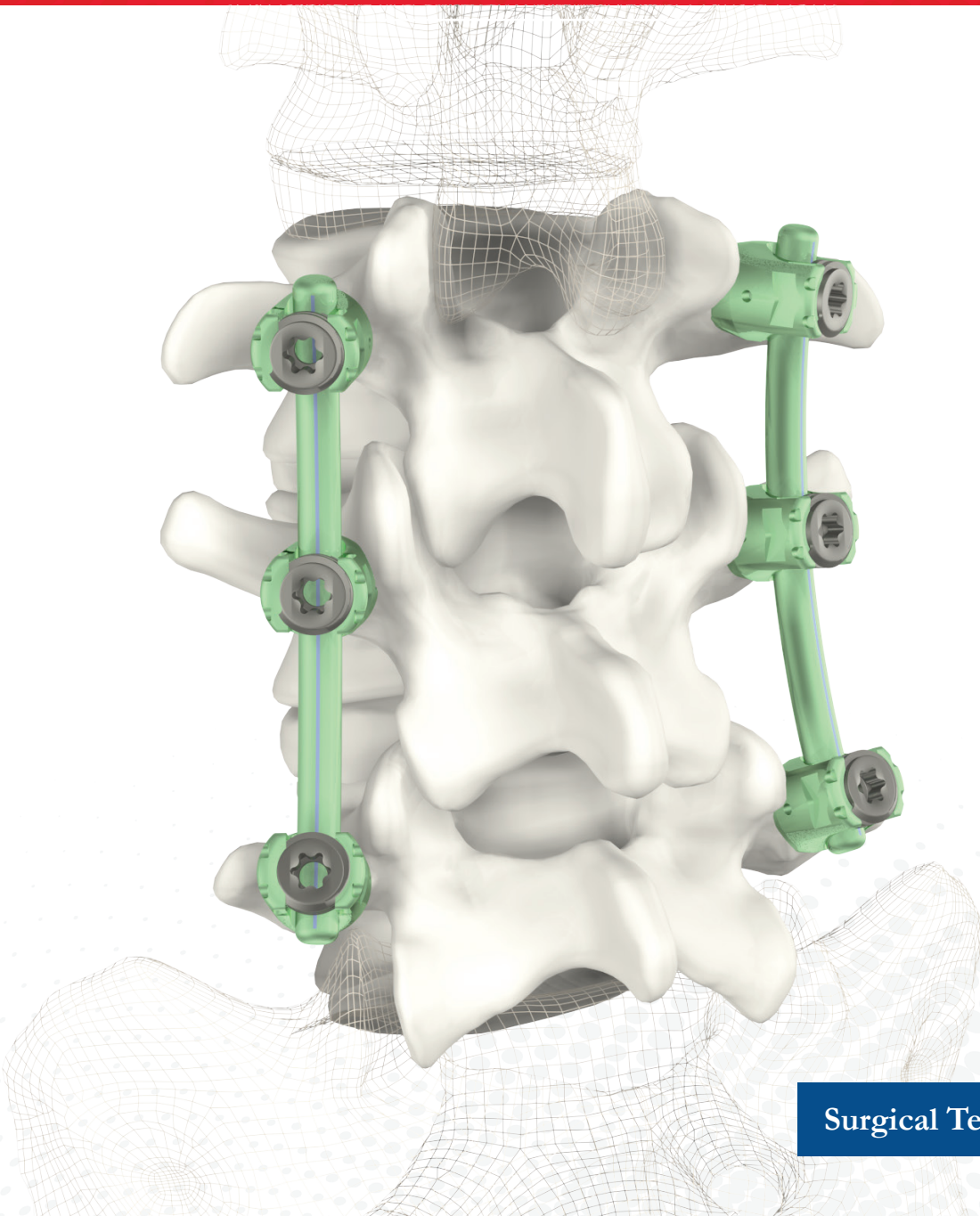




ZAVATION®

TIGER® 2

Pedicle Screw System



Surgical Technique Guide

THE TIGER 2 DIFFERENCE

Tiger 2 is a versatile thoracolumbar pedicle screw fixation system that maximizes surgeon options, minimizes operative steps, and provides intuitive instrumentation that addresses common pain points of degenerative, deformity, and revision spine surgeries.

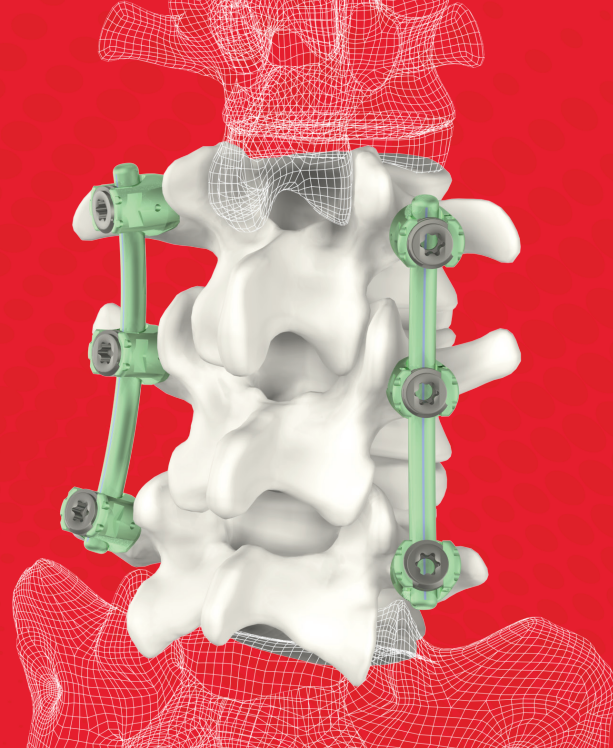


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SYSTEM OVERVIEW

Features & Benefits

Featuring a modular tulip head and transitional saddle, Tiger 2 pedicle screws can be assembled on the back-table or in-situ, while also accepting 5.5mm and 6.0mm rod diameters.

This versatility accommodates varying physician preference and provides interoperative flexibility for optimal anatomic correction.

The screw shanks feature a unique dynamic thread form, designed for optimal fixation and ease of placement under power or by hand.

Quick-connect attachment of reduction instrumentation minimizes operative steps, eases placement, and provides reliable reduction even in the most challenging anatomic scenarios.

Feature	Benefit
Screw thread	Designed for safety and ease of placement under power or by hand
Dynamic thread form (Cortical-Cancellous-Cortical)	Mitigates the need for pedicle prep, and optimizes purchase in the pedicle and vertebral body bone
Modular screws	Improve visualization, act as a visual fiducial for anatomic orientation, provide better access to lateral gutters, and improve access for interbody placement
Friction fit tulips	Reduce frustration and minimize placement time
Transitional saddle accepts cobalt chrome or titanium alloy Ø 5.5mm and 6.0mm rods	Creates interoperative flexibility and variability of stiffness
Higbee thread start on set screw	Tactile feel of thread engagement and reduced chance of cross-threading
Quick-connect reducer attachment	Minimizes effort and time
Undercut reducer attachment points on the tulip	Optimize reducer security during demanding maneuvers

IMPLANTS OVERVIEW

Modularity

Pedicle screw implants are provided as screw shanks and independent tulip heads, designed to be assembled in situ or on the back table.

