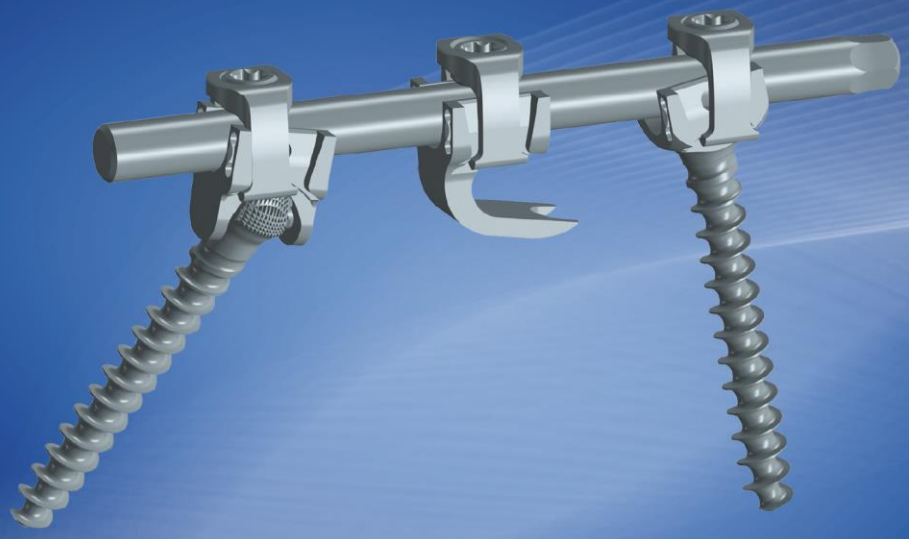
+Plus®

Pivot Link Universal System



Surgical Technique

SpineVision®

Innovation that matters

Pivot Link Universal System

Surgical Technique

English Version

Reference document: GU1-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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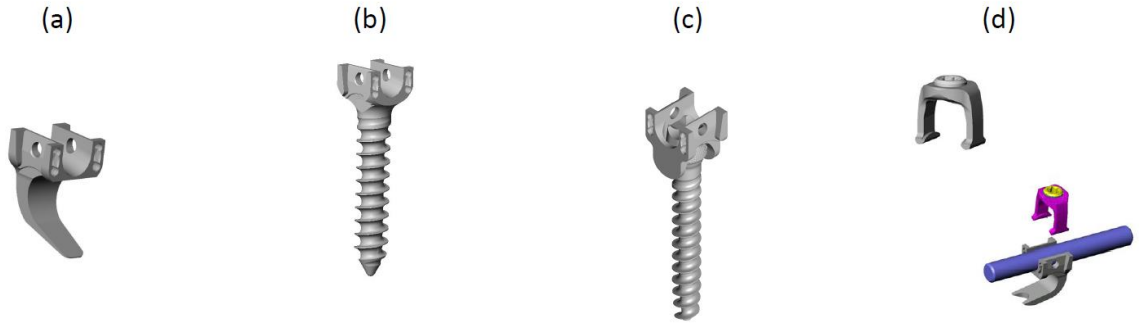
General Description of the System

The Pivot Link Universal System (P.L.U.S.®) has been designed for the surgical correction and stabilization of the spinal column during the development of bone fusion.

The components of the P.L.U.S.® system are made of "INOX" stainless steel (ASTM F138 and ASTM F1586 – ISO 5832-1 and ISO 5832-9) or Titanium alloy Ti-6Al-4V (ASTM F136) and pure Titanium (ASTM F67 – ISO 5832-3 & ISO 5832-2). The distinction between "INOX" implants and "Titanium" implants is made by the presence of a T at the end of the reference when the implant is in Titanium.
Unless otherwise stated, the implants presented in this document are available in "INOX" and in "Titanium".

The system comprises hooks (a), monoaxial vertebral screws (b) and multi-axial vertebral screws (c) fixed onto the vertebra and linked together by two rods. The implants are connected to the rod by a "clip" connector (d) that forms part of the pivoted connection of the implant with the rod.

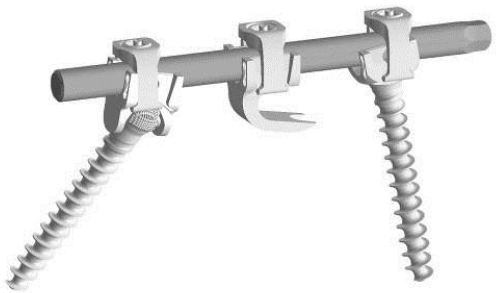


The P.L.U.S.® system is designed to permit surgical orthopaedic treatment of spinal, traumatic, tumour, degenerative and deformative thoracolumbar pathologies of adults and children.
With scoliosis, it permits the combined use of different surgical correction techniques such as:

- Rod rotation
- Distraction/Compression
- In-situ bending
- Translation

The Direct Vertebral Derotation Technique can be easily used in indications of rib hump reduction without associated thoracoplastic actions, so reducing morbidity.

The concept offers versatility and reduction power in an extremely small implant volume.



Presentation of Implants

Pedicle Screws

TECHNICAL CHARACTERISTICS

- ✓ They have a cylindrical core threaded part
- ✓ Their design offers very good pull out resistance
- ✓ Extended range, up to the upper thoracic vertebra

Remark: How do I read a U1-**TDLL**(T) screw reference?

U1-	T	D	LL	(T)
	S (= monoaxial screw)	Indicates the diameter of the threaded part in mm to which 0.5mm must be added	Indicates the length of the threaded part of the screw in mm	Indicates whether the implant is in Titanium
	M (= multi-axial screw)			

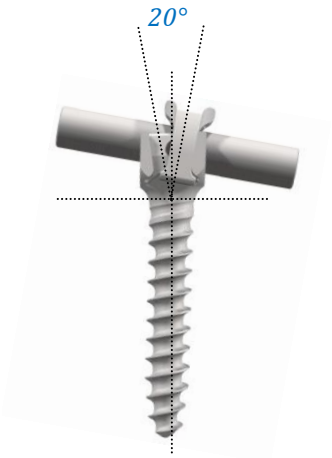
Example: U1-S430T is a Titanium monoaxial screw with threaded part diameter 4.5mm and length 30mm.

MONOAXIAL SCREW U1-SXXX(T)

❖ Description

- ✓ Low profile
- ✓ Transverse stability for optimum correction

The screw head cradle, which is convex in the sagittal plane, allows the clip to move through 20°, optimum load distribution between the screws, and limits bone stresses.



Monoaxial screw U1-SXXX(T)

❖ Available range:

Refer to the P.L.U.S.® set composition for more information (Document R-RA23).

Stainless steel (U1-SXXX):

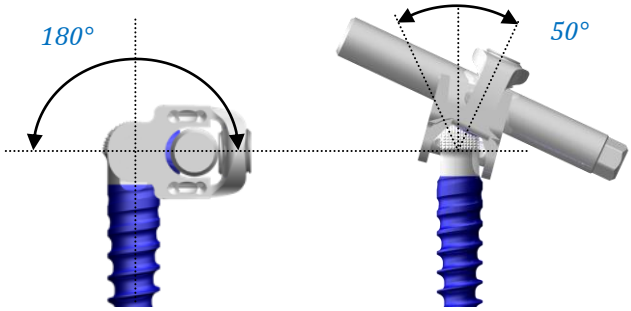
Length/Diameter (in mm)	4.5	5.5	6.5	7.5	8.5
20					
25					
30					
35					
40					
45					
50					
55					
60					
65					
70					
75					
80					
85					
90					

Titanium (U1-SXXXT):

Length/Diameter (in mm)	4.5	5.5	6.5	7.5	8.5
20					
25					
30					
35					
40					
45					
50					
55					
60					
65					
70					
75					
80					
85					
90					

MULTI-AXIAL SCREW U1-MXXX(T)

❖ Description



Lateral mobility *Sagittal mobility*

❖ Anodisation

To ease their use in the operating room, the titanium multi-axial screws are anodised.

- Yellow: Diameter 4.5mm
- Pink: Diameter 5.5mm
- Blue: Diameter 6.5mm
- Green: Diameter 7.5mm
- Turquoise: Diameter 8.5mm

Note, the Stainless screws are not anodised.

❖ Available range

Refer to the P.L.U.S.® set composition for more information (Document R-RA23).

Stainless steel (U1-MXXX):

Length/Diameter (in mm)	4.5	5.5	6.5	7.5	8.5
20					
25					
30					
35					
40					
45					
50					
55					
60					
65					
70					
75					
80					
85					
90					

Titanium (U1-MXXXT):

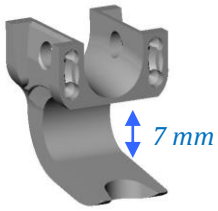
Length/Diameter (in mm)	4.5	5.5	6.5	7.5	8.5
20					
25					
30					
35					
40					
45					
50					
55					
60					
65					
70					
75					
80					
85					
90					

Hooks U1-HXXX(T)

PEDICLE HOOKS

❖ Pedicle hook – U1-H100(T)

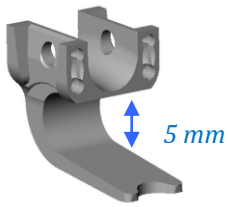
- ✓ Low height
- ✓ Bifid blade
- ✓ Easy adapted to upper thoracic levels



U1-H100(T)

❖ Small pedicle hook – U1-H101(T)

- ✓ Reduced groove depth for paediatric mounting
- ✓ Can be used when inferior articular thickness is small for an optimal anatomic adaptation

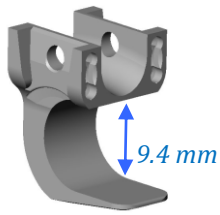


U1-H101(T)

LAMINAR HOOKS

❖ Laminar hook – U1-H200(T)

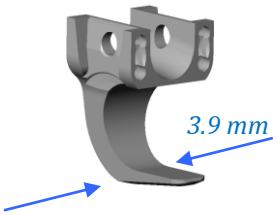
- ✓ For lumbar infra-laminar positions
- ✓ Can also be used as a transverse hook
- ✓ Reduced height to allow claws on the same vertebra



U1-H200(T)

❖ Narrow laminar hook – U1-H201(T)

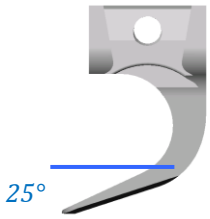
- ✓ Gradually reduced blade to avoid the risk of overlapping blades inside the canal when two hooks are placed at the same level
- ✓ Can also be used as a transverse hook



U1-H201(T)

❖ Angled laminar hook – U1-H202(T)

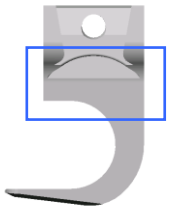
- ✓ Special design for the infra laminar position in the lumbar region permitting better contact with the lower part of the lamina.



