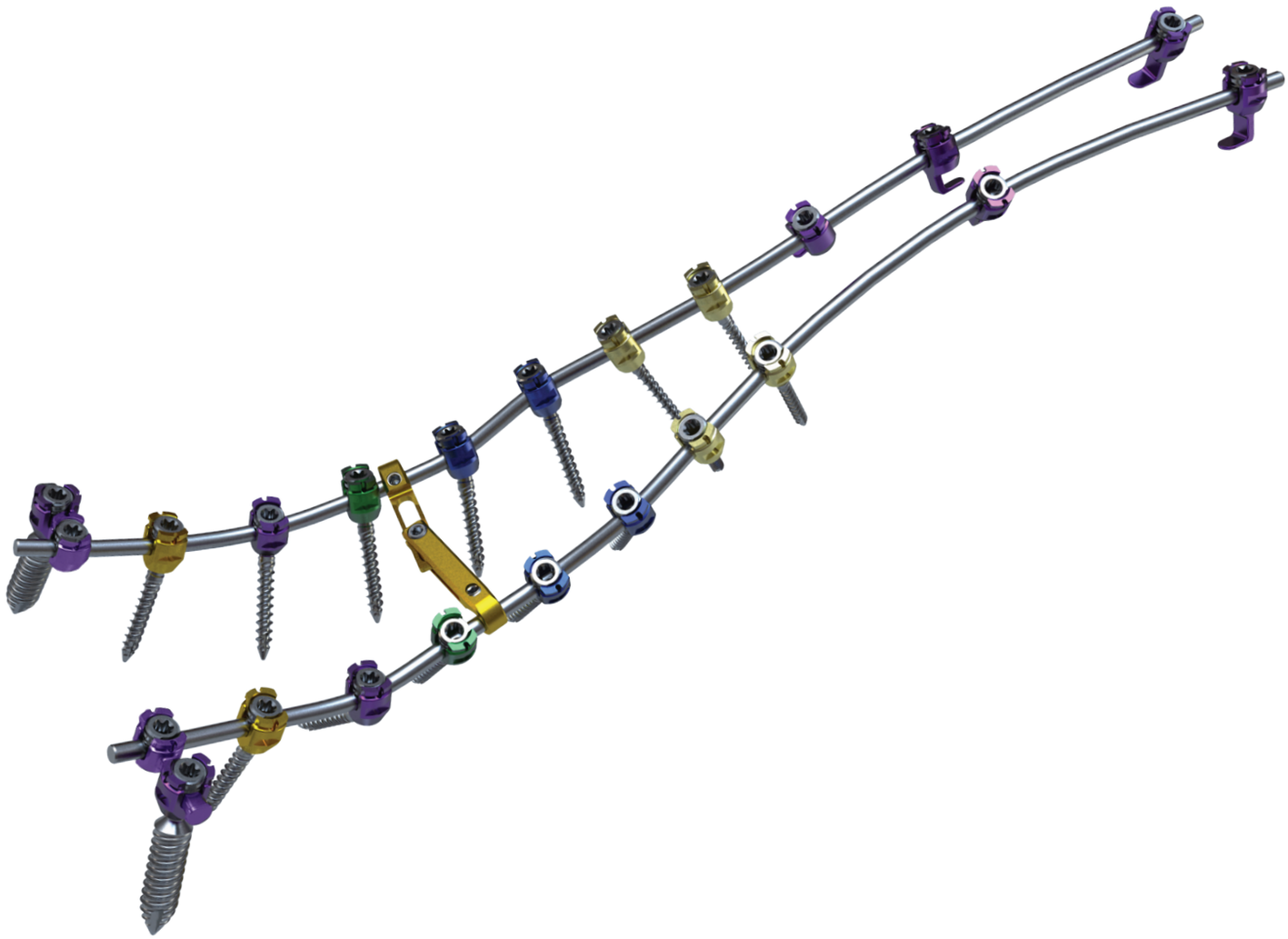
ChoiceSpine™
Propelling Spinal Surgery



LANCER™

Pedicle Screw System

A Simple, Comprehensive Solution

Surgical Technique

ChoiceSpine™
Propelling Spinal Surgery

LANCER™

Description

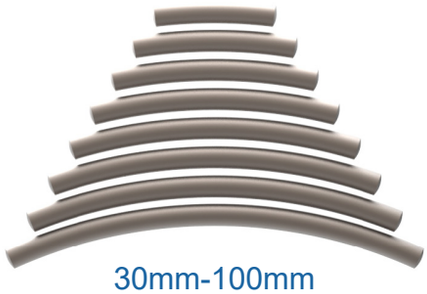
The ChoiceSpine LANCER open pedicle screw system is a posterior spinal fixation system consisting of various polyaxial screws, rods, cross-connectors, and hooks to accommodate various spinal anatomies. LANCER is intended to provide immobilization and stabilization of spinal segments in skeletally mature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

Implants

Pedicle Screws

Ø5.5mm Ø6.5mm Ø7.5mm

Titanium Rods



30mm-100mm
(10mm increments)

Cross-Connectors

51-75mm

41-55mm

35-43mm

31-35mm

Rod-to-Rod Connectors

Hooks

- Lamina
- Transverse
- Pedicle

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 is used to create an entry hole into the pedicle.
- Enlarge the pathway utilizing a pedicle probe (Fig. 1).
- Observe the depth markings on the shaft to determine the appropriate screw length.
- A ball tipped pedicle feeler may be used to palpate the floor and walls of the pedicle inside the pilot hole.
- Taps are provided should the need arise for further screw hole preparation.
- If tapping is required, select the appropriate diameter and tap to desired depth.

NOTE: Tap diameter is undersized by 1mm

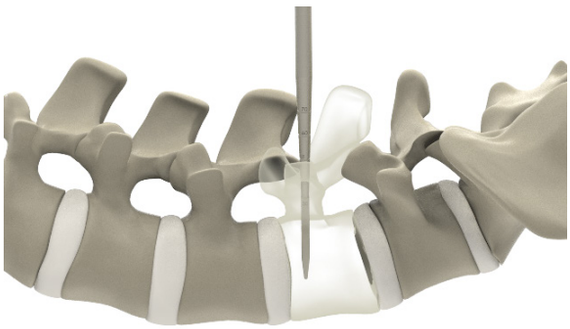


Fig. 1

Step 2 Loading The Screw Driver

- Compress the distal end of the ratcheting handle and insert the screw driver. The screw driver 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 screw driver into the tulip so that the tip of the screw driver seats into the hexalobe feature of the screw (Fig. 3).

