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.

EC REP

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

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.

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.

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 with 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.

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 ∅ 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
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
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.

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Instructions for Use:
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