SURGICAL TECHNIQUE

sintea PLUSTEK

3LOCK DUAL-LEAD

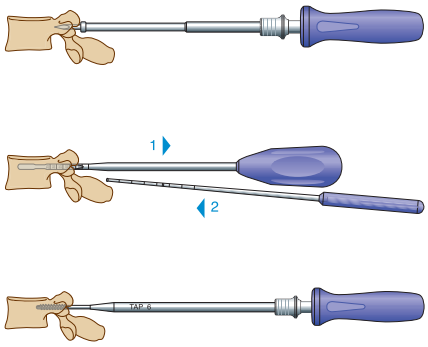
Thoraco-Lumbo-Sacral Posterior Stabilization System

3LOCK DUAL-LEAD

Thoraco-Lumbo-Sacral Posterior Stabilization System

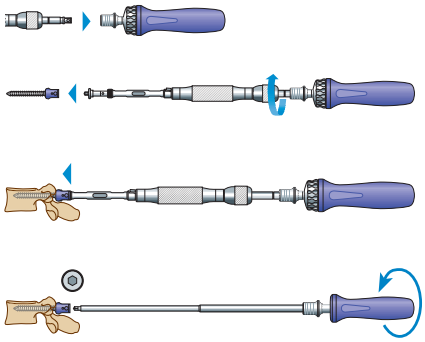
SURGICAL TECHNIQUE

STEP 01 • PEDICLE PREPARATION



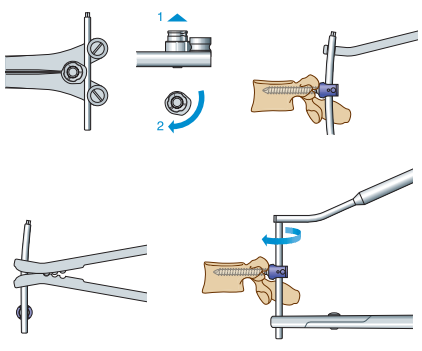
Determine the access point to the pedicle and create the access hole in the cortical bone using the awl assembled on the universal handle. The thoracic awl can be used to introduce thoracic screws (the diameter of the instrument is 2,5mm). Insert the straight or curved bone probe in the established entry point and then proceed with caution within the pedicle checking the depth from the entry hole. Verify that the circumference of the pedicle wall is undamaged with the straight or curved probe.
Use the appropriate tap assembled on the universal handle (match the tap size with the corresponding screw diameter) to prepare the pedicle canal, if necessary.

STEP 02 • SCREW INSERTION



Select the correct screw size and connect the screw to the screwdriver assembled on the universal handle or the ratcheting handle. Insert the hexagonal tip of the instrument into the head of the screw. Slide the screwdriver sleeve down into the head of the screw and thread it, making sure the screw shank is straight.
Insert the multiaxial screw in the pedicle previously prepared.
Disconnect the instrument from the implant and repeat the procedure with all of the necessary implants.
Whenever it is required, reposition the screw head using the dedicated instrument. Use the adjustment screwdriver to adjust the screw height.

STEP 03 • CHOOSING AND BENDING THE ROD

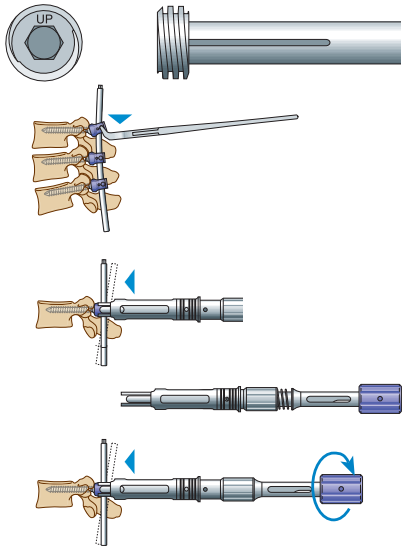


Straight and pre-curved rods are available, both in titanium alloy and in cobalt-chrome.
Select the appropriate type and length and if necessary model the rod by using the rod bender. There are three different radius of curvature available, choose the right one by pulling upwards and rotating the central mechanism in the instrument.
Use the rod holder to position the rod.
You can use the right and left in situ rod benders or, as an alternative, the right and left curved rod benders to remodel the rod after it has been positioned in the implant site. If the rod needs to be adjusted once it is in position, use either the hexagonal wrench or the rod holder.