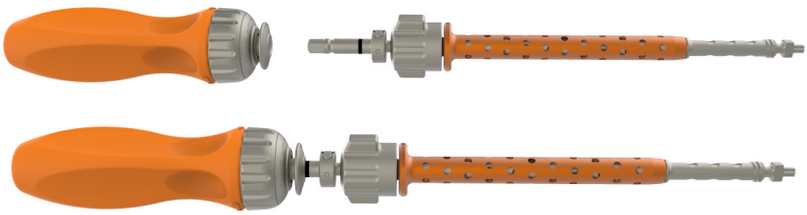


Fig. 2

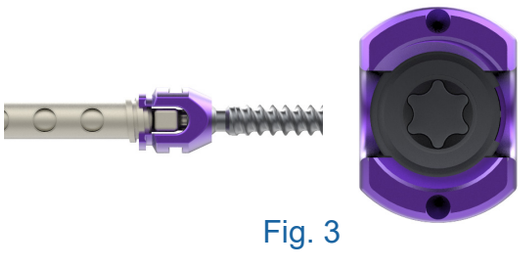


Fig. 3

NOTE: HOLDING THE SCREW SHANK INSTEAD OF THE SCREW TULIP WILL PROVIDE EASY ALIGNMENT OF THE SCREW AND DRIVER.

Step 2 Loading The Screw Driver(Cont.)

- Tighten the screw driver onto the screw by rotating the winged housing clockwise. This will advance the distal feature of the screw driver into the thread pattern of the tulip. Rotate the winged housing until it will no longer advance and is tight (Fig. 4).
- Move the ratcheting handle into the forward position before delivering the screw.

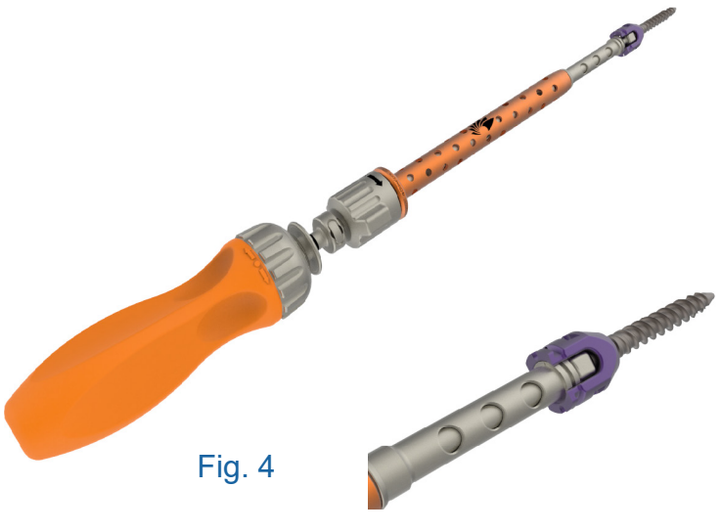


Fig. 4

Step 3 Screw Insertion

- Advance the screw to desired depth. Verify screw position with fluoroscopy (Fig. 5).
- Repeat until all screws are seated to desired depth.
- Rotate the winged housing counterclockwise to disengage it from the screw.

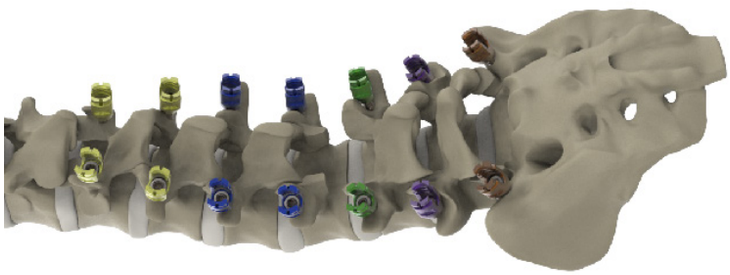


Fig. 5

Step 4 Hook Placement

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

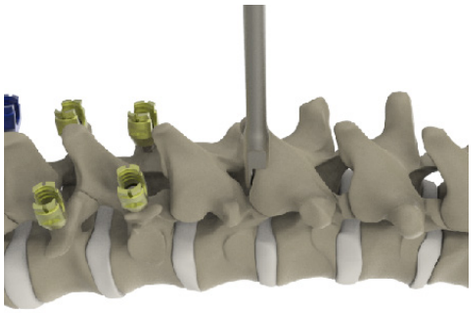


Fig. 6

Step 5 Rod Insertion

- Select the desired rod length to span entire construct. A rod template is available to help determine length and shape.
- A tulip positioner is available to adjust the orientation of the pedicle screw tulips and facilitate alignment.
- Utilize rod holders to place rod into the screw tulips (Fig 8).
- It may be necessary to adjust the curvature of the rod by using the rod benders. In-situ benders are available.
- A rod gripper can be used for further adjustment.

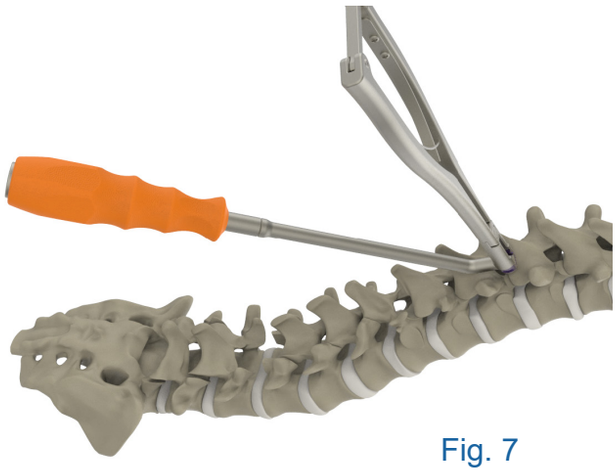


Fig. 7

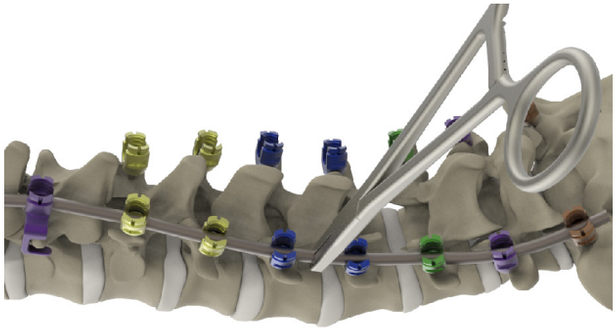


Fig. 8

Step 6 Set Screw Placement

- Load the set screw onto the tip of the set screw starter.
- Confirm that the rod is adequately positioned and that the rod length is adequate.
- Provisionally tighten the set screw (Fig 9).
- Repeat the above step to continue provisionally locking the rods into the screw tulips and/or hooks.
- The rod pusher, rod holder, or rod gripper may be used to hold the rod inside the screw or hook while provisionally tightening each set screw.

