True Position®

Pivoting Spacer System

Surgical Technique

SpineWave

Spine Wave Mission Statement

Spine Wave is dedicated to developing and delivering high-quality, innovative technologies that assist physicians in treating spinal disorders and improving patients' lives; exceeding the expectations of our customers; complying with statutory, regulatory, and customer requirements; maintaining the effectiveness of the quality management system; providing a challenging and rewarding work environment with exceptional growth opportunities for deserving employees; and delivering superior returns for our shareholders.

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IMPLANT OVERVIEW

The True Position® Pivoting Spacer System features patented Central Pivot Point Technology for controlled and precise positioning

Center Pivot Technology

Allows the spacer to be rotated in the disc space while maintaining control throughout actuation.

Optimal Control

Offers control while providing tactile feel throughout the rotation process.

True MIS Approach

The instrumentation requires no medial-lateral movement upon rotation of the implants making it ideal for MIS approaches.

Cat. #	12 x 27 mm Implants
11-6100	27 (L) x 7.5 (H) mm
11-6101	7° Lordotic, 27 (L) x 9 (H) mm
11-6102	7° Lordotic, 27 (L) x 10 (H) mm
11-6103	7° Lordotic, 27 (L) x 11 (H) mm
11-6104	7° Lordotic, 27 (L) x 12 (H) mm
11-6105	7 ° Lordotic, 27 (L) x 13 (H) mm
11-6106	7° Lordotic, 27 (L) x 14 (H) mm
11-6107	7° Lordotic, 27 (L) x 15 (H) mm

Cat. #	13 x 36 mm Implants
11-6130	36 (L) x 7.5 (H) mm
11-6131	7° Lordotic, 36 (L) x 9 (H) mm
11-6132	7° Lordotic, 36 (L) x 10 (H) mm
11-6133	7° Lordotic, 36 (L) x 11 (H) mm
11-6134	7° Lordotic, 36 (L) x 12 (H) mm
11-6135	7° Lordotic, 36 (L) x 13 (H) mm
11-6136	7° Lordotic, 36 (L) x 14 (H) mm
11-6137	7° Lordotic, 36 (L) x 15 (H) mm

INSTRUMENT OVERVIEW

Trial Inserter - Inner Shaft

Trial Inserter - Outer Shaft

Slap Hammer

27 mm Lordotic Trial

Straight Tamp

Implant Removal Tool

Trial Draw Knob

Knob Assembly

Articulating Trial

36 mm Lordotic
Articulating Trial

Implant Inserter

Inline Slap Hammer

Gear Driver

27 mm Spacer

30+ mm Spacer

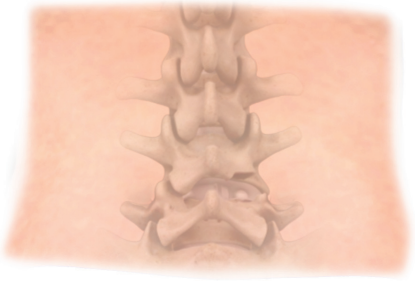
Cat. #	Description
2008-04-0000	Trial Inserter Assembly
	Trial, Inner Shaft
	Trial, Outer Shaft
ITS-01-000	Slap Hammer
10-6210	Articulating Trial Assembly
	Articulating Trial Inserter
10-6224	Trial Draw Knob Assembly
10-6215	In-Line Slap Hammer
10-6223	Gear Driver

Cat. #	Description
2008-09-0000	Straight Tamp
2008-07-0000	Implant Removal Tool
	Implant Inserter Assembly
2008-13-0000	Implant Inserter
2008-16-0000	Inserter Knob Assembly
2008-14-2700	27 mm Spacer
2008-14-3000	30 + mm Spacer
*	27 mm Lordotic Trials (7.5 mm -15 mm)
*	36 mm Lordotic Trials

** See Page 15 for Trial Cat. #s*

Step 1 PRE-OPERATIVE PLANNING AND APPROACH

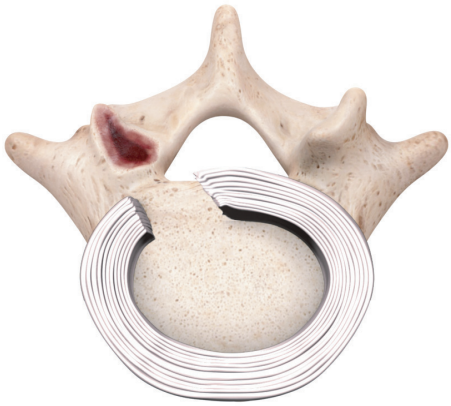
Perform pre-operative planning to ensure that the implant length and height offering is appropriate for the patient. The patient is placed in the prone position for optimal access to the targeted level(s). Expose the operative segment.



Step 2 DISC PREPARATION

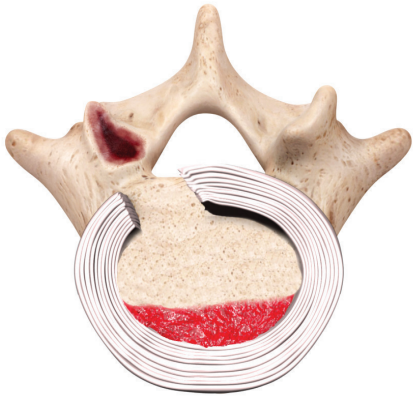
Expose the disc space and remove disc material with the help of commonly used surgical instruments such as rongeurs, curettes, rasps and other appropriate instruments.

