extender by making sure the locking ring is up.
2. Slide down the locking ring.
3. Secure the system by screwing the nut clockwise.

Laser marks confirm the locked position of the ring.



Lumis Universal Screwdriver
MS2-A221

Or

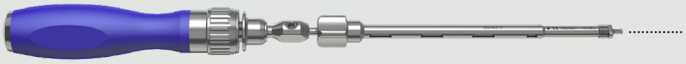


Cannulated ratcheting cylindrical handle
SD-A411LSH

Cannulated ratcheting T-handleSD-A411TSH

To connect a **Lumis universal screwdriver** *MS2-A221* to the **cannulated ratcheting cylindrical handle** *SD-A411LSH* or **cannulated ratcheting T-handle** *SD-A411TSH*, repeat the maneuver described in the previous step (page 4).

Enlarged screw extender connected to a screw
MS1-A214 + MS2-MXXXT



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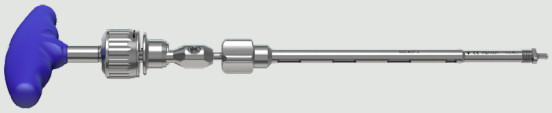
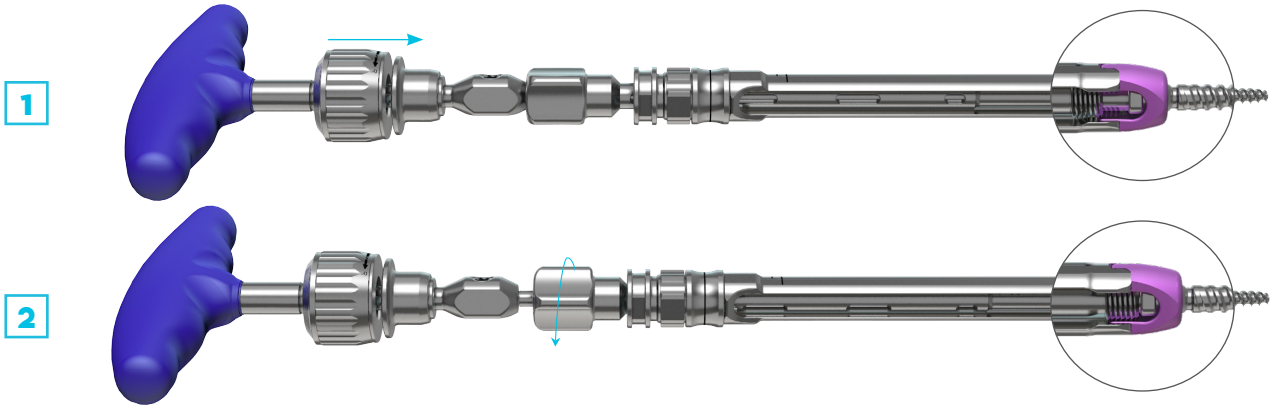


Lumis Universal Screwdriver connected to the Cannulated ratcheting cylindrical handle
MS2-A221 + SD-A411LSH

Lumis Universal Screwdriver connected to the Cannulated ratcheting T-handle
MS2-A221 + SD-A411TSH

To connect the screwdriver to the screw:

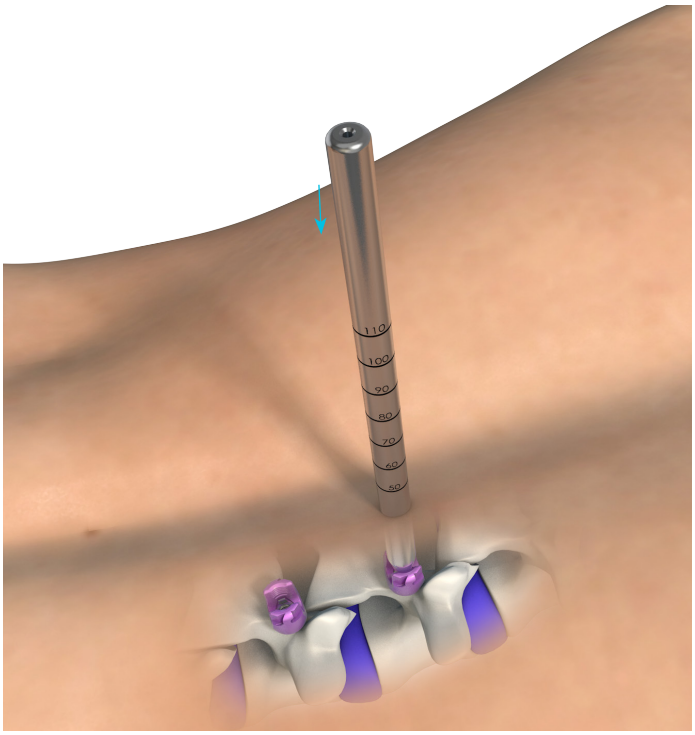
1. Insert the screwdriver in the screw head. Ensure that the screwdriver is fully seated in the screw head.
2. Turn the square piece to engage the screwdriver with the screw.



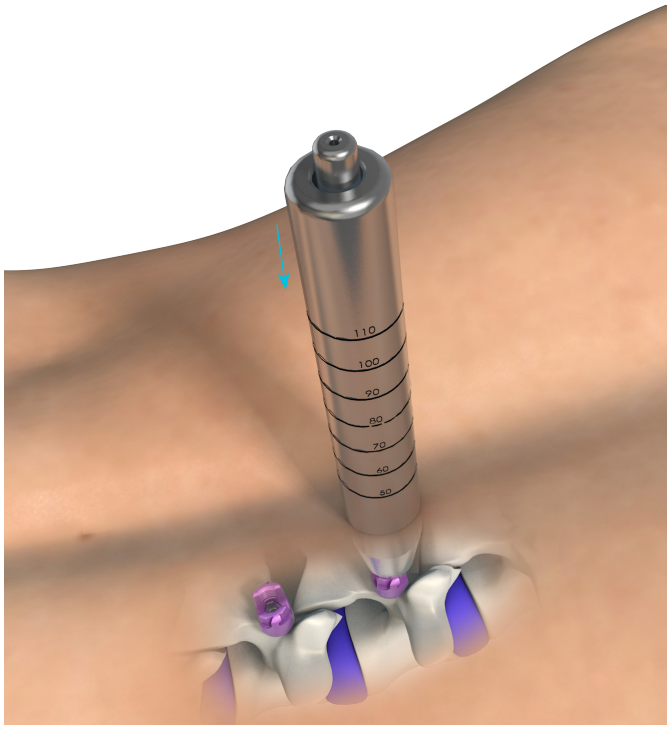
Please check the correct engagement between the screw and the screwdriver before handing parts over to the surgeon.

To protect soft tissues, it is recommended to first insert the expanders to create an opening for the passage of the screw. Then the screw will be inserted in the last expander.

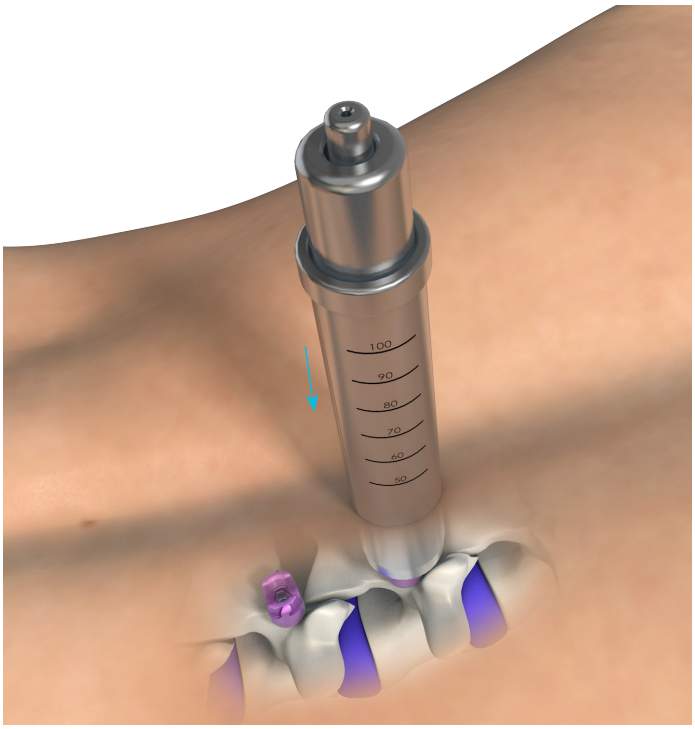
Insert **the expander 1** *MS1-A110*.



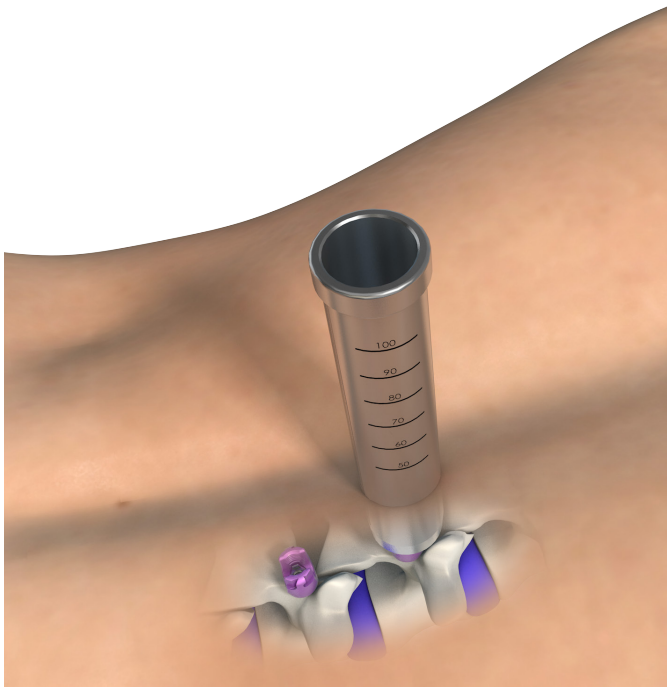
Insert **the expander 2** *MS1-A112* over the first expander.



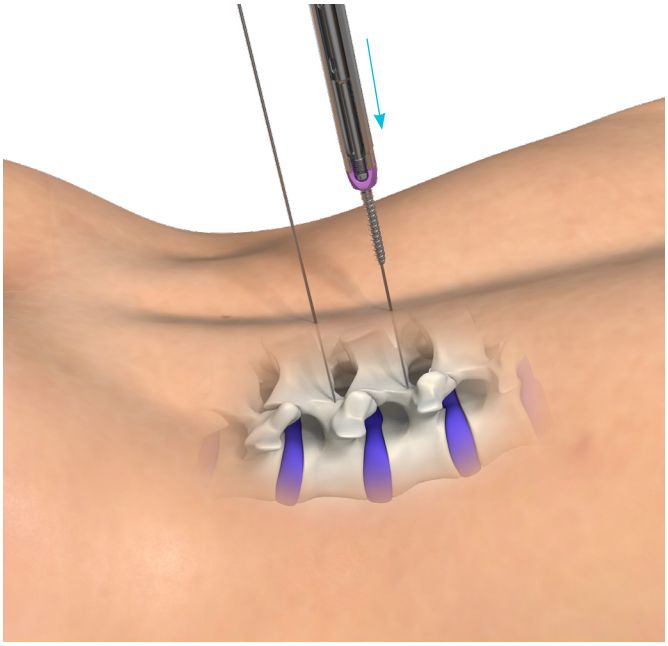
Insert **the expander 3** *MS1-A113* over the second expander.



Remove the expanders 1 & 2 to keep only the expander 3.
The next steps can then be done through the expander 3.

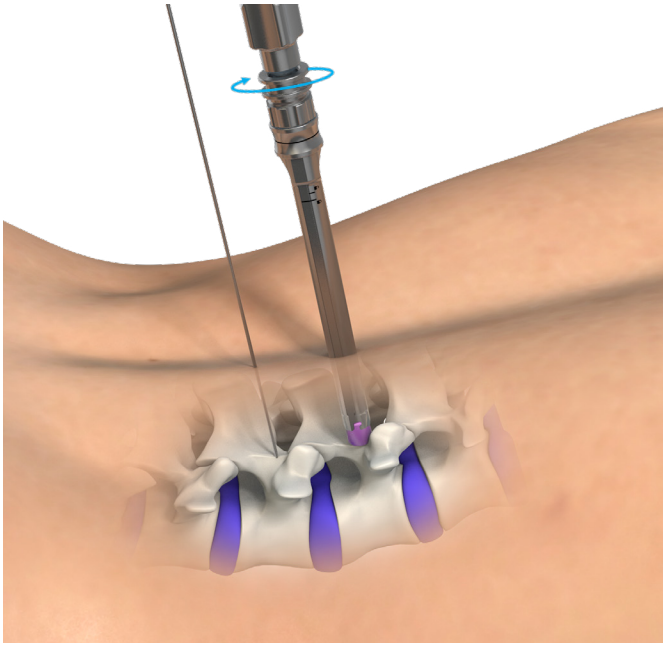


Insert the screw assembled with the screwdriver and screw extender construct over the guide wire. During all the insertion, please control the position of the wire using x-ray to prevent any migration in the anterior part.



