

# U.i.i.S.™

Universal Lumbar Intuitive System



Surgical Technique



**SpineVision®**  
Innovation that matters



## Surgical Technique

*Reference document: GIS2\_ST\_05GB*

**Caution:** Federal (USA) law restricts this device to sale on or by the order of a physician

**Caution:** Certain products listed in this Surgical Technique are not yet cleared by FDA. These products are clearly marked with “**Not for Sale in the USA.**”



See package insert for labeling limitation

CE 0123

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## Device Description

The Universal Lumbar Intuitive System (U.L.I.S.<sup>®</sup> System) is 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.

The Universal Lumbar Intuitive System (U.L.I.S.<sup>®</sup> System) is composed of pedicle screws, set screws and fusion rods. The 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.<sup>®</sup> system are made of titanium alloy (Ti-6Al-4V ELI) complying with ASTM F136 (ISO 5832-3) or ASTM F1537 Cobalt Chromium.

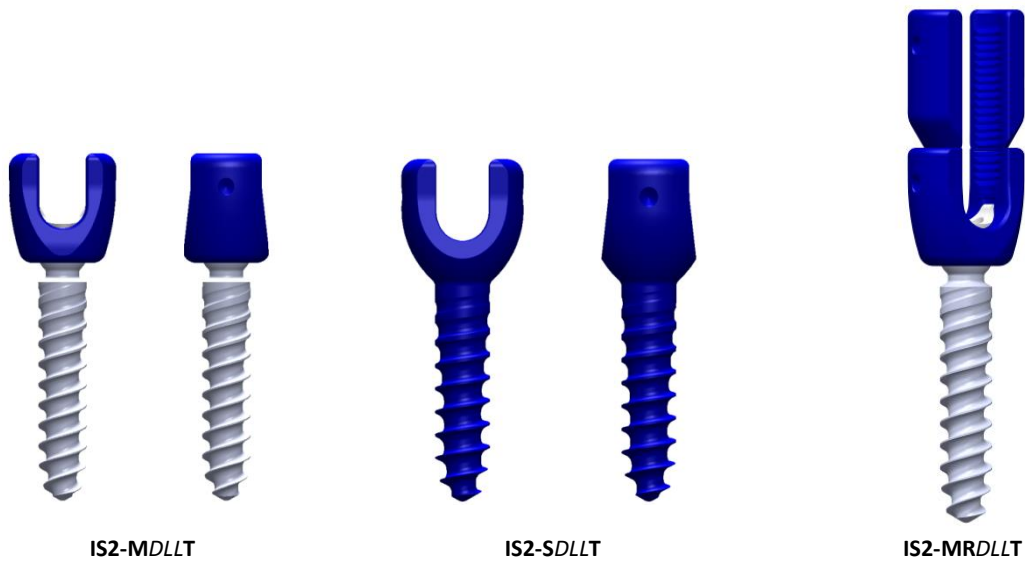
Implants must never be reused.

Components of the U.L.I.S.<sup>®</sup> system must not be used with components derived from another manufacturer.

# Implants

## Screws

U.L.I.S.<sup>®</sup> includes three types of screws: Multi-axial screws (IS2-MDLLT), Mono-axial screws (IS2-SDLLT) and Multi-axial Reduction screws (IS2-MRDLLT). In each reference, 'D' stands for the diameter (from 4 to 10, corresponding to 4.5mm to 10.5mm diameter) and 'LL' stands for the length (from 25mm to 90mm).



		Diameter (mm)					
		4.5	5.5	6.5	7.5	8.5	10.5
Length (mm)	25	■					
	30	■					
	35	■	■	■	■	■	■
	40	■	★	★	★		
	45	■	★	★	★		
	50		★	★	★		
	55		★	★			
	60		★	★			
	65					■	■
	70					■	■
	75					■	■
	80					■	■
	85					■	■
90					■	■	

■ Multi-axial and Mono-axial screws

★ Reduction screws also available

See current Set Composition for the detail between standard or on demand references.