A meticulous nucleus removal and endplate preparation maximizes the amount of space for bone graft which may increase the potential for a successful fusion.



Step 3 PRE-PACKING GRAFT MATERIAL

Once the site preparation is complete, the disc space is pre-packed with autograft. Sweep graft material to appropriate location using a tamp. A trial should be used to confirm positioning and to compact the graft material. Quantity of bone graft shown is not representative and will vary from patient to patient.



Step 4 TRIAL INSERTION

STANDARD TRIAL INSERTION

Trials are provided for all available implant sizes and have the identical footprint, height, and lordosis of the corresponding implants.

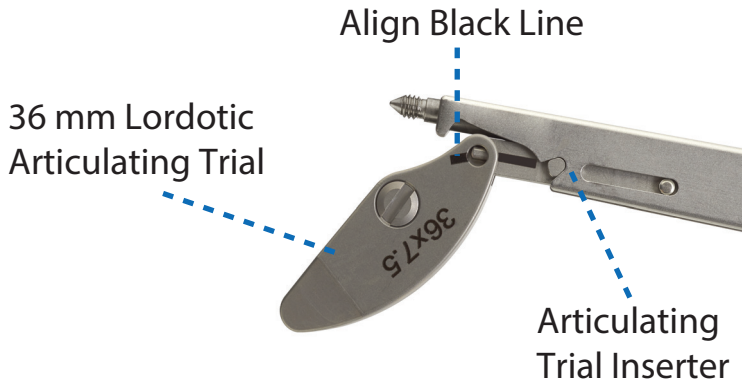
To assemble trial, insert the inner shaft of the trial inserter into the outer shaft and snap together. To connect to the trial, insert the distal end of the instrument into the trial and rotate the handle clockwise until tight.

A slap hammer is available to aid in removal of the trial from the disc space. To attach, engage the slap hammer onto the loading zone at the proximal end of the trial inserter.

Step 4 TRIAL INSERTION (CONT'D)

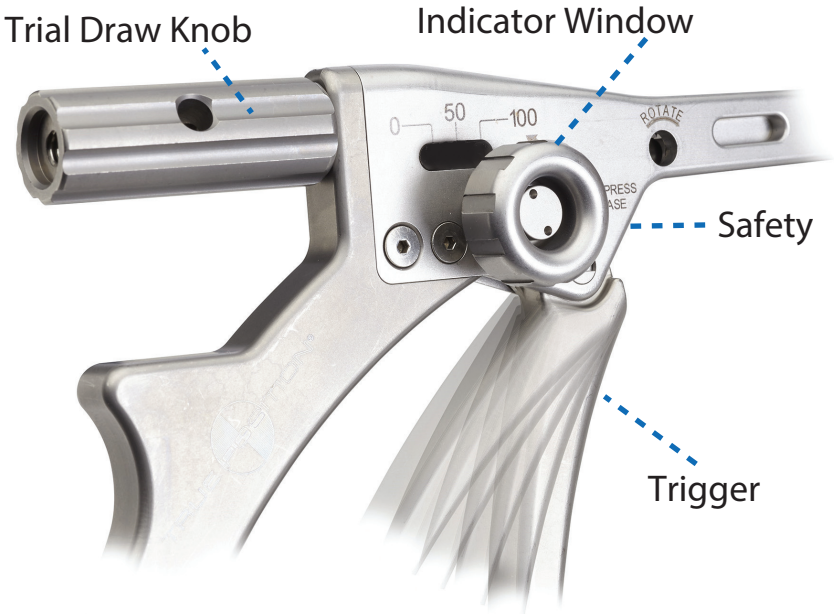
ARTICULATING TRIAL INSERTION

An articulating trial is available to assess the height and footprint.



To load the articulating trial, align the marking on the articulating trial with the marking on the articulating trial inserter and then rotate the trial up to mate with the Inserter. Ensure that the groove on the pivot pin is aligned with the draw rod.

Advance the grey trial draw knob until the trial is secured against the instrument. Rotate the safety clockwise to ensure the trial does not articulate inadvertently during insertion.



When ready to articulate the trial, rotate the draw knob counterclockwise a half turn.

Then rotate the safety knob counterclockwise until it stops and push and hold it in.

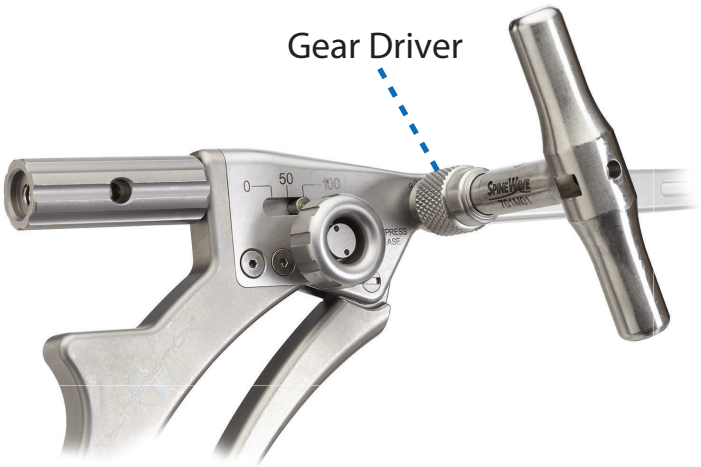
Finally, pull the trigger to articulate the implant.

