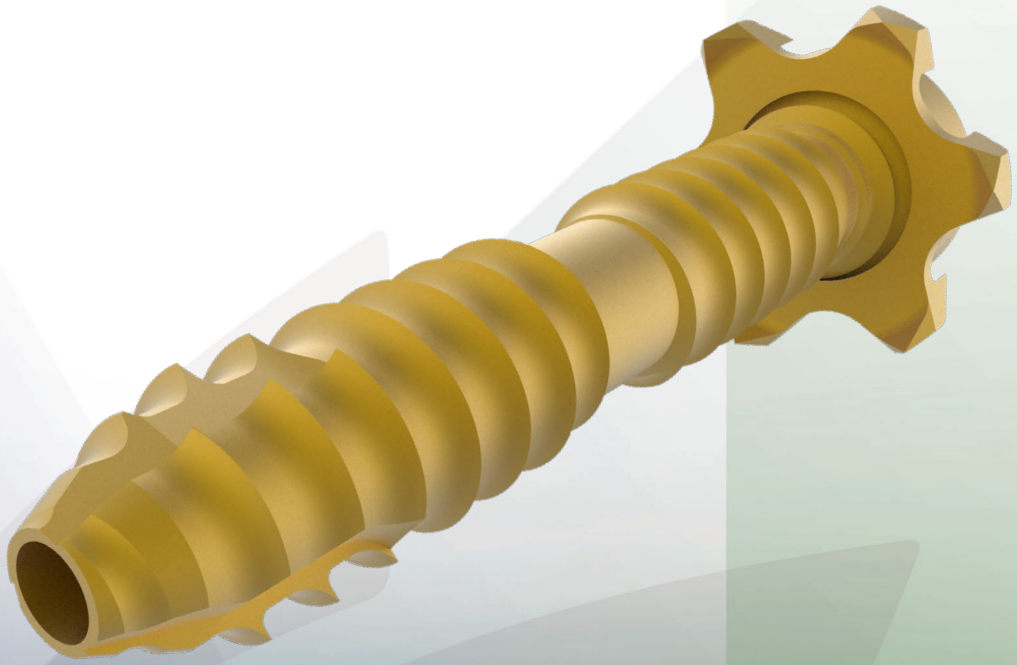
ChoiceSpine™
Propelling Spinal Surgery



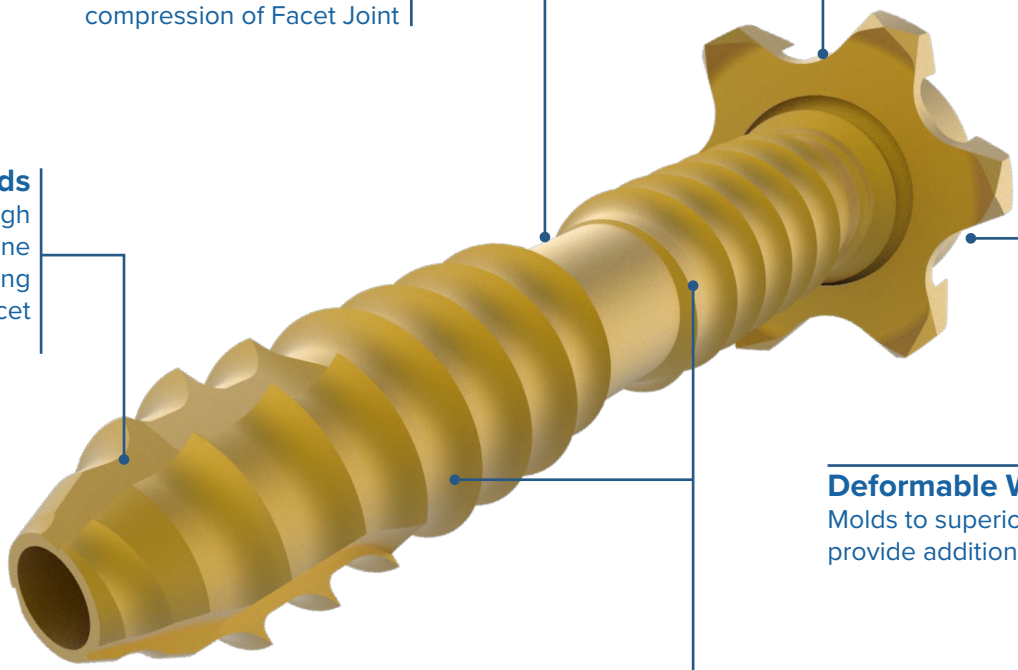
# TYPHOON™ Surgical Technique

## Facet Screw System

**Screw Head**
Fixation into cortical bone of superior facet

**Lag Section**
Designed to facilitate compression of Facet Joint

**Sharp Threads**
Easily advances through three Cortical bone interfaces while minimizing damage to superior Facet



**Deformable Washer**
Molds to superior Facet Joint to provide additional fixation

**Dual Pitch Screw Thread**
Maximizes purchase & compression of Facet Joint

**Developed in Cooperation with**
**William O. Reed, Jr., MD, MBA**
**Leawood, KS**

## Step 1 Determination of Skin Incision Location

Identify and target the appropriate level(s) using fluoroscopy.