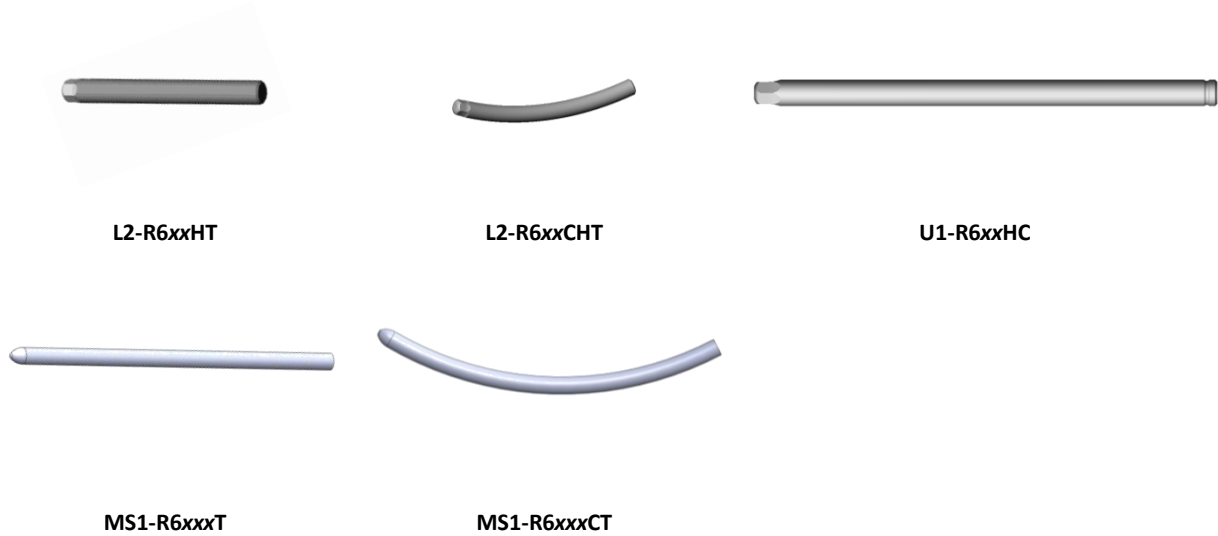
The same set screws (MS1-L100T) are to be used with all U.L.I.S.<sup>®</sup> screws.



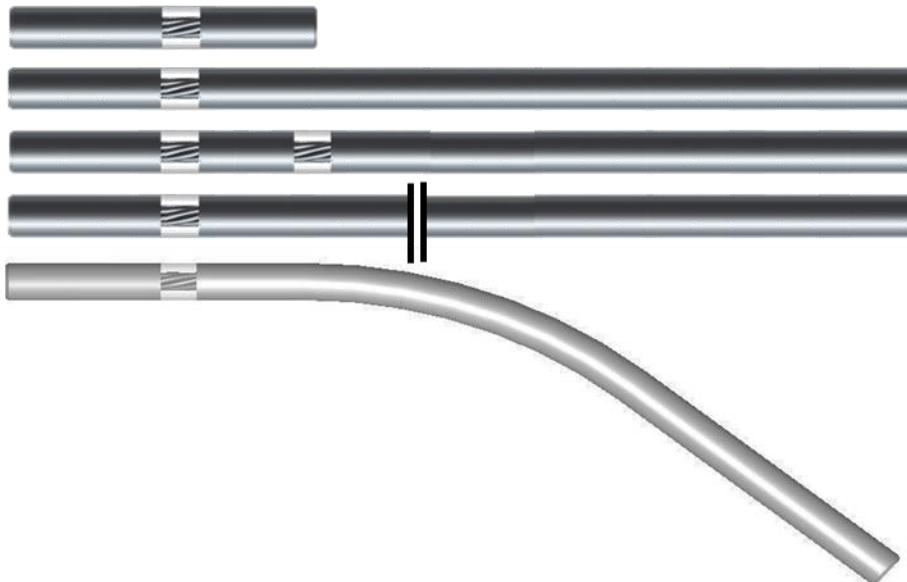
## Rods

U.L.I.S.<sup>®</sup> screws can be used with Titanium Alloy fusion rods or Cobalt-Chromium fusion rods.

- **UNI-Thread<sup>®</sup> straight and prebent titanium fusion rods** (L2-R6xxHT or L2-R6xxCHT)
- **Cobalt-Chrome fusion rods** (U1-R6xxHC)<sup>1</sup>
- **LUMIS<sup>®</sup> straight and prebent rods** (MS1-R6xxxT or MS1-R6xxxCT)



**In Europe only**, the U.L.I.S.<sup>®</sup> screws can be used in combination with the Flex<sup>+2</sup> rods (F1-RxxxxT)<sup>2</sup>.



From top to bottom F1-R1609T, F1-RH1609T, F1-RH2609T, F1-RHL1609T, F1-RH1609CT  
Not for sale in the USA.

<sup>1</sup> Only available in Europe and United States of America

<sup>2</sup> Not for Sale in USA or Canada, only available in Europe.

# Surgical Steps

## Pedicle Preparation and Screw Insertion

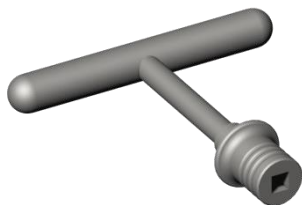
Standard instruments for pedicle preparation (awl, spatula, curette, probe and taps) are available. Taps are intended to be used with a handle such as the T-handle (PL1-A011), the Dual Purpose Handle (U1-A622), or the Cannulated Ratcheting Handle (L2-ALIS411).