Note: Rotating the safety clockwise prevents the trial from rotating. Rotating the safety counterclockwise allows for deployment of the trigger by pushing and holding the safety in.

Step 4 TRIAL INSERTION (CONT'D)

ARTICULATING TRIAL INSERTION CONT'D

When fully rotated to the "100" position, the articulating trial can be locked in position. To do this, rotate the safety clockwise until it bottoms out.

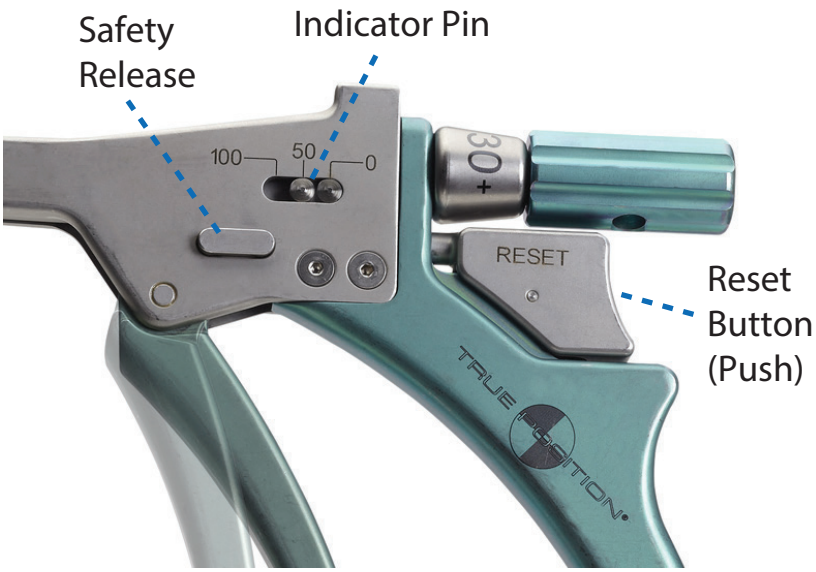


A gear driver offers an alternative option for a controlled rotation of the articulating trial as shown. Ensure the driver is fully engaged prior to articulating.

The in-line slap hammer can be threaded into the back of the draw knob to remove the trial inserter as necessary.

Step 5 INSERTER ASSEMBLY

RESETTING THE INSERTER



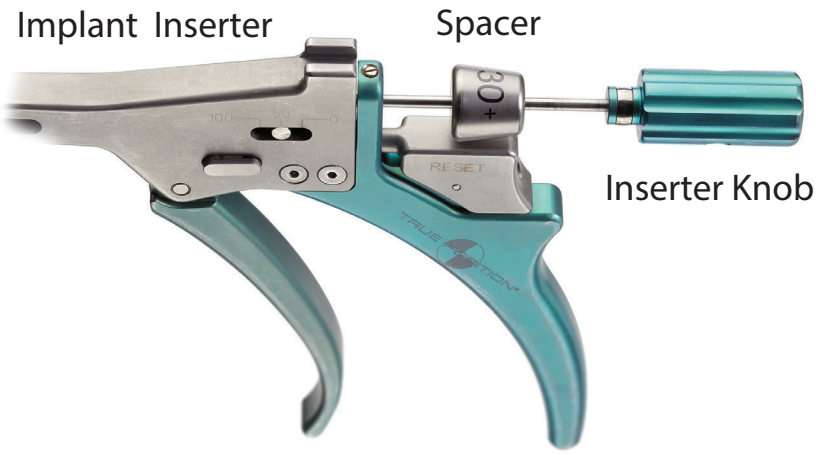
Prior to loading the implant, ensure that the inserter has been properly reset after the last usage.

Verify that the indicator pin is at the "0" position.

Check that the safety release is flush against the inserter and not protruding out.

If the inserter needs to be reset, push in the reset button while pulling the trigger away from the handle until a click is heard and the indicator pin returns to the "0" position.