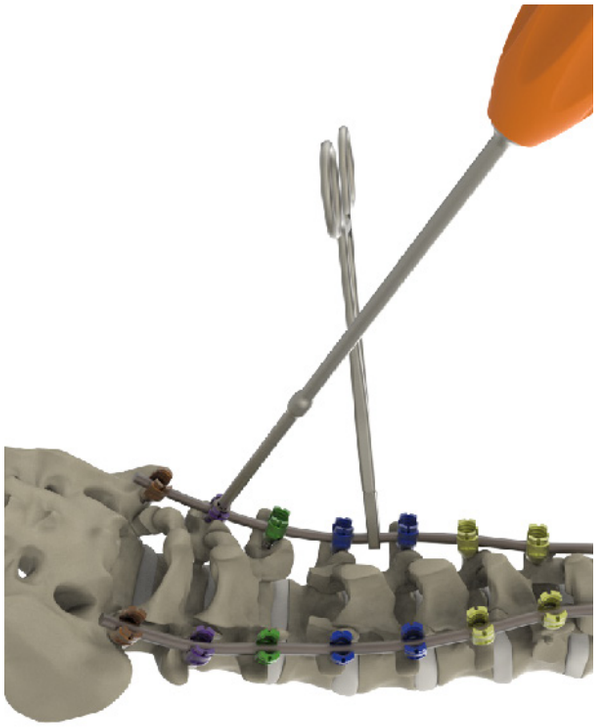


Fig. 9

Step 7 Rod Reduction

- A persuader may be used if additional rod reduction is required.
- To attach the 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 10).
- Proper seating is achieved when the shoulder inside the persuader is at rest on top of the screw tulip as shown (Fig 11).

Fig. 10

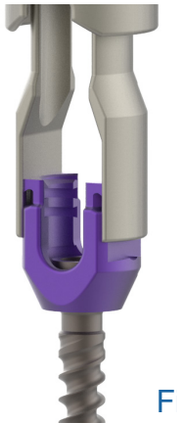


Fig. 11

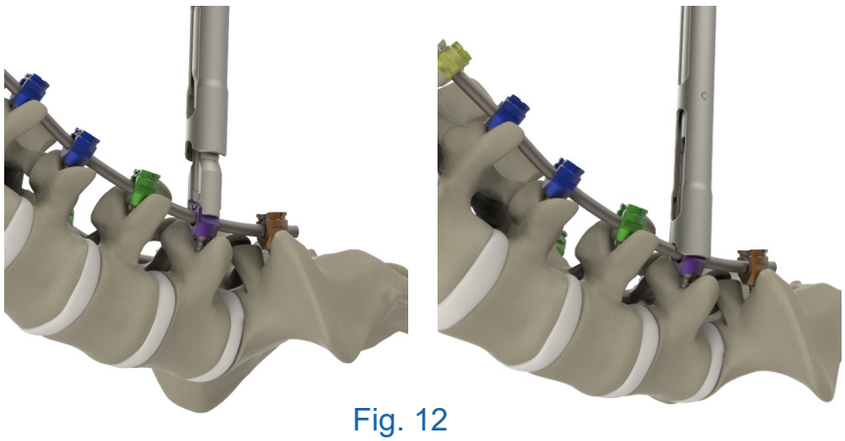


Fig. 12

Step 7 Rod Reduction (cont.)

- Reduce the rod by turning the proximal housing clockwise (Fig 12).
- Use the set screw starter to provisionally lock the set screw through the persuader (Fig 13).
- A rod rocker 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 pocket (Fig. 14).

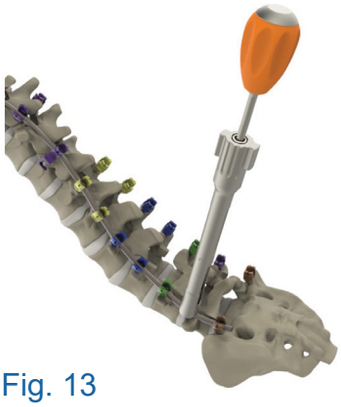


Fig. 13

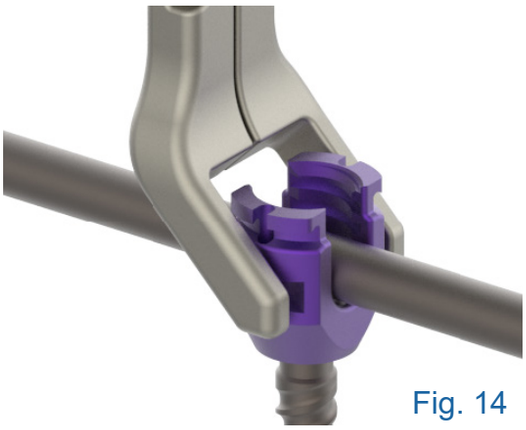


Fig. 14

Step 8 Compression/Distraction

- Utilize the compressor or distractor to achieve the desired level of compression or distraction (Fig 15).
- 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 screw will be provisionally locked to maintain the distracted or compressed position.

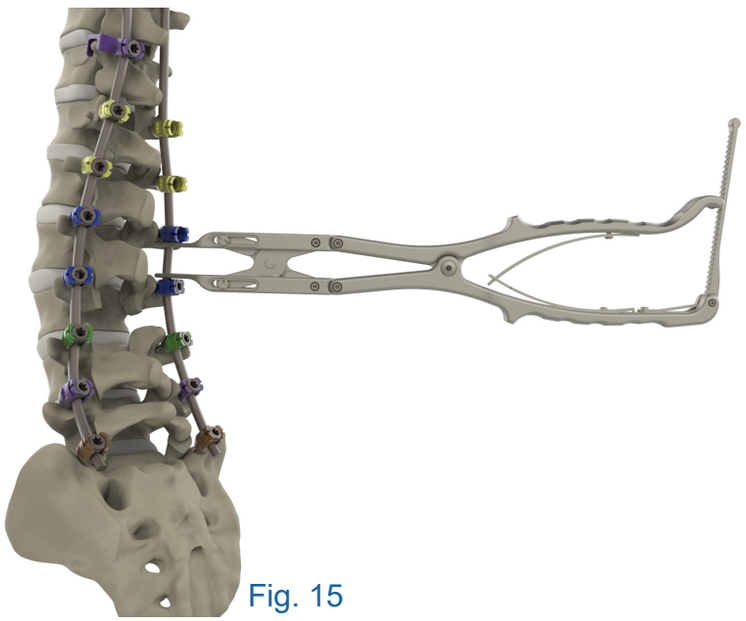


Fig. 15

Step 9 Set Screw Locking

- Final tighten the set screws using the appropriate torque handle and set screw final driver to lock the pedicle screws to 70 in-lb (orange) and the hooks to 100 in-lb (black).
- Position the counter torque over screw tulips or hooks, ensuring it is all the way down against the rod where it exits on both sides (Fig. 16). A separate counter torque is provided for the hooks in the LANCER deformity set (Fig. 17).
- Pass the set screw final driver through the counter torque tube and engage the set screw.
- Rotate the torque handle clockwise until 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”.

