

FACET FIXX[®] - TF
TransFacet 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® - TF

TransFacet 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.

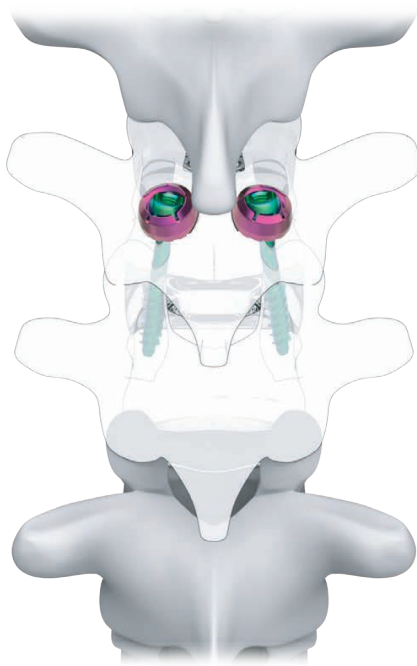
Utilizing intuitive percutaneous over-the-wire methods, Facet Fixx® is a cannulated screw system that represents an exciting addition to the Exxpress MIS portfolio. The system features superior implant control, excellent tactile response during screw implantation, washer serrations to grip the bony cortex, 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® TransFacet Screw System provides simplified posterior fixation and an anatomical alignment for a wide range of constructs including:

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

Accurate visualization of anatomic landmarks and fluoroscopic visualization of the facet joints is imperative for using the Facet Fixx® System.



Figure 1

2. Approach

Anatomical Landmarks

The following must be identified prior to initial incision:

- Starting Point on the Facet
- Entry Point on the Patient's Skin
- Trajectory of the Facet Screw

Starting Point on the Facet

Using A/P and lateral views, locate the starting point on the facet. This point is located at the transition of the pars interarticularis and inferior articular process (Figure 2). The entry point should be in-line with the inferior endplate of the superior vertebral body.

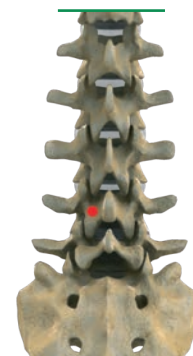


Figure 2

Entry Point on the Skin

The entry point on the skin is where the access needle is inserted and is usually located at the spinous process 1 or 2 levels above the targeted level (Figure 3).

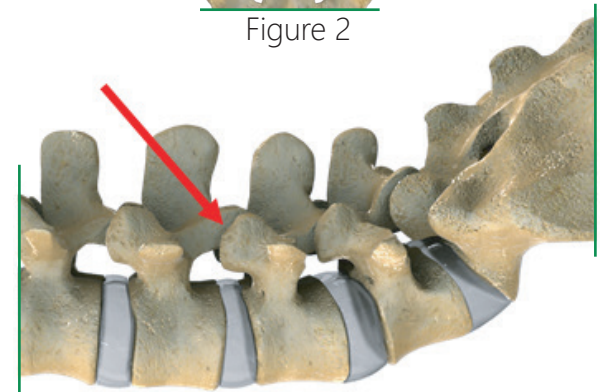


Figure 3

Trajectory of the Facet Screw

Determine the trajectory of the facet screw by locating the entry point on the patient's skin and the starting point on the facet through the inferior pedicle (Figure 4).

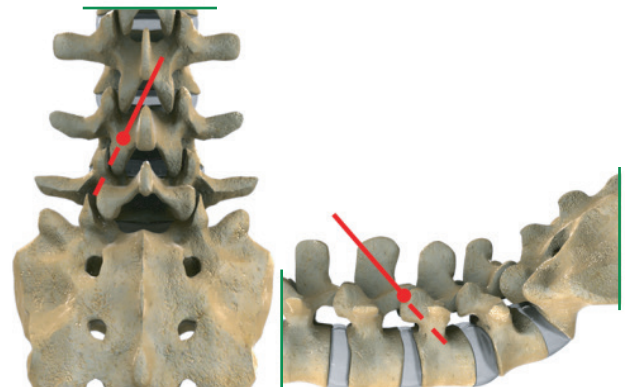


Figure 4

3. Targeting Anatomy Instruments

K-Wire

Use AP and Lateral fluoroscopy to target the appropriate spinal level, the start point on the facet, the trajectory of the implant, and the entry point on the skin.