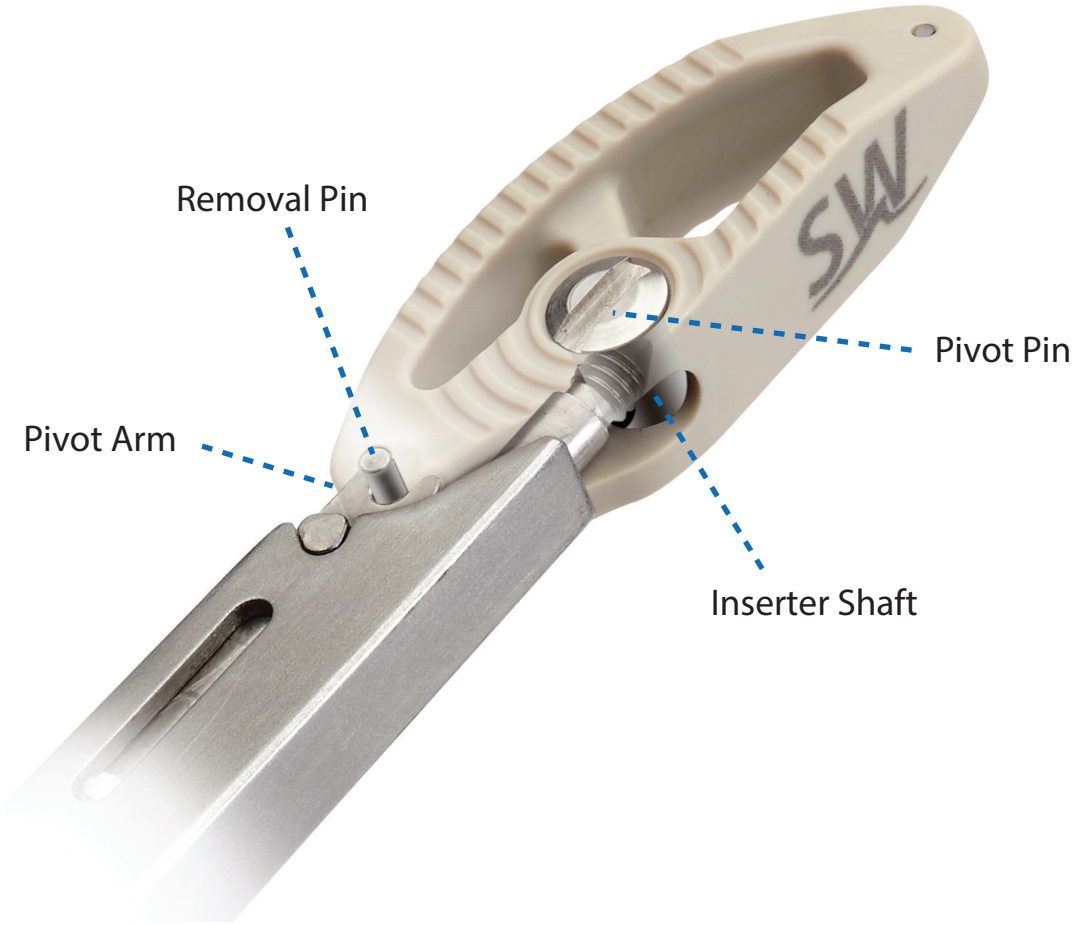
INSERTER ASSEMBLY



Once the appropriate implant length and height are selected, choose the corresponding 27 mm (green) or 30+ mm (grey) spacer and slide it onto the inserter shaft.

Note: Using the incorrect combination of spacer and implant can lead to malfunction of the inserter.

Step 6 LOADING THE IMPLANT



Align groove on the pivot pin of the implant until it is facing the threaded tip on the inserter shaft. While ensuring that the removal pin on the implant is engaging the female pocket on the pivot arm, begin rotating the green inserter knob clockwise until fully threaded and finger tight.

Tug on the implant to ensure it is loaded correctly.

Note: Use caution to ensure the inserter does not cross thread into the implant. If any resistance is felt, remove the implant and start again.

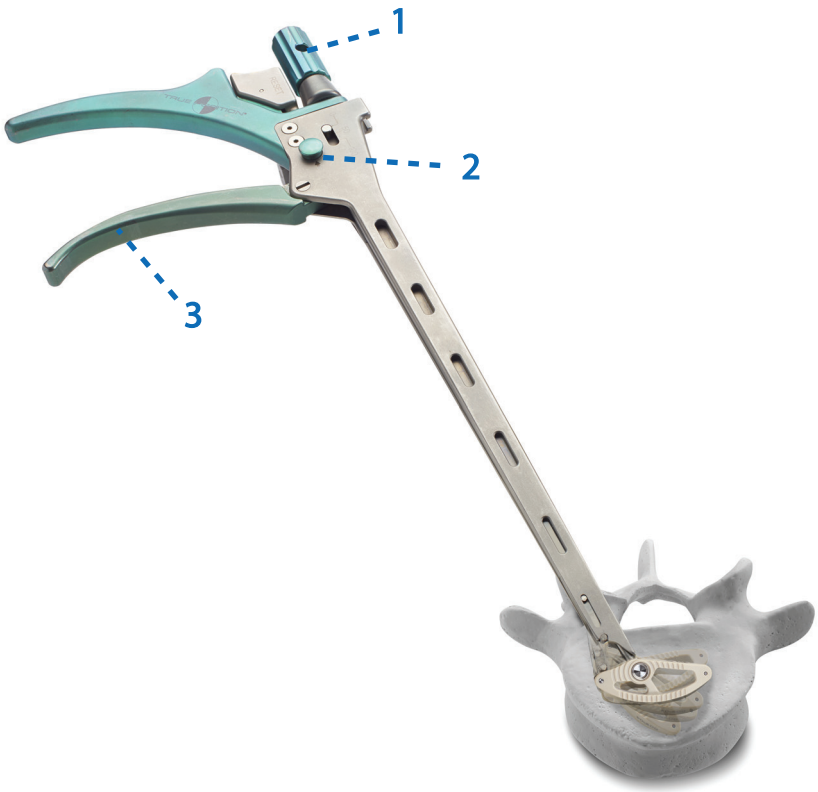
Step 7 IMPLANT INSERTION

The surgeon can introduce the inserter into the disc space by malleting the inserter draw knob.

The inserter is designed to achieve a final implant orientation which is perpendicular to the midline in the axial plane. An approximate approach angle of 15° is recommended to accomplish this orientation when fully actuated. To optimize final placement, it is recommended that the implant be centered midline in the axial plane prior to actuation, and confirmed with an A/P radiographic image.