U1-H202(T)

❖ Tall body hook – U1-H203(T)

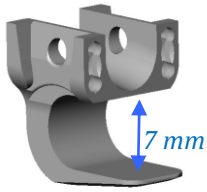
- ✓ The rod axis is positioned 5mm higher than with a classic laminar hook
- ✓ This eases the insertion of the rod in the sagittal plane when in a supra laminar position in the lumbar region
- ✓ It can be used in combination with the angled laminar hook as a "inverted claw", i.e. when the hooks are placed back to back in the same inter vertebral space



U1-H203(T)

❖ Small laminar hook – U1-H204(T)

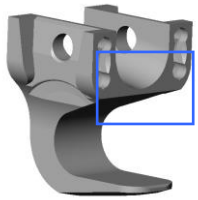
- ✓ Reduced groove depth for low profile
- ✓ Can also be used as a transverse hook



U1-H204(T)

❖ Oblique laminar hook– U1-H300(T)

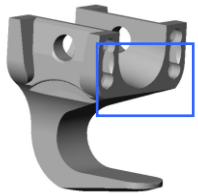
- ✓ Oblique in the upper part of the groove to reduce the risk of protrusion into the canal.



U1-H300(T)

❖ Narrow oblique laminar hook – U1-H301(T)

- ✓ The same functions as the U1-H300(T), but the blade width is reduced to avoid any overlapping into the canal when two hooks are on the same vertebra.



U1-H301(T)

❖ Right/Left offset hook –U1-H30R[*Right*]/L[*Left*](T)

- ✓ The blade is laterally displaced to facilitate a pedicle-laminar claw at the upper thoracic levels (T1-T2).

U1-H30R/L(T)

❖ Right/Left offset closed hook – U1-H20R[*Right*]/L[*Left*](T)

- ✓ This hook has a closed body with an offset blade.
- ✓ The rod is fixed by a 6mm set screw.
- ✓ The hook is specifically designed to be used in combination with pedicle screws to protect them at the construct extremities

U1-H20R/L(T)

➢ Temporary Blocker U1-L500T

Not for Sale in the USA

- ✓ This hook has a « C » shaped body and a set screw which enables to attach it onto a 6mm diameter rod.
- ✓ This Temporary Blocker is designed to maintain the position of the hook while performing the correction maneuvers.

U1-L500T

Rods U1-R6XXH(T)/U1-R6XXHS/L2-R6XXHT/U1-R6XXHC

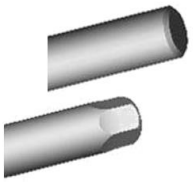
DESCRIPTION

The P.L.U.S.® system rods are 6mm diameter. They have a hexagonal end allowing better manipulation and better control of rotation.

MALLEABLE RODS

They withstand plastic deformation more easily and are particularly suited to in-situ bending.

- ✓ Malleable stainless steel rod: U1-R6XXH
- ✓ Malleable titanium rod: U1-R6XXHT



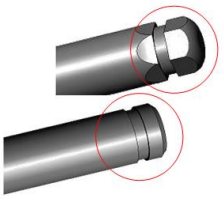
Remark: For patients with doubtful bone quality or patients needing excessive rod curvature, it can be appropriate to use a malleable rod on one side and a rigid rod on the other side.

RIGID RODS

Rigid rods are used where long assemblies needing reduction manoeuvres by rod rotation or translation are indicated.

- ✓ Rigid stainless steel rod: U1-R6XXHS
- ✓ Rigid titanium rod: L2-R6XXHT

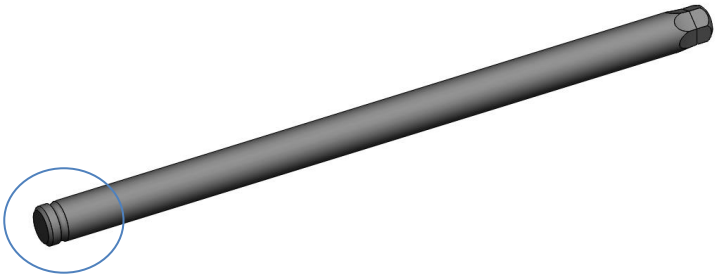
A groove at each end permits rapid identification of the rigid rods in the box.



- ✓ Chromium-Cobalt rod : U1-R6XXHC

Not for Sale in the USA

The Chromium-Cobalt rod has only one groove at one end.



AVAILABLE RANGE

Standard rods are supplied 420mm long for both rigid and malleable versions. On request, 600mm long rods or shorter rods are available.

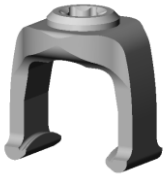
Refer to the P.L.U.S.® set composition for more information (Document R-RA23).

Clips U1-L100(T)

DESCRIPTION

Key system component for optimum screw/hook-rod connection.

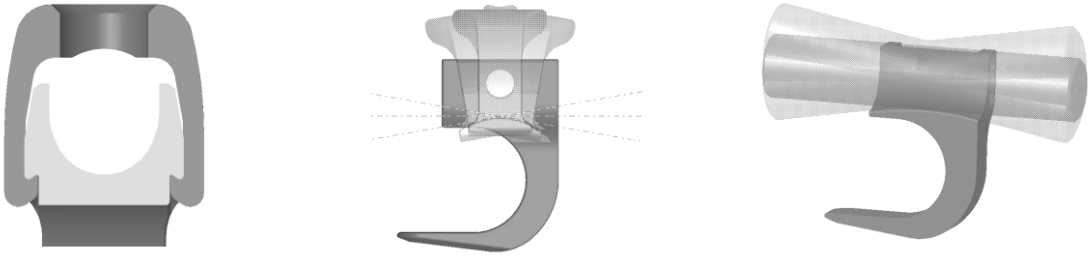
- ✓ Pre-loaded set screw – no risk of incorrect engagement
- ✓ Simplifies implant closure
- ✓ Solid assembly of implant and clip
- ✓ Audible "click" check when put in place



U1-L100(T)

PIVOT CONNECTION

The clip closes the implant imprisoning the rod. Clip pivoting on the implant body is permitted by its two protrusions that slide along the semi-circular groove machined in the implant body.
The clip can then be fixed in an ideal position within a 20° range in the sagittal plane by tightening the pre-installed set screw.
The clip provides excellent resistance to rod sliding and can be withdrawn without damaging the implants.



Rod connectors

DUAL CONNECTOR U1-L301(T)

- ✓ To connect two rods in parallel

U1-L301(T)

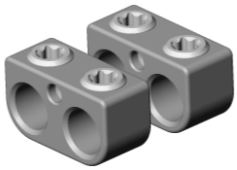
AXIAL CONNECTOR U1-L302(T)

- ✓ To connect two rods on the same axis
- ✓ Frequently used at thoracic level

U1-L302(T)

SMALL DUAL ROD CONNECTOR U1-L303(T)

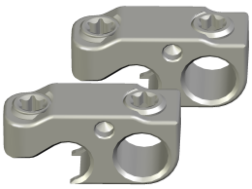
- ✓ For parallel connection
- ✓ Small dual rod connectors must be used in pairs
- ✓ The small dual rod connectors replace the dual connector when the anatomical configuration or assembly related constraints do not permit it



U1-L303(T)

SMALL ALTERNATE OPEN DUAL ROD CONNECTOR U1-L310(T)

- ✓ For parallel lumbar level connection
- ✓ Small alternate open dual rod connectors must be used in pairs
- ✓ They can be positioned side by side on the rod or on either side of an implant



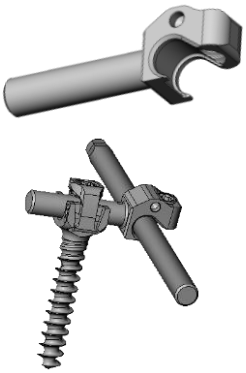
U1-L310(T)

Lateral connectors

LATERAL CONNECTOR U1-L400(T)

- ✓ 30mm rod
- ✓ Click fit auto stable connector with integrated lock
- ✓ Permits connection to the longitudinal rod with unaligned screws and iliac screws

For optimal strength in ilio-sacral assemblies, the iliac screw must connect to the lateral connector at 90. It also must connect to the longitudinal rod below screw at S1.



U1-L400(T)

LONG TI LATERAL CONNECTOR U1-L400LT

Only available in titanium

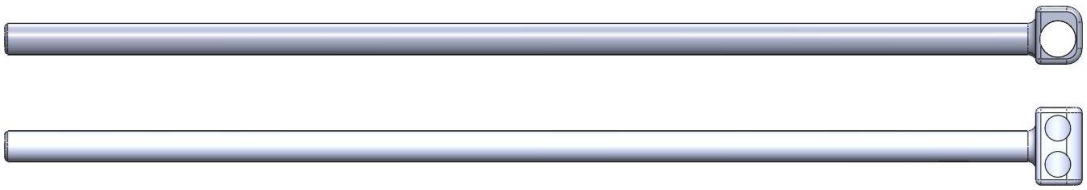
- ✓ 90mm rod
- ✓ Click fit auto stable connector with integrated lock
- ✓ Permits connection to the longitudinal rod with unaligned screws and iliac screws

U1-L400LT

For optimal strength in ilio-sacral assemblies, the iliac screw must connect to the lateral connector at 90. It also must connect to the longitudinal rod below screw at S1. The 90mm rod portion of the lateral connector can be cut using the rod cutter.

