SURGICAL TECHNIQUE GUIDE

THUNDERBOLT™ EXTAB

Minimally Invasive Extended Tab Pedicle Screw System



ChoiceSpine™

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THUNDERBOLT™ EXTAB

Minimally Invasive Extended Tab Pedicle Screw System



Introduction: Thunderbolt™ EXTAB

The ChoiceSpine THUNDERBOLT™ Minimally Invasive Extended Tab Pedicle Screw System (MIS) is a cannulated low-profile, top-loading polyaxial pedicle screw. The extended screw incorporates a removable tab stabilizer for a hybrid open-closed system. In addition, the screw provides 25mm of internal reduction.

Thunderbolt™ EXTAB Features



- 25mm internal rod reduction capability.
- Low-profile tulip designed for a minimally invasive approach.
- Beveled corners on the extended tabs allow for a secure instrument interface.
- Dovetail set screw is designed to minimize head splay and cross-threading.
- Tab Stabilizer can be removed for a fully open design to optimize multi-level construct organization during the procedure.
- Streamlined instrumentation provides a simple removal of extended tabs.
- Screw diameters 5.5mm, 6.5mm, and 7.5mm in lengths from 35mm-55mm (in 5mm increments).
- Rod diameter is 5.5mm, comes in a variety of lengths, and is available in pre-bent configurations.
- Sleek MIS Rod Inserter for easy rod delivery.



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 the pedicle's entry point of the desired level. Confirm the position by using A/P and lateral fluoroscopy.
- Advance the targeting needle through the 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 the needle has reached the desired depth (Figure 1).
- Remove the inner stylet of the targeting needle (Figure 2).

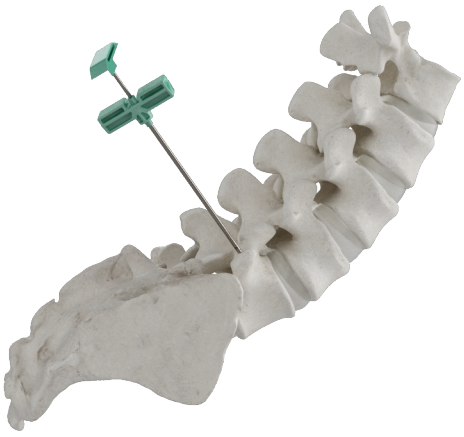


Figure 2

3. Guide Wire Insertion

- Insert the guide wire through the targeting needle (Figure 3).
- Advance the guide wire to desired depth. Take care not to bend or kink the 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.

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

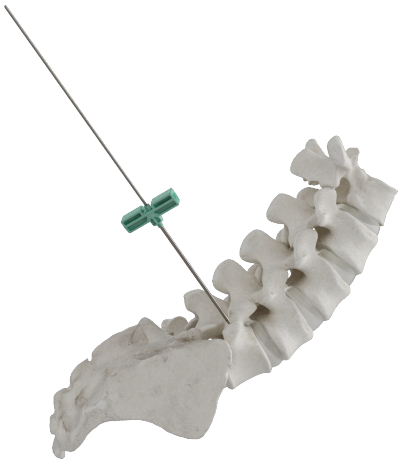


Figure 3

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 before dilator placement, after dilator removal, and before placement of the screw to separate soft tissue for access to the pedicle (Figure 7).*

*NOTE: Note: The **Adjustment Driver (M070-0059)** can be used to adjust screw height if necessary.*



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 size tap.
- Advance the tap over the guide wire under fluoroscopy (Figure 9).

