

uni-Thread™

Versatile Thoraco-Lumbar Spinal System



Surgical Technique



SpineVision®
Innovation that matters

Uni-Thread™

Versatile Thoraco-Lumbar Spinal System

Surgical Technique

English Version

Reference document: GL2-ST_03GB

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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General Description of the System

The UNI-Thread™ System implants and instruments are designed for correction and surgical stabilization of the spine during development of solid bone fusion. The components of the UNI-Thread™ System are made from titanium alloy (Ti-6Al-4V).

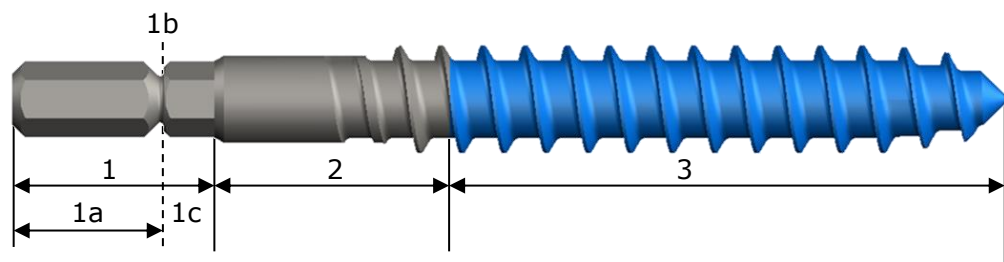
The UNI-Thread™ Spinal System has a single-threaded screw and a three-dimensional connector which allows adjustment of the height of both components at any stage of the procedure. Bone screw depth can thus be easily optimized at any time.

The UNI-Thread™ posterior thoracolumbar spinal system is truly versatile due to the novel design characteristics of the UNI-Thread™ screw and connector. Only a few specific instruments are necessary for all spinal correction needs.

Presentation of Implants

Screws

DESCRIPTION



UNI-Thread™ screws are single-threaded self-tapping screws and are comprised of:

- A proximal hex shape [1] for insertion into a specific screwdriver (the hexagonal post [1a] of the screw initially protrudes through the top of the connector, and is sheared flush at the end of the procedure, a break-off groove [1b], a hex head [1c] for adjustment or removal of the screw after hexagonal post breakage)
- A portion to place the connector onto the screw including a more or less important threaded portion [2] to adjust height of connectors and screws at any stage of the procedure.
- A colored portion [3] to indicate the minimal depth of insertion and the diameter of the screw.

Depending on the length of the threaded portion [2], UNI-Thread™ screws can be used either for standard procedures or for Spondylolisthesis reduction maneuver.

The UNI-Thread™ system offers two types of screws: standard screws and reduction screws.

STANDARD SCREWS



L2-C(H)DLLT, screw with Cylindrical post
where:

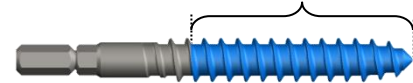
- D is the first digit of the screw diameter
- LL is the length of the screw

Note: L2-C643T is an Ø6.5 mm screw diameter that permits a penetration range from 38 mm up to 43 mm.





38mm

Length of the blue portion is 38 mm.

Generally speaking, it is a "40 mm screw".



To ease their use in the operating room, the UNI-Thread™ screws are anodized.

		Diameter 5.5mm	Diameter 6.5mm	Diameter 7.5mm	Diameter 8.5mm
		Pink	Blue	Green	Turquoise
					
Length (mm)	23-28 = '25'	<i>L2-CH528T</i>	<i>L2-C628T</i>	<i>L2-C728T</i>	<i>L2-C828T</i>
	28-33 = '30'	<i>L2-CH533T</i>	<i>L2-C633T</i>	<i>L2-C733T</i>	<i>L2-C833T</i>
	33-38 = '35'	L2-CH538T	L2-C638T	L2-C738T	<i>L2-C838T</i>
	38-43 = '40'	L2-CH543T	L2-C643T	L2-C743T	<i>L2-C843T</i>
	43-48 = '45'	L2-CH548T	L2-C648T	L2-C748T	<i>L2-C848T</i>
	48-53 = '50'	<i>L2-CH553T</i>	L2-C653T	<i>L2-C753T</i>	<i>L2-C853T</i>
	53-58 = '55'	<i>L2-CH558T</i>	<i>L2-C658T</i>	<i>L2-C758T</i>	<i>L2-C858T</i>

References indicated in bold characters are part of a standard set composition.
Italic references can be provided on demand.

REDUCTION SCREWS






L2-S(H)DLLT, fully threaded screw for Spondylolisthesis reduction where:

- D is the first digit of the screw diameter
- LL is the length of the screw

Note: L2-S643T is an Ø6.5 mm screw diameter that permits a penetration range from 38 mm up to 43 mm. Length of the blue portion is 38 mm. Generally speaking, it is a “40 mm screw”.

To ease their use in the operating room, the UNI-Thread™ screws are anodized.

		Diameter 5.5mm	Diameter 6.5mm	Diameter 7.5mm	Diameter 8.5mm
		Pink	Blue	Green	NOT AVAILABLE
Length (mm)	23-28 = '25'				
	28-33 = '30'	<i>L2-SH528T</i>	<i>L2-S628T</i>	<i>L2-S728T</i>	
	33-38 = '35'	<i>L2-SH533T</i>	<i>L2-S633T</i>	<i>L2-S733T</i>	
	38-43 = '40'	L2-SH538T	L2-S638T	L2-S738T	
	43-48 = '45'	L2-SH543T	L2-S643T	L2-S743T	
	48-53 = '50'	L2-SH548T	L2-S648T	L2-S748T	
	53-58 = '55'	<i>L2-SH553T</i>	<i>L2-S653T</i>	<i>L2-S753T</i>	
		<i>L2-SH558T</i>	<i>L2-S658T</i>	<i>L2-S758T</i>	


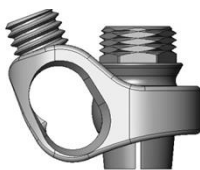
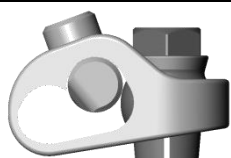




References indicated in bold characters are part of a standard set composition.
Italic references can be provided on demand.

Note: L2-S(H)xxxT screws can replace L2-C(H)xxxT.

Three-Dimensional Connectors

CONNECTOR OPTIONS DESCRIPTION

According to the type of construct various UNI-Thread™ three-dimensional connectors are available.

	Standard construct		Reduction construct	
Standard connectors	L2-L1xxT		L2-LSPL1xxT	
Offset connectors	L2-L9xxT		NOT AVAILABLE	
Rod connectors	<i>L2-RC609RT</i>		<i>L2-RCS609RT</i>	
	<i>L2-RC609LT</i>		<i>L2-RCS609LT</i>	

*References indicated in bold characters are part of a standard set composition.
Italic references can be provided on demand.*

Note: All UNI-Thread™ connectors are provided pre-assembled.

All connectors are color-coded:



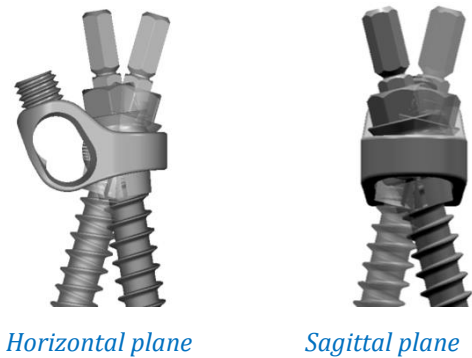
Blue ones are compatible with 5,5 and 6,5 diameter screws

Green ones are compatible solely with 7,5 and 8,5 diameter screws

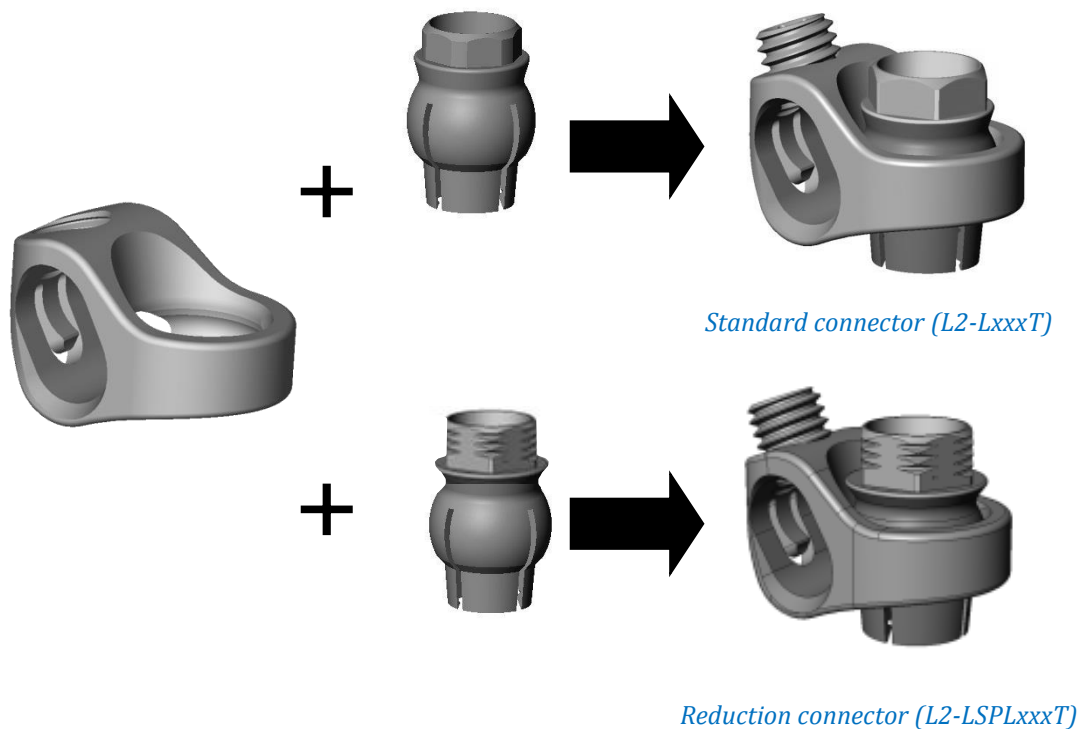
See section about Connector compatibility with screws for further information.

Once the screws are inside the connector, their angulation capacity is:

- 25° in sagittal plane for standard connector (~20° for offset connectors)
- 27° in transversal plane for standard connector (~20° for offset connectors)



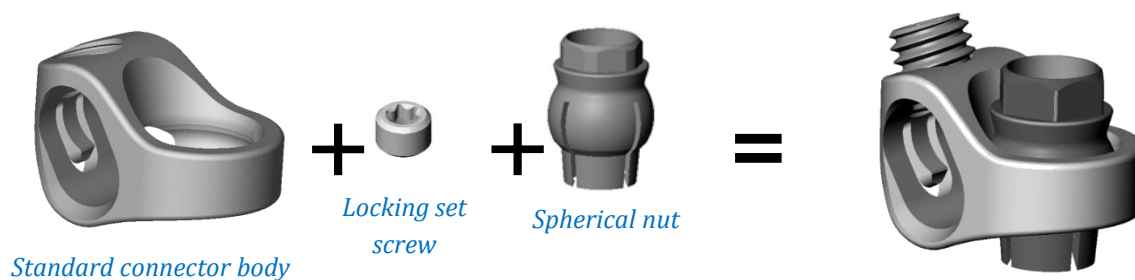
As shown, UNI-Thread™ three-dimensional reduction connectors feature a threaded hex tip to allow attachment with reduction instruments.