The ability to place screw shank first provides improved visualization and an anatomical landmark for interbody approach and joint location. Interbody placement and lateral gutter preparation is no longer challenged due to presence of bulky tulip head.

The surgeon may combine the tulip head with the screw shank size best suited for a given clinical situation. The tulip forms a permanent, robust link with the screw shank using the head inserter.

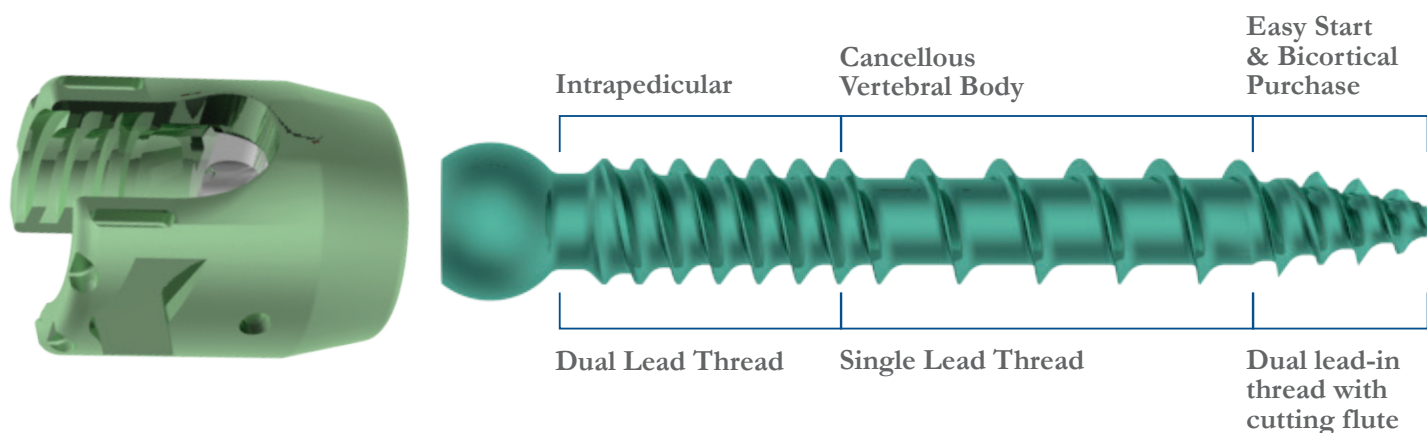
Screw Shank Design

The research-based screw shank design optimizes bone-screw interface to resist pullout and is well-controlled when placed under power.

A dynamic three-part thread form has a quick start tip, followed by a single-lead cancellous portion, ending with a dual-lead section for optimal intrapedicular purchase.

The cortical thread pitch is based on studies of the length of pedicles to optimize fixation.

After the taper of the screw tip, the minor diameter of the screw is 2mm less than the nominal (major) diameter and remains consistent along the length. The drive feature is T-27. Shanks are fabricated of titanium alloy (Ti-6Al-4V).



IMPLANTS

OVERVIEW (Continued)

Tiger 2 Screw Shanks

Diameters: 4.5mm - 10.5mm

Lengths: 25mm - 110mm

Drive Interface: T27



Length	Ø 4.5mm	Ø 5.5mm	Ø 6.5mm	Ø 7.5mm	Ø 8.5mm	Ø 9.5mm	Ø 10.5mm
25mm	380-4525-S	380-5525-S	380-6525-S	380-7525-S			
30mm	380-4530-S	380-5530-S	380-6530-S	380-7530-S	380-8530-S		
35mm	380-4535-S	380-5535-S	380-6535-S	380-7535-S	380-8535-S	380-9535-S	380-10535-S
40mm	380-4540-S	380-5540-S	380-6540-S	380-7540-S	380-8540-S	380-9540-S	380-10540-S
45mm	380-4545-S	380-5545-S	380-6545-S	380-7545-S	380-8545-S	380-9545-S	380-10545-S
50mm	380-4550-S	380-5550-S	380-6550-S	380-7550-S	380-8550-S	380-9550-S	380-10550-S
55mm	380-4555-S	380-5555-S	380-6555-S	380-7555-S	380-8555-S	380-9555-S	380-10555-S
60mm	380-4560-S	380-5560-S	380-6560-S	383-7560-S	383-8560-S	383-9560-S	383-10560-S
65mm				383-7565-S	383-8565-S	383-9565-S	383-10565-S
70mm				383-7570-S	383-8570-S	383-9570-S	383-10570-S
75mm				383-7575-S	383-8575-S	383-9575-S	383-10575-S
80mm				383-7580-S	383-8580-S	383-9580-S	383-10580-S
85mm				383-7585-S	383-8585-S	383-9585-S	383-10585-S
90mm				383-7590-S	383-8590-S	383-9590-S	383-10590-S
95mm				383-7595-S	383-8595-S	383-9595-S	383-10595-S
100mm				383-75100-S	383-85100-S	383-95100-S	383-105100-S
105mm				383-75105-S	383-85105-S	383-95105-S	383-105105-S
110mm				383-75110-S	383-85110-S	383-95110-S	383-105110-S

Kit #	Kit Name
KTG005	Standard Caddy
KTG023	Sacroiliac Caddy

IMPLANTS

OVERVIEW (Continued)

Polyaxial Tulip Heads

Modular tulip heads are offered as **top loading (980-2000)** and **reduction (980-2001)**, which may be selected by the surgeon depending on the spinal pathology being treated.

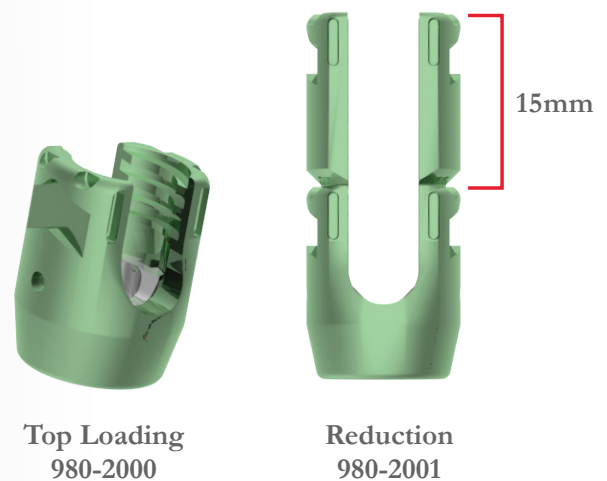
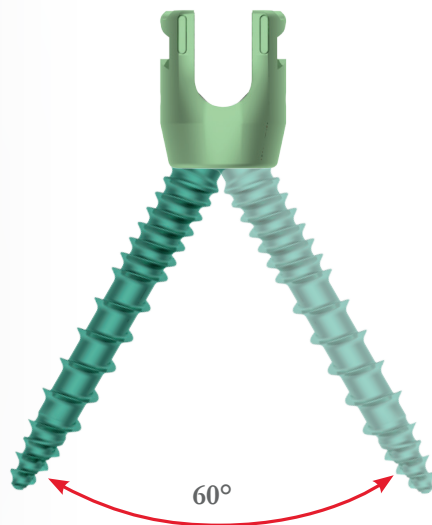
They may be assembled on the back table or in situ. Both offer polyaxial adjustment to the rod within a 60° cone of angulation.