Note: Do not push the green safety release button during impaction or the implant may rotate prematurely.

Step 8 IMPLANT POSITIONING



1) To actuate the inserter, first rotate the inserter draw knob approximately a half turn counterclockwise.

2) Next, press and hold the safety release button.

3) Finally, squeeze the trigger to rotate the implant to the desired position.

   After rotation, and before removal of the inserter, the implant can be tamped anteriorly to increase lordosis as desired.

Note: Squeezing the trigger prior to pressing the safety release button will make it difficult to release the safety.

Note: The trigger should remain squeezed during additional impaction. Do not rotate the inserter in the axial plane or the pivot arm may disengage from the implant.

Step 9 FINAL VERIFICATION

The implants are designed with tantalum markers for assessment under radiographic imaging.

In Anterior/Posterior radiographs, as the implant is rotated from a starting point of the pivot pin on the midline, the anterior tantalum marker will rotate toward and eclipse the right side of the pivot pin.*

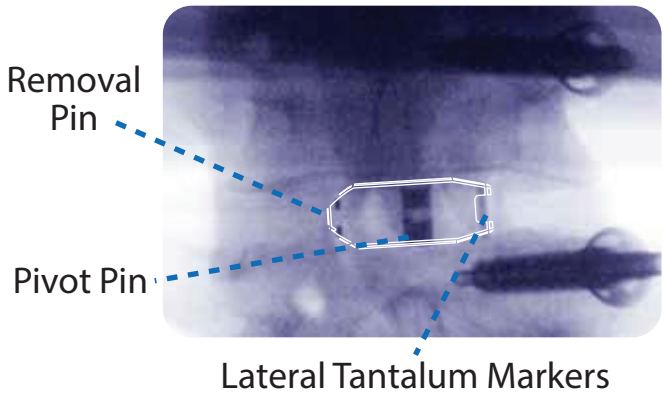
In lateral radiographs, the lateral tantalum markers and the removal pin will rotate toward the pivot pin and eventually be eclipsed by the pivot pin.

After verifying placement, rotate the green Inserter draw knob counterclockwise until it disengages. Remove the inserter from the wound and reset for subsequent usage.

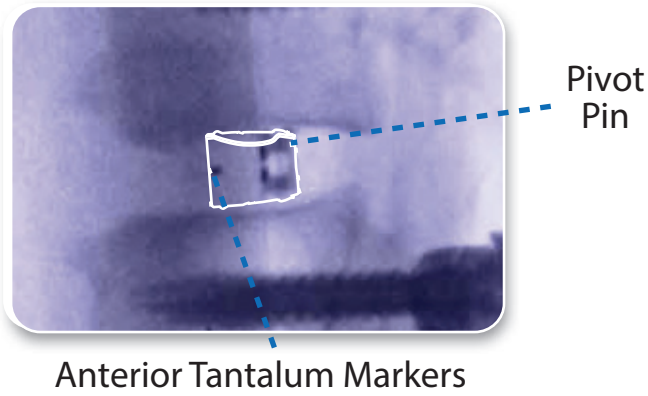
*Note that for 36+ mm options the pivot pin will not be midline but the anterior tantalum marker will be midline.

(%) Rotation	Axial Representation	True AP View*	True Lateral View*
0% Rotation			
20% Rotation			
40% Rotation			
60% Rotation			
80% Rotation			
100% Rotation			