The AP view should be adjusted to the lordosis of the level being treated (Figure 5). Place the C-arm so the inferior end plate of the superior level being treated appears as a single line.

Using a K-wire or similar tool, locate the midline of the spine, the inferior endplate of the superior vertebral body being treated (B), and a line connecting the medial borders of the pedicles of the levels above and below the level being treated (C) (Figure 6).

The intersection of these two lines represents the docking point for the Jamshidi Needle.

Switching to a lateral view, determine the trajectory of the access needle. This will help determine the entry point through the skin (Figure 7).

The entry point is usually a level or two above the level being treated. The trajectory should go through the superior and inferior facet, and continue through the center of the pedicle into the vertebral body (Figure 8).

Once you have determined the docking point on the facet on the lateral trajectory, a midline entry point can be established.

On the AP view, mark the point on the midline where a line from the medial half of the pedicle through the docking point on the facet intersects midline with the same line from the opposite side (Figure 9).

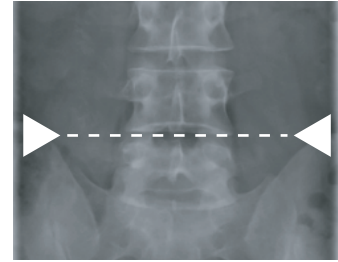


Figure 5

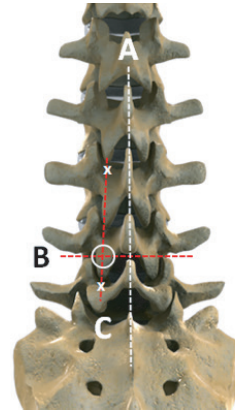


Figure 6

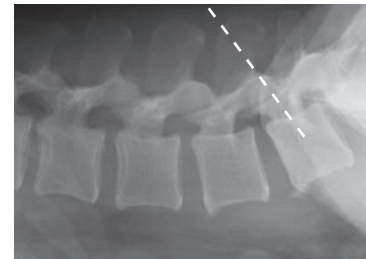


Figure 7



Figure 8

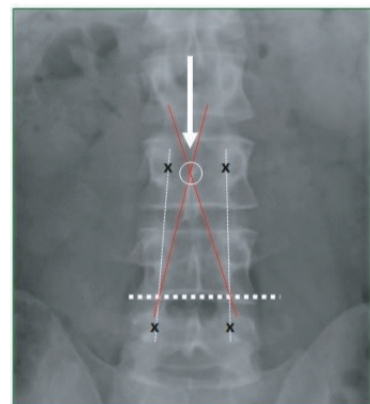


Figure 9

4. Surgical Access & Jamshidi Needle Placement Instruments

Jamshidi Needle, Sterile, 11G x 150mm

Once the entry point is determined, introduce the Jamshidi Needle through a small midline stab incision. The trajectory of the implant will be medial to lateral at approximately 10° (Figure 10).

Utilize fluoroscopy to confirm precise placement of the Jamshidi Needle (Figure 11).

Once precise placement is confirmed, tap the Jamshidi Needle into the cortex of the superior facet (Figure 12).

5. K-wire Insertion Instruments

Jamshidi Needle, Sterile, 11G x 150mm

K-wire

Optional:

I10-14-01 K-wire Installer

At this point the Jamshidi Needle can be carefully advanced through the superior facet and into the inferior facet. Remove the inner stylet of the Jamshidi needle and insert K-wire (Figures 13a, 13b).

The K-wire can be driven manually with the K-wire Installer or under the assistance of a power driver. Drive the K-wire across the facet joint and through the center of the pedicle into the posterior third of the inferior vertebral body (Figure 14).

Advancement of the K-wire should be accompanied by a series of fluoroscopy images to ensure the wire does not change trajectory as it is passed across the facet joint and into the pedicle. Once the K-wire is placed, remove the access needle (Figure 15).