Tulip heads are fabricated from titanium alloy (Ti 6Al-4V ELI), and have a transitional saddle compatible with Zavation titanium alloy or cobalt chrome 5.5mm and 6.0mm rods.

The chevron geometry on the medial/lateral sides of the tulip are for reduction instrumentation engagement, and feature a slight undercut for robust attachment.

Polyaxial Reduction Tabs

Reduction tulip heads offer 15mm of additional thread above the rod slot. They aid in seating the rod while reducing the need for instrumentation, and create an overall streamlined procedure.

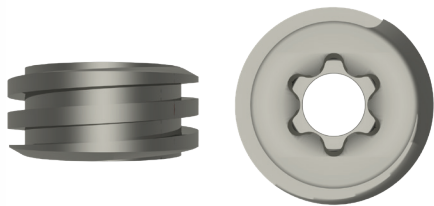


IMPLANTS

OVERVIEW (Continued)

Set Screws

The **set screw (980-2003)** features reverse buttress threads to mitigate tulip splay, and a Higbee lead for tactile feel of thread engagement, and a reduced chance of cross threading. It has a T27 drive feature to combat stripping. The implant is fabricated from titanium alloy (Ti-6Al-4V).



Set Screw
980-2003

Rods

Ø 5.5mm pre-lordosed titanium alloy (Ti 6Al-4V ELI) rods are provided standard in lengths as indicated in the table below.

The radius of curvature is 150mm. A line is visible along the length of the rod at the inner apex to aid in alignment. Straight, cobalt chrome (CoCrMo), and Ø 6.0mm rods are available upon request.

Standard:

Length	Ø 5.5mm
35mm	380-C035
40mm	380-C040
45mm	380-C045
50mm	380-C050
55mm	380-C055
60mm	380-C060
65mm	380-C065
70mm	380-C070
75mm	380-C075
80mm	380-C080
85mm	380-C085
90mm	380-C090
95mm	380-C095

Special Order:

Length	Ø 6.0mm
35mm	381-C035
40mm	381-C040
45mm	381-C045
50mm	381-C050
55mm	381-C055
60mm	381-C060
65mm	381-C065
70mm	381-C070
75mm	381-C075
80mm	381-C080
85mm	381-C085
90mm	381-C090
95mm	381-C095



INSTRUMENTS OVERVIEW: BONE PREPARATION

Handles



Axial Handle, Ratcheting
Z-1057



T-Handle, Ratcheting
Z-1058

Awl



Awl, 7.5mm Depth Stop
989-1007

Pedicle Probes



Steffee Pedicle Probe, Straight
989-1005



Steffee Pedicle Probe, Curved
989-1006



Lenke Pedicle Probe, Straight
989-1003



Lenke Pedicle Probe, Curved
989-1004

INSTRUMENTS OVERVIEW: BONE PREPARATION (Continued)

Taps

Taps (989-1010-XX) have a single-lead thread, a cutting flute, and a tip with a 0.5mm radius. The taps are line-to-line with the screw implant, having a minor diameter that is 2mm less than the nominal (major) screw diameter.

Since the tap is single lead, and the screw is dual-lead, cortical engagement is improved and palpable to the surgeon.

It is generally accepted to under-tap by 1mm, but in very dense bone, line to line tapping may be preferred.

The shaft features depth markings to 60mm or 110mm, depending on diameter.



Tap, 4.5mm
989-1010-45



Tap, 7.5mm
989-1010-75



Ball Tip Sounder
989-1002

Ball Tip Sounder

The **ball tip sounder (989-1002)** is marked in 10mm increments from 20mm to 60mm.

INSTRUMENTS OVERVIEW: SCREW PLACEMENT

Screw Shank Driver

The **screw shank driver (989-1016-SP)** is used to implant a pedicle screw shank. The tulip head may be affixed in situ during a subsequent procedural step.



Screw Shank Driver
989-1016-SP

Polyaxial Driver

The tulip head may alternately be affixed to a screw shank ex situ. Use the **polyaxial screwdriver (989-1016-SP)** to implant the assembly.



Polyaxial Driver
989-1016-SP

Decorticator

After placing pedicle screw shanks, the **decorticator (389-1012-S)** may be used to abrade the bone surrounding the screw. This clears space for the placement of the tulip, creates a bed for bone graft, and may promote bone growth.

NOTE: The decorticator is not designed for use with power drivers.



Decorticator
389-1012-S

INSTRUMENTS OVERVIEW: SCREW PLACEMENT (Continued)

Head Inserter

The **head inserter (989-1021)** must be used to affix a tulip head to a screw shank creating a robust linkage.

Tulip heads may be affixed while shanks are in the caddy or in situ. It is not recommended to hold a screw shank in hand while making a connection.

NOTE: Improper assembly of the modular tulip head to the screw shank can cause inadvertent dissociation in subsequent steps, such as rod reduction.



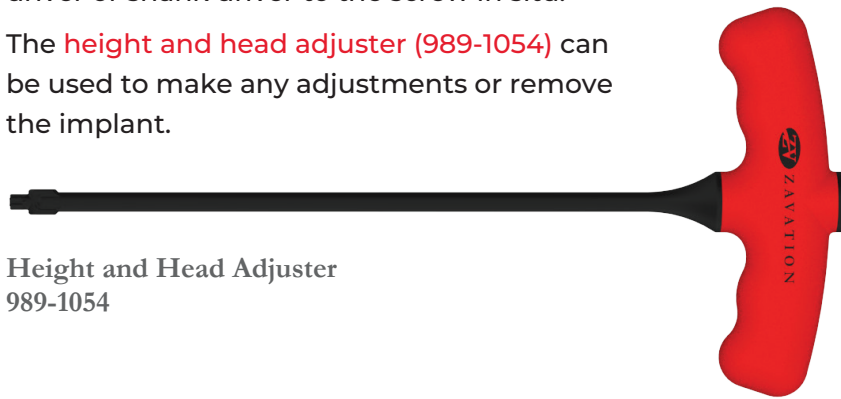
Head Inserter
989-1021

INSTRUMENTS OVERVIEW: ROD PLACEMENT

Height and Head Adjustment

It is not recommended to reattach a polyaxial driver or shank driver to the screw in situ.

The **height and head adjuster (989-1054)** can be used to make any adjustments or remove the implant.



Height and Head Adjuster
989-1054

Rod Adjustment

Rod holding forceps (989-1031) with carbide inserts.



Rod Forceps
989-1031

To adjust for the rod diameter, pull and turn wheel on the **French bender (989-1030)**.



French Bender
989-1030

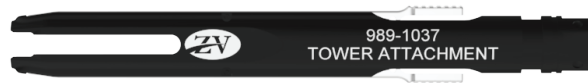
INSTRUMENTS OVERVIEW: REDUCTION

Rod Reduction into the Tulip

The distal end of the reduction instruments engages with geometry of the medial/lateral sides of the tulip, and may be released by pressing the two buttons on the sides of the reducer selected.