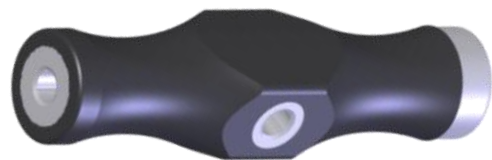
U1-A121N1, U1-A122S, U1-A123L



U1-A124N1



PL1-A011

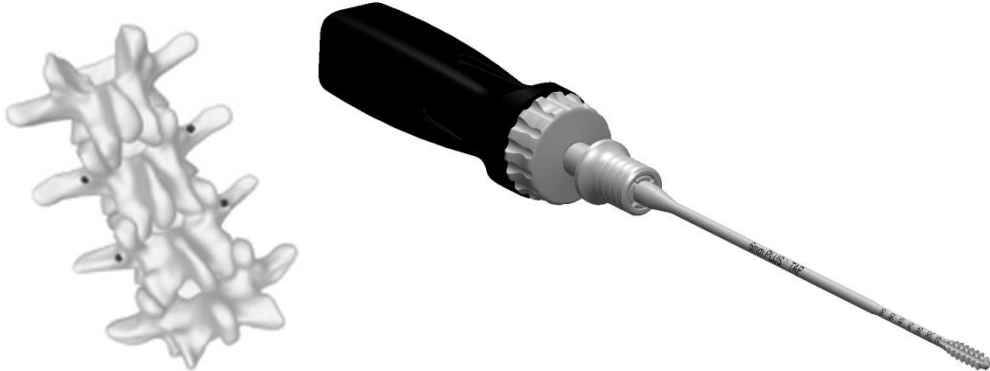


U1-A622

Prepare the entry point with the Square Awl (U1-A121N1). Then create the pilot hole for screw insertion using either the Spatula (U1-A122S) or the Curette (U1-A123L). Both of them have laser marks to determine the appropriate screw length.

The pedicle probe with ball tip can be used to check the trajectory before inserting the screw.

It is then possible to use the P.L.U.S.® taps (U1-A134/U1-A135/U1-A136/U1-A137/U1-A138) assembled with the Cannulated Ratcheting Handle (L2-ALIS411) or any other handle provided to finish the preparation, in the case of hard bone.



**U1-A136 assembled with L2-ALIS411**

The Screwdriver (IS2-A221) and Screw Removal Instrument (IS2-A420) are both intended to be used with a handle such as the Cannulated Ratcheting Handle (L2-ALIS411). An Over Handle (MS1-A315) is available to manipulate the square part of the Screwdriver if necessary.



**IS2-A221**



**IS2-A420**



**L2-ALIS411**



**MS1-A315**



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.

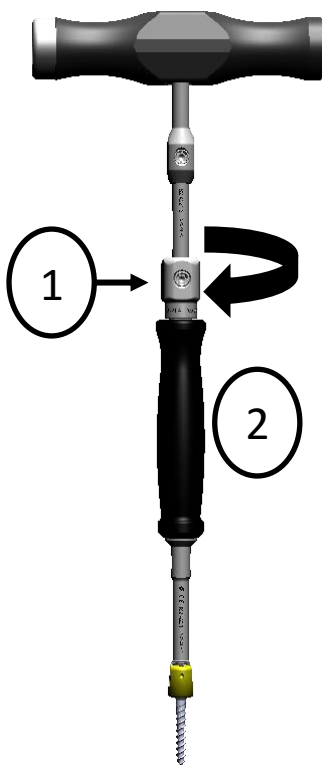


**Insertion of the tip of the Screwdriver in the screw head**

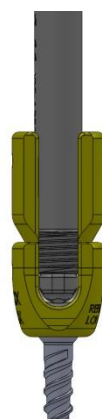
Block the screw's multiaxiality with the U.L.I.S.<sup>®</sup> Universal Screwdriver (IS2-A221) by turning the square part (1) clockwise.

While inserting the screw in the pedicle, take care not to grip the Screwdriver shaft above or below the black sleeve (2).

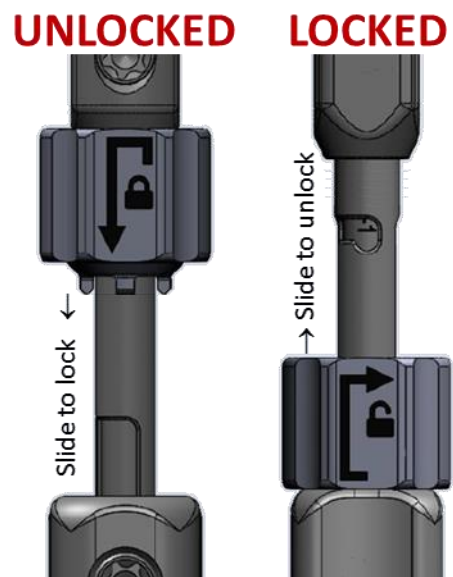
As of version 'C' of the Screwdriver, a locking collar has been added to lock the Screwdriver in the screw head during insertion. Locking and unlocking are performed by sliding the collar up and down; this is indicated by laser-etching on the collar itself. Former versions without a locking collar can also be used.