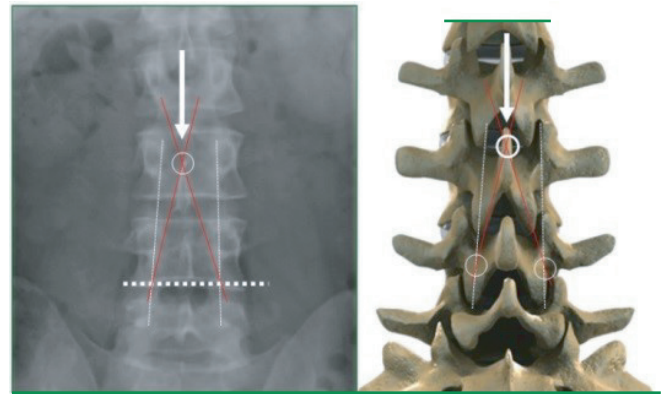


Figure 10

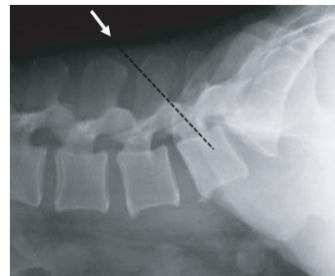


Figure 11

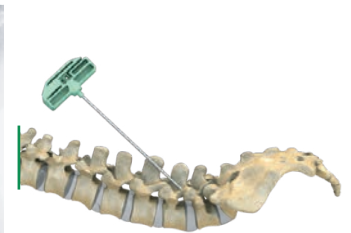


Figure 12

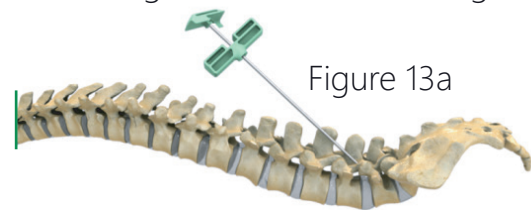


Figure 13a

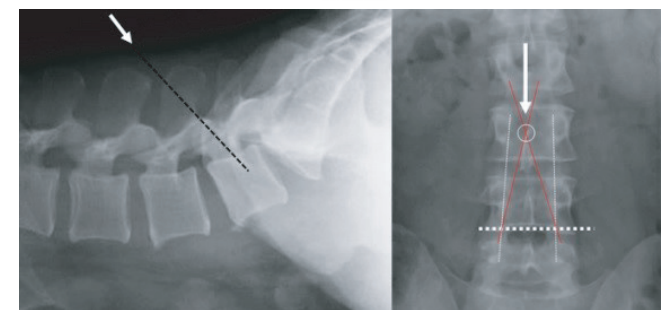


Figure 13b



Figure 14

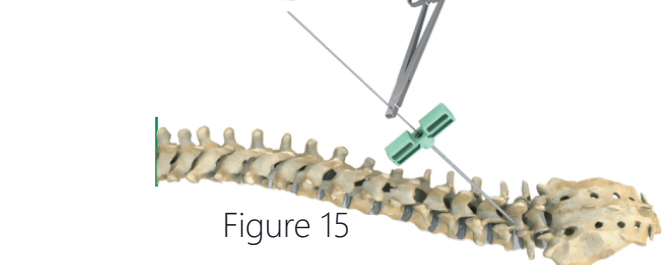


Figure 15

6a. Initial Dilatation (Option A)

Instruments

I14-14-11 #1 Dilatation Tube, Stainless

I14-16-01 Facet DTS Guide

I14-16-02 Facet DTS Guide Dilatation Tube #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 Dilatation Tube #2 inside DTS Guide (Figure 16).

Insert Dilatation Tube #1 over the K-wire and advance until the dilator is docked on the facet.

Advance DTS Guide over Dilator #1 until the dilator is docked on the facet (Figure 17).

Once DTS Guide containing Dilator #2 is in position, remove Dilatation Tube #1, leaving the K-wire and the DTS Guide in position docked against the facet (Figure 18).

