

FACET FIXX® - TL
TransLaminar Screw System

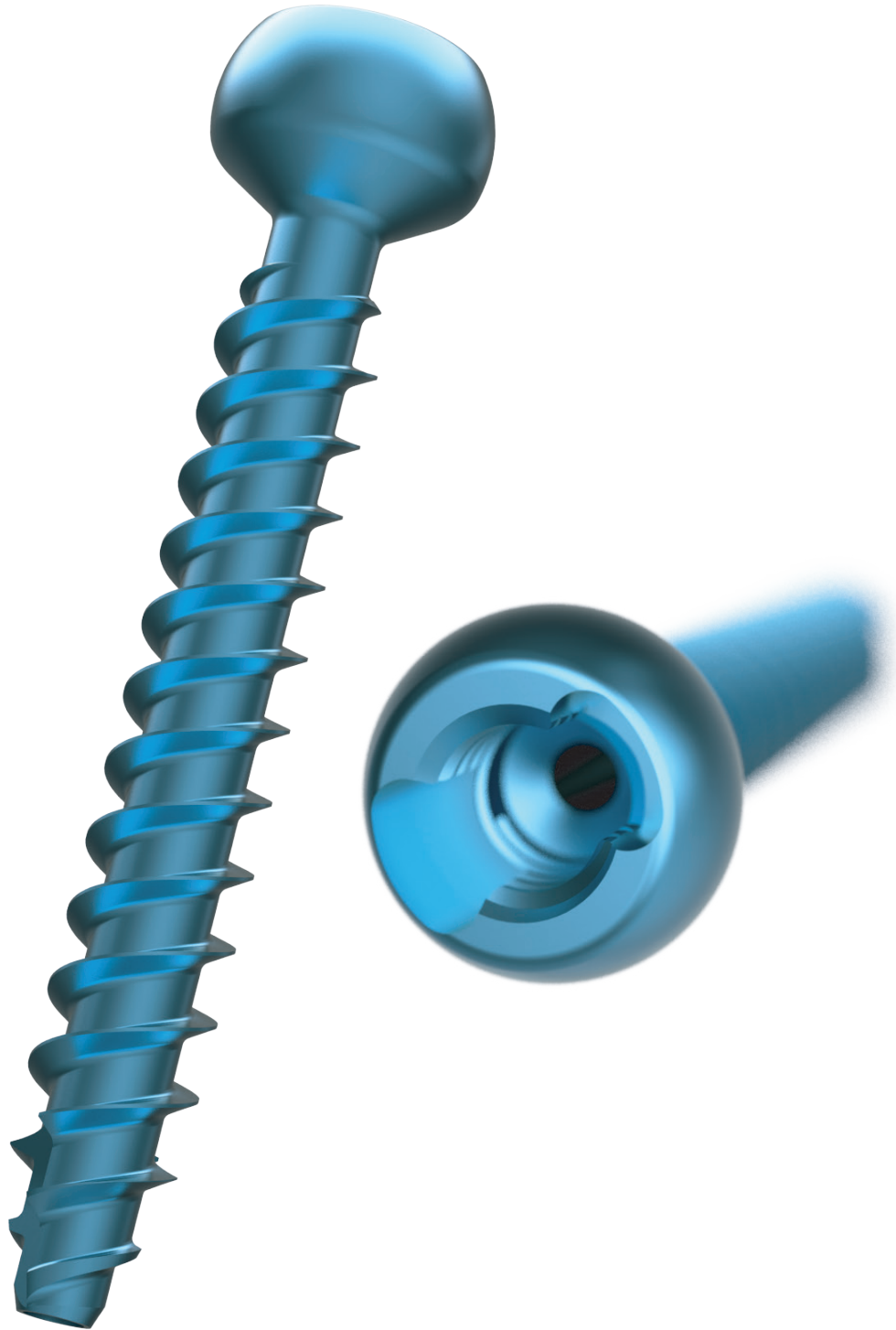


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Caution: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

FACET FIXX® - TL

TransLaminar Screw System

A minimally invasive system designed to reduce damage to adjacent soft tissue while providing sufficient segmental spinal stabilization for select patients.