**IS2-A221 version 'B' assembled with U1-A622**



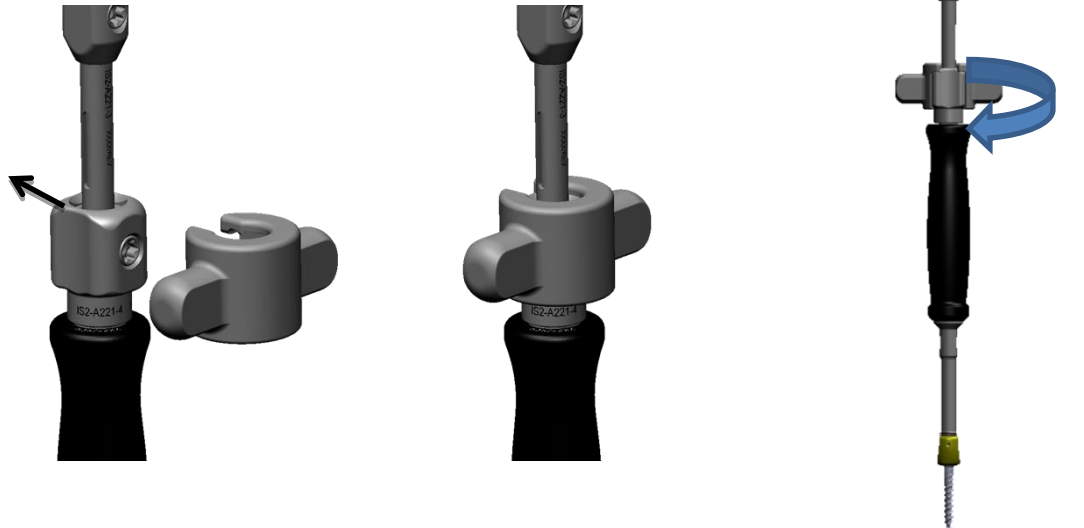
**IS2-A221 on the Reduction screw**



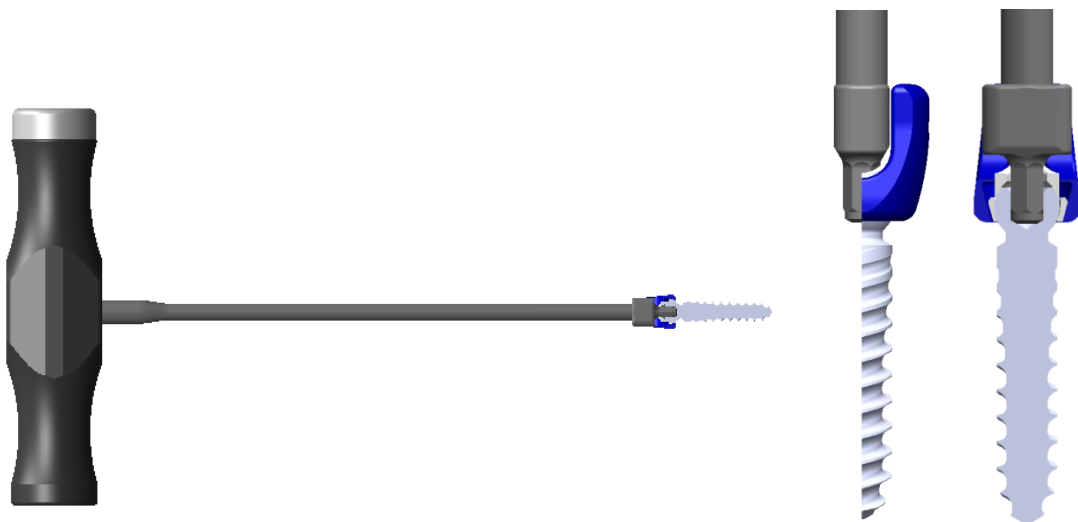
**Use of the locking collar of IS2-A221 from version 'C'**

Once the screw is inserted, remove the Screwdriver by turning counter-clockwise the square part.

In case the square part is difficult to turn, it is possible to use the Over Handle (MS1-A315) for extra strength. The Over Handle has to be placed on the square part of the Screwdriver, over its set screw.



Repeat the previous steps to insert as many pedicle screws as needed. Once the Screwdriver is removed, the screw depth can be adjusted using the Screw Removal Instrument (IS2-A420). The hex tip of the instrument must be fully inserted in the screw-shaft, so that the wider part of the tip is flush with the top of the screw head.



