Instructions for Use
T-PAL™
Transforaminal Posterior Atraumatic Lumbar Cage System

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

Not all products are currently available in all markets.

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Instructions for Use

T-PAL™
T-PAL is a Transforaminal Posterior Atraumatic Lumbar Cage System.
The T-PAL interbody cages are comprised of kidney-shaped spacer implants or cages that are available in two material versions, polymeric (PEEK) and titanium alloy (TAN). These cages were designed to be implanted via an open or a minimally invasive (MI), transforaminal approach. The T-PAL PEEK cages are radiolucent and therefore contain three titanium alloy marker pins. The TAN implants feature additional graft windows.
The cages (PEEK and TAN) are offered in multiple footprints, heights, and angles to accommodate ranges in patient anatomy.

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

Material:	Standard:
PEEK (Polyetherether-ketone)	ASTM F 2026
TAN (Ti-6Al-7Nb)	ISO 5832-11

Intended Use
The T-PAL implant is intended for use as an intervertebral body fusion device in skeletally mature patients with degenerative disease of the lumbar spine (L1-S1). The T-PAL implant is designed for a transforaminal approach.

Indications
The T-PAL implant is indicated for degenerative spine disease.

Important: T-PAL implants must be applied in combination with posterior fixation.

Contraindications
- Vertebral body fractures
- Spinal tumours
- Major spinal instabilities
- Primary spinal deformities
- Osteoporosis

Patient Target Group
The product is 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
This IFU alone does not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the instructions for use and, the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure as appropriate.

Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits
Expected clinical benefits of interbody devices such as T-PAL when used according to instructions for use and recommended technique include the symptomatic improvement obtained from spinal fusion surgery.

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
Synthes has established the performance and safety of T-PAL implants and that they represent state-of-the-art medical devices for transforaminal intervertebral body cages when used according to the instructions for use and labeling.

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, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, complex regional pain syndrome (CRPS), allergy/hypersensitivity reactions, symptoms associated with implant or hardware prominence, malunion, non-union, ongoing pain; damage to adjacent bones (e.g. subsidence), disc (e.g. adjacent level degeneration), or soft tissue, dural tear or spinal fluid leak; spinal cord compression and/or contusion, cage displacement, vertebral angulation.

Sterile Device

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.


Do not resterilize

Resterilization of T-PAL can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

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 T-PAL is implanted only by operating surgeons who are experienced in spinal surgery and who are aware of general risks of spinal surgery and 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.

Discectomy
– The annulus should be preserved as much as possible to provide additional support for the T-PAL implant and prevent migration of bone graft and bone graft substitute into the spinal canal.
– Provide enough lateral exposure to the disc to reduce dural retraction.

Disc space preparation
– During preparation of endplates, excessive removal of the subchondral bone may weaken the vertebral endplate. The entire removal of the endplate may result in subsidence and a loss of segmental stability.

Assemble applicator and connect non detachable trial implant.
– Ensure the arrows on the end of the applicator align with those on the trial implant. The contact surfaces between the trial and the applicator should have no gap.
– Please read the "Applicator Instructions" listed in section "Additional Device-Specific Information".

Insert trial implant
– The trial tip indicates approximate final anterior position of the trial implant.
– When using the Standard Applicator (03.812.001/03.812.003) for trial implant insertion, maintain 10–15° between the applicator handle and the sagittal plane.

Position trial implant
– Ensure applicator knob is turned counterclockwise until it stops to avoid trial or applicator outershaft deformation.
– When using the Standard Applicator (03.812.001/03.812.003) for final trial implant insertion, maintain 10–15° between the applicator handle and the sagittal plane.

Remove non detachable trial implant
– The applicator must be in the pivoting position to remove the trial implant.

Assemble applicator and connect implant to the applicator
– The T-PAL Advanced Applicator Outer Shaft (03.812.520) and Inner Shaft (03.812.521) should not be used in combination with the Standard Applicator Outer Shaft (03.812.001) and Inner Shaft (03.812.003).
– Ensure the arrows on the end of the applicator align with those on the implant. The contact surfaces between the implant and the applicator should have no gap.
– Note that the clamp on the inner shaft of the Advanced Applicator is asymmetric. When attaching the implant to the applicator the longer finger must be attached to the lateral (convex) side of the implant. There is an etch line on the edge of the longer finger so that proper attachment can be confirmed.