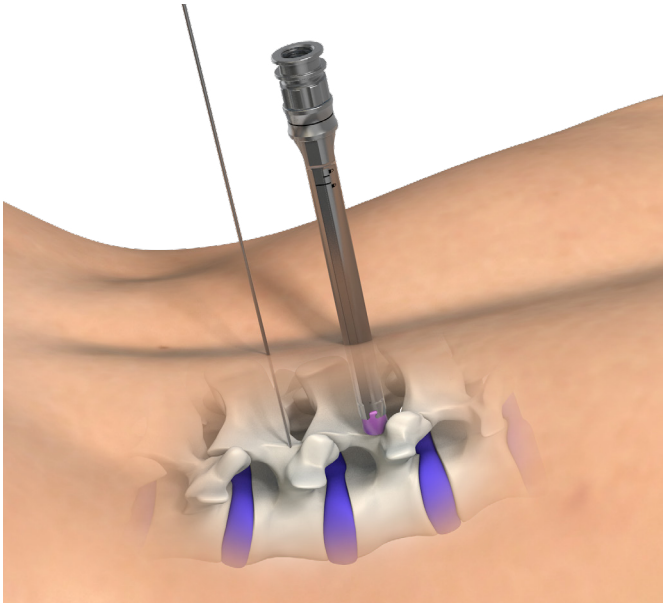
Once the screw tip is advanced far enough in the vertebral body, it is recommended to remove the guide wire to prevent any breach of the anterior wall.

The screw can then be fully inserted.



Remove the screwdriver, leaving the screw with the extender by turning the square part of the cannulated screwdriver counterclockwise.

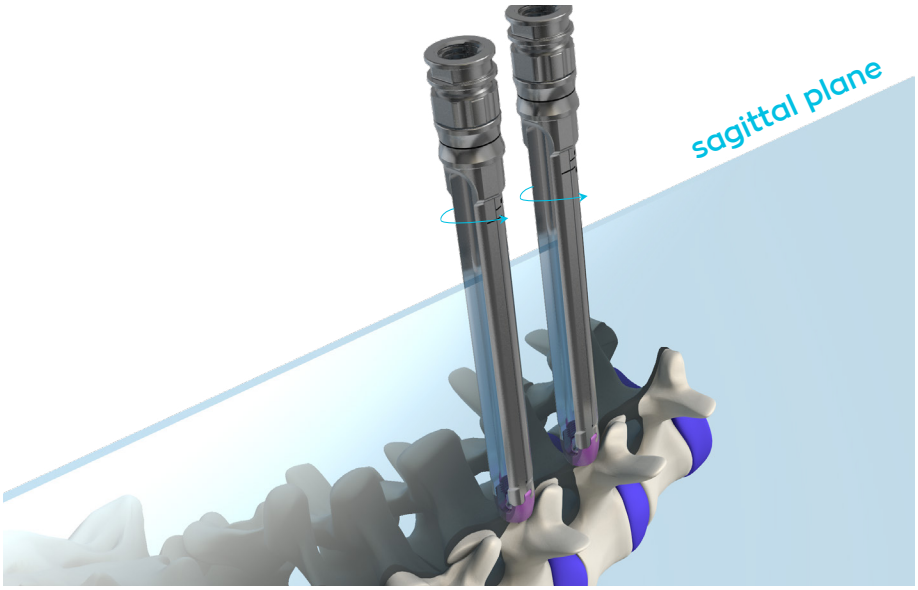
Repeat the previous surgical steps to insert as many pedicle screws as needed.



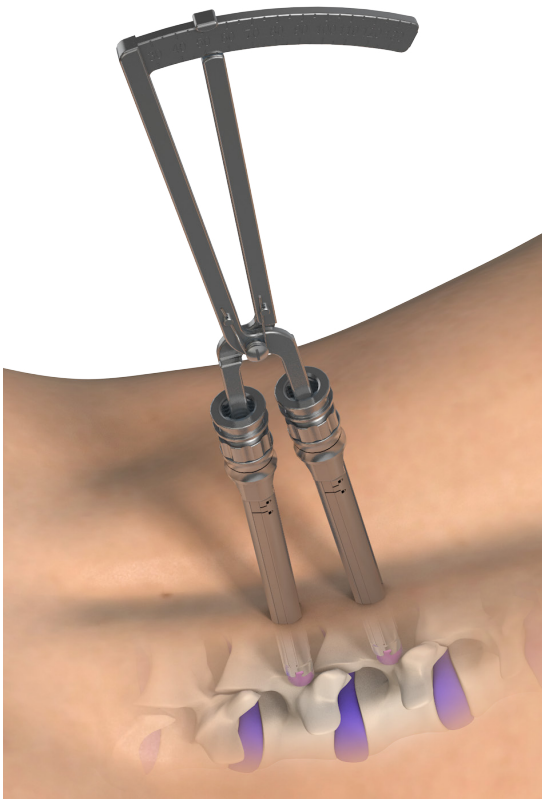
FINAL TIGHTENING

Rod gauge
MS1-A261

Once all screws are placed, rotate the extender sleeve so that the slots line up in the sagittal plane.



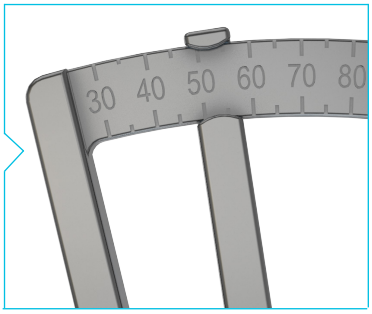
The **rod gauge** *MS1-A261* is inserted into the two most proximal and distal screw extenders until the ball tips are positioned at the bottom of the pedicle screws head.



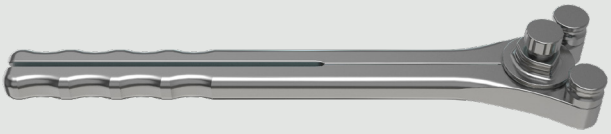
! WARNING !
For a good measurement, spheres must be positioned at the bottom of each screw head.

The rod length needed is indicated on top of the rod gauge.

In case of doubt, choose the larger size.



ROD PLACEMENT



French bender
U1-A321

Prebent rod
MS1-R6XXXCT

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

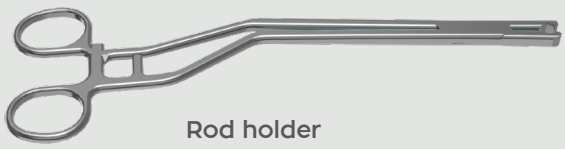
The system can also be used with **straight rigid rod** *L2-R6XXHT* or a **Flex+2 rod**.

If needed the rigid part of the rod can be contoured prior to insertion using the **French bender** *U1-A321*.

The rod introduction can be realized:

- A : By a mini-open approach using a **rod holder** *MS1-A271*.
- B : By a percutaneous approach using a **rod introducer** *MS1-A274*.
- C : By a percutaneous approach using a reversed **rod introducer** *MS1-A275*.

A. Mini-open approach using a rod holder



Rod holder
MS1-A271

The **rod holder** *MS1-A271* can be used to insert the rod inside the extenders, and then drive it in the bottom of the screw heads.

B. Percutaneous approach using a rod introducer

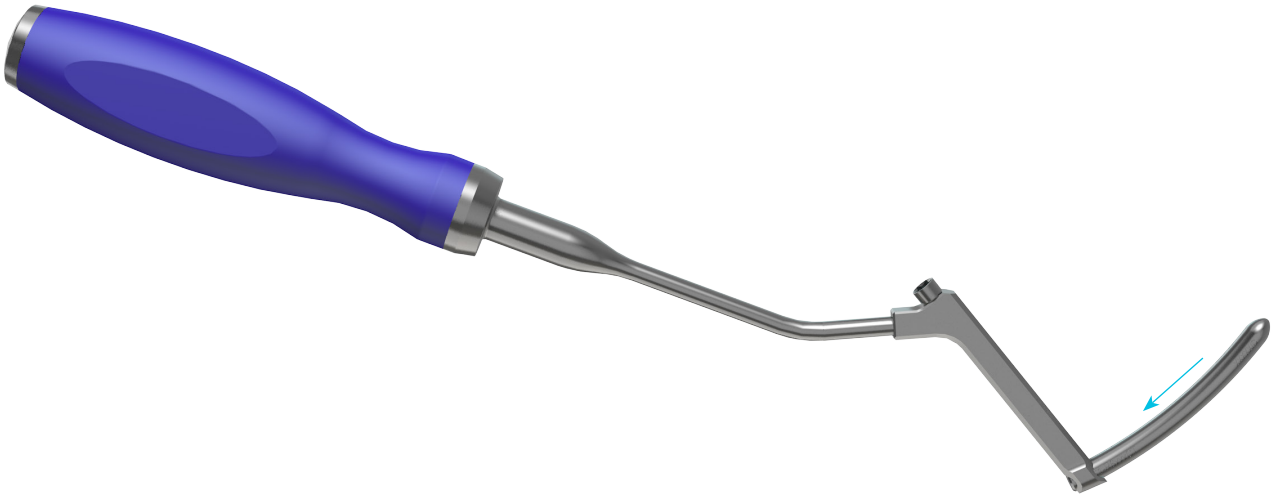
Rod introducer
MS1-A274

T30 shaft connected to the cannulated ratcheting cylindrical handle
MS1-A411 + SD-A411LSH

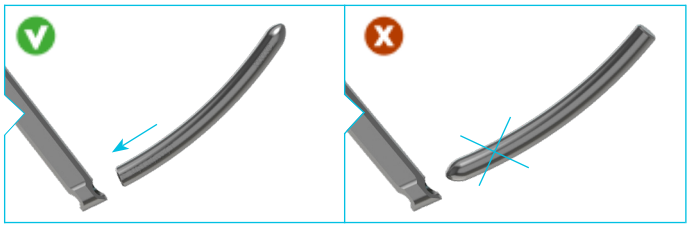
Or

T30 shaft connected to the Cannulated ratcheting T-handle
MS1-A411 + SD-A411TSH

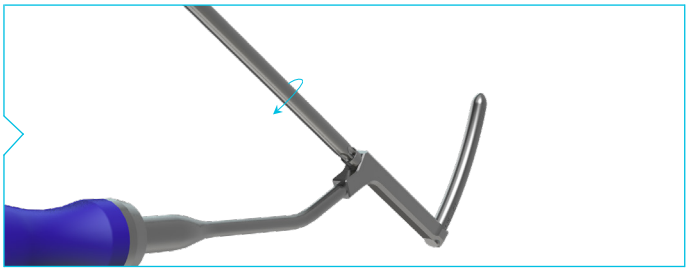
Insert the rod into the slot located at the end of the instrument, ensuring that the end of the rod points upwards.



If the **Lumis percutaneous rod** *MS1-R6xxxT / MS1-R6xxxCT* is used, take care to insert the non-bulleted extremity in the rod introducer.

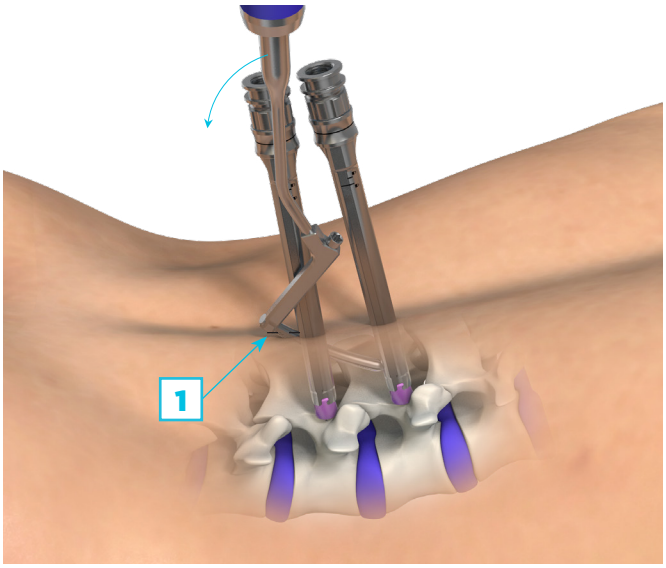


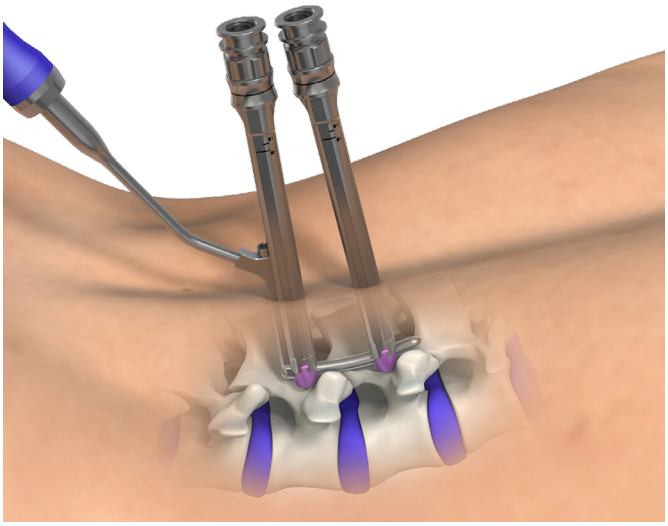
Lock the rod in the instrument by tightening the locking screw with the **T30 shaft** *MS1-A411* preassembled with the **cannulated ratcheting cylindrical handle** *SD-A411LSH* or **cannulated ratcheting T-handle** *SD-A411TSH.*



Insert the rod tip (rigid rod or Flex+2) or bullet nose (Lumis percutaneous rod) beneath the muscles and then rotate the **rod introducer** *MS1-A274*.