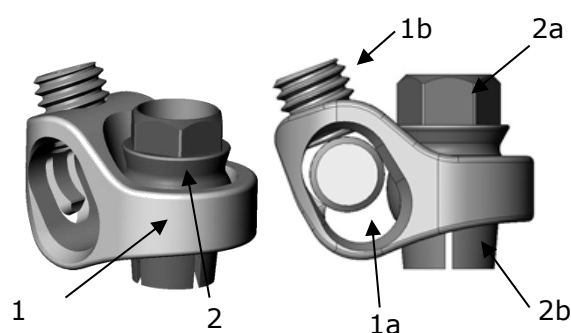
Note: Reduction connectors (L2-LSPL1xxT) can be used as standard connectors (L2-L1xxT), more information about the Screw/Connectors compatibility can be found in section CONNECTOR COMPATIBILITY WITH SCREWS

STANDARD CONNECTORS (L2-L1XXT / L2-LSPL1XXT)

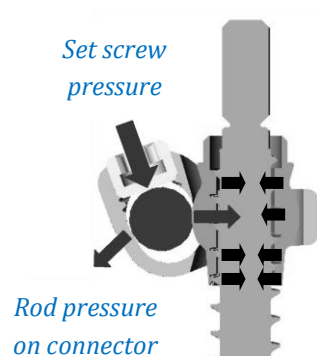
Standard (reduction) connectors are comprised of:



- The standard connector body [1], features a rod canal for rod insertion [1a] and a locking set screw [1b], which locks the system as it is pushing down the rod



- The spherical nut [2], which features :
 - a color-coded outer hex part [2a] allowing for its height adjustment
 - a spherical elastic nut [2b] including an internal thread identical to the external thread of the pedicle screw thus giving the one-step locking mechanism.

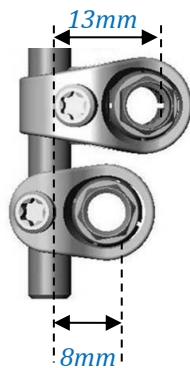


Complete locking of rod and screw position in relation with connector is obtained by the locking set screw tightening only.

Its pressure is transmitted to the rod first, the spherical nut second and then onto the pedicle screw so as to lock every possible motion.

For 5.5 and 6.5mm UNI-Thread™ screws		For 7.5 and 8.5mm UNI-Thread™ screws	
<i>L2-L165T</i>	<i>L2-LSPL165T</i>	<i>L2-L175T</i>	<i>L2-LSPL175T</i>

OFFSET CONNECTORS (L2-L9XXT)

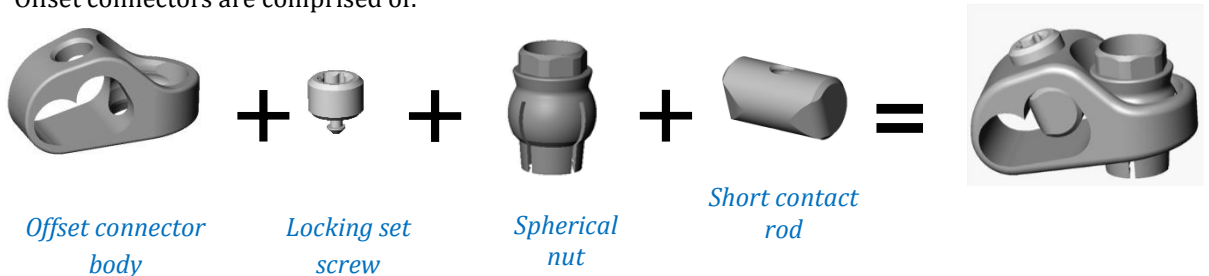


The offset connector is available to accommodate screw misalignment.

Offset in frontal plane between the rod and the screw, is

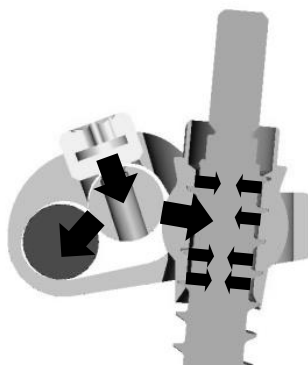
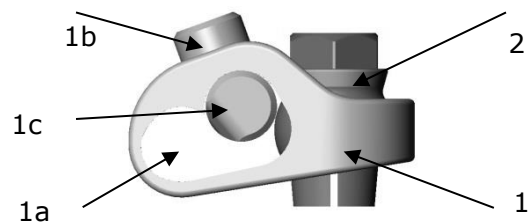
- 8mm for the standard connector
- 13mm for the offset connector

Offset connectors are comprised of:



➤ A connector body [1], which features :



- a rod canal for rod insertion [1a]
- a locking set screw [1b], which locks the system as it is pushing down the pre-loaded short contact rod [1c].



A spherical nut [2] – identical to the one of the standard connector featuring a 'one-step' locking mechanism

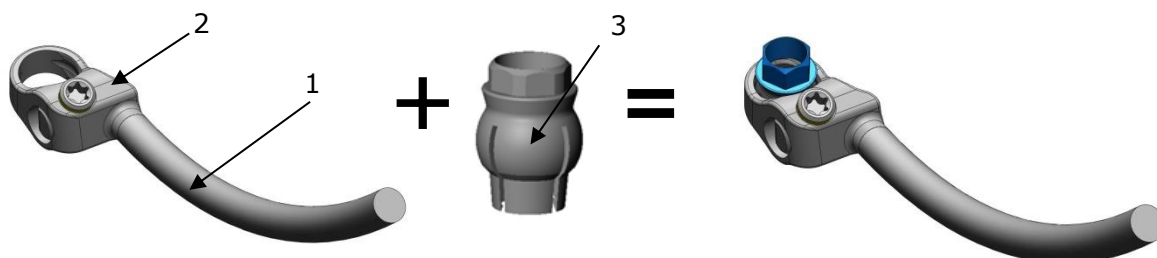
Offset connectors can also be used as dominos for construct extension. In that case, remove the set screw [1b] and the short contact rod [1c] and use a standard connector setscrew to lock the rod in the connector.



For 5.5 and 6.5mm UNI-Thread™ screws	For 7.5 and 8.5mm UNI-Thread™ screws
 <i>L2-L965T</i>	 <i>L2-L975T</i>

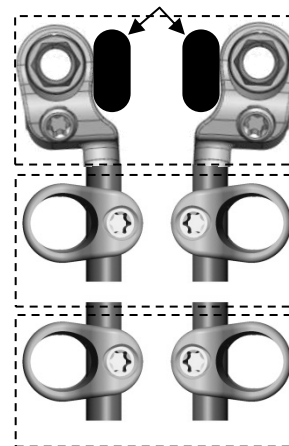
ROD CONNECTORS (L2-RC(S)609RT / L2-RC(S)609LT)

Rod (reduction) connectors are comprised of:



A pre-bent Titanium Alloy rod [1] (90mm long – 6mm diameter) assembled to a connector body [2] and a spherical nut [3].

Inferior facet joints



Rod connectors are used to preserve inferior facet joints of the vertebra above the construct

To fit anatomical constraints, rod connectors are different for Right or for Left implantation

Right rod connector : L2-RC(S)609RT



Left rod connector : L2-RC(S)609LT

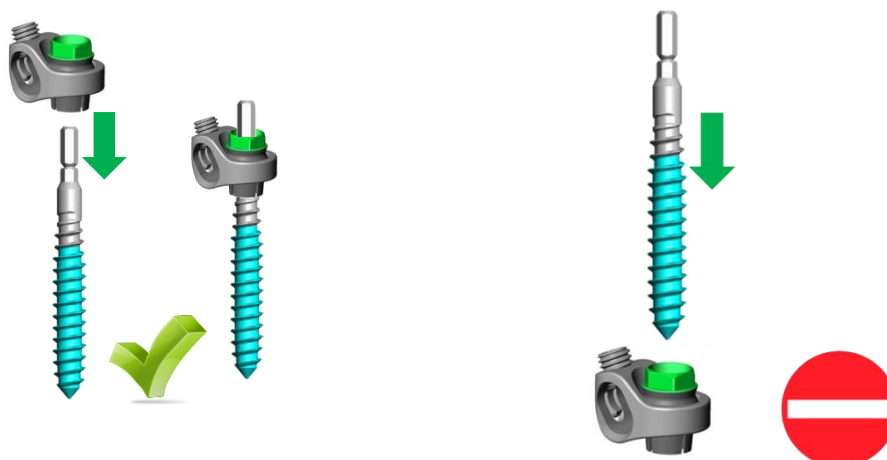


CONNECTOR COMPATIBILITY WITH SCREWS

		Connector				
		Standard		Offset	Rod	
	Screw diameter	Standard	Reduction	Standard	Standard	Reduction
Standard screws	5.5mm	L2-L165T	L2-LSPL165T	L2-L965T	L2-RC609RT L2-RC609LT	L2-RCS609RT L2-RCS609LT
	6.5mm	L2-L165T	L2-LSPL165T	L2-L965T	L2-RC609RT L2-RC609LT	L2-RCS609RT L2-RCS609LT
	7.5mm	L2-L175T	L2-LSPL175T	L2-L975T	NOT AVAILABLE	
	8.5mm	L2-L175T	L2-LSPL175T	L2-L975T	NOT AVAILABLE	
Reduction screws	5.5mm	L2-L165T	L2-LSPL165T	L2-L965T	L2-RC609RT L2-RC609LT	L2-RCS609RT L2-RCS609LT
	6.5mm	L2-L165T	L2-LSPL165T	L2-L965T	L2-RC609RT L2-RC609LT	L2-RCS609RT L2-RCS609LT
	7.5mm	L2-L175T	L2-LSPL175T	L2-L975T	NOT AVAILABLE	

CAUTION: References in bold characters indicate constructs which allow performing Spondylolisthesis reduction maneuver using the UNI-Thread™ reduction instrumentation.

Standard screws in Ø 8,5mm are compatible with the 7,5 connectors (L2-L175T/L2-LSPL175T) providing they are pre-assembled in the appropriate manner.



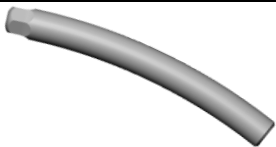
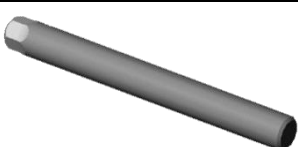
Rods (L2-R6xx(C)HT)

DESCRIPTION



Made of Titanium Alloy, UNI-Thread™ rods are 6mm diameter and are compatible with all connectors. They have a hexagonal end allowing better manipulation and better control of rotation.