Rod Rocker
989-1036



Tower Reducer
989-1037



Inner Reducer
989-1038



Socket
989-1039



Provisional Set Screw Driver
989-1049



Double-ended Set Screw Driver
989-1052

INSTRUMENTS OVERVIEW: REDUCTION (Continued)

Auxiliary Reducer Options

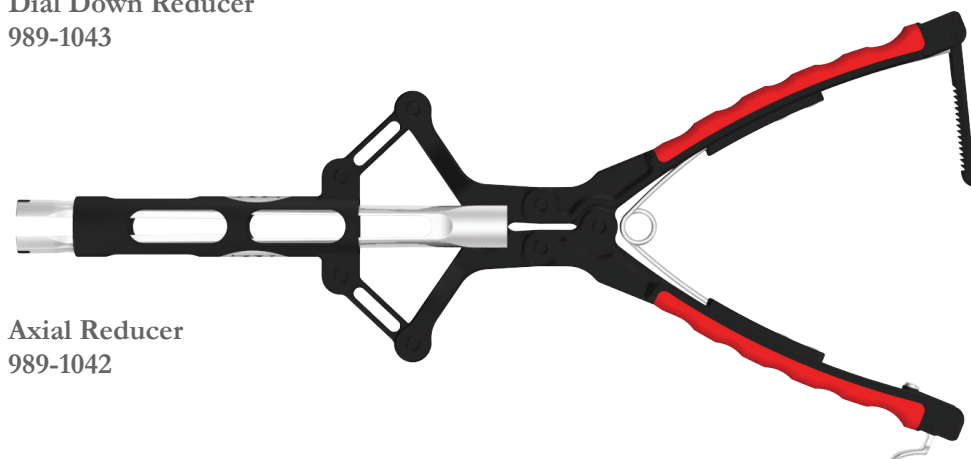
Additional reduction instruments are available to meet surgeon preferences and intraoperative demands.



Pistol Reducer
989-1911



Dial Down Reducer
989-1043

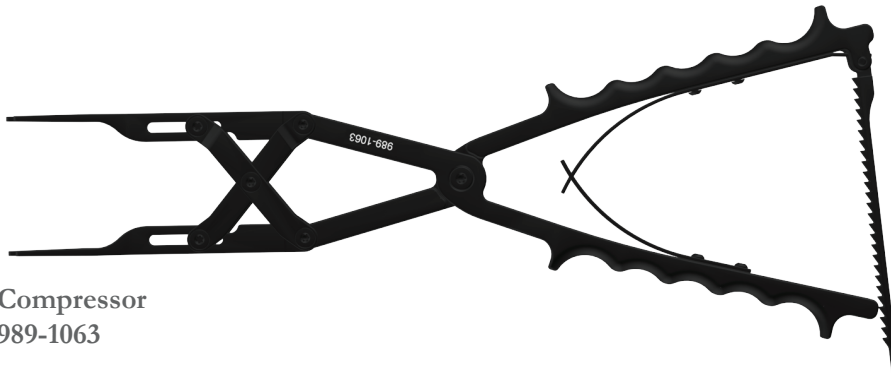


Axial Reducer
989-1042



Provisional Set Screw Driver, Long (used with Axial Reducer)
989-1051

INSTRUMENTS OVERVIEW: COMPRESSION & DISTRACTION



Compressor
989-1063



Distractor
989-1064

INSTRUMENTS OVERVIEW: FINAL LOCKING

Final Tightening

Insert the **final tightening driver (989-1056)** into the **torque limiting wrench (Z-1059)** which contains a $\frac{1}{4}$ " square connection. The torque value of the torque limiting wrench is 90in-lbs.

Once the set screw is placed, place the **counter torque (989-1047)** over the head of the tulip. Insert the final tighter assembly through the shaft of the counter torque and tighten until the torque limiting wrench "torques out."

An audible click can be heard once the torque limit is reached.



Final Tightening Driver
989-1056

SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION

Tiger 2 bone screw implants are designed to be placed in a transpedicular path into the vertebral body. Use caution when using instrumentation in the pedicle to avoid lateral breach into the neural foramen or medially into the spinal canal.

Patient Positioning

The patient is placed under general anesthesia, positioned prone, and draped. Location of the appropriate levels of treatment are confirmed with fluoroscopy.

A posterior midline skin incision is created over the operative levels. Superficial and deep fascia are dissected longitudinally.

Exposure

Working subperiosteal to maintain hemostasis, the bony elements are meticulously cleaned to the lateral extent of the transverse process.

The facet joints are stripped of soft tissue and facetectomies may be performed to enhance arthrodesis.

SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

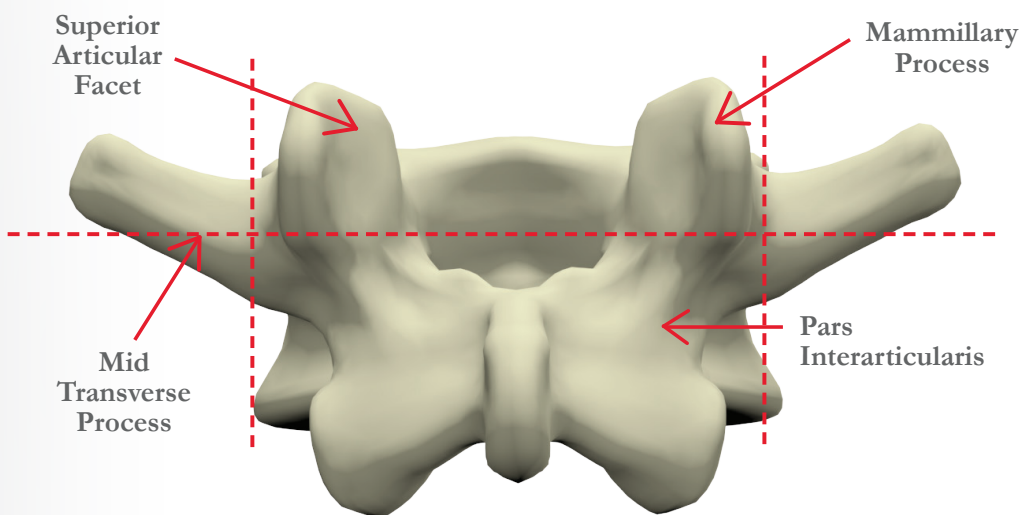
Screw Trajectory

The screws are placed transpedicular into the vertebral body. Care is taken to avoid medial penetration of the spinal canal or lateral penetration into the neural foramen.

The two contralateral screws should essentially converge in the anterior of the vertebral body, without any degree of cortical penetration of the vertebral body cortex at that depth.

Pedicle Entry Point

The entry point of the pedicle is defined as the confluence of any of the pars interarticularis, mammillary process, lateral border of the superior articular facet, and the mid transverse process.