LONG LATERAL CONNECTOR U1-L403T

Not for Sale in the USA
Only available in titanium



U1-L403T

The long lateral connector (U1-L403T) comprises a connection block and a 6mm diameter 200mm long cylindrical rod. Like the lateral connector (U1-L400T), it permits an assembly constructed on the spine to be linked to fixing components situated on the pelvis. The connection block part is positioned on the longitudinal rod of the scoliosis correction assembly and once the rod has been trimmed to length it is fixed to the pelvis by a screw inserted into the iliac wing.

TI CLOSED LATERAL CONNECTOR U1-L404T

Not for Sale in the USA
Only available in titanium

U1-L404T

The Ti closed lateral connector (U1-L404T) comprises a connection block and a 6mm diameter 90mm long cylindrical rod. Like the lateral connector (U1-L400T), it permits an assembly constructed on the spine to be linked to fixing components situated on the pelvis. The connection block part is positioned on the longitudinal rod of the scoliosis correction assembly and once the rod has been trimmed to length it is fixed to the pelvis by a screw inserted into the iliac wing.

Sacral fixations

SACRAL PLATES U1-P100LT & U1-P100RT

Not for Sale in the USA
Only available in titanium

U1-P100L/RT

The right (U1-P100RT) and left (U1-P100LT) sacral plates permit pelvic orientation correction and extend the fusion to the sacrum.

A sacral plate comprises the following components:

- An implant head with:
  - A cradle that permits the rod to pivot +/- 10° in the sagittal plane
  - A groove that retains the clip whilst permitting +/- 10° angular movement of the rod in the sagittal plane.
- Lateral sockets for the implant to be gripped by the lateral implant holder (U1-A212)
- 2 holes housing the Ø6.5mm bone screw
  - A hole for the screw in S1 with a guided tightening corner
  - A hole for the screw that will be inserted in S2

SACRAL SCREWS U1-P6XXT

U1-P6XXT

- ✓ Available in 6.5 mm diameter
- ✓ Lengths:
  - 30 mm - U1-P630T
  - 35 mm - U1-P635T
  - 40 mm - U1-P640T
  - 45 mm - U1-P645T

Iliac fixation systems

ILIAC SCREWS AND RODS

Only available in stainless steel

❖ Iliac screws U1-FXXX

- ✓ Identical screw head design permitting clip connection and 20° movement
- ✓ The threaded part of the screw engages when the screw is half inserted. It provides the force to terminate screw insertion.
- ✓ Blunt end to allow the screw to be guided into the iliac wing. The end of the screw slides on the internal face of the cortical walls and easily penetrates into the spongy bone

U1-FXXX

❖ Iliac rods U1-IR600R/L

- ✓ Optimum for correcting oblique pelvises by detraction and/or compression actions between the main longitudinal rods and the iliac rods.
- ✓ Increased pre-curved iliac rod stability relative to lateral connectors.

U1-IR600R/L

ILIO-SACRAL FIXATION FOR PATIENTS WITH THIN ILIAC CREST

Not for Sale in the USA

❖ Ilio-S1 connectors U1-I600(T) and iliac screw-S1 U1-I7XX(T)

- ✓ Used to correct pelvic obliquity.
- ✓ Can be used for ambulatory patients because they permit micro-movements of the sacro-iliac articulation.
- ✓ Very suitable even for patients with extremely thin iliac crests.

U1-I600(T) & U1-I7XX(T)

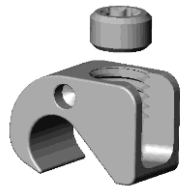
U1-I600(T)

U1-I7XX(T)

Transverse connection systems

MULTI-AXIAL TRANSVERSE CONNECTOR U1-T610 OR L2-T610T

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



U1-T610 or L2-T610T

BAR FOR MULTI-AXIAL TRANSVERSE CONNECTOR U1-T6XX OR L2-T6XXT

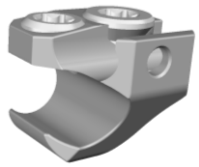
The multi-axial transverse connector bars are available in lengths from 20mm to 65mm in 3mm increments.

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

U1-T6XX or L2-T6XXT

FIXED TRANSVERSE CONNECTOR U1-T613 OR L2-T613T

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

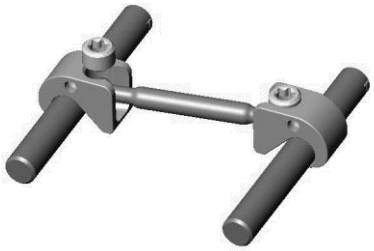


U1-T613 or L2-T613T

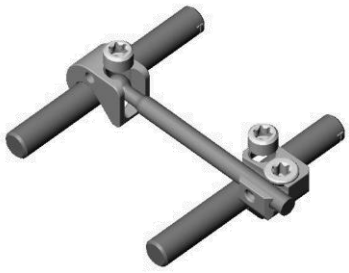
BAR FOR MULTI-AXIAL TRANSVERSE CONNECTOR / FIXED TRANSVERSE CONNECTOR U1-T614 OR L2-T614T

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.

U1-T614 or L2-T614T



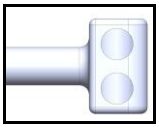
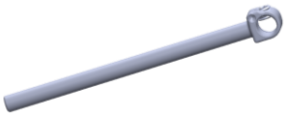
Connection assembly
for multi-axial transverse connectors



Connection assembly
for multi-axial / fixed

Set screws

There are two types of set screws: the flat end set screws and the spherical end set screws. The table below indicates the type of screw used for each implant.

Implant	Per implant	Per implant
Clip U1-L100(T)	1	0
Rod connectors U1-L301(T)	4	0
U1-L302(T)	4	0
U1-L303(T)	2	0
Small alternate open dual connectors U1-L310(T)	1	1
Connectors for transverse connection system U1-T610/L2-T610T	1	0
U1-T613/L2-T613T	2	0
Lateral connector U1-L400(T)	0	1
U1-L400LT	0	1
Long lateral connector **Not for Sale in the USA** U1-L403T 	2	0
Ti Closed lateral connector **Not for Sale in the USA** U1-L404T 	1	0

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

It can be necessary to tap the pilot hole to make the screw insertion secure.

Taps are available in 5 diameters:

- ✓ U1-A134, Ø4 mm tap
- ✓ U1-A135, Ø5 mm tap
- ✓ U1-A136, Ø6 mm tap
- ✓ U1-A137, Ø7 mm tap
- ✓ U1-A138, Ø8 mm tap

They connect to the dual purpose handle (U1-A622) or the straight ratcheting handle (L2-ALIS411) with which they must be assembled to be used.

The black button situated at the end of the dual purpose handle (U1-A622) is used to lock and release the tap shaft.

Two configurations can be obtained:

- ✓ The handle in line with the tap
- ✓ The handle forming a "T"

U1-A622

The dual purpose handle can be replaced by a straight ratcheting handle (L2-ALIS411).
Lift the handle trigger to assemble it to the tap.

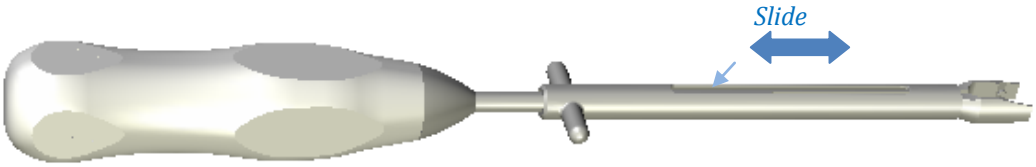
L2-ALIS411

INSERTING THE PEDICLE SCREWS

❖ Monoaxial screw U1-SXXX(T)

Use the pedicle screwdriver (U1-A231) with the screw support on a flat surface.

The pedicle screwdriver (U1-A231) has gripping jaws, it permits the screw to be withdrawn from the support without being touched.



U1-A231

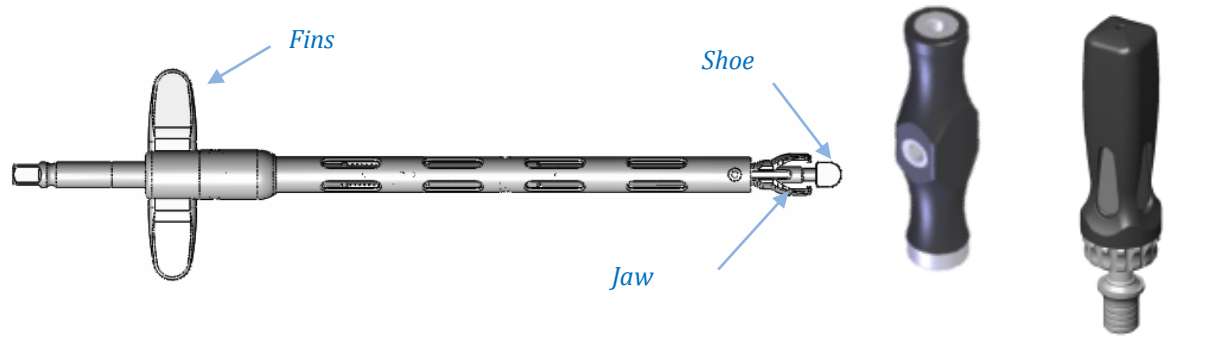
Tighten the screwdriver slide to move it down by using the fins. The two studs will come into position in the holes in the screw head.
The screw is ready for insertion.

