3LOCK DUAL-LEAD

Thoraco-Lumbo-Sacral Posterior Stabilization System

Implants

Dual-lead multiaxial screw Ø 4.5mm – 5mm – 6mm – 7mm – 8mm Length 30mm – 35mm – 40mm – 45mm – 50mm – 55mm – 60mm	PLS-5XXT5X	1
Dual-lead monoaxial screw Ø 4.5mm – 5mm – 6mm – 7mm – 8mm Length 30mm – 35mm – 40mm – 45mm – 50mm – 55mm – 60mm	PLS-7XXT5X	1
Dual-lead multiaxial reduction screw Ø 5mm – 6mm – 7mm Length 40mm – 45mm – 50mm	PLS-6XXT55	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 – DX/SX	PLS-176T57X	10
Locking cap for 3LOCK screw and hook	PLS-133T50	11
Pre-curved rod Ø 5.5mm Length 50mm - 60mm - 70mm - 80mm - 90mm	PLS- 49T5X	12
Rod - Ø 5.5mm Length 40mm - 50mm - 60mm - 70mm - 80mm - 90mm - 100mm - 120mm - 150mm - 250mm - 350mm - 450mm - 500mm	PLS-4XT5X	13
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

Instruments

Screws instruments set	PLS-0004S
Hooks instruments set	PLS-0003S

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.

CONTRANDICATIONS

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

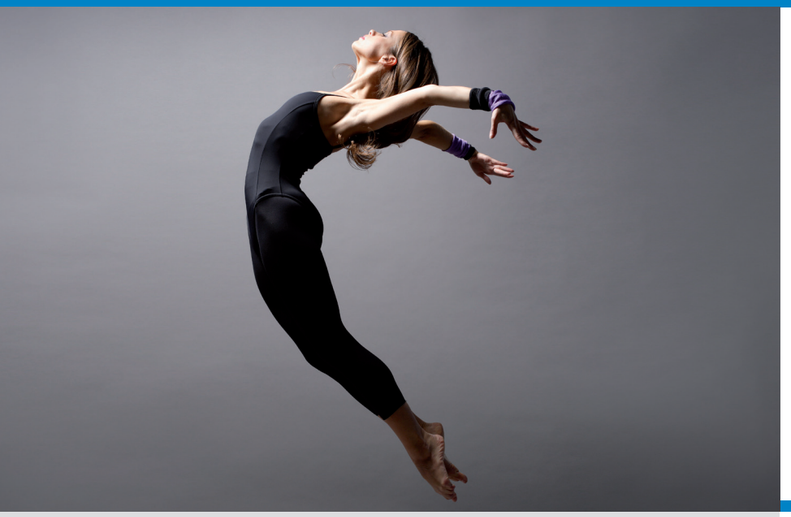
407 Lincoln Rd. Suite 10/L
33139 Miami Beach (FL) – USA
Tel. +1 305 67 36 226
Fax +1 305 67 33 312
E-mail: sinteaplustek@alapec.it

SISTEMA DI GESTIONE CERTIFICATO
ITALCERT
UNI EN ISO 9001
UNI EN ISO 13485

www.sinteaplustek.com

3LOCK DUAL-LEAD

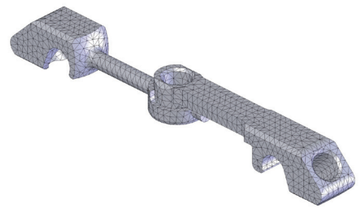
Thoraco-Lumbo-Sacral Posterior Stabilization System

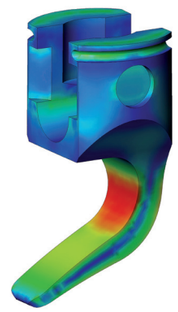


3Lock dual-lead posterior stabilization system was designed with the aim to provide surgeons with a complete device that would allow them to treat the different pathologies that affect the rachis, both degenerative, traumatic or tumoral, and for the treatment of deformities.
The screws are characterized by a dual-lead thread that allows easy insertion and better grip inside the pedicle. The special conical shape of their tip ensures an accurate positioning, thus granting insertion along the desired trajectory.
The screws, in monoaxial and multiaxial version, are available in 5 different diameters (4.5, 5, 6, 7 and 8mm), to better adapt to the patient's anatomy according to the levels to stabilize. Multiaxial reduction screws are also available (Ø 5, 6 and 7mm): these screws are particularly indicated for treating spondylolisthesis and they are characterized by a pre-carved head for easy removal of the long tulips.
The system is completed by a set of hooks available in different sizes and types.
The three-way connection between implants and instruments make 3Lock dual-lead effective and flexible, thus offering the surgeon a very easy-implant device.
In order to ensure optimal biomechanical performances and to facilitate X-ray monitoring of the implant, the components of 3Lock dual-lead are made of biocompatible titanium.

All components of the system are compliant with Directive 93/42/EEC.

TECHNOLOGY AND INNOVATION





COMPONENTS

1. DUAL-LEAD SCREWS
2. DUAL-LEAD MULTIAXIAL REDUCTION SCREWS
3. HOOKS
4. LOCKING CAP
5. ROD
6. PRE-CURVED ROD
7. LATERAL CONNECTION ELEMENT
8. LONGITUDINAL CONNECTION ELEMENT
9. MODULAR CROSS-LINK
10. RIGID CROSS-LINK
11. LOCKING NUTS

DESIGN AND ENGINEERING

The application of advanced methods of structural analysis based on continuum mechanics led to the optimization of 3Lock dual-lead components. The design phase was based on the validations obtained through numerical methods and experimental static and fatigue tests in order to reproduce the most critical loading conditions. The geometries of the system were optimized so as to combine functionality and dimensioning with performances, in order to fulfil end-user's requirements in terms of easiness and versatility of use.

INNOVATIVE ASPECTS

The main characteristic of 3Lock dual-lead is the innovative design of its thread: thanks to the double-helix thread, with a 180° stagger, the screw has a double pitch that allows a more rapid insertion and ensures a better grip. Moreover, the cone-like shape of the screw guarantees an efficient hold in the bone segment where it is most required.
The system has a single square-threaded locking cap for all of its components, which allows a safer and faster blocking in comparison to conventional cap thread, thus avoiding any possible seizing.

MAIN FEATURES

DUAL-LEAD SCREWS

CONICAL TIP

REDUCED INSERTION TIME

THREE-WAY CONNECTION

ANTI-SEIZING SQUARE-THREADED LOCKING CAP

MONO AND MULTIAXIAL SCREWS (25° POLYAXIALITY)

SELF-TAPPING

sintea PLUSTEK