SURGICAL TECHNIQUE GUIDE

THUNDERBOLT™

Minimally Invasive Pedicle Screw System

ChoiceSpine™

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Introduction

The ChoiceSpine Thunderbolt™ Minimally Pedicle Screw System (MIS) is a cannulated top-loading polyaxial pedicle screw. The Thunderbolt System provides a robust and secure connection between the pedicle screws and the Screw Extenders. The Screw Extenders offer 20mm of reduction.

System Features

- Robust and secure connection between pedicle screws and Screw Extenders
- Strong interface between rod and rod inserter allows excellent control over rod insertion
- Strong and fast rod reduction
- Internal (20mm) and external (30mm) reduction options available

Thunderbolt Tower Features

- 20mm of internal reduction up to 30mm of reduction when using external reducer
- Strong interface between rod and rod inserter allows excellent control during rod insertion
- Dovetail set screw is designed to minimize head splay and cross-threading.
- Screw diameters 5.5mm, 6.5mm, 7.5mm lengths from 35mm - 55mm (in 5mm increments)
- Pre-bent Rod diameter is 5.5mm, comes in a variety of lengths
- Thunderbolt™ Screws are also compatible with Lancer™ Open Pedicle Screw System instrumentation.

1. Positioning and Planning

- Patient position should be prone, laying 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.

Figure 1

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 the 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 (Figure 1).
- Remove the inner stylet of the targeting needle (Figure 2).

Figure 2

3. Guide Wire Insertion

- Insert the guide wire through targeting needle (Figure 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 (Figure 4).
- To optimize fluoroscopic imaging during guide wire placement, repeat these steps for all guide wires.

Figure 3

NOTE: K-Wires are made to order. K-Wires are available in Stainless Steel and Nitinol.

4. Muscle Dilation

- Begin muscle dilation by placing **Dilator 1 (M070-0005)** (smallest) over the guide wire (Figure 5).
- Pass **Dilator 2 (M070-0004)** (larger) over Dilator 1 to complete dilation (Figure 6).

NOTE: The Splitter Knife (M070-0052) can be used to separate soft tissue for access to the pedicle (Figure 7).

Figure 4

Figure 5

Figure 6

Figure 7

5. Pedicle Tapping

- Remove **Dilator 1 (M070-0005)** (Figure 8).
- **Dilator 2 (M070-0004)** is held in position for soft tissue protection during tapping.
- Select appropriate sized tap.
- Advance the tap over the guide wire under fluoroscopy (Figure 9).

CAUTION: Do not tap beyond the tip of the Guide Wire.

Figure 8

- Determine screw length by referencing the depth gauge on the tap shaft. Tap depth is indicated by depth gauge in line with proximal end of Dilator 2 (Figure 10).

Figure 9

Figure 10

NOTE: The length of the Tap threads is 25mm. Taps are undersized by 1mm. The 4.5 tap is undersized by 0.5mm. Actual size is listed on the Tap.

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

NOTE: The distal tip of Dilator 2 (M070-0004) contains radiographic markers to verify Dilator depth.

6. Screw Extender Loading:

The Thunderbolt™ MIS system is equipped with eight threaded reduction **Screw Extenders (M070-0151) (green)** and two smooth **Screw Extenders (M070-0012) (blue).** 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 the appropriate size pedicle screws.
- 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 (Figure 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 the Screw Extender with the tulip by advancing the Screw Extender locking pins (Figure 12).
- Repeat these steps for all screws.

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

Figure 11

Figure 12

7. Screw Insertion

- Attach a **Ratcheting Axial Handle (M070-0003)** to **Polyaxial Screw Driver (M070-0126)**. Rotate the ratcheting handle setting to the neutral or reverse position.
- Insert the screw driver into the Screw Extender until the driver tip seats in the hexalobe feature of the screw body.
- Tighten the driver onto the screw by rotating the knob on the driver clockwise while holding the ratcheting handle fixed. This will advance the distal feature of the driver into the thread pattern of the tulip (Figure 14). Continue to rotate the knob on the Screw Driver Outer Shaft until it will no longer advance. Proper seating of the driver can be confirmed by observing rigidity of the screw shank relative to the screw tulip and screw driver (Figure 15).
- Remove Dilator 2, taking care not to disturb the guide wire.
- Rotate the Ratcheting Axial Handle setting to the forward position, load the screw driver over the guide wire, and advance the screw under fluoroscopy to the desired depth (Figure 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 on the Screw Driver Outer Shaft counterclockwise until the driver is no longer engaged with the tulip and Screw Extenders.
- Remove guide wires upon successful insertion of all screws.