Note:
A small additional incision **1** may be necessary to be able to insert the rod.





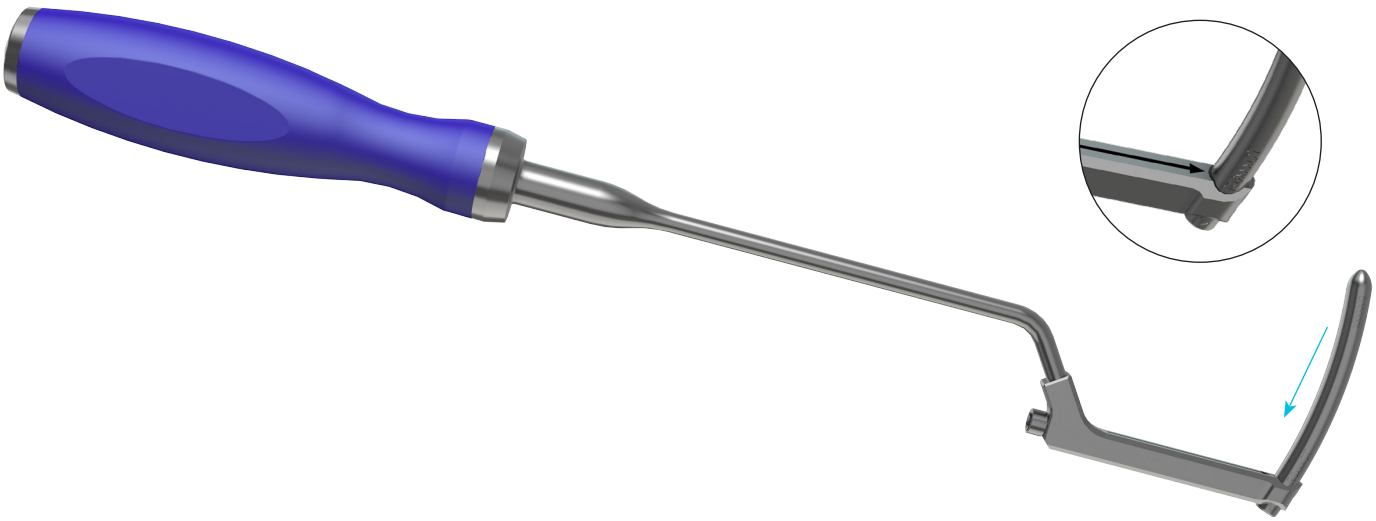
C. Percutaneous approach using the reversed rod introducer

Reversed rod introducer
MS1-A275

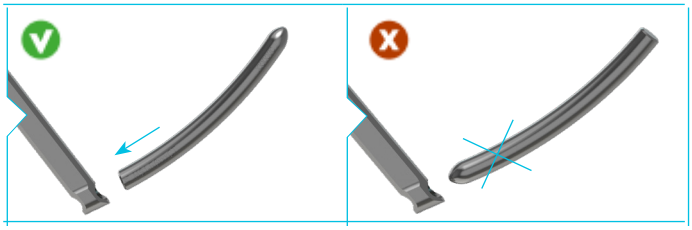
T30 shaft connected to the Cannulated ratcheting cylindrical handle
MS1-A411 + SD-A411LSH

T30 shaft connected to the Cannulated ratcheting T-handle
MS1-A411 + SD-A411TSH

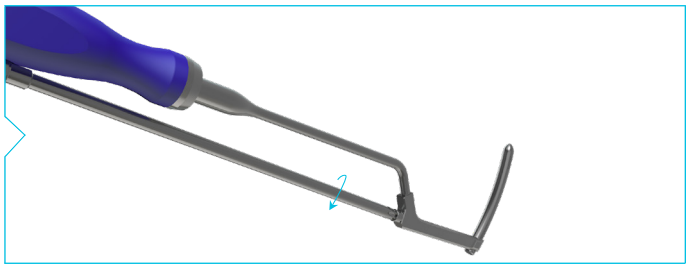
Insert the rod into the slot located at the end of the instrument, ensuring that the tip of the rod points upwards. A laser mark indicates which side the rod must be placed.



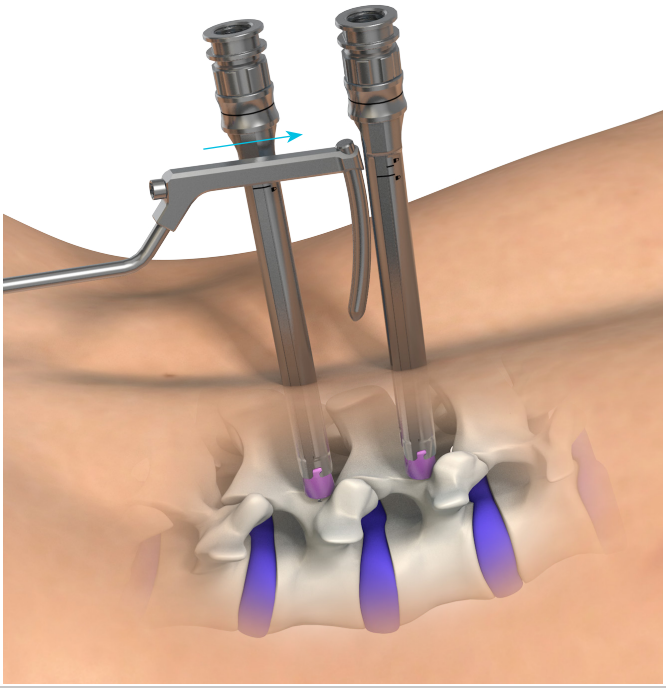
When the **Lumis percutaneous rod** is used (*MS1-R6XXXT / MS1-R6XXXCT*), take care to insert the non-bulleted extremity in the **rod introducer.**

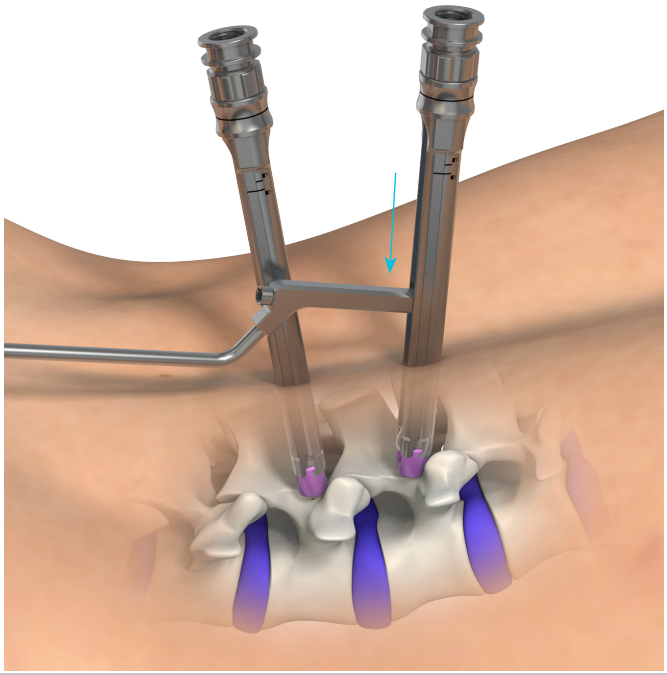


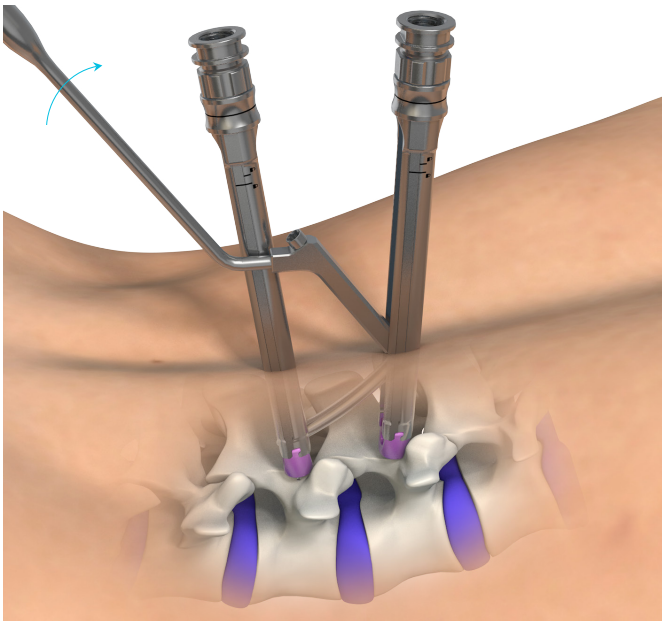
Lock the rod in the instrument by tightening the locking screw with the **T30 shaft** *MS1-A411* preassembled with the **cannulated ratcheting cylindrical handle** *SD-A411LSH* or **cannulated ratcheting T-handle** *SD-A411TSH.*

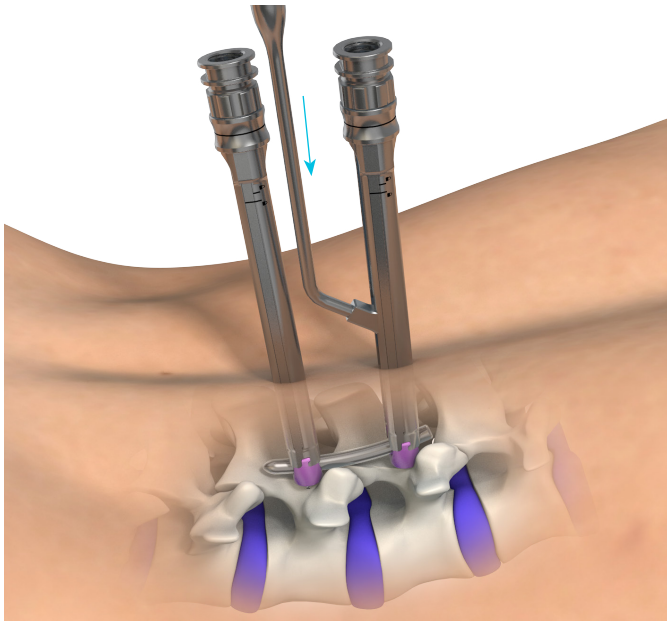


Lower the rod into the enlarged screw extender at the end of the construct and rotate the rod into the screw heads.

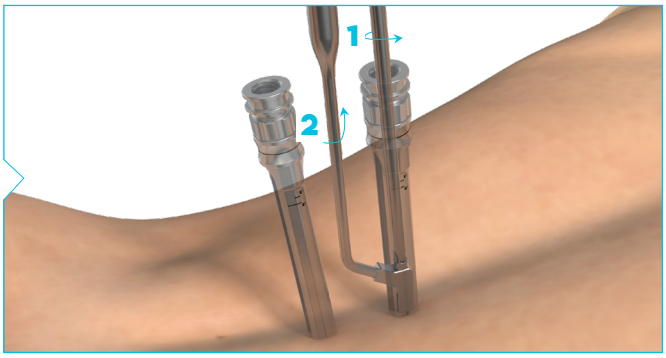






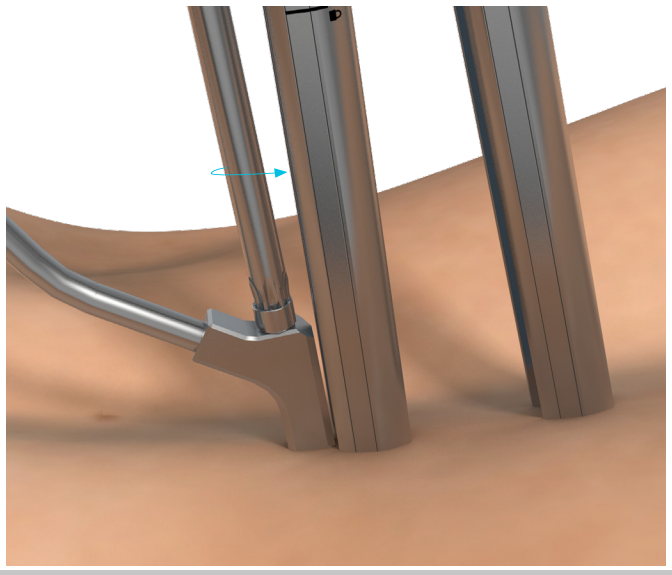


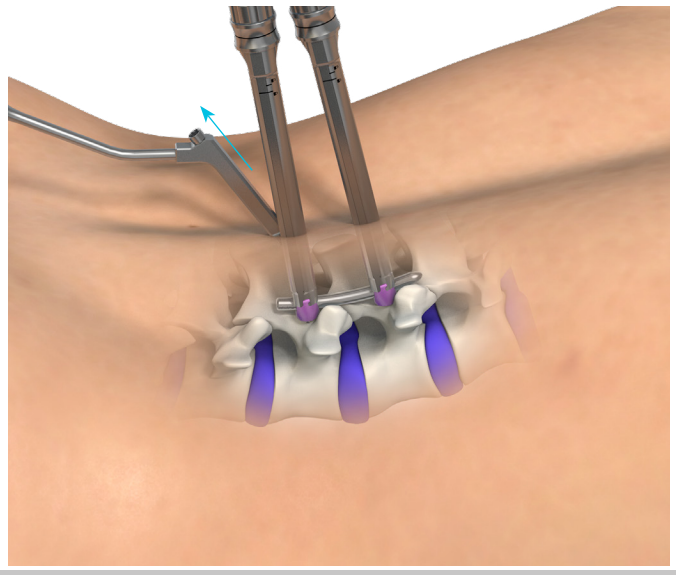
To release the rod, unscrew the locking screw with the **T30 shaft** *MS1-A411* preassembled with the **cannulated ratcheting cylindrical handle** *SD-A411LSH* or **cannulated ratcheting T-handle** *SD-A411TSH.*



Regardless of which rod introducer is used, it is obligatory to insert and tighten slightly a setscrew into one of screw heads before removing the rod introducer. Doing this will keep the rod inside the screw heads and prevent it from moving during the rod introducer removal.

