

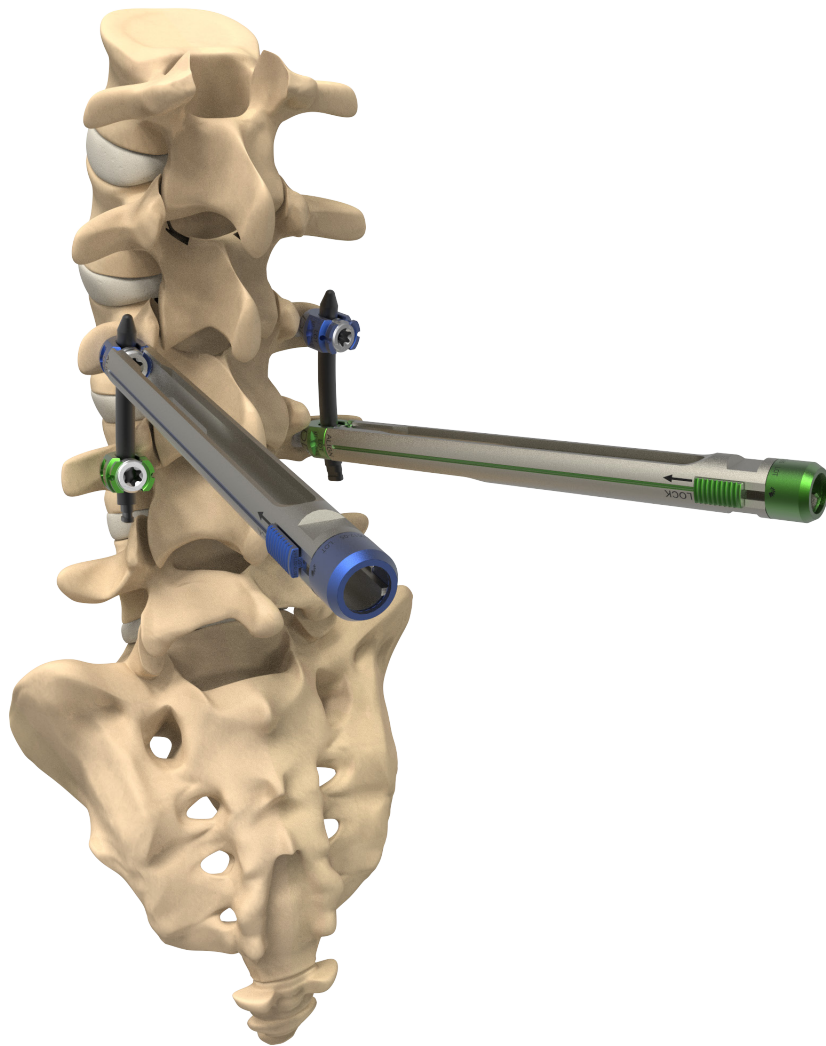
THUNDERBOLTTM
MIS PEDICLE SCREW SYSTEM

WHERE NIMBLE AND SECURE INTERSECT

SURGICAL TECHNIQUE

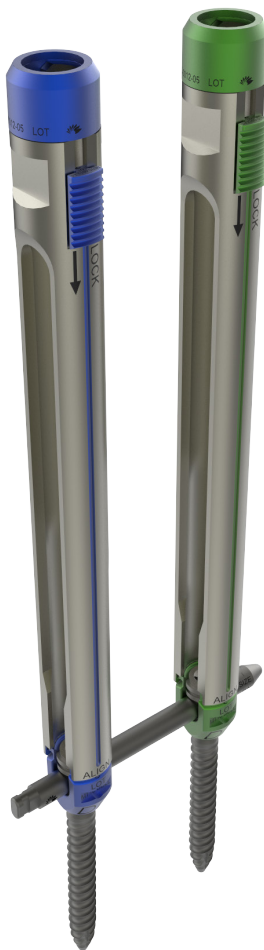
THUNDERBOLT[™]

MINIMALLY INVASIVE PEDICLE SCREW SYSTEM



System Features

- Dovetail set screw: Minimizes head splay and cross-threading
- Secure connection between pedicle screw and screw extender
- Tulip Design: Small/sleek design to reduce anatomical impact
- Interface between rod and rod inserter is robust
- Effective and user friendly rod reduction



The ChoiceSpine THUNDERBOLT™ Minimally Invasive Pedicle Screw System is a posterior spinal fixation system. The system contains pedicle screws in diameters 5.5mm to 7.5mm in lengths from 30mm to 55mm. The rod diameter is 5.5mm and is available in straight and prebent contours.**

** 4.5mm and 8.5mm pedicle screws available upon request

** Additional screw and rod lengths available upon request

Step 1 Positioning & Planning

- Patient position should be prone, lying face down on a radiolucent table.
- Confirm adequate table clearance for easy C-Arm rotation between the lateral, oblique, and A/P positions.
- Target the appropriate spine segments using A/P fluoroscopy.
- The lateral pedicle wall of adjacent levels may also be estimated at this time.
- Begin surgical procedure with skin incision.