IS2-A420

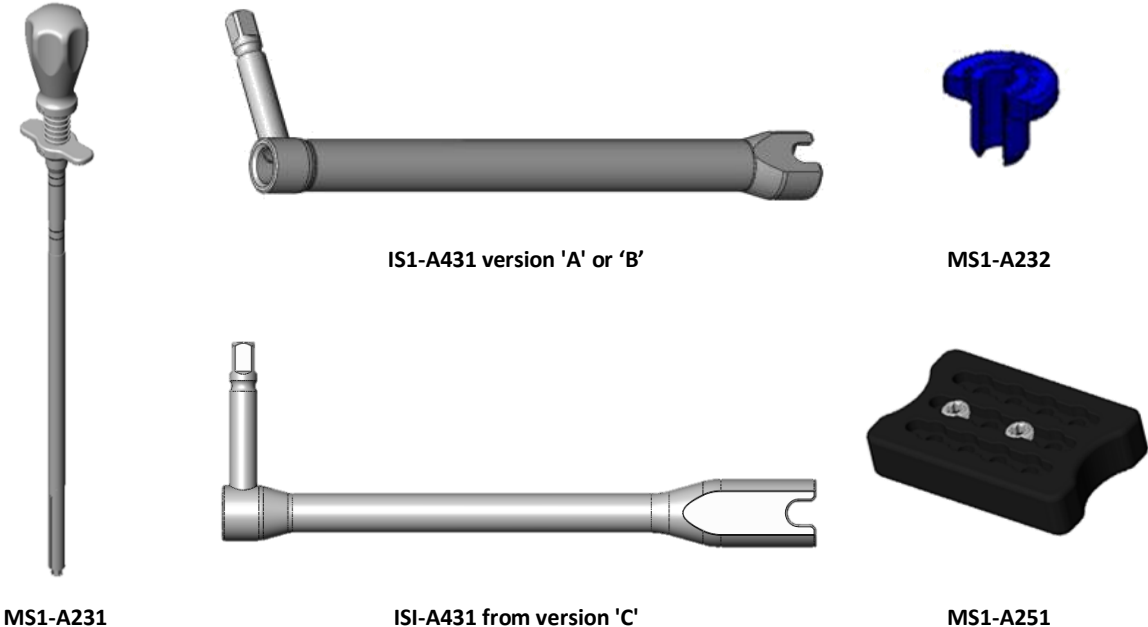
### Rod Placement

The Short Rod Template (SD-A324S) can be used to help determining the rod's length and curvature prior to its placement. The rod can be contoured prior to insertion using the French Bender (U1-A321). Handling and placement of the rod is performed with the Rod Holder (U1-A213N1 or U1-A214) while the Hex Wrench (U1-A344N1) enables repositioning of rods with a hex tip (L2-R6xxHT or L2-R6xxCHT).



### Setscrew Placement When No Rod Persuasion is Needed

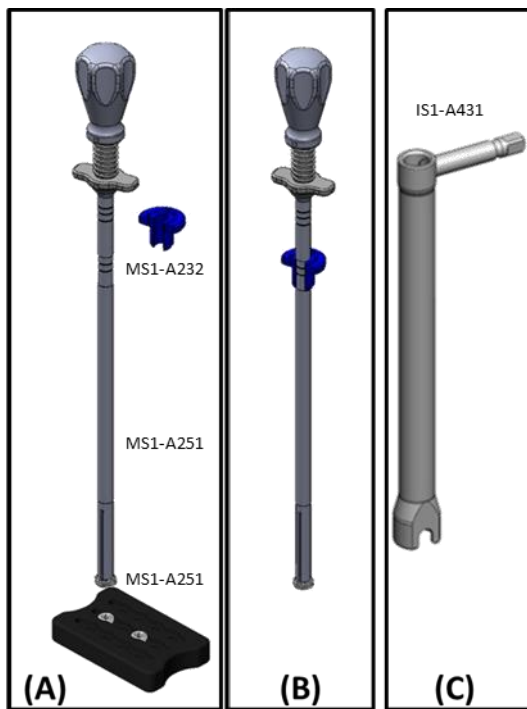
The Set Screw Holder (MS1-A231) is used to take a set screw (MS1-L100T) out of the Setscrew Support (MS1-A251) and place the set screw.



To prevent cross-threading, the Set Screw Holder can be used in combination with the Counter-torque (IS1-A431). Versions 'A' and 'B' of the Counter-torque are provided with an Index Ring (MS1-A232) to be attached to the Set Screw Holder (MS1-A231) while later versions are to be used alone.

*Note: Versions 'A' and 'B' of the Counter-torque (IS1-A431) are **not compatible** with the Multi-axial Reduction Screws (IS2-MRDLLT); only later versions can be used.*

### Use of versions 'A' and 'B' of the Counter torque



(A) Grip a Set Screw from the Set Screw Support (MS1-A251) by pulling on the trigger of the Set Screw Holder (MS1-A231).

(B) Attach the Index Ring for Set Screw Holder (MS1-A232) onto the narrowest part of the Set Screw Holder (MS1-A231)

(C) Slide the assembly inside the Counter-torque (IS1-A431) to prevent any cross-threading.

It is then possible to engage the set screw by turning the superior part of the Set Screw Holder (MS1-A231) clockwise. Laser marks on the Set Screw Holder will indicate that the setscrew is engaged.

Pull on the trigger to release the set screw and remove the Set Screw Holder.

### Use of version 'C' or later versions of the Counter-torque

Slide the Set Screw Holder (MS1-A231) into the Counter-torque (IS1-A431) before grabbing the set screw.

It is then possible to engage the set screw by turning the superior part of the Set Screw Holder (MS1-A231) clockwise. Laser marks on the Set Screw Holder will indicate that the set screw is engaged.