Trends within the spine market call for less invasive procedures that are simple, reliable and reproducible. Next Spine's Exxpress MIS Technologies are designed to address this growing market demand, while maintaining a focus on streamlined procedural efficiency and positive clinical outcomes.

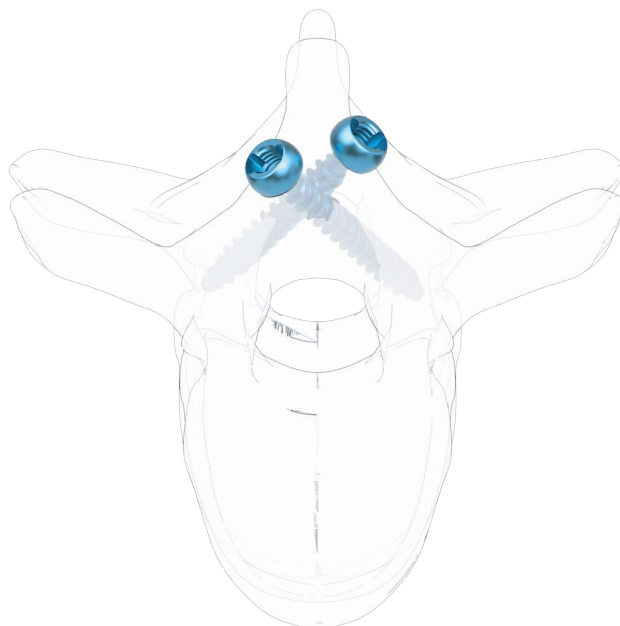
Utilizing intuitive percutaneous over-the-wire methods, Facet Fixx® is a cannulated screw system that represents an exciting addition to the Exxpress MIS portfolio. The system features superior implant control, excellent tactile response during screw implantation, washer serrations to "grip" the bony cortex, and full-thread or lag screw options for transfacet applications.

SUPPLEMENTAL FIXATION

The advanced alternative to pedicle screws, designed by surgeons for surgeons, the Facet Fixx® TransLaminar Screw System provides simplified posterior fixation and an anatomical alignment for a wide range of constructs including:

- TLIF with supplemental posterior Facet Fixx®-TL screw fixation
- tPLIF with supplemental posterior Facet Fixx®-TL screw fixation
- ALIF with supplemental posterior Facet Fixx®-TL screw fixation
- Lateral Interbody Fusion with supplemental posterior Facet Fixx®-TL screw fixation

NOTE: This manual is intended as a guide only. There are multiple techniques for the implantation of spinal fixation systems and, as with any surgical procedure the surgeon should be trained and thoroughly familiar with the implant system components before proceeding.



PREPARATION

1. Patient Positioning

Position the patient on a radiolucent OR table in the prone position (Figure 1).

To obtain optimal visualization of the spine, the OR table should have enough clearance available for a fluoroscopic C-arm to rotate freely for AP, oblique and lateral views.



Figure 1

2. Preoperative Measurement of Lamina Angles

An axial MRI or CT scan is obtained visualizing the lamina of the upper vertebral body of the segment to be fused.

A lamina angle line extending to the skin is drawn and the distance from this line to the midline of the body is measured (Figure 2a).

The measured distance represents the distance of the skin entry point from the midline. In the operating room, the distance lines are drawn on the patient's back as two paravertebral vertical lines (Figure 2b).

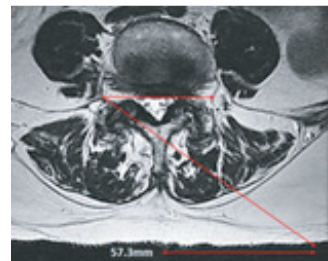


Figure 2a



Figure 2b

3. Intraoperative Measurement of Caudal Angles Instruments

Jamshidi Needle, Sterile, 11G x 150mm

A Jamshidi Needle is placed on the patient's skin under fluoroscopic guidance so that its trajectory is from the pedicle of the upper vertebrae of the motion segment to be fused, passing the cranial one third of the base of the spinous process, to the superior-lateral quadrant of the opposite pedicle of the lower vertebra.

Lines are drawn on the patient's back that correspond with the needle placement. These are the caudal angle lines of the screw trajectory (Figures 3, 4).