AVAILABLE RANGE

	Prebent	Straight
Length		
40mm	L2-R604CHT	<i>L2-R604HT</i>
50mm	L2-R605CHT	<i>L2-R605HT</i>
60mm	L2-R606CHT	<i>L2-R606HT</i>
70mm	<i>L2-R607CHT</i>	L2-R607HT
80mm	<i>L2-R608CHT</i>	L2-R608HT
90mm	<i>L2-R609CHT</i>	L2-R609HT
250mm	NOT AVAILABLE	L2-R625HT

*References indicated in bold characters are part of a standard set composition.
Italic references can be provided on demand.*

Transverse connection systems

MULTI-AXIAL TRANSVERSE CONNECTOR L2-T610T

The multi-axial transverse connector permits 15° angular movement in all planes which guarantees a good match regardless of the positions of the rods to be joined.



L2-T610T

BAR FOR MULTI-AXIAL TRANSVERSE CONNECTOR L2-T6XXT

The multi-axial transverse connector bars are available in lengths from 20mm to 65mm in 3mm increments.

The transverse bars show two 5mm diameter spheres at each end.



L2-T6XXT

FIXED TRANSVERSE CONNECTOR L2-T613T

The fixed transverse connector permits compression and distraction between the two longitudinal rods.



L2-T613T

BAR FOR MULTI-AXIAL TRANSVERSE CONNECTOR / FIXED TRANSVERSE CONNECTOR L2-T614T

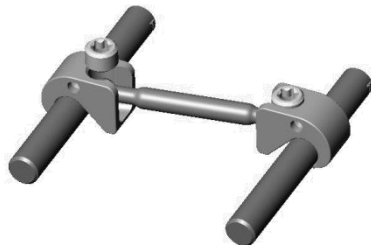
The transverse bar has a 5 mm sphere at one end only. It is supplied in only one length and can be shortened to suit the situation.

The transverse bar sphere is fixed to the multi-axial transverse connector.

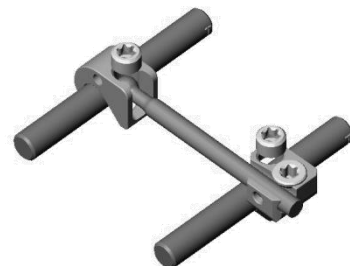
A fixed transverse connector is locked at the end of the assembly on the longitudinal rod.



L2-T614T



*Connection assembly
for multi-axial transverse connectors*



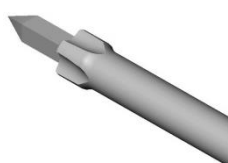
*Connection assembly
for multi-axial / fixed connectors*

Surgical steps

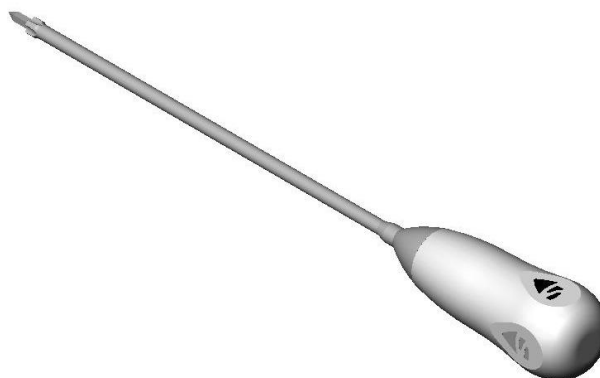
Preparing the pedicle and inserting the pedicle screws

DRILLING THE PILOT HOLE

A pilot hole is made in the vertebral pedicle.
The entry point is prepared using the square awl (U1-A121N1).



U1-A121N1



The pilot hole is drilled using the curette (U1-A123L) or the spatula (U1-A122S).



U1-A123L



U1-A122S



The pedicle probe with ball tip (U1-A124N1) can be used for tactile checking.



U1-A124N1

TAPPING

If needed, taps are available in 3 diameters to facilitate screw insertion:



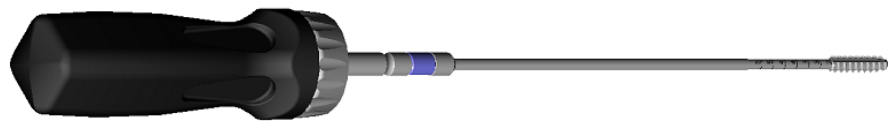
- L2-A155, Ø5 mm tap for 5.5 diameter screws (pink)
- L2-A165, Ø6 mm tap for 6.5 diameter screws (blue)
- L2-A175, Ø7 mm tap for 7.5 diameter screws (green)
- L2-A185, Ø8 mm tap for 8.5 diameter screws (turquoise) [not represented]

CAUTION: Taps are not part of a standard set composition. They are provided solely on demand.

They connect to the straight ratcheting handle (L2-A411) with which they must be assembled to be used.



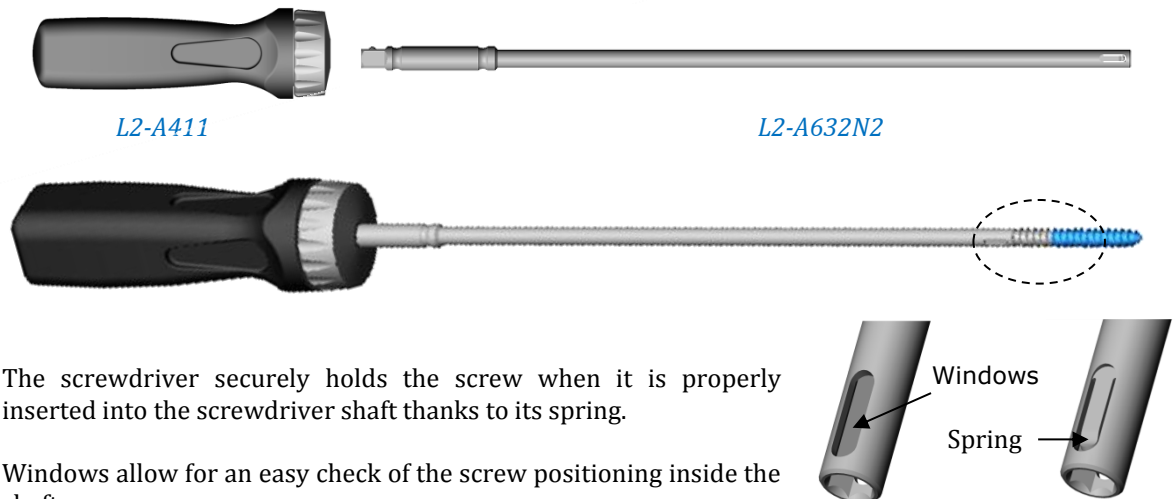
L2-A411



L2-A411 + L2-A165

INSERTING THE PEDICLE SCREWS

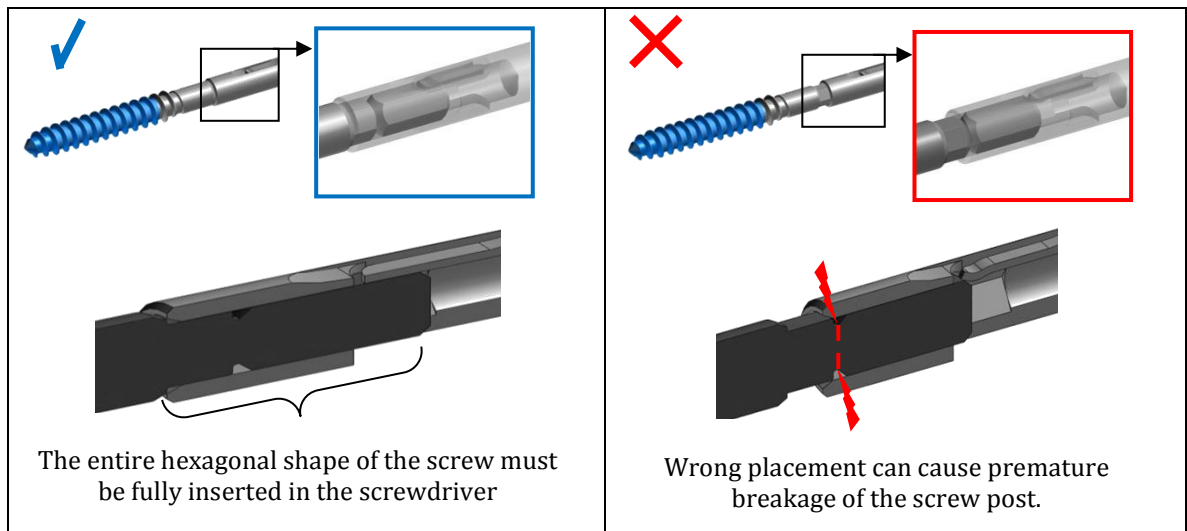
Pedicle screws are inserted with a straight ratcheting handle (L2-A411) and an adaptable shaft for pedicle screwdriver (L2-A632N2).



The screwdriver securely holds the screw when it is properly inserted into the screwdriver shaft thanks to its spring.

Windows allow for an easy check of the screw positioning inside the shaft.

Special attention must be paid to screw positioning in the shaft (L2-A632N2) and firm downward pressure must be maintained during insertion of the pedicle screw.



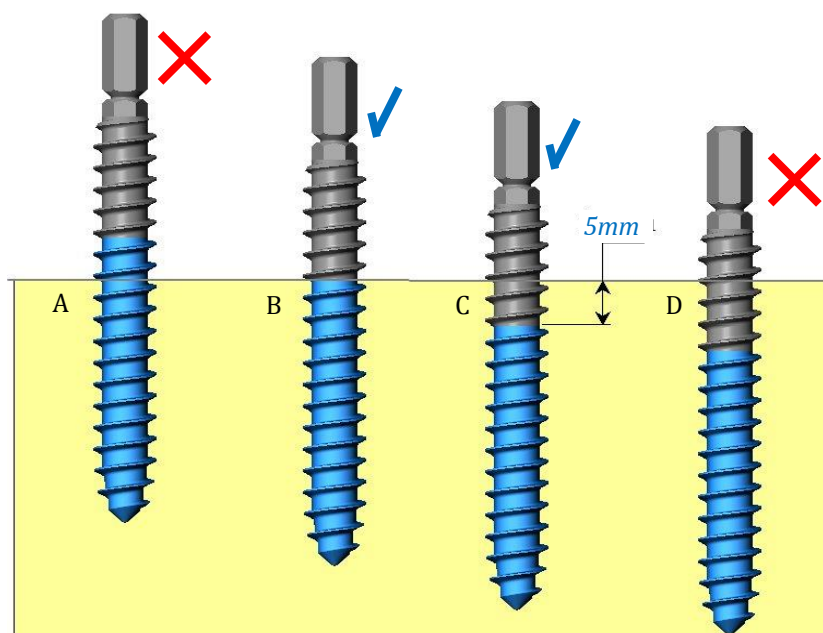
Depending on the surgical planning, standard screws or reduction screws must be used and placed in the vertebral pedicles.

For a standard fusion construct, it is recommended to use standard screws (L2-C(H)xxxT) since their cylindrical hex post allow a fast placement of the three-dimensional UNI-Thread™ connectors.

