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# Lumbar Mini Invasive System



Surgical Technique



### **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>TM</sup> and LUMIS<sup>TM</sup> systems are 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> and LUMIS<sup>™</sup> 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.







### **Intended uses and Indications**

In addition, the U.L.I.S.<sup>™</sup> and LUMIS<sup>™</sup> 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.







### **Device Description**

The Universal Lumbar Intuitive System (U.L.I.S.<sup>™</sup> System), and Lumbar Universal Minimally Invasive System (LUMIS<sup>™</sup> 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.<sup>™</sup> System), and Lumbar Universal Minimally Invasive System (LUMIS<sup>™</sup> System) instrumentations are composed of pedicle screws and Titanium fusion rods from the UNI-Thread<sup>®</sup> 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.<sup>™</sup> 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<sup>™</sup> system are made of titanium alloy (Ti-6AI-4V ELI) complying with ASTM F136 (ISO 5832-3).

Implants must never be reused.

Components of the U.L.I.S.<sup>™</sup> and LUMIS<sup>™</sup> systems must not be used with components derived from another manufacturer.







### Contra-indications (1/2)

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.







### Contra-indications (2/2)

- 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.









- 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.





# Interconnection of the parts and connection to other devices

#### Interconnection of the parts:

When used as a posterior pedicle screw based system, the LUMIS<sup>™</sup> screws can be connected to :

- LUMIS<sup>™</sup> percutaneous rods (Ref MS1-R6xxxT or MS1-R6xxxCT)

MS1-R6xxxT		MS1-R6xxxCT
Uni-Thread <sup>™</sup> rods (Ref L2-R6xxHT or	L2-R6xxCHT)	
L2-R6xxHT		L2-R6xxCHT

- LUMIS<sup>™</sup> and UNI-Thread<sup>™</sup> fusion rods are made of Titanium Ta6V Eli (ASTM F136)
- Diameter of rods : Ø6 mm





# Interconnection of the parts and connection to other devices

#### Connection to other devices:

	Screw extender (MS1-A211/MS1- A214)	GuideWire (MS1-WB1450)	Cannulated screwdriver (MS2-A221)	Setscrew Holder (MS1-A231)	T30 shaft (MS1-A411)
LUMIS <sup>™</sup> multiaxial screw (MS2-MDXXT)	From the insertion of the screw into the pedicle until the closure of the implants	Insertion of the screw in the pedicle	Insertion of the screw in the pedicle		
LUMIS <sup>™</sup> setscrew (MS1-L100T)				Setscrew placement	Final tightening







**Multi-Axial Screws** 

MS2-MDLLT

Screw system



D = diameter, L = length





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Rods

#### Titanium Alloy LUMIS<sup>™</sup> percutaneous rods



MS1-R6xxxT (straight percutaneous rod)

MS1-R6xxxCT (prebent percutaneous rod)

Titanium Alloy LUMIS percutaneous rods (MS1-R6xxxT, MS1-R6xxxCT) are not available for sale in CANADA.

Titanium Alloy Uni-Thread<sup>™</sup> rods



L2-R6XXHT (Hex rod)



L2-R6XXCHT (Prebent rod)









#### Hybrid and Dynamic Stabilization rods :

F1-R1609T 



- F1-RH1609T
- F1-RH2609T
- F1-RHL1609T





F1-RH1609CT 



Hybrid and Dynamic stabilization rods (F1-R1609T, F1-RH1609T, F1-RH2609T, F1-RHL1609T, F1-RH1609CT) are not available for Sale in USA or Canada.





### Instruments for pedicle preparation

Innovation that matters

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Lumis Universal Screwdriver MS2-A221

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### **Instruments for rod placement**





See package insert for labeling limitation





### Instruments for rod placement







#### Instruments for compression-distraction





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T30 shaft MS1-A411





Index ring for setscrew holder MS1-A232

### Instruments for final tightening





Rescue instrument MS1-A23

### **Instruments for rescue procedure**



See package insert for labeling limitation



Place Jamshidi needles (11 gauge) according to patient anatomy and place the guide wires (MS1-WB1450) inside the Jamshidi needles after having checked they are straight (ensure that the laser marks are visible after insertion to allow control of the guide wires positions).



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### **Pedicle Preparation & Screw Insertion**

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

Cannulated taps (MS1-A115/MS1-A116/MS1-A117/MS1-A118) can be assembled with the cannulated ratcheting handle (L2-ALIS411) or dual purpose handle (U1-A622), or T handle (PL1-A011).



To protect soft tissue from the sharp edges of the taps, the expander 1 (MS1-A110) and the protection sleeve for taps (MS1-A111) can be inserted onto the guide wire prior to insertion of the cannulated tap. The laser marks must be located at the superior end to remain visible.





MS1-A110



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MS1-A111



Insert the appropriate tap depending on the pedicle size (MS1-A115/MS1-A116/MS1-A117/MS1-A118) over the guide wire.

	0 5 5 5 8 8 8 5 5 8
<u>ਝ 8 8 8 ਹੈ</u> 120mm	
The insertion depth of the tap inside the vertebra is indicated by laser marking on the tap shaft.	Tap Tap 40mm insertion depth
Thus, the appropriate screw length cable determined.	Protection sleeve 90mm insertion depth

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The laser marks on the upper extremity of the guide wire allow control of the guide wire position while tapping.

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







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The enlarged screw extender (MS1-A214) must be used on the end of the construct through which the rod will be introduced percutaneously as the rod introducers will not fit through the standard screw extender.

The enlarged screw extender can be identified by a single laser mark on the locking ring.











Attach the screw extender (MS1-A211/MS1-A214) to the screw (MS2-MxxxT) by sliding down the locking ring down (1) and locking the assembly by screwing the nut clockwise (2).

Laser markings indicate when the locking ring is in the locked position.



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Insert the Lumis Universal Screwdriver (MS2-A221 + U1-A622) into the screwhead and screw extender to lock the screw's polyaxiality.

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





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Insert the screw with the screwdriver/screw extension construct over the guide wire. Once the screw is advanced far enough into 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.











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







### **Rod Length Measurement**

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 screw extenders until the ball tips rest in the heads of the pedicle screws.

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









### **Rod placement**

Laser etching

To facilitate insertion of the rod, the counter torque (MS1-A432) can be used to adjust the positions of the screws heads by inserting it into the screw extenders until the laser etching is flush with the superior end of the screw extender.

<u>CAUTION</u>: the screw extenders must NEVER be used to change the screw alignment without first inserting the counter-torque.



If needed the rigid part of the rod can be contoured prior to insertion using the french bender (U1-A321).



**MS1-A432** 



The rod holder (MS1-A271) can be used to insert the rod between the screw extenders when an incision is made between the screw extenders.





### **Rod placement**



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Three options for rod introduction are available for a percutaneous introduction.

- Rod introducer : MS1-A274
- Reversed rod introducer : MS1-A275
- Rotating rod introducer : MS1-A276









(a)

b

### With the rod introducer : MS1-A274

Insert the rod (UNI-Thread<sup>TM</sup> rod [a] or LUMIS<sup>TM</sup> percutaneous rod [b]) into the slot located at the end of the instrument, ensuring that the end of the rod points up and away from the user.



If the LUMIS<sup>™</sup> 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 dual purpose handle (U1-A622).







### With the rod introducer : MS1-A274

Insert the rod beneath the muscles by inserting its tip (UNI-Thread™<br/>rod) or bullet nose (LUMIS™ percutaneous rod) and then rotating the<br/>rod introducer (MS1-A274).Image: A standard transformed beneath the muscles by inserting its tip (UNI-Thread™<br/>rod introducer (MS1-A274).Image: A standard transformed beneath the muscles by inserting its tip (UNI-Thread™<br/>rod introducer (MS1-A274).Image: A standard transformed beneath the muscles by inserting its tip (UNI-Thread™<br/>rod introducer (MS1-A274).Image: A standard transformed beneath the muscles by inserting its tip (UNI-Thread™<br/>rod introducer (MS1-A274).Image: A standard transformed beneath the muscles by insert the rod.

To release the rod, unscrew the locking screw with the T30 shaft (MS1-A411) preassembled with the dual purpose handle (U1-A622).



# With the reversed rod introducer : MS1-A275



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

When the LUMIS<sup>™</sup> percutaneous rod is used, take care to insert the non bulleted extremity in the reversed rod introducer.

Extremity to insert into the reversed rod introducer





Lock the rod in the instrument by tightening the locking screw with the T30 shaft (MS1-A411) preassembled with the dual purpose handle (U1-A622).







## With the reversed rod introducer : MS1-A275



To avoid having to make an additional skin incision, it is necessary to use the enlarged screw extender (MS1-A214) in combination with the reversed rod introducer. Lower the rod into the enlarged screw extender on the end of the construct, and rotate the rod into the screw heads.





# With the reversed rod introducer : MS1-A275





To release the rod, unscrew the locking screw with the T30 shaft (MS1-A411) preassembled with the dual purpose handle (U1-A622).







- Make sure that screw A is tightened (compatible with MS1-A411).
- Use the MS1-A235 screwdriver to attach the rod onto the rotating rod introducer (MS1-A276). Take care to place the non-bulleted extremity of the LUMIS<sup>TM</sup> percutaneous rod in the rotating rod introducer.
- Unscrew screw A to pivote the rod (with MS1-A411).







# With the rotating rod introducer : MS1-A276



Ensure that the rod is vertically positioned by unscrewing screw A. Insert the ord into the enlarged screw extender.



Turn screw A clockwise using fingers or the T30 shaft with U1-A622, L2ALIS411, PL1-A011 to pivot the rod into the screw heads.



To release the rod, unscrew the locking screw with the MS1-A235 (T10 screwdriver for rod introducer).







### **Rod placement check**

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

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



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



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

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Regardless of which rod introducer is used, a set screw must be inserted into the screw next to the screw through which the rod was introduced.

Doing this will secure the rod and the rod introducer to be used as a rod pusher.

There are three different options for rod reduction.

<u>Caution</u>: The setscrew must never be placed on the bulleted part of the rod.





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

<u>Step 1:</u> Engage a setscrew from the screw support (MS1-A251) by pulling on the trigger of MS1-A231.

<u>Step 2</u>: Attach the index ring for the setscrew holder (MS1-A232) onto the narrowest part of the setscrew holder (MS1-A231)

<u>Step 3:</u> Slide the assembly into the screw extender and turn the upper part of the setscrew holder clockwise to engage the setscrew with the screw head.

Step 3











MS1-A251

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

Slide the setscrew holder (MS1-A231) into the rod persuader (MS1-A311) (A).

Engage a setscrew from the setscrew support (MS1-A251) by pulling on the trigger of MS1-A231 (B).





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

Depending on the distance (D) between the rod and the head of the screw (B), 3 options are possible.

<u>Option 1</u>: If D<38mm then then the screw for the rod persuader (MS1-A313) can be used to reduce the rod.



MS1-A313



<u>Option 2</u>: If 35mm<D<45mm, then the long screw for the rod persuader (MS1-A314) can be used to reduce the rod.

<u>Option 3</u>: If 45mm<D, then the rod persuader plier (MS1-A312) can be used to well position the rod.







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### <u>Options 1 & 2</u>

Assemble the screw (MS1-A313/MS1-A314) and the rod persuader (MS1-A311), by sliding the square piece onto the end of the rod persuader.

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













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

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### Option 3

- (1) The upper fork must be slid onto the upper ring of the rod persuader,
- (2) The lower fork must be slid onto the upper ring of the screw extender. Use the laser marks (3) to find the appropriate position for the rod persuader plier.









Squeeze the persuader plier (MS1-A312) to reduce the rod.







### **Setscrew Placement**



Once the rod has been pushed down into the screw head, it is possible to engage the setscrew by turning the superior part of the setscrew holder (MS1-A231) clockwise.

Laser etchings will indicate when the setscrew is engaged.

**<u>Caution</u>** : The MS1-A231 must not be used to finally tighten the setscrew.

Once the setscrew is engaged, pull on the trigger to release the setscrew and remove the setscrew holder.

Then,

-Rod reduction Options 1 & 2 : unscrew the screw for the rod persuader and remove the rod persuader (MS1-A313/MS1-A314 + MS1-A311)

- Rod reduction Option 3 : release the rod persuader plier (MS1-A312) and remove the rod persuader (MS1-A311)







# Final Tightening (percutaneous)

Pre-assemble the instruments for the final tightening.

-MS1-A432 + U1-A622 **(A)** 

-MS1-A411 + MS1-A421 (B)

Place the counter torque into the screw extender and insert the T30 shaft to tighten the set screw.

Final locking is achieved by applying a 8.5N.m torque.





### Option for final tightening (mini-open)



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### **Distraction with the spreader**

### Distraction with the spreader (MS1-A321)









### **Compression-Distraction**



Make sure that one setscrew is sufficiently tightened to be used as a reference for compressiondistraction



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



distractor over







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

- MS1-A334: Fulcrum connector for distractorcompressor
- MS1-A335: Multiple connector for distractorcompressor



It is recommended to place one handle (U1-A622, PL1-A011) on one of the counter-torques to secure the fulcrum.







### **Compression-Distraction**



Once the correction has been performed, it is possible to perform the final tightening on the setscrew which was not used as the reference screw, while maintaining the compressor-distractor in position.

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





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### **Screw Extender Removal**

Release the screw extender (MS1-A211/MS1-A214) by screwing the nut (1) counter clockwise and sliding the ring (2) 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 (1)[**A**] or by lifting up below the ring (2)[**B**].

Repeat the previous surgical steps for all screws









#### Insertion of the Rescue Instrument (MS1-A223).



### **Rescue Instrument**

Tightening of the rescue instrument into the screw head.









#### **Rescue Instrument**

The screw extender can be slided onto the rescue Instrument and attached to the screw.



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



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#### **Percutaneous rescue instruments**





The dilators can be inserted one over the other.









MS1-A223

#### Rescue procedure, before rod placement





The rescue instrument can be inserted into the screw head through the largest dilator, followed by a screw extender.







# Rescue procedure, once the rod has been placed







Laser marks indicate which way the screw extender must be placed







- List of needed items for Lumis<sup>™</sup> screws removal <u>using an open approach</u>
  - 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 MS2-A221 (Lumis Universal Screwdriver)







Unlock the setscrew using the countertorque (IS1-A431) and the T30 shaft (MS1-A411)

Note : The counter torque must be placed perpendicularly to the patient axis to ensure a proper leverage 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/release the set screw.





- Once all setscrews have been removed, it is possible to remove the rod using the rod holder (U1-A213N1)
- Place the Lumis Universal Screwdriver (MS2-A221) into the head of the screw and turn the handle counter-clockwise to remove each screw.