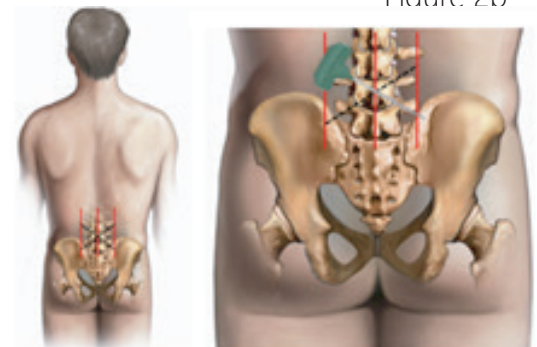


Figure 3

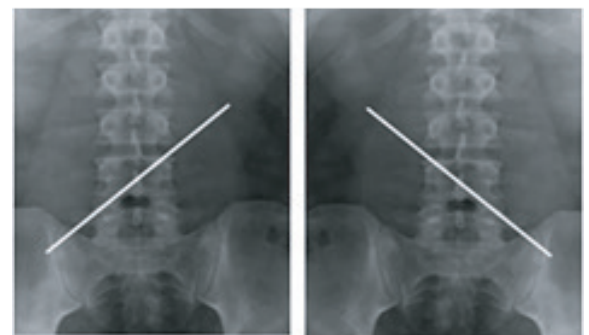


Figure 4

4. Surgical Access & Jamshidi Needle Placement

Instruments

Jamshidi Needle, Sterile, 11G x 150mm

The point of skin entry is at the intersection of the caudal angle line with the paravertebral line representing the distance from the midline of the spine (Figure 5).

A Jamshidi Needle is inserted into the skin through a stab wound at the entry point. The needle is introduced along the laminar angle and caudal angle until the tip of the needle is anchored at the cranial one third of the base of the spinous process (Figure 6).

5. K-wire Insertion

Note: K-wires and Jamshidi Needles are single use instruments.

Instruments

Jamshidi Needle, Sterile, 11G x 150mm

K-wire

Optional:

I10-14-01 K-wire Installer

Remove the stylet and insert the K-wire into the Jamshidi needle (Figure 7). To prevent the K-wire from bending, place Dilator #1 over the wire until it rests against the top of the Jamshidi needle (Figure 8).

Advance the K-wire toward the superior-lateral quadrant of the opposite pedicle of the lower vertebra. Confirm placement with A/P and lateral fluoroscopy.

Once the K-wire is placed to desired depth, carefully remove the Jamshidi Needle while holding the K-wire to ensure that it remains in position.

Warning: Ensure the K-wire remains securely in position throughout the entire duration of the procedure.

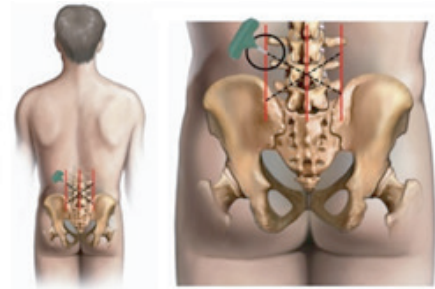


Figure 5



Figure 6



Figure 7



Figure 8

6a. Initial Dilation (Option A)

Instruments

I14-14-11 #1 Dilation Tube, Stainless

I14-16-01 Facet DTS Guide

I14-16-02 Facet DTS Guide Dilator 2

With the K-wire placed, extend the skin incision and facial incisions to 15mm for placement of the DTS Guide.

Assemble the DTS Guide by placing Dilation Tube #1 inside DTS Guide Shaft (Figure 9).

Insert Dilation Tube #1 over the K-wire and advance until the dilator is docked on the cranial one third of the base of the spinous process.

Advance DTS Guide over Dilator #1 until the dilator is docked on the cranial one third of the base of the spinous process (Figure 10).

Once DTS Guide (containing Dilator #2) is in position, remove Dilation Tube #1, leaving the K-wire and the DTS Guide in position docked against the cranial one third of the base of the spinous process (Figure 11).

The working DTS Guide is now in place and is a clear working channel to drill and tap (optional) the lamina.

Warning: To prevent inadvertent advancement of the K-wire while inserting the Dilation Tubes, monitor the K-wire position using fluoroscopy.

