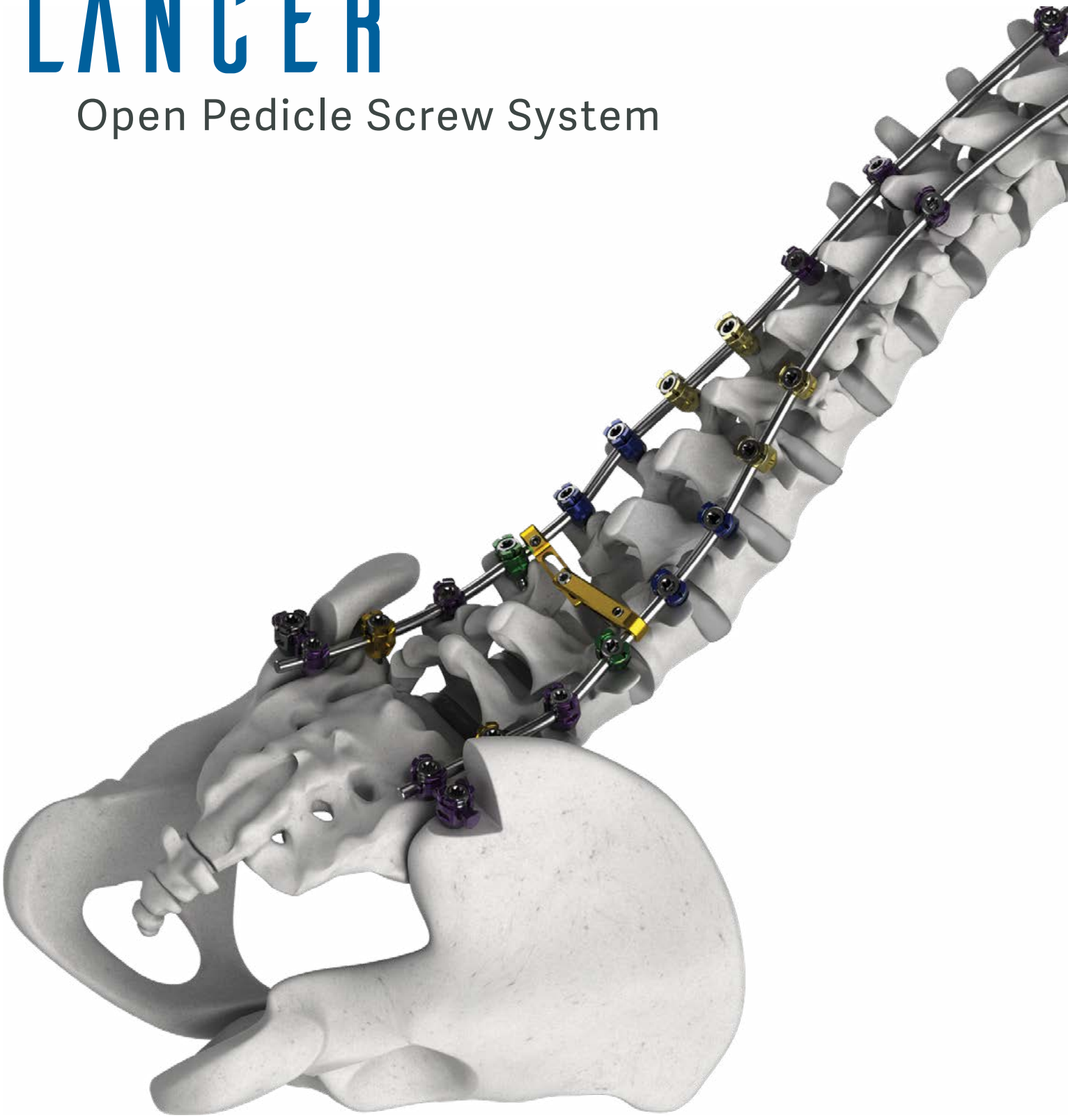
SURGICAL TECHNIQUE GUIDE

LANCER™

Open Pedicle Screw System



ChoiceSpine™

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Open Pedicle Screw System

Introduction

The ChoiceSpine Lancer™ open pedicle screw system is a posterior spinal fixation system consisting of various polyaxial screws, rods, cross-connectors, and hooks to accommodate various spinal anatomies. Lancer is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for degenerative disc disease, spondylolisthesis, trauma, spinal stenosis, deformities, tumor, and/or pseudoarthrosis.

Implants

Pedicle Screws

Titanium Rods

30mm - 100mm
(10mm increments)

NOTE: CoCr rods are available for domestic use only.

Hooks

Lamina Transverse Pedicle

NOTE: Hooks are available for domestic use only.

Cross-Connectors

Rod-to-Rod Connectors

Step 1: Fluoroscopic Planning and Pedicle Preparation

- Identify and target the appropriate level(s) using A/P and lateral fluoroscopy.
- After the pedicle entry point has been determined, an **Awl (E070-0026)** is used to create an entry hole into the pedicle.
- A **Curved (E070-0028)** and **Straight (E070-0027)** Lenke Probe are provided to enlarge a pathway for screw placement. The Lenke probe also has depth markings to determine length of screw (Fig. 1).
- A **Straight Ball Tip Probe (E070-0051)** may be used to palpate the floor and walls of the pilot hole.
- 5.5, 6.5, and 7.5mm taps are provided for screw hole preparation.
- Select the appropriate diameter tap and tap to desired length.