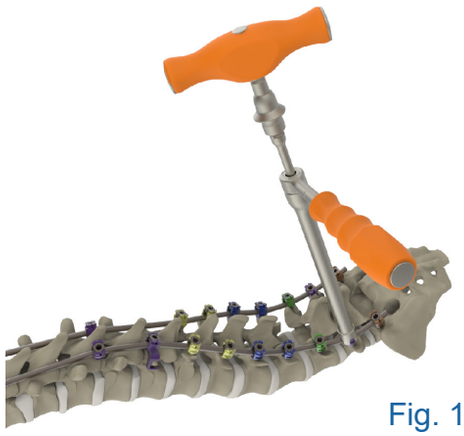


Fig. 16

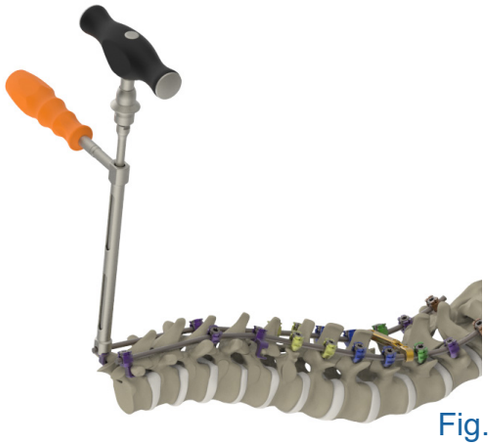
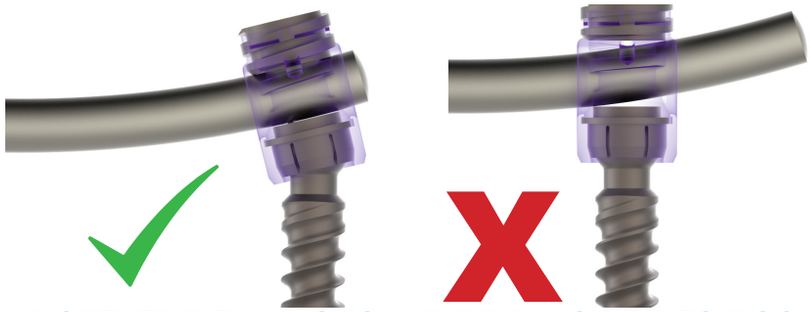


Fig. 17



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

- Multiple connector options are available in the LANCER system: cross-connectors, domino, inline, and lateral offset.

- To use the rod to rod connectors, select the appropriate style and place it on the rods to be joined. 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 connector set screw driver 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 (red) to the connector set screw driver and turning the set screws clockwise until the 40 in-lb torque limit is achieved.

• Use the 2.5mm hex drivers in the LANCER instrument sets for locking the cross-connector (Fig. 18a).

• Use the T20 hexalobe driver in the LANCER deformity set for locking the domino and inline connectors.

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. 18b). 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. 18c).

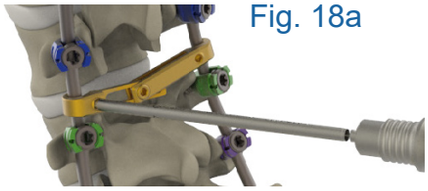


Fig. 18a

Fig. 18b

Lateral Offset Connectors

Lateral offset connectors are available in 20mm, 30mm and 40mm offsets. To utilize the lateral offset connectors, select the appropriate size and place it on the rod and adjacent screw in the Ilium. Use the set screw starter to engage the set screw by turning it clockwise to provisionally secure the lateral offset connector to the adjacent pedicle screw in the ilium. 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 counter torque and 100 in-lb torque handle are provided in the LANCER instrument set 1.

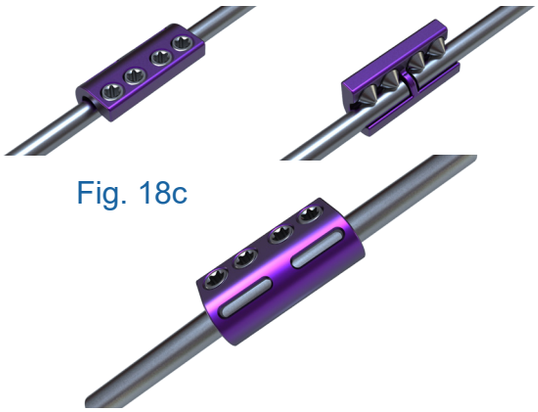


Fig. 18c

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.

