Instructions for Use
T-PAL™ Implant

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

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each
manual is always available online.
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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

T-PAL™ Implant
T-PAL is a Transforaminal Posterior Atraumatic Lumbar Cage System.
The T-PAL interbody cages are comprised of kidney-shaped spacer implants or cages. These cages were designed to be implanted via an open or a minimally invasive (MI), transforaminal approach. The T-PAL cages are made from PEEK and contain three titanium alloy marker pins which allows for visualization of the implant. The axial canal of the implant can be filled with bone graft material.
The cages are offered in multiple footprints, heights, and angles to accommodate ranges in patient anatomy.

These instructions for use contain information about the following products:

08.812.007S	08.812.207S
08.812.008S	08.812.208S
08.812.009S	08.812.209S
08.812.010S	08.812.210S
08.812.011S	08.812.211S
08.812.012S	08.812.212S
08.812.013S	08.812.213S
08.812.015S	08.812.215S
08.812.017S	08.812.217S

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
PEEK: Polyetheretherketone according to ASTM F 2026
Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium) according to 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 T-PAL 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
When the T-PAL implants are used as intended and according to the instructions for use and labeling, these devices provide stabilization of the motion segment(s) after intervertebral disc removal as an adjunct to fusion, which is expected to provide relief of back and/or leg pain caused by degenerative conditions of the spine.

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 T-PAL implants are intervertebral body fusion devices, designed to provide stability at the motion segment(s) prior 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; death; swelling, abnormal wound healing or scar formation; heterotopic ossification; functional impairment of the musculoskeletal system; paralysis (temporary or permanent); complex regional pain syndrome (CRPS); allergy/hypersensitivity reactions; symptoms associated with implant or hardware prominence, implant breakage, loosening or migration; malunion, non-union or delayed union; decrease in bone density due to stress shielding; adjacent segment degeneration; ongoing pain or neurological symptoms; damage to adjacent bones, discs, organs, or other soft tissues; dural tear or spinal fluid leak; spinal cord compression and/or contusion; device or graft material 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 the device 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 the T-PAL implant is 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: Special considerations should be taken with patients with known allergies or hypersensitivities to implant materials.

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 material 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 tip marker pin 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 applied using associated T-PAL Instruments.

03.605.507	Rasp, dual-sided, bayoneted, black
03.605.508	Osteotome, straight, black
03.605.510	Ring Curette, straight, bayoneted, black
03.605.511	Rasp, dual-sided, angled, bayoneted
03.605.514	Rongeur, curved, 4.0 mm, black
03.605.520	Laminectomy Punch, 40°, 4.0 mm, black
03.605.527	Rongeur, straight, 4.0 mm, black
03.605.529	Curette, rectangular, angled, right, bayoneted
03.605.530	Curette, rectangular, angled, left, bayoneted
03.605.532	Impactor, curved, standard, bayoneted, black
03.803.054	Curette, rectangular, bayoneted, black
03.809.972	Oracle Slide Hammer
03.812.001	Applicator Outer Shaft
03.812.003	Applicator Inner Shaft
03.812.004	Applicator Knob
03.812.005	Removal Tool f/T-PAL
03.812.040	Lamina Spreader f/T-PAL
03.812.043	Cancellous Bone Impactor f/T-PAL
03.812.044	Packing Block f/T-PAL
03.812.307	T-PAL Small Trial Implant, 7 mm, non detachable
03.812.308	T-PAL Small Trial Implant, 8 mm, non detachable
03.812.309	T-PAL Small Trial Implant, 9 mm, non detachable
03.812.310	T-PAL Small Trial Implant, 10 mm, non detachable
03.812.311	T-PAL Small Trial Implant, 11 mm, non detachable
03.812.312	T-PAL Small Trial Implant, 12 mm, non detachable
03.812.313	T-PAL Small Trial Implant, 13 mm, non detachable
03.812.315	T-PAL Small Trial Implant, 15 mm, non detachable
03.812.317	T-PAL Small Trial Implant, 17 mm, non detachable
03.812.507	T-PAL Large Trial Implant, 7 mm, non detachable
03.812.508	T-PAL Large Trial Implant, 8 mm, non detachable
03.812.509	T-PAL Large Trial Implant, 9 mm, non detachable
03.812.510	T-PAL Large Trial Implant, 10 mm, non detachable
03.812.511	T-PAL Large Trial Implant, 11 mm, non detachable
03.812.512	T-PAL Large Trial Implant, 12 mm, non detachable
03.812.513	T-PAL Large Trial Implant, 13 mm, non detachable
03.812.515	T-PAL Large Trial Implant, 15 mm, non detachable
03.812.517	T-PAL Large Trial Implant, 17 mm, non detachable
03.812.520	Advanced Applicator Outer Shaft
03.812.521	Advanced Applicator Inner Shaft
389.767	Shaver f/Intervertebral Discs, size 7 mm
389.768	Shaver f/Intervertebral Discs, size 8 mm
389.769	Shaver f/Intervertebral Discs, size 9 mm
389.770	Shaver f/Intervertebral Discs, size 10 mm
389.771	Shaver f/Intervertebral Discs, size 11 mm
389.772	Shaver f/Intervertebral Discs, size 12 mm
389.773	Shaver f/Intervertebral Discs, size 13 mm
389.775	Shaver f/Intervertebral Discs, size 15 mm
389.777	Shaver f/Intervertebral Discs, size 17 mm
389.857	Soft Tissue Retractor, width 6 mm
389.858	Soft Tissue Retractor, width 8 mm
389.859	Soft Tissue Retractor, width 10 mm
394.951	T-Handle w/Quick Coupling
SFW691R	Combined Hammer