NOTE: Tap diameter is undersized by 1mm

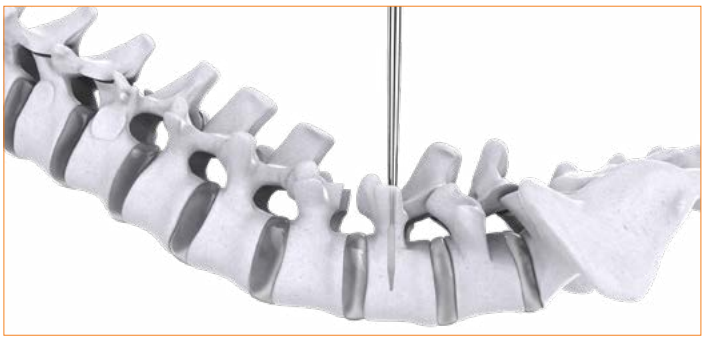


Figure 1

Step 2: Loading The Screwdriver

- Attach the distal end of the **Ratcheting Handle (M070-0003)** to the **Screwdriver (M070-0022)**. The screwdriver is fully seated when the **Ratcheting Handle** meets the black line (Fig. 2).
- Rotate the **Ratcheting Handle** into the neutral or reverse setting.
- Select the desired screw diameter and length. Then insert the distal end of the **Screwdriver** into the tulip so that the tip of the **Screwdriver** seats into the hexalobe feature of the screw (Fig. 3).

Figure 2

Figure 3

NOTE: Holding the screw shank instead of the screw tulip will provide easy alignment of the screw and driver.

Step 2: Loading The Screwdriver (cont.)

- Tighten the **Screwdriver (M070-0022)** onto the screw by rotating the winged wheel clockwise. This will advance the distal feature of the **Screwdriver** into the thread pattern of the tulip. Rotate the winged wheel until it will no longer advance and is tight (Fig. 4).

- Move the **Ratcheting Handle (M070-0003)** into the forward position before delivering the screw.

Figure 4

Step 3: Screw Insertion

- Advance the screw to the desired depth. Verify screw position with fluoroscopy.

- Repeat until all screws are seated to the desired depth (Fig. 5).

- Rotate the winged wheel counterclockwise on the **Screwdriver** to disengage it from the screw.

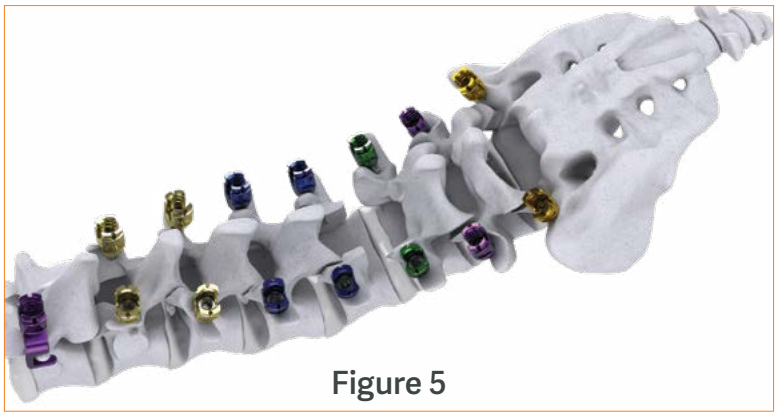


Figure 5

(Optional) Step 4: Hook Placement

Hooks are provided in the Lancer Deformity set.

NOTE: Hooks are available for domestic use only.

- Prepare vertebral anatomy for hook placement. Lamina, transverse, and pedicle hook starters are provided (Fig. 6).
- Attach the appropriate hook to the **Straight Hook Inserter (M070-D006)**. Place the hook in the desired location (Fig. 7).
- Repeat the steps above to place the remaining hooks as determined in the preoperative plan.
- A **Hook Impactor (M070-D008)** is provided to assist with hook placement (Fig. 7).

Figure 6

Figure 7

Step 5: Rod Insertion

- Select the desired rod length to span the entire construct.
- A **Tulip Positioner (M070-0026)** is available to adjust the orientation of the pedicle screw tulips and facilitate alignment Fig. 8).
- Utilize the **Rod Holder (M070-0039)** to place the rod into the screw tulips (Fig. 9).
- It may be necessary to adjust the curvature of the rod by using the **Rod Benders (2070-5023)**. In-situ benders are available.
- A **Rod Gripper (M070-0038)** can be used for further adjustment.