Note: If it is difficult to remove the screwdriver at the end of screwing in, despite unscrewing the slide, it is then sufficient to rock the instrument slightly to remove the studs from the holes in the screw head.

❖ Multi-axial screws U1-MXXX(T)

The screwdriver for placing multi-axial screws comprises:

- ✓ The universal pedicle screwdriver (U1-A237)
- ✓ A handle (U1-A622 or L2-ALIS411 – refer to the section on tapping for more information about their use)

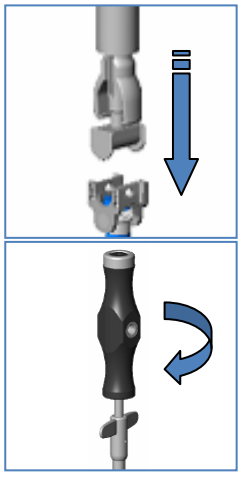


U1-A237 *U1-A622* *L2-ALIS411*

To guarantee correct position of the axis of the threaded part of the screw when putting it into the instrument, it is imperative that the multi-axial screw support is used during manipulation.

Ensure that the screwdriver tightening slide is in the upper position and that the screw cradle is accurately centred in the screw head.

Place the screwdriver shoe in the screw head, push the screwdriver down



Lower the tightening slide by using the fins. Both jaws then come into engagement in the notches in the screw head, so fixing it to the screwdriver. Extract the screw from its support and insert it.

Note: If it is difficult to remove the screwdriver at the end of screwing in, even with the slide in the upper position, it is then sufficient to press along the instrument axis to remove the jaws from the notches in the screw head.

❖ Manipulating the screws

It is possible to adjust the screw insertion depth by using the screw repositioner (U1-A251).

U1-A251

It is possible to manipulate the screws by using the universal implant holder (U1-A211) or the lateral implant holder (U1-A212).

U1-A211

U1-A212

Preparing and placing the hooks

PREPARATION

The P.L.U.S.® system offers feelers to prepare the hook locations on the pedicles, the lamina and the transverse processes.

Pedicle feeler U1-A111

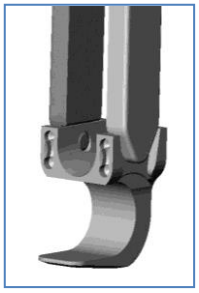
Lamina feeler U1-A112

Transverse process feeler U1-A113

MANIPULATING THE HOOKS

Once the locations on the lamina or transverse processes have been prepared, the hooks are manipulated in placed using implant-holder clamps.

The universal implant holder (U1-A211) and lateral implant holder (U1-A212) are used to place laminar and transverse hooks.



Universal implant holder U1-A211
and laminar hook U1-H200(T)

Lateral implant holder U1-A212
and laminar hook U1-H200(T)

The Temporary Blocker (U1-L500T) is manipulated and placed using the Universal Implant Holder (U1-A211).

Universal implant holder U1-A211
Temporary Blocker U1-L500T

The hook pusher (U1-A222) and the lateral implant pusher (U1-A226) can also be used during these installation steps.

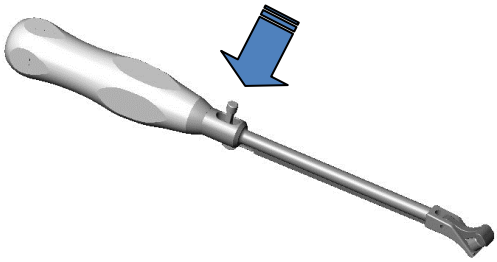
U1-A222

U1-A226

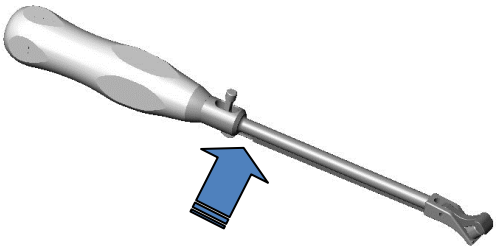
In addition to the preparation (Pedicle feeler U1-A111) and manipulation instruments (implant holders U1-A211, U1-A212, hook pusher U1-A222, lateral implant pusher U1-A226), the P.L.U.S.® system offers a hook holder-pusher (U1-A221) that allows hook preparation and placing.

Pedicle hook
U1-H100(T) on hook
holder-pusher U1-A221

To grip the pedicle hook: push the trigger to grip the hook, then press on the other side of the handle to fix the pedicle hook.



Opening the instrument



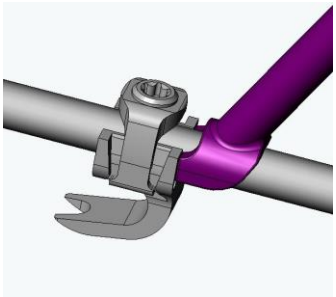
Closing the instrument

U1-A221

The hook re-positioner (U1-A227) allows the hook position to be modified.

U1-A227

End of U1-A227



U1-A227 pushing a pedicle hook U1-H100(T)

Use the Temporary Blocker (U1-L500T) to maintain the position of the hook on the rod.,

Use the long T20 screwdriver (U1-A415) to secure the Temporary Blocker by tightening the set screw.

Preparing and placing the rods

CUTTING THE ROD TO LENGTH AND BENDING IT

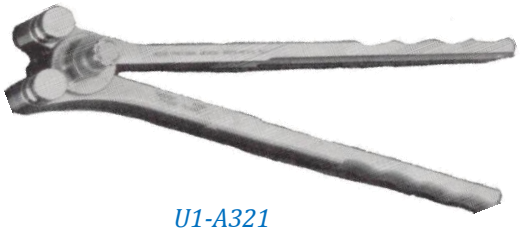
A graduated (in centimetres) Aluminium moldable rod template (U1-A324) is available to measure the definitive rod.

U1-A324

The rod cutter (U1-A241) is then used to cut the rod to length.

U1-A241

The french bender permits the rod to be given the desired curves.



U1-A321

PLACING THE ROD IN THE SCREWS AND HOOKS

The rod is placed in the implants using the rod holder (U1-A214). The hex wrench (U1-A344 or with open end U1-A344N1) permits the correct position of the rod in rotation to be checked.

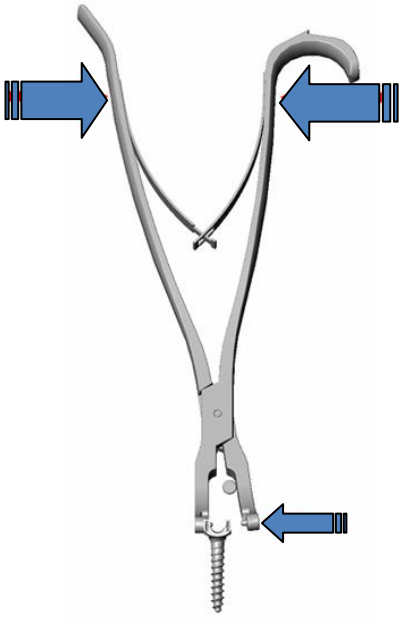
U1-A214

U1-A344N1

APPROXIMATION OPERATIONS

Use the rod pusher (U1-A224) or rod approximator (U1-A370) to permit the rod to be placed in the implants.

U1-A224



U1-A370

Correction operations

DISTRACTION/COMPRESSION

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

Spreader U1-A342

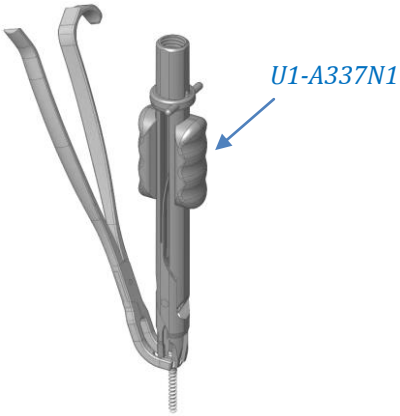
Offset compressor U1-A343

The offset compressor has jaw spacing adjustment to allow the implant compression to be optimised.

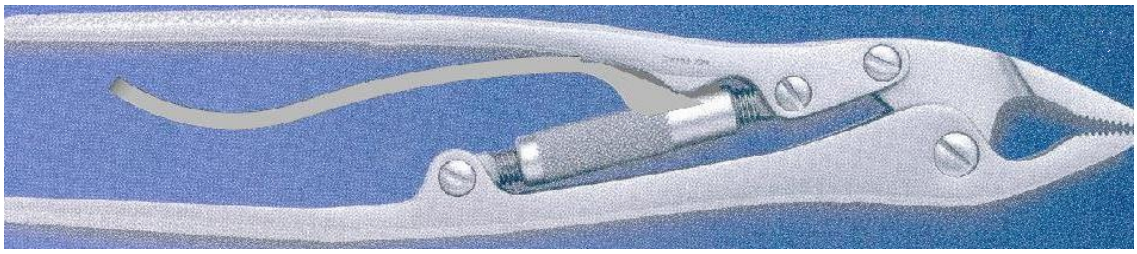
TRANSLATION

The rod approximator (U1-A370) can be used for rod translation when the rod is laterally positioned relative to the implants.
Once the instrument is closed, the clip guide (U1-A337 or U1-A337N1) can then be inserted and a sagittal reduction made by inserting the clip.

Refer to the 'Closing implants' section for more information on clip guides.



ROD ROTATION



U1-A311

Two standard rod grippers (U1-A311) are available for corrections by rod rotation.