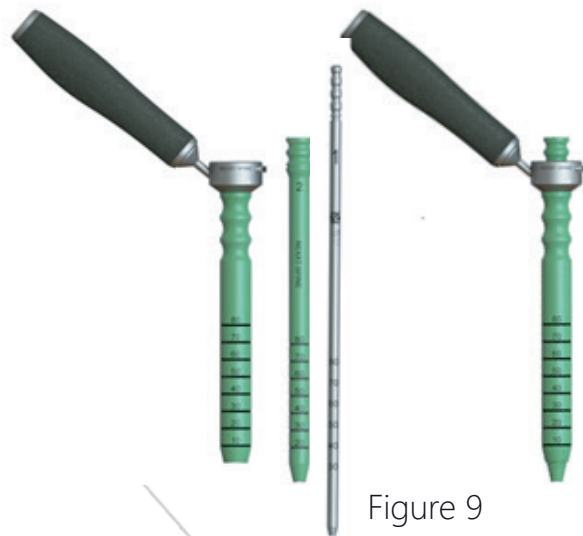


Figure 9

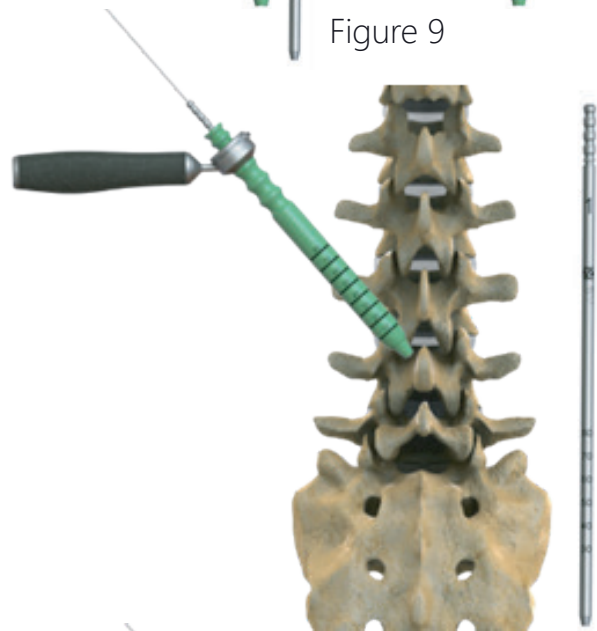


Figure 10

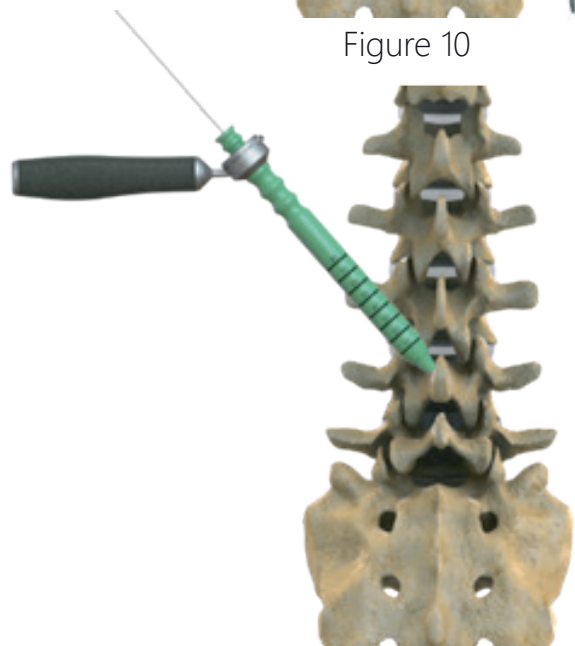


Figure 11

6b. Initial Dilation (Option B)

Instruments

I14-14-11 #1 Dilation Tube, Stainless

I14-14-12 #2 Dilation Tube

I14-14-13 #3 Dilation Tube

With the K-wire placed, extend the skin incision and facial incisions to 15mm for placement of Dilation Tubes #1 & #2.

Insert Dilation Tube #1 over the K-wire and advance until the dilator is docked on the cranial one third of the base of the spinous process (Figure 12).

Insert Dilation Tube #2 over the K-wire and Dilation Tube #1 (Figure 13).