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

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

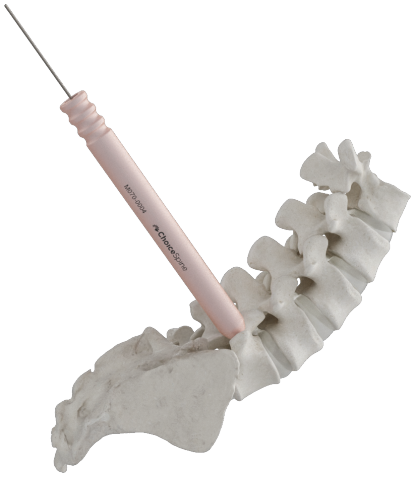


Figure 8



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 Loading

- Determine the appropriate size pedicle screw.
- Assemble the screwdriver. Insert the **Screwdriver Inner Shaft (M070-0126-02)** through the distal end of the **Screwdriver Outer Shaft (M070-0160-01)**. Then connect the **Screwdriver Quarter Square (M070-0126-A1)** to the proximal end of the **Screwdriver Inner Shaft**.
- Attach a **Ratcheting Axial Handle (M070-0212)** to the screwdriver. Rotate the **Ratcheting Axial Handle** setting to the neutral or reverse position (Figure 11).
- Insert the screwdriver into the extended tab until the driver tip seats in the hexalobe feature of the screw body (Figure 12).
- 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 12). Continue to rotate the knob on the **Screwdriver 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 screwdriver.
- Remove **Dilator 2 (M070-0004)**, taking care not to disturb the guide wire.
- Rotate the **Ratcheting Axial Handle** setting to the forward position, load the screwdriver over the guide wire, and advance the screw under fluoroscopy to the desired depth (Figure 13).
- 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 **Screwdriver Outer Shaft** counterclockwise until the driver is no longer engaged with the tulip and extended tabs.
- Remove guide wires upon successful insertion of all screws.

NOTE: If desired, the tab stabilizer may be removed at the beginning of this step. See Step 12 for tab stabilizer removal.

*NOTE: The **Double–Sided Countertorque (M070-0227)** can assist in stabilizing the tab when removing the screwdriver.*

*NOTE: The **Double–Sided Countertorque (M070-0227)** can be used to help tighten/loosen the rod holder on to the rod.*



Figure 11



Figure 12



Figure 13

Tab Stabilizer

If the tab stabilizer is removed, the **Modular Tab Stabilizer (M070-0202)** can be utilized to add support to the extended tab screw if needed (Figure 14a). Place the **Modular Tab Stabilizer** on top of the extended tab screw until the locking tabs engage the holes on the proximal end of the extended tabs (Figure 14b).



Figure 14a Figure 14b

7. Rod Length Determination

- Insert the **Rod Caliper (M070-0013A)** in the extended tabs until seated with the laser mark bands on top of the extended tabs. There are two laser mark bands for both tab heights to indicate the rod calipers are fully seated: one aligns with the top of the tab stabilizer and one aligns with the top of the extended tab with the tab stabilizer removed (Figure 15).
- Read the corresponding rod length as indicated (Figure 16).

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



Figure 15



Figure 16

Fascia Blades (Optional Step)

- **Fascia Blades** can be utilized to separate soft tissue between the extended tabs to assist with rod placement (Figure 17). **Fascia Blades** load on to the rod inserter in the same manner as a rod.
- **Fascia Blades** come in 3 different sizes: **50mm (M070-0053)**, **75mm (M070-0054)**, and **100mm (M070-0055)**.



Figure 17

8. Rod Placement

- Select the correct rod length.
- Open the working end of the **Bayoneted Rod Inserter (M070-0093)** by turning the knob counterclockwise (Figure 18).
- 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 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 the outside face of the extended tabs and position the rod tip within the slotted openings of the extended tabs. Rod placement may be simplified if the tab stabilizer openings are facing the cranial and caudal ends of the construct (Figure 21). Align the extended tab openings to allow the rod to pass through each extended tab. If needed the **Tulip Postitioner (M070-0208)** can be used to easily rotate the extended tab tulips (Figure 20).
- Under fluoroscopy, work the rod tip through the tissue until the rod tip spans the extended tabs, passing between all the tabs.
- Fully seat the rod into the extended tab tulips (Figure 21).



Figure 18

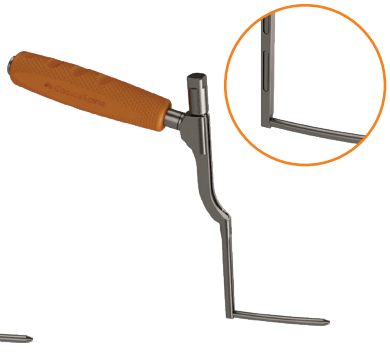


Figure 19



Figure 20



Figure 21

NOTE: Extended Tab Screws and Rod Inserter are not to be removed at this step.

9. Set Screw Placement

- Load the **Set Screw (MT20-0002)** onto tip of the **Set Screw Starter (M070-0207).**
- 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 extended tabs (Figure 22).
- Engage the **Set Screw** with screw tulip head and provisionally tighten the set screw.
- The **Set Screw** is seated when the top of the extended tab is aligned with the corresponding colored band on the **Set Screw Starter**: the yellow bands aligns with the top of the tab stabilizer and the white bands aligns with the top of the extended tabs after the tab stabilizer has been removed.
- Repeat for all screws.