Figure 14

Figure 15

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

NOTE: Dilator 3 (M070-0060) may be used as a port for screw insertion. Pass Dilator 2.5 (M070-0081) over Dilator 2 and Dilator 3 over Dilator 2.5. Remove Dilator 2, then Dilator 2.5, while holding Dilator 3 in position for screw placement.

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 (M070-0078) into the tulip. Slide the Screw Extender over the reattachment instrument and repeat the Screw Extender loading steps, then unscrew the Reattachment Instrument (Figure 17).

Figure 17

8. Rod Length Determination

- Insert the **Rod Caliper (M070-0013A)** into the Screw Extenders until seated with the laser mark bands on top of the Screw Extenders (Figure 18).
- Read the corresponding rod length as indicated (Figure 19).

NOTE: If the measurement falls between two sizes use the larger size.

Figure 18

Figure 19

9. Rod Placement

- Select the correct rod length
- Open the working end of the **Bayoneted Rod Inserter (M070-0093)** 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 (Figure 20).
- 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 the rod tip through tissue until the rod tip spans the Screw Extenders, passing through both slotted openings.
- Fully seat the rod into the screw tulips (Figure 21).

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

Figure 20

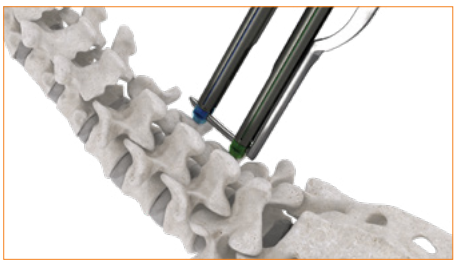


Figure 21

Fascia Blades (Optional Step)

- Fascia Blades can be utilized to separate soft tissue between Screw Extenders to assist with rod placement. Fascia Blades load on to the rod inserter in the same manner as a rod (Figure 22).
- Fascia Blades come in 3 different sizes: 50mm (M070- 0053), 75mm (M070-0054), and 100mm (M070-0055).

Figure 22

10. Screw Placement

- Load the **Set Screw (MT20-0002)** onto the tip of the **Set Screw Starter (M070-0100).**
- Verify the rod is in each screw tulip head prior to inserting the Set Screw.
- To insert the Set Screw, pass the loaded Set Screw Starter down through the Screw Extender (Figure 23).
- Engage the Set Screw with the screw tulip head and provisionally tighten the Set Screw.
- The Set Screw is seated when the top of the black line labeled "EXTENDER" on the Set Screw Starter is aligned with the top of the Screw Extender.
- Repeat for all screws.

Figure 23

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

Set Screw Retrieval (Optional Step):

A **Set Screw Retriever (M070-0105)** is available in event that a Set Screw disengages from the Set Screw Starter inside of the Screw Extender (Figure 24).

Figure 24

11. Rod Reduction

As mentioned in Step 6, the primary means of rod reduction 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.

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 Starter Shaft is aligned with the top of the extender (Figure 25).

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

Figure 25

To use the **External Rod Reducer (M070-0129)**:

- First verify that the External Rod Reducer is in the start position. If needed, rotate the handle counterclockwise to achieve the required position.
- Orient the External 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 Rod Reducer locking tabs click into place (Figure 25). Pulling up on the reducer will confirm that it is locked into place.
- Once fully seated rotate the handle of the External Rod Reducer clockwise to achieve desired reduction.

NOTE: The reduction Screw Extenders perform 20 mm of reduction and the External Rod Reducer performs 30 mm of reduction.