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

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



Figure 16

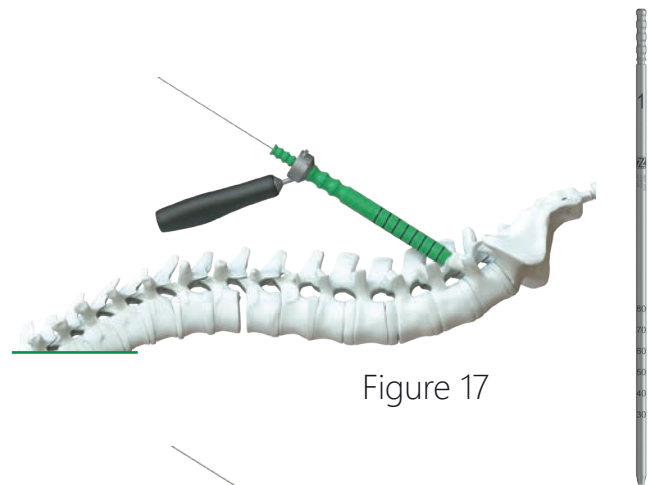


Figure 17

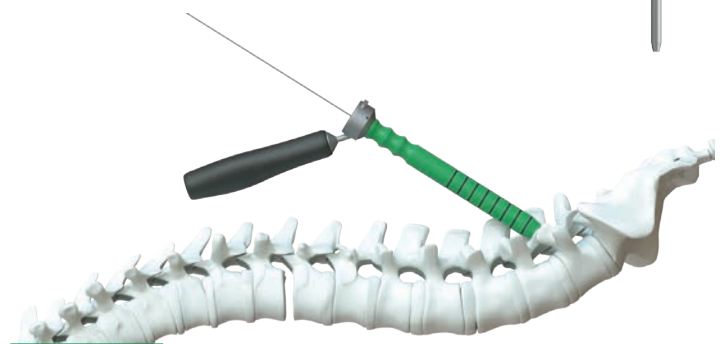


Figure 18

6b. Initial Dilation (Option B)

Instruments

I14-14-11 #1 Dilation Tube, Stainless

I14-14-12 #2 Dilation Tube, Radel

I14-14-13 #3 Dilation Tube, Radel

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 facet (Figure 19).

Insert Dilation Tube #2 over the K-wire and Dilation Tube #1 (Figure 20).

Once both dilators are in position on the surface of the facet, remove Dilation Tube #1, leaving the K-wire and Dilator #2 in position (Figure 21).

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

Dilation Tube #3 is inserted after drilling and tapping prior to screw placement (see page 10).

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



Figure 19

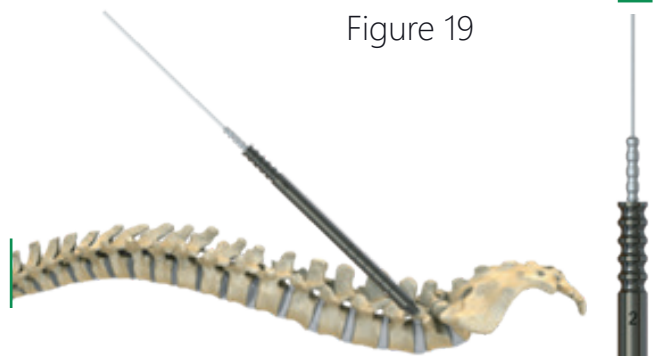


Figure 20

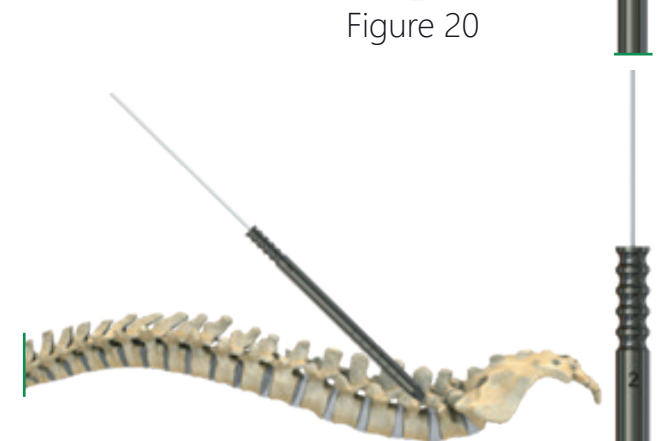


Figure 21

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 22). Pass the Cannulated Drill over the K-wire and through DTS Guide (Figure 23a) (or Dilation Tube #2 (Figure 23b)).

Utilizing fluoroscopy to ensure the K-wire does not advance; simultaneously drill to the desired depth.