Using fluoroscopy, determine precise location of skin incision(s).

## Step 2 Awl

After the Facet entry point has been determined (Fig 1), an Awl is used to penetrate the Cortex of the superior Facet.

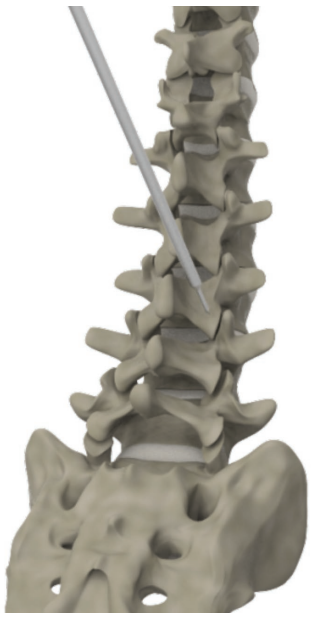


Figure 1

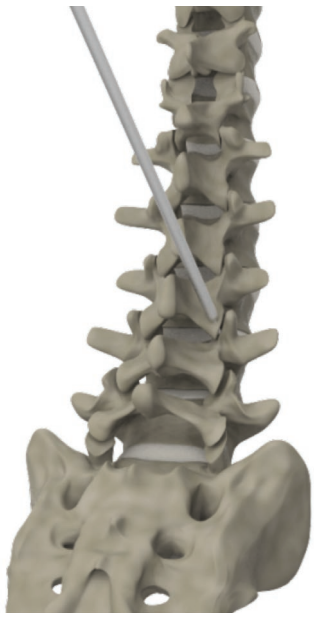


Figure 2

Place the Awl tip on the desired entry point of the Facet Joint (Fig 2). Make sure the angle of the entry hole is the approximate desired angle and is positioned to access the superior and inferior Facet of the joint, aiming for the Pedicle. The Impacting Cap can be placed over the proximal end of the Awl to assist in penetrating the Cortex of the superior Facet.

