
Instructions for Use

TSLP™ Thoracolumbar Spine Locking Plate

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

Products available non-sterile and sterile can be differentiated with the suffix "S" added to the article number for sterile products.

Instructions for Use

TSLP™ Thoracolumbar Spine Locking Plate

TSLP implants consist of mono-segmental and bi-segmental plates and self-locking screws. The plates are anatomically shaped for kyphotic and lordotic placement.

The plates are available in different sizes. Screws are offered in different lengths.

These instructions for use contain information about the following products:

489.140	489.174	489.475	489.142S	489.440S	489.480S
489.142	489.440	489.480	489.145S	489.443S	489.483S
489.145	489.443	489.483	489.147S	489.446S	489.487S
489.147	489.446	489.487	489.150S	489.450S	489.489S
489.150	489.450	489.489	489.154S	489.453S	489.490S
489.154	489.453	489.490	489.156S	489.456S	489.493S
489.156	489.456	489.493	489.160S	489.458S	489.497S
489.160	489.458	489.497	489.162S	489.461S	489.500S
489.162	489.461	489.500	489.165S	489.463S	489.506S
489.165	489.463	489.506	489.168S	489.466S	489.510S
489.168	489.466	489.510	489.170S	489.470S	489.512S
489.170	489.470	489.512	489.171S	489.474S	
489.171	489.474	489.140S	489.174S	489.475S	

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure “Important Information” carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

For accompanying information, such as Surgical Techniques, please visit www.jnjmedtech.com/en-EMEA/product/accompanying-information or contact local customer support.

Materials

Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium) according to ISO 5832-11

Intended Use

The TSLP implants are intended for anterolateral or lateral fixation of the thoracolumbar spine (T3–L5) as an adjunct to fusion in skeletally mature patients.

Based on the nature of the pathology and instability, supplemental posterior fixation may be required.

Indications

- Conditions requiring disc and/or vertebral body removal/corpectomy inclusive of Fractures, Tumors and Degenerative Spine Disease

Contraindications

- Poor bone quality in which adequate anterior support cannot be established

Patient Target Group

The TSLP implants are intended for use in skeletally mature patients. These products are to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User

These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device.

Please read the instructions for use and the Synthes brochure “Important Information” carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Expected Clinical Benefits

The TSLP implants, when used as intended and according to the instructions for use and labeling, provide stabilization of the spinal segment(s), which is expected to provide maintenance or improvement of patient function and/or relief of pain.

A summary of safety and clinical performance can be found at the following link (upon activation): <https://ec.europa.eu/tools/eudamed>

Performance Characteristics of the Device

The TSLP implants are designed to provide mechanical stability of the spinal segment(s) as an adjunct to fusion.


Potential Adverse Events, Undesirable Side Effects and Residual Risks

As with all major surgical procedures, there is a risk of adverse events. Possible adverse events may include: problems resulting from anesthesia and patient positioning; thrombosis; embolism; infection; excessive bleeding; neural and vascular injury; swelling, abnormal wound healing or scar formation; functional impairment of the musculoskeletal system; complex regional pain syndrome (CRPS); allergy/hypersensitivity reactions; symptoms associated with implant or hardware prominence; malunion, delayed union or non-union; decrease in bone density due to stress shielding; adjacent segment degeneration; ongoing pain or neurological symptoms; damage to adjacent bones, organs, discs, or other soft tissues; dural tear or spinal fluid leak; spinal cord compression and/or contusion; implant loosening or breakage; device or graft material displacement; vertebral angulation.

Sterile Device


STERILE R Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.

 Do not use when packaging is damaged.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.

Single Use Device

 Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.

Furthermore, re-use or reprocessing of single use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings and Precautions

- It is strongly advised that the TSLP implants are implanted only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.
- Implantation is to take place as per the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- Warning: Allergic reactions to implant materials (e.g. Titanium Alloy).

Select plate size

Determine the appropriate TSLP plate size over the defect space.

- Be careful to avoid damaging the endplate.
- The indicated plate lengths refer to the entire length of the implant.

Determine the screw length

Determine the required screw length using CT or an X-ray, or use the depth gauge.

- Select a length to fully exploit the vertebral width without perforating the opposite side of the cortical bone.

Screw insertion

- Select a length to fully exploit the vertebral width without perforating the opposite side of the cortical bone.

For more information, please refer to the Synthes brochure "Important Information".

Combination of Medical Devices

The TSLP plates and screws are applied using the associated Lumbar Plates Instrumentation. The following screw option is available for use with the plates.

- Cancellous Bone Locking Screw Ø 5.5 mm

Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance Environment

MR Conditional:

Non-clinical testing of the worst-case scenario has demonstrated that the implants of the TSLP system are MR conditional. These articles can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla.
- Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
- Maximum whole body averaged specific absorption rate (SAR) of 1.75 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the TSLP implant will produce a temperature rise not greater than 5.6 °C at a maximum whole body averaged specific absorption rate (SAR) of 1.75 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.

MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the TSLP device.