Pull on the trigger to release the set screw and remove the Set Screw Holder.



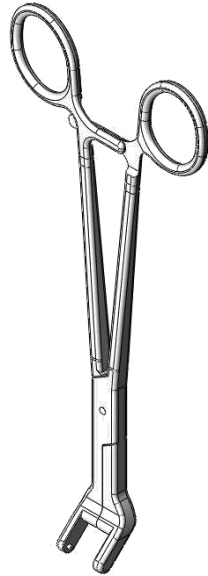
**MS1-A231 and IS1-A431**

## Rod Approximation

Different instruments are provided for rod persuasion: A Rod Pusher (U1-A224), a Rocker (IS1-A312), a Rod Persuader (IS1-A311) and an Axial Rod Persuader (IS1-A314). All of these instruments are compatible with all U.L.I.S.® screws.



U1-A224



IS1-A312



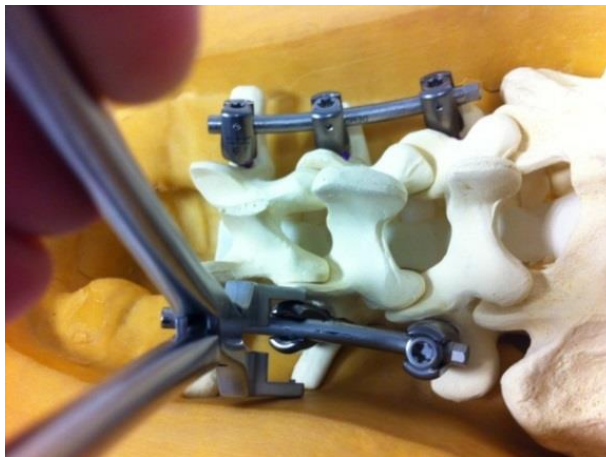
IS1-A311



IS1-A314

## Use of the Rocker

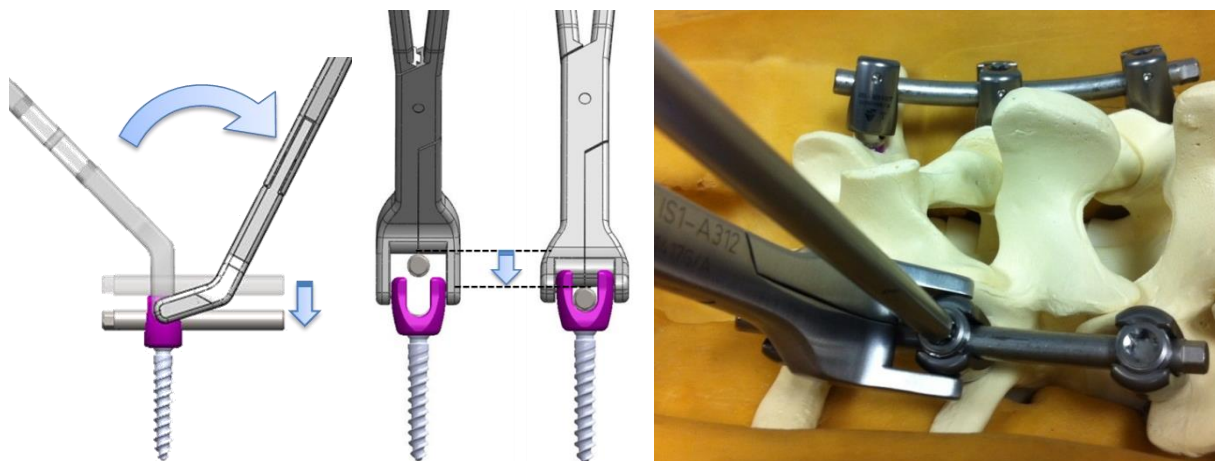
Place the tip of the Rocker in the hole located at the medial part of the screw head.



Squeeze the Rocker handle to lock the instrument on the screw.



Once the Rocker is attached to the screw, rotate its handle to push the rod down into the screw saddle. A U.L.I.S.<sup>®</sup> set screw can be then placed using the Set Screw Holder (MS1-A231) while maintaining the rod position with the Rocker (IS1-A312).



Remove the Rocker (IS1-A312) by opening its handle and tilting it to release the tips from the screw holes.

## Use of the Rod Persuader



**IS1-A311**

Position the instrument so that the handle is perpendicular to the rod and slide it onto the screw head until it stops. Make sure that the instrument is well-seated on the screw head and squeeze the plier handle to:

- First, lock the head of the screw inside the Rod Persuader
- Second, push the rod down into the screw saddle.

Grip a set screw from the Setscrew Support (MS1-A251) by pulling on the trigger of MS1-A231. Assemble the Set Screw Holder (MS1-A231) and the Rod Persuader by sliding the Set Screw Holder along the superior groove of the Rod Persuader.



**MS1-A231 used in combination with IS1-A311**

It is then possible to engage the set screw by turning the superior part of the Set Screw Holder (MS1-A231) clockwise. Laser marks on Set Screw Holder will indicate that the set screw is engaged.