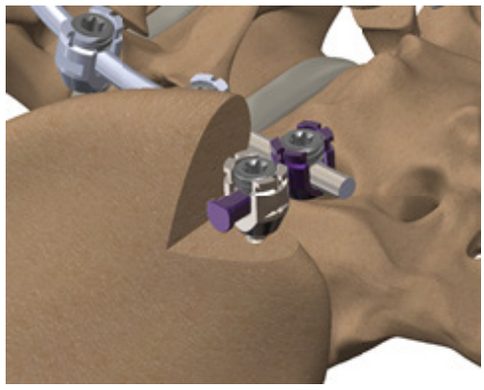


Fig. 19

Removal

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

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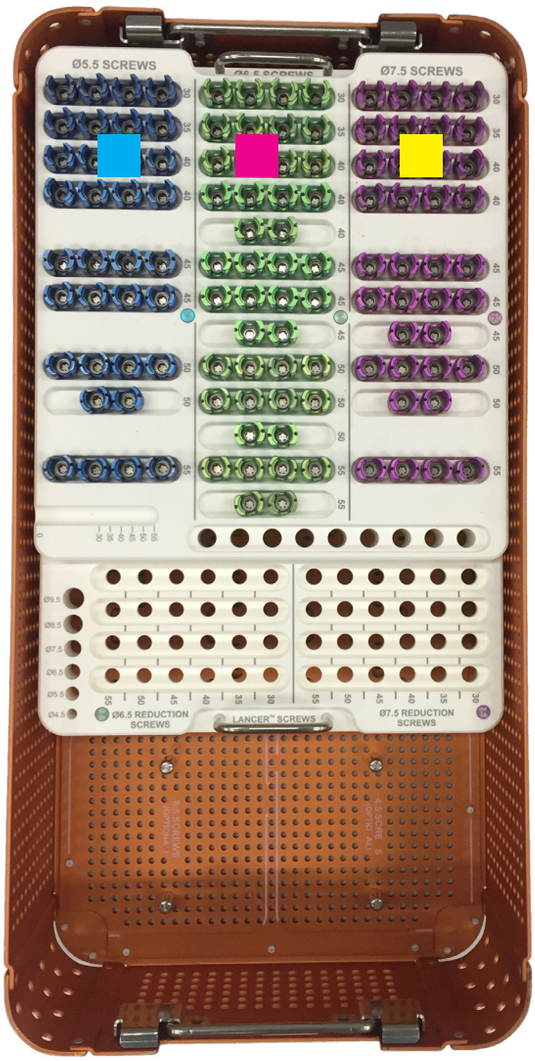
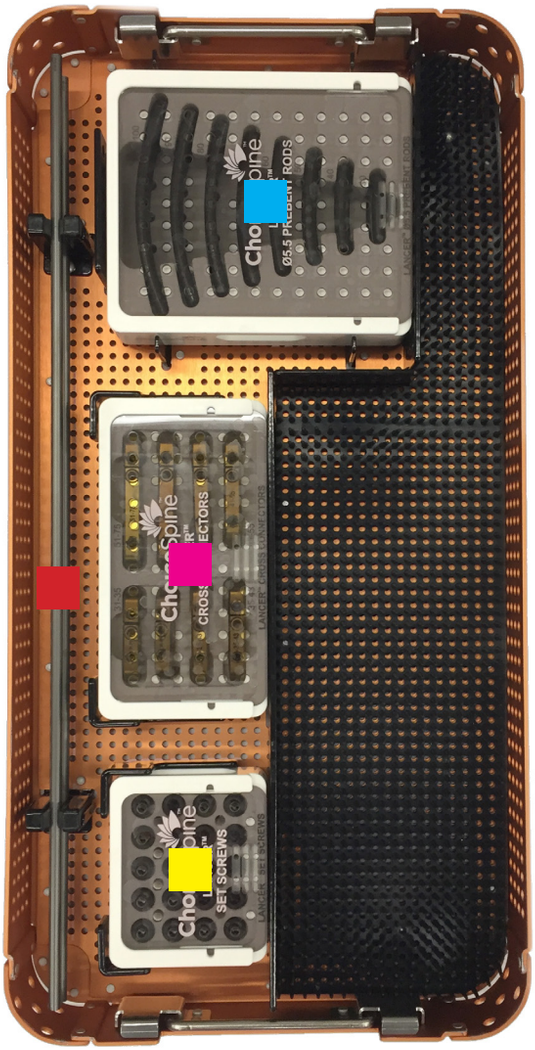
Implant Set

Top Tray



- Ø5.5 Screws
- Ø6.5mm Screws
- Ø7.5mm Screws

Bottom Tray



- Prebent Rods
- Set Screws
- Cross Connectors
- 440mm Straight Rods

Instrument Set 1

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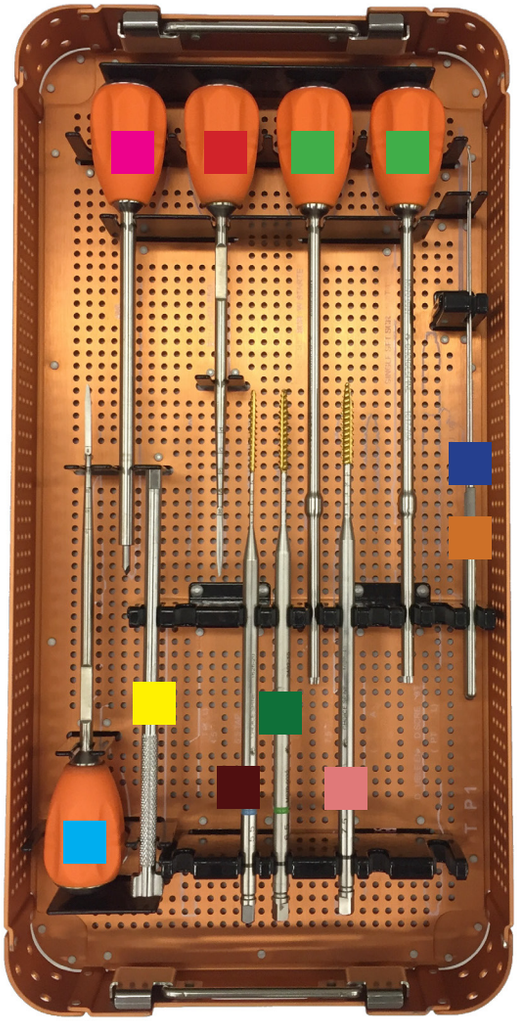
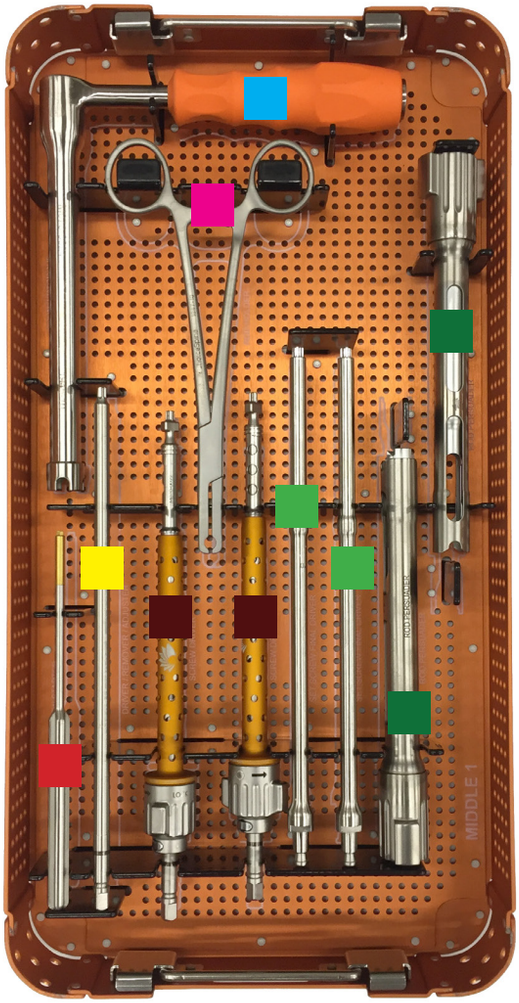
Top Tray



Middle Tray



- Curved Lenke Probe
- Awl
- Tulip Positioner
- Straight Lenke Probe
- Set Screw Starter (2x)
- Curved Feeler
- Straight Feeler
- Ø5.5 Tap
- Ø6.5 Tap
- Ø7.5 Tap
- Countertorque
- Rod Holder
- Driver Remover/Adjuster
- Cross-Connector Set Screw Starter
- Screwdriver (2x)
- Set Screw Final Driver (2x)
- Rod Persuader (2x)