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 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.

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.

Implant Removal
The T-PAL 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 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 slide 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.

Advanced applicator instructions:
– The T-PAL advanced applicator outer shaft and inner shaft have three etch lines to distinguish them from the standard applicator outer shaft and inner shaft.
– Note that the advanced applicator outer shaft is compatible with the existing trial implants but the shaft of the trial implants does not have three etch lines.

Special Operating Instructions

Patient positioning
– Position the patient in a restored physiological lordosis, avoiding abdominal restriction to reduce venous stasis.

Access and exposure: Minimally invasive transforaminal approach
Approach
– Locate the correct operative level with fluoroscopic views. Push the Kirschner wire into the desired facet joint. Separate the posterior soft tissue by inserting the smallest diameter dilator over the Kirschner wire. Repeat with next larger diameter dilator until required dilation is achieved. Use fluoroscopy to determine the location of dilator.

Retraction
Retraction with Insight tubes
– Determine the appropriate tube length from the depth indicators on the dilators.
– Slide the tube over the dilators until it contacts the facet joint.
– Use the flex arm to stabilize the tube to the operation room (OR) table. Remove the dilators and the Kirschner wire.

Retraction with Insight retractor
– Determine the appropriate retractor lengths of the cranial/caudal and medial/lateral blades from the depth indicators on the dilators.
– Slide the retractor with the cranial/caudal blades over the dilators until the blades contact the facet joints. Distract the blades and introduce the second retractor with the medial/lateral blades.
– Use the flex arm to stabilize the retractor to the OR table. Remove the dilators and the Kirschner wire.

Cut transforaminal window
– Prepare a window for the transforaminal approach using the osteotome to remove the inferior facet of the cranial vertebra and the superior facet of the caudal vertebra.
– With the laminectomy punch, additional bone or osteophytes can be removed.

Access and exposure: Open transforaminal approach
Retraction with an open transforaminal approach
– Make a standard open incision, retract the muscle layer to view the desired segment.
– Distract the segment if desired. Position the lamina spreader for T-PAL at the base of the spinous processes. Distract carefully until required distraction is achieved.
– Distraction opens the posterior disc space and promotes exposure both for decompression and delivery of the implant.

Cut transforaminal window
– Prepare a window for the transforaminal approach using the osteotome to remove the inferior facet of the cranial vertebra and the superior facet of the caudal vertebra.
– With the laminectomy punch, additional bone or osteophytes can be removed.