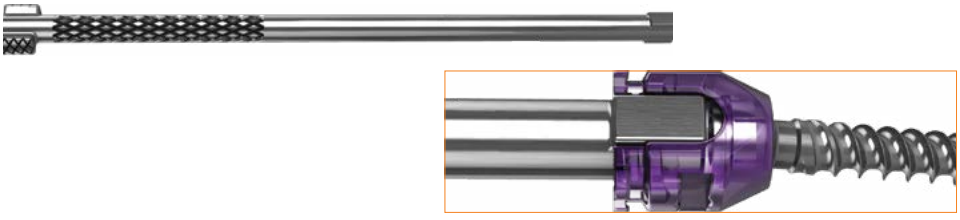


Figure 8

Figure 9

Step 6: Set Screw Placement

- Load the set screw onto the tip of the **Set Screw Starter (M070-0037)** by placing downward pressure so the set screw engages with the **Set Screw Starter.**
- Confirm that the rod is adequately positioned and that the rod length is adequate.
- Provisionally tighten the set screw (Fig. 10).
- Repeat the above step to continue provisionally locking the rods into the screw tulips and/or hooks.
- The **Rod Pusher (M070-0036)**, **Rod Holder (M070-0039)**, or **Rod Gripper (M070-0038)** may be used to hold the rod inside the screw or hook while provisionally tightening each set screw.

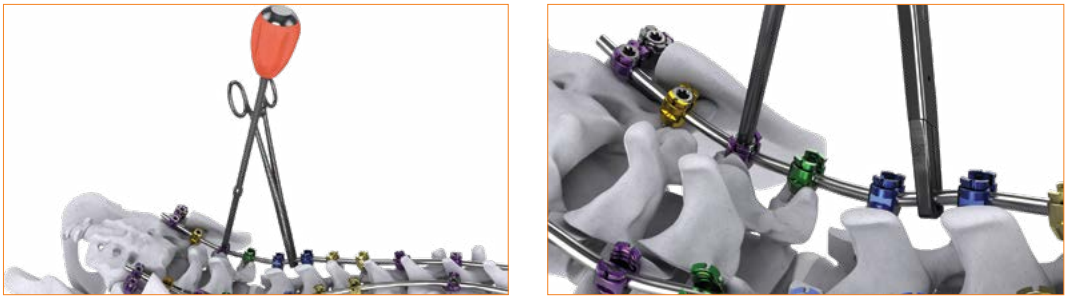


Figure 10

Step 7: Rod Reduction

- A **Tower Persuader (M070-0074)** may be used if additional rod reduction is required.
- To attach the Tower Persuader to the screw or hook, rotate the proximal housing of the persuader counterclockwise to fully extend the inner shaft.
- Align the distal tips over the tulip as shown and apply downward pressure until the forks snap into the lower cut-outs on the tulip (Fig. 11).
- Proper seating is achieved when the shoulder inside the **Tower Persuader** is at rest on top of the screw tulip as shown (Fig. 12).

Figure 11

NOTE: A Pistol Reducer is available upon request.

Figure 12

Step 7: Rod Reduction (cont.)

- Reduce the rod by turning the proximal housing clockwise (Fig. 13).
- There is a **Persuader Extender T-Handle (M070-0075)** that can be placed on top of the persuader for more mechanical advantage.
- Use the **Set Screw Starter (M070-0037)** to provisionally lock the set screw through the persuader (Fig. 14).
- A **Rod Rocker (M070-0084)** is available if desired.
- Position the forks in the lower cut-out feature of the tulip and engage the rod with the base of the **Rod Rocker** (Fig. 15).

Figure 13

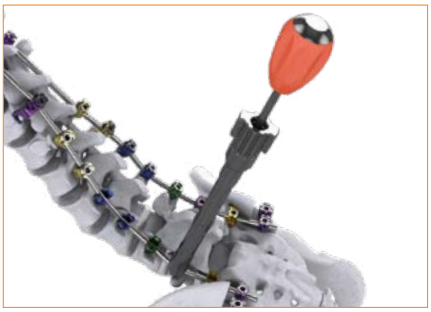


Figure 14

Figure 15

Step 8: Compression/Distraction

- Utilize the **Compressor (M070-0040)** or **Distractor (M070-0041)** to achieve the desired level of compression or distraction (Fig. 16).
- Compression or distraction will require one provisionally locked set screw which allows an adjacent pedicle screw or hook to move along the rod in the desired direction.
- Once desired compression or distraction is achieved the "floating" set screws will be provisionally locked to maintain the distracted or compressed position.

Figure 16

Step 9: Final Locking

- Lock the set screws using the appropriate torque handle and **Set Screw Final Driver (M070-0029),** lock the pedicle screws to **70 in-lb (M070-0016)** (orange) and the hooks to **100 in-lb (M070-D000)** (black).

*NOTE: **100 in-lb Torque Handle** is only sent with the Lancer Deformity set and is not standard in the Lancer set.*

- Position the **Countertorque (M070-0024)** over the screw tulips or hooks, ensuring it is all the way down against the rod where it exits on both sides (Fig. 18a). A separate **Countertorque** is provided for the hooks in the Lancer deformity set (Fig. 18b). Hooks require a **100 in-lb Torque Handle** (black).

- Pass the **Set Screw Final Driver** through the **Countertorque** tube and engage the set screw.

- Rotate the torque handle clockwise until the final torque setting is achieved and confirmed with audible "clicks".

- Repeat the above steps until all set screws are final locked.

- Torque limit is achieved with audible "click".

