T-PAL. Transforaminal posterior atraumatic lumbar spacer system.
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**Spacers**
Spacers are offered in two footprints, eleven heights and a lordotic angle of 5° (0° for 7 mm height spacers) to accommodate individual patient anatomy.

**Pyramidal teeth**
Provide resistance to spacer migration

**Rails on the surface**
Guide and turn the spacer into position

**Self-distracting bullet nose**
Facilitates insertion

**Connection cylinder**
Permits pivoting action of the applicator

**Two anterior radiographic marker pins**
Enable visualization of the anterior spacer position. The 1.4 mm diameter pins are located approximately 2 mm from the anterior edge of the spacer

**Material**
PEEK with titanium alloy (Ti-6Al-7Nb) x-ray markers

**Axial window**
Accommodates autogenous bone graft to allow fusion to occur through the spacer

**One radiographic marker pin at tip**
Enable visualization of the spacer tip for position control during insertion. The 1.4 mm diameter, 5 mm long pin is located in the middle of the spacer, and stops at the bullet nose tip of the spacer.

**5° lordotic angle**
Accommodates the natural spine lordotic curve (7 mm height is 0°)
T-PAL Applicator

- One instrument for the insertion of the spacer and trials
- Pivoting option for controlled insertion
- Rigid 0° and 80° positioning of the spacer when connected to the applicator
- Security button to avoid spacer disengagement

Guided insertion technique

- Trial spacers can be placed at the final spacer location
- AP and lateral markers on trial spacers allow position control in final placement
- Guided trial and spacer insertion facilitated by pivoting of the applicator and by rails on the surface of the trials and spacers
- Secure attachment of spacer to applicator
- Simple OR technique based on a single instrument: the applicator
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.¹ They are:

- Anatomic reduction
- Stable internal fixation
- Preservation of blood supply
- Early, active mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. A specific goal in the spine is returning as much function as possible to the injured neural elements.²

AO Principles as Applied to the Spine³

Anatomic alignment
In the spine, this means reestablishing and maintaining the natural curvature and the protective function of the spine. By regaining this natural anatomy, the biomechanics of the spine can be improved, and a reduction of pain can be experienced.

Stable internal fixation
In the spine, the goal of internal fixation is to maintain not only the integrity of a mobile segment, but also to maintain the balance and the physiologic three-dimensional form of the spine.³ A stable spinal segment allows bony fusion at the junction of the lamina and pedicle.

Preservation of blood supply
The proper atraumatic technique enables minimal retraction or disturbance of the nerve roots and dura, and maintains the stability of the facet joints. The ideal surgical technique and implant design minimize damage to anatomical structures, i.e., facet capsules and soft tissue attachments remain intact, and create a physiological environment that facilitates healing.

Early, active mobilization
The ability to restore normal spinal anatomy may permit the immediate reduction of pain, resulting in a more active, functional patient. The reduction in pain and improved function can result when a stable spine is achieved.

². Ibid.
Indications and Contraindications

**Intended Use**
The T-PAL Spacer is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the T-PAL Spacer should be packed with autogenous bone graft (i.e., autograft).

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of nonoperative treatment.

The T-PAL Spacer is intended to be used with Synthes supplemental fixation, e.g., TSLP, ATB, Antegra, Synthes USS (including MATRIX, USS Small Stature, Click’X, Pangea, USS Polyaxial, USS Iliosacral, and ClampFix).

**Contraindications**
- Use of the Synthes T-PAL Spacer implant is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in patients with such conditions must be made by the physician, taking into account the risks versus the benefits to the patient.
- Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions. These patients may place undue stresses on the implant during bony healing and may be at higher risk of implant failure.
- Prior fusion at the level(s) to be treated.
- Any condition not described in the indications for use.