CAUTION: Do not advance the handle past the "REDUCED" line on the External Rod Reducer.

- Load a Set Screw onto tip of the Set Screw Starter.
- Pass the Set Screw Starter through the External Rod Reducer.
- Engage Set Screw with screw tulip.
- Provisionally tighten the Set Screw and verify the Rod is fully seated by confirming that the "REDUCER" laser mark line on the Set Screw Starter shaft is located at the top of the reducer handle (Figure 26).
- Disengage the External Rod Reducer from the Screw Extender by squeezing the top of the reducer locking tabs and lifting the reducer off of the extender.

NOTE: Removable handles (M070-0061 & M070-0062) included in the set will mate to the External Reducer for additional leverage.

Figure 26

12. Compression/Distraction

- Load the **Compressor/Distractor (M070-0019)** onto the Screw Extenders (Figure 27).
- Compression or distraction will require one provisionally locked Set Screw which allows the other Set Screw and tulip head to move, or float, along the Rod in the 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 with the Set Screw Starter to maintain the distracted or compressed position.

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

Figure 27

13. Set Screw Final Tightening

- Final tighten the Set Screws to 70 in-lb using the **Torque Handle (M070-0016)** and the **Set Screw Final Driver (M070-0112)**.
- Position the **Countertorque (M070-0018)** to the flat features on the proximal end of the Screw Extender.
- Insert the Torque Handle and Set Screw Final Driver through the Screw Extender and engage the Set Screw.
- Rotate the Torque Handle clockwise until the final torque setting is achieved (Figure 28). An audible "click" occurs when the 70 in-lbs is reached.
- Repeat the above steps until all Set Screws are final locked.

Figure 28

14. Rod Inserter Removal

- After final tightening and verification of the construct using fluoroscopy, the **Rod Inserter (M070-0093)** can 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 (Figure 29).

15. Screw Extender Removal

- Screw Extenders can be removed after disengaging the Rod Inserter.
- Retract Screw Extender Locking Pins (Figure 30).
- Rotate the Screw Extenders 90° so the Distal Tips are aligned over the "U" shaped cut outs of the Tulip.
- Extract the Screw Extenders.

Figure 29

Figure 30

Screw Removal

If screw removal is needed, use the Set Screw Starter to remove the Set Screws. Then remove the rods with surgical forceps or similar instrumentation.

Attach an Axial Ratcheting Handle to the **Screw Driver/Remover/Adjuster (M070-0059)**. Rotate the Axial Ratcheting Handle to the reverse position. Locate and engage the hexalobe of the screw body with the distal end of the driver.

Rotate the driver counterclockwise to remove the screw.

Instrument List

Part Number	Description	Qty	
M070-0003	AXIAL RATCHET HANDLE	4	
M070-0052	SPLITTER KNIFE	1	
M070-0005	DILATOR 1	1	
M070-0004	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 EXTENDERS	2	
M070-0151	REDUCTION SCREW EXTENDER	8	
M070-0093	BAYONETED ROD INSERTER	1	
M070-0053	FASCIA BLADE, 50MM	1	
M070-0054	FASCIA BLADE, 75MM	1	
M070-0055	FASCIA BLADE, 100MM	1	