Pull on the trigger to release the set screw and remove the Set Screw Holder. Open the Rod Persuader's handle to release it and remove it from the screw head. Do not hesitate to repeat this step if needed.

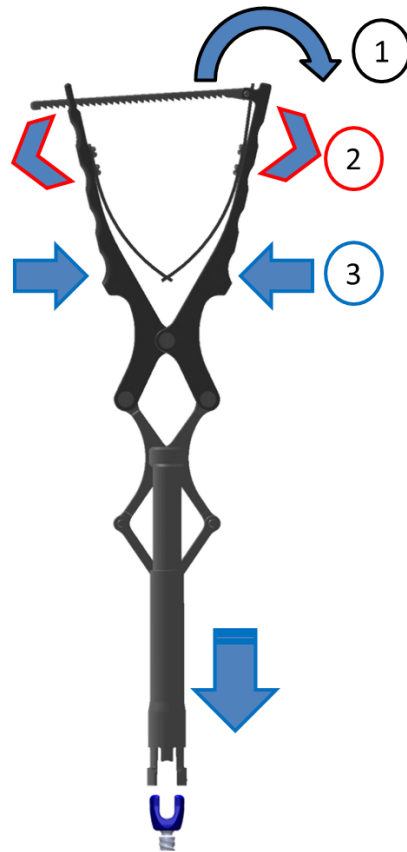
## Use of the Axial Persuader

Position the Axial Persuader perpendicular to the rod.

- Remove the rack to fully open the instrument (1)
- Place it onto the screw head until it stops and make sure the instrument is well-seated on the screw head.
- Squeeze the handle to grip the screw head and push the rod into the screw saddle(3)

Grip a set screw from the Setscrew Support (MS1-A251) by pulling on the trigger of MS1-A231. Slide the Set Screw Holder (MS1-A231) in the Axial Persuader. It is then possible to engage the set screw by turning the superior part of the Set Screw Holder (MS1-A231) clockwise.

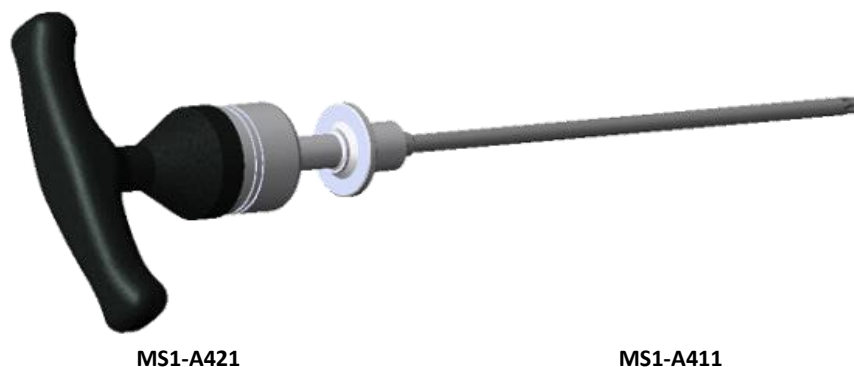
Pull on the trigger to release the set screw and remove the Set Screw Holder. Open the Axial Persuader by lifting the rack to release and remove it from the screw head.



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## Final tightening

Final tightening is performed with the MIS Torque Limiting Handle (MS1-A421) assembled with the T30 Shaft (MS1-A411). Final locking of the construct is performed by applying a 8.5Nm torque, corresponding to a click.



To perform the final tightening, slide the T30 Shaft into the Counter-torque (IS1-A431) assembled with the Dual Purpose Handle (U1-A622).



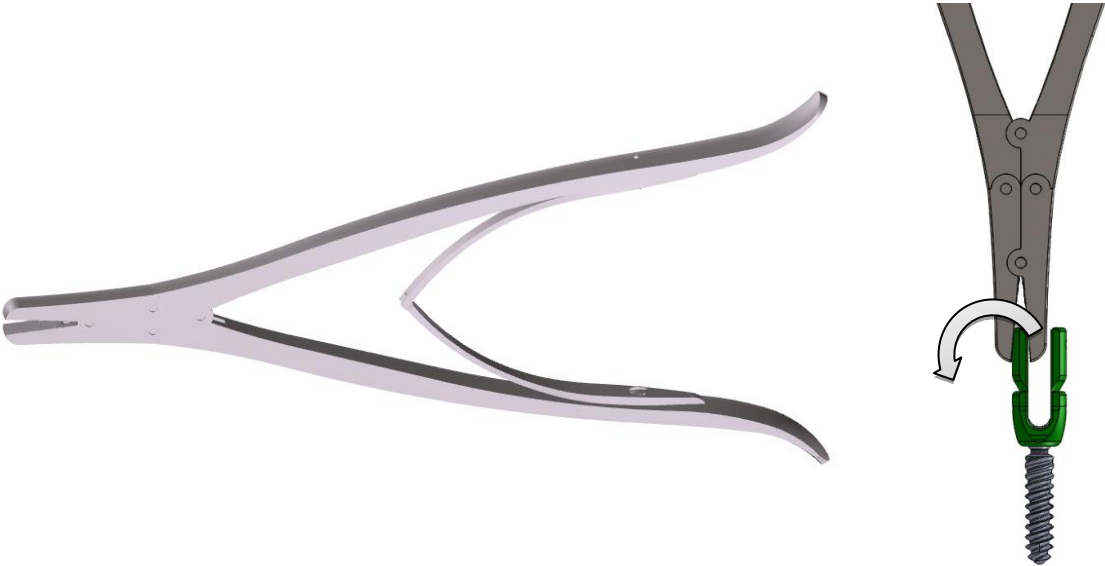
*Note: If necessary, the Index Ring (MS1-A232) can be added at the top of the Counter-torque to center the T30 shaft in the Counter-torque (version 'A' or 'B'). Version 'C' and later versions of the Counter-torque (IS1-A431) must be used for reduction screws.*