Once both dilators are in position on the base of the spinous process, remove Dilation Tube #1, leaving the K-wire and Dilator #2 in position (Figure 14).

The working cannula (Dilation Tube #2) is now placed and is a clear working channel to drill and tap (optional) the lamina.

Warning: To prevent inadvertent advancement of the K-wire while inserting the Dilation Tubes, monitor the K-wire position using fluoroscopy.



Figure 12



Figure 13



Figure 14

7. Drilling

Note: Drilling can also be performed under power.

Instruments

I10-01-28 Axial Handle, Ratchet Cannulated

I14-03-02 Cannulated Drill

Securely attach the Ratcheting Handle to the Cannulated Drill (Figure 15). Pass the Cannulated Drill over the K-wire and through DTS Guide (Figure 16a) (or Dilation Tube #2 (Figure 16b)).

Utilize fluoroscopy to ensure the K-wire does not advance while simultaneously drilling to the desired depth.

Select appropriate screw length according to the depth measurement on the drill. Confirm screw length with fluoroscopy (Figure 17).

Warning:

- DTS Guide or Dilation Tube #2 must be fully seated against base of spinous process for accurate depth.
- To prevent inadvertent advancement of the K-wire, align the trajectory of the drill with the K-wire and monitor the K-wire position using fluoroscopy.



Figure 15

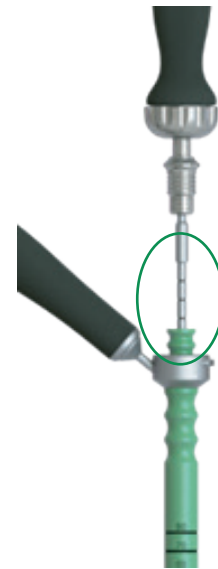


Figure 17



Figure 16a



Figure 16b

8. Tapping (Optional)

Note: The Facet Fixx® Screw is Self-Tapping.

Instruments

I10-01-28 Axial Handle, Ratchet Cannulated

I14-15-45 4.5mm Cannulated Tap

Securely attach the Ratcheting Handle to the Cannulated Tap (Figure 17). Pass the Tap through DTS Guide (Figure 18a) (or Dilation Tube #2 (Figure 18b)).

Utilize fluoroscopy to ensure the K-wire does not advance while simultaneously tapping to the desired depth. Tapping must be performed by hand.

Select appropriate screw length according to the depth measurement on the tap. Confirm screw length with fluoroscopy (Figure 19).

Warning:

- To prevent inadvertent advancement of the K-wire, align the trajectory of the tap with the K-wire and monitor the K-wire position using fluoroscopy.
- DTS Guide (or Dilation Tube #2) must be fully seated against base of spinous process for accurate depth measurement with the tap.



Figure 17



Figure 18a



Figure 18b



Figure 19

9. Facet Screw Insertion

Instruments

I10-01-28 Axial Handle, Ratchet Cannulated

I14-01-01 Facet Screw Inserter

Securely attach the ratcheting handle to the Facet Screw Inserter (Figure 20).

Attach the desired implant to the screw driver by placing the bi-lobe tip of the screw driver into the head of the facet screw (Figure 21). Visually confirm axial alignment of screw shaft and driver shaft before threading draw rod into the screw head by turning knurled knob on driver shaft clockwise until tight.

Remove Dilation Tube #2 by pressing release button and pulling up and out of DTS Guide.

Insert the screw through DTS Guide (or Dilation Tube #3) to the starting point at the base of the spinous process. Advance screw while confirming depth fluoroscopically. Insert the screw until the screw head is against the base of the spinous process and threads are tight within the bone.

Warning: To prevent inadvertent advancement of the K-wire, align the trajectory of the facet screw and screw driver with the K-wire and monitor the K-wire position using fluoroscopy.

10. Facet Screw Height Adjustment (Optional)

Note: If the facet screw is being placed under direct visualization and a K-wire is not utilized, the in-situ screw adjuster can be used to retain the screw to the driver during screw insertion.

Instruments

I14-02-01 In-Situ Adjuster

Optional Adjustment Method:

I10-01-28 Ratchet Cannulated

I14-01-01 Facet Screw Inserter

Utilize the in-situ screw adjuster to adjust the height of the screws as needed (Figure 22).