ANTERIOR/POSTERIOR*



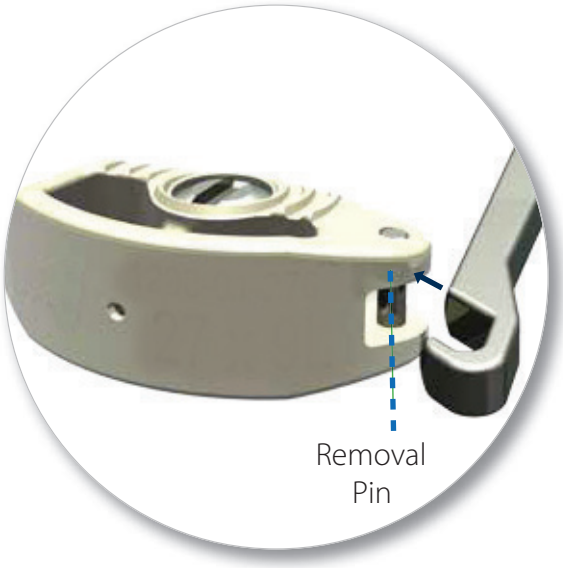
LATERAL



FINAL CONSTRUCT

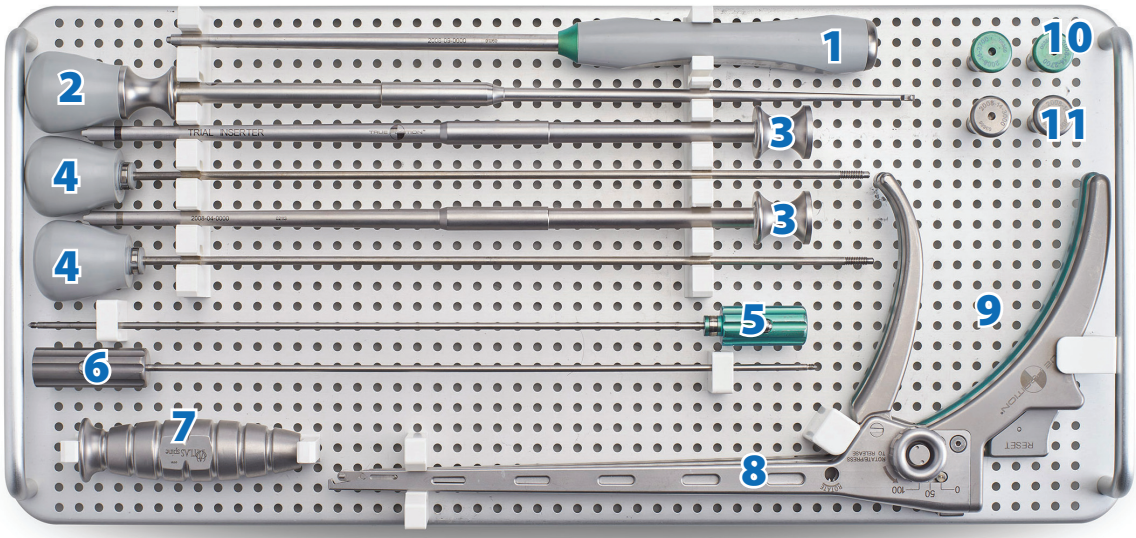
The True Position® Spacer System is intended to be used with supplemental fixation. Prepare the site for application of supplemental fixation in accordance with the fixation device's instructions for use (IFU).

IMPLANT REMOVAL



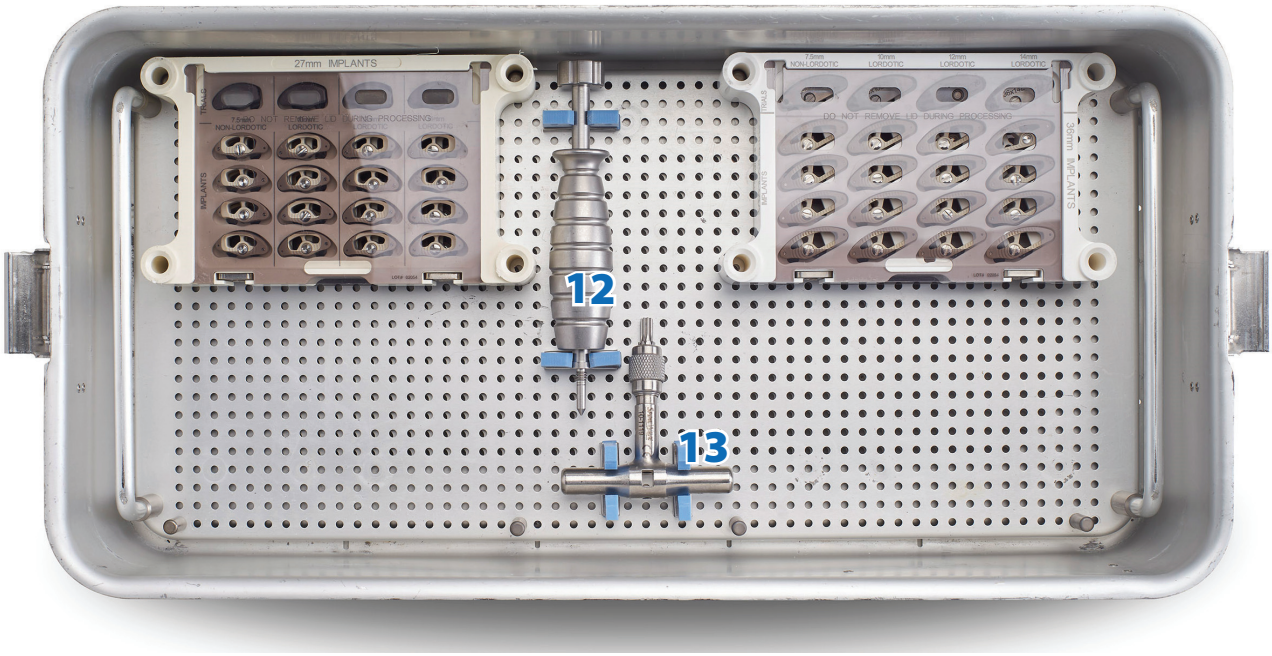
An implant removal tool is available should the implant need to be removed after detachment from the inserter. Hook the distal tip of the instrument around the removal pin and tug lightly to ensure proper engagement. While maintaining upward tension on the removal tool, attach the slap hammer to remove.

TRAY LAYOUT



INSTRUMENT CATALOG NUMBER

1	Straight Tamp	5	Implant Inserter Knob Assembly (Green)	9	Implant Inserter (Green)
2	Implant Removal Tool	6	Articulating Trial Knob Assembly (Grey)	10	27 mm Spacer (Green)
3	Trial Inserter Outer Shaft	7	Slap Hammer	11	36 mm Spacer (Grey)
4	Trial Inserter Inner Shaft	8	Articulating Trial Inserter (Grey)	12	In-Line Slap Hammer
				13	Gear Driver



NOTE: Caddies are double sided with even numbers on top and odd numbers on the bottom.