NOTE: The Extended Tab Screws and Rod Inserter are not to be removed at this step.



Figure 22

Set Screw Retriever (Optional Step)

A **Set Screw Retriever (M070-0105)** is available in the event that a **Set Screw** disengages from the **Set Screw Starter** inside of the extended tab screw (Figure 23).



Figure 23

10. Set Screw Final Tightening

NOTE: If the Modular Tab Stabilizer was used, it will need to be removed before final tightening.

- Final tighten **Set Screws (MT20-0002)** with the **100in-lb Torque Handle (M070-0178)** and **Set Screw Final Driver (M070-0211)**. To prevent the tulip from rotating during final tightening, use the **Short Countertorque (M070-0219)**. Proximal end of **Short Countertorque** is flush with proximal end of tulips.

NOTE: Final tightening can be achieved with or without the tab stabilizer in place.

NOTE: If the tab stabilizer is still attached, align the laser marked side of the Short Countertorque that says, "Tab Stabilizer" with the tab stabilizer. If the tab stabilizer is removed, align the laser marked sides of the Short Countertorque that say "Tabs" with the extended tabs.

- Insert **Torque Handle** and **Set Screw Final Driver** through the **Short Countertorque** and extended tabs then engage the **Set Screw**.
- Rotate the **Torque Handle** clockwise until the final torque setting is achieved (Figure 24). An audible "click" occurs when the 100 in-lbs is reached.
- Repeat the above steps until all **Set Screws** are final locked.



Figure 24

11. 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 25).

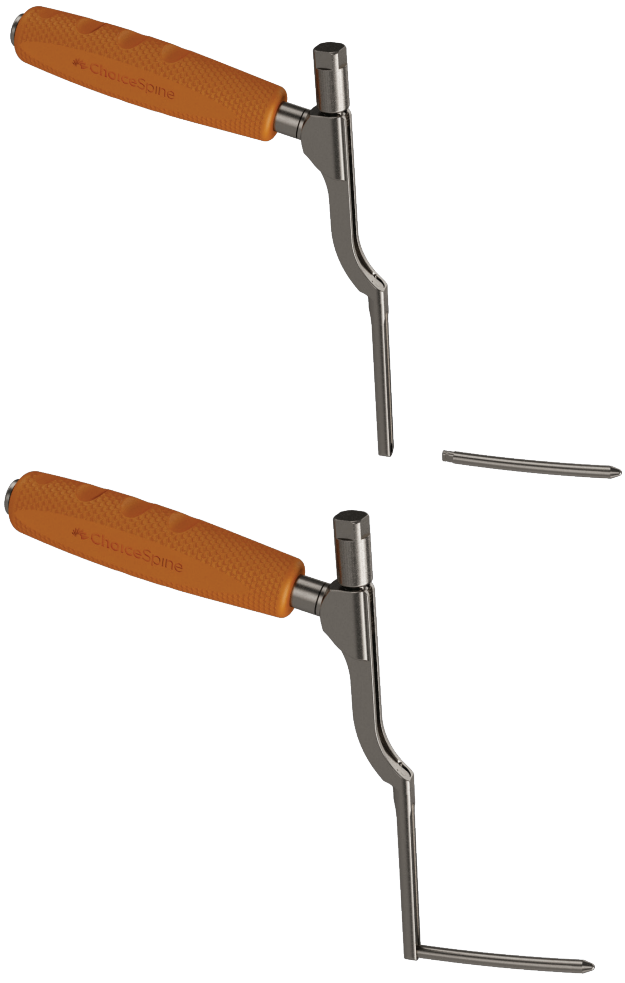


Figure 25

12. Tab Stabilizer and Extended Tab Removal

- Slide the tab stabilizer into the **Tab Breaker (M070-0218)** and rock the tab breaker slightly back and forth until the tab stabilizer breaks off the extended tabs.
- Repeat for all the extended tabs in the construct (Figure 26).
- Extended tabs can be removed after removing the rod inserter.
- Once all screws are fully tightened, then slide the **Tab Breaker** through one side of the extended tabs until fully seated. Rock the **Tab Breaker** in the direction of the tab until one extended tab is broken, pull the **Tab Breaker** up and remove the extended tab. Repeat for the other extended tab and for all other screws in the construct (Figure 27).