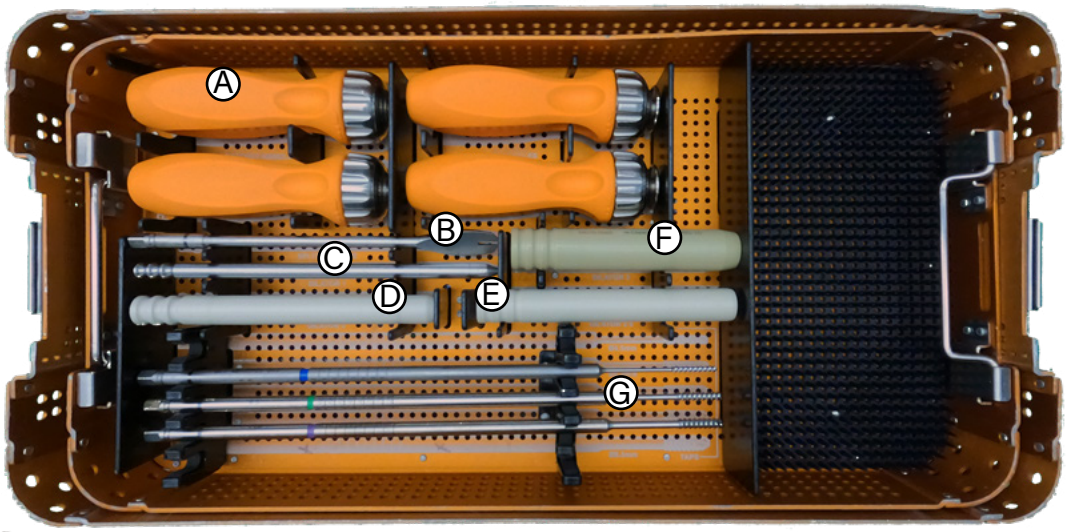
M070-0013A	ROD CALIPER	1	
M070-0018	COUNTERTORQUE	1	
M070-0126	SCREW DRIVER	3	
M070-0129	EXTERNAL ROD REDUCER	2	
M070-0105	SET SCREW RETRIEVER	1	
M070-0059	SCREW DRIVER/REMOVER/ADJUSTER	1	
M070-0112	SET SCREW FINAL DRIVER, EXTENDED	2	

K-Wires are made to order. Contact Sales Support (salessupport@choicespine.com) to order prefered K-Wires.

Avaliable in Stainless Steel and Nitinol: Blunt - Blunt, Blunt - Trocar, Trocar - Trocar Lengths: 12 inches, 20 inches, 22 inches, 24 inches

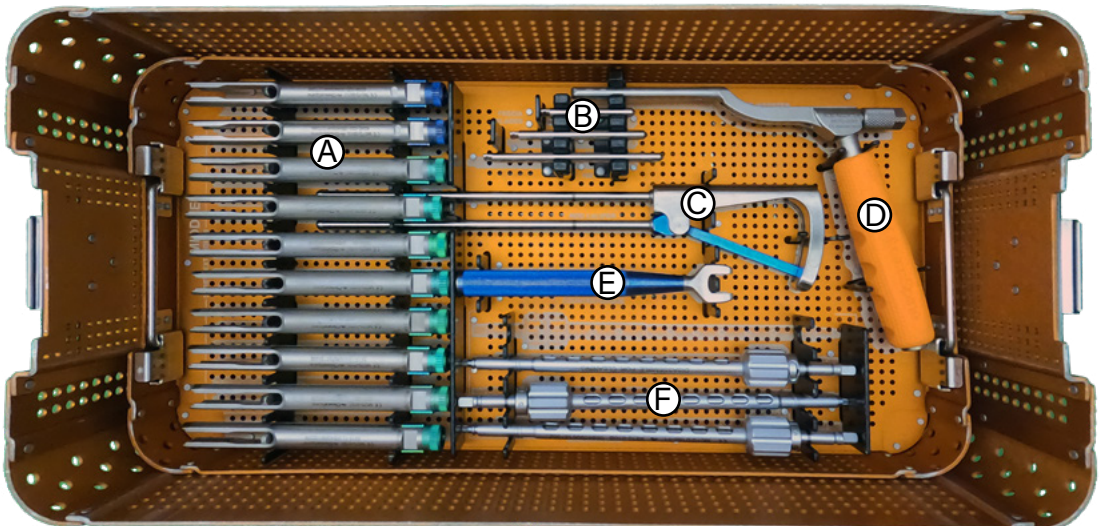
M070-0100	SET SCREW STARTER, EXTENDED	2	
M070-0061	ROD REDUCER T HANDLE	1	
M070-0062	ROD REDUCER ¼ SQ BIT	1	
M070-0016	70 in-lb TORQUE HANDLE	1	
M070-0019	COMPRESSOR/DISTRACTOR	1	
M070-0078	SCREW EXTENDER REATTACHER	1	
2070-5023	ROD BENDER	1	