For a reduction construct, reduction screws are mandatory in the vertebrae involved in the Spondylolisthesis: as an example, a L5-S1 Spondylolisthesis reduction would need reduction screws both in L5 and in S1 pedicles.

After having selected the appropriate screws, they can be inserted in the vertebra.

The following chart shows different scenarios for initial screw depth insertion:



- | | | |
|-------------------|---|--|
| Case A: NO | ➔ | It is recommended to advance the screw. |
| Case B: OK | ➔ | Minimal insertion depth. |
| Case C: OK | ➔ | Maximal insertion depth. |
| Case D: NO | ➔ | Not satisfactory. The screw should be unscrewed. |

PLACING THE ROD AND THE CONNECTORS

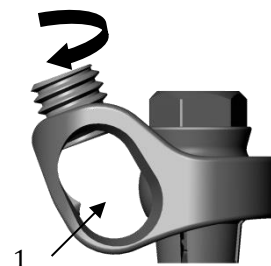
Once screws are in place, the way of placing the rod and connectors depends on the type of construct.

- For a standard fusion construct, a rod-connectors assembly will be prepared and then positioned on the screws.
- For a reduction construct, reduction connectors will have to be placed on screws firstly and rod will be then inserted.

In both constructs, the locking set screw should be unscrewed first without being removed using the long T20 screwdriver (U1-A415) to clear the rod canal [1] and thus facilitate longitudinal rod introduction in the connector.



U1-A415



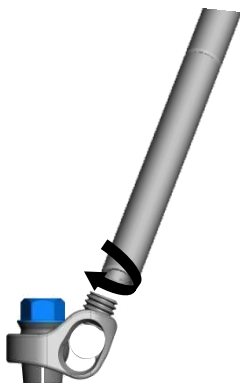
❖ *Standard Fusion Construct*

Step1: Rod-connectors assembly preparation



U1-A321

Once the appropriate length of the rod has been determined and the rod cut, the french bender (U1-A321) permits the rod to be given the desired curves.

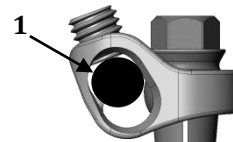


L2-L165T+L2-A310

The connector holder (L2-A310) is screwed onto the exposed threads of the locking set screw of the connector.

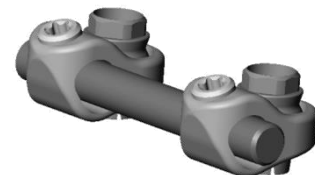


U1-A214



The rod is then placed in the connectors using the rod holder (U1-A214). It is important to insert the rod above the bump in the rod canal so that the rod will be maintained in the upper part of the rod canal [1] preventing the spherical nut from being in contact with the rod prior to final tightening and allowing the screw insertion.

Note: Connectors are positioned on the rod depending on the medial or lateral optimal positioning with respect to the screws. It is usually recommended to have the rods medially and the connectors laterally positioned.



CAUTION: In order to prevent the rod from sliding, connectors can be pre-loaded and provisionally tightened on the rod. Beware not to have the rod impinging the spherical nut to be able to insert the rod-connectors assembly onto the screws afterwards.

Step2: Rod-connectors assembly positioning

Insertion of the rod-connectors assembly may be facilitated by the use of flexible guides (L2-A340N1).

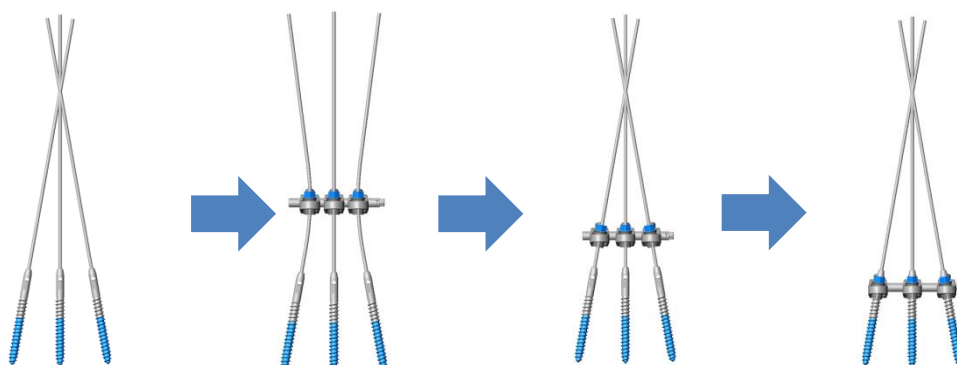
Note: Flexible guides are made of a flexible material and can be reshaped as desired.



L2-A340N1

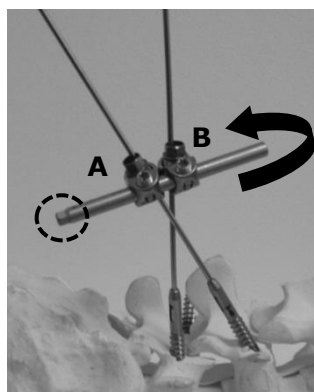


The flexible guides are positioned on the screws hexagonal posts.

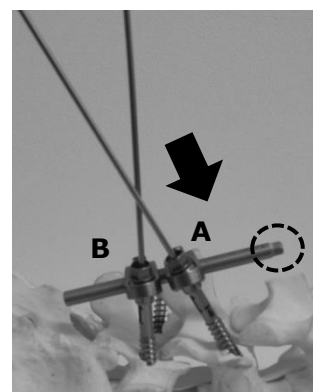


Rod and connectors assembly are then slid down along flexible guides (L2-A340N1) until they reach screws without stressing the pedicle anchorage.

For 1-Level construct, in case the lordosis does not allow to slide directly on the flexible guides in case they are too close to one another, the connectors will be positioned on the medial side first [1] and then rotated together with the rod to be positioned laterally [2].

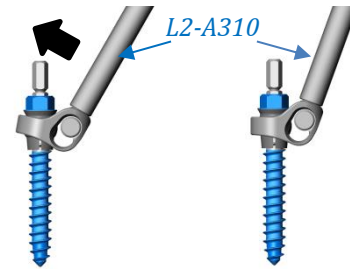


[1]: Connectors inserted on the medial side

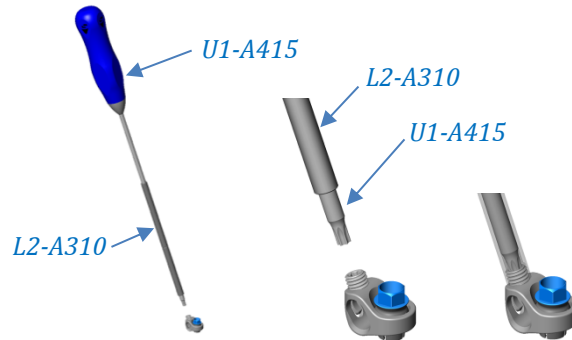


[2]: After rotation maneuver, connectors are positioned laterally

If needed, the connector holder (L2-A310) can help reposition the connector more horizontally.

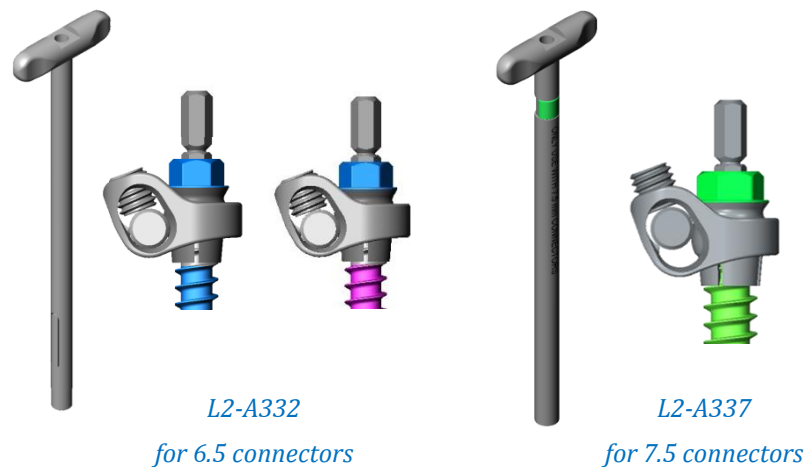


The long T20 screwdriver (U1-A415) can be used to help the positioning and or removal of the connector holder onto the locking set screw. The long T20 screwdriver (U1-A415) is inserted through the connector holder (L2-A310), to maintain the locking set screw while the connector holder is removed.

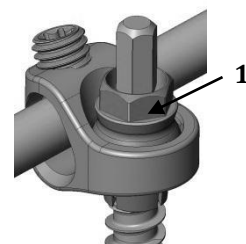


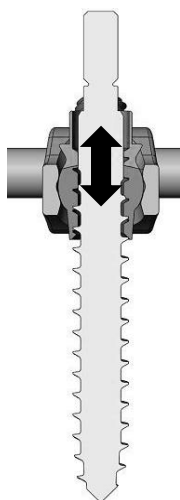
Step3: Loading of the Rod-connectors assembly onto the screws

Once the rod-connectors assembly is positioned onto the screws, the nut drivers (L2-A332, L2-A337) can be used to load the rod-connectors assembly on the screws.

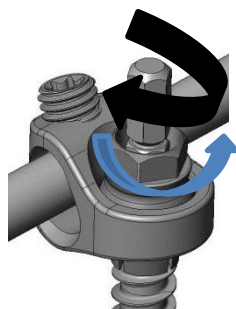


Nut drivers are positioned on the hex portion of the spherical nut of the connectors [1].





Due to the unique design of the single-threaded screw and the threaded connector, screw depth can be adjusted even after rod-connectors assembly loading (except for the 8.5mm diameter screw due to its design)



The height of the screw relative to the connector can also be adjusted using the shaft for pedicle screwdriver (L2-A632N2) through the nut driver (L2-A332/L2-A337).

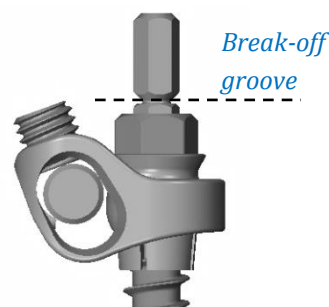


L2-A632N2

L2-A332

L2-A337

CAUTION: to ensure proper mechanical resistance of the construct and allow final tightening of the construct, the break-off groove must be visible above the hex part of the spherical nut.



<u>MINIMAL SCREW INSERTION</u> ✓	<u>MAXIMAL SCREW INSERTION</u> ✓	<u>SCREW INSERTED TOO DEEPLY</u> ✗
Screw threads are caught in the connector.		The break-off groove is not visible

In case the break-off groove is not visible, it is **MANDATORY** to use the shaft for pedicle screwdriver (L2-A632N2) together with the nut driver (L2-A332/L2-A337) to change the height of the connector with respect to the screw.

Step4: Construct fine tuning

Before final tightening, it is possible to adjust the position of the rod using the hex wrench (U1-A344(N1)) on the hex extremity of the rod.



U1-A344N1

If necessary, the spreader (U1-A342) and offset compressor (U1-A343) allow correction operations in the sagittal plane.