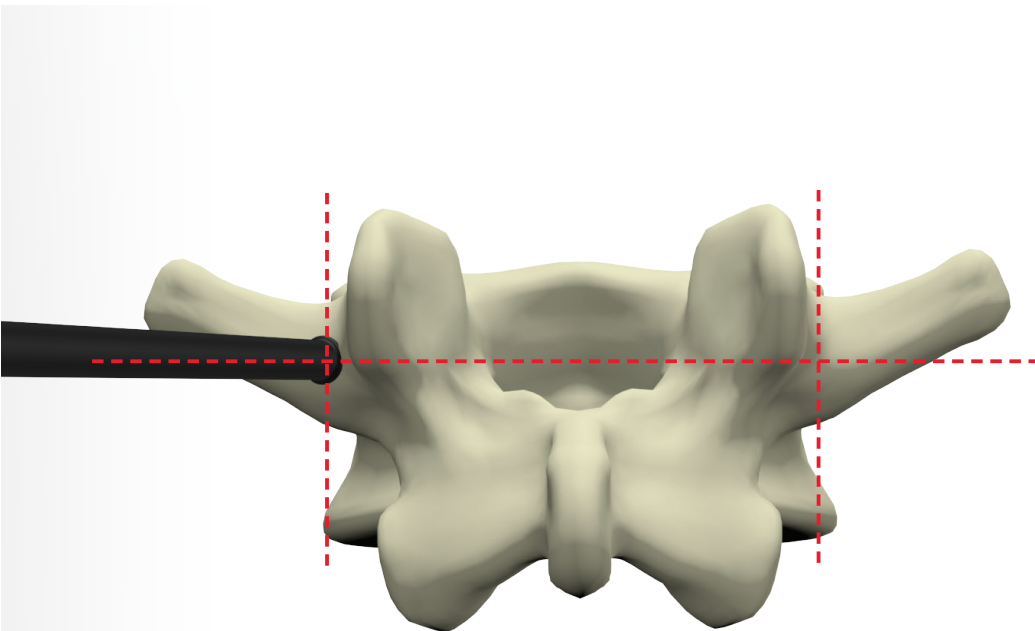


SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

Cortical Divot

After the desired entry point is selected, the awl may be used to breach the cortex of the cortical bone and create a pilot hole. The awl inserts to a depth of 7.5mm.

Other options for creating a cortical divot include the use of a high speed drill equipped with a burr, osteotome, or rongeurs.



SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

Gearshift Probing

A pedicle probe is used to tactilely navigate down the spongy cancellous isthmus of the pedicle.

A curved pedicle probe is placed in the previously created cortical divot, searching for a cancellous “soft spot” indicating entrance to the pedicle.

The curve of the “gearshift” is initially pointed lateral, as a safety measure to avoid medial wall perforation.

The tip should descend the cancellous portion of the pedicle, by allowing the pedicle finder to “fall” into the pedicle with slight back-and-forth rotational movement.

After the tip reaches the base of the pedicle, and beyond the medially based spinal canal (approximately 15–20mm), the “gearshift” is removed and the tip turned to face medial.

The path down the pedicle is then continued medially into the vertebral body with an ultimate depth averaging 35–50mm.

Once the desired endpoint is reached, after advancing the finder to the approximate length of the desired screw, rotate the finder 180° back-and-forth to make room for the screw.



SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

Ball Tip Sounder

The **ball tip sounder (989-1002)** may be used to assess the integrity of the pathway and ensure the pedicle or the anterior wall of the vertebral body has not been breached.

Depth markings on the ball tip sounder or “gearshift” may be utilized to select the proper length implant.



Depth Markings

Tapping

It is recommended to fully tap the intended screw trajectory to improve purchase and accuracy of implant placement. **Taps (989-1010-XX)** are sized line-to-line with the screw shanks, although selecting a tap size 1mm less than the intended screw shank diameter is acceptable. More tenuous bone should be tapped line to line.

Taps are single lead. Most pedicle screw implants will have a dynamic thread form with a dual-lead interpedicular component at the proximal end. Therefore, even when tapping line-to-line with an onsize tap, purchase is greatly improved by having one of the thread leads untapped.



SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

Screw Shank Placement

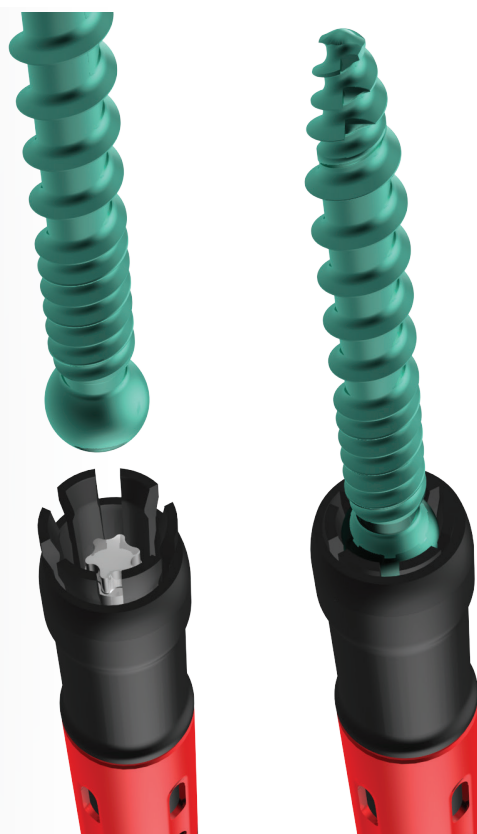
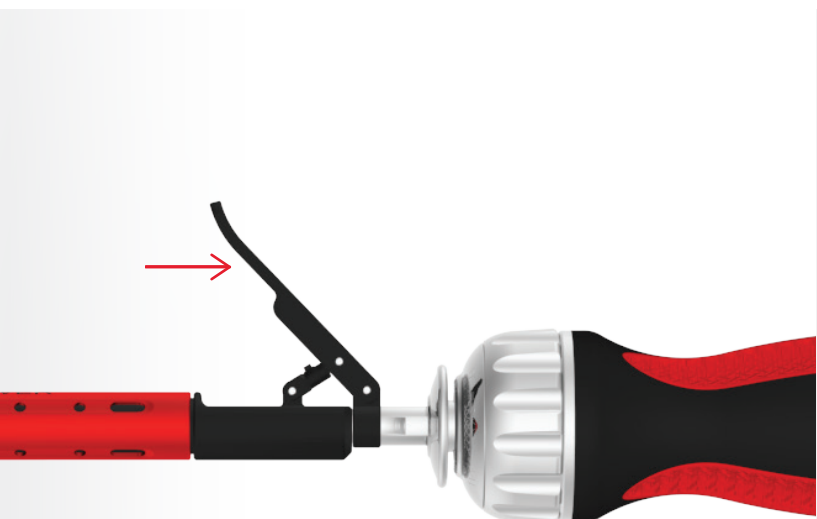
Assemble the **screw shank driver (989-1016-SP)** with a handle or power driver. The standard connection is ¼" square drive.

Ensure the shank driver is unlocked by retracting the black lever on the shaft toward the handle.



Screw Shank Placement

Align the distal end of the screwdriver with the screw shank head and engage the T27 hex in the drive feature of the screw. You may need to rotate the driver slightly to align the hexalobe.



SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

Lock the screw by depressing the lever
toward the instrument shaft.



SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

Screw Shank Placement

The screw is inserted into the prepared pathway and driven to the desired depth.

To remove the shank driver from the screw shank, retract the black lever and disengage the driver from the screw.



Decorticating

The **decorticator (389-1012-S)** may be used to clear away bone, soft tissue, and provide adequate clearance for the tulip. Assemble the decorticator with a handle. **NOTE:** Do not use the decorticator with a power drill.

Place over the head of the inserted screw shank and rotate the decorticator clockwise with moderate downward force until the desired tissue effect is achieved. Angling the instrument will allow it to clear tissue closer to the screw shank.

After placement of the screw shank, but before placement of the tulip, the surgeon may perform additional dissection, decompression, disc prep, or placement of an interbody.



SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

Unitized Screw Placement

Optionally, the tulip can be attached to the shank on the back table and implanted using the **polyaxial screwdriver (989-1017-SP)**.

In this fashion, the head inserter is used to attach the tulip head to the screw shank using the method previously described while the shank is seated in the caddy.

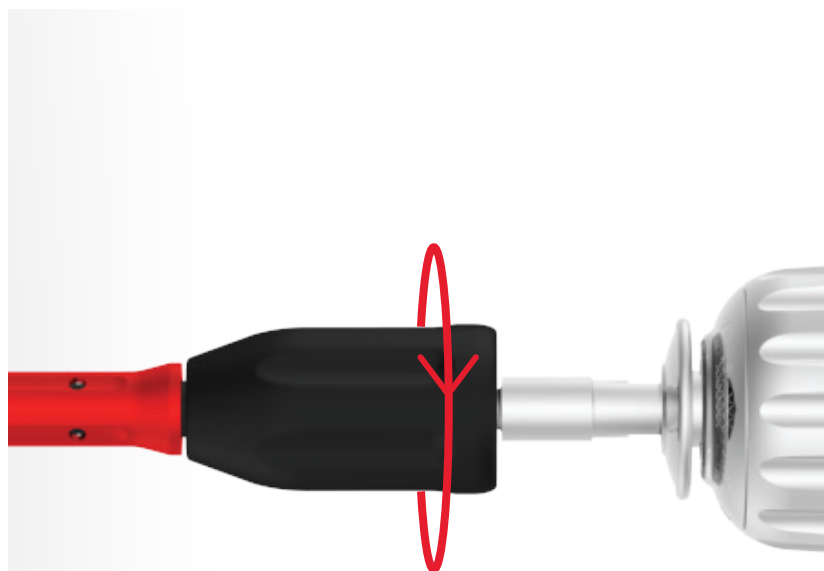
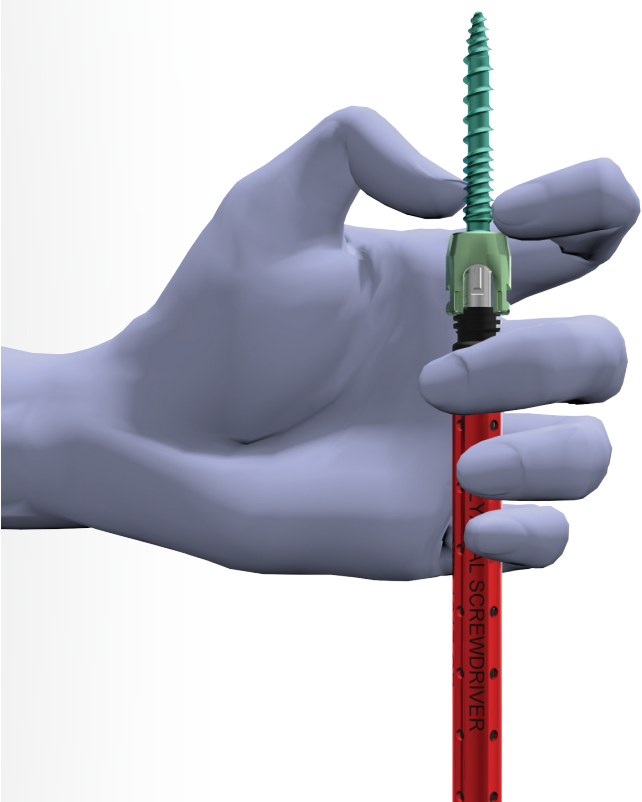
To use the polyaxial driver, assemble the screwdriver with a handle or power driver. The standard connection is $\frac{1}{4}$ " square drive.

While holding the screw by the thread, place it on the tip of the polyaxial screwdriver and rotate the screw shank until the tip of the screwdriver fully engages in the hexalobe drive of the screw.

Rotate the black knob on the shaft clockwise to thread the outer sleeve into the tulip.

Once secure, the screw is inserted into the prepared pathway and driven to desired depth.

To remove the driver, rotate the black knob counterclockwise until the screw is released.



SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

Height Adjustment & Alignment

After initial placement, the combined **height and head adjuster (989-1054)** can be used to both adjust the screw height and align the tulip head rod slots in preparation for rod placement. Bottom the instrument into the screw shank drive feature to drive, back-out, or remove a screw. Disengage the drive feature to only adjust the head position.

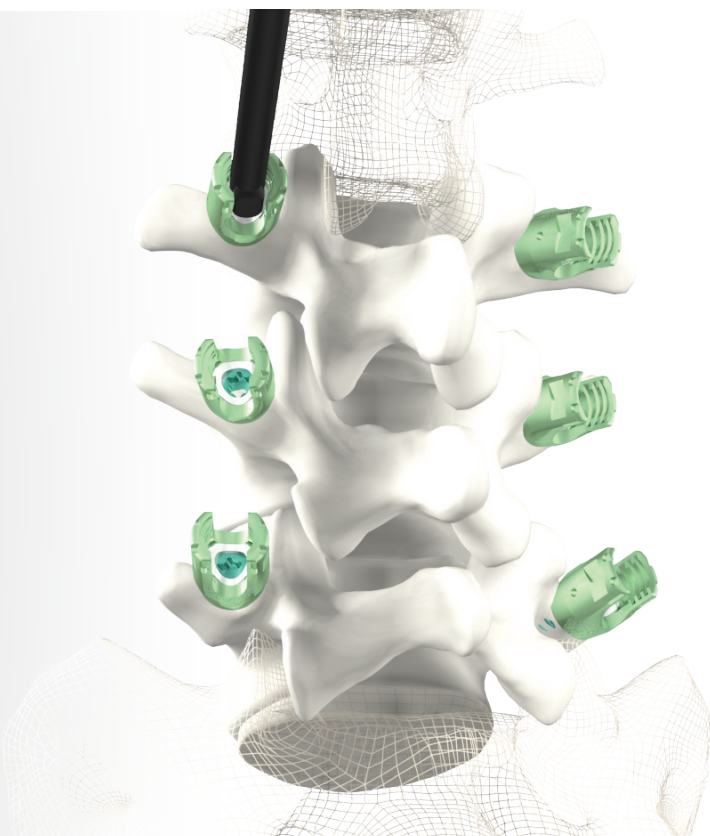
NOTE: It is not recommended to reattach the shank driver or polyaxial driver in situ.



Rod Measurement & Bending

A malleable rod template is laid into the rod slot to assist the surgeon in determining a suitable rod length. The rod template has length markings in 5mm increments and can be contoured with the **French bender (989-1030)**.

WARNING: Excessive contouring / bending should be limited. Over-bending can cause fatigue to the rod.



SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

Rod Insertion

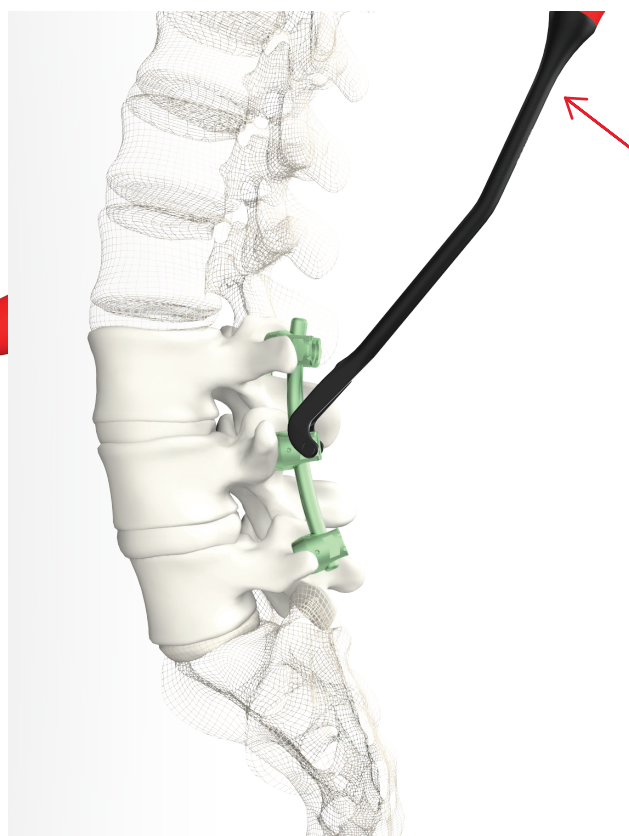
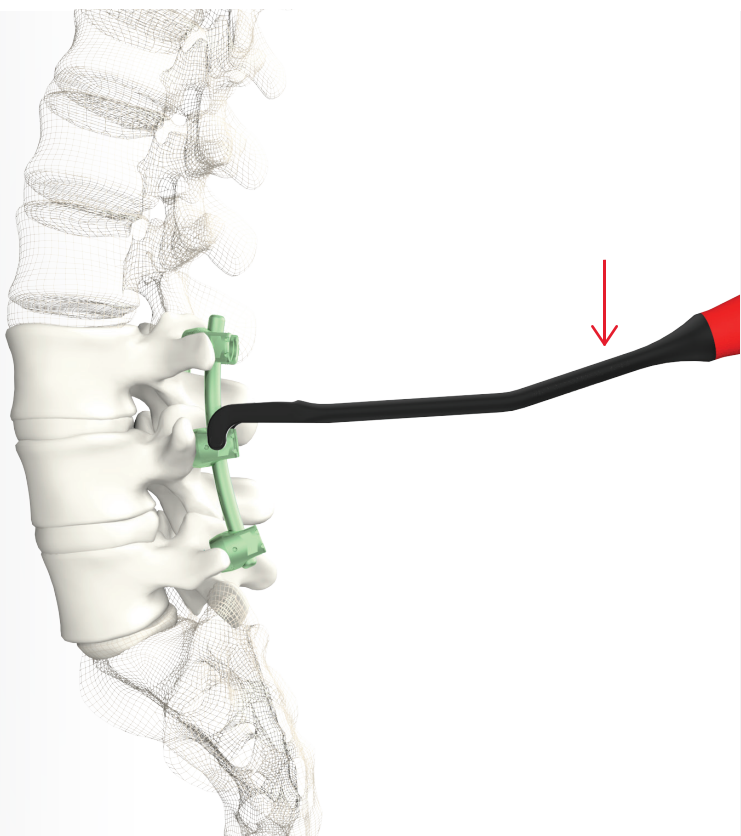
Once the desired length of rod is selected, the **rod holding forceps (989-1031)** can be used to insert the rods into the tulip heads.



Rod Reduction

The Zavation Tiger 2 Pedicle Screw System provides multiple rod reduction options to aid in reduction of the rod into the tulip.

The **rod rocker (989-1036)** is inverted and slid into place in line with the rod slot. Hook into V-notches on medial/lateral side of tulip.



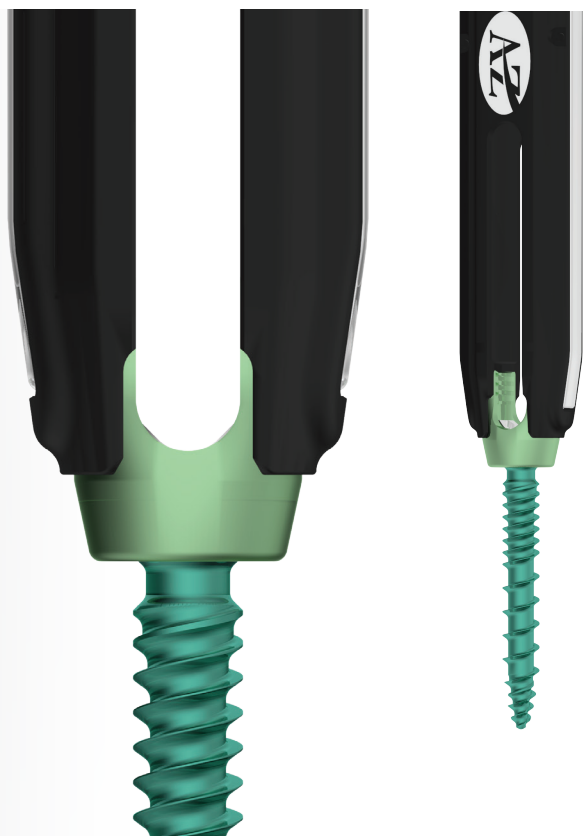
SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

Rod Reduction

Assemble the **tower (989-1037)** with the **inner reducer (989-1038)** by inserting the inner reducer into the tower and partially threading it down so as to hold it in place.

The distal end of the reduction instruments engages with geometry of the medial/lateral sides of the tulip and is driven by the **tower adapter socket (989-1039)** and a ratcheting handle. The reducer may be released by pressing the two buttons on the sides of the reducer.

The Zavation Tiger 2 Pedicle Screw System provides multiple rod reduction options, as seen on page 12, to aid in reduction of the rod into the tulip.



SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

Set Screw Insertion

Once the rod is fully seated into the saddle of the tulip, the **provisional set screw driver (989-1049)** can be used to insert the set screw into the tulip. The set screw and set screw driver feature a T27 hexalobe driving mechanism.

The provisional set screw driver is self retaining.

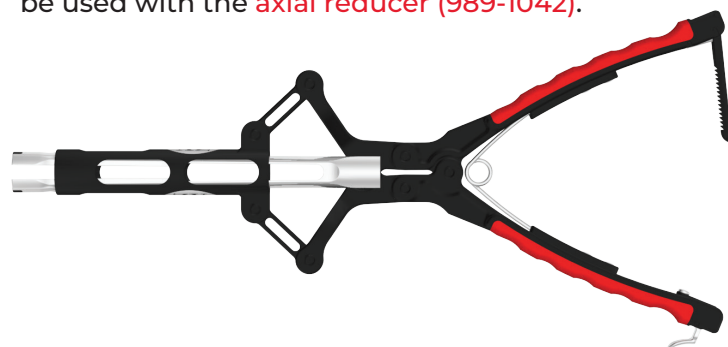
Load the set screw directly from the caddy. After loading, the driver tip can be lightly tapped on a table to make the screw attach more tightly.

The provisional set screw driver and screw are designed to pass through the cannulation of the reducer.

NOTE: The provisional driver should only be used to make the set screw fit snug or “finger tight”.