**IS1-A431 assembled with MS1-A232 and U1-A622**

**Tab removal for reduction screws**

After the final tightening has been performed the tabs of the reduction screws can be broken using the Tab Remover (IS2-A421), by bending one tab at a time.



**IS2-A421**

## Removal or revision procedure

### List of needed items for U.L.I.S.® screw removal

- 2 x U1-A622 (Dual Purpose Handle)
- 1 x IS1-A431 (Counter-torque)
- 1 x U1-A213N1 (Rod holder)
- 1 x MS1-A411 (T30 shaft)
- 1 x MS1-A231 (Setscrew holder)
- 1 x IS2-A221 (U.L.I.S.® Universal Screwdriver) or IS2-A420 (Screw Removal Instrument)

### Removal steps

Unlock the setscrew using the Counter-torque (IS1-A431) and the T30 shaft (MS1-A411), assembled with available handles.

*Note: The Counter-torque must be placed perpendicularly to the patient axis to ensure a secure screw holding while unlocking the set screw.*



**IS1-A431 and MS1-A411 both assembled with U1-A622**

Once the set screw is unlocked, the Set Screw Holder (MS1-A231) can be used to finish the unscrewing and hold the set screw. To catch/release the Setscrew, the trigger of the Set Screw Holder must be pulled.

Once all set screws have been removed, it is possible to remove the rod using the rod holder (U1-A213N1)

Either the Universal Screwdriver (IS2-A221) or Screw Removal Instrument (IS2-A420) can be used to unscrew the pedicle screw. Place the instrument in the head of the screw, ensuring that the distal tip is inserted entirely inside the implant's head, and turn the screwdriver counterclockwise to remove the screw.

## Intended Uses and Indications

When used for anterior screw fixation or as a posterior, non-pedicle system of the non-cervical spine, the U.L.I.S.<sup>®</sup> system is indicated for:

- degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- fracture
- spinal stenosis
- curvatures (i.e. scoliosis, kyphosis, and/or lordosis)
- tumors
- failed previous fusion (pseudoarthrosis)

The U.L.I.S.<sup>®</sup> system is a pedicle screw system 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.<sup>®</sup> system is a pedicle screw system 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.**

## Contra-indications

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 tumor 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.

## Precautions and 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 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.

## Interconnections of the parts and connection to other devices

### Interconnection of the parts

When used as a posterior pedicle screw based system, the U.L.I.S.® screws can be connected to:

- **UNI-Thread® fusion straight and prebent rods** (Ref L2-R6xxHT or L2-R6xxCHT)
- **Cobalt-Chrome Fusion Rods** (U1-R6xxHC)
- **LUMIS® straight and prebent rods** (MS1-R6xxxT or MS1-R6xxxCT)
- **LUMIS® setscrew** (MS1-L100T)

**In Europe only**, the U.L.I.S.® screws can be used in combination with the Flex+2 rods (F1-RxxxxT).

### Connection to other devices

The parts of the U.L.I.S.® system are connected with other devices during several surgical steps:

	Screwdriver (IS2-A221)	Rod holder (U1-A214 or U1-A213N1), Hex Wrench (U1-A344)	Rod pusher (U1-A224), Rocker (IS1-A312), Rod Persuader (IS1-A311), Axial Rod Persuader (IS1-A314)	Screw Removal instrument (IS2-A420)	Spreader (U1-A342) and Compressor (U1-A343)	Setscrew Holder (MS1-A231)	T30 shaft (MS1-A411)	Counter-torque (IS1-A431)
U.L.I.S.® screws (IS2-SDLLT, IS2-MDLLT, IS2-MRDLLT)	Insertion of the screw in the pedicle			Screw removal				
Rods (L2-R6xxHT, L2-R6xxCHT, U1-R6xxHC, MS1-R6xxxT, MS1-R6xxxCT, F1-RxxxxT)		Rod placement	Rod approximation		Compression -distraction			Final tightening
LUMIS® setscrew (MS1-L100T)						Setscrew placement	Final tightening	





**SpineVision®**

Innovation that matters

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