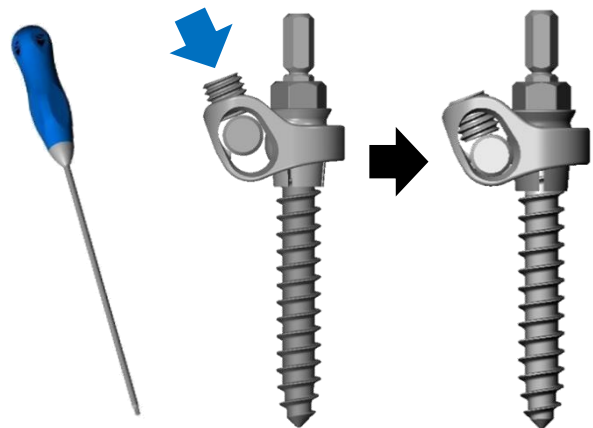


Spreader U1-A342



Offset compressor U1-A343

The offset compressor (U1-A343) has jaw spacing adjustment to allow the implant compression to be optimized.



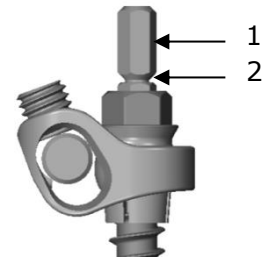
U1-A415

Provisional tightening can then be done in a sequential manner with the long T20 screwdriver (U1-A415).

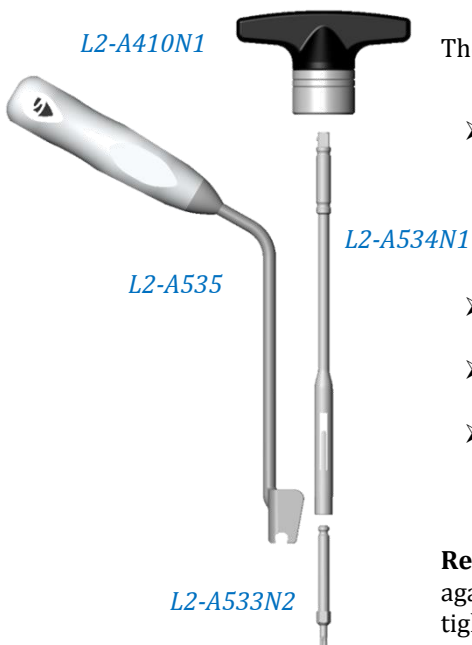
Step5: Final tightening

Preliminary check:

The hexagonal post [1] of the screw must initially protrude and the break-off groove [2] must be visible above the hex part of the spherical nut.

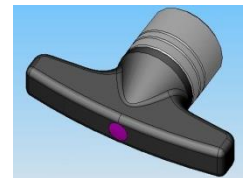


Final tightening maneuver:



The final tightening is performed using:

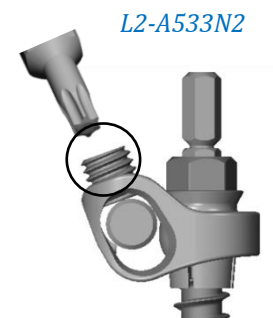
- The torque limiting T-handle (L2-A410N1) which releases at 9 Nm.
- The long T20 holder shaft (L2-A534N1)
- The long T20 tip (L2-A533N2)
- The counter torque (L2-A535)



Remark: the counter torque instrument (L2-A535) protects against accidental slippage from the set screw during tightening and also prevents transmission of torque to the instrumented spine segment

Final tightening is applied on the locking set screw.

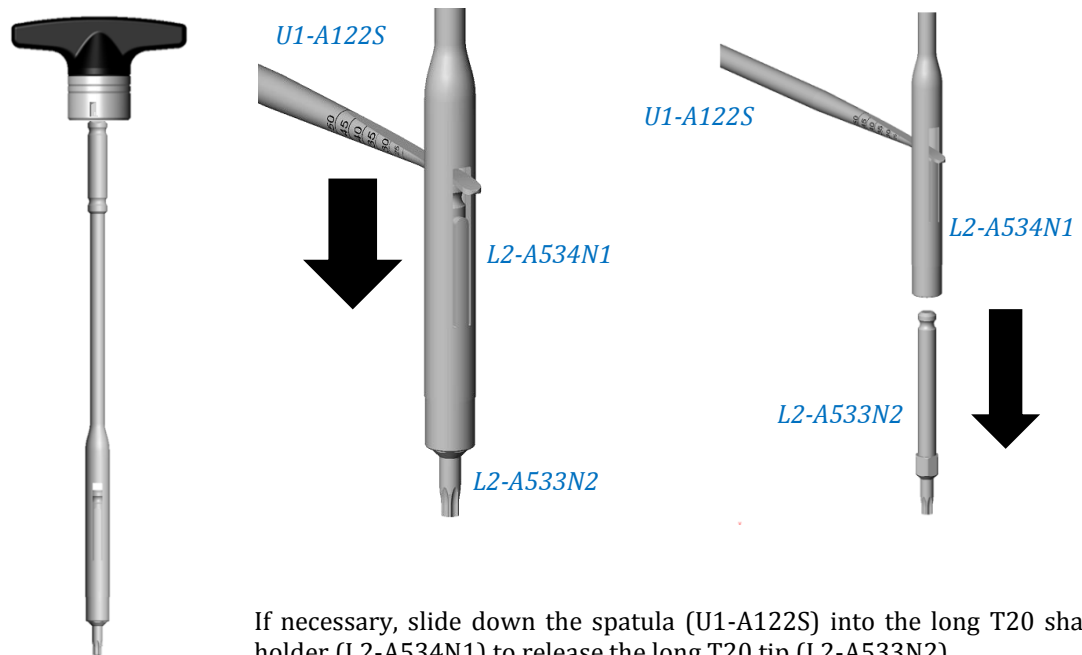
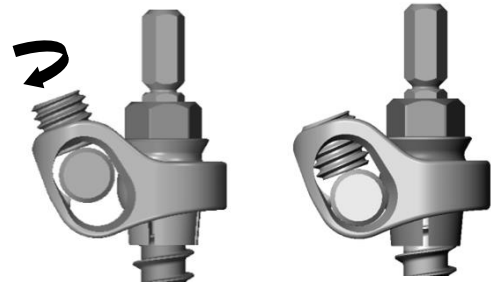
The locking set screw should be first carefully advanced in a sequential manner for every screw of the construct, until it is almost flush with the connector surface.



Then, the torque limiting T-handle (L2-A410N1) is tightened until the first click can be heard.

Final tightening is obtained once 3 successive clicks have been heard.

Note: It is recommended to wait between two consecutive clicks so that the torque limiting can release and apply optimal torque.

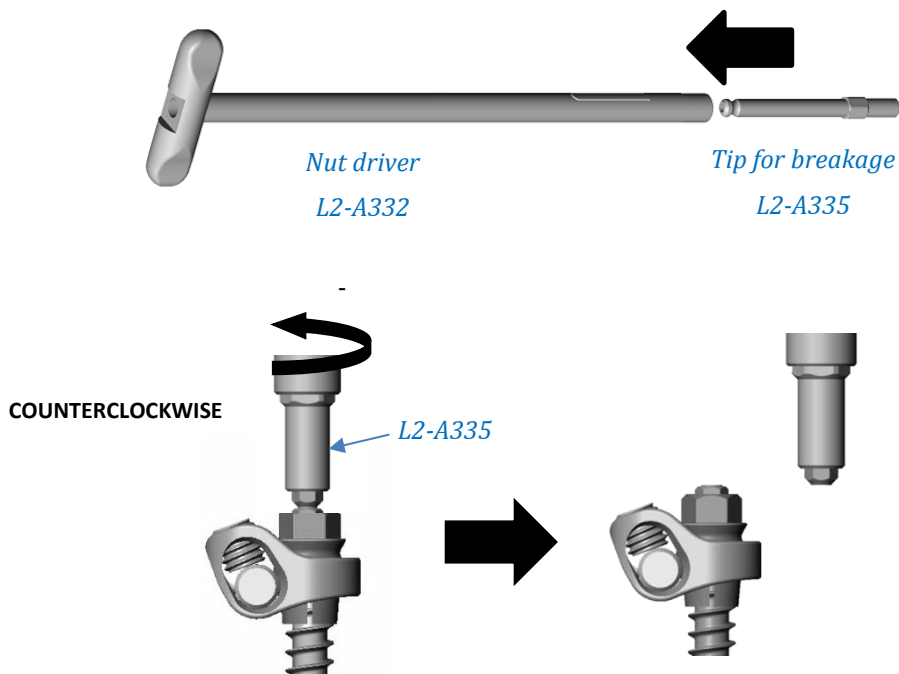


If necessary, slide down the spatula (U1-A122S) into the long T20 shaft holder (L2-A534N1) to release the long T20 tip (L2-A533N2).

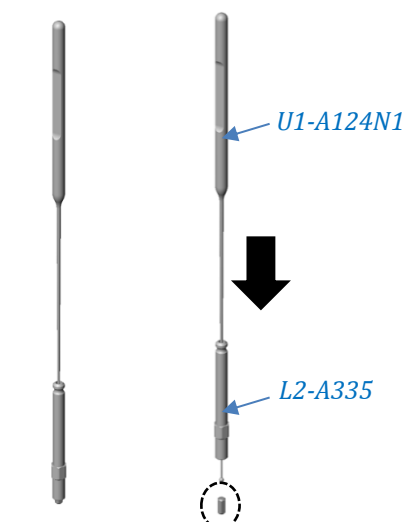
Evidence of proper final tightening:

Breakage of the hexagonal post will confirm that sufficient final torqueing has been achieved.

- Assemble the nut driver (L2-A332) and the tip for breakage (L2-A335).



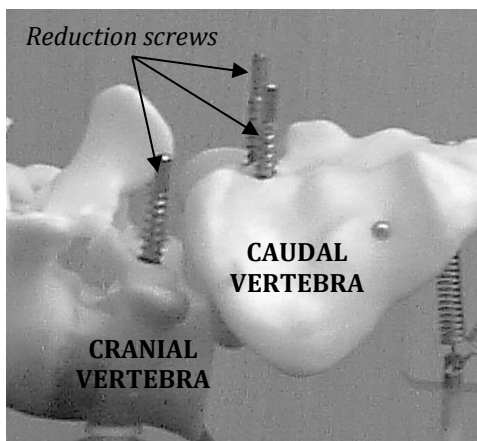
- Slide the tip for breakage on the screw hex post
- Turn the L2-A332/L2-A335 assembly **COUNTERCLOCKWISE** until post breaks.