Treatment before Device is Used

Sterile Device:

The devices are provided sterile. Remove products from the package in an aseptic manner.

Store sterile devices in their original protective packaging.

Do not remove them from the packaging until immediately before use.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging by visual inspection:

- Inspect the entire area of sterile barrier package including the sealing for completeness and uniformity.
- Inspect the integrity of the sterile packaging to ensure there are no holes, channels or voids.

Do not use if the package is damaged or expired.

Non-Sterile Device:

Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Implant Removal

The TSLP implant is intended for permanent implantation and is not intended for removal. Any decision to remove the device must be made by the surgeon and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

If a TSLP implant must be removed, the following technique is recommended:

- Insert threaded drill guide with the threaded drill guide inserter, cannulated on a middle plate hole of the plate.
- Mount the construct holder to the threaded drill guide.
- Place the ratchet wrench with T-handle on the hexagonal screwdriver shaft, and introduce it into the holding sleeve.
- Set the ratchet wrench to the reverse direction.
- Insert the screwdriver shaft tip into the recess of the screw. Remove the screw while turning counter-clockwise up to ¼ of its length.
- Then push the holding sleeve downward, and continue to remove the screw.
- Repeat for the remaining screws.
- Remove the plate with the construct holder.

Clinical Processing of the Device

Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Disposal

Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Special Operating Instructions

Standard procedure

Prepare the vertebrae

- Expose the operating site, decompress neural structures, and insert structural bone graft or a vertebral body replacement device with bone graft material.
- If necessary, incorporate additional bone graft material around the ventral and lateral aspects of the vertebral replacement device.
- In preparation of the TSLP plate placement, remove osteophytes from the vertebral surface to give the TSLP plate a flat resting surface.

Select plate size

- Determine the appropriate TSLP plate size over the defect space. Hard bone for favorable screw purchase is near the end plates. Consider the use of X-ray to verify plate length.
- The screw holes for fixation should lie adjacent to the outside endplates.

Prepare plate for implantation

- Insert a threaded drill guide into the required caudal and cranial holes.
- Mount the construct holder with a threaded drill guide on a middle plate hole and move the TSLP plate into position.

Position and temporarily fix the plate

- Position the plate so that all the screws can be anchored in the vertebrae, and the plate curvature follows the shape of the vertebrae.
- Mount the threaded drill guide inserter onto the cranial, posterior drill guide, and perforate the cortical bone with the awl Ø 3.3 mm through the cannulated drill guide inserter. The maximum drill depth will be 20 mm.
- By leaving the awl in place, the plate is temporarily fixed to the vertebrae.
- If the awl is directly inserted through the drill guide, the maximum drill depth will be 23 mm.
- Place a fixation pin on the driver, and temporarily affix the plate to the vertebrae through the caudal posterior drill guide.
- Also insert a fixation pin in the remaining cranial and caudal drill guides.
- Optional (without an awl): The primary fixation can be achieved using just 4 temporary fixation pins.
- Remove the construct holder for better visualisation of the operative site.

Prepare the first screw hole

- Remove the drill guide inserter, the drill guide and the awl together in a single step.
- If temporary fixation is provided by four fixation pins, first remove the fixation pin from the drill guide selected for locating the screw, and then the drill guide with the drill guide inserter.
- Optional: Remove the inserter and awl but leave the drill guide. Mount the handle with the quick coupling on the drill bit Ø 3.3 mm and drill the screw hole.

Determine the screw length

- Determine the required screw length using CT or an X-ray or use the depth gauge.
- The indicated lengths of the locking screws refer to the distance from the first thread on the shaft to the tip.

Insert the first screw

- Place the ratchet wrench with T-handle on the hexagonal screwdriver shaft and introduce it into the holding sleeve. Select a \varnothing 5.5 mm screw of the appropriate length and screw it into the prepared plate hole.
- Insert the screw up to 3/4 of its length. Then pull the holding sleeve upward and continue to screw in the screw until the screw head is seated in the plate.
- The torque-limiting T-handle is only used to finally lock the screw after the remaining \varnothing 5.5 mm locking screws have been inserted.

Insert remaining screws

- First remove the fixation pin with the driver, and then the drill guides with the inserter.
- Begin to insert the other screws cross-wise as previously described.

Lock the screws

- Place the torque-limiting T-handle on the hexagonal screwdriver shaft, and finally lock all screws.
- A clear clicking from the T-handle signals that the necessary torque has been reached.

Bone graft fixation (optional)

- This section would be applicable when using structural bone graft material.

Drill bone graft

- Mount the drill guide in a middle screw hole. Mount the drill bit engaged in the quick coupling and drill the bone graft.
- The drill bit has an effective drilling depth of 24 mm.
- Remove the drill bit and drill guide.
- Optional: Tap the thread. In the case of hard bone, mount the tap on the ratchet wrench with T-handle, and pretap the thread.

Insert bone graft screw

- Place the torque-limiting T-handle on the hexagonal screwdriver shaft and introduce it into the holding sleeve. Select a screw of the appropriate length and screw it through the plate hole into the bone graft.



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