Discectomy
- Through an incision above the pedicle, access the foramen and remove disc material, using any of the following instruments: box and ring curettes, rongeurs as well as disc shavers.
- The shavers can initially be used to ream out disc material or for final removal of the disc material and cartilaginous tissue.
- For removal of the tissue in the far lateral disc space, use the left/right angled curettes and the curved rongeur.

Disc space preparation
Prepare endplates
- When the discectomy is completed, use the rasp to remove the superficial cartilaginous layers of the endplates to expose the bleeding bone.

Pack disc space
- Before the T-PAL cage is implanted, the anterior and far lateral disc space should be filled with bone graft material.

Trial for implant size
Assemble applicator and connect non detachable trial implant
- The applicator must be assembled before insertion of the trial.
- Attach the applicator knob to the proximal end of the applicator outer shaft by turning the knob counterclockwise until it stops.
- Select an appropriately sized trial implant. Insert the trial implant shaft into the applicator outer shaft making sure that the arrow on the outer shaft is aligned with the distal opening of the trial implant shaft. The trial implant shaft should now be trapped inside the applicator outer shaft.
- Turn the applicator knob clockwise to secure the trial implant. During this attaching procedure the security ring moves upwards, so that the green color band is visible. Continue to turn the knob until it is tightened.
- For disassembly pull the security ring down, turn the applicator knob counterclockwise until it stops. Push the small button on the applicator knob and simultaneously pull the trial implant shaft out of the applicator outer shaft. Turn the applicator knob clockwise. For detailed disassembly instructions please refer to section “Additional Device-Specific Information”.

Insert trial implant
- Recheck the firm connection of trial implant to applicator. Insert the trial implant into the disc space, ensuring that the orientation of the trial implant is correct. The trial implant tip should be orientated medially. Maintain 10–15° between the applicator handle and the sagittal plane during trial implant insertion.
- Controlled and light hammering on the applicator may be required to advance the trial implant into the intervertebral disc space. Use fluoroscopy to confirm position and fit of the trial implant. The tip should be positioned near the anterior edge of the adjacent vertebral bodies.
- Firm connection of trial implant to applicator can be checked manually by applying pressure on the lateral side of the trial implant with the thumb. Trial implant should not pivot.
- Use soft tissue retractor to reduce soft tissue damage/injury.
- Use fluoroscopy during the insertion to confirm anterior positioning of the trial implant.

Position trial implant
- Turn the applicator knob counterclockwise until it stops.
- Controlled and light hammering on the applicator may be required to pivot the trial implant into final position.
- Use fluoroscopy during the pivoting procedure and confirm fit and position of the trial implant. Each trial has a medial/lateral and an anterior/posterior opening for position control. If the trial implant appears too small or too tight, try the next larger or smaller size height until the adequate fit is achieved.
- Ensure that the trial implant is positioned where the implant will be placed.

Optional: Position trial implant
- If trial implant does not pivot automatically, turn the applicator handle medially to initiate pivoting upon impaction. After pivoting is initiated the applicator handle must be turned back to an angle of 10–15° from the sagittal plane to pivot the trial implant into final position.

Remove non detachable trial implant
- Slide the slide hammer onto the end of the applicator knob with quick coupling. While holding the handle with one hand, apply an upward force to the slide hammer with the other hand. Repeat this procedure until the trial implant is removed.
- Optionally the combination hammer may also be used to remove the trial implant.
- Remove the slide hammer from the handle by pushing on the end of the slide hammer.
- To detach the trial implant from the applicator, pull the security ring down and simultaneously turn the knob counterclockwise until it stops. Push the small button on the applicator knob and remove the trial implant.
- Insert the applicator inner shaft into the applicator outer shaft making sure that the arrow on the outer shaft is aligned with the distal opening of the inner shaft. The applicator inner shaft should now be trapped inside the outer shaft. The applicator is now ready to accept the implant.
- If the security ring cannot be pulled down, turn the knob clockwise a quarter turn. The ring can now be pulled down.

Implant preparation
Select implant
- Select the T-PAL implant that corresponds to the height and size determined using the trial implant in the previous steps.
- Insert the selected implant into the appropriate packing block place.