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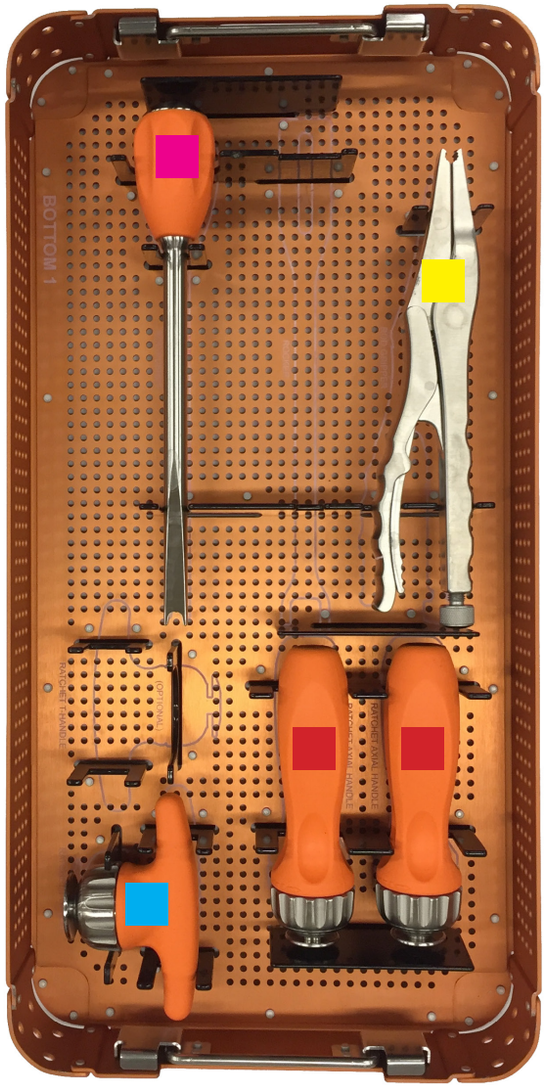
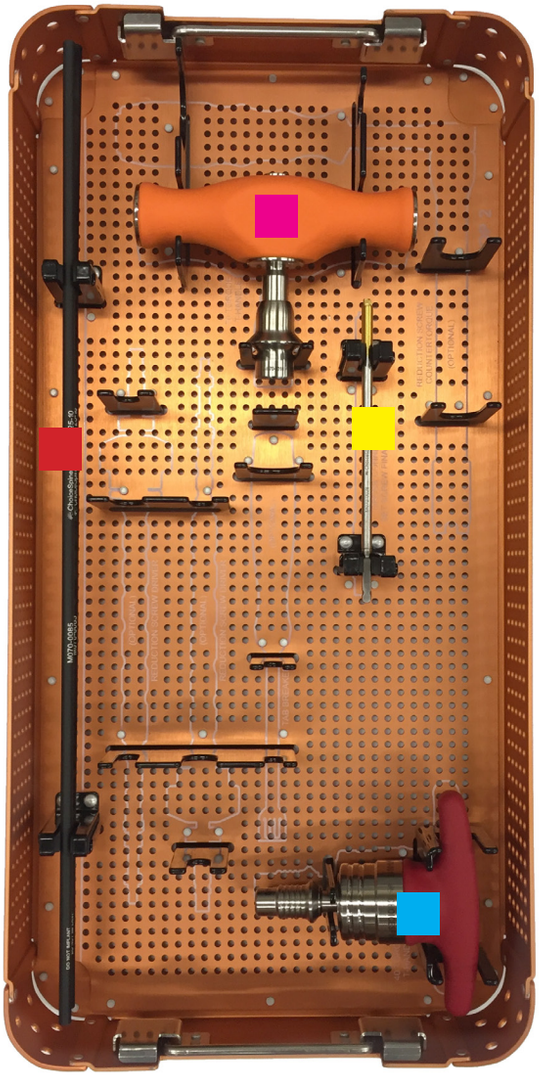
Instrument Set 2

Bottom Tray



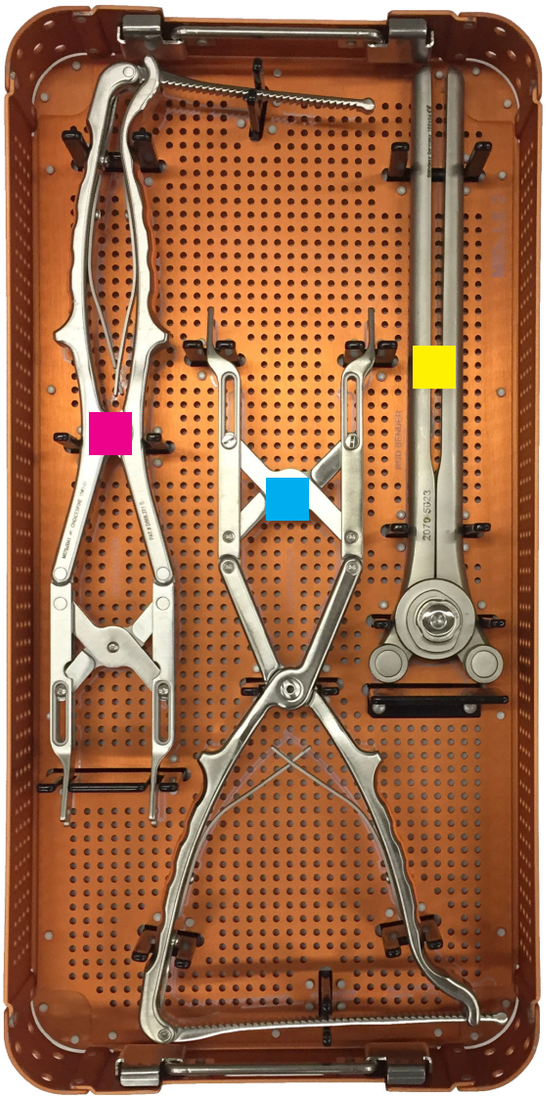
- Ratcheting T-Handle
- Rod Pusher
- Rod Gripper
- Ratcheting Axial Handle (2x)

Top Tray



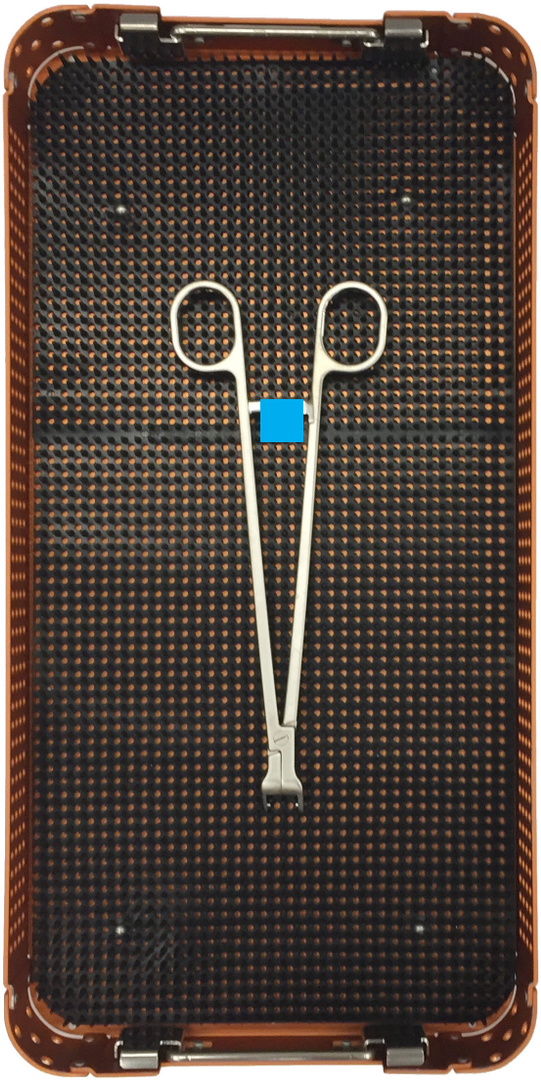
- 40 in-lb Torque Handle
- 70 in-lb Torque T-Handle
- Cross Connector Set Screw Final Driver (2x)
- Rod Template (2x)