Step 2 Targeting Needle Placement

- A longitudinal incision is made through the skin and fascia. Pass the targeting needle through the incision towards pedicle's entry point of the desired level. Confirm position by using A/P and lateral fluoroscopy.
- Advance the targeting needle through pedicle using A/P fluoroscopy to direct the tip towards the center of the pedicle. Continue advancement until the needle enters the vertebral body. Confirm placement with A/P and lateral fluoroscopy to ensure that the targeting needle does not breach the wall of the pedicle. Continue advancement and fluoroscopy monitoring until needle has reached desired the depth (Fig 1).
- Remove the inner stylet of the targeting needle (Fig 2).



Figure 1



Figure 2

Step 3 *Guide Wire Insertion*

- Insert the guide wire through targeting needle (Fig 3).
- Advance guide wire to desired depth. Take care not to bend or kink guide wire during advancement.
- Remove the targeting needle while holding the guide wire to ensure that it remains in position (Fig 4).
- To optimize fluoroscopic imaging during guide wire placement, repeat these steps for all guide wires.



Figure 3

Step 4 *Muscle Dilation*

- Begin muscle dilation by placing dilator 1 (smallest) over the guide wire (Fig 5).
- Pass dilator 2 (larger) over dilator 1 to complete dilation (Fig 6).

NOTE: The splitter knife can be used to separate soft tissue for access to the pedicle (Fig 7).

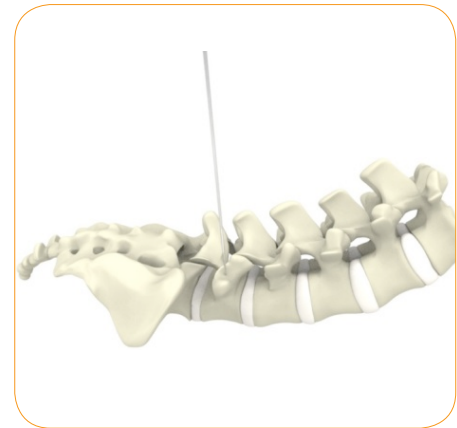


Figure 4



Figure 5



Figure 6



Figure 7

Step 5 *Pedicle Tapping*

- Remove dilator 1 (Fig 8).
- Dilator 2 is held in position for soft tissue protection during tapping.
- Select appropriate sized tap.
- Advance the tap over the guide wire under fluoroscopy (Fig 9). **Caution: Do not tap beyond the tip of the Guide Wire.**
- Determine screw length by referencing the depth graduations on the tap shaft. Tap depth is indicated by depth graduation in line with proximal end of dilator 2 (Fig 10).



Figure 8

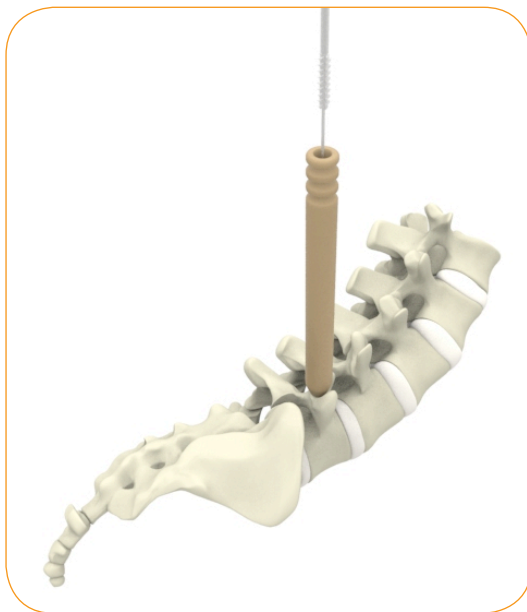


Figure 9

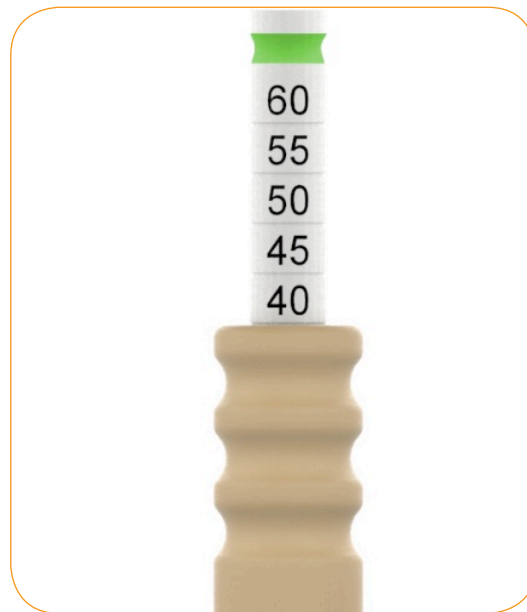


Figure 10

NOTE: Taps are undersized by 1mm. Actual size is listed on the Tap.