Figure 3

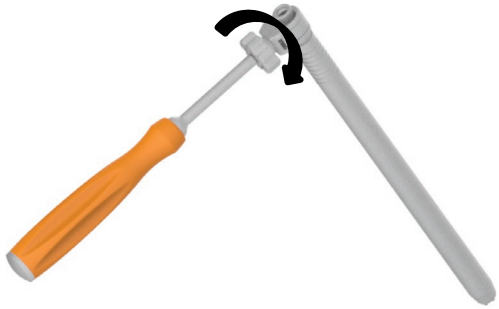


Figure 4

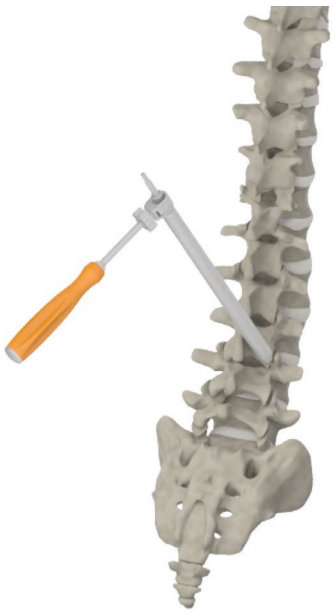


Figure 5

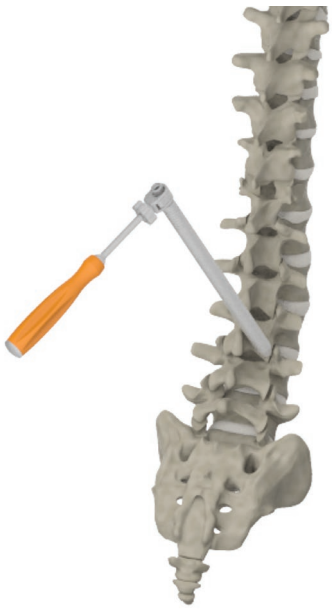


Figure 6

## Step 4 Drill

Set the desired depth of the Drill using the Adjustable Depth Stop. Depth is labeled on all drills on the proximal shaft. To change the length on an Adjustable Drill, depress the button on the stop & relocate the stop to the appropriate distance.

**The number closest to the proximal end of the Stop is the depth (Fig 7).**


Figure 7

Load a Ratchet Handle to the Drill. Drill to desired depth (Fig 8). Depth can be verified using fluoroscopy.

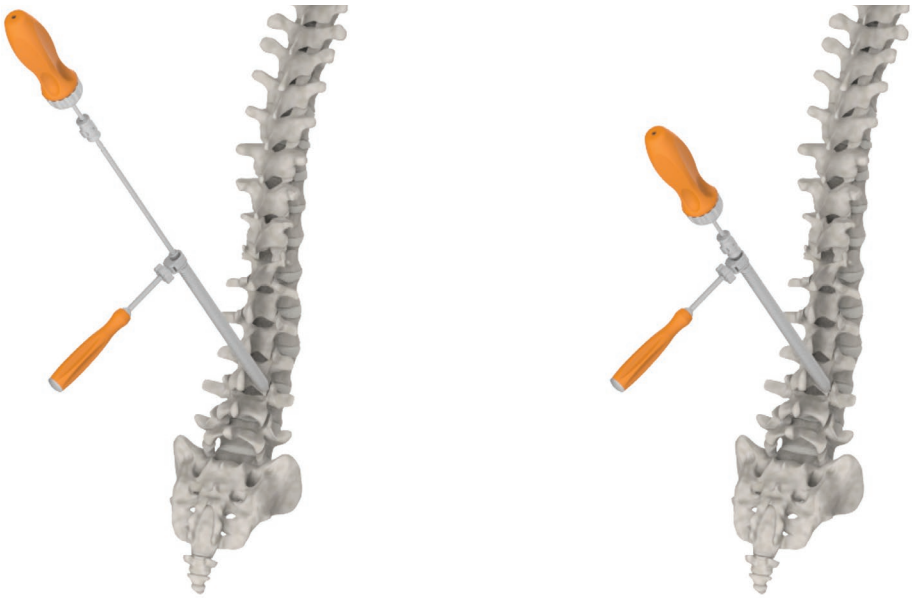


Figure 8

The color on the Drills matches the color of the Screws.

## Step 5 Guide Wire Placement

Remove the Drill while keeping the DT Guide/Dilator in place (Fig 9).