To release the rod, unscrew the locking screw with the **T30 shaft** *MS1-A411* preassembled with the **cannulated ratcheting cylindrical handle** *SD-A411LSH* or **cannulated ratcheting T-handle** *SD-A411TSH.*





Control of the rod placement

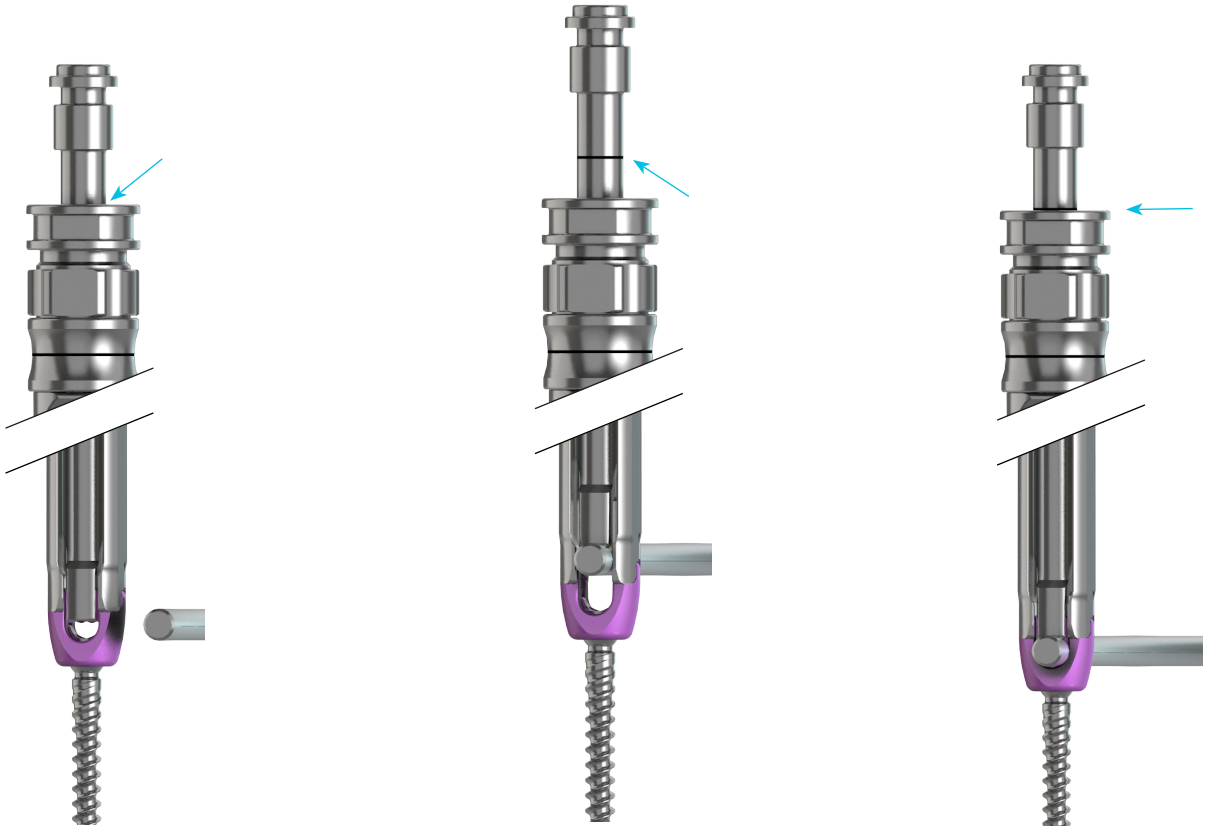
Rod persuadeur
MS1-A311

To verify that the rod is fully seated in the screw heads, insert the **rod persuader** *MS1-A311* into the screw extender and check that the laser mark is visible.

1 The laser mark is not visible. There is no rod in the screw head.

2 The laser mark is visible and not flush with the screw extender.
Rod reduction is required.

3 The laser mark is visible and flush with the screw extender. There is no need to reduce the rod.



! WARNING !
The setscrew must never be placed on the bulleted part of the rod.

Allowed area
for the placement of the setscrew

ROD REDUCTION

A · The rod is perfectly seated

Setscrew
MS1-L100T

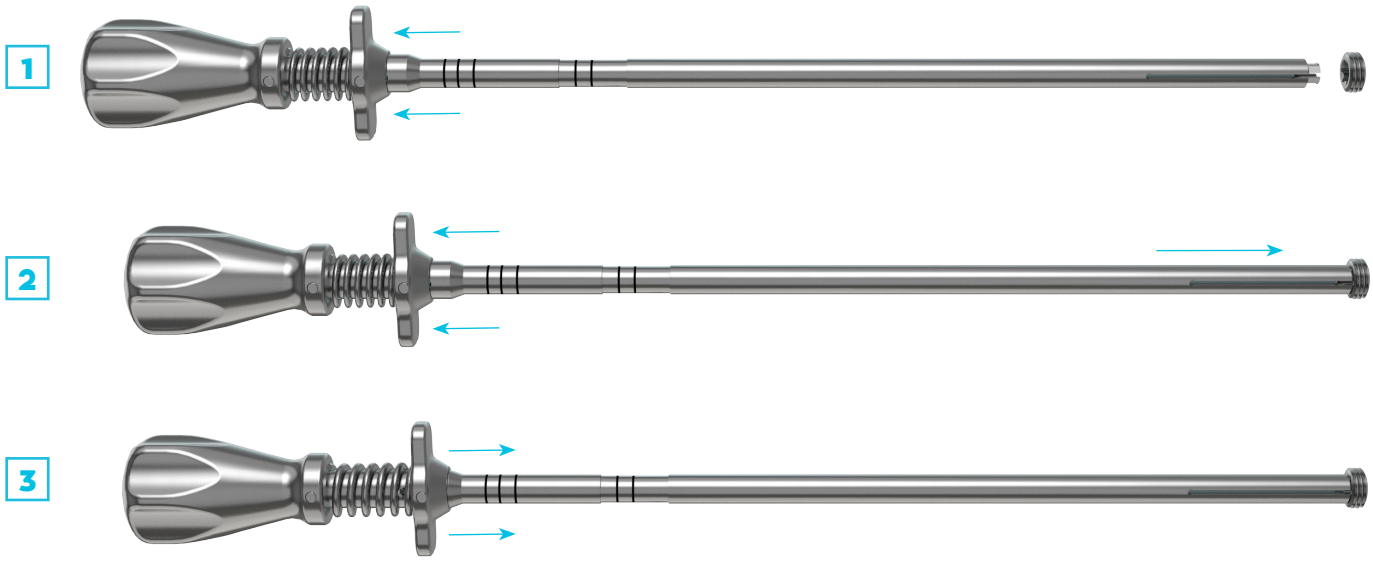
Setscrew holder
MS1-A231

Index ring
MS1-A232

If the rod is perfectly seated in the screw head, it is possible to engage the **setscrew** *MS1-L100T* using only the **index ring** *MS1-A232* and **setscrew holder** *MS1-A231*.

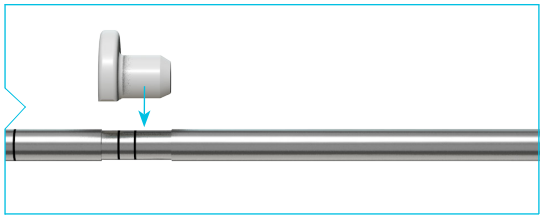
To load a **setscrew** *MS1-L100T* on the **setscrew holder** *MS1-A231*:

1. Pull up the trigger of the setscrew holder.
2. While maintaining this position, slide the tip of the instrument in the "star" footprint of the setscrew.
3. Finally release the trigger of the setscrew holder.

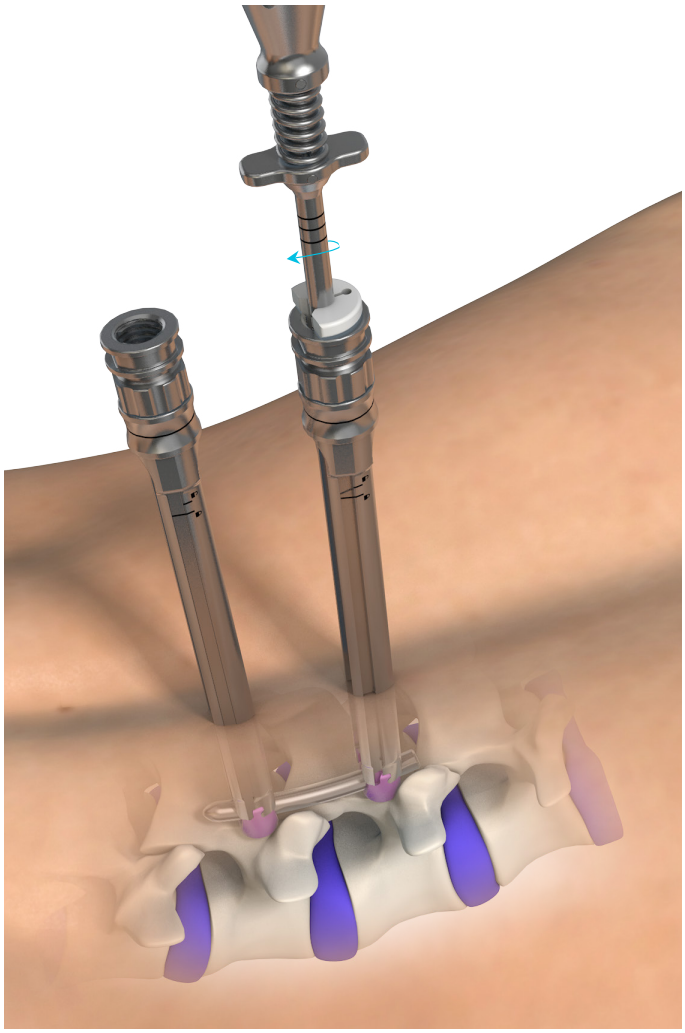


! WARNING !
Never use the setscrew holder MS1-A231 for the final tightening.

Attach the **index ring** *MS1-A232* of the setscrew holder onto the narrowest part of the **setscrew holder** *MS1-A231*.



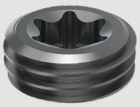
Slide the assembly into the screw extender and turn the upper part of the setscrew holder clockwise to engage the setscrew in the screw head.