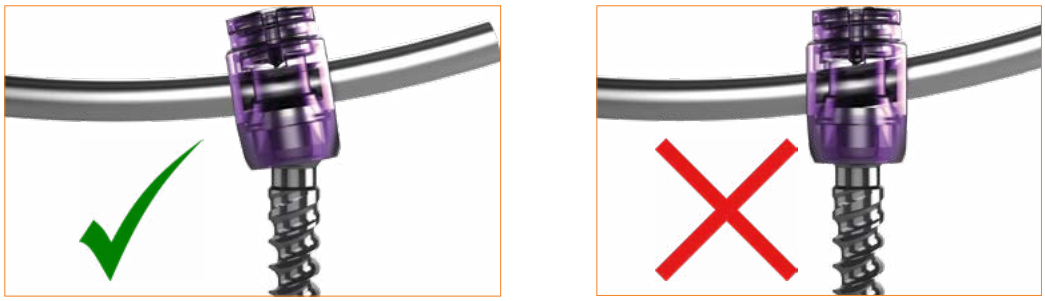


Figure 17

Figure 18a
Set Screw Final Locking

Figure 18b
Hook Final Locking

NOTE: THE TULIP SHOULD BE ALLOWED TO ROCK BACK TO ITS NATURAL POSITION ALONG THE ROD CURVATURE DURING FINAL TIGHTENING OF THE SET SCREW. EXCESSIVE FORCE SHOULD NOT BE APPLIED WITH INSTRUMENTATION THAT PREVENTS THE TULIP FROM REMAINING IN THIS POSITION.

Step 10: Connectors

- Cross-Connectors are available in the Lancer set. Domino, inline, and lateral offset connectors are available in the Lancer Deformity Set.

- To use the cross-connectors, select the appropriate size and place it on the rods. Verify that the set screws do not restrict the connector from fully seating on the rods. Keep in mind that it may be necessary to resect bony landmarks to ensure proper use of the connectors.

- Use a **Cross-Connector Set Screw Driver (M070-D011)** to engage the set screws and turn them clockwise to secure the rod(s) provisionally. Final tightening can be achieved by attaching the **40 in-lb Torque Handle (M070-0015)** (red) to the **Connector Set Screw Driver** and turning the set screws clockwise until the 40 in-lb torque limit is achieved.

- Use the **Cross-Connector Set Screw Driver** in the Lancer or Lancer Deformity set for locking the cross-connectors, domino, and inline connectors (Fig. 19a).

NOTE: It is recommended to leave a slight amount of overhang on the rod(s) when using the domino rod to rod connector, as it may "walk" slightly when securing the connector set screws on the rods. Lock down domino connector set screws in a crisscross pattern to limit connector "walking" (Fig. 19b). Likewise, for the inline rod to rod connector, ensure the opposing rod ends are in contact with the stop on the underside of the connector. Visual confirmation of rod placement can be achieved by looking through the windows along the connector's top surface (Fig. 19c).

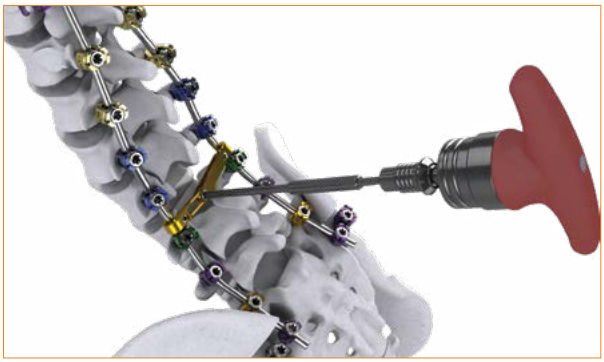


Figure 19a

Figure 19b

Figure 19c

Lateral Offset Connectors

Lateral offset connectors are available in 20mm, 30mm, and 40mm offsets in the deformity set. To utilize the lateral offset connectors, select the appropriate size and place it on the rod and adjacent to the screw in the Ilium. Use the **Set Screw Starter (M070-0037)** to engage the set screw by turning it clockwise to provisionally secure the lateral offset connector to the adjacent pedicle screw in the ilium (Fig. 20). Repeat to provisionally lock the connector to the rod. Final tightening can be achieved by attaching the **100 in-lb Torque Handle** (black) to the **Set Screw Final Driver** and turning the set screws clockwise until the 100 in-lb torque limit is achieved. The appropriate **Countertorque** and **100 in-lb Torque Handle** are provided in the Lancer Deformity Instrument Set 1.

NOTE: When used for Iliac fixation, the lateral offset connectors must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level. Use of the lateral offset connectors is contraindicated when the sacrum is absent or insufficient for implantation of pedicle screws at the S1 or S2 spinal level.

NOTE: Lateral offset connectors are only available for domestic use.

Removal

- To remove the Lancer components, first remove all connectors.
- Remove all set screws and rods.
- Remove pedicle screws and hooks.