CAUTION: Use caution not to disturb guide wire while interfacing with instrumentation.

NOTE: The distal tip of Dilator 2 contains radiographic markers to verify Dilator depth.

Step 6 Screw Extender Loading

The THUNDERBOLT MIS system is equipped with eight threaded reduction screw extenders (green) and two smooth (blue) screw extenders. The threaded reduction extenders are timed to the pedicle screw tulips to allow the user to reduce a rod into the underlying screw tulip using the set screw. The smooth screw extenders allow quick passage of the set screw into the screw tulip, when internal rod reduction is not desired. Rod reduction is described further in Step 11.

To attach a screw extender to a pedicle screw:

- Select appropriate size pedicle screw.
- Retract both screw extender locking pins.
- Align distal tips of the screw extender over the “U” shaped cut outs of the tulip until it seats (Fig 11).
- Rotate the screw extender 90° so the distal tip is aligned with tulip. Visually confirm that the “ALIGN” laser mark on the screw tulip and distal tip of the screw extender are located on the same side. This will ensure smooth passage of the set screw between the reduction extender and pedicle screw tulip.
- Secure screw extender with tulip by advancing screw extender locking pins (Fig 12).
- Repeat these steps for all screws.

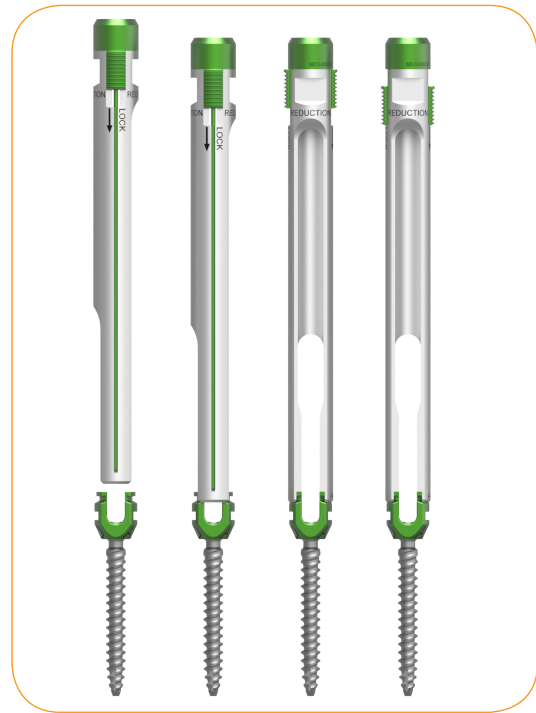


Figure 11



Figure 12

Step 7 Screw Insertion

- Attach a ratcheting handle to screw driver. Rotate the ratcheting handle setting to the neutral or reverse position.
- Insert screw driver into screw extender until the driver tip seats in the Hexalobe Feature of the screw body. The screw body may have to be rotated to align the screw into the driver.
- Tighten the driver onto the screw by rotating the knob on the driver clockwise while holding the ratcheting handle fixed (Fig 14). This will advance the distal feature of the driver into the thread pattern of the tulip. Continue to rotate the knob on the driver until it no longer advance (Fig 15). Proper seating of the driver can be confirmed by observing rigidity of the screw shank relative to the screw extender and screw driver.
- Remove dilator 2, taking care not to disturb the guide wire.
- Rotate the ratcheting handle setting to the forward position, load the screw driver over the guide wire, and advance the screw under fluoroscopy to the desired depth (Fig 16).
- Observe the guide wire throughout the screw insertion process to verify position is maintained.
- Repeat these steps for placement of additional screws.
- Remove the driver by rotating the knob counterclockwise until the driver is no longer engaged with the tulip and/or screw extender.
- Remove guide wires upon successful insertion of all screws.

NOTE: Screw extenders are not to be removed at this step.

NOTE: Dilator 3 may be used as a port for screw insertion.