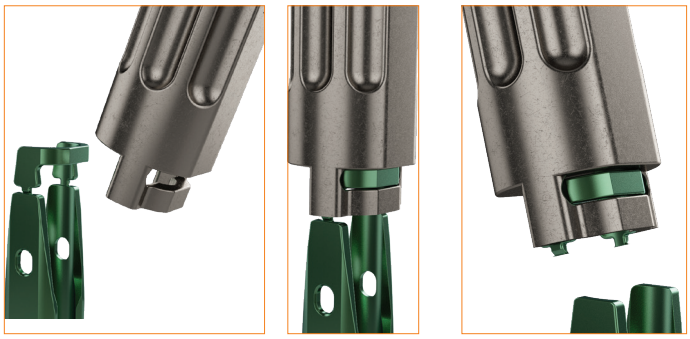


Figure 26

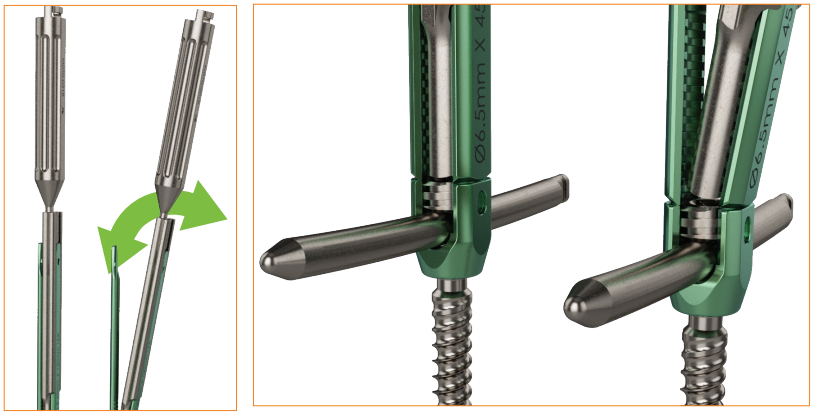


Figure 27

Screw Removal

- If a screw removal is needed, use the **Set Screw Starter (M070-0207)** to remove the **Set Screws (MT20-0002).** Then remove the rods with surgical forceps or similar instrumentation.
- Attach an **Axial Ratcheting Handle (M070-0212)** to the **Dorsal Height Adjustment Driver (M070-0059).** Rotate the **Axial Ratcheting Handle** to reverse position. Locate and engage the screw hexalobe of the extended tab screw with the distal end of the driver.
- Rotate the driver counterclockwise to remove the screw.

Instrument List

Part #	Description	Qty
M070-0212	AXIAL RATCHET HANDLE	4
M070-0052	SPLITTER KNIFE	1
M070-0005	DILATOR 1	1
M070-0004	DILATOR 2	1
M070-0007	Ø5.5 TAP	1
M070-0008	Ø6.5 TAP	1
M070-0009	Ø7.5 TAP	1
M070-0093	ROD INSERTER	2
M070-0053	FASCIA BLADE, 50MM	1
M070-0054	FASCIA BLADE, 75MM	1
M070-0055	FASCIA BLADE, 100MM	1
M070-0013A	ROD CALIPER	1
M070-0126-A1	SCREWDRIVER QUARTER SQUARE	3
M070-0160-01	SCREWDRIVER OUTER SHAFT	3
M070-0126-02	SCREW DRIVER INNER SHAFT	3