**Note:**
**Use caution not to change position of the DT Guide/Dilator when removing the Drill & inserting the Guide Wire.**

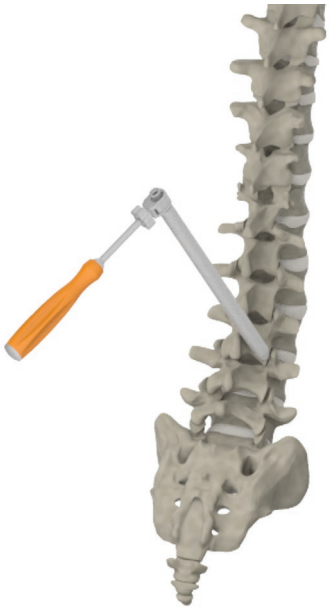


Figure 9

Insert the Guide Wire through the DT Guide/Dilator (Fig 10). Advance through the drilled hole until the Guide Wire penetrates bone. Verify Guide Wire depth with fluoroscopy.

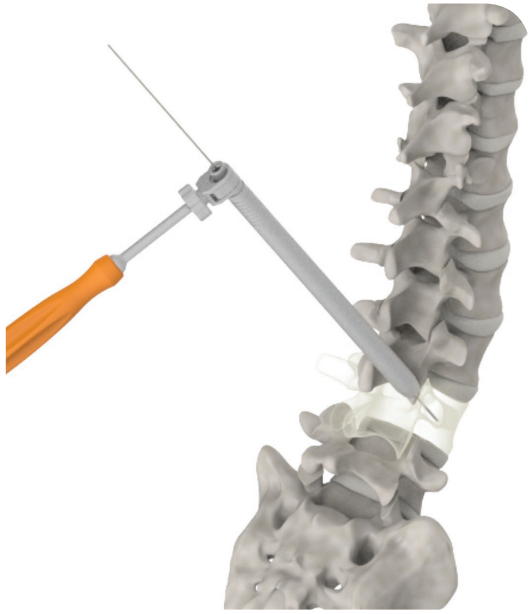


Figure 10

## Step 6 Tap

Set the desired depth of the Tap using the Adjustable Depth Stop. Depth is labeled on all Taps on the proximal shaft. To change the length on an Adjustable Tap, depress the button on the Stop & relocate the Stop to the appropriate distance.

**The number closest to the proximal end of the Stop is the depth.**

Load a Ratchet Handle to the Tap. Tap to desired depth. Depth can be verified using fluoroscopy (Fig 11).

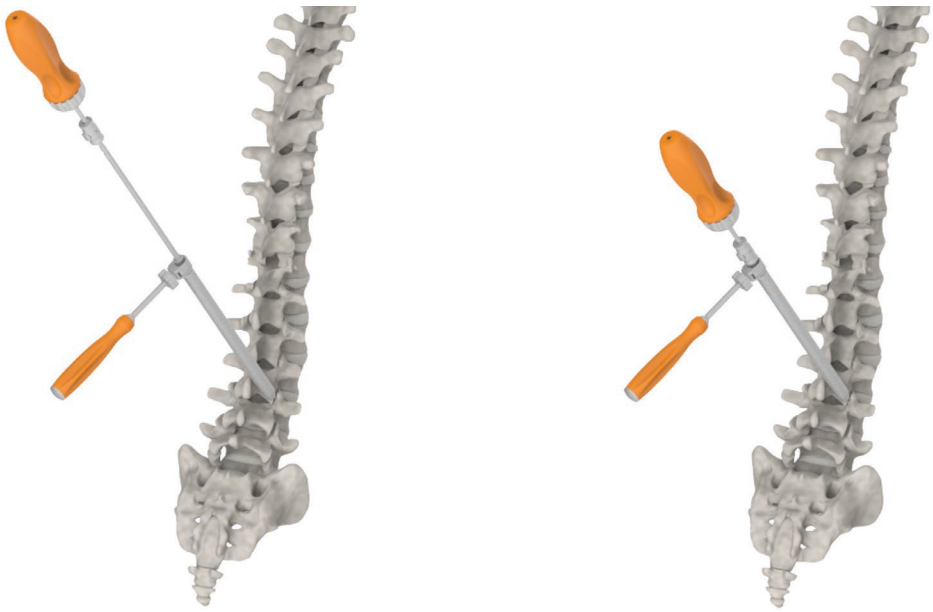


Figure 11

The color on the Taps matches the color of the Screws.