27 mm, 36 mm Lordotic Implants & Trials

27 mm Lordotic Catalog Numbers

10-6230	Trial, 27 (L) x 7.5 (H) mm
10-6231	Trial 7° Lordotic, 27 (L) x 9 (H) mm
10-6232	Trial 7° Lordotic, 27 (L) x 10 (H) mm
10-6233	Trial 7° Lordotic, 27 (L) x 11 (H) mm
10-6234	Trial 7° Lordotic, 27 (L) x 12 (H) mm
10-6235	Trial 7° Lordotic, 27 (L) x 13 (H) mm
10-6236	Trial 7° Lordotic, 27 (L) x 14 (H) mm
10-6237	Trial 7° Lordotic, 27 (L) x 15 (H) mm
*	27 mm Implants

36 mm Lordotic Catalog Numbers

10-6260	Trial, 36 (L) x 7.5 (H) mm
10-6261	Trial 7° Lordotic, 36 (L) x 9 (H) mm
10-6262	Trial 7° Lordotic, 36 (L) x 10 (H) mm
10-6263	Trial 7° Lordotic, 36 (L) x 11 (H) mm
10-6264	Trial 7° Lordotic, 36 (L) x 12 (H) mm
10-6265	Trial 7° Lordotic, 36 (L) x 13 (H) mm
10-6266	Trial 7° Lordotic, 36 (L) x 14 (H) mm
10-6267	Trial 7° Lordotic, 36 (L) x 15 (H) mm
*	36 mm Implants

 # See Page 4 for Implant Cat. #s

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION
The Spine Wave TRUE POSITION® Pivoting Spacer System is a radiolucent device in various sizes. The device design includes five (5) radiopaque markers that allow postoperative radiographic confirmation of the device position and orientation.

INDICATIONS FOR USE
The TRUE POSITION® Pivoting Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The TRUE POSITION® Pivoting Spacer System is to be used with a supplemental fixation system and autogenous bone graft.

MATERIALS
The TRUE POSITION® Pivoting Spacer implants are manufactured from implantable PEEK-OPTIMA® LT1 (polyetheretherketone) polymer in conformance with ASTM F-2026, Standard specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications; the radiopaque markers are made from biocompatible tantalum conforming to ASTM F-560, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400); and the pins are made from titanium alloy conforming to ASTM F-136, Standard specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).

CLEANING AND STERILIZATION
The TRUE POSITION® Pivoting Spacer System is supplied clean and non-sterile and is intended to be sterilized prior to use. Sterilize following AAMI ST79 standards and a validated cycle to achieve a sterility assurance level (SAL) of 10^{-6} or better. Spine Wave Inc. recommends an FDA cleared wrap, pre-vacuum steam sterile at 132° C for a minimum of 8 minutes. Following sterilization, implants should be dried and/or cooled to prevent condensation.

Cycle Type	Pre-Vacuum
Preconditioning Pulse	3
Cycle Time	8 minutes
Temperature	270° F (132° C)
Dry Time Article	40 minutes
Configuration	Wrapped in two layers of 1-ply polypropylene wrap using sequential wrapping techniques with a surgical towel placed between the wraps and the bottom of the tray.

Only sterile products should be used in the operative field.

STORAGE
Store in a cool, dry place.

GENERAL CONDITIONS OF USE
The physician must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant but must also be aware of the mechanical and material limitations of metallic and biocompatible polymer surgical implants. Appropriate postoperative care is extremely important for achieving successful results.

PATIENT SELECTION
When considering prospective surgical candidates, the following factors can significantly influence the eventual outcome and success of the procedure:
1. Occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor,
2.Diminished mental capacity. Conditions such as senility, mental illness, alcoholism and drug abuse can contribute to noncompliance with prescribed limitations and precautions and thereby impede or prevent postoperative rehabilitation.
3. Degenerative disease. Progressive musculoskeletal, metabolic, or neurologic degenerative disease may be so advanced as to prevent satisfactory implantation, impair stabilization, and/or limit the useful life of the implant and surgery should only be undertaken as a short-term, palliative measure under severe circumstances.
4. Foreign body sensitivity. A history of foreign body sensitivity may warrant against implantation as no pre-operative test can completely exclude the possibility of hypersensitivity or allergic reaction.
5. Smoking. Current or recent smokers tend to experience higher rates of fusion failure and are at higher risk for pseudoarthrosis development. Smoking has also been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to recurring pain symptoms despite successful fusion and initial clinical improvement.

The TRUE POSITION® Pivoting Spacer System has a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking the implant.

CONTRAINDICATIONS
The following specific contraindications, warnings, precautions and adverse effects should be understood fully by the physician and explained to the patient whenever relevant.
• The TRUE POSITION® Pivoting Spacer System is contraindicated in the presence of active systemic infection, open wounds, infection localized to the proposed surgical site and in cases where the patient has demonstrated allergic or foreign body sensitivity to any of the implanted materials.
• Severe osteoporosis may prevent adequate fixation of screws and thus preclude the use of this or any other implanted orthopedic devices.
• The TRUE POSITION® Pivoting Spacer System is contraindicated in cases where the patient could be expected to achieve similarly satisfactory results using safer and/or predictable therapeutic alternatives.
• Relative contraindications include conditions where excessive stresses may be placed on the bone and implants due to obesity, degenerative diseases other than Degenerative Disc Disease (DDD), lifestyle, and/or psychological factors contributing to inability to properly adhere to restrictions in the immediate post-operative period.
• The TRUE POSITION® Pivoting Spacer System is contraindicated for prior fusion at the level(s) to be treated; and any condition not described in the Indications for Use.
•In the presence of relative contraindications, the physician should weigh alternative risks and benefits when deciding whether a patient is a suitable candidate for these devices.