Figure 14



Figure 15



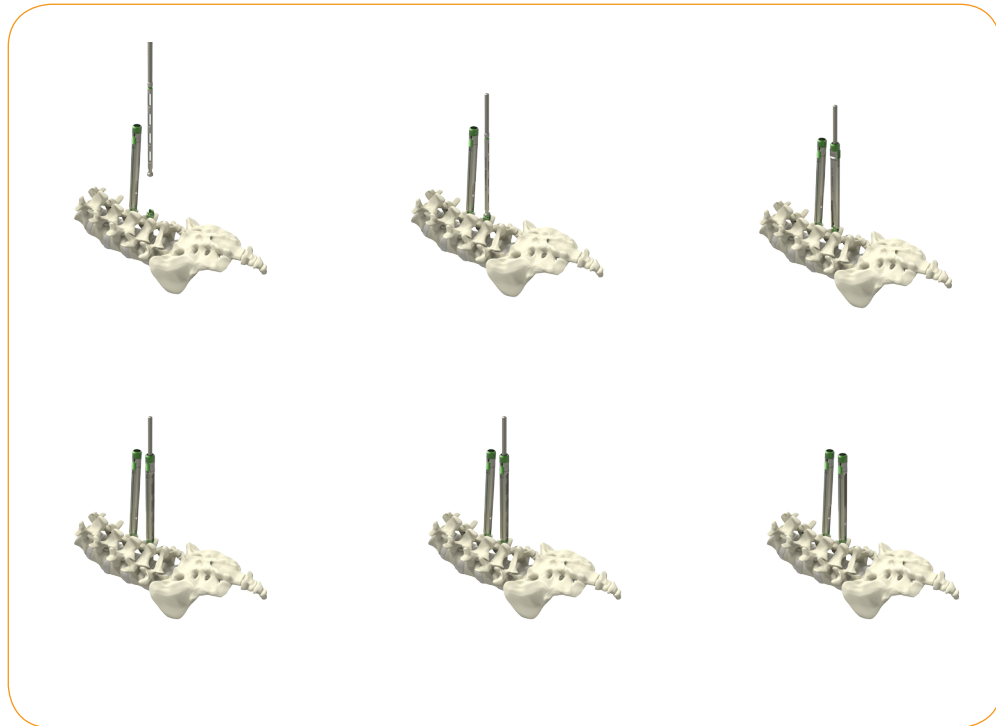
NOTE: If using the Reduction Screw Extender be sure both "ALIGN".



Figure 16

Screw Extender Reattachment

In the event that a Screw Extender becomes disengaged from an implanted screw, a screw extender reattachment instrument is available. To reattach, thread the distal tip of the reattachment instrument into the tulip. Slide the screw extender over the reattachment instrument and repeat screw extender loading steps and unscrew the reattachment instrument.



Step 8 Rod Length Determination

- Insert rod caliper into screw extenders until seated (Fig 17).
- Read corresponding rod length as indicated (Fig 18).

NOTE: Caliper measures usable rod length.



Figure 17

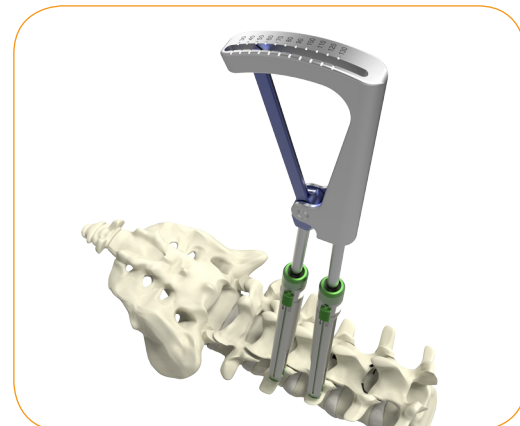


Figure 18

Step 9 Rod Placement

- Select the correct rod length.
- Open the working end of the Bayoneted Rod Inserter by turning the knob counterclockwise.
- * Load the rod into the rod inserter by placing the notched end of the rod into the working end of the inserter until the shoulder on the rod end becomes flush with the face of the rod inserter (Fig. 19).
- Rotate the knob on the rod inserter clockwise to lock the rod in place. Rod security is confirmed when there is no toggle between the rod and inserter.
- Pass rod tip downward along outside face of the screw extender and position rod tip within the slotted openings of the screw extender. Rod placement may be simplified if the large slotted opening is on the superior and inferior ends of the construct.
- Under fluoroscopy work rod tip through tissue until rod tip spans screw extenders, passing through both slotted openings.
- Fully seat the rod into the screw tulips (Fig 20).

NOTE: Screw Extenders are not to be removed at this step.

Fascia Blades

- Fascia Blades can be utilized to separate soft tissue between screw extenders to assist with rod placement. fascia blades load to the rod inserter in the same manner as a rod (Fig 21).



Figure 19

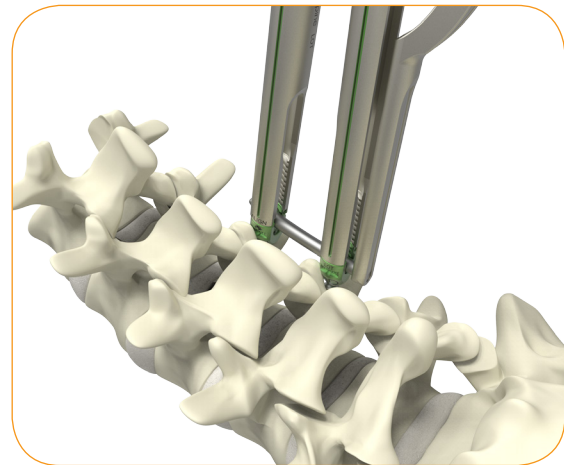


Figure 20



Figure 21

Step 10 Set Screw Placement

- Maintain rod inserter connection to rod and hold rod in position.
- Load set screw onto tip of set screw starter.
- Pass set screw starter down screw extender (Fig 22).
- Engage set screw with screw tulip.
- Provisionally tighten set screw.
- Verify rod is fully seated by the line on the set screw starter.
- Repeat for all screws.