**DO NOT SPIN THE TAP AT A CONSISTENT DEPTH AS IT WILL STRIP THE HOLE.**

**Note:**
**Labeled tap length is 1.5mm less than the Screw length.**

## Step 7 Screw Insertion

Load a Ratchet Handle to the Driver. Select the appropriate size Facet Screw & corresponding Washer. Assemble the Washer & Screw onto the assembled Driver Shaft & Driver Sleeve. The Sleeve will hold the Washer (Fig 12).

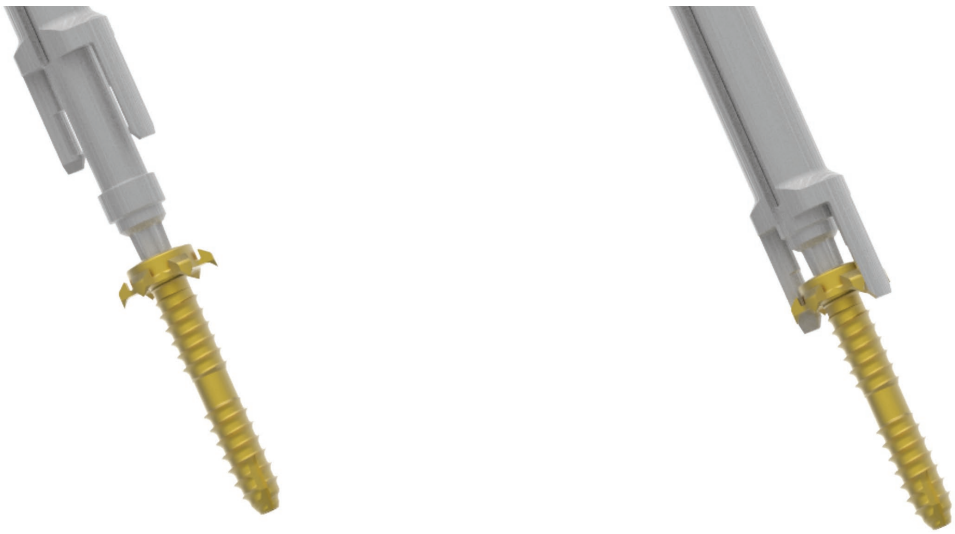


Figure 12

An alternate method of mating the Screw to the Driver Assembly is to use the 4.5 Loading Block. Drop the 4.5 Screw & 4.5 Washer into the Block. Orient the Driver Assembly to fit in the pocket & push down to engage (Fig 13).