IN-SITU BENDING

In-situ correction operations by bending can be done by using the frontal benders (U1-A326 & U1-A327) and in-situ benders (U1-A322 & U1-A323)

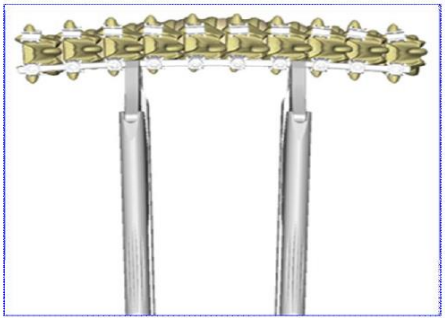
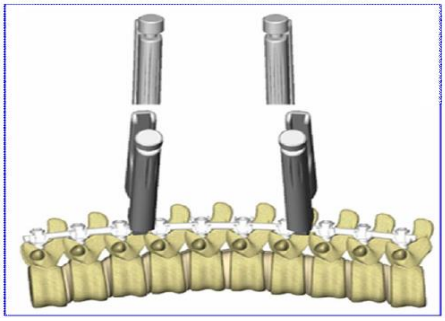
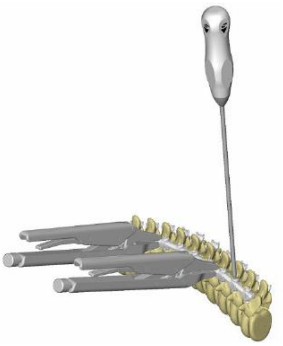
U1-A326 & U1-A327

U1-A322 & U1-A323

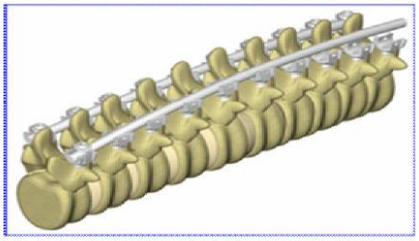
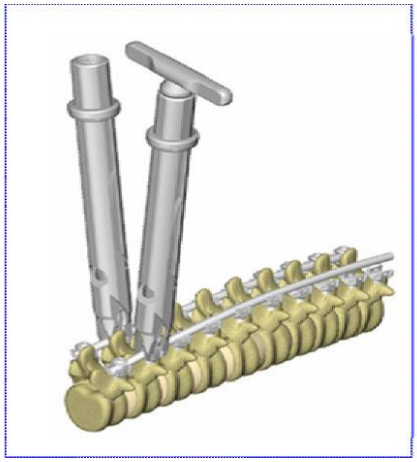
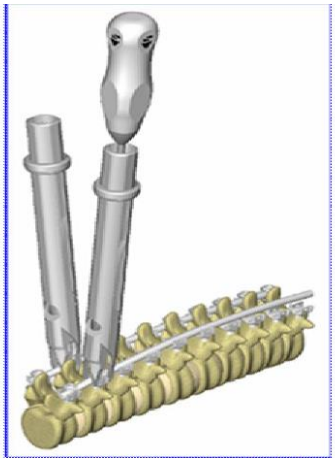
DIRECT VERTEBRAL DEROTATION

The Direct Vertebral Derotation technique comes as an addition to the usual correction techniques and permits to reduce rib hump.

ATTENTION: It can only be implemented when using monoaxial screws (U1-SXXX(T)) bilaterally and instrumented at all stages.

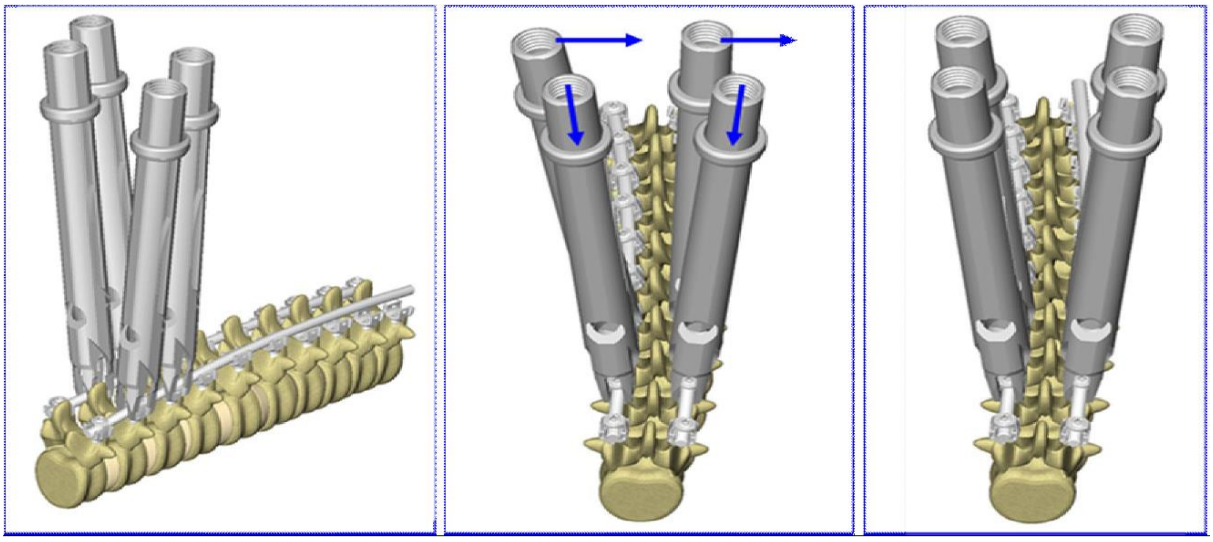




It is done following the rotation operation on the first rod situated on the concave side of the deformation.

Once the preliminary tightening has been done on the concave side implants, the second rod is put in place on the convex side. The lower neutral vertebrae are provisionally tightened using the long T20 screwdriver (U1-A415).

It is possible to use universal implant holder (U1-A211) to allow the rod position above the convex side implants to be maintained.



Clip guides (U1-A337) are positioned stage by stage on the levels underlying the lower neutral vertebra so as always to have at least two consecutive vertebrae equipped. The clip guides are then used to 'derotate' each of the vertebra individually using the directly underlying vertebra as reference. A clip is then introduced and tightening is done using the long T20 screwdriver (U1-A415).

Remark: refer to the 'locking implants' section for more information about manipulating the long T20 screwdriver (U1-A415)

Closing implants

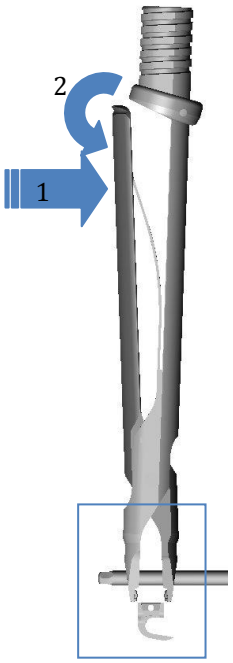
PRESENTATION OF INSTRUMENTS

Clip guide
U1-A337

Clip guide (with black handle)
U1-A337N1

Clip introducer
U1-A338

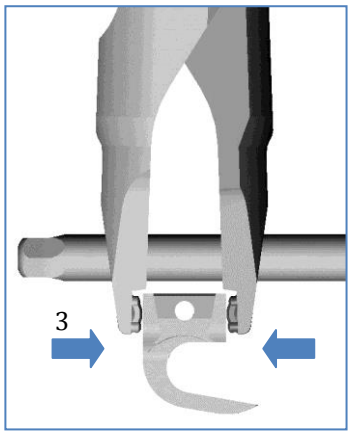
PLACING THE CLIP



❖ Step 1:

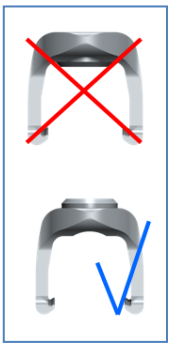
✓ Insert the clip guide onto the implant body and lock it. The male protrusions present at the distal end of the instrument must come into position in the female cavities situated on either side of the implants (screws or hooks)(3).

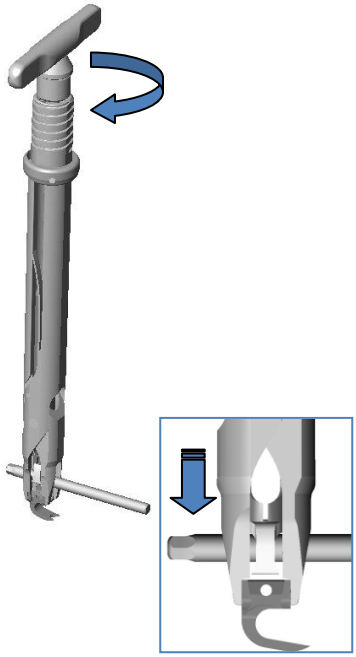
✓ The instrument (U1-A337 or U1-A337N1) is correctly positioned when the clip guide arm is closed (1) and the locking ring lowered (2).



❖ Step 2:

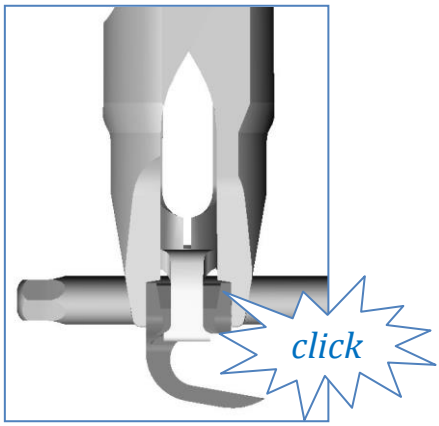
After checking that the set screw does not appear inside the clip, position the clip introducer (U1-A338) on the clip support and tilt it whilst pressing on it to grasp the clip.





❖ Step 3:

- ✓ Carrying a clip, the clip introducer (U1-A338) is inserted into the clip guide (U1-A337 or U1-A337N1).
- ✓ Screwing the clip introducer handle permits the rod to be progressively pushed to the bottom of the implant whilst inserting the clip.
- ✓ Inserting the clip is completed when the maximum screwing travel is reached. Generally, one or two "clicks" are heard at the moment when the clip is placed in position on the implant.
- ✓ Then unscrew the clip introducer and lift the ring from the clip guide to remove it from the implant.