Implant insertion
– The implant tip (TAN cage) or tip marker pin (PEEK cage) indicates approximate final anterior position of implant.
– When using the Standard Applicator (03.812.001/03.812.003) for implant insertion, maintain 10–15° between the applicator handle and the sagittal plane.

Position implant
– Ensure applicator knob is turned counterclockwise until it stops to avoid deformation of the applicator outershaft.
– When using the Standard Applicator (03.812.001/03.812.003) for final implant insertion, maintain 10–15° between the applicator handle and the sagittal plane.
– With the Advanced Applicator (03.812.520/03.812.521) it is possible for the implant to pivot greater than 90 degrees. Therefore, careful attention should be paid to fluoroscopy to ensure the implant is in the desired position.

Implant removal with the applicator
– The applicator must be in the pivoting position to remove the implant.

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

Combination of Medical Devices
T-PAL implants are intended to be used with associated T-PAL instruments. Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance Environment

T-PAL (PEEK)

MR Conditional:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the T-PAL (PEEK) 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 90 mT/cm (900 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the T-PAL (PEEK) implant will produce a temperature rise not greater than 1.5 °C at a maximum whole body averaged specific absorption rate (SAR) of 2 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 T-PAL (PEEK) device.

T-PAL (TITANIUM)

MR Conditional:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the T-PAL (TITANIUM) 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 4 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the T-PAL (TITANIUM) implant will produce a temperature rise not greater than 4.0 °C at a maximum whole body averaged specific absorption rate (SAR) of 4 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 T-PAL (TITANIUM) 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, and 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. Do not use if the package is damaged.

Implant Removal
If a T-PAL implant must be removed, the following technique is recommended.

Implant removal with the applicator
– Ensure that the applicator is in the fully open position. Locate the implant and close the applicator by turning the knob clockwise until the security ring is moving upwards.
– There should be no gap between the applicator knob and the security ring.
– To ensure that the knob is in contact with the security ring, turn the knob counterclockwise until it stops, in this position the implant can pivot but not detach from the applicator. The implant can now be removed.
– The slap hammer may be required to facilitate removal.

Note: Distraction of the segment may facilitate implant removal. However, if possible, do not distract before ensuring a firm connection between the implant and the applicator.

Implant removal with the removal tool
– Ensure that the removal tool for T-PAL is in the fully open position.

– Locate the implant and squeeze the handle firmly. Advance the speed nut to lock the handle. The implant can now be removed.
– The slide hammer may be required to facilitate removal.

Notes:
– When the removal tool handle is squeezed, the implant can pivot but not detach from the removal tool.
– Distraction of the segment may facilitate implant removal. However, if possible, do not distract before ensuring a firm connection between the implant and the removal tool.

Please note that precautions/warnings related to implant removal are listed in section "Warnings and Precautions".

Additional Device-Specific Information

Applicator Instructions:

Attach position
– Pull the security ring down and simultaneously turn the knob counterclockwise.
– No gap between the handle, security ring and the applicator knob should be present.
– The green color band should not be visible.
– The implant or trial can be attached.

Insertion position
– Turn the applicator knob clockwise to close the jaws.
– During this closing procedure the security ring moves upwards, so that the green color band is visible.
– Continue to turn the knob until it is tightened.
– In the insertion position; the implant or trial is fixed.
– The implant or trial cannot pivot or detach.

Pivoting position
– Turn the applicator knob counterclockwise until it stops.
– The applicator knob and the security ring will now be in contact.
– In this position the implant or trial can pivot 80°.
– Implant or trial cannot detach from applicator.

Detach position
– Pull the security ring down and simultaneously turn the knob counterclockwise.
– No gap between the handle, security ring and the applicator knob should be present.
– The green color band should not be visible.
– The implant or trial can be detached.

Note: If the security ring cannot be pulled down, turn the knob clockwise a quarter turn. The ring can now be pulled down.

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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