NOTE: Screw Extenders and Rod Inserter are not to be removed at this step.

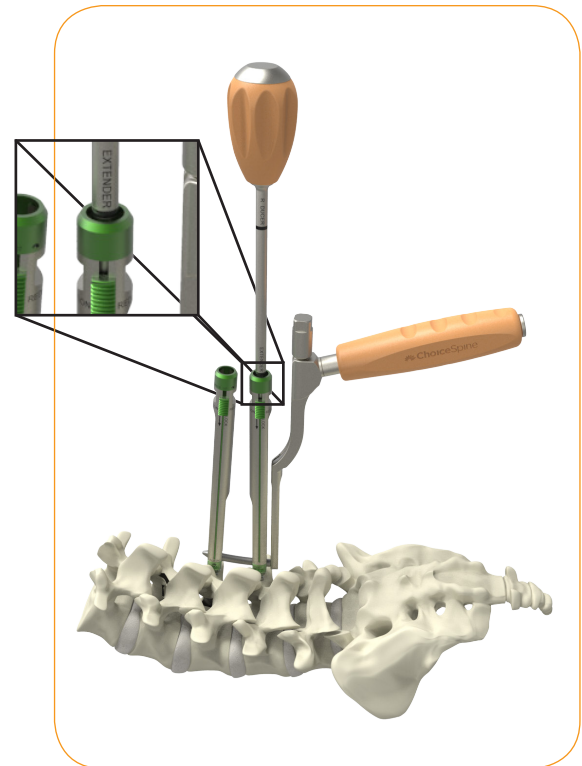


Figure 22

Set Screw Retrieval

A set screw retriever is available in event that a set screw disengages inside of the screw extender from the set screw starter (Fig 23).



Figure 23

Step 11 Rod Reduction

As mentioned in Step 6, the primary means of rod reduction for the THUNDERBOLT MIS system is through the threaded reduction screw extenders. When the extender is properly attached to the pedicle screw tulip (i.e. “ALIGN” laser markings are located on the same side), the threads are timed together to allow passage of the set screw between the screw extender and pedicle screw tulip.

NOTE: Internal threads of the Reduction Extender perform 20mm of reduction.

To reduce a rod, thread the set screw into and through the screw extender, forcing the rod into the screw tulip. The set screw and rod are fully seated in the screw tulip when the “EXTENDER” laser mark line on the set screw driver shaft is aligned with the top of the extender (Fig. 22).

NOTE: An External Rod Reducer is available if additional reduction force is needed or the smooth screw extenders are in use.

To use the External Rod Reducer:

- First verify that the Reducer is in the start position. If needed, rotate the Handle counterclockwise to achieve the required position (Fig 24).
- Orient the Rod Reducer to the Screw Extender such that the screw extender pins are aligned with the square notches on the distal end of the reducer and slide the Reducer over the Screw Extender until the external reducer locking tabs click into place (Fig. 24 inset). Pulling up on the reducer will confirm that it is locked into place.
- Once fully seated rotate the Handle of the Reducer clockwise to achieve desired reduction.

Note: The External Reducer performs 30mm of reduction.

Caution: do not advance the Handle past the “reduced” line on the Reducer.

- Load a Set Screw onto Tip of the Set Screw Starter.
- Pass the Set Screw Starter through the Reducer.
- Engage Set Screw with Screw Tulip.
- Provisionally tighten Set Screw and verify Rod is fully seated by confirming that the “REDUCER” laser mark line on the set screw driver shank is located at the top of the reducer handle (Fig 25 inset).
- Disengage the Rod Reducer from the Screw Extender by squeezing the top of the reducer locking tabs and lifting the reducer off of the extender (Fig. 24 inset).

NOTE: Removable handles will mate to the Reducer for additional leverage.