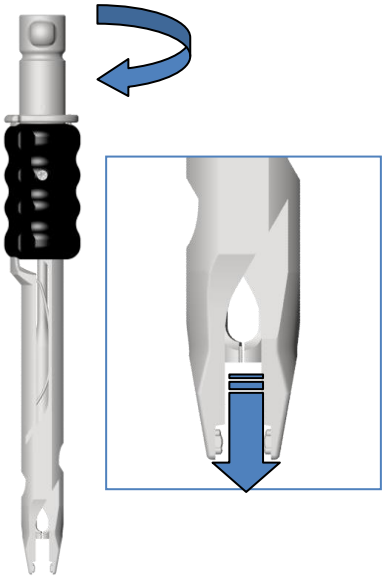


OTHER OPTION: USING THE QUICK CLIP INTRODUCER (U1-A362)

Remark: the quick clip introducer is not part of the standard P.L.U.S.® set composition.

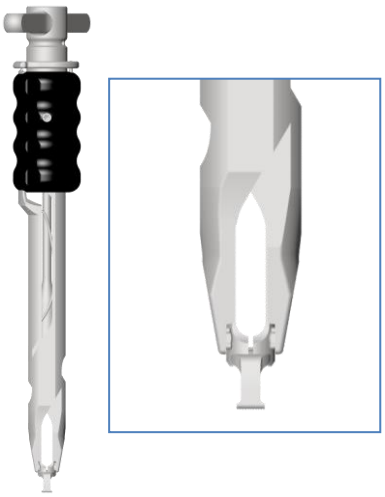
U1-A362

The quick clip introducer combines all the functions described above in a single instrument.



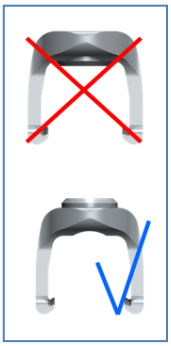
❖ Step 1:

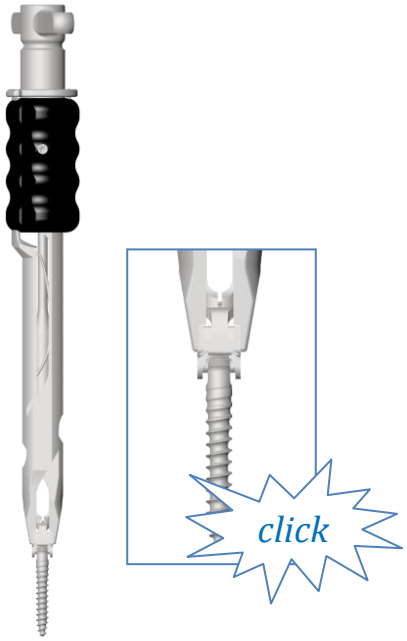
Turn the T handle until the end of the instrument passes the end of the clip introducer and a small click is heard.



❖ Step 2:

After checking that the set screw does not appear inside the clip, position the quick clip introducer (U1-A362) on the clip support and tilt it whilst pressing on it to grasp the clip.

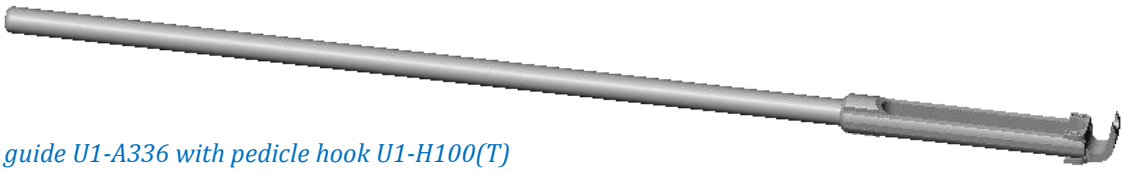




❖ Step 3:

- ✓ Unscrew the T handle to raise the clip.
- ✓ Reclose the quick clip introducer onto the implant. Compress the handle until the lock ring falls.
- ✓ Insert the clip whilst holding the instrument with one hand; turn the T handle clockwise with the other hand.
- ✓ Inserting the clip is completed when the maximum screwing travel is reached. Generally, one or two clicks are heard at the moment when the clip is placed in position on the implant.
- ✓ Use the thumb to open the closure ring whilst compressing the black handle. Release the instrument from the implant.

TIPS AND ADVICE ABOUT INSERTING CLIPS



Fork guide U1-A336 with pedicle hook U1-H100(T)

The fork guide (U1-A336) is useful for immobilising the rod on the implant and facilitates placing the clip guide. The fork guide remains in place until the clip guide is locked (U1-A337 or U1-A337N1).

The fork guide must be withdrawn before inserting the clip introducer.

ATTENTION: The fork guide is not compatible with the quick clip introducer (U1-A362).

Sometimes the bone can make clip insertion difficult so that it closes on the implant body without an audible click. If in doubt, the long T20 screwdriver (U1-A415) must then be used to provisionally tighten the clip set screw.

U1-A415

If the clip lifts or if the set screw can be turned without offering resistance, then the clip is not correctly inserted.
In this case:

- ✓ Loosen the set screw again and reposition the clip introducer (U1-A338) to attempt to insert the clip correctly in the implant
- ✓ Remove the clip (Then refer to the 'Material removal' section) and put a new one in place.
- ✓ In all cases, final tightening will ensure perfect fixing of the clip on the implant.

Note: Eye protection is recommended when inserting clips, because blood splashes can occur.

Locking implants

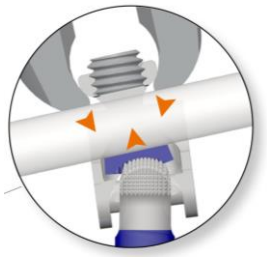
TEMPORARY TIGHTENING

U1-A415

- ✓ The long T20 screwdriver (U1-A415) is used for provisional tightening when making correction manipulations.
- ✓ The screwdriver can be used through the clip guide, which is useful in the direct vertebral derotation case.

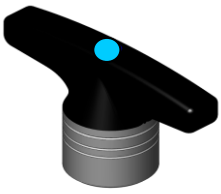
FINAL TIGHTENING

- ✓ Final tightening done with the counter-torque pliers (U1-A414) guarantees optimum positioning of the rod before application of the final tightening torque. This prevents transmission of the tightening torque onto the assembly and reduces the torque needed for final tightening.



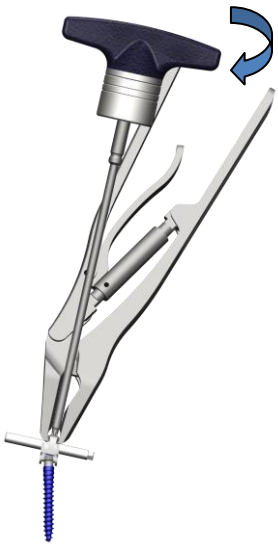
Counter-torque pliers
U1-A414

T20 Shaft
U1-A416



Handle with 6.5Nm torque limiter for PLUS™ Titanium U1-A418T (Blue plug)

Handle with 7.5Nm torque limiter for PLUS™ steel U1-A418 (Black plug)

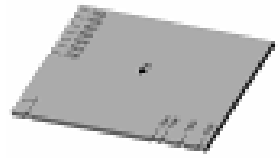


For tightening position the T20 shaft (U1-A416) so that it is supported on the counter-torque pliers.

The set screw must be tightened until the handle causes three successive clips to be heard.
Note: The clicks must be sufficiently spaced in time to obtain optimum tightening.

Placing transverse connection systems

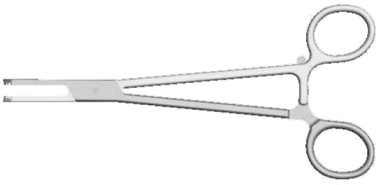
PRESENTATION OF INSTRUMENTS



Gage for transverse connectors
U1-A325

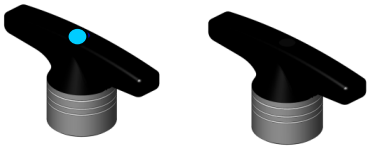
Locking screw holder
U1-A215

Transverse connector support
U1-MTRAB(T)



Universal implant holder
U1-A211

T20 Shaft
U1-A416



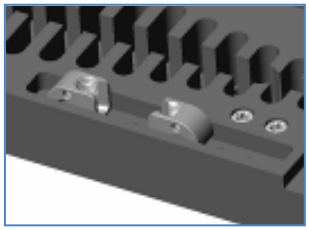
Torque limiting handles
U1-A418(T)

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 set screw.

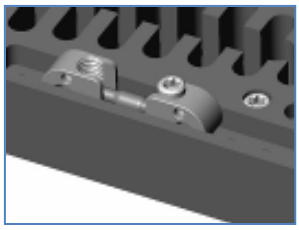
TRANSVERSE MULTI-AXIAL CONNECTOR CASE (U1-T610 OR L2-T610T)

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).



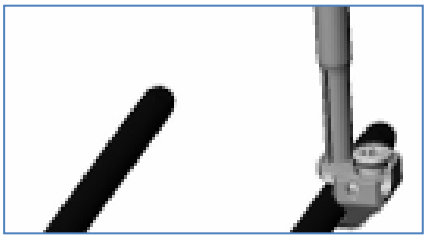
- ✓ Offer up the complete assembly with both universal implant holders (U1-A211) or by combining a universal implant holder (U1-A211) with the locking screw holder (U1-A215).

Final tightening of the connectors is then done by using the T20 shaft (U1-A416) and the corresponding torque limiting handle (U1-A418(T)).

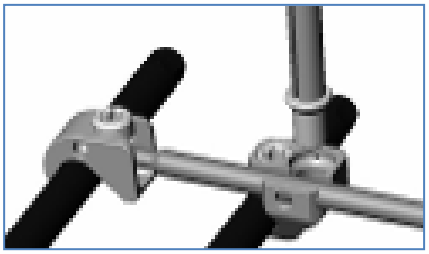
FIXED TRANSVERSE CONNECTOR CASE (U1-T613 OR L2-T613T)

- ✓ 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.