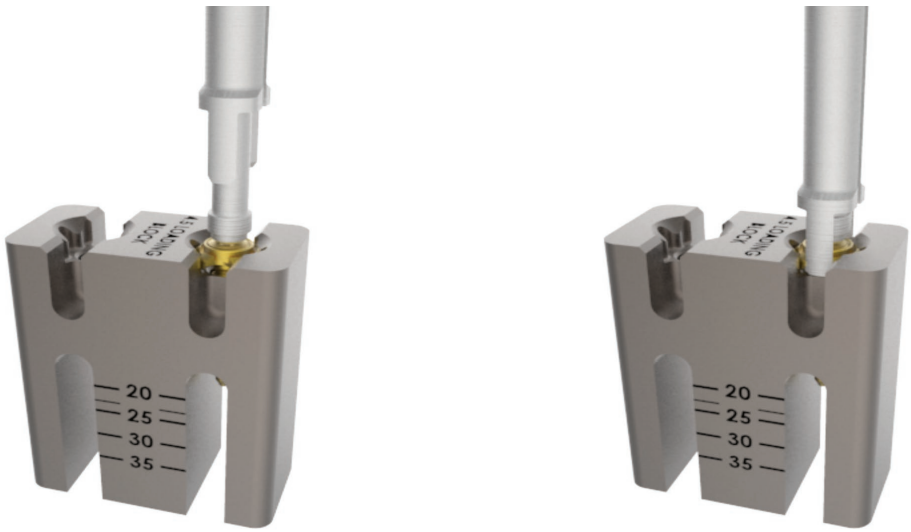



Figure 13

**THE LOADING BLOCK ONLY WORKS FOR THE 4.5 SCREW & WASHER (GOLD)**

Disengage the Guide Handle from the DT Guide/Dilator by rotating the knob counterclockwise (Fig 14).

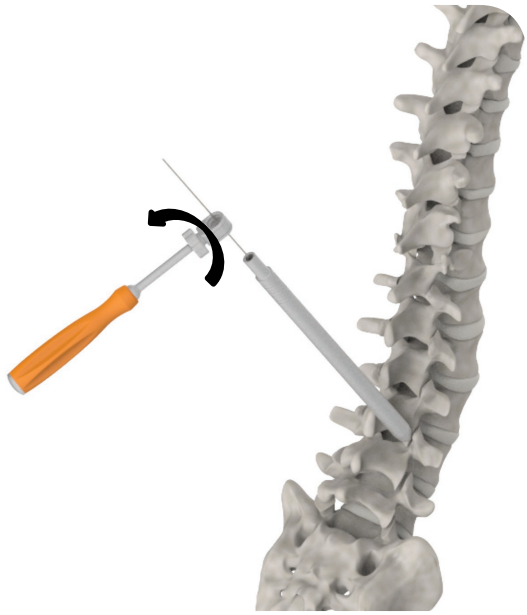


Figure 14

Slide the Final Dilator over the DT Guide/Dilator Sleeve. Remove the DT Guide/Dilator (Fig 15).