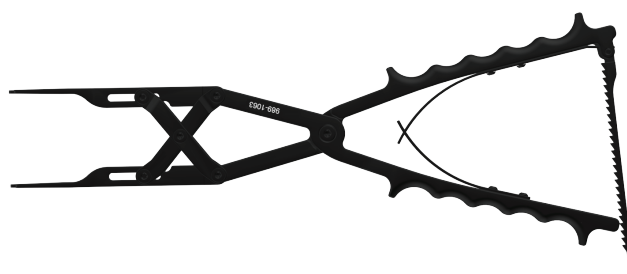
A **long provisional set screw driver (989-1051)** is included with the auxiliary reducers and must be used with the **axial reducer (989-1042)**.



Compression & Distraction

A **compressor (989-1063)** and **distractor (989-1064)** are available should compression/distraction be desired.

Ensure at least one set screw on the tulips capture is sufficiently loosened to allow adjustment along the rod in the direction desired.



SURGICAL TECHNIQUE: OPEN APPROACH TO PEDICLE SCREW FIXATION (Continued)

Final Tightening

Insert the **final tightening driver (989-1056)** into the **torque limiting wrench (Z-1059)** which contains a ¼" square connection. The torque value of the torque limiting wrench is 90in-lbs. Once the set screw is placed, place the **counter torque (989-1047)** over the head of the tulip.

Insert the final tightener assembly through the shaft of the counter torque and tighten until the torque limiting wrench "torques out." An audible click can be heard once the torque limit is reached.

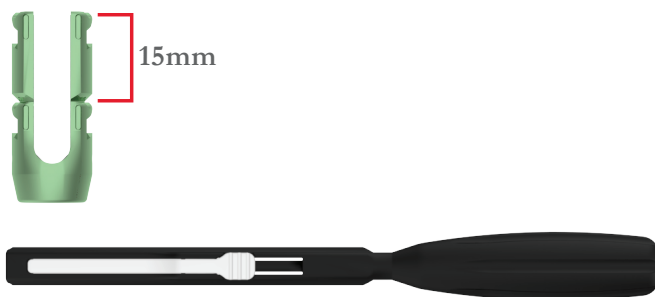
NOTE: A counter-torque is required for final tightening of the set screw.



Reduction Tab Removal

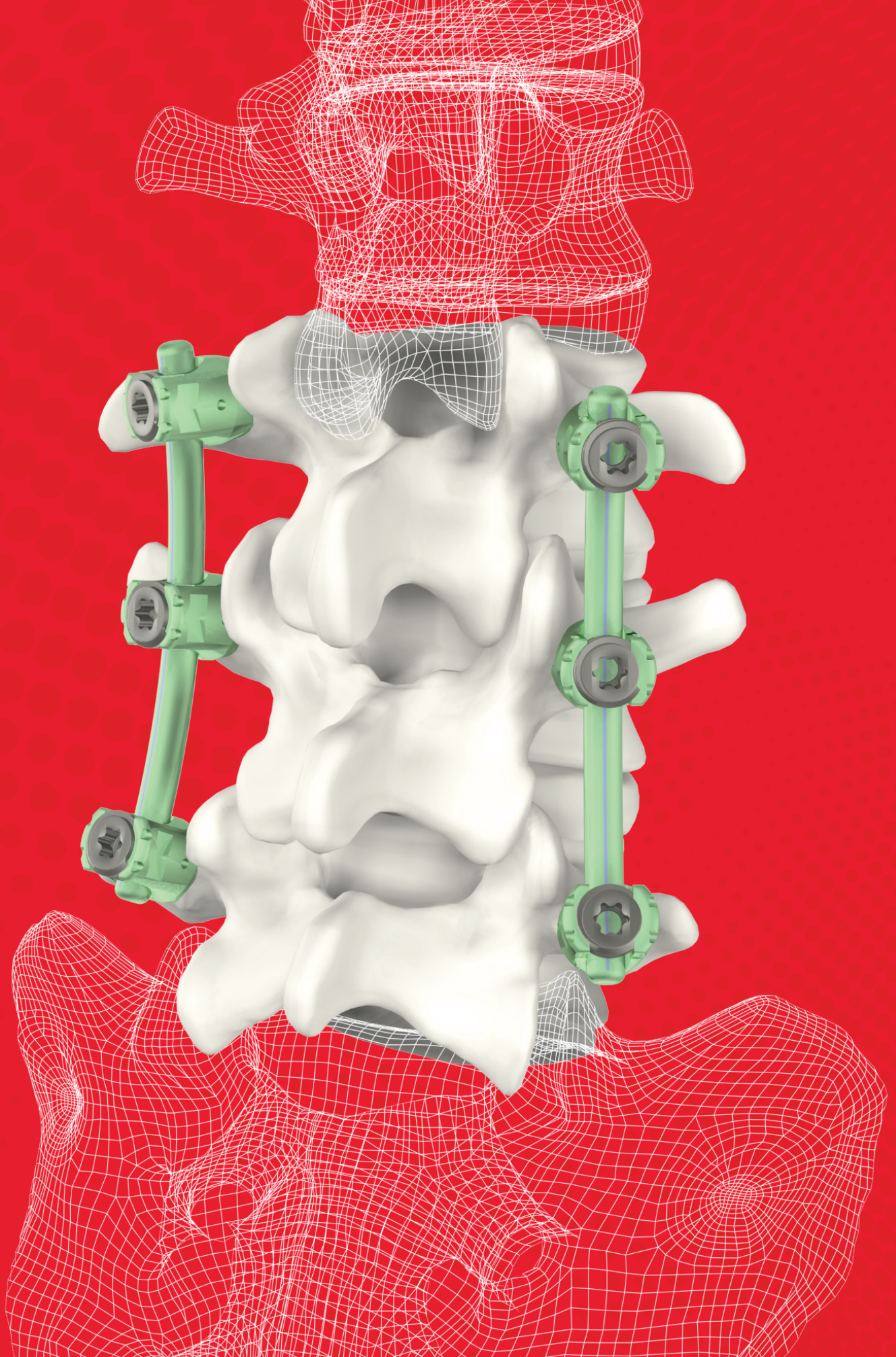
When using modular tulip head assemblies with integrated reduction tabs, the tabs must be removed after final tightening, prior to closure. Reduction tabs are designed to break at the top of the tulip at the proximal set screw junction.

Removal can be performed by using the **tab breaker (989-1023)** or by grabbing the proximal end of the reduction tabs with heavy needle drivers and moving in a lateral then medial motion.



Removal

The Zavation Tiger 2 Pedicle Screw System pedicle screws may be removed, if necessary. For revision or removal of this system, reverse all the insertion steps to remove implants.



TRAY MODULARITY

Proposed Standard Layout

The Tiger 2 System features modular trays to accommodate several shipping arrangements.

It is recommended to stack the Pedicle Prep Tray (#KTG001) with the Screw Placement Tray (#KTG002), and to stack the Reduction Tray (#KTG003) with the Implant Tray (#KTG005).



- A. Pedicle Prep Tray
- B. Screw Placement Tray



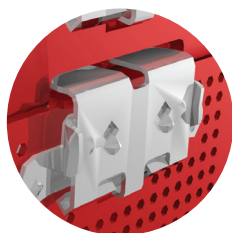
- C. Reduction Tray
- D. Implant Tray

TRAY MODULARITY (Continued)

Proposed Standard Layout