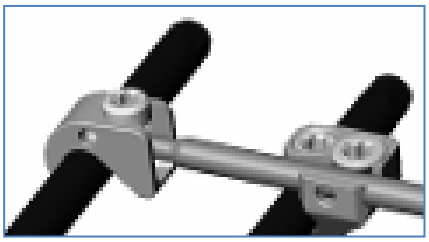
- ✓ Offer up the fixed transverse connector with the locking screw holder (U1-A215).
- ✓ Loosen both set screws.
- ✓ The fixed transverse connector can then be clamped onto the rod.



- ✓ 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 (U1-A418(T)).

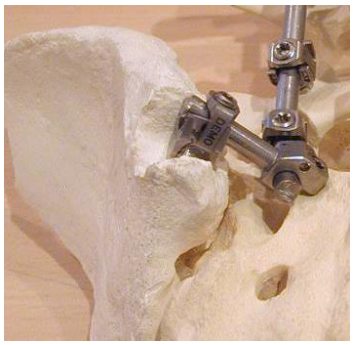


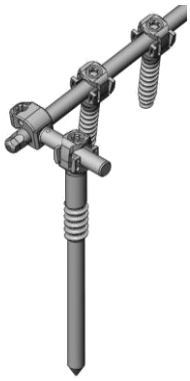
Putting pelvis fixation in place

USING LATERAL CONNECTORS U1-L400(T)/U1-L400LT AND U1-L403T

U1-L403T is Not for Sale in the USA

❖ Placing the screw in the iliac crest

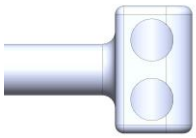




- Prepare and insert the screw into the iliac crest (U1-FXXX/U1-SXXX(T)/U1-MXXX(T)) according to the type of assembly that has been made.

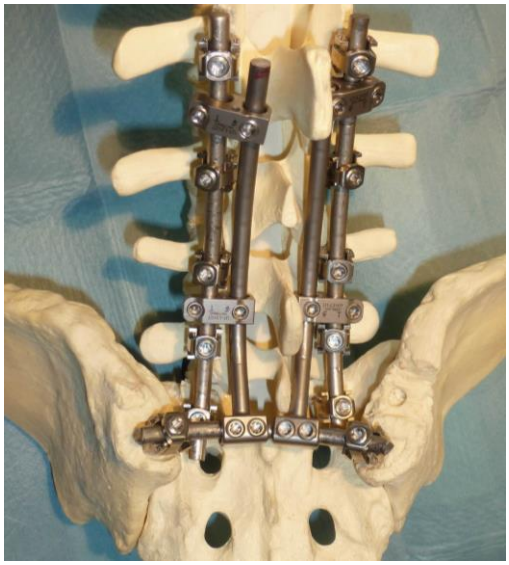
❖ Placing the connector

- Position the click in end of the lateral connector (U1-L400(T) / U1-L400LT) on the rod using the implant holder clamp (U1-A211).
- For the long lateral connector (U1-L403T), the longitudinal rod must be slid into the connector block (marked A on the image).



U1-L403T
(Top View)

U1-L403T
(Side View)



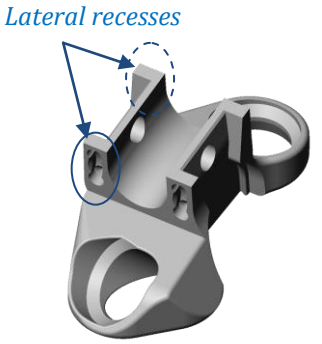
❖ Closing the implants and locking the longitudinal rod

- A clip then links the bar part of the connector with the iliac screw (refer to the Closing Implants Section for more information).

- Definitive locking of the click on part or the connection block on the rod is obtained by using the long T20 screwdriver (U1-A415) or the T20 shaft (U1-A416) pre-assembled with the appropriate torque limiting handle (U1-A418(T)) without releasing it.

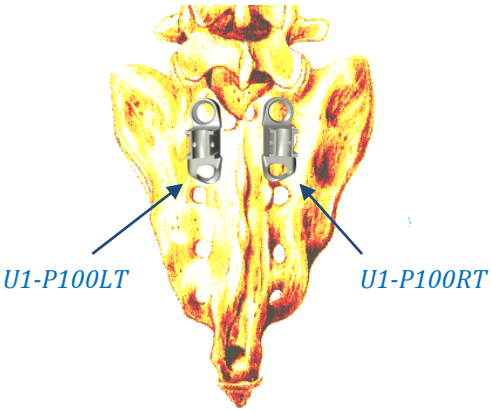
❖ Manipulating sacral plates

Position the sacral plates (U1-P100L/RT) relative to vertebra S1 and S2 by using the universal implant holder (U1-A211) or the lateral implant holder (U1-A212) mounted on the lateral recesses of the implant.



Right sacral plate - U1-P100RT

❖ Step 1: Positioning plates on the sacrum



The sacral plates are positioned as shown opposite relative to vertebra S1 and S2.

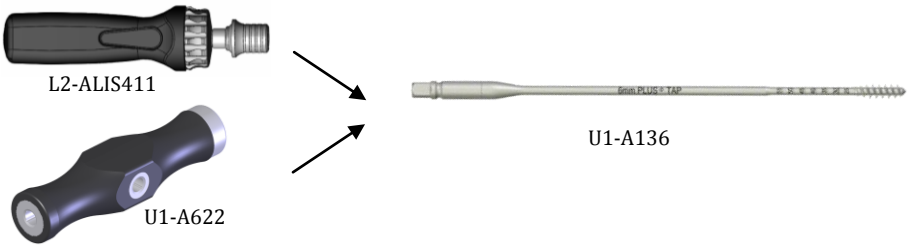
The convex side of the plate must be oriented towards the patient's median plane (the plate references indicate which side they must be positioned, U1-P100LT = left side, U1-P100RT = right side).

❖ Step 2: Preparing anchorages and placing the screws

Once the plates are positioned on the sacrum, the holes for the bone screws are prepared through the plate holes using the square awl (U1-A121N1).

U1-A121N1

The P.L.U.S.® Ø6mm tap (U1-A136 + L2-ALIS411 or U1-A622) can be used to finalise the preparation of the anchorages.



The sleeve (U1-A238) is mounted on the long screwdriver T20 (U1-A415).

The long T20 screwdriver (U1-A415) is then positioned on the Ø6mm bone screw (U1-P6XXT). The sleeve is then pushed onto the screw to secure the assembly.

The screws can then be inserted through the holes in the plates.

❖ Step 3: Putting the rod in place

The distal end of the rod used to correct the deformation must cover the lower screw of the sacral plate so at to prevent any unscrewing of the bone screw in S2.

❖ Step 4: Closing the implants and final screwing

Once the clip is in place and the correction operations have been done, it remains to close the sacral plate by using a clip on the central part and final locking.

USING ILIAC SCREWS & RODS

❖ Precautions to be taken for longitudinal correction rods

The pedicle screws in L5 or S1 must have been put in place but must not be linked to the longitudinal correction rods so as to permit the pelvic obliquity correction operation.

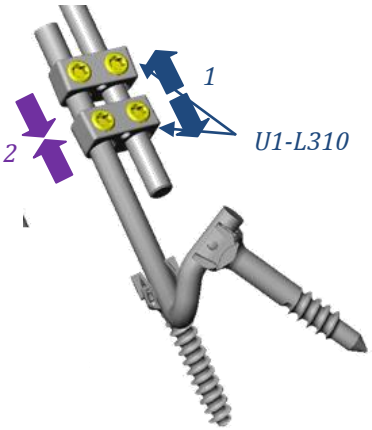
❖ Putting iliac screws in place (U1-FXXX)

Prepare and insert a screw in the iliac crests (U1-FXXX/U1-SXXX(T)/U1-MXXX(T)) ensuring that it does not go through the cortical wall of the crests.

❖ Putting longitudinal correction rods in place

- Put the longitudinal correction rods in place and perform the spinal deformation correction operations.
- Ensure that 3 to 4 cm of rods is left free at the distal end to permit connection with the iliac rods.

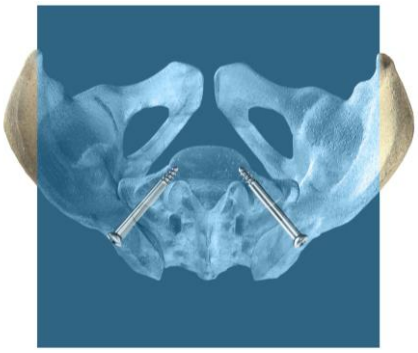
❖ Connecting longitudinal rods and iliac rods (U1-IR600R/L)



- Place two half open connectors (U1-L310) with their lower part closed on the iliac rod on each side of the assembly by sliding them on the rods.
- Insert the iliac rods into the iliac screws and the pedicle screws (in L5 and/or S1) starting with the concave side of the pelvic inclination.
- This step must permit a first correction of the sacrum position in the sagittal plane.
- Then connect the open parts of the open half-connectors onto the longitudinal rods, and do the preliminary tightening of the connectors' set screws using the long screwdriver (U1-A415).
- Perform the pelvic obliquity correction operations in the frontal plane using distraction (1) and/or compression (2) using support on the connectors and the spreader (U1-A342) and offset compressor (U1-A343). This step can be completed in one or more steps depending on the size of correction to be obtained.
- Final tightening of the connectors is then done by using the T20 shaft (U1-A416) and the torque limiting handle (U1-A418).

Not for Sale in the USA

❖ Step 1: Determining the position of the screws (U1-I7XX(T))



Identify the orientation of the sacrum in all planes, giving particular attention to the sagittal plane.