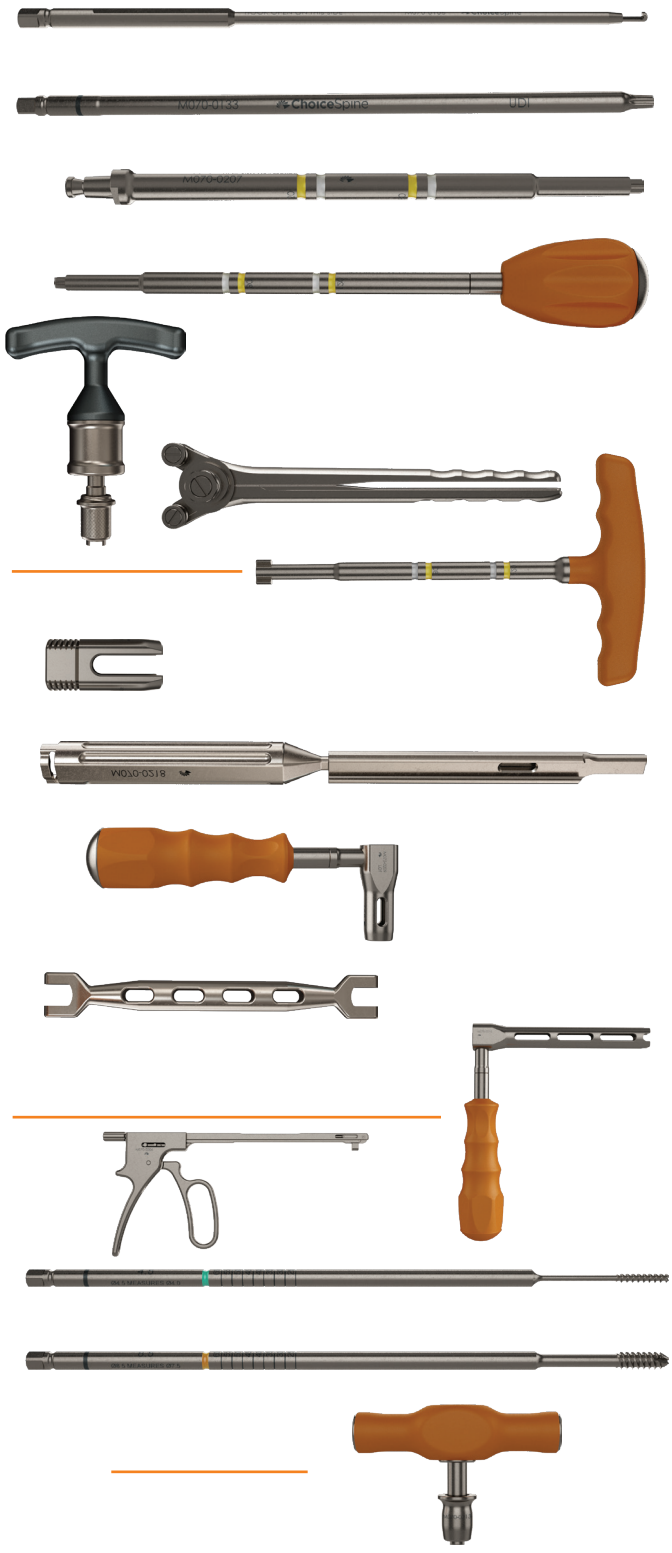






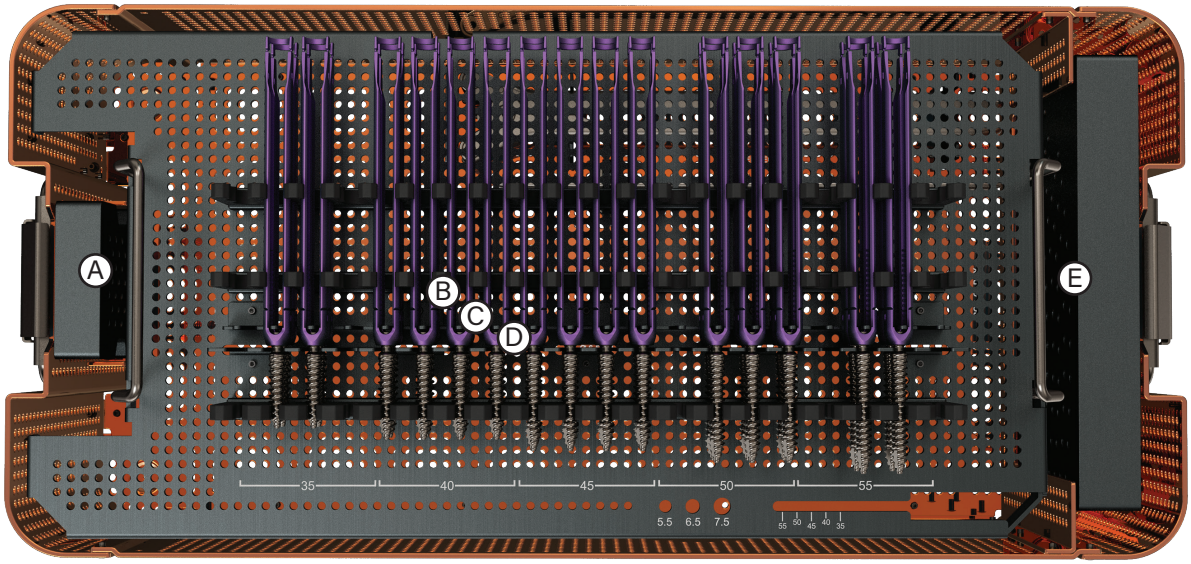
Instrument List

Part #	Description	Qty
M070-0105	SET SCREW RETRIEVER	1
M070-0059	DORSAL HEIGHT ADJUSTMENT DRIVER	1
M070-0211	SET SCREW FINAL DRIVER	2
M070-0207	SET SCREW STARTER	2
M070-0178	100 IN-LB TORQUE HANDLE	1
2070-5023	ROD BENDER	1
M070-0208	TULIP POSITIONER	1
M070-0202	MODULAR TAB STABILIZER	6
M070-0218	TAB BREAKER	1
M070-0219	SHORT COUNTERTORQUE	1
M070-0227	DOUBLE-SIDED COUNTERTORQUE	1
M070-0210	LONG COUNTERTORQUE	(OPTIONAL)
M070-0206	ARTICULATING ROD INSERTER	(OPTIONAL)