This driver is cannulated and may be used over a K-wire (Figure 23).

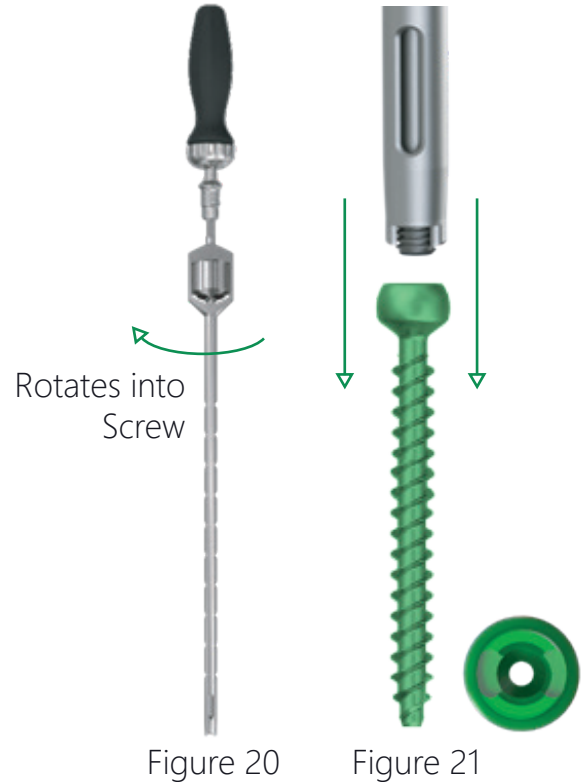


Figure 22



Figure 23

11. Facet Screw Placement

Repeat steps for bilateral facet screw placement (Figures 24 and 25).

12. Removal

Instruments

I10-01-28 Axial Handle, Ratchet Cannulated

I14-01-01 Facet Screw Inserter

Optional:

I14-02-01 In-Situ Adjuster

Securely attach the ratcheting handle to the screw inserter (Figure 26). Place the bi-lobe tip of the screw driver into the head of the facet screw. Visually confirm axial alignment of screw shaft and driver shaft before threading draw rod into the screw head by turning knurled knob on driver shaft clockwise until tight.

Turn the screw driver counter clockwise until the entire screw is removed (Figure 27).

In the event the screw inserter cannot be reattached to the facet screw, the in-situ screw adjuster can be used for screw removal (Figure 28).

13. Closure

Wound closure is performed in the customary manner (Figure 29).