Pack implant
- Turn the packing block on its side and use the cancellous bone impactor to firmly pack the bone graft material into the implant cavities.
- Make sure the implant is well placed in the packing block to avoid implant damage while bone graft material filling.
- It is important to fill the implant until the bone graft material protrudes from its perforations in order to ensure optimal contact with the vertebral endplates.

Connect implant to the applicator
- To connect the implant to the applicator, turn the packing block upwards again. Pull the security ring down and simultaneously turn the knob at the proximal end of the applicator counterclockwise. The applicator jaws open. Place the jaws over the proximal end of the implant making sure to align the arrows on the end of the applicator with those on the implant.
- 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.
- When the applicator knob is tightened, the implant cannot pivot or detach.

Implant insertion
Insert implant
- Recheck the firm connection of implant to applicator. Insert the implant into the disc space, ensuring that the orientation of the implant is correct. The implant tip should be orientated medial. Maintain 10–15° between the applicator handle and the sagittal plane during implant insertion.
- Controlled and light hammering on the applicator may be required to advance the implant into the intervertebral disc space.
- Use fluoroscopy to confirm position and fit of the implant.
- The tip should be positioned near the anterior edge of the adjacent vertebral bodies.
- Firm connection of implant to applicator can be checked manually by applying pressure on the lateral side of the implant with the thumb. Implant should not pivot.
- Use soft tissue retractor to reduce soft tissue damage/injury.
- Use fluoroscopy during the insertion to confirm anterior position of the implant.
- The anterior marker pins of the implant are located approximately 2 mm from the edge of the implant.

Position implant
- Turn the applicator knob counterclockwise until it stops.
- Controlled and light hammering on the applicator may be required to pivot the implant into final position.
- Use fluoroscopy during the pivoting procedure and confirm fit and position of the implant.
- With a medial/lateral fluoroscopic image of the cage in the final position, the two anterior pins of the implant should appear as one line.
- In an anterior/posterior fluoroscopic image, the two anterior pins should be equidistant to the pedicles. The tip pin indicates the lateral edge of the implant.
- If bone graft material is placed into the disc space after trialing, the implant may not reach the same position as the trial.

Optional: Position implant
- If implant does not pivot automatically, turn the applicator handle medially to initiate pivoting upon impaction. After pivoting is initiated the applicator handle must be turned back to an angle of 10–15° from the sagittal plane to pivot the implant into final position.

Detach implant
- To detach the implant, pull the security ring down and simultaneously turn the applicator knob counterclockwise until it stops. The applicator can now be removed from the implant.
- Use fluoroscopy to verify final position of the implant. With a medial/lateral fluoroscopic image, the two anterior pins of the implant should appear as one line and the tip marker as a dot.
- If the security ring cannot be pulled down, turn the knob clockwise a quarter turn. The ring can now be pulled down.
- If the applicator does not disengage from the implant move the applicator handle laterally to free the instrument.

Implant positioning and verification
- From the lateral view the T-PAL implant markers should appear as one single line as they will be superimposed one on top of the other if the implant is properly seated. The distance from the superimposed line to the edge of the PEEK is approximately 2 mm. Additionally the horizontal marker will appear as a single dot.
- Verify that the T-PAL implant is properly positioned in the anteroposterior (AP) view. If properly seated, the vertical markers should appear to be equidistant from the midline of the spinous process of the spinal column. The horizontal marker will appear perpendicular to the vertical markers. From an AP perspective these two markers will straddle the spinous process.

Posterior support
Pack disc space
– After the T-PAL cage is implanted, fill the posterior disc space and the lateral disc space with bone graft material to create desired conditions for fusion.

Supplemental fixation
– The T-PAL cage must be applied in combination with posterior fixation.

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.

Implant Card & Patient Information Leaflet
If supplied with the original packaging, provide the implant card as well as the relevant information according to the patient information leaflet to the patient. The electronic file containing the patient information can be found at the following link: ic.jnjmedicaldevices.com

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Instructions for Use:
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