INDICATIONS

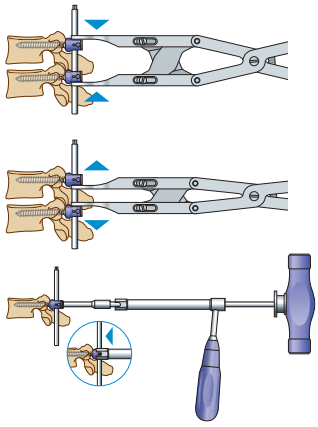
Appropriately used, Sintea Plustek 3Lock dual-lead posterior stabilization system is indicated to promote the development of a solid vertebral arthrodesis. It is recommended for the treatment of scoliosis, kyphosis and lordosis, fractures, instability resulting from neoplasia, spinal stenosis, spondylolisthesis, pseudoarthrosis and previous unsuccessful attempts of vertebral arthrodesis.

STEP 04 • CAP TIGHTENING



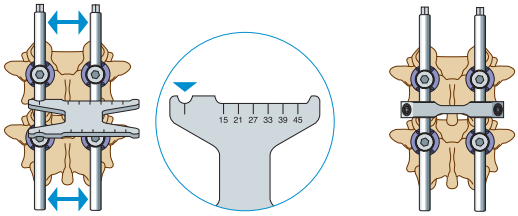
Assemble the cap holder on the universal handle and place the locking cap on it; then screw it into the screw head.
Warning: the locking cap can be inserted in one only direction; keep the part of the locking cap that shows the batch number upwards.
Once all the caps have been positioned, assemble the locking cap screwdriver on the 9Nm dynamometric handle and slip it inside the counter torque to tighten the caps completely.
Rotate the dynamometric handle until it clicks: the locking cap is now fully tightened.
If the rods are not perfectly housed in the screws grooves, they can be re-aligned by means of the rod pusher or the rocker. Use the axial persuader if the rods are particularly dislocated in relation to the screws.

STEP 05 • COMPRESSION/DISTRACTION



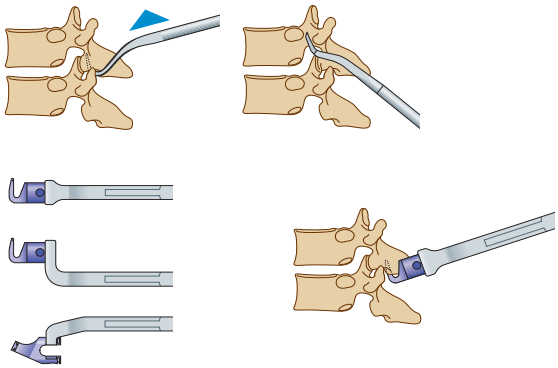
Provisionally tighten the locking cap at the side of the segment where compression or distraction is required to allow sliding of the rod and completely tighten the contralateral cap.
Compress or distract the segment using the compressor or the spreader.
If the distance between one cap and the other is larger than the instrument opening, use the autostatic gripper to create a stable support to apply force.
Once the correction is accomplished, tighten the caps completely.

STEP 06 • CROSS-LINK



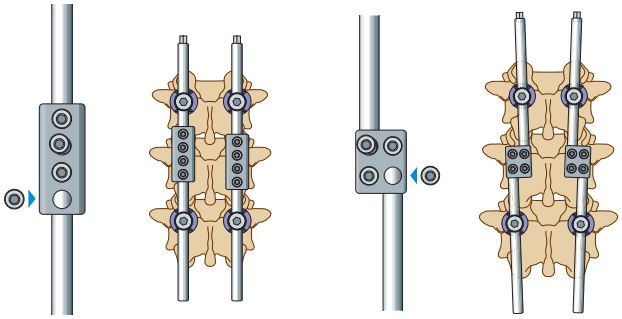
Select the preferred typology among the cross-link selection. Determine the appropriate length of the cross-link with the gauge. Tighten the cross-link nuts with the locking screwdriver assembled on the universal handle.