Middle Tray



- Compressor
- Distractor
- Rod Bender

Bottom Tray



- Scissor-Style Rod Rocker

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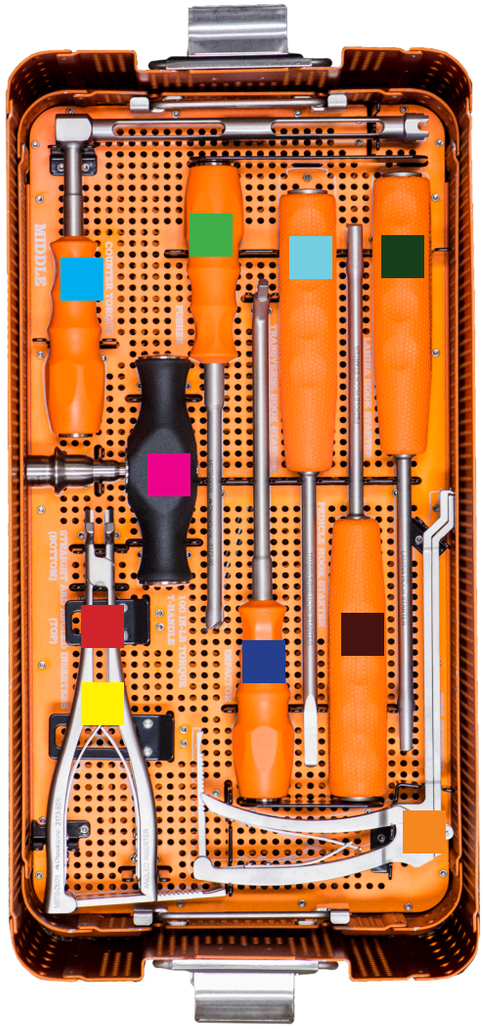
Deformity Set

Top Tray

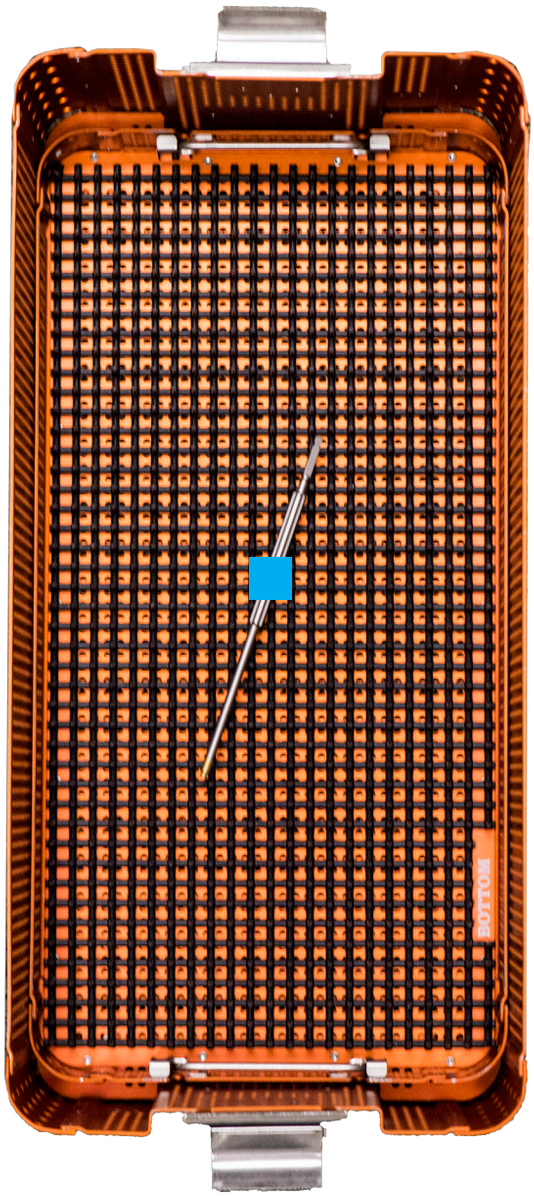
- Lamina Hooks
- Transverse Hooks
- Pedicle Hooks
- L/R Angled Hooks
- L/R Offset Hooks
- Set Screws
- Rod Connectors

Middle Tray



- Countertorque
- 100 in-lb Torque Handle
- Angled Inserter
- Straight Inserter
- Pusher
- Impactor
- Transverse Hook Starter
- Pedicle Hook Starter
- Side Inserter
- Lamina Hook Starter