Break-off part can be removed from the tip for breakage (L2-A335) using the pedicle probe (U1-A124N1)

❖ Reduction Construct

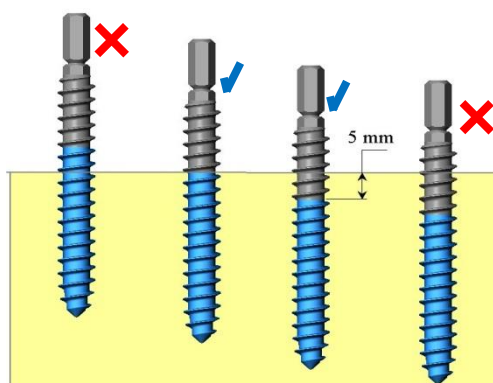
In case a Spondylolisthesis reduction needs to be achieved using the UNI-Thread™ reduction specific ancillary, it is mandatory to use reduction screws and connectors in the involved vertebrae : as an example, a L5-S1 Spondylolisthesis reduction would need reduction screws and connectors both in L5 and S1.



First step consists of placing screws as for a standard fusion construct (see Section 'Preparing the pedicle and inserting the pedicle screws' for further information).

Preliminary checks:

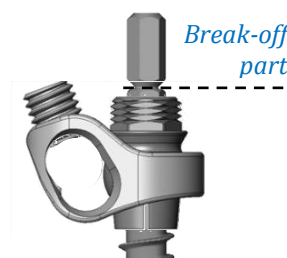
- As for standard screws, screw depth insertion must be verified according to the chart.



- Screw post check: A connector used as a template (L2-LSPL165T) is loaded on each screw with the nut driver (L2-A332) in order to check the connector position in relation to screw position.



CAUTION: to ensure proper mechanical resistance of the construct and allow final tightening of the construct, the break-off groove must be visible above the hex part of the spherical nut.

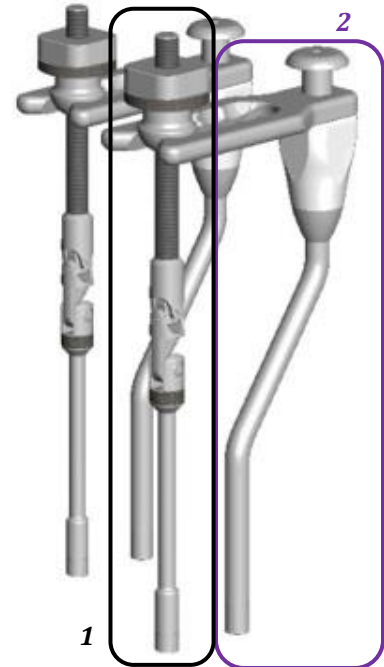


Remove the connector-template (L2-LSPL165T).

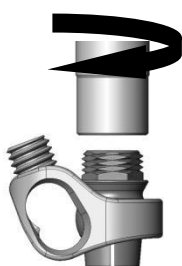
Spondylolisthesis reduction instrumentation presentation:

The UNI-Thread™ Spondylolisthesis reduction instrumentation allows for monosegmental reduction with multiple possible constructs and consists of:

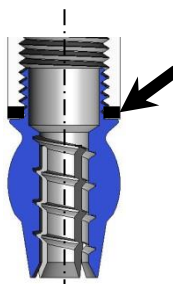
1. A mobile part which will be used to reduce the cranial vertebra, so-called upper arm.
2. A fixed part which will be positioned on the caudal vertebra, so-called lower arm.



Step1: Insertion of the reduction connectors on the reduction screws on the caudal vertebra



Properly screw the adaptor for the lower arm on a reduction connector.



CAUTION: Both surfaces must be in contact to avoid cross threading.

L2-ASPL001

L2-LSPL165T

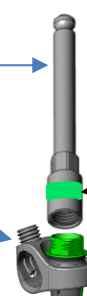


For 6,5mm reduction connectors (L2-LSPL165T), use the 6.5mm adaptor for the lower arm (L2-ASPL001).

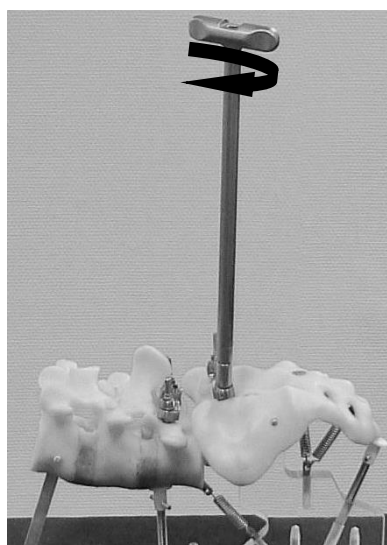
L2-ASPL008

L2-LSPL175T

Green ring

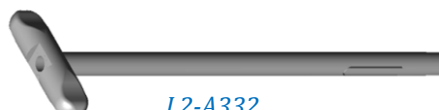


For 7,5mm reduction connectors (L2-LSPL175T), use the 7.5mm adaptor for the lower arm (L2-ASPL008).

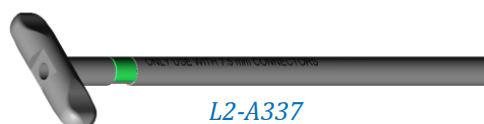


Load the assembly "reduction connector + adaptor for the lower arm" on the caudal screw using the nut driver (L2-A332 for 6.5mm connector / L2-A337 for 7.5mm connector).

Screw the connector until it reaches the bone. Remove the nut driver (L2-A332 / L2-A337).

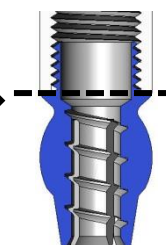
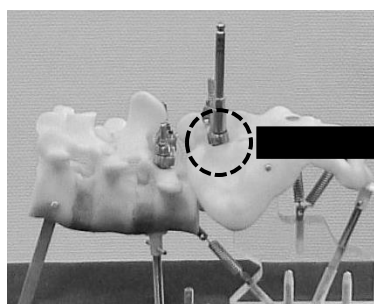


L2-A332

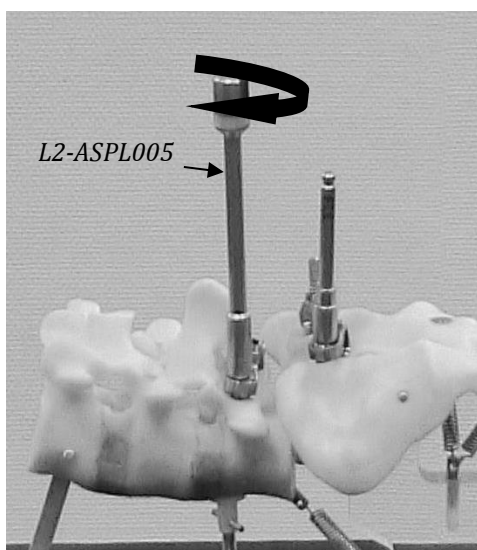


L2-A337



Check for good connection between the connector and the adaptor (visual check).

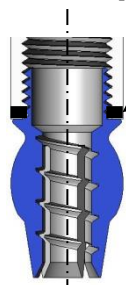


Step2: Insertion of the reduction connectors on the reduction screws on the cranial vertebra



Properly screw the upper arm on a reduction connector:

- In case the connector is 6,5mm, use the 6.5mm upper arm (L2-ASPL005). 
- In case the connector is 7,5mm, use the 7.5mm upper arm (L2-ASPL009). 

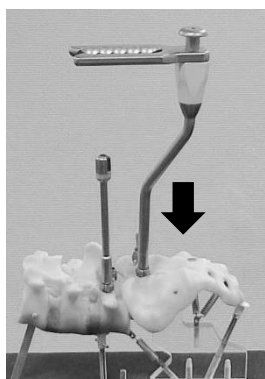
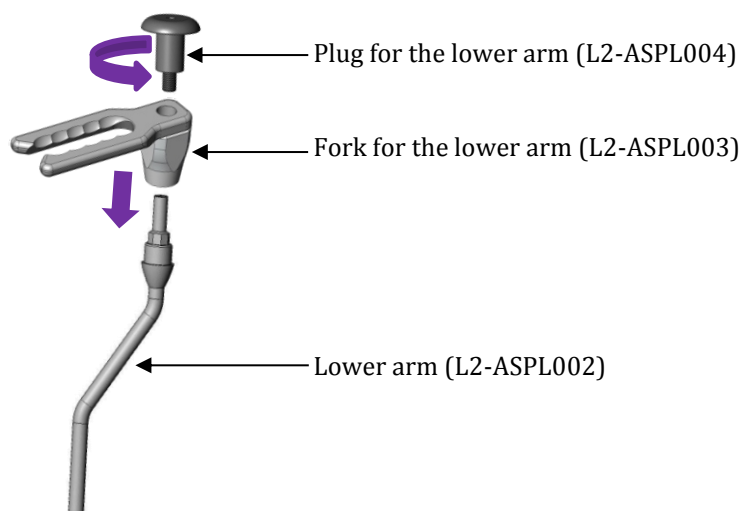


CAUTION: there must be contact between both surfaces in order to avoid cross threading.

Load the assembly "reduction connector + upper arm" on the cranial screw.

Step3: Lower arm insertion

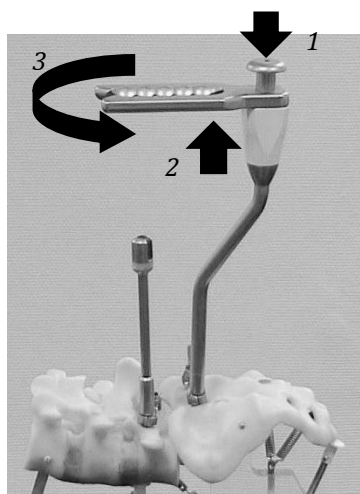
Some parts of the lower arm must be preassembled outside the operating field before loading on the lower arm adaptor (L2-ASPL001, L2-ASPL008).



The assembly is then slid onto the adaptor.

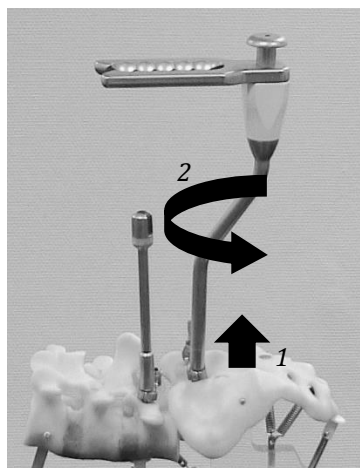
Lower arm of the UNI-Thread™ Spondylolisthesis reduction instrumentation can be positioned in different ways so that it fits the anatomical conditions of the patient.