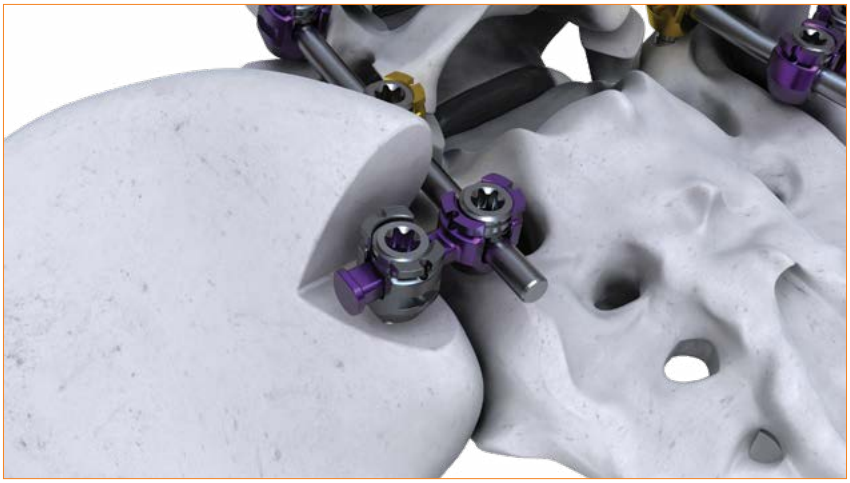
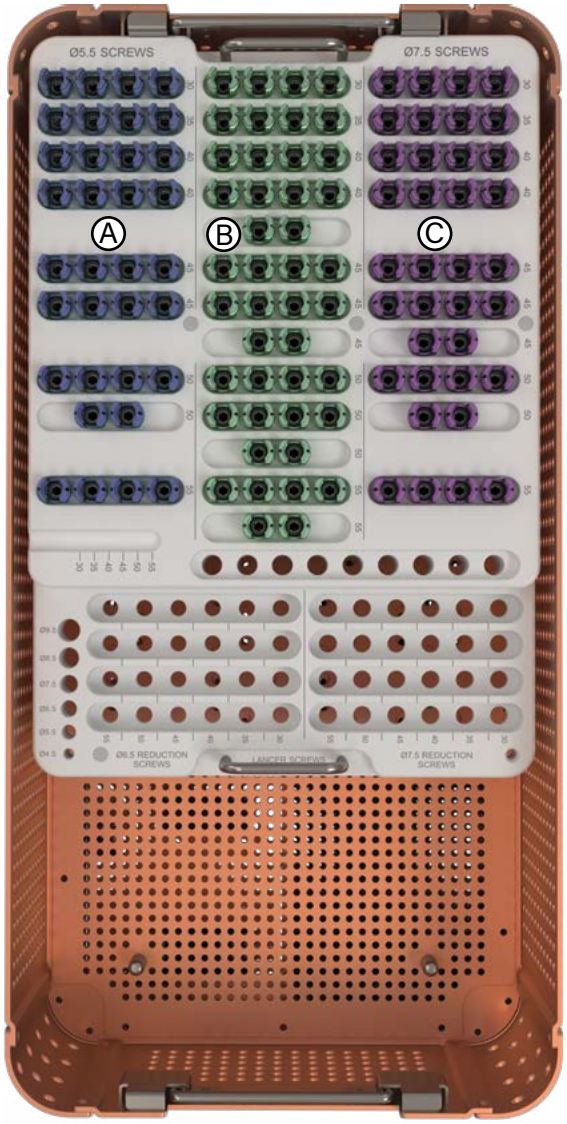