Figure 24

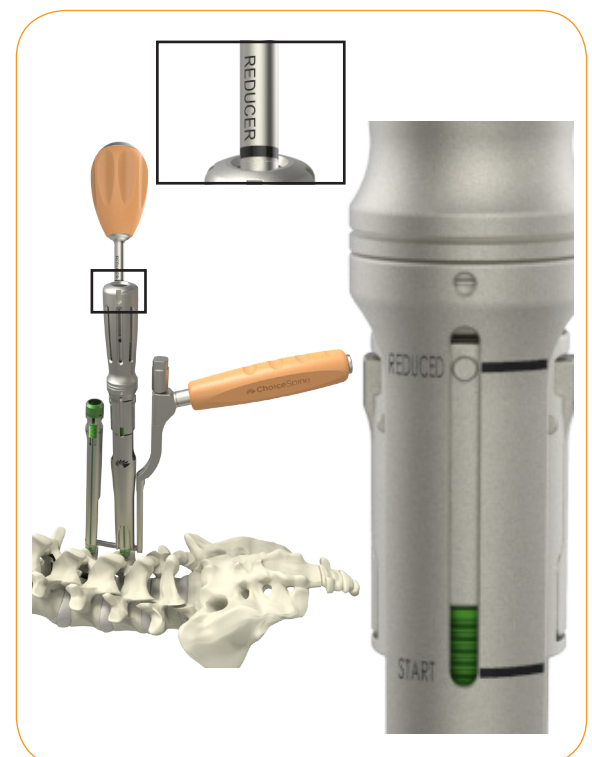


Figure 25

Step 12 Compression/Distraction

- Load the Compressor/Distractor to the Screw Extenders (Fig 26).
- Compression or distraction will require one provisionally locked Set Screw which allows the other Set Screw to move, or float, along the Rod in desired direction.
- Rotate the winged handle to compress or distract.
- Once desired compression or distraction is achieved the “floating” Set Screw will be provisionally locked to maintain the distracted or compressed position.

NOTE: Set Screws may be provisionally and final tightened through the Compressor/Distractor.



Figure 26

Step 13 Set Screw Final Tightening

- Final tighten Set Screws to 70 in-lb using the Torque Handle and Set Screw Final Driver.
- Position Countertorque to the flat features on the proximal end of Screw Extender.
- Insert Torque Handle and Final Driver through Screw Extender and engage Set Screw.
- Rotate the Torque Handle clockwise until the final torque setting is achieved (Fig 27).
- Repeat the above steps until all Set Screws are final locked.

NOTE: Final tightening can occur through the Screw Extender and Compressor/Distractor.

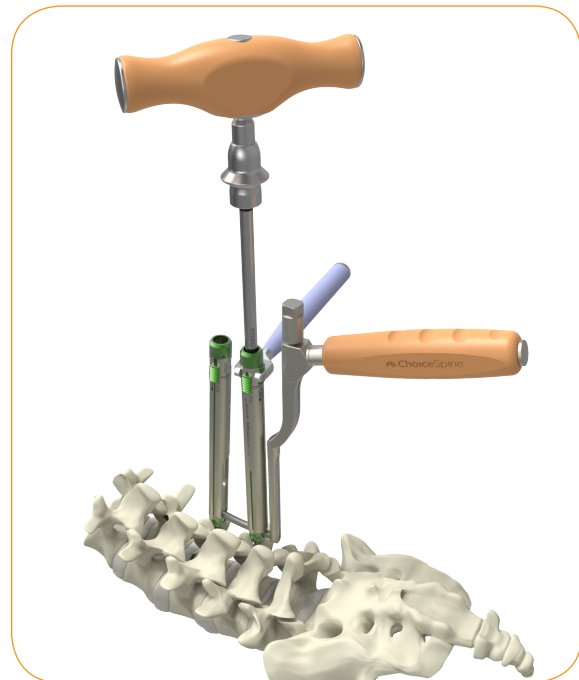


Figure 27

Step 14 Rod Inserter & Screw Extender Removal

- After final tightening and verification using fluoroscopy the Rod Inserter can now be disengaged from the Rod.
- To remove the Rod Inserter, rotate the knob counterclockwise until the rod is released and withdraw the inserter from the Rod (Fig 28).
- Screw Extenders can be removed after disengaging the Rod Inserter.
- Retract Screw Extender Locking Pins (Fig 29).
- Rotate the Screw Extenders 90° so the Distal Tips are aligned over the “U” shaped cut outs of the Tulip.
- Extract the Screw Extenders.

Screw Removal

- After exposure is complete, use the Set Screw Final Driver and Hudson T-Handle* to remove the Set Screws.
- Remove the Rods with Surgical Forceps or similar instrumentation.
- Attach a ratchet handle to the Driver/Remover/Adjuster or screwdriver and remove screws.

*Hudson T-Handle is available upon request.