M070-0006	Ø4.5 TAP	(OPTIONAL)
M070-0010	Ø8.5 TAP	(OPTIONAL)
M070-0213	70 IN-LB TORQUE HANDLE	(OPTIONAL)



K-Wires are made to order. Contact Sales Support (salessupport@choicespine.com) to order preferred K-Wires.
Available in Stainless Steel and Nitinol: Blunt - Blunt, Blunt - Trocar, Trocar - Trocar
Lengths: 12 inches, 20 inches, 22 inches, 24 inches

Implant Tray - Screw Caddies (Upper)



Ⓐ Set Screw Caddy M090-6005

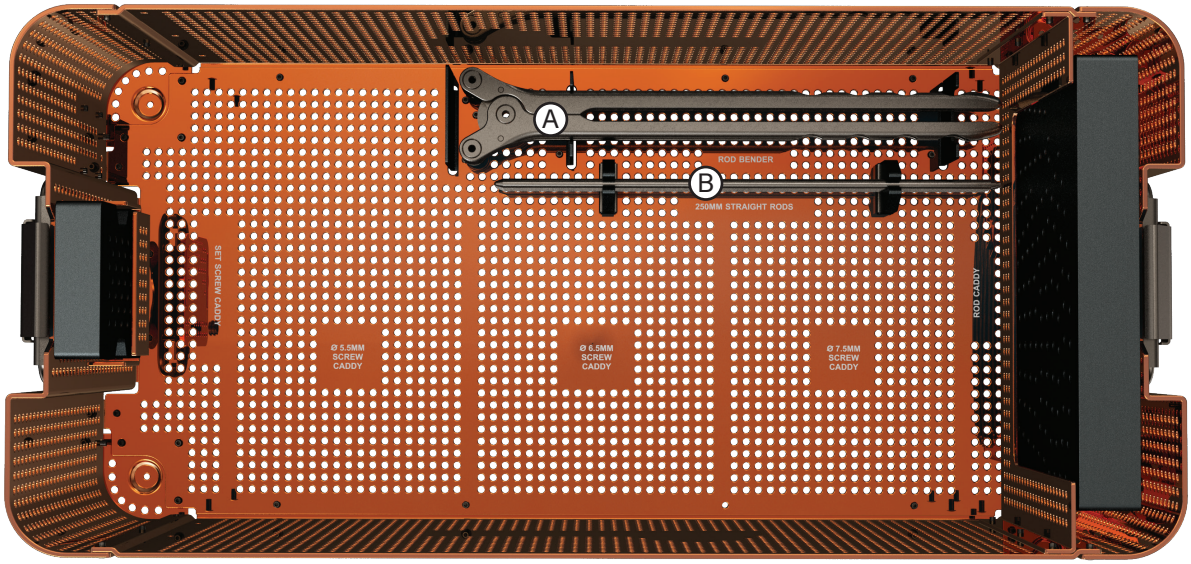
Ⓑ Ø7.5mm Screw Caddy M070-6007 (Purple)

Ⓒ Ø5.5mm Screw Caddy M070-6007 (Blue)

Ⓓ Ø6.5mm Screw Caddy M070-6007 (Green)