Figure 20

Implant Set: Top Tray

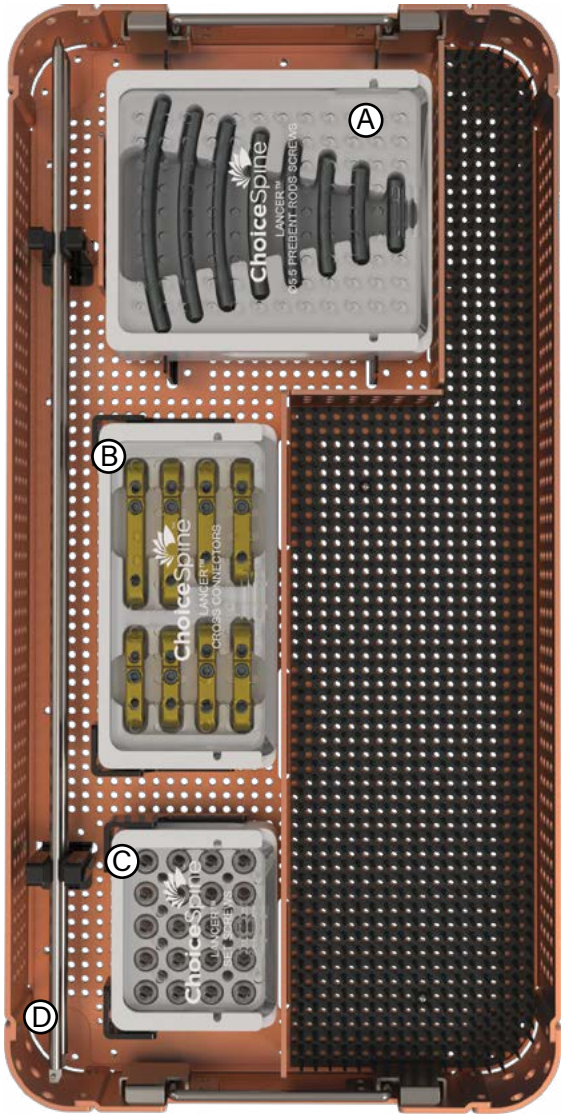


Ⓐ **Ø5.5 Screws**

Ⓑ **Ø6.5 Screws**

Ⓒ **Ø7.5 Screws**

Implant Set: Lower Tray



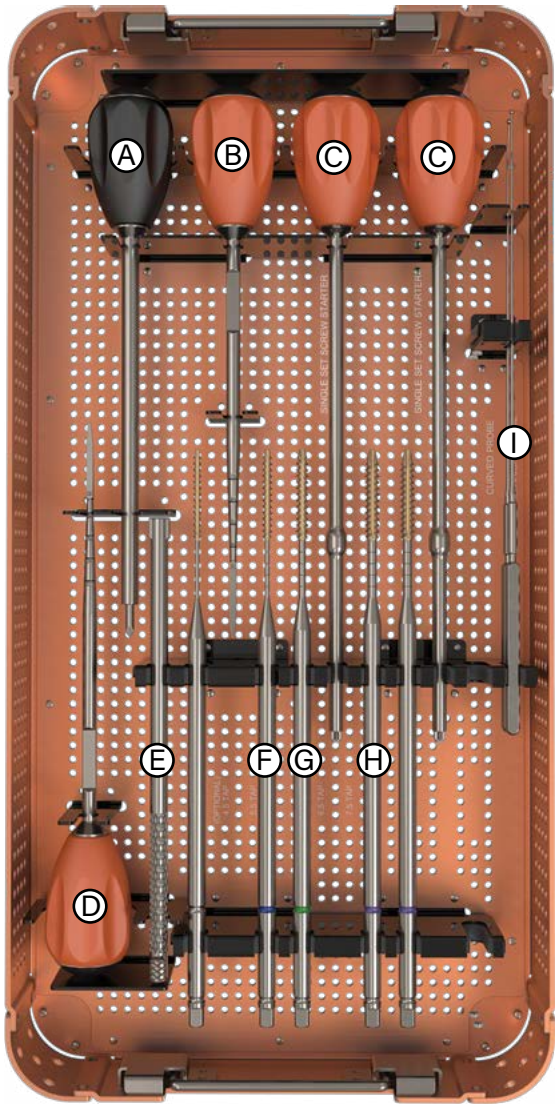
Ⓐ **Prebent Rods**

Ⓑ **Cross Connectors**

Ⓒ **Set Screws**

Ⓓ **440mm Straight Rods**

Instrument Set 1: Top Tray



Ⓐ Awl (E070-0026)

Ⓑ Curved Lenke Probe (E070-0028)

Ⓒ Set Screw Starter (M070-0037) x2

Ⓓ Straight Lenke Probe (E070-0027)

Ⓔ Tulip Positioner (M070-0026)

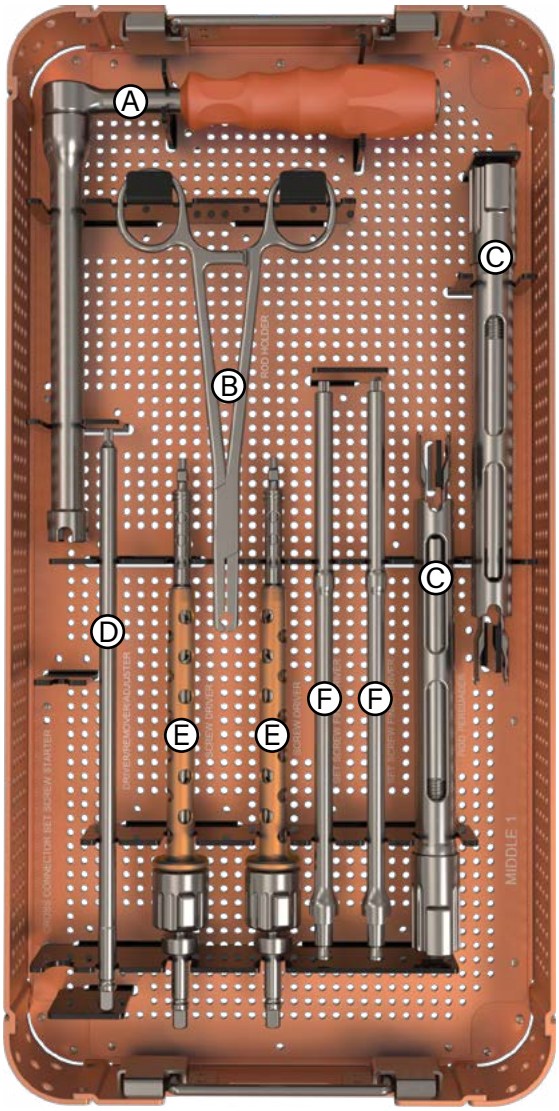
Ⓕ Ø5.5 Tap (M070-0031)

Ⓖ Ø6.5 Tap (M070-0032)

Ⓗ Ø7.5 Tap (M070-0033)