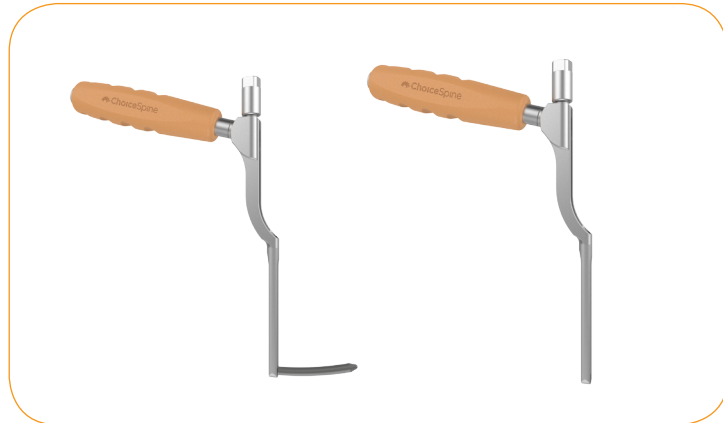








Figure 28

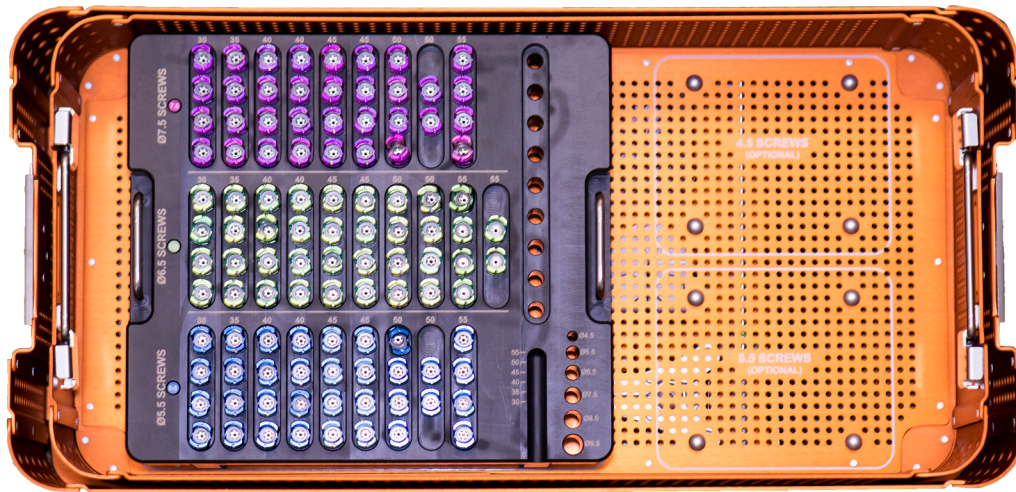


Figure 29

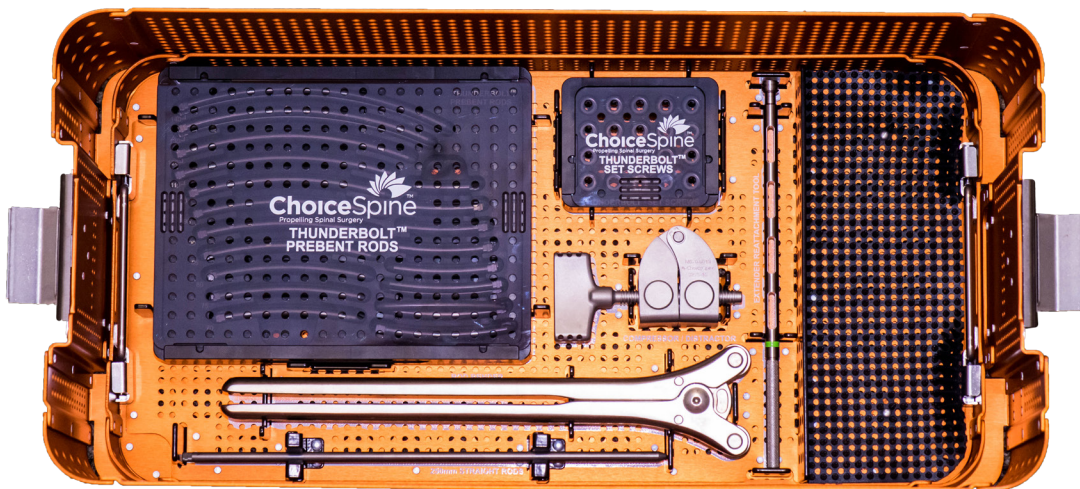
Item #	Description	QTY	
M070-0003	AXIAL RATCHET HANDLE	4	
M070-0052	SPLITTER KNIFE	1	
M070-0004	DILATOR 1	1	
M070-0005	DILATOR 2	1	
M070-0060	DILATOR 3	1	
M070-0081	DILATOR 2.5	1	
M070-0007	5.5 TAP	1	
M070-0008	6.5 TAP	1	
M070-0009	7.5 TAP	1	
M070-0012	SCREW EXTENDER	2	
M070-0092	REDUCTION SCREW EXTENDER	8	
M070-0093	BAYONETTED ROD INSERTER	1	
M070-0053	FASCIA BLADE, 50MM	1	
M070-0054	FASCIA BLADE, 75MM	1	
M070-0055	FASCIA BLADE, 100MM	1	
M070-0013	ROD CALIPER	1	
M070-0018	COUNTERTORQUE	1	
M070-0114	SCREW DRIVER	4	
M070-0098	EXTERNAL ROD REDUCER	2	
M070-0105	SET SCREW RETRIEVER	1	
M070-0059	SCREW DRIVER/REMOVER/ADJUSTER	1	
M070-0112	SET SCREW FINAL DRIVER, EXTENDED	2	

Item #	Description	QTY	
M070-0100	SET SCREW STARTER, EXTENDED	2	
M070-0061	ROD REDUCER T HANDLE	1	
M070-0062	ROD REDUCER QC BIT	1	
M070-0019	COMPRESSOR/DISTRACTOR	1	
M070-0078	SCREW EXTENDER REATTACHER	1	
2070-5023	ROB BENDER	1	