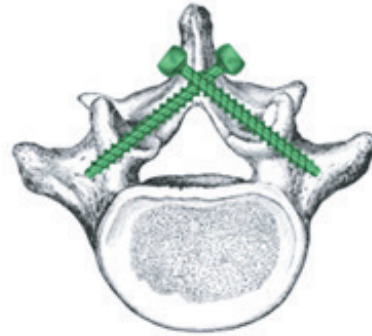


Figure 24



Figure 25



Figure 26

Figure 28

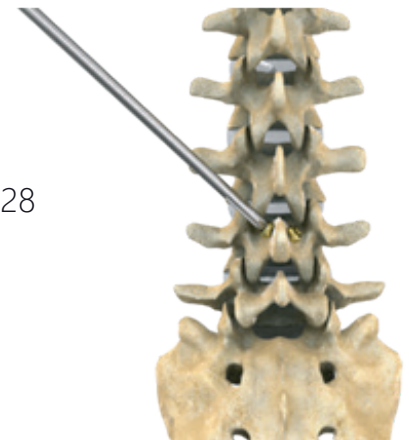


Figure 27



Figure 29

FACET FIXX® - TL INSTRUMENTS

MIS WIRES

- 110-14-192** Inertia, MIS, K-Wire, 1.4mm x 480mm
- 110-14-194*** Inertia, MIS, K-Wire, Nitinol, Threaded Trocar Tip, Rounded End, Long
- 110-14-191*** Inertia, MIS, K-Wire, 1.4mm x 480mm, Threaded Trocar Tip, Rounded End
- 110-14-193*** Inertia, MIS, K-Wire, 1.4mm x 480mm, Threaded Blunt Tip, Nitinol
- 110-14-195*** Inertia, MIS, K-Wire, Nitinol, Threaded Blunt Tip, Long
- 110-14-291*** Inertia, MIS, K-Wire, Stainless Steel, 1.4mm x 480mm, Threaded Trocar Tip, Rounded End
- 110-14-292*** Inertia, MIS, K-Wire, Stainless Steel, 1.4mm x 480mm
- 110-14-293*** Inertia, MIS, K-Wire, 1.4mmX480mm, Threaded Blunt Tip, SST
- 110-14-294*** Inertia, MIS, K-Wire, Stainless Steel, Threaded Trocar Tip, Rounded End, Long
- 110-14-295*** Inertia, MIS, K-Wire, Stainless Steel, Threaded Blunt Tip, Long



RAN-1115N
Jamshidi Needle, Sterile,
11 Ga x 150mm,
Trocar Tip



110-14-01
K-Wire Installer



114-14-11
Facet Fixx, #1 Dilation
Tube, Stainless



114-16-01
Facet Fixx, Facet DTS
Guide



114-16-02
Facet Fixx, Facet DTS
Guide, Dilator #2



114-14-12
Facet Fixx, #2 Dilation
Tube



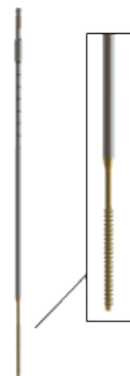
114-14-13
Facet Fixx, #3 Dilation
Tube



110-01-28
Handle, Axial, Ratchet
Cannulated



114-03-02
Facet Fixx, Cannulated Drill,
AO, 3.0 x 60mm



114-15-45
Facet Fixx,
Cannulated Tap, AO,
4.5 x 60mm



114-01-01
Facet Fixx,
Screw Inserter

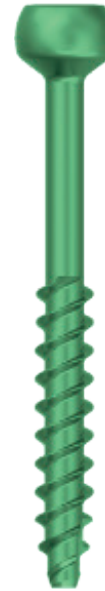


114-02-01
Facet Fixx,
In-Situ Driver

***Optional instruments available by request.**

FACET FIXX® - TransLaminar Cannulated Screws

Partially Threaded		Screw Color
14-09-4535	4.5 x 35mm	Green
14-09-4540	4.5 x 40mm	Light Blue
14-09-4543	4.5 x 42.5mm	Dark Blue
14-09-4545	4.5 x 45mm	Gold
14-09-4548	4.5 x 47.5mm	Seafoam
14-09-4550	4.5 x 50mm	Magenta
14-09-4555	4.5 x 55mm	Blue
14-09-4560	4.5 x 60mm	Teal
<hr/>		
14-09-5035	5.0 x 35mm	Green
14-09-5040	5.0 x 40mm	Light Blue
14-09-5043	5.0 x 42.5mm	Dark Blue
14-09-5045	5.0 x 45mm	Gold
14-09-5048	5.0 x 47.5mm	Seafoam
14-09-5050	5.0 x 50mm	Magenta
14-09-5055	5.0 x 55mm	Blue
14-09-5060	5.0 x 60mm	Teal



Fully Threaded		Screw Color
14-12-4535	4.5 x 35mm	Green
14-12-4540	4.5 x 40mm	Light Blue
14-12-4543	4.5 x 42.5mm	Dark Blue
14-12-4545	4.5 x 45mm	Gold
14-12-4548	4.5 x 47.5mm	Seafoam
14-12-4550	4.5 x 50mm	Magenta
14-12-4555	4.5 x 55mm	Blue
14-12-4560	4.5 x 60mm	Teal
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14-12-5035	5.0 x 35mm	Green
14-12-5040	5.0 x 40mm	Light Blue
14-12-5043	5.0 x 42.5mm	Dark Blue
14-12-5045	5.0 x 45mm	Gold
14-12-5048	5.0 x 47.5mm	Seafoam
14-12-5050	5.0 x 50mm	Magenta
14-12-5055	5.0 x 55mm	Blue
14-12-5060	5.0 x 60mm	Teal



**Fully Threaded (Lag) Screws are a standard inventory item.
Partially Threaded Screws are available by Special Request.**



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71-016, Rev. C