Ⓘ Ball-Tip Probe (E070-0051)

Instrument Set 1: Middle Tray



Ⓐ Countertorque (M070-0024)

Ⓑ Rod Holder (M070-0039)

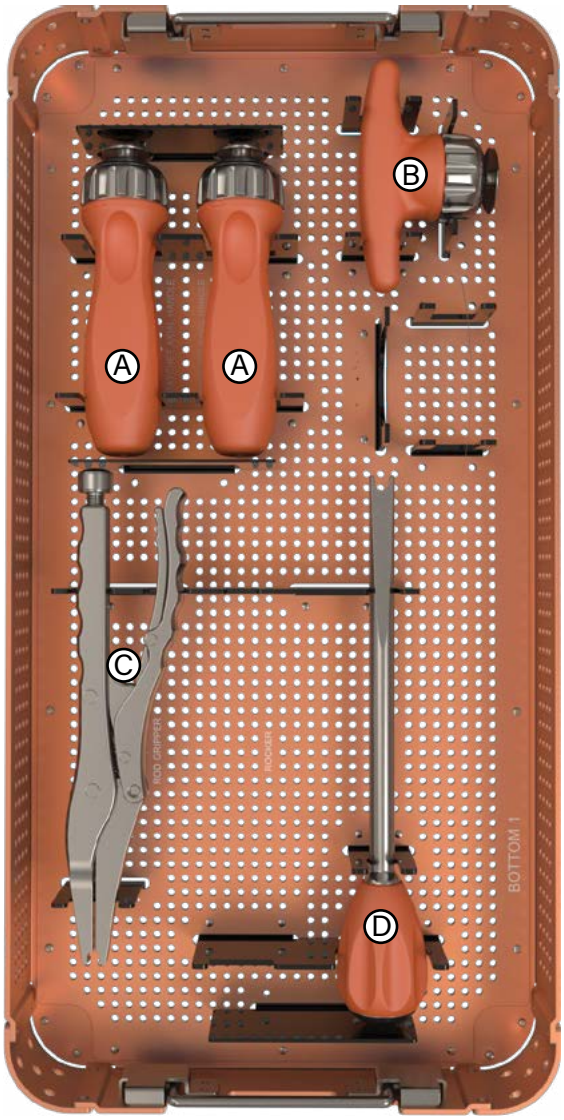
Ⓒ Tower Persuader (M070-0074) x2

Ⓓ Driver Remover/Adjuster (M070-0035)

Ⓔ Screwdriver (M070-0022) x2

Ⓕ Final Driver (M070-0029) x2

Instrument Set 1: Lower Tray



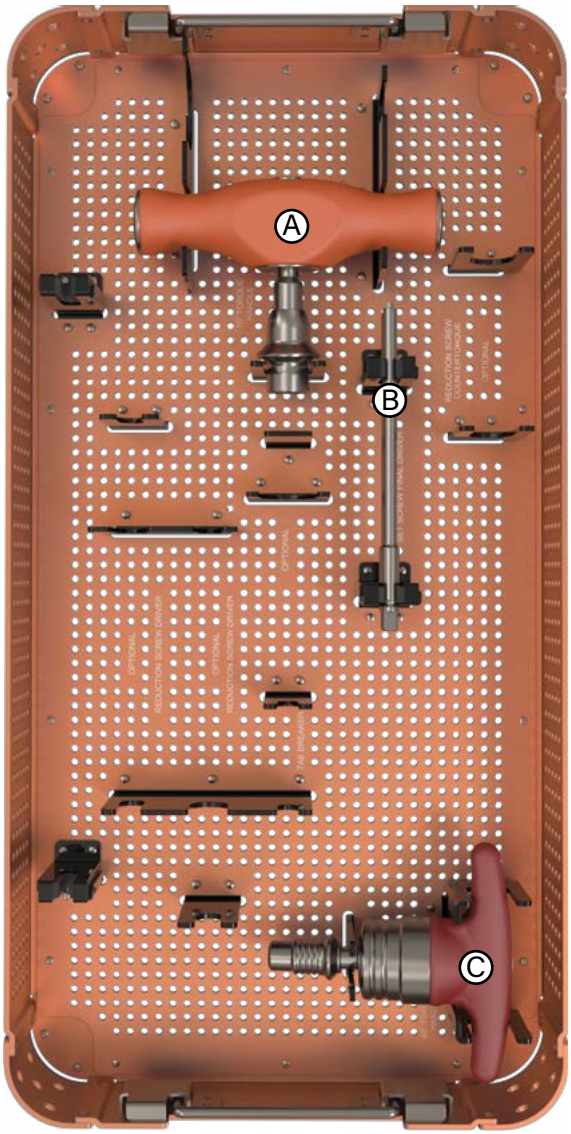
Ⓐ Ratcheting Axial Handle (M070-0003) x2

Ⓑ Ratcheting T-Handle (M070-0002)

Ⓒ Rod Gripper (M070-0038)

Ⓓ Rod Pusher (M070-0036)