Implant Tray



Top

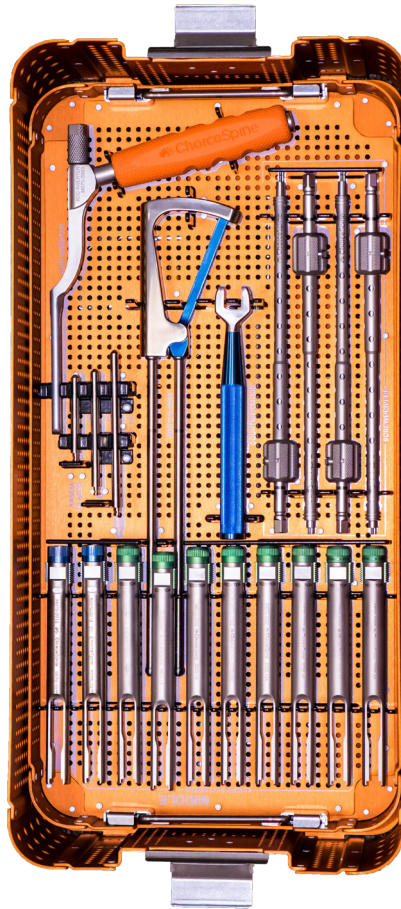


Bottom

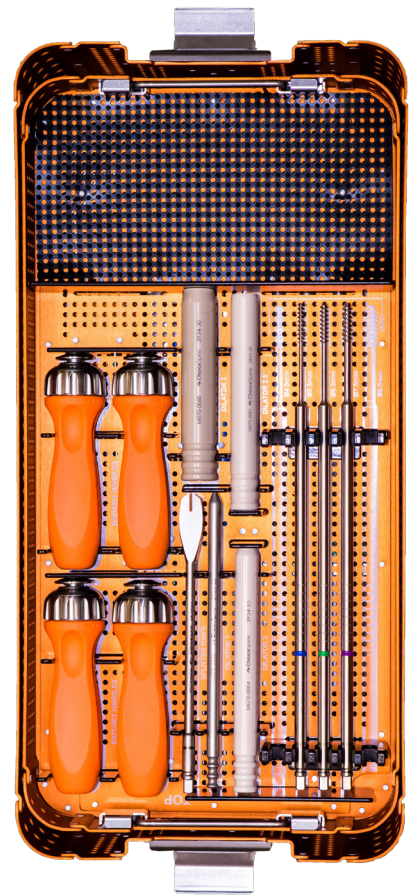
Instrument Tray



Bottom



Middle



Top

Description:

The Thunderbolt™ Minimally Invasive Pedicle Screw System includes implant components made of implant grade titanium alloy (Ti-6Al-4V ELI; ASTM F136) and cobalt chrome alloy (Co-28Cr-6Mo; ASTM F1537). The system also includes instruments made of PEEK (ASTM F2826), Tantalum (ASTM F560), stainless steel (ASTM F899/A564) and aluminum (ASTM B221). These components are available in various designs and sizes that allow the surgeon to build an implant construct suited to a patient's anatomical and physiological requirements.

The components include: polyaxial pedicle screws, set screws, rods, instruments and sterilizer trays.

Indications:

The Thunderbolt Minimally Invasive Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (DDD; defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

When used in a posterior percutaneous approach with MIS instrumentation, the Thunderbolt System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Contraindications:

Contraindications include, but are not limited to:

- infection, systemic or localized
 - signs of local inflammation
 - morbid obesity
 - fever or leukocytosis
 - mental illness
 - alcoholism or drug abuse
 - pregnancy
 - severe osteopenia
 - suspected or documented sensitivity or allergies to the implant materials
 - presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which prevents secure implant screw fixation and/or decreases the useful life of the device
 - any condition having inadequate tissue coverage over the operative site
 - any circumstances not described under Indications for Use
 - patients unwilling or unable to follow post-operative instructions
- Cautions, Precautions, Warnings, Possible Adverse Effects

CAUTIONS:

- Mixing of dissimilar metals can accelerate the corrosion Process. Stainless steel and titanium components must NOT be used together.
- Do not use components of the Thunderbolt and Lancer Pedicle Screw Systems with components from any other manufacturer.
- As with all orthopedic implants, none of the Thunderbolt and Lancer Pedicle Screw Systems components should ever be reused under any circumstances.

Precautions:

- The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.

Warnings:

- The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

This device system is not intended to be the sole means of spinal support. Its use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and compliance of the patient will greatly affect the results.

- The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.
- The Thunderbolt Minimally Invasive Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. The Thunderbolt Minimally Invasive Pedicle Screw System has not been tested for heating or migration in the MR environment.



ChoiceSpineTM

Propelling Spinal Surgery

LIT # Thunderbolt STG
REV 02
08/17

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