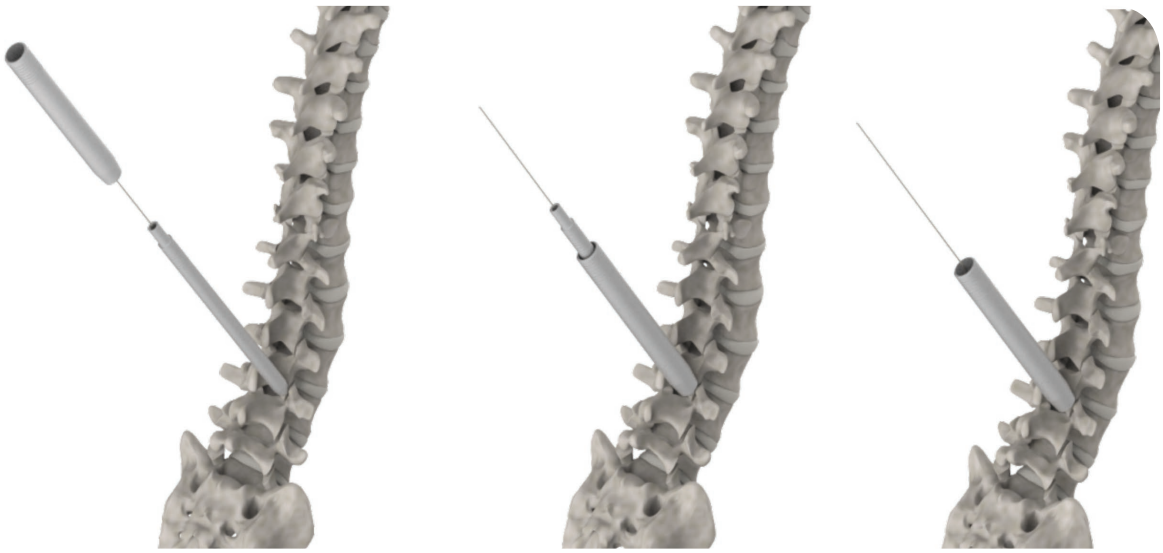


Figure 15

**Note:**
**When removing the DT Guide/Dilator take extra caution not to dislodge the Guide Wire.**

Position the Screw and Driver over the Guide Wire. Drive the Screw. Advance the Screw to traverse the Facet Joint aiming for the Screw tip to be within the Pedicle (Fig 16).

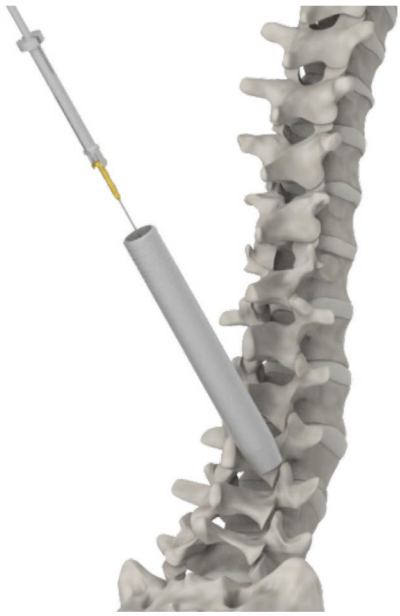


Figure 16

The Final Dilator has a feature that will catch the Driver Sleeve to hold the Driver Sleeve proximal to prevent interference with advancing the Screw (Fig 17).

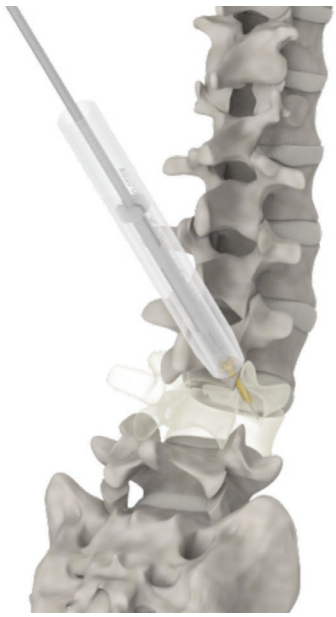


Figure 17

Stop driving the Screw once the Washer touches the superior Facet (Fig 18). Verify the final Screw position with fluoroscopy and/or EMG screw test.

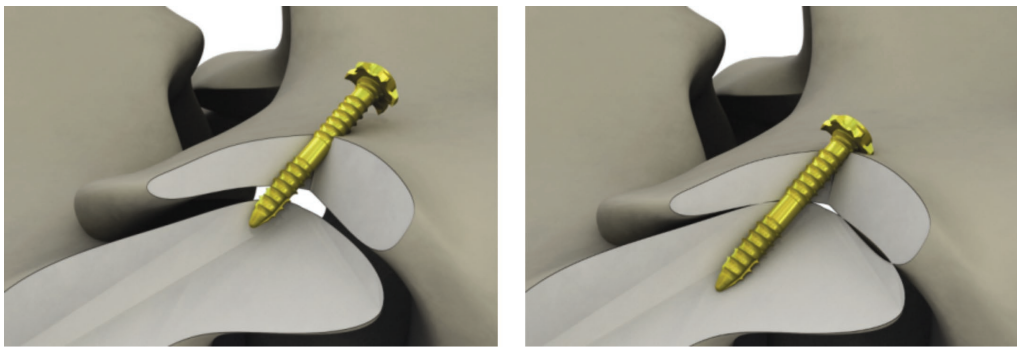
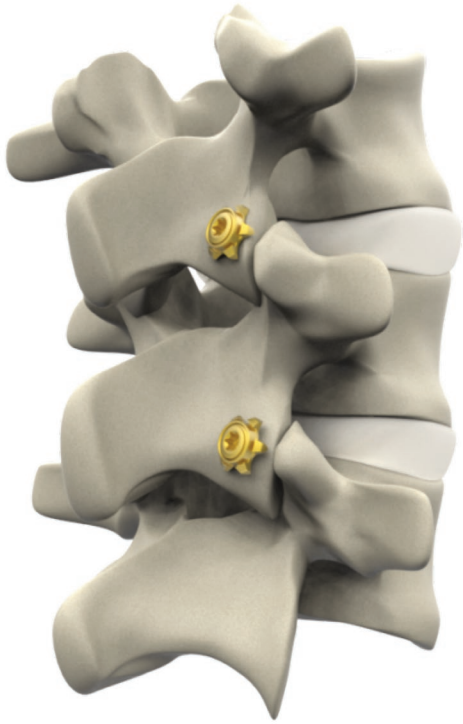