Instrument Set 2: Top Tray

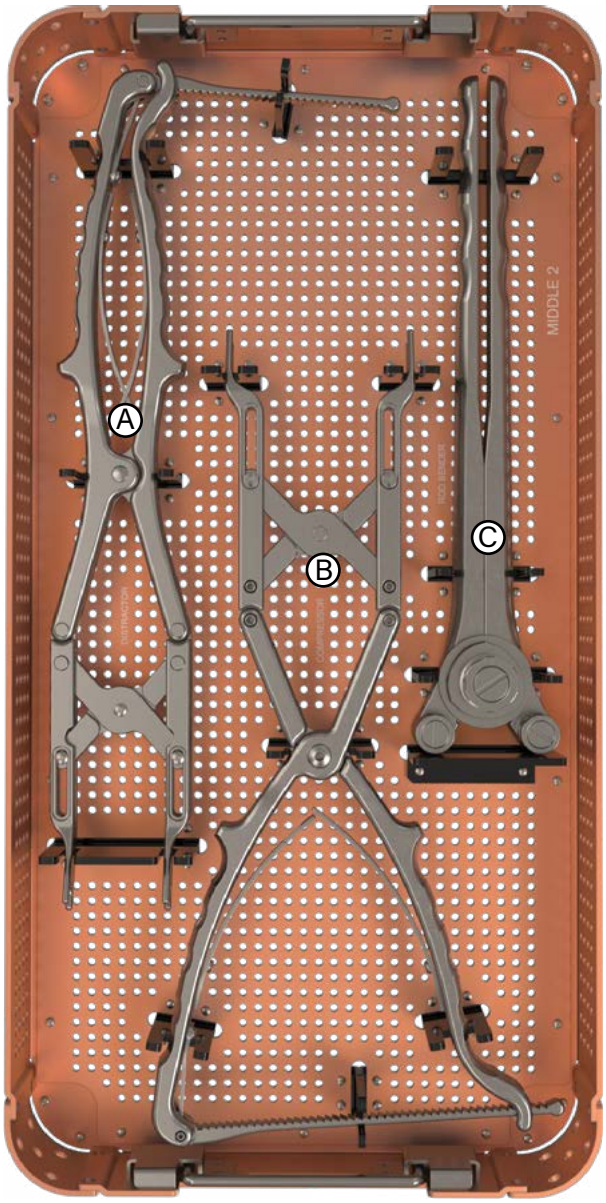


Ⓐ 70 in-lb Torque T-Handle (M070-0016)

Ⓑ Cross Connector Set Screw Final Driver (M070-D011) x2

Ⓒ 40 in-lb Torque Handle (M070-0015) x2

Instrument Set 2: Middle Tray



Ⓐ **Distractor (M070-0041)**

Ⓑ **Compressor (M070-0040)**

Ⓒ **Rod Bender (2070-5023)**

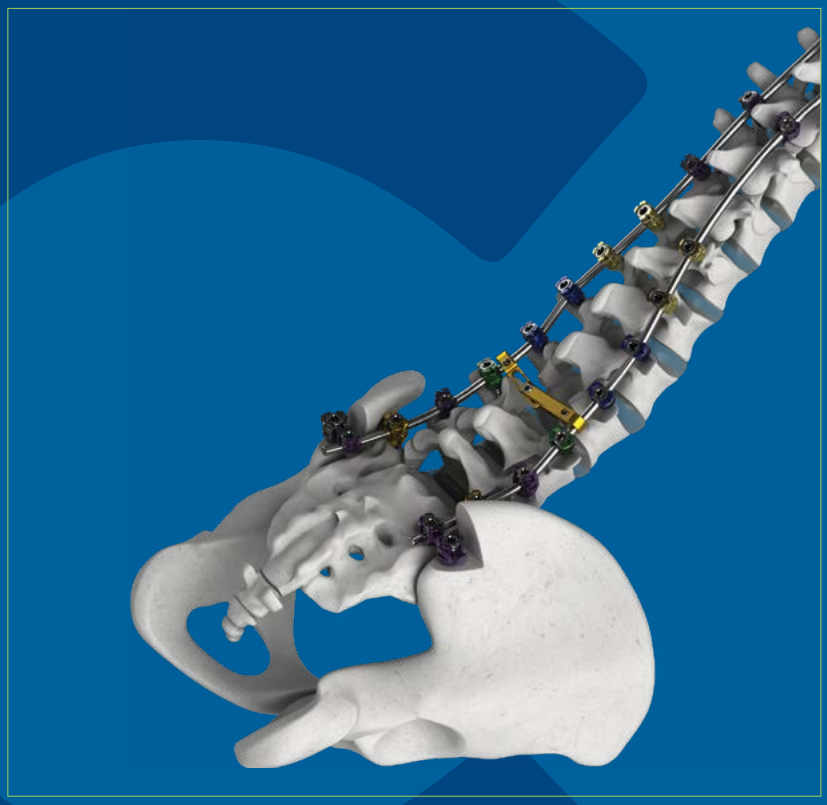
Instrument Set 2: Bottom Tray

Ⓐ **Scissor-Style Rod Rocker (M070-0084)**

Ⓑ **Persuader Extender T-Handle (M070-0075)**

Notes:

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



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Spine the Right Way.™

ChoiceSpine™

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