Select appropriate screw length according to the depth measurement on the drill. Confirm screw length with fluoroscopy (Figure 24).

Warning:

-Dilation Tube #2 must be fully seated against facet for accurate depth measurement with drill.

-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 22



Figure 24

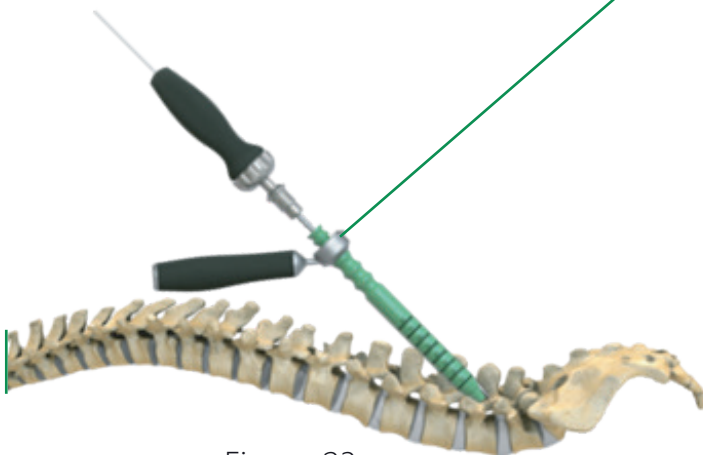


Figure 23a



Figure 23b

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 25). Pass the Cannulated Tap over the K-wire and through DTS Guide (Figure 26a) (or Dilation Tube #2 (Figure 26b)).

Utilizing fluoroscopy to ensure the K-wire does not advance; simultaneously tap 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 27).

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.
- Cannulated Guide must be fully seated against facet for accurate depth measurement with the tap.