Figure 18

**CAUTION:**
**DO NOT CONTINUE TO DRIVE THE SCREW ONCE THE WASHER HAS BIT ON THE FACE, AS PURCHASE ON THE FACE MAY BE COMPROMISED.**



## Screw Removal

**To remove the Facet Screw, mate the Driver onto the Screw and rotate counterclockwise. The Screw will back out of the Facet. Separate the Washer from the Screw. Do not reuse either the Screw or the Washer.**

The Typhoon™ Facet Fixation System is a posterior Facet spinal fixation system consisting of screws and washers, manufactured from titanium alloy (Ti6Al4V ELI; ASTM F136). The bone screws are designed to transfix the facet articular process in the spine to enhance spinal fusion and stability. The self-tapping screws are 4.5mm and 5.5mm in diameter the 4.5mm screws are supplied in length ranging from 20mm to 60mm and the 5.5 mm screws range in length from 25mm to 60mm.

**WASHERS:**

Washers are available to increase the load bearing area of the screw in contact with the bone. These washers are designed to angulate about the head of the bone screw to provide optimal bony contact over the range of screw trajectories.

**INDICATIONS FOR USE**

The Typhoon™ Facet Screw Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from L1 to S1 inclusive.

The Typhoon™ Facet Screw System is indicated for treatment of any or all of the following: degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient history and radiographic studies; degenerative disease of the facets with instability; Spondylolisthesis; Spondylolysis; Pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; and trauma, including spinal fractures and/or dislocations.

When properly used, facet screws will provide temporary stabilization as an adjunct to spinal bone grafting processes. After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer, or support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient. The decision should consider the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

**CONTRAINDICATIONS**

Contraindications for the TYPHOON™ Facet Screw Fixation System are similar to those of other systems of similar design, & include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures.
2. Absence of posterior spinal elements including the pedicle, pars interarticularis, facet joints, spinous process & the majority of the lamina.
3. Conditions, such as morbid obesity, which may put excessive stress on the bone & implants.
4. Severe osteopenia or osteoporosis may prevent adequate fusion.
5. Pregnancy
6. Use of these implants is relatively contraindicated in patients whose activity level, metal capacity, mental illness, alcohol abuse, occupation or lifestyle may interfere with their ability to follow post-operative instructions.

**WARNINGS**

- The safety and effectiveness of facet screw fixation spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation.
- 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 Typhoon™ Facet Screw Fixation System Implants have not been tested for safety and compatibility in the MR environment. The Typhoon™ Facet Screw Fixation System Implant have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Typhoon™ Facet Screw Fixation System Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

**PRECAUTIONS**

- The implantation of the Typhoon™ Facet Screw Fixation System should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patent.
- Before use, instruments should be visually inspected and function should be tested to ensure instruments are functioning properly.
- 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.

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400 Erin Drive, Knoxville, TN 37919 | O: 865.246.3333 | F: 865.246.3334 | choicespine.com

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