The ilio-sacral screws (U1-I7XX(T)) must be placed as follows:
- parallel to the vertebral endplate of S1,
- perpendicular to the posterior cortex of S1 in the sagittal plane,
- in most cases the ilio-sacral screw must form an angle of 30 to 40° with the transverse plane.

❖ Step 2: Creating a notch for the connector (U1-I600(T))

Remove the lower facet of L5 and identify the upper facet of S1.

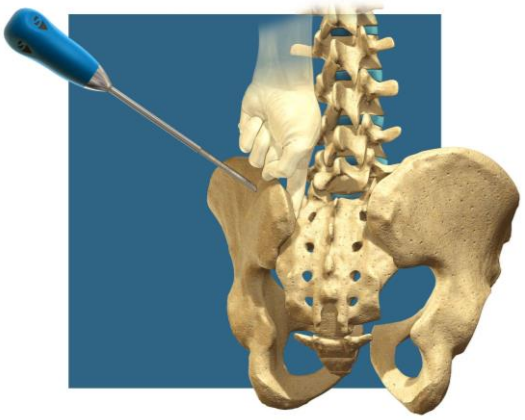
Using a curette (U1-A123L) or a graft remover, create a notch for the ilio-S1 connector (U1-I600(T)). This notch must be positioned laterally and slightly below the lower limit of the S1 facet, inside the ala sacralis.

Locate the first sacral hole so as to avoid any conflict with the root of S1.

❖ Step 3: Preparing the route in the iliac crest

Place the end of the index finger in the notch prepared for the connector, and the thumb on the iliac crest that has been previously exposed by the subfascial dissection. If the patient is obese, make a small incision in the skin (the size of the head of the ilio-sacral screw).

Find the correct route by directing the cannulated trifine for ilio sacral fixation (U1-A125) towards the end of the index finger, taking care not to damage the glove with the instrument.



U1-A125

❖ Step 4: Preparing the pilot hole in the sacrum

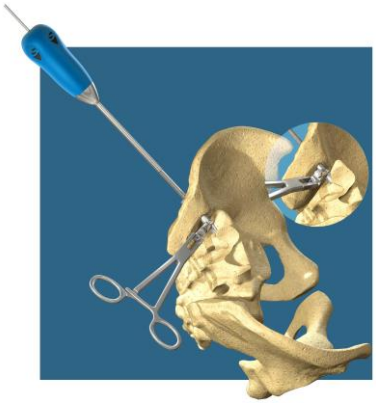
Extend the trifine route up to the sacrum anterior cortical wall. After penetrating the sacrum cancellous bone, the next point important of resistance is the anterior cortex of S1.

If this resistance occurs immediately, it is possible that the trifine has been directed too medially.

Insert the pin for ilio sacral fixation (U1-A126) gently into the trifine using a hammer until it touches the anterior cortical wall.

ATTENTION: We recommend that the pin should not be pushed through the cortex because it is possible that it could move forward when the screws are put in place.

If the pin only penetrates 2-3cm into the sacrum, the ilio-sacral screw will not be correctly oriented.
Generally the screw length varies between 55mm (in children) and 65mm (rarely 70) in the standard population.



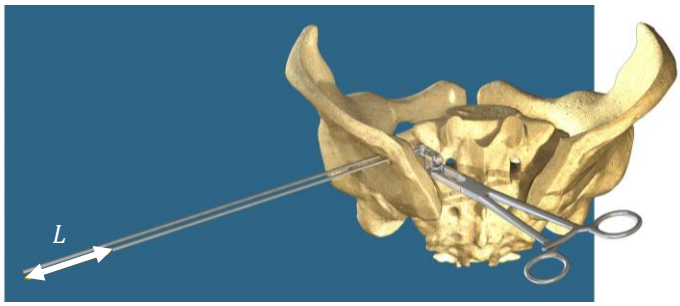
❖ Step 5: Inserting the connector and removing the trifine

Prepare the connector by tightening its ring parallel to its body.
Remove the trifine in order to insert the ilio-S1 connector (U1-I600(T)) held by the universal implant holder (U1-A211).
Pull the ilio-S1 connector gently to verify that the trifine is actually inside the ring.
Remove the trifine taking care to hold the pin (U1-A126) in position by placing another drill at its end.

Note: Check that the pin is in contact with the cortical wall after removing the trifine.

❖ Step 6: Choosing the screw length

Determine the length of the ilio-S1 screw by placing a second pin (U1-A126) of identical length to the first against the iliac crest and measuring the difference in length between the two pins (marked L on the drawing).



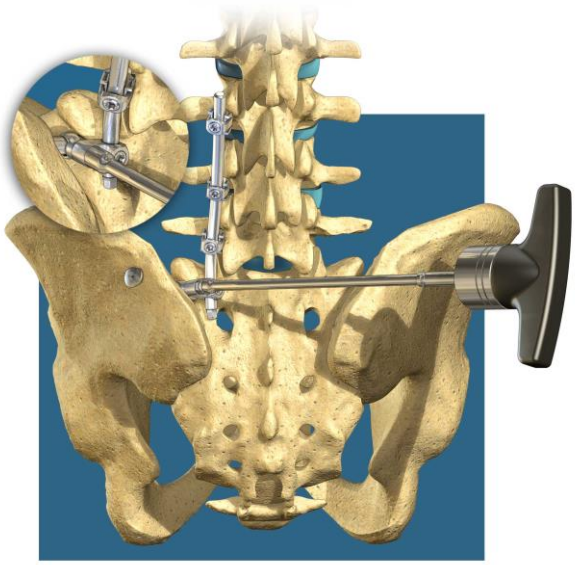
❖ Step 7: Inserting the ilio-s1 screw

U1-A232

Use the hex cannulated screwdriver (U1-A232) to insert the Ilio-S1 screw (U1-I7XX(T)) until the connector locks.
Unlock the connector by unscrewing the lock using the innex hex screwdriver (U1-A413).
Remove the pin (U1-A126) before complete insertion of the screw into the sacrum to avoid any involuntary perforation of the anterior cortex of S1.
Tighten the Ilio-S1 screw until the screw head is in contact with the iliac crest.

Do the same for the opposite side and check the position of the ilio-S1 screws by lateral radiography.

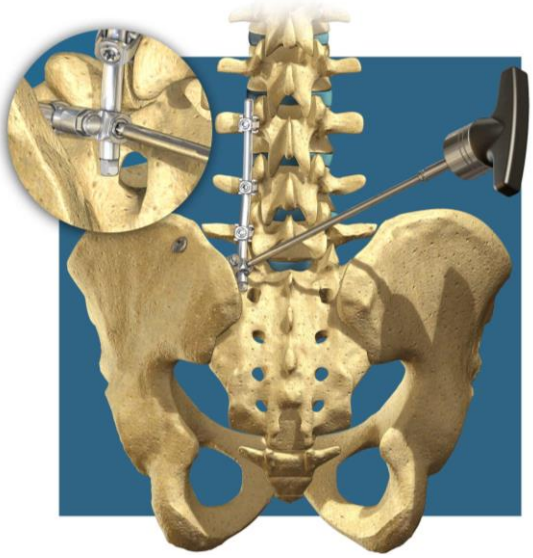
❖ Step 8: Final tightening



Final tightening of the Ilio-S1 connector is done using the torque limiting handle (U1-A418(T)) and the inner hexdriver (U1-A413).

U1-A418(T)

U1-A413



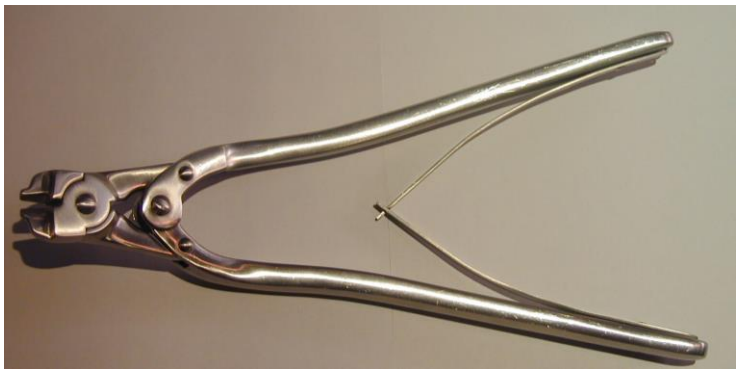
Final tightening of the ilio-S1 screw in place is done by using the T20 shaft (U1-A416) and the torque limiting handle (U1-A418(T)).

Material removal

REMOVING TRANSVERSE CONNECTION SYSTEMS

Use the long T20 screwdriver (U1-A415) to loosen the fixed and/or multi-axial transverse connectors set screws and withdraw the transverse connections using the universal implant holder (U1-A211).

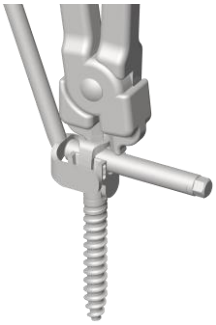
REMOVING A CLIP



Clip remover U1-A422

Clip guard U1-A421

- ✓ Remove the clip (U1-L100(T)) set screw using the long T20 screwdriver (U1-A415) and hold the setscrew using the Locking Screw Holder (U1-A215)



- ✓ Place the clip guard (U1-A421) on the implant and the clip remover (U1-A422) as shown opposite to cut one side of the clip.
- ✓ Cut the first side of the clip.
- ✓ Place the clip remover on the opposite side of the clip and repeat the cutting operation.

WARNING

If they are not held both parts of the clip risk being ejected during the second cut. *It is important to use the clip guard (U1-A421).*

REMOVING THE ROD

Once the clips have been removed, use the rod holder (U1-A214) to remove the rod from the implants.

REMOVING THE HOOKS

Use the universal implant holder (U1-A211) to remove the hooks.

REMOVING THE SCREWS

Use the pedicle screwdriver (U1-A231) to loosen the screws and then use the screw repositioner (U1-A251) to unscrew them completely.

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