Thunderbolt™: Instrument Top Tray



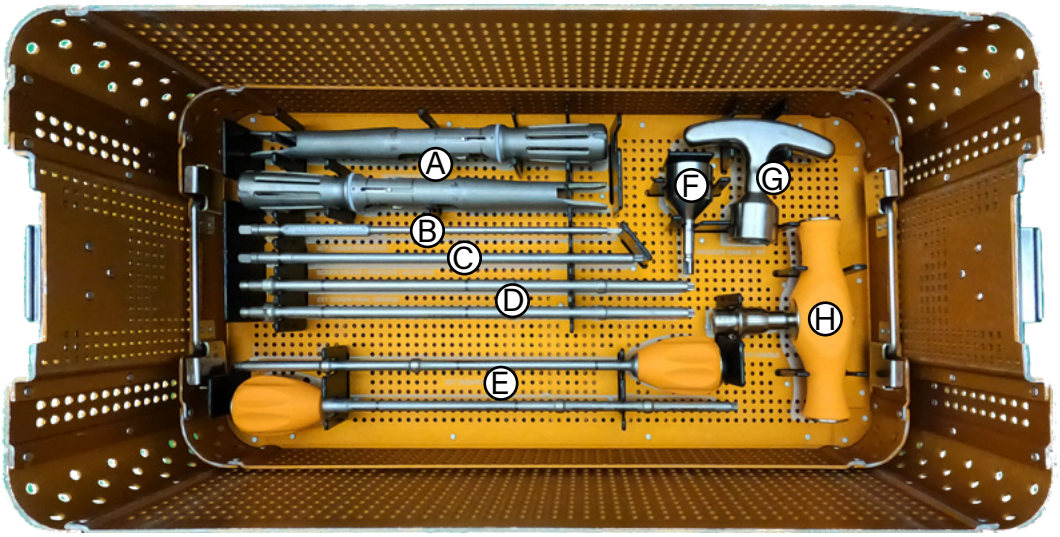
Ⓐ Axial Ratchet Handles x4 (M070-0003)
Ⓑ Splitter Knife (M070-0052)
Ⓒ Dilator 1 (M070-0005)
Ⓓ Dilator 2 (M070-0004)
Ⓔ Dilator 2.5 (M070-0081)
Ⓕ Dilator 3 (M070-0060)
Ⓖ Taps (M070-0007, M070-0008 & M070-0009)

Thunderbolt™: Instrument Middle Tray



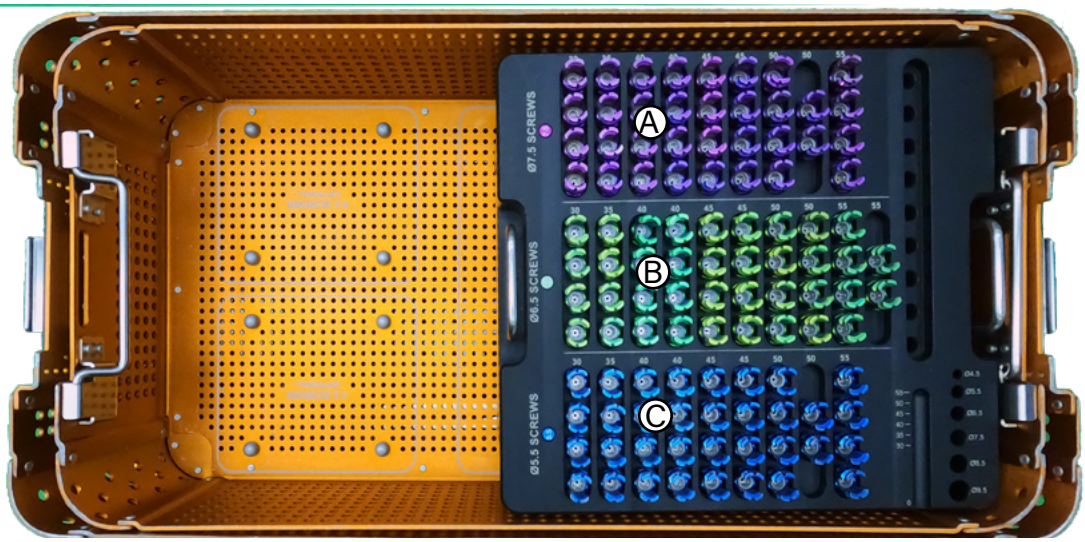
Ⓐ Screw Extenders (M070-0012 (x2) & M070-0151 (X8))
Ⓑ Fascia Blades (M070-0053, M070-0054 & M070-0055)
Ⓒ Bayoneted Rod Inserter (M070-0093)
Ⓓ Rod Caliper (M070-0013A)
Ⓔ Countertorque (M070-0018)
Ⓕ Screw Drivers x3 (M070-0126)