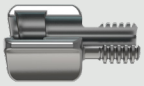
B· The rod is not perfectly seated inside the screw head

Setscrew holder
MS1-A231

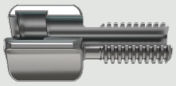
Rod Persuader
MS1-A311



Setscrew
MS1-L10OT



Screw for rod persuader
MS1-A313



Long screw for rod persuader
MS1-A314

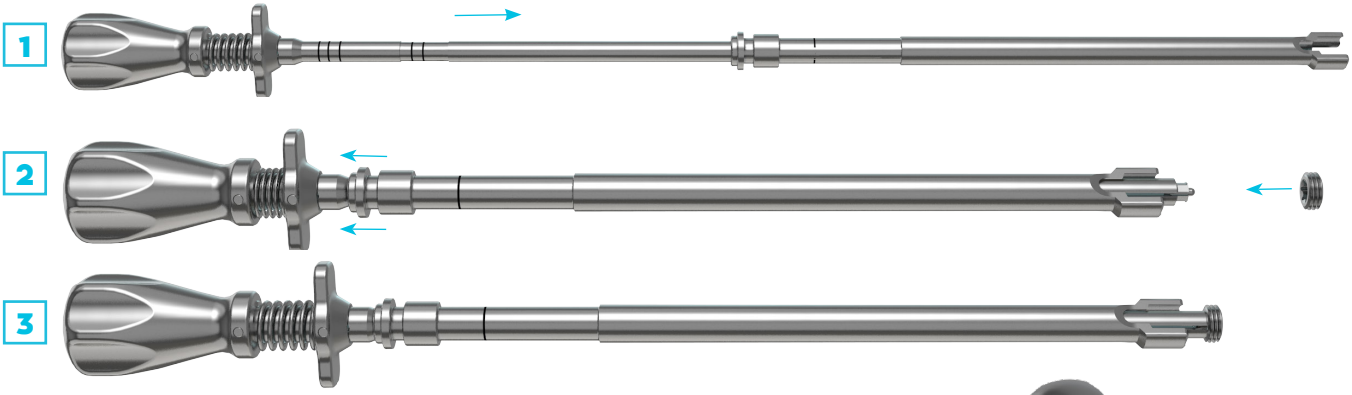
Over handle
MS1-A315

OPTION

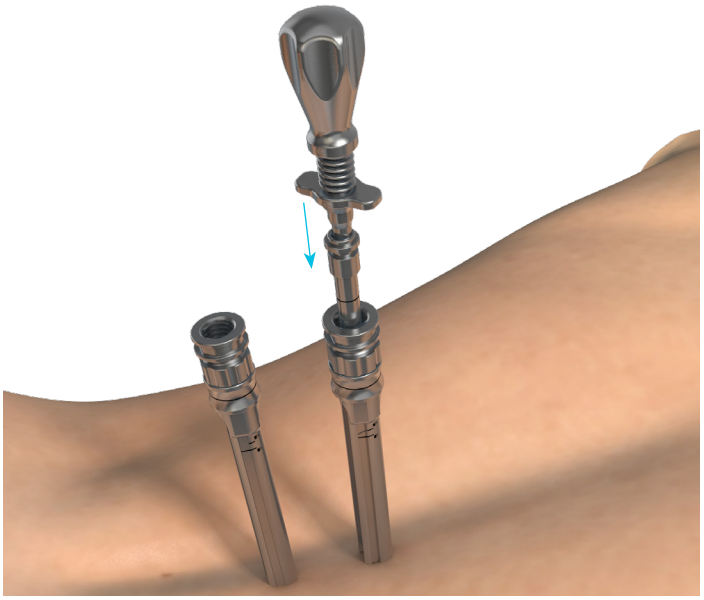
If the rod is not perfectly seated inside the screw head:

1 Slide the **setscrew holder** *MS1-A231* into the **rod persuader** *MS1-A311*

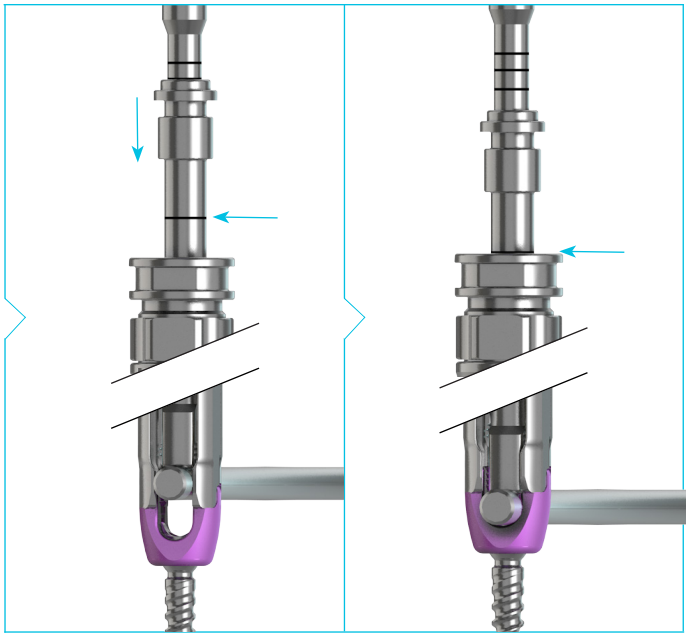
2 Then, load the **setscrew** *MS1-L10OT* on the setscrew holder (as described above page 15.).



Slide the setscrew holder assembled with the rod persuader and the Lumis setscrew into the screw extender.



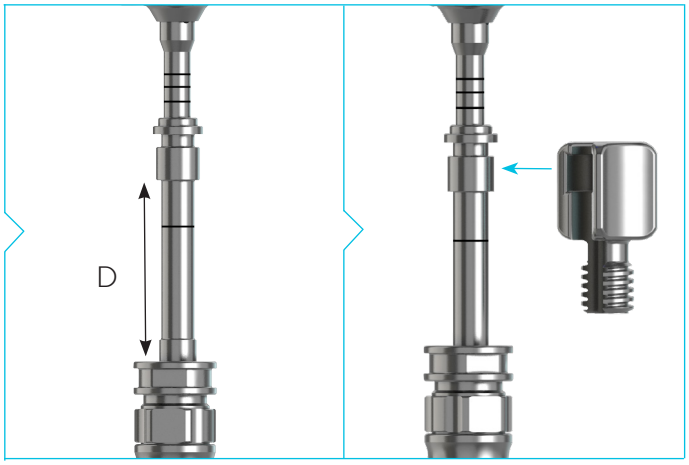
Manually reduce the rod by pushing on the rod persuader until the laser mark flushes with the level of the screw extender.



If the distance (D) between the rod and the screw head is too large use the screw for rod persuader:

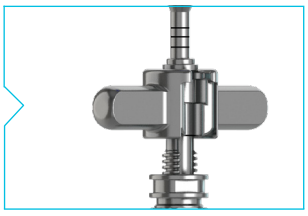
- If D < 38mm, assemble the screw for **rod persuader** *MS1-A313* on the persuader by sliding the square part on the instrument tip.

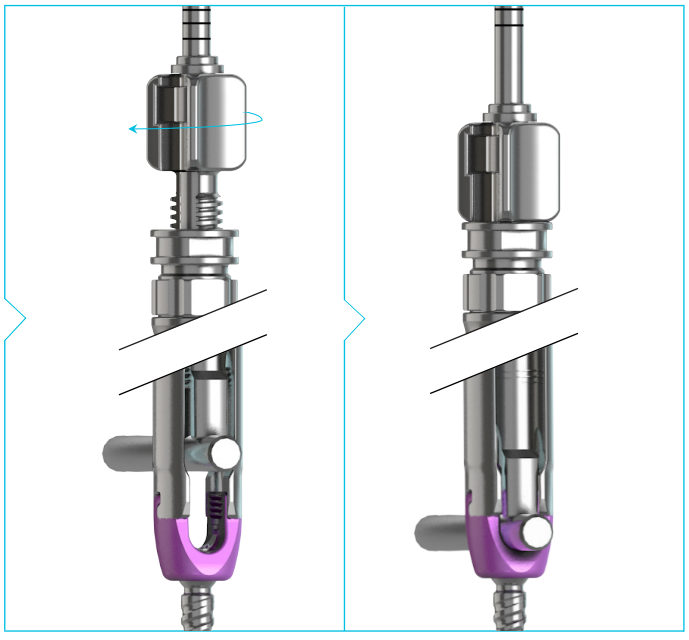
- If D > 38mm, assemble the **long screw for rod persuader** *MS1-A314.*



By turning the screw, the rod is pushed down the screw heads.

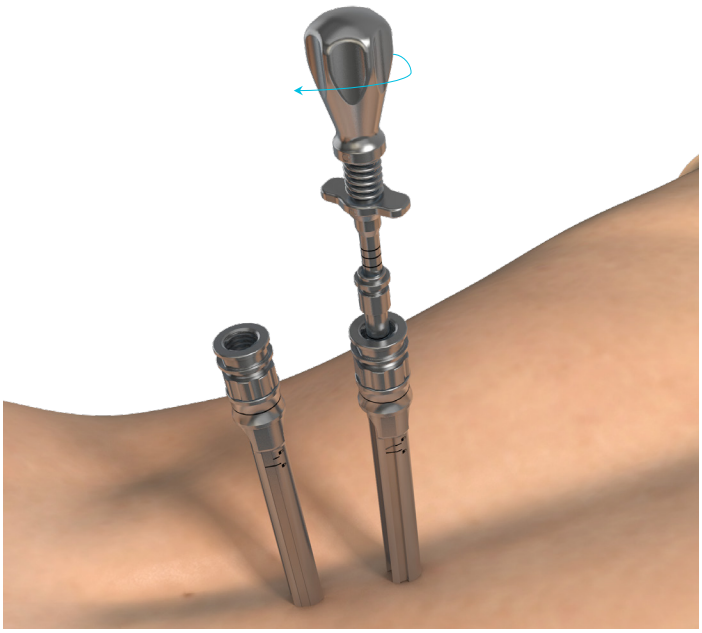
For extra leverage, it is possible to use the **over handle** *MS1-A315.*



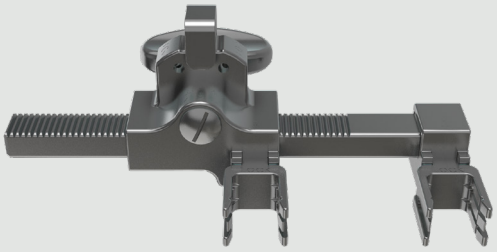


! WARNING !
The rod introduction in force induces stress on the implants and their anchorage in the bone. It may be better to adjust the rod bending.

Once the rod perfectly inserted, turn the upper part of the setscrew holder clockwise to insert the setscrew in the screw head.

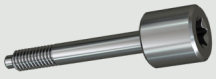


VIII COMPRESSION / DISTRACTION

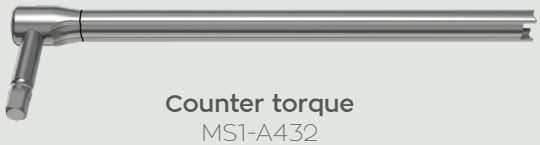


Distractor - Compressor
MS1-A331

Extender plug for distractor-compressor
MS1-A332



Screw fixation for distractor-compressor
MS1-A333



Counter torque
MS1-A432

Fulcrum connector for distractor / compressor
MS1-A334

Multiple connector for distractor / compressor
MS1-A335

Cannulated ratcheting cylindrical handle
SD-A411LSH

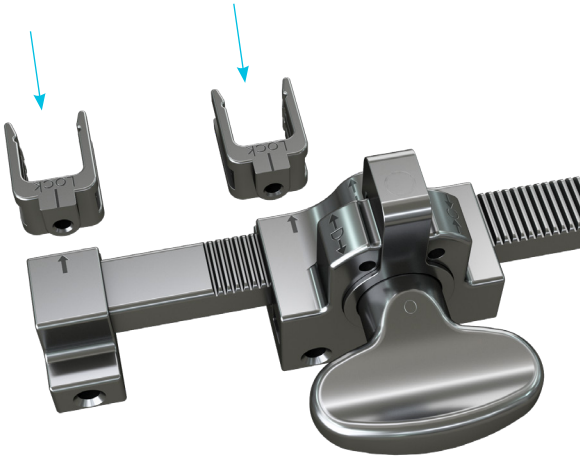
OPTION

First assemble the distractor - compressor :

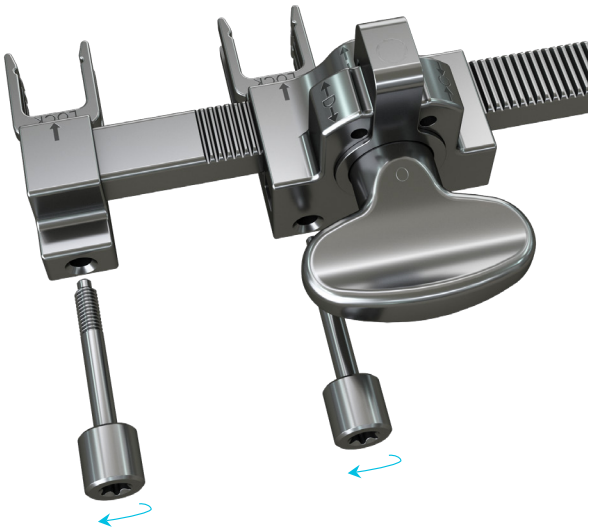
1 Insert the 2 **extender plugs** *MS1-A2332* in the **Distractor - Compressor** *MS1-A331*