STEP 07 • HOOK POSITIONING



Prepare the appropriate housing for the hooks using the laminar or the pedicle elevator. Place the implant on one of the hook holders available in the instruments set: straight, with off-set, lateral, or threaded holder.
Insert the hooks and, if necessary, adjust their position with the straight or the curved hook inserter. In addition, the rod pusher might be necessary.

STEP 08 • LATERAL/LONGITUDINAL CONNECTION ELEMENT



The lateral or the longitudinal connection elements can be used to connect two rods together.
Place the connection element at the end of two adjoining rods and tighten the nuts with the locking screwdriver assembled on the universal handle.

REMOVAL PROCESS

In case of implant revision or removal procedure, expose the implant and follow the steps hereafter.

For screws:
Clean debris or tissue off the screws.
Place the counter torque on the screw head, insert the locking cap screwdriver and loosen the locking cap by turning the screwdriver counter-clockwise.
Repeat the procedure with all of the locking caps and then remove the rods.
Use the proper screwdriver to back the screw out of the pedicle.

For hooks:
Clean debris or tissue off the hooks.
Place the counter torque on the hook, insert the locking cap screwdriver and loosen the locking cap by turning the screwdriver counter-clockwise.
Repeat the procedure with all the locking caps and then remove the rods.
Use the hook holder to remove the hook off the pedicle or the lamina.

3LOCK DUAL-LEAD

Thoraco-Lumbo-Sacral Posterior Stabilization System

Implants

Dual-lead multiaxial screw Ø 4mm - 5mm - 6mm - 7mm - 8mm Length 30mm - 35mm - 40mm - 45mm - 50mm - 55mm - 60mm	PLS-5XXT5XX	1
Dual-lead multiaxial screw Ø 7mm - 8mm Length 65mm - 70mm - 75mm - 80mm - 85mm - 90mm - 95mm - 100mm	PLS-5XXXT5X*	
Dual-lead monoaxial screw Ø 4mm - 5mm - 6mm - 7mm - 8mm Length 30mm - 35mm - 40mm - 45mm - 50mm - 55mm - 60mm	PLS-7XXT5X	
Dual-lead multiaxial reduction screw Ø 5mm - 6mm - 7mm Length 40mm - 45mm - 50mm	PLS-6XXT5X	2
Offset hook - Right/Left	PLS-177T59X	3
Wide-blade lumbar hook h. 7 x 7mm - 9 x 7mm - 11 x 7mm	PLS-171T5X	4
Pedicle hook h. 5 x 8mm - 7 x 8mm - 9 x 8mm	PLS-174T5X	5
Extended body hook h. 7 x 5mm - 9 x 5mm - 11 x 5mm	PLS-175T5X	6
Narrow-blade lumbar hook h. 7 x 5mm - 9 x 5mm - 11 x 5mm	PLS-172T5X	7
Angled-blade hook h. 7 x 5mm - 9 x 5mm - 11 x 5mm	PLS-173T5X	8
Thoracic hook h. 5 x 4.5mm - 7 x 4.5mm - 7 x 5.5mm	PLS-170T5X	9
Angled hook - Left/Right	PLS-176T57X	10
Locking cap for 3LOCK screw, hook and off-set connector	PLS-133T50	11
Lateral off-set connector Length 20mm - 30mm - 60mm	PLS-182T5X0	
Pre-curved rod Ø 5.5mm Length 50mm - 60mm - 70mm - 80mm - 90mm	PLS- 49T5X	12
Rod - Ø5.5 Length 40mm - 50mm - 60mm - 70mm - 80mm - 90mm - 100mm - 120mm - 150mm - 250mm - 350mm - 450mm - 500mm	PLS-4XT5X	13
Cr-Co Rod - Ø5.5 Length 350mm - 450mm - 500mm	PLS-4XCCX*	
Lateral and longitudinal connection element	PLS-180T3X	14
Modular cross-link Ø 5.5mm Interaxis 30-38mm - 37-52mm - 50-70mm	PLS-150T5XX	15
Rigid cross-link Ø 5.5mm Width 15mm - 18mm - 21mm - 24mm - 27mm - 30mm - 33mm - 36mm - 39mm - 42mm - 45mm - 48mm	PLS-150T3XX	16
Locking nut for modular and rigid cross-link	PLS-191T30	17
Locking nut for connection element and modular cross-link	PLS-181T30	18