9. Dilation (Option B only)

Instruments

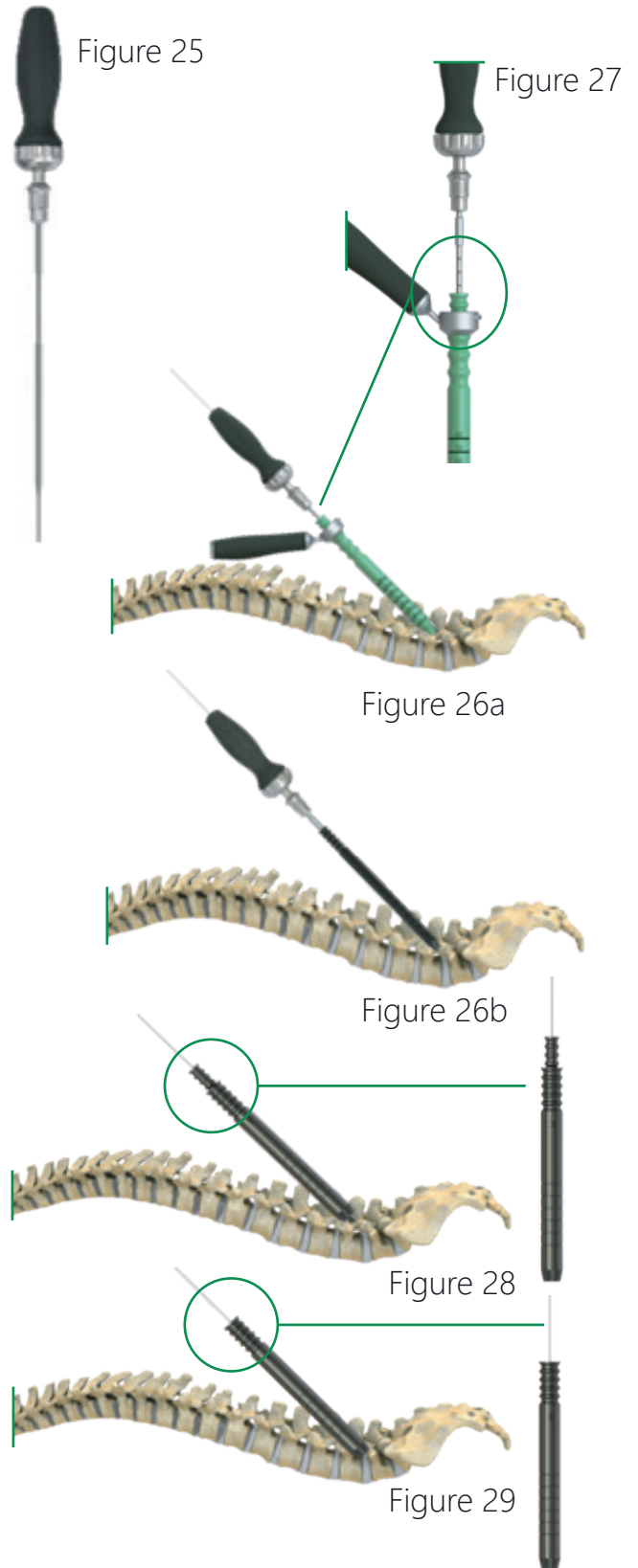
I14-14-13 Dilation Tube #3

Once drilling is complete, insert Dilation Tube #3 over Dilation Tube #2 (Figure 28).

Once Dilation Tube #3 is in position, remove Dilation Tubes #2, leaving the K-wire and Dilation Tube #3 in position (Figure 29).

Warning:

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



10. 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 Driver (Figure 30).

Attach the desired implant to the screw driver by placing the bi-lobe tip (Figure 31) 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.

If utilizing DTS Guide, remove Dilation Tube #2 by pressing release button and pulling up and out on tube.

Insert the screw and screw driver over the K-wire and through DTS Guide (or Dilation Tube #3) and then into the bone. Confirm screw depth fluoroscopically. Insert the screw until the screw head and washer are against the inferior articular process and threads are tight within the bone.

The K-wire can be removed once the screw is secure within the desired anatomy.

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.

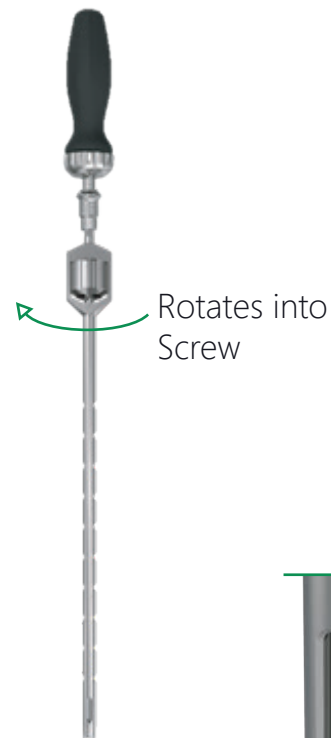


Figure 30



Figure 31

11. Facet Screw Height Adjustment (Optional)

Instruments

I10-01-28 Axial Handle, Ratchet Cannulated

I14-02-01 In-Situ Adjuster

Optional:

I14-01-01 Facet Screw Inserter

Utilize the in-situ screw adjuster to adjust the height of the screws as needed (Figure 32).

This driver is cannulated and may be used over a K-wire (Figure 33).

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.

12. Facet Screw Placement

Repeat steps for bilateral facet screw placement (Figure 34).



Figure 32



Figure 33



Figure 34

13. 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 35). 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 (Figure 36).

Turn the screw driver counter clockwise until the entire screw is removed.

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 37).

14. Closure

Wound closure is performed in the customary manner (Figure 38).



Figure 36



Figure 35

Figure 37



Figure 38

FACET FIXX® - TF INSTRUMENTS

MIS WIRES

- I10-14-192** Inertia, MIS, K-Wire, 1.4mm x 480mm
- I10-14-194*** Inertia, MIS, K-Wire, Nitinol, Threaded Trocar Tip, Rounded End, Long
- I10-14-191*** Inertia, MIS, K-Wire, 1.4mm x 480mm, Threaded Trocar Tip, Rounded End
- I10-14-193*** Inertia, MIS, K-Wire, 1.4mm x 480mm, Threaded Blunt Tip, Nitinol
- I10-14-195*** Inertia, MIS, K-Wire, Nitinol, Threaded Blunt Tip, Long
- I10-14-291*** Inertia, MIS, K-Wire, Stainless Steel, 1.4mm x 480mm, Threaded Trocar Tip, Rounded End
- I10-14-292*** Inertia, MIS, K-Wire, Stainless Steel, 1.4mm x 480mm
- I10-14-293*** Inertia, MIS, K-Wire, 1.4mmX480mm, Threaded Blunt Tip, SST
- I10-14-294*** Inertia, MIS, K-Wire, Stainless Steel, Threaded Trocar Tip, Rounded End, Long
- I10-14-295*** Inertia, MIS, K-Wire, Stainless Steel, Threaded Blunt Tip, Long