Ⓔ Pre-Bent Rod Caddy M090-6006

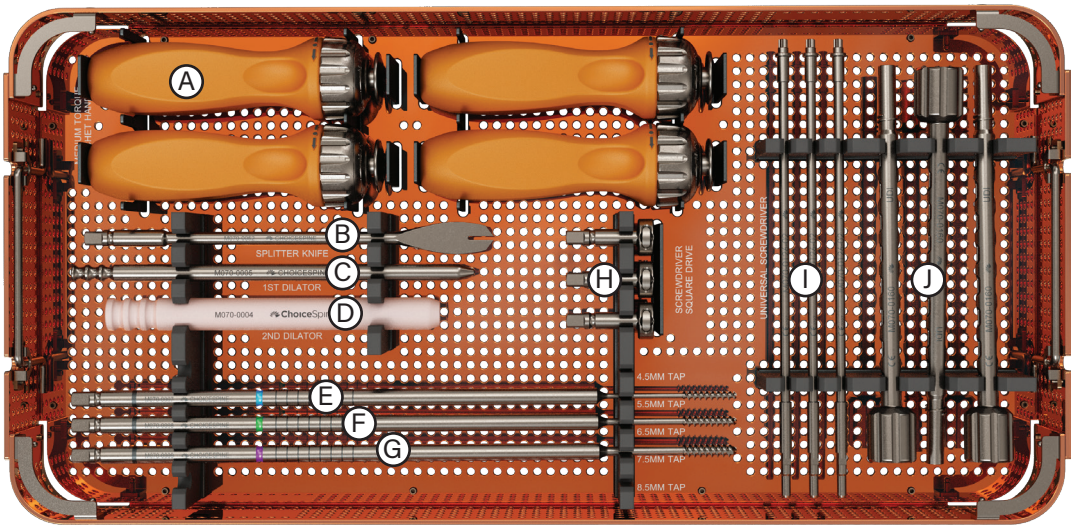
Implant Tray - Lower



Ⓐ Rod Bender 2070-5023

Ⓑ 250mm Straight Rods MT20-S250

Upper Instrument Tray



Ⓐ **Axial Ratchet Handle (x4) M070-0212**

Ⓑ **Splitter Knife M070-0052**

Ⓒ **Dilator 1 M070-0005**

Ⓓ **Dilator 2 M070-0004**

Ⓔ **Ø5.5 Tap M070-0007**

Ⓕ **Ø6.5 Tap M070-0008**

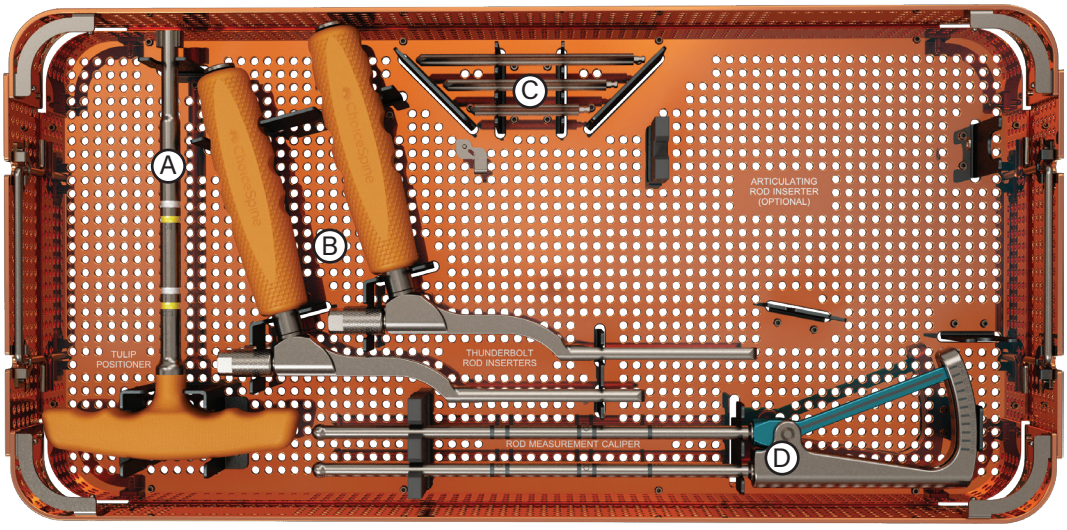
Ⓖ **Ø7.5 Tap M070-0009**

Ⓗ **Screw Driver Quarter Square (x3) M070-0126-A1**

Ⓘ **Screw Driver Inner Shaft (x3) M070-0126-02**

Ⓙ **Screw Driver Outer Shaft (x3) M070-0160-01**

Middle Instrument Tray



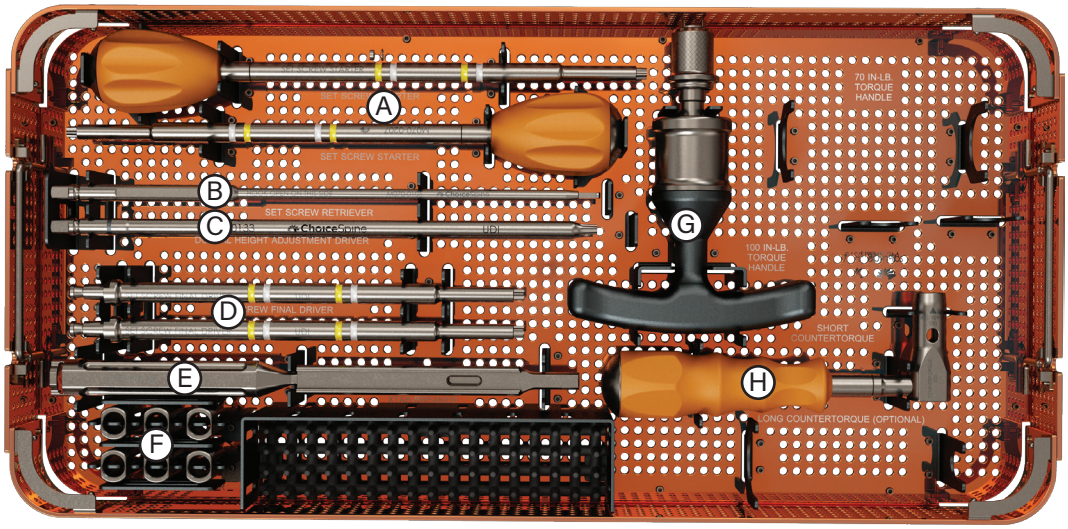
Ⓐ **Tulip Positioner M070-0208**

Ⓑ **Bayonetted Rod Inserters (x2) M070-0093**