To change the fork position:



1. Push the button
2. Lift the fork
3. Turn the fork

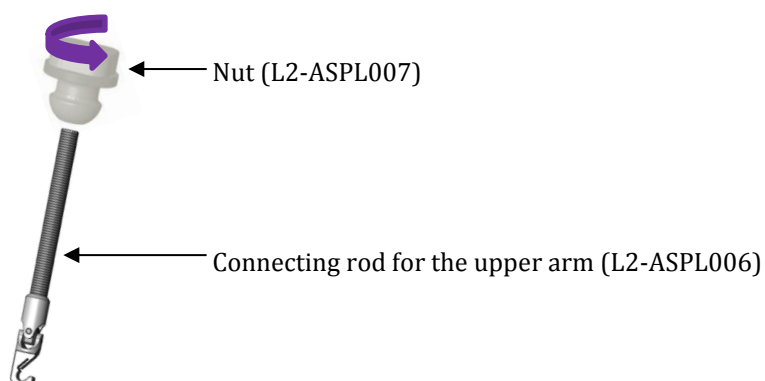
To change the lower arm position:

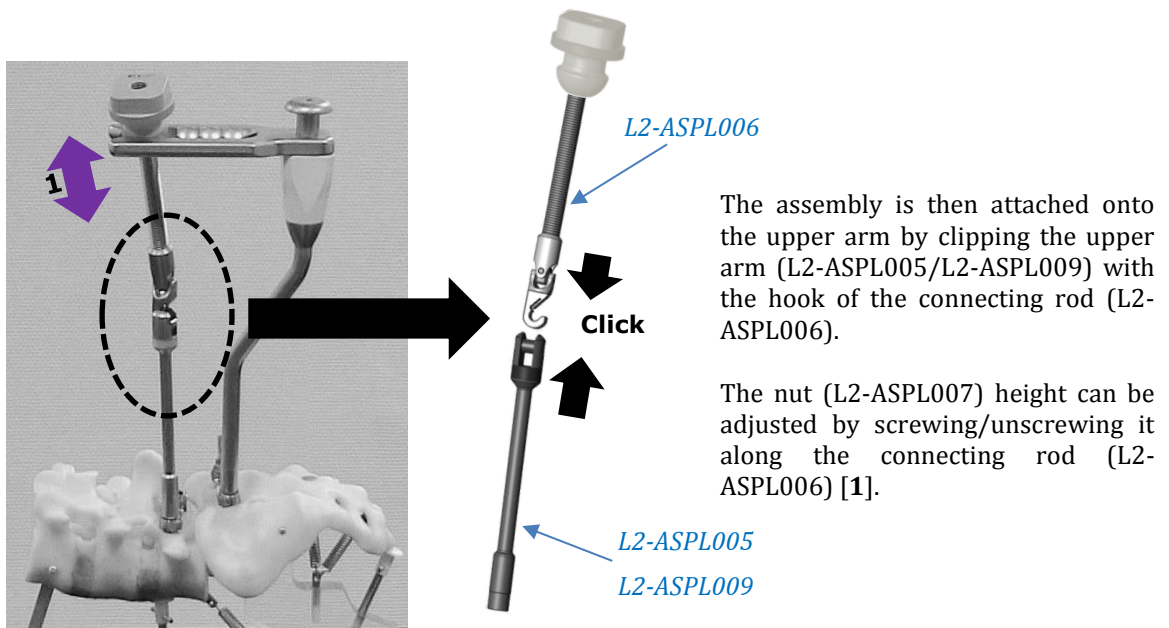


1. Lift the arm
2. Turn the arm

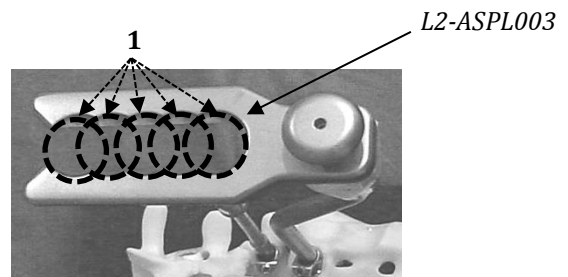
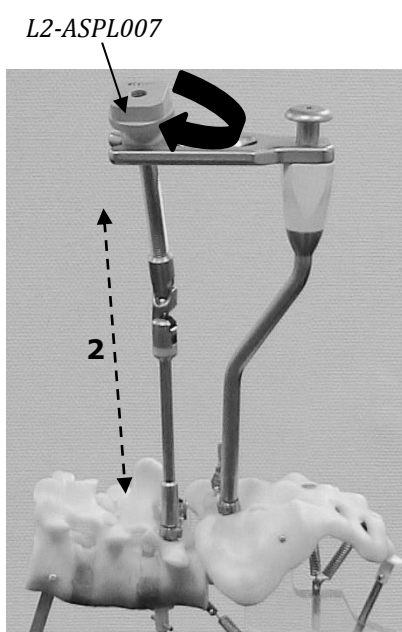
Step4: Upper arm insertion

Some parts of the upper arm must be preassembled outside the operating field before loading on the caudal adaptor.





Step5: Positioning the upper arm in the lower arm



Introduce the upper arm in the lower arm by sliding it inside the fork (L2-ASPL003) and screw the nut (L2-ASPL007) until its bottom gets in contact with the fork.

Five possible positions [1] are available to position the nut inside the fork to fit the anatomical condition of the patient.

To start reduction, it is recommended to align the fork with the screw as in the picture [2].

Repeat previous steps on the other side to place the second similar instrument.

Note: it is possible to introduce both instruments simultaneously.



Step6: Reduction maneuver



Once the appropriate position has been chosen, turn the nuts carefully to start reducing the Spondylolisthesis.

It is recommended to perform reduction under radiographic surveillance. Turn both nuts carefully and simultaneously to avoid any axial torsion of the lumbar spine.

Thanks to its design, UNI-Thread™ Spondylolisthesis Reduction can be stopped whenever it is necessary (millimetric reduction).

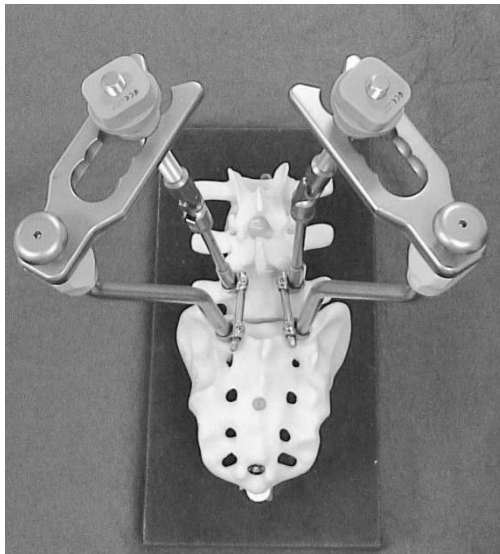
Note: It is recommended to perform a PLIF or TLIF procedure with SpaceVision™ PLIF or SpaceVision™ TLIF cages systems for example after the reduction to ensure its maintenance.

SpaceVision™ PLIF and SpaceVision™ TLIF systems are Not for Sale in the U.S.A.

Step7: Rod insertion

Preliminary checking:

Check the position of the setscrew of connectors, which could prevent the rod from being inserted.



U1-A214



U1-A213N1

Insert the rods with rod holder (U1-A214 /U1-A213N1).

To facilitate loading of the rod, the long T20 screwdriver (U1-A415) can be used to position the connector more horizontally.



U1-A415



Step8: Construct fine tuning

Before final tightening, it is possible to adjust the position of the rod using the hex wrench (U1-A344(N1)) on the hex extremity of the rod.



U1-A344N1

If necessary, the spreader (U1-A342) and offset compressor (U1-A343) allow correction operations in the sagittal plane.



Spreader U1-A342

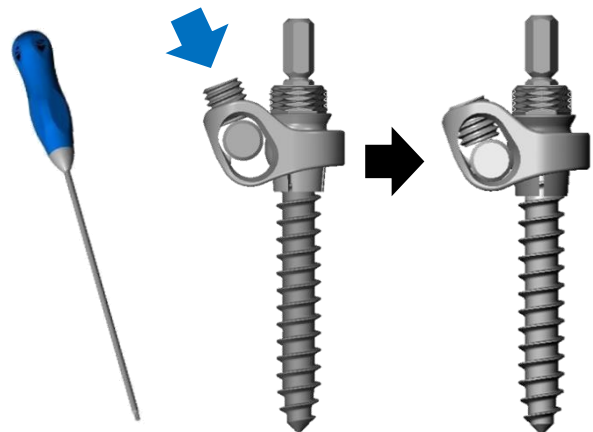


Offset compressor U1-A343

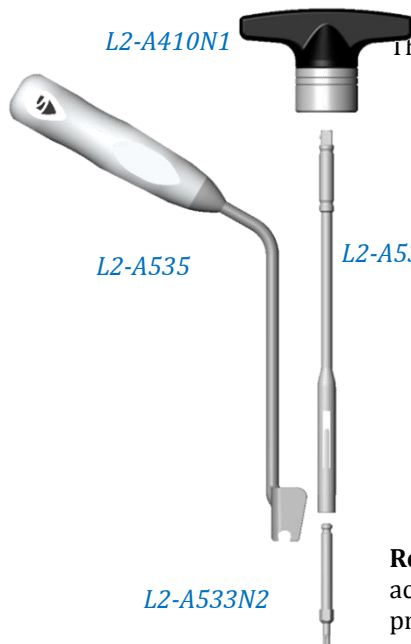
The offset compressor (U1-A343) has jaw spacing adjustment to allow the implant compression to be optimized.

Provisional tightening can then be done in a sequential manner with the long T20 screwdriver (U1-A415).

- Lock first the connectors of the lower vertebra (left and right side)
- Then, lock the connectors of the upper vertebra (left and right side).

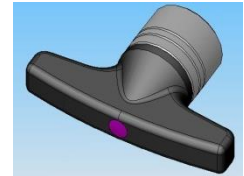


Step9: Final tightening



The final tightening is performed using:

- The torque limiting T-handle (L2-A410N1) which releases at 9 Nm.
- The long T20 holder shaft (L2-A534N1)
- The long T20 tip (L2-A533N2)
- The counter torque (L2-A535)

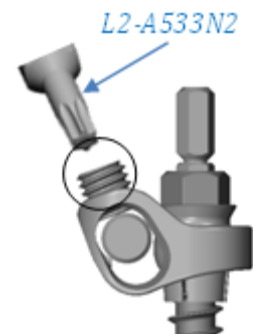


Remark: the counter torque instrument (L2-A535) protects against accidental slippage from the set screw during tightening and also prevents transmission of torque to the instrumented spine segment

Final tightening is applied on the locking set screw.

The recommended tightening sequence is:

1. Dismantle the instrument at the right side.
2. Perform the final tightening of the right side.
3. Then, do the same manipulation on the left side.