Thunderbolt™: Instrument Bottom Tray



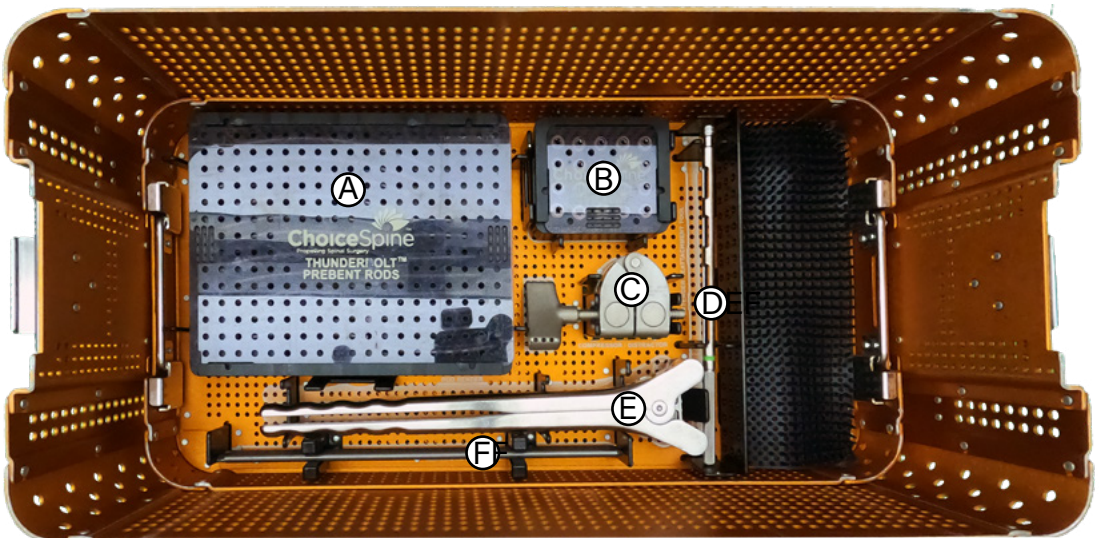
Ⓐ External Rod Reducer x2 (M070-0129)
Ⓑ Set Screw Retriever (M070-0105)
Ⓒ Screw Driver/Remover/Adjuster (M070-0059)
Ⓓ Set Screw Final, Extended x2 (M070-0112)
Ⓔ Set Screw Starter, Extended (M070-0100)
Ⓕ Rod Reducer ¼ SQ Bit (M070-0062)
Ⓖ Rod Reducer T-Handle (M070-0061)
Ⓗ 70 in-lb Torque Handle (M070-0016)

Thunderbolt™: Implant Top Tray



Ⓐ 7.5mm Screws (Purple)
Ⓑ 6.5mm Screws (Green)
Ⓒ 5.5mm Screws (Blue)

Thunderbolt™: Implant Bottom Tray



Ⓐ **Pre-Bent Rods**

Ⓑ **Set Screws (MT20-0002)**

Ⓒ **Compressor / Distractor (M070-0019)**

Ⓓ **Screw Extender Reattacher (M070-0078)**

Ⓔ **Rod Bender (2070-5023)**

Ⓕ **250mm Straight Rod**

Notes:

For Instructions for Use please visit https://choicespine-eifu.com/

THUNDERBOLT™

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Spine the Right Way.™

ChoiceSpine™

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