Ⓒ **Fascia Blades: 50mm M070-0053, 75mm M070-0054, 100mm M070-0055**

Ⓓ **Rod Caliper M070-0013A**

Lower Instrument Tray



Ⓐ **Set Screw Starter (x2) M070-0207**

Ⓑ **Set Screw Retriever M070-0105**

Ⓒ **Dorsal Height Adjustment Driver M070-0059**

Ⓓ **Set Screw Final Driver (x2) M070-0211**

Ⓔ **Tab Breaker M070-0218**

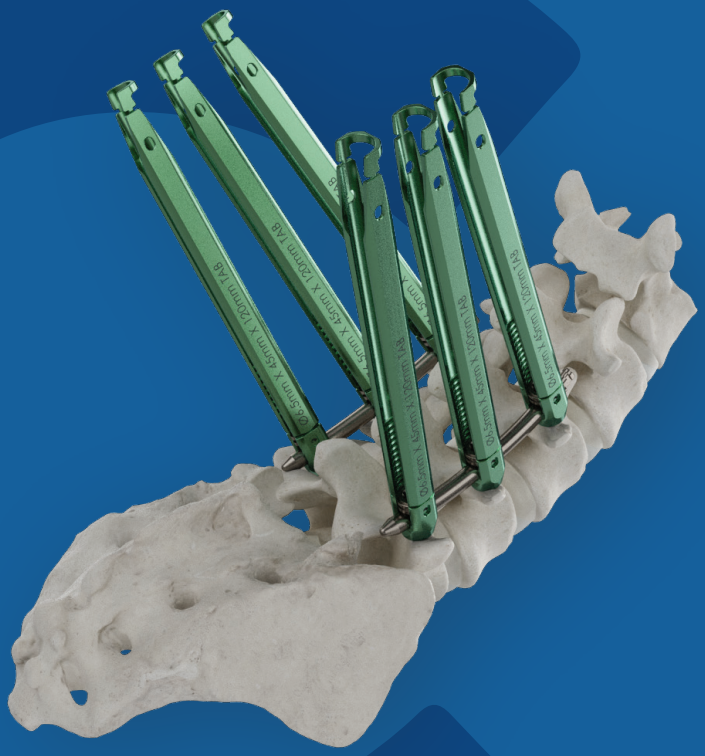
Ⓕ **Modular Tab Stabilizer (x6) M070-0202**

Ⓖ **100in-lb Torque Handle M070-0178**

Ⓗ **Short Countertorque M070-0219**

Notes:

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



THUNDERBOLT™ EXTAB

Minimally Invasive Extended Tab Pedicle Screw System

Spine the Right Way.℠

ChoiceSpine™

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