2 Secure the assembly thanks to the **screw fixation** *MS1-A333*.

1

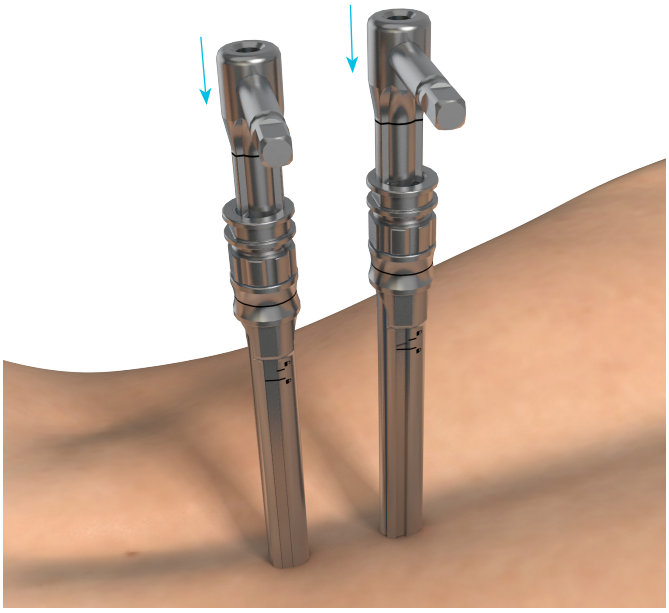


2

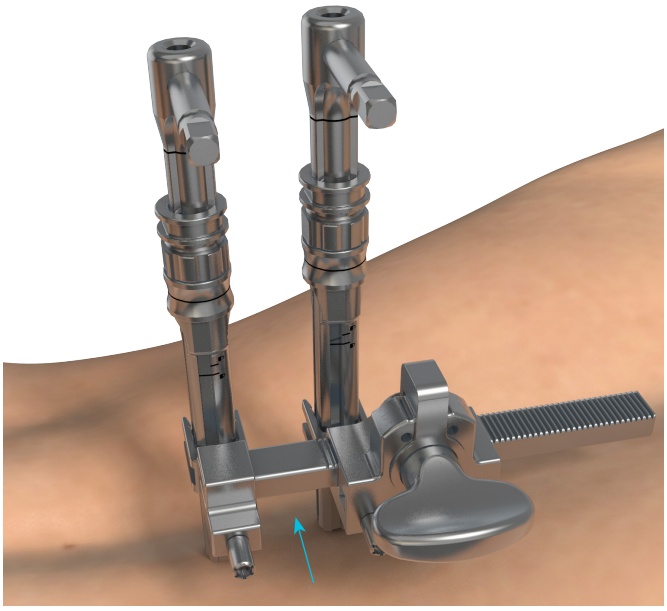


Choose a screw to be used as fulcrum and lock its setscrew to the final torque (as described in the part IX page 21 for the final tightening).

Place two **counter torques** *MS1-A432* into the screw extenders.



Place the **distractor / compressor** *MS1-A331* on the screw extenders.

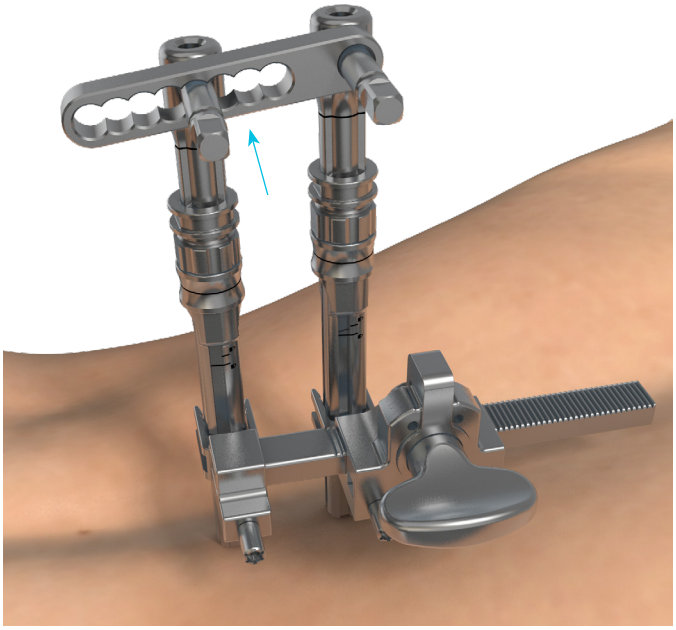


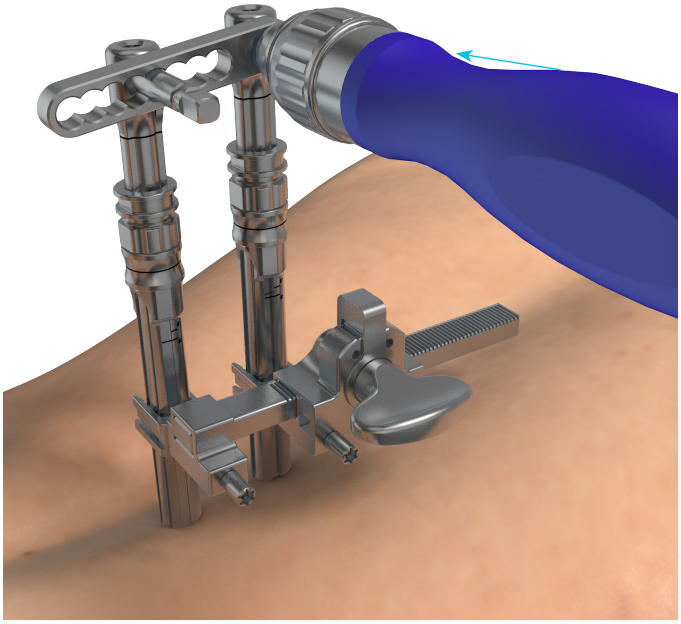
Depending on the space between the two counter-torques, choose the appropriate connector:

- Fulcrum connector for distractor / compressor *MS1-A334*

- Multiple connector for distractor / compressor *MS1-A335*

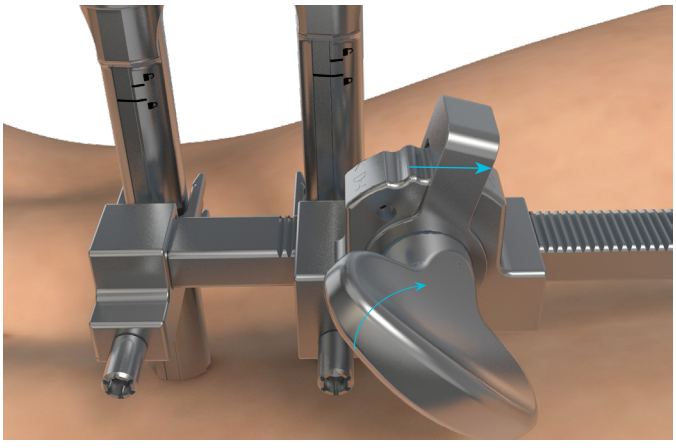
It is recommended to place a **cannulated ratcheting cylindrical handle** *SD-A411LSH* on one of the counter-torques to secure the fulcrum.



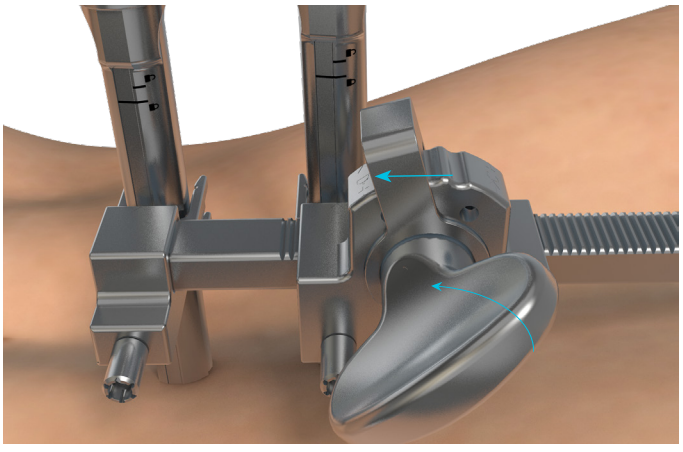


Select the desired action (compression or distraction) with the trigger and turn the turnkey.

DISTRACTION



COMPRESSION

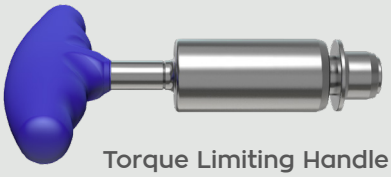


Once the correction has been performed, it is possible to perform the final tightening (part IX) on the setscrew which was not used as fulcrum while maintaining the compressor / distractor in position.

Remove the distractor / compressor by pulling it away from the screw-extenders and removing the two counter-torques.

IX FINAL TIGHTENING

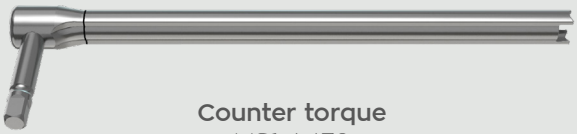
A · Percutaneous approach



Torque Limiting Handle
MS1-A421

T30 shaft
MS1-A411

Cannulated Ratcheting Cylindrical Handle
SD-A411LSH

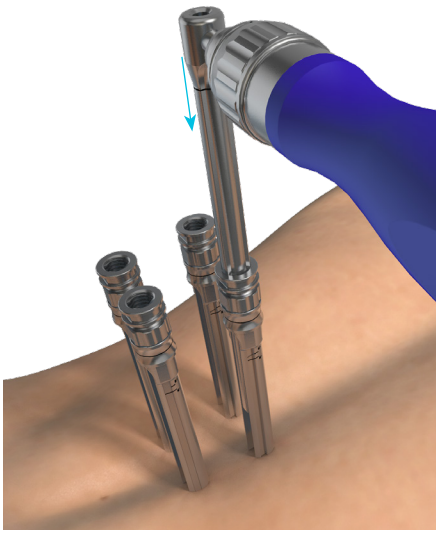


Counter torque
MS1-A432

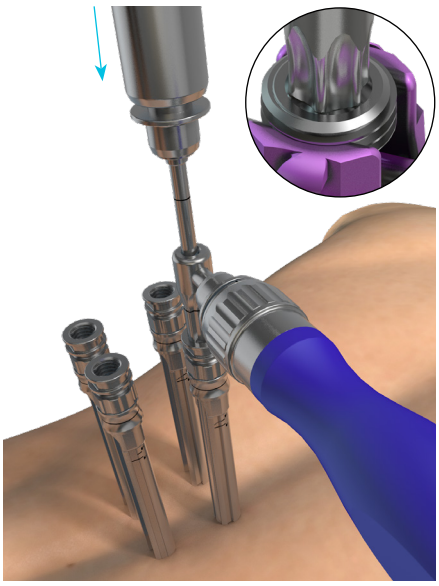
Connect the **T30 shaft** *MS1-A411* to the **torque limiting handle** *MS1-A421.*

Connect the **counter torque** *MS1-A432* to the **cannulated ratcheting cylindrical handle** *SD-A411LSH.*

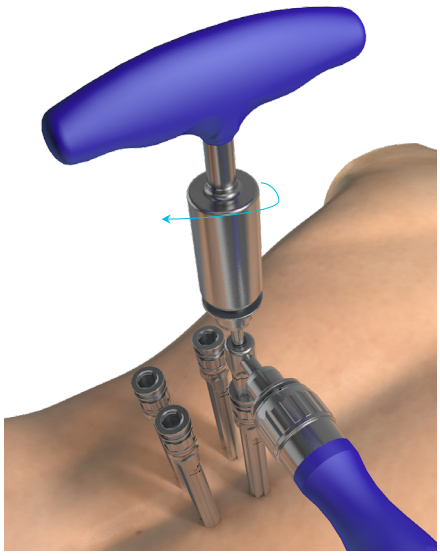
Position the **counter torque** *MS1-A432* into the screw extender and until you press the screw head.



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



While strongly holding the counter torque with the cylindrical handle, turn clock wisely the torque limiting handle until it clicks 3 times.



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

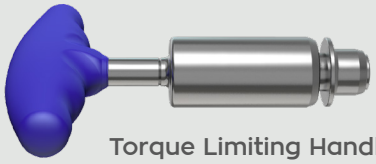
!WARNINGS!

The proper tightening of the screw is ensured by the 3 "clicks" produced by the torque limiting handle when performing tightening.

Never use the torque limiting handle to unscrew a setscrew.

Always be sure to be on the neutral position of the ratcheting handle when performing tightening.