*Available on request

3LOCK DUAL-LEAD

Thoraco-Lumbo-Sacral Posterior Stabilization System

Instruments

Screws instruments set	PLS-0004S
Hexagonal wrench	PLS-0100S
Rod pusher	PLS-0200S
Thoracic awl	PLS-0300S
Awl	PLS-0301S
Tap double helix – 5 mm	PLS-0315S
Tap double helix – 6 mm	PLS-0316S
Tap double helix – 7 mm	PLS-0317S
Tap double helix – 8 mm	PLS-0318S
Rocker	PLS-0202S
Straight probe	PLS-0400S
Curved probe	PLS-0403S
Curved bone probe	PLS-0401S
Straight bone probe	PLS-0404S
Adjustment screwdriver	PLS-0504S
Screwdriver for multiaxial screw	PLS-0505S
Multiaxial screw head-driver	PLS-1900S
Rod holder	PLS-0600S
Axial rod holder	PLS-0603S
Derotation gripper	PLS-0601S
Rod bender	PLS-0700S
“In situ” rod bender left	PLS-08SXS
“In situ” rod bender right	PLS-08DXS
“In situ” curved rod bender right	PLS-08D1S
“In situ” curved rod bender left	PLS-08S1S
Cap holder	PLS-0902S
Locking cap screwdriver	PLS-0903S

Spreader	PLS-1200S
Compressor	PLS-1300S
Connection element, modular and rigid cross-link locking screwdriver	PLS-1401S
Autostatic gripper	PLS-1500S
Counter torque for multiaxial standard and reduction screw	PLS-1702S
Axial persuader	PLS-1804S
Universal handle	PLS-2001S
Universal ratcheting handle	PLS-2002S
Dynamometric handle – 9 Nm	PLS-2007S
Cross-link gauge	PLS-2300S
Screws case	PLS-CS11
Implants case	PLS-CS13
Instruments case 1	PLS-CS14
Instruments case 2	PLS-CS15
Hooks instruments set	PLS-0003S
Hook inserter for rod	PLS-1605S
Straight hook inserter	PLS-1606S
Curved hook inserter	PLS-1607S
Threaded hook holder	PLS-1608S
Straight hook holder	PLS-2100S
Hook holder with off-set	PLS-2101S
Lateral hook holder	PLS-2102S
Pedicle elevator	PLS-2200S
Laminar elevator	PLS-2201S
Hooks case	PLS-CS12

CONTRAINDICATIONS

The contraindications to the implant of Sintea Plustek 3Lock dual-lead posterior stabilization system are analogous to those of similar products currently available on the market and include but are not limited to the following:

ABSOLUTE:
- Active infections
- Allergy to the metal components
- Patients who are either unwilling or unable to follow prescriptions

RELATIVE:
- Metastasis
- Severe muscular, neurological or vascular diseases
- Fever or leukocytosis
- Pregnancy, with the exception of unstable vertebral fractures
- Signs of phlogosis of the implant area
- Inadequate coverage of soft tissues at the implant site
- Severe osteoporosis

If Sintea Plustek 3Lock dual-lead posterior stabilization system is considered the best solution for the patient and if the latter presents one or more of the above contraindications, it is absolutely necessary to inform him/her about any possible adverse effect that may influence the success of the procedure.

Sintea Plustek S.r.l.
Commercial, administrative and registered office:
Via E. Fermi 44 – 20090 Assago (MI) – Italia
Tel. +39 02 45 79 02 31 – Fax +39 02 45 79 02 66
E-mail: sinteaplustek@alapec.it
VAT NO. 04874470968 - Fully paid up capital € 100.000,00
National Business Register: Milan (Italy) no. 1778805

Manufacturing plant:
Via Aquileia 33/H – 20021 Baranzate (MI) – Italia
Tel. +39 02 45 79 02 31
Fax +39 02 45 79 02 66
E-mail: sinteaplustek@alapec.it

Sintea Plustek LLC
407 Lincoln Rd. Suite 10/L
33139 Miami Beach (FL) – USA
Tel. +1 305 67 36 226
Fax +1 305 67 33 312
E-mail: sinteaplustek@alapec.it

sintea PLUSTEK
www.sinteaplustek.com