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



I10-14-01
K-Wire Installer



I14-14-11
Facet Fixx, #1 Dilation
Tube, Stainless



I14-16-01
Facet Fixx, Facet DTS
Guide



I14-16-02
Facet Fixx, Facet DTS
Guide, Dilator #2



I14-14-12
Facet Fixx, #2 Dilation
Tube



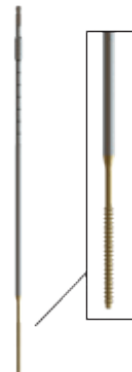
I14-14-13
Facet Fixx, #3 Dilation
Tube



I10-01-28
Handle, Axial, Ratchet
Cannulated



I14-03-02
Facet Fixx, Cannulated Drill,
AO, 3.0 x 60mm



I14-15-45
Facet Fixx,
Cannulated Tap, AO,
4.5 x 60mm



I14-01-01
Facet Fixx,
Screw Inserter

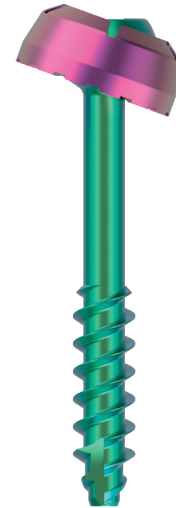


I14-02-01
Facet Fixx,
In-Situ Driver

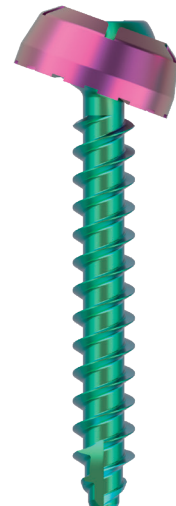
Optional instruments available by request.

FACET FIXX® - TransFacet Cannulated Screws

Partially Threaded		Screw Color	Washer Color
14-10-4525	4.5 x 25mm	Dark Blue	
14-10-4528	4.5 x 27.5mm	Magenta	
14-10-4530	4.5 x 30mm	Bronze	
14-10-4533	4.5 x 32.5mm	Teal	
14-10-4535	4.5 x 35mm	Green	Magenta
14-10-4540	4.5 x 40mm	Light Blue	
14-10-4545	4.5 x 45mm	Gold	
14-10-4550	4.5 x 50mm	Magenta	
<hr/>			
14-10-5025	5.0 x 25mm	Dark Blue	
14-10-5028	5.0 x 27.5mm	Magenta	
14-10-5030	5.0 x 30mm	Bronze	
14-10-5033	5.0 x 32.5mm	Teal	Green
14-10-5035	5.0 x 35mm	Green	
14-10-5040	5.0 x 40mm	Light Blue	
14-10-5045	5.0 x 45mm	Gold	
14-10-5050	5.0 x 50mm	Magenta	



Fully Threaded		Screw Color	Washer Color
14-11-4525	4.5 x 25mm	Dark Blue	
14-11-4528	4.5 x 27.5mm	Magenta	
14-11-4530	4.5 x 30mm	Bronze	
14-11-4533	4.5 x 32.5mm	Teal	
14-11-4535	4.5 x 35mm	Green	Magenta
14-11-4540	4.5 x 40mm	Light Blue	
14-11-4545	4.5 x 45mm	Gold	
14-11-4550	4.5 x 50mm	Magenta	
<hr/>			
14-11-5025	5.0 x 25mm	Dark Blue	
14-11-5028	5.0 x 27.5mm	Magenta	
14-11-5030	5.0 x 30mm	Bronze	
14-11-5033	5.0 x 32.5mm	Teal	Green
14-11-5035	5.0 x 35mm	Green	
14-11-5040	5.0 x 40mm	Light Blue	
14-11-5045	5.0 x 45mm	Gold	
14-11-5050	5.0 x 50mm	Magenta	



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



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71-015, Rev. D