Bottom Tray



Connector Set Screw Driver

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LANCER Implants

Part Number	Description	QTY
MT30-5530	LANCER Polyaxial Screw 5.5 X 30mm	4
MT30-5535	LANCER Polyaxial Screw 5.5 X 35mm	4
MT30-5540	LANCER Polyaxial Screw 5.5 X 40mm	8
MT30-5545	LANCER Polyaxial Screw 5.5 X 45mm	8
MT30-5550	LANCER Polyaxial Screw 5.5 X 50mm	6
MT30-5555	LANCER Polyaxial Screw 5.5 X 55mm	4
MT30-6530	LANCER Polyaxial Screw 6.5 X 30mm	4
MT30-6535	LANCER Polyaxial Screw 6.5 X 35mm	4
MT30-6540	LANCER Polyaxial Screw 6.5 X 40mm	10
MT30-6545	LANCER Polyaxial Screw 6.5 X 45mm	10
MT30-6550	LANCER Polyaxial Screw 6.5 X 50mm	10
MT30-6555	LANCER Polyaxial Screw 6.5 X 55mm	6
MT30-7530	LANCER Polyaxial Screw 7.5 X 30mm	4
MT30-7535	LANCER Polyaxial Screw 7.5 X 35mm	4
MT30-7540	LANCER Polyaxial Screw 7.5 X 40mm	8
MT30-7545	LANCER Polyaxial Screw 7.5 X 45mm	10
MT30-7550	LANCER Polyaxial Screw 7.5 X 50mm	6
MT30-7555	LANCER Polyaxial Screw 7.5 X 55mm	4
MT40-P030	LANCER Prebent Titanium Rod 5.5 X 30mm	3
MT40-P040	LANCER Prebent Titanium Rod 5.5 X 40mm	3
MT40-P050	LANCER Prebent Titanium Rod 5.5 X 50mm	3
MT40-P060	LANCER Prebent Titanium Rod 5.5 X 60mm	3
MT40-P070	LANCER Prebent Titanium Rod 5.5 X 70mm	3
MT40-P080	LANCER Prebent Titanium Rod 5.5 X 80mm	3
MT40-P090	LANCER Prebent Titanium Rod 5.5 X 90mm	3
MT40-P100	LANCER Prebent Titanium Rod 5.5 X 100mm	3
MT20-0001	LANCER Set Screw	20
MT40-3135	LANCER Cross-Connector 31-35mm	2
MT40-3543	LANCER Cross-Connector 35-43mm	2
MT40-4155	LANCER Cross-Connector 41-55mm	2
MT40-5175	LANCER Cross-Connector 51-75mm	2
MT40-S440	LANCER Straight Titanium Rod 5.5 X 440mm	2

LANCER Instruments

Part Number	Description	QTY
M070-0002	RATCHETING T-HANDLE	1
M070-0003	RATCHETING AXIAL HANDLE	2
M070-0022	SCREW DRIVER	2
M070-0074	TOWER PERSUADER	2
M070-0024	COUNTERTORQUE	1
M070-0026	TULIP POSITIONER	1
M070-0027	CROSS CONNECTOR SET SCREW STARTER	1
M070-0029	SET SCREW FINAL DRIVER	2
M070-0031	5.5 TAP	1
M070-0032	6.5 TAP	1
M070-0033	7.5 TAP	1
M070-0035	DRIVER/REMOVER/ADJUSTER	1
M070-0036	ROD PUSHER	1
M070-0037	SINGLE SET SCREW STARTER	2
M070-0038	ROD GRIPPER	1
M070-0039	ROD HOLDER	1
E070-0026	AWL	1
E070-0027	LENKE STRAIGHT PROBE	1
E070-0028	LENKE CURVED PROBE	1
E070-0051	STRAIGHT FEELER	1
E070-0056	CURVED FEELER	1
M070-0015	40 TORQUE T-HANDLE	1
M070-0016	70 TORQUE T-HANDLE	1
2070-5023	ROD BENDER	1
M070-0028	CROSS CONNECTOR SET SCREW FINAL DRIVER	2
M070-0040	COMPRESSOR	1
M070-0041	DISTRACTOR	1
M070-0043	ROD TEMPLATE	2
M070-0084	SCISSOR-STYLE ROD ROCKER	1

LANCER Deformity Hooks

Part Number	Description	QTY
MT80-LAS60	LAMINA, SMALL	6
MT80-LAM80	LAMINA, MEDIUM	6
MT80-LAL96	LAMINA, LARGE	6
MT80-TRS60	TRANSVERSE, SMALL	6
MT80-TRM80	TRANSVERSE, MEDIUM	6
MT80-TRL96	TRANSVERSE, LARGE	6
MT80-PES52	PEDICLE, SMALL	4
MT80-PEM65	PEDICLE, MEDIUM	4
MT80-PEL75	PEDICLE, LARGE	4
MT80-ALS55	ANGLED, LEFT, SMALL	4
MT80-ALM65	ANGLED, LEFT, MEDIUM	4
MT80-ALL75	ANGLED, LEFT, LARGE	4
MT80-ARS55	ANGLED, RIGHT, SMALL	4
MT80-ARM65	ANGLED, RIGHT, MEDIUM	4
MT80-ARL75	ANGLED, RIGHT, LARGE	4
MT80-DLS60	OFFSET, LEFT, SMALL	4
MT80-DLM80	OFFSET, LEFT, MEDIUM	4
MT80-DLL96	OFFSET, LEFT, LARGE	4
MT80-DRS60	OFFSET, RIGHT, SMALL	4
MT80-DRM80	OFFSET, RIGHT, MEDIUM	4
MT80-DRL96	OFFSET, RIGHT, LARGE	4
MT20-0001	SET SCREW	20

LANCER Deformity Connectors

Part Number	Description	QTY
MT40-DS00	INLINE CONNECTOR	3
MT40-DD10	DOMINO CONNECTOR, 10.5MM OFFSET	2
MT40-DD13	DOMINO CONNECTOR, 13MM OFFSET	2
MT40-DD15	DOMINO CONNECTOR, 15MM OFFSET	2
MT40-DL20	LATERAL OFFSET CONNECTOR, 20MM OFFSET	2
MT40-DL30	LATERAL OFFSET CONNECTOR, 30MM OFFSET	2
MT40-DL40	LATERAL OFFSET CONNECTOR, 40MM OFFSET	2

Lancer Deformity Instruments

Part Number	Description	QTY
M070-D000	100 IN-LB TORQUE HANDLE	1
M070-D001	TRANSVERSE HOOK STARTER	1
M070-D002	LAMINA HOOK STARTER	1
M070-D003	PEDICLE HOOK STARTER	1
M070-D004	SIDE INSERTER	1
M070-D005	ANGLED INSERTER	1
M070-D006	STRAIGHT INSERTER	1
M070-D008	IMPACTOR	1
M070-D009	PUSHER	1
M070-D010	COUNTERTORQUE	1
M070-D011	CONNECTOR SET SCREW DRIVER	1

ChoiceSpine™
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Description:
The Lancer Open 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 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, connectors, hooks, instruments and sterilizer trays.

Indications:
The Lancer Open 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 for posterior, non-cervical pedicle, and non-pedicle fixation The Lancer Open Pedicle Screw System is indicated for the following: 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; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. Overall levels of fixation are T1 to the Sacrum/Ilium. When used for fixation to the ilium, the lateral offset connectors on the Lancer Open Pedicle Screw System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

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
-Use of the Lateral Offset Connectors of the Lancer Open Pedicle Screw System is contraindicated when the Sacrum is absent or insufficient for implantation of Pedicle Screws at the S1 or S2 spinal level.

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 Lancer Open Pedicle Screw System with components from any other manufacturer.
• As with all orthopedic implants, none of the Lancer Pedicle Screw System 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. It's 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 Lancer Open Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. The Lancer Open Pedicle Screw System has not been tested for heating or migration in the MR environment.

Notes

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LIT# Lancer STG
Rev 4
11/17

400 ERIN DRIVE
KNOXVILLE, TN 37919
865.246.3333 *OFFICE* 865.246.3334 *FAX*
WWW.CHOICESPINE.COM