WARNINGS

• Magnetic Resonance (MR) - The TRUE POSITION® Pivoting Spacer System has not been evaluated for safety and compatibility in the MR environment. The TRUE POSITION® Pivoting Spacer System has not been tested for heating or migration in the MR environment.

• Proper size selection - The potential for satisfactory fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants.

• Breakage - Implants are designed to load-share with adjacent bone to maintain alignment until normal healing occurs. The physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system. If healing is delayed or does not occur, the implant may eventually break due to implant fatigue. The degrees of bony union, weight bearing, and activity levels influence the longevity of the implant.

• Dissimilar metals - Dissimilar metals should never be used when applying supplemental fixation to enhance the stability and preserve the alignment of the implant. Internal fixation devices, such as rods, hooks, wires, and screws that come into contact with other metal objects must be made from like or compatible materials. There are many forms of corrosion damage and several of these occur on surgically implanted metals. General or uniform corrosion is present on all implanted metals and alloys and usually occurs at an acceptably slow rate due to the presence of passive surface films. Dissimilar metals in contact can accelerate this corrosion process which can, in turn, increase the risk of fatigue.

• Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

PRECAUTIONS

• Do Not Reuse. An explanted implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

• Use Bone Graft. Internal orthopedic fixation devices cannot withstand activity levels equal to those placed on normal healthy bone and no implant can be expected to withstand indefinitely the unsupported stress of full weight bearing. These types of implants are more likely to fail if no bone graft is used or if a pseudoarthrosis develops. Supplemental bone graft material is strongly recommended to help ensure the attainment of a solid fusion mass.

• Use Supplemental Internal Fixation. This device must be used with supplemental internal fixation systems cleared for the same condition(s) for which the patient is being treated.

• Restrict Postoperative Activity. Until maturation of the fusion is confirmed by radiographic examination, external immobilization (such as bracing) may be recommended, based on clinical judgement.

• Provide Patient Instructions. The patient must be made aware of the limitations of internal fixation devices and the need for post-operative activity restrictions during the healing phase. The patient must be instructed in the limitations of the PEEK and titanium alloy implant and supplemental internal fixation device and should be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instruction should lead to failure of the implant and possible need thereafter for additional surgery to remove the device.

• Postoperative Care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and participation in sporting activities. The patient should understand that an implant is not as strong as normal bone. Excessive demands can loosen, bend and/or break the implant if excessive demands are placed on it, especially in the absence of complete bone healing.

• Removal of Supplemental Fixation. The physician should carefully weigh the risks versus benefits if and when deciding whether to remove the supplemental fixation used to help maintain stability and alignment after placement of the implant.

If the device is not removed after the completion of its intended use, any of the following complications may occur: corrosion, with localized tissue reaction or pain, migration of implant position resulting in injury, risk of breakage, which could make removal impractical or difficult, pain, discomfort, or abnormal sensations due to the presence of the device, possible increased risk of infection, and bone loss due to stress shielding. The possibility of, and the risks associated with, a second surgical procedure must also be discussed with the patient. When elected, removal of supplemental fixation should be followed by adequate postoperative management to avoid refracture or deformity. If the patient is older and has a low activity level, the physician may choose not to remove the implant thus eliminating the risks involved in a second surgery.

The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of this device.

POSSIBLE ADVERSE EFFECTS

Complications arising from use of the TRUE POSITION® Pivoting Spacer System and complications that may arise from the use of supplemental fixation devices in general, include the following:

1. General risks attendant with surgery including those risks related to general anesthesia
2. Bending, fracture, or loosening of the device component (implant)
3. Sensitivity to the implant material
4. Allergic foreign body reaction
5. Early or late infection
6. Diminished bone density due to stress shielding
7. Loss of fixation of the implant and/or the supplemental internal fixation
8. Delayed fusion or non-union
9. Pain, discomfort, or abnormal sensations due to the presence of the device
10. Nerve injury due to surgical trauma or the presence or migration of the device
11. Neurological injury including bowel or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paresthesia
12. Vascular injury that could result in catastrophic bleeding, malpostioned implants or implant migration that could result in erosion of adjacent arteries or veins long after the initial postoperative period
13. Dural tears during the implantation procedure that could require further surgery for repair, chronic cerebrospinal fluid leak or fistula, and possible meningitis
14. Visceral injury due to the implantation procedure, breakage of the device and/or loss of fixation
15. Bursitis
16. Paralysis
17. Death
18. Spinal cord impingement or damage
19. Vertebral fracture
20. Fracture of other bony structures
21. Reflex sympathetic dystrophy
22. Degenerative changes or instability in segments adjacent to fused vertebral levels
23. Local osteolysis in articulating joints if pseudoarthrosis develops and leads to mechanical grinding and generation of wear debris.

PRODUCT COMPLAINTS

Any health care professional who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify SPINE WAVE, INC. If any SPINE WAVE, INC. product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, SPINE WAVE, INC. should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name, catalog number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report is requested.

PATIENT INFORMATION

Covered by one or more U.S. patents or patent applications. See www.spinewave.com/legal-notice.html for details.

Additional True Position® Marketing Material

True Position® Demo Set

True Position® Animation

True Position® Sell Sheet

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