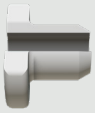
B · Mini-open approach



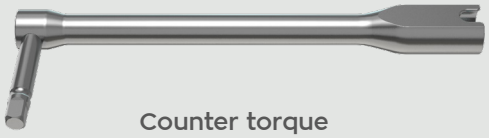
Torque Limiting Handle
MS1-A421

T30 shaft
MS1-A411

Cannulated ratcheting cylindrical handle
SD-A411LSH

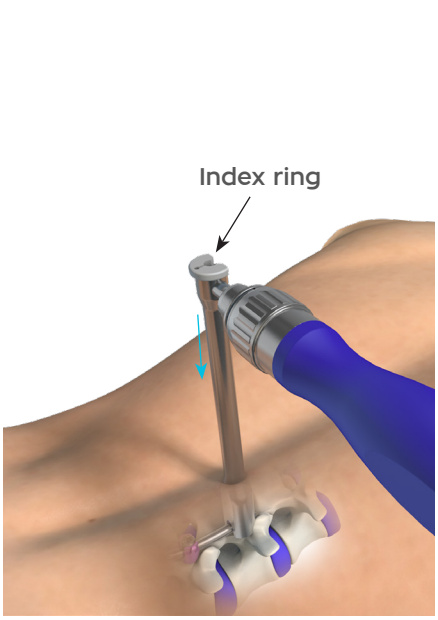


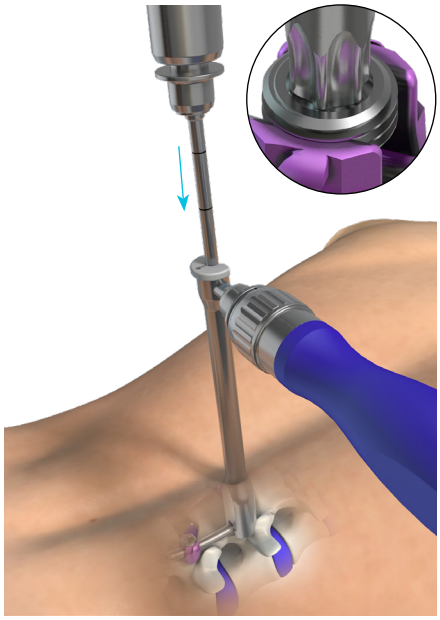
Index ring for setscrew holder
MS1-A232

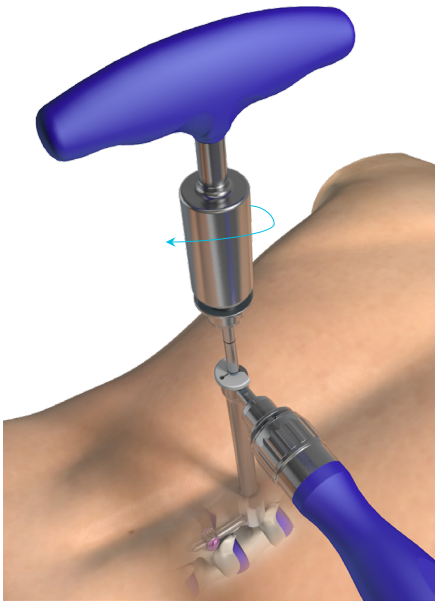


Counter torque
IS1-A431

If the surgeon wants to perform the final tightening without the screw extenders, it is possible to use the **counter torque** *IS1-A431* in combination with **the index ring for setscrew holder** *MS1-A232* to ensure a good alignment between the setscrew and the screw head.





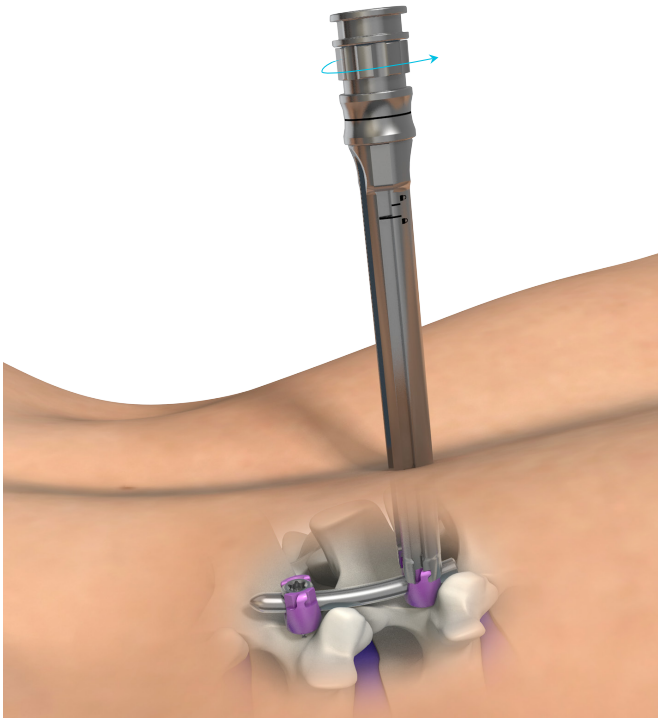


While strongly holding the counter torque with the cylindrical handle, turn clock wisely the torque limiting handle until it clicks 3 times.

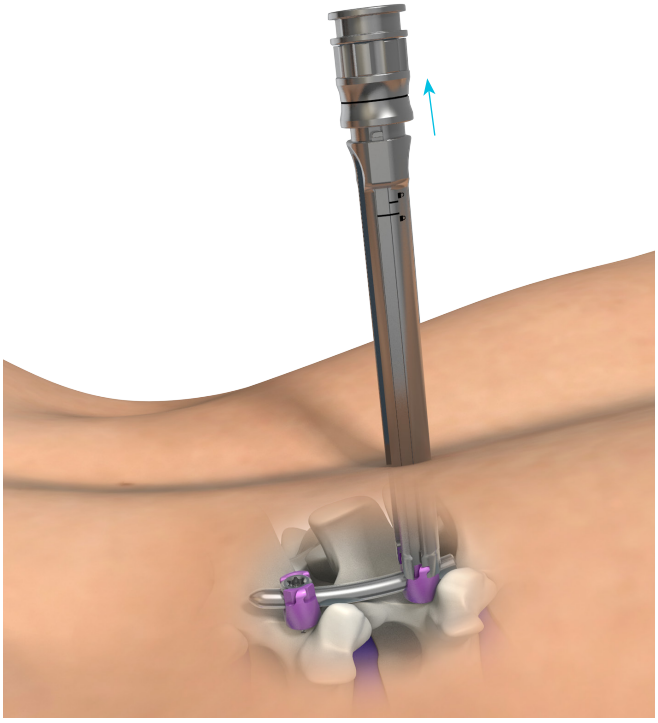
SCREW EXTENDER REMOVAL

Extender Wrench
MS1-A213

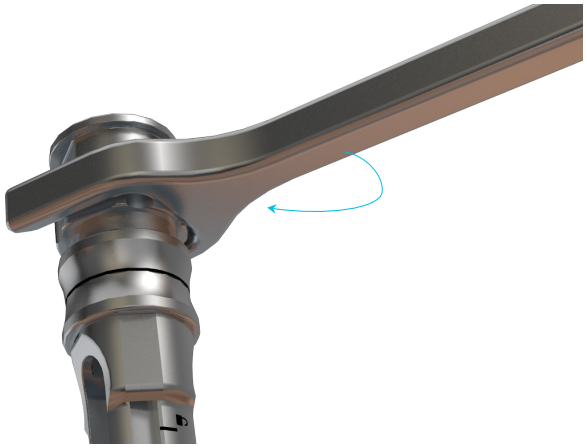
Release the **screw extender** *MS1-A214* by screwing the nut counterclockwise.

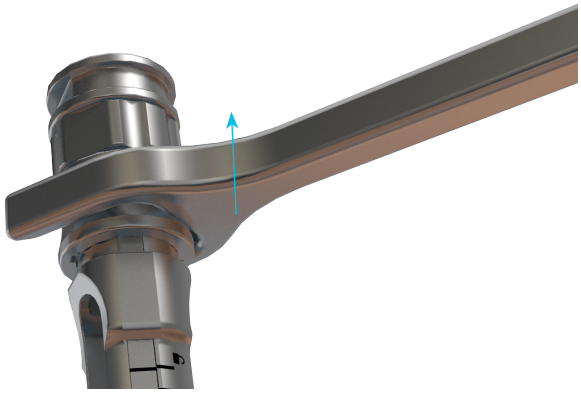


Slide the ring up to unlock the assembly.



The **extender wrench** *MS1-A213* can be used to help unlock and remove the screw extender by unscrewing the nut or by lifting the ring.





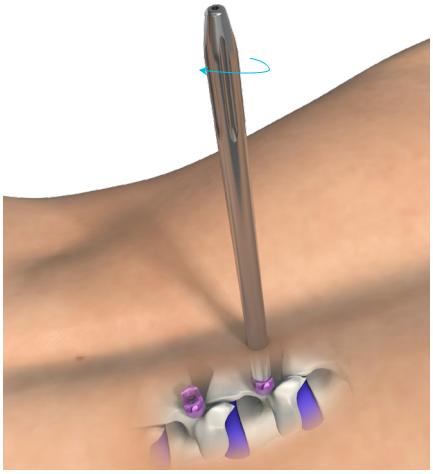
RESCUE PROCEDURE

Rescue Instrument
MS1-A223

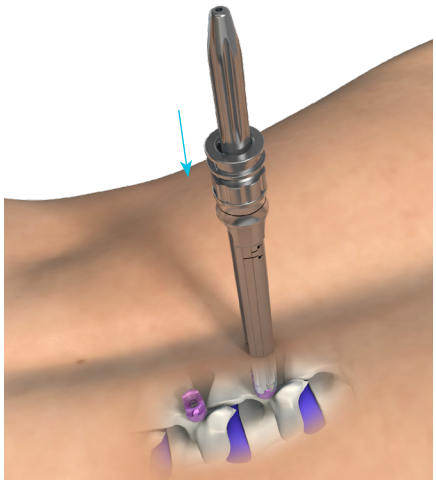
Expanders
MS1-A11X

The **rescue instrument** *MS1-A223* can be used to reconnect a screw extender to a screw if needed.

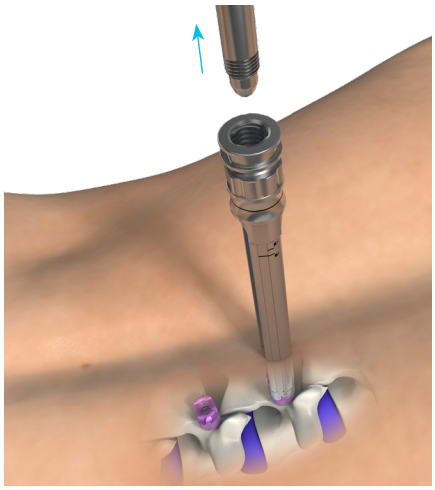
Insert the r**escue instrument** *MS1-A223* and tighten it into the screw head.



Insert the screw extender by sliding it on the rescue instrument connected to the screw.

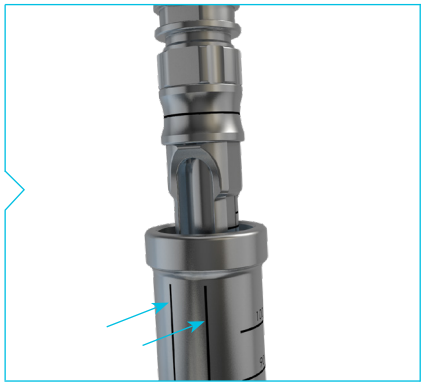


Once the screw extender is in place, unscrew the rescue instrument to remove it.

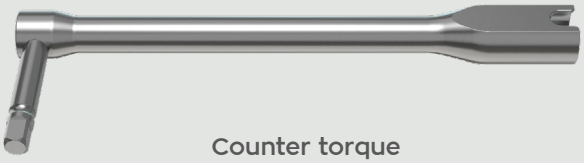


The expanders can be inserted first to facilitate the placement of the rescue instrument (see p7).

If the rod is already in place, the laser marks indicate which way the screw extender must be placed.

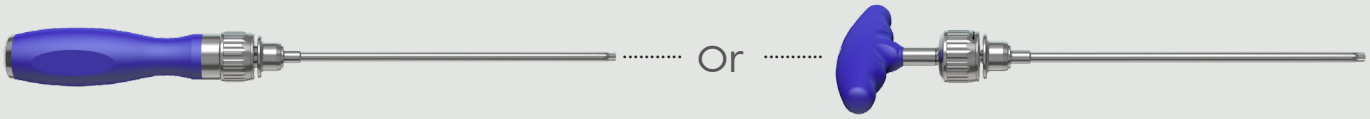


REMOVAL OR REVISION PROCEDURE



Counter torque
IS1-A431

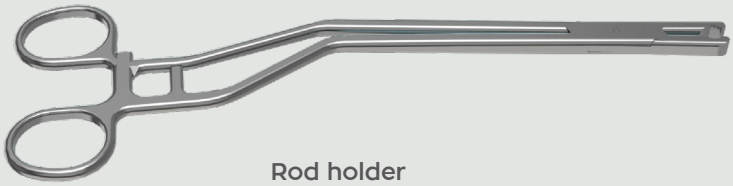
Setscrew holder
MS1-A231



T30 shaft connected to the cannulated ratcheting cylindrical handle
MS1-A411 + SD-A411LSH

Or

T30 shaft connected to the cannulated ratcheting T-handle
MS1-A411 + SD-A411TSH



Rod holder
MS1-A271

Lumis Universal screwdriver connected to the cannulated ratcheting cylindrical handle
MS2-A221 + SD-A411LSH

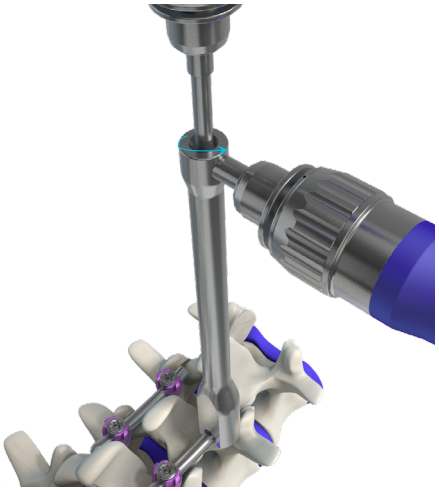
Or

Lumis Universal screwdriver connected to the cannulated ratcheting T-handle
MS2-A221 + SD-A411TSH

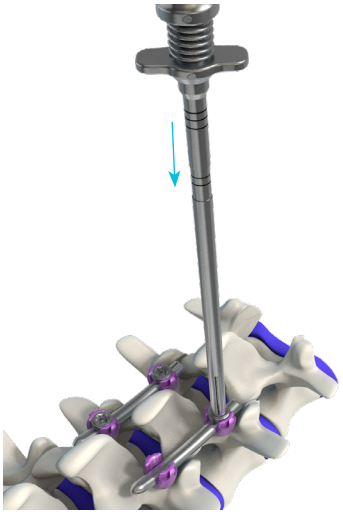
The removal of Lumis screws will be done using an open approach.

Unlock the setscrew using the **counter torque** *IS1-A431* and the **T30 shaft** *MS1-A411*.

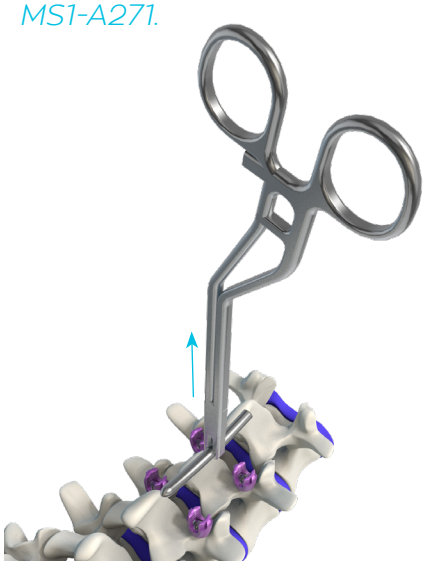
The counter torque must be placed in the axis of the screw head and as deep as possible to ensure the good position of the rod in the notch of the counter torque to ensure a proper grip while unlocking the setscrew.



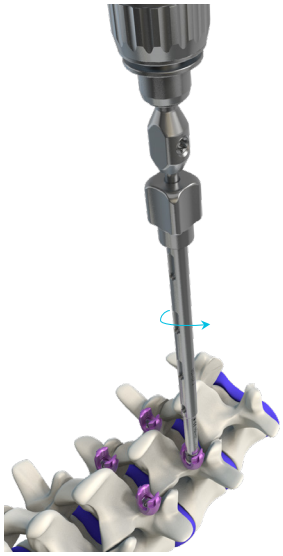
Once the setscrew is unlocked, the **setscrew holder** *MS1-A231* can be used to finish the unscrewing and remove the setscrew: pull the trigger of the setscrew holder to catch and release the setscrew.



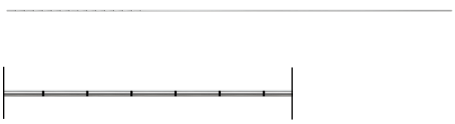
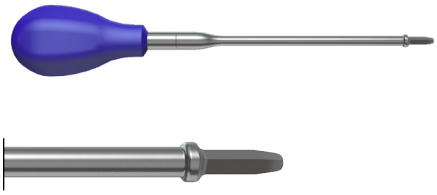
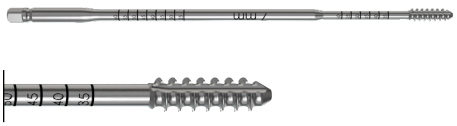
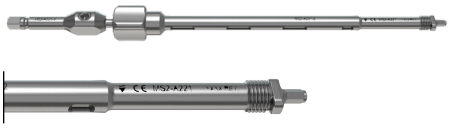
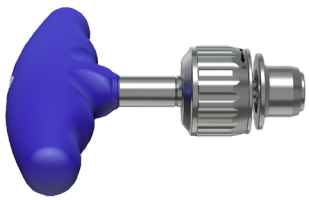
Capture the rod using the rod holder and then continue to remove all setscrews with the setscrew holder. Once all setscrews have been removed, remove the rod using the **rod holder** *MS1-A271.*

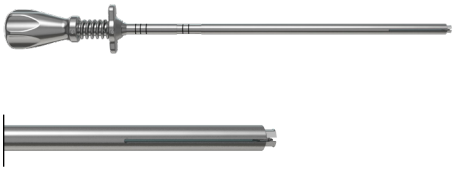
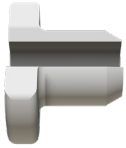
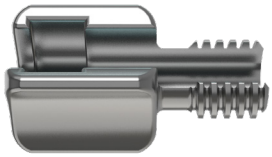
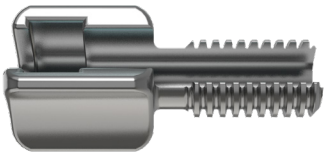
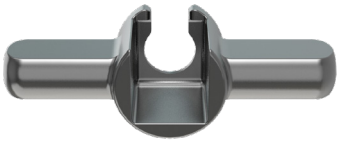


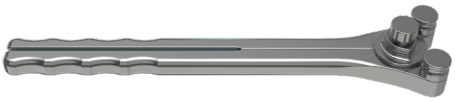
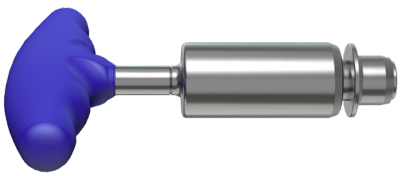
Place the **Lumis Universal Screwdriver** *MS2-A221* into the screw head and turn the handle counter-clockwise to remove each screw.

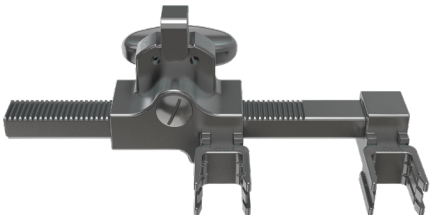
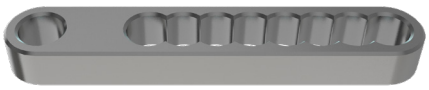


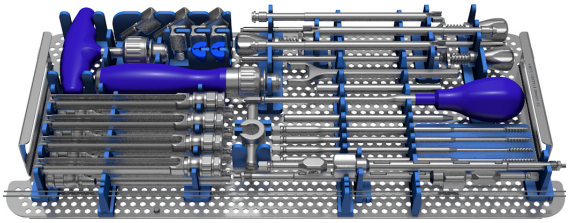
INSTRUMENTS

	**Guidewire**	MS1-WB1450
	**Cannulated square awl**	MS1-A121
	**Protection sleeve for taps**	MS1-A111
	**cannulated taps**	MS1-A11X
	**Lumis Universal Screwdriver**	MS2-A221
	**Enlarged screw extender**	MS1-A214
	**Cannulated Ratcheting T-Handle**	SD-A411TSH

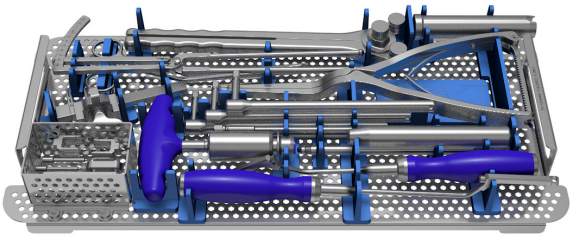
	**Cannulated Ratcheting Cylindrical Handle**	SD-A411LSH
	**Expander 1**	MS1-A110
	**Setscrew Holder**	MS1-A231
	**Index ring for setscrew holder**	MS1-A232
	**Rod persuader**	MS1-A311
	**Screw for rod persuader**	MS1-A313
	**Long screw for rod persuader**	MS1-A314
	**Over Handle**	MS1-A315

	**Extender Wrench**	MS1-A213
	**Rod gauge**	MS1-A261
	**Rod holder**	MS1-A271
	**French bender**	U1-A321
	**Rod introducer**	MS1-A274
	**Reversed rod introducer**	MS1-A275
	**T30 Shaft**	MS1-A411
	**Torque Limiting Handle**	MS1-A421

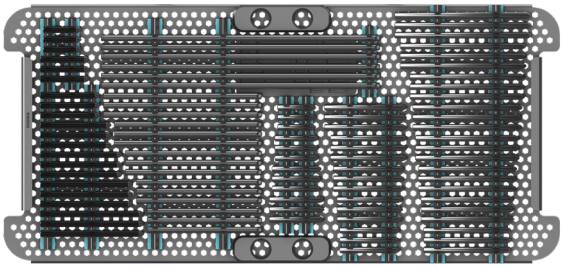
	**Counter torque**	MS1-A432
	**Compressor-Distractor**	MS1-A331
	**Fulcrum connector for distractor-compressor**	MS1-A334
	**Multiple connector for distractor-compressor**	MS1-A335
	**Expander 2**	MS1-A112
	**Expander 3**	MS1-A113
	**Rescue instrument**	MS1-A223
	**Counter torque**	IS1-A431



Tray 1 LUMIS
MS1-TRAY111

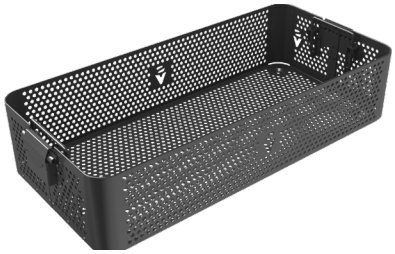


Tray 2 LUMIS
MS1-TRAY112



Tray 5 ULIS
IS1-TRAY115

Screws Rack
SD-RACK1

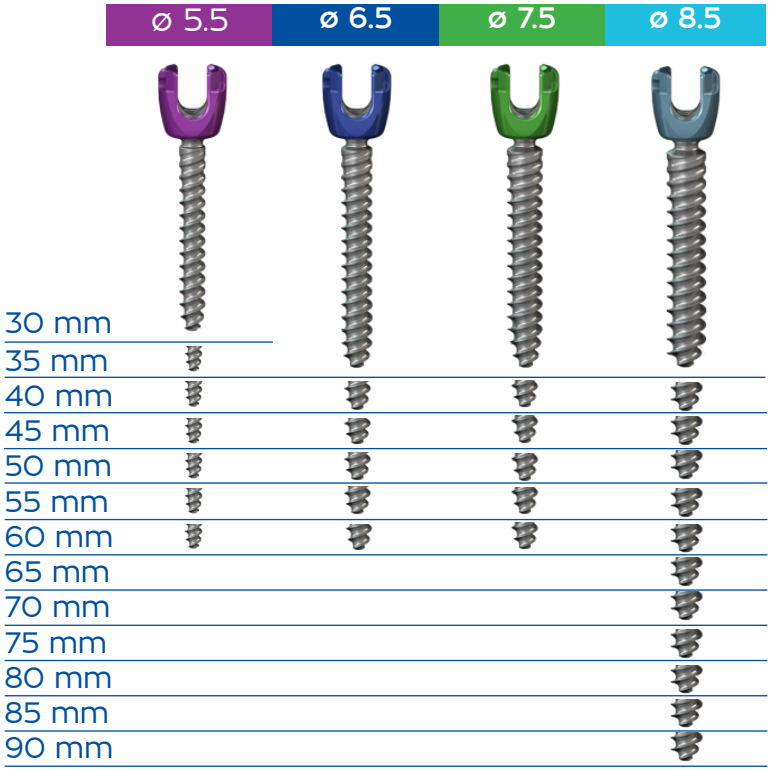


SV Common Base (2 levels)
SD-BASE11117

SCREWS

REFERENCE :

MS2-M6XXT (Ex : MS2-M640T)
MS2-MDiameterLengthTitane



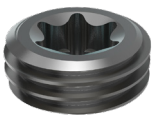
ROD

REFERENCE :

MS1-R6XXXT ou MS1-R6XXXCT ou L2-R6XXCHT ou L2-R6XXHT
MS1-RDiameterLengthCurveHexagonalTitane

	Désignation	Longueur	Référence
	Prebent Percutaneous Rod	30 > 100mm (5 mm inc.) 110 et 120mm	MS1-R6XXXCT
	Straight Percutaneous Rod	250mm	MS1-R6XXXT
	Prebent Rod with Hexagonal End	40 > 120mm (10mm inc.)	L2-R6XXCHT
	Straight Rod with Hexagonal End	110 > 140mm (10mm inc.)	L2-R6XXHT

SETSCREW



MS1-L100T

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