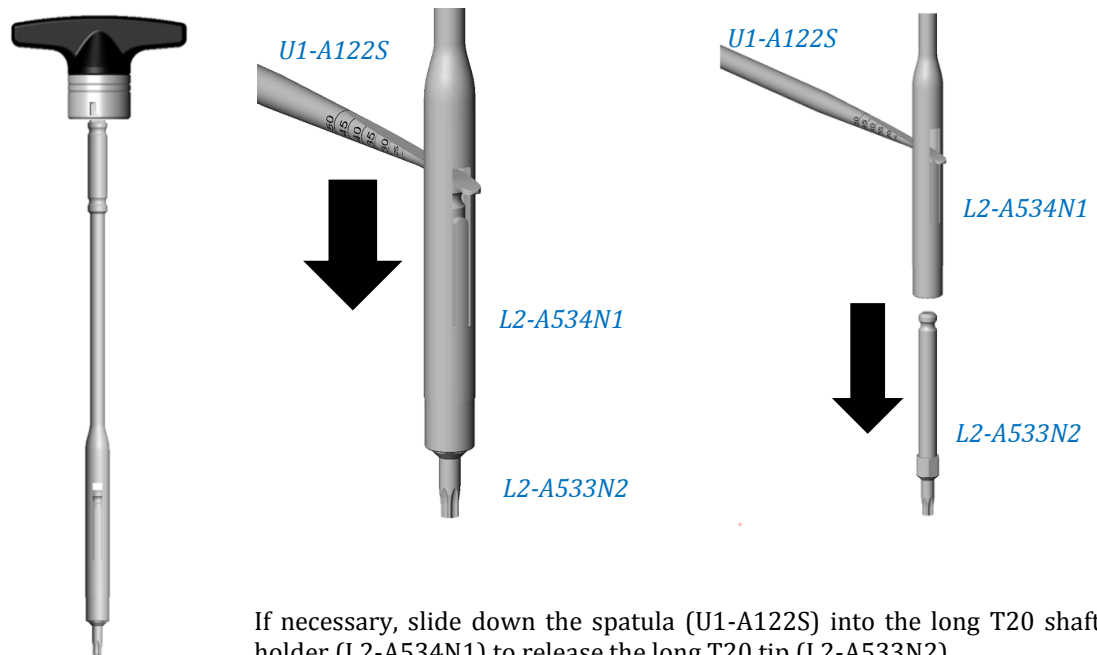
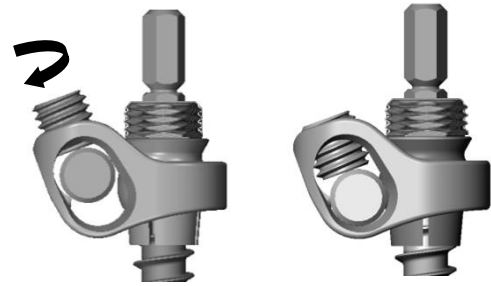


The locking set screw should be first carefully advanced in a sequential manner for every screw of the construct, until it is almost flush with the connector surface.

Then, the torque limiting T-handle (L2-A410N1) is tightened until the first click can be heard.

Final tightening is obtained once 3 successive clicks have been heard.

Note: It is recommended to wait between two consecutive clicks so that the torque limiting can release and apply optimal torque.

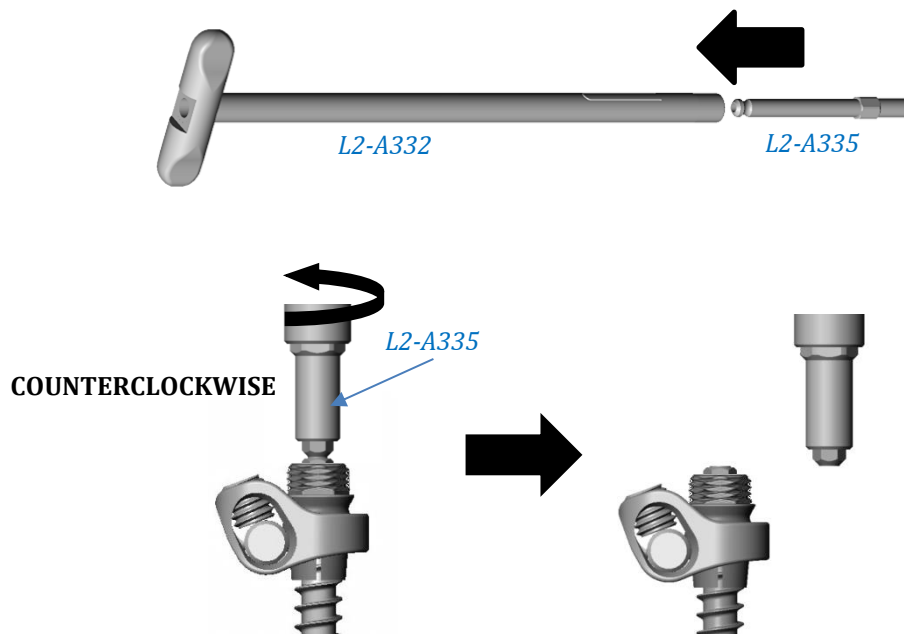


If necessary, slide down the spatula (U1-A122S) into the long T20 shaft holder (L2-A534N1) to release the long T20 tip (L2-A533N2).

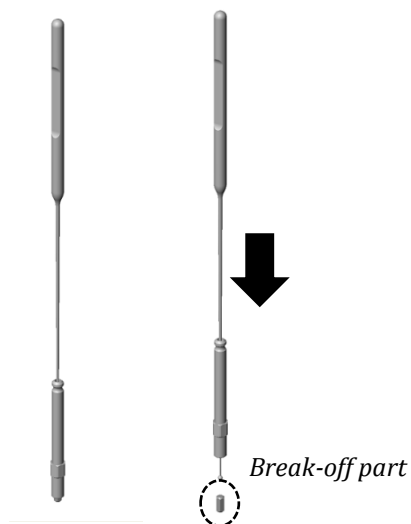
Evidence of proper final tightening:

Breakage of the hexagonal post will confirm that sufficient final torqueing has been achieved.

- Assemble the nut driver (L2-A332) and the tip for breakage (L2-A335).



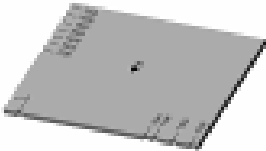


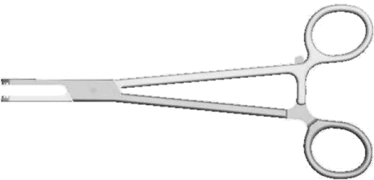

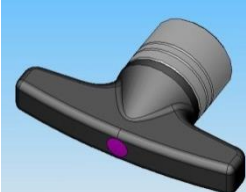
- Slide the tip for breakage on the screw hex post
- Turn the L2-A332, L2-A335 assembly **COUNTERCLOCKWISE** until post breaks.



Break-off part can be removed from the tip for breakage (L2-A335) using the pedicle probe (U1-A124N1)

Placing transverse connection systems

PRESENTATION OF INSTRUMENTS

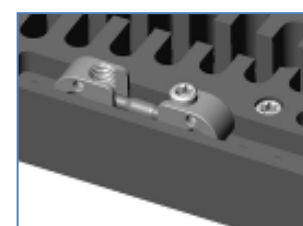
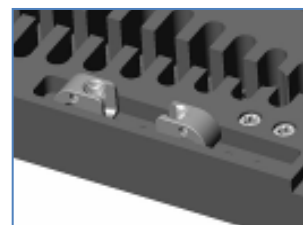
		
<i>Gage for transverse connectors U1-A325</i>	<i>Locking screw holder U1-A215</i>	<i>Transverse connector support U1-MTRAB(T)</i>
		
<i>Universal implant holder U1-A211</i>	<i>T20 Shaft U1-A416</i>	<i>Torque limiting T-handle L2-A410N1</i>

Note: Because there is a risk that final tightening might not be possible beside transverse connectors, it is important to insert the transverse connectors after final tightening of the connectors.

TRANSVERSE MULTI-AXIAL CONNECTOR CASE (L2-T610T)

Use the gage for transverse connectors (U1-A325) to determine the length of the transverse bar

- ✓ Remove the set screw from the two transverse connectors using the locking screw holder (U1-A215).
 - ✓ Use the transverse connector implants holder to hold them and position the two connectors in the housing provided for them.
-
- ✓ Insert the spherical ends of the selected transverse bar into the two connectors.
 - ✓ Reinsert the set screw making a single turn of the set screw by using the locking screw holder (U1-A215).
-
- ✓ Offer up the complete assembly with both universal implant holders (U1-A211) or by combining a universal implant holder (U1-A211) with the locking screw holder (U1-A215).



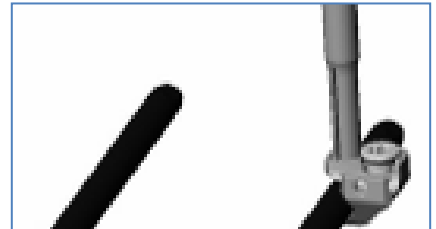
Final tightening of the connectors is then done by using the T20 shaft (U1-A416) and the corresponding torque limiting handle (L2-A410N1).

FIXED TRANSVERSE CONNECTOR CASE (L2-T613T)

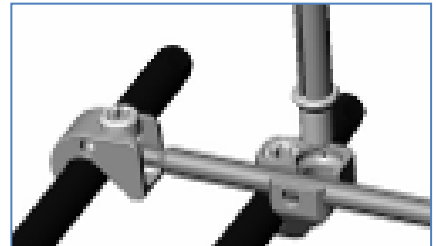
- ✓ Remove the set screw from a transverse multi-axial connector using the locking screw holder (U1-A215). Insert the spherical end of the transverse bar into the connector. The excess part of the transverse bar can then be cut.
- ✓ Reinsert the set screw by one turn of the set screw.



- ✓ Offer up the fixed transverse connector with the locking screw holder (U1-A215).
- ✓ Loosen both set screws.
- ✓ The fixed transverse connector can then be clamped onto the rod.



- ✓ Insert the multi-axial connector and the transverse bar onto the other rod by positioning the bar in the transverse fixed connector.



- ✓ Final tightening of all the screws is then done by using the T20 shaft (U1-A416) and the corresponding torque limiting handle (L2-A410N1)

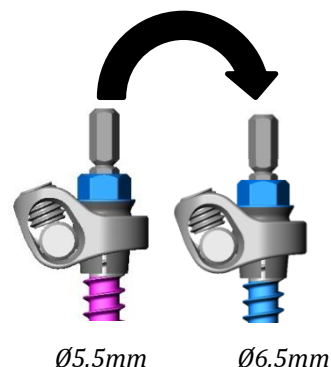


System Revision

Screw change

DIAMETER CHANGE

Due to the unique design of this smooth post screw, a Ø5.5 mm smooth post screw can be replaced by a Ø6.5 mm screw through the Ø6.5 mm connector in place



LENGTH CHANGE

Even after the rod and the connectors are in place, any screw can be exchanged for a longer (or shorter) screw of the same diameter (same color) **except for 8,5mm diameter screws.**

Material removal

REMOVING TRANSVERSE CONNECTION SYSTEMS

Use the long T20 tip (L2-A533N2) preassembled with the long T20 shaft holder (L2-A534N1) and the Torque limiting T-handle (L2-A410N1) to loosen the fixed and/or multi-axial transverse connectors set screws and withdraw the transverse connections using the universal implant holder (U1-A211).

REMOVING THE RODS

Loosen the connectors setscrews with the long T20 tip (L2-A533N2) preassembled with the long T20 shaft holder (L2-A534N1) and the Torque limiting T-handle (L2-A410N1) whilst maintaining the counter-torque (L2-A535) on the assembly and use the rod holder (U1-A214) to remove the rod from the connectors.

REMOVING THE CONNECTORS

Use the nut drivers (L2-A332 or L2-A337 according to the connectors diameters) to remove the connectors.

REMOVING THE SCREWS

Use the straight ratcheting handle (L2-A411) assembled with the shaft for pedicle screwdriver (L2-A632N2) to unscrew the screws.



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