Please refer to the package insert for the full list of indications, contraindications, warnings and/or precautions.
## Preparation

**Set**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>01.812.001</td>
<td>T-PAL Spacer Instrument and Implant Set</td>
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</tbody>
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**Optional sets**

<table>
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<th>Code</th>
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<tr>
<td>01.605.500</td>
<td>Minimally Invasive Posterior Instrument Set (MIPI)</td>
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<tr>
<td>01.803.100</td>
<td>OPAL System</td>
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<tr>
<td>105.151</td>
<td>T-PLIF Minimally Invasive Instrument Set</td>
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<tr>
<td>105.152</td>
<td>T-PLIF Auxiliary Instrument Set</td>
</tr>
</tbody>
</table>

Resect the posterior anatomy and perform the discectomy. Use a standard transforaminal approach for insertion of the spacers.
1

Assemble applicator with trial spacer

**Instruments**

- 03.812.001  T-PAL Spacer Applicator Handle
- 03.812.004  T-PAL Spacer Applicator Knob
- 03.812.307 – T-PAL Trial Spacers, 10 mm x 28 mm,
  03.812.317  7 mm – 17 mm heights
- 03.812.507 – T-PAL Trial Spacers, 12 mm x 32 mm,
  03.812.517  7 mm – 17 mm heights

Attach the applicator knob to the threaded end of the applicator handle by turning the knob counterclockwise until it stops.

Select an appropriately sized trial spacer. Start conservatively to minimize disruption to the endplates. Insert the trial spacer shaft into the applicator handle shaft, ensuring that the arrow on the handle shaft is aligned with the arrow on the trial. The trial spacer shaft should now be captured inside the applicator handle.

Turn the knob clockwise. The security ring will click up to reveal the green color band. Continue to turn the knob until it is tightened. As long as the applicator knob is firmly tightened, the trial spacer cannot pivot.

**Important:** The trial spacer must fit flush against the applicator without a gap.

**Note:** In this insertion position, the trial spacer is fixed at 0° and cannot pivot.
Insert trial spacer

Check the applicator and trial spacer connection. Insert the trial spacer into the disc space, ensuring that the orientation of the trial spacer is correct. The distal tip of the trial spacer should be curved medially. Controlled, light hammering on the applicator may be required to advance the trial spacer into the intervertebral disc space.

Use fluoroscopy to confirm the position of the trial spacer.

**Note:** At this time, the trial spacer is fixed at 0° and cannot pivot.

**Important:** The trial tip indicates the approximate final anterior position of the trial spacer.
3

**Position trial spacer**

Turn the applicator knob counterclockwise until it stops at the security ring (a). The trial spacer can now pivot. Advance the trial spacer into the disc space. Controlled, light hammering on the applicator may be required to pivot the trial spacer into the final position.

Use fluoroscopy during the pivoting procedure to confirm fit and position of the trial spacer. Each trial spacer has a lateral and an AP opening for position control. If the trial spacer appears too small or too tight, try the next larger or smaller size until the most secure fit is achieved.

**Important:** Be sure to position the trial spacer in the final desired location of the disc space.

**Note:** In pivoting position, the trials can pivot up to 80°.
4

Remove trial spacer

Instrument

03.809.972 Oracle Slap Hammer

Slide the slap hammer onto the end of the applicator knob with quick coupling. While holding the handle in one hand, apply an upward force to the slap hammer with the other hand. Repeat this procedure until the trial spacer is removed.

**Important:** The applicator must be in the pivoting position to remove the trial spacer.

Remove the slap hammer from the handle.

Remove the trial spacer from the applicator by pushing down on the security ring (a) so that the green line is no longer visible, and turning the applicator knob (b) counterclockwise until the knob touches the ring. Push the button on the applicator knob (c) and remove the trial spacer.
1

Select implant

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>03.812.001</td>
<td>T-PAL Spacer Applicator Handle</td>
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<tr>
<td>03.812.003</td>
<td>T-PAL Spacer Applicator Inner Shaft</td>
</tr>
<tr>
<td>03.812.004</td>
<td>T-PAL Spacer Applicator Knob</td>
</tr>
</tbody>
</table>

Select the T-PAL spacer that corresponds to the size and height determined with the trial spacer.

Install the applicator inner shaft into the shaft of the applicator handle until the release button clicks into place.

Attach the spacer to the applicator by tightening the applicator knob until the spacer fits flush with the distal end of the applicator shaft. The security ring will click up to reveal the green color band. Continue to turn the knob clockwise until it is firmly tightened. As long as the applicator knob is tightened, the spacer cannot pivot or detach.

**Important:** Be sure to align the arrows on the end of the applicator with those on the spacer. The spacer must fit flush against the applicator without a gap.

**Note:** In the insertion position, the spacer is fixed at 0° and cannot pivot.
2

Insert implant

Recheck the connection between the applicator and T-PAL spacer. Insert the spacer into the disc space, ensuring that the orientation of the spacer is correct (the tip of the spacer will be curved medially). Controlled, light hammering on the applicator may be required to advance the spacer into the intervertebral disc space to the appropriate position.

Use fluoroscopy to confirm the position of the spacer.

**Note:** In the insertion position, the spacer is fixed at 0° and cannot pivot.
3

Position implant

Turn the applicator knob counterclockwise until it stops at the security ring. The spacer can now pivot. Advance the spacer into the disc space. Controlled, light hammering on the applicator may be required to pivot the spacer into the final position.

Use fluoroscopy during the pivoting procedure and confirm the position of the spacer. In a mediolateral fluoroscopic image of the spacer in the final position, the two anterior marker pins on the spacer should appear as one line.

Note: In the pivoting position the spacer can pivot up to 80°.

Important: If the spacer requires repositioning, use the applicator or T-PAL spacer remover. If complete removal of the spacer is necessary, refer to page 16.
4

**Detach implant**
To detach the spacer, push the security ring down and simultaneously turn the applicator knob counterclockwise until it stops. The applicator can now be removed from the spacer.

Use fluoroscopy to verify final position of the spacer.

**Note:** If the security ring cannot be pushed down, turn the knob one-quarter turn clockwise. The ring can now be pushed down.
Supplemental fixation

Supplemental fixation, e.g., posterior fixation with trans-pedicular screws (Click‘X, VAS, Pangea or USS screws), is required, to enhance the biomechanical stability of the motion segment and the stability of the T-PAL spacer.

Refer to the appropriate technique guide for additional information.
Implant Removal

Remove implant

Option A: Using the applicator

Instruments

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<tr>
<th>Item Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>03.812.001</td>
<td>T-PAL Spacer Applicator Handle</td>
</tr>
<tr>
<td>03.812.003</td>
<td>T-PAL Spacer Applicator Inner Shaft</td>
</tr>
<tr>
<td>03.812.004</td>
<td>T-PAL Spacer Applicator Knob</td>
</tr>
</tbody>
</table>

To assemble the applicator, attach the knob to the threaded end of the handle by turning the knob counterclockwise until it stops. Slide the inner shaft into the shaft of the handle until it clicks into place.

Attach the applicator to the spacer. Close the applicator by turning the knob clockwise only until the security ring clicks up. There should be no gap between the security ring and the knob. To ensure that the knob is flush against the security ring, turn it slightly counterclockwise. In this position, the spacer will pivot freely. The spacer can now be removed. The slap hammer may be attached to the applicator to facilitate removal.

Option B: Using the spacer remover

Instrument

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<th>Item Code</th>
<th>Description</th>
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<tbody>
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<td>03.812.005</td>
<td>T-PAL Spacer Remover</td>
</tr>
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</table>

The spacer remover is in the fully open position prior to squeezing the pistol handle. Locate the spacer and squeeze the handle firmly. Advance the speed nut to lock the spacer remover to the spacer. The spacer will pivot freely. The spacer can now be removed. The slap hammer may be attached to the spacer remover to facilitate removal.
Applicator Instructions

1. **Attach/detach position**
   Pull the security ring down and simultaneously turn the knob counterclockwise. There should be no gap between the handle, security ring and the applicator knob. The green color band should not be visible.

   The spacer can now be attached or detached.

2. **Insertion position**
   Turn the applicator knob clockwise until the jaws of the applicator have a tight grip on the spacer. The security ring will click up to reveal the green color band.

   Continue to turn the knob until it is tightened.

   In the insertion position the spacer is fixed at 0° and cannot pivot or detach.

3. **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 spacer can pivot 80° and cannot detach from the applicator.
### T-PAL Spacers, 10 mm x 28 mm

<table>
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<th>Height</th>
<th>Posterior Height</th>
<th>Graft Volume*</th>
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<tr>
<td>08.812.007</td>
<td>7 mm</td>
<td>0.39 cc</td>
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<td>08.812.008</td>
<td>8 mm</td>
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<tr>
<td>08.812.009</td>
<td>9 mm</td>
<td>0.50 cc</td>
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<tr>
<td>08.812.010</td>
<td>10 mm</td>
<td>0.58 cc</td>
</tr>
<tr>
<td>08.812.011</td>
<td>11 mm</td>
<td>0.66 cc</td>
</tr>
<tr>
<td>08.812.012</td>
<td>12 mm</td>
<td>0.77 cc</td>
</tr>
<tr>
<td>08.812.013</td>
<td>13 mm</td>
<td>0.88 cc</td>
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<tr>
<td>08.812.014</td>
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<tr>
<td>08.812.017</td>
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<td>1.31 cc</td>
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### T-PAL Spacers, 12 mm x 32 mm

<table>
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<th>Height</th>
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<th>Graft Volume*</th>
</tr>
</thead>
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<tr>
<td>08.812.208</td>
<td>8 mm</td>
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</tr>
<tr>
<td>08.812.209</td>
<td>9 mm</td>
<td>0.81 cc</td>
</tr>
<tr>
<td>08.812.210</td>
<td>10 mm</td>
<td>0.94 cc</td>
</tr>
<tr>
<td>08.812.211</td>
<td>11 mm</td>
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<td>08.812.212</td>
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<td>08.812.215</td>
<td>15 mm</td>
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<td>08.812.216</td>
<td>16 mm</td>
<td>1.89 cc</td>
</tr>
<tr>
<td>08.812.217</td>
<td>17 mm</td>
<td>2.05 cc</td>
</tr>
</tbody>
</table>

*Approximate graft volume that T-PAL spacers can hold.

**Total depth**
- 10 mm x 28 mm spacers: 14 mm
- 12 mm x 32 mm spacers: 16 mm

**Insertion depth**
- 10 mm x 28 mm spacers: 10 mm
- 12 mm x 32 mm spacers: 12 mm

**Length**
- 10 mm x 28 mm spacers: 28 mm
- 12 mm x 32 mm spacers: 32 mm
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>03.605.500</td>
<td>Impactor, standard, bayoneted</td>
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<tr>
<td>03.809.972</td>
<td>Oracle Slap Hammer</td>
</tr>
<tr>
<td>03.809.973</td>
<td>Bayoneted Scalpel Handle</td>
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<tr>
<td>03.812.001</td>
<td>T-PAL Spacer Applicator Handle</td>
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<tr>
<td>03.812.003</td>
<td>T-PAL Spacer Applicator Inner Shaft</td>
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<tr>
<td>03.812.004</td>
<td>T-PAL Spacer Applicator Knob</td>
</tr>
<tr>
<td>03.812.005</td>
<td>T-PAL Spacer Remover</td>
</tr>
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</table>
03.812.307 – T-PAL Trial Spacers, 10 mm x 28 mm,
03.812.317  7 mm – 17 mm heights

03.812.507 – T-PAL Trial Spacers, 12 mm x 32 mm,
03.812.517  7 mm – 17 mm heights

PDL102  Slotted Mallet
T-PAL Implant and Instrument Set (01.812.001)

Graphic Case
60.812.001 Graphic Case, for T-PAL Instruments and Implants

Instruments
03.605.500 Impactor, standard, bayoneted
03.809.972 Oracle Slap Hammer
03.809.973 Bayoneted Scalpel Handle
03.812.001 T-PAL Spacer Applicator Handle, 2 ea.
03.812.003 T-PAL Spacer Applicator Inner Shaft, 2 ea.
03.812.004 T-PAL Spacer Applicator Knob, 2 ea.
03.812.005 T-PAL Spacer Remover
03.812.307 – T-PAL Trial Spacers, 10 mm x 28 mm,
03.812.317 7 mm – 17 mm heights
03.812.307 – T-PAL Trial Spacers, 12 mm x 32 mm,
03.812.517 7 mm – 17 mm heights
08.812.007 7 mm
08.812.008 8 mm
08.812.009 9 mm
08.812.010 10 mm
08.812.011 11 mm
08.812.012 12 mm
08.812.013 13 mm
08.812.014 14 mm
08.812.015 15 mm
08.812.016 16 mm
08.812.017 17 mm

Note: For additional information, please refer to package insert.
For detailed cleaning and sterilization instructions, please refer to http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm
or to the below listed inserts, which will be included in the shipping container:
- Processing Synthes Reusable Medical Devices—Instruments, Instrument Trays and Graphic Cases—DJ1305
- Processing Non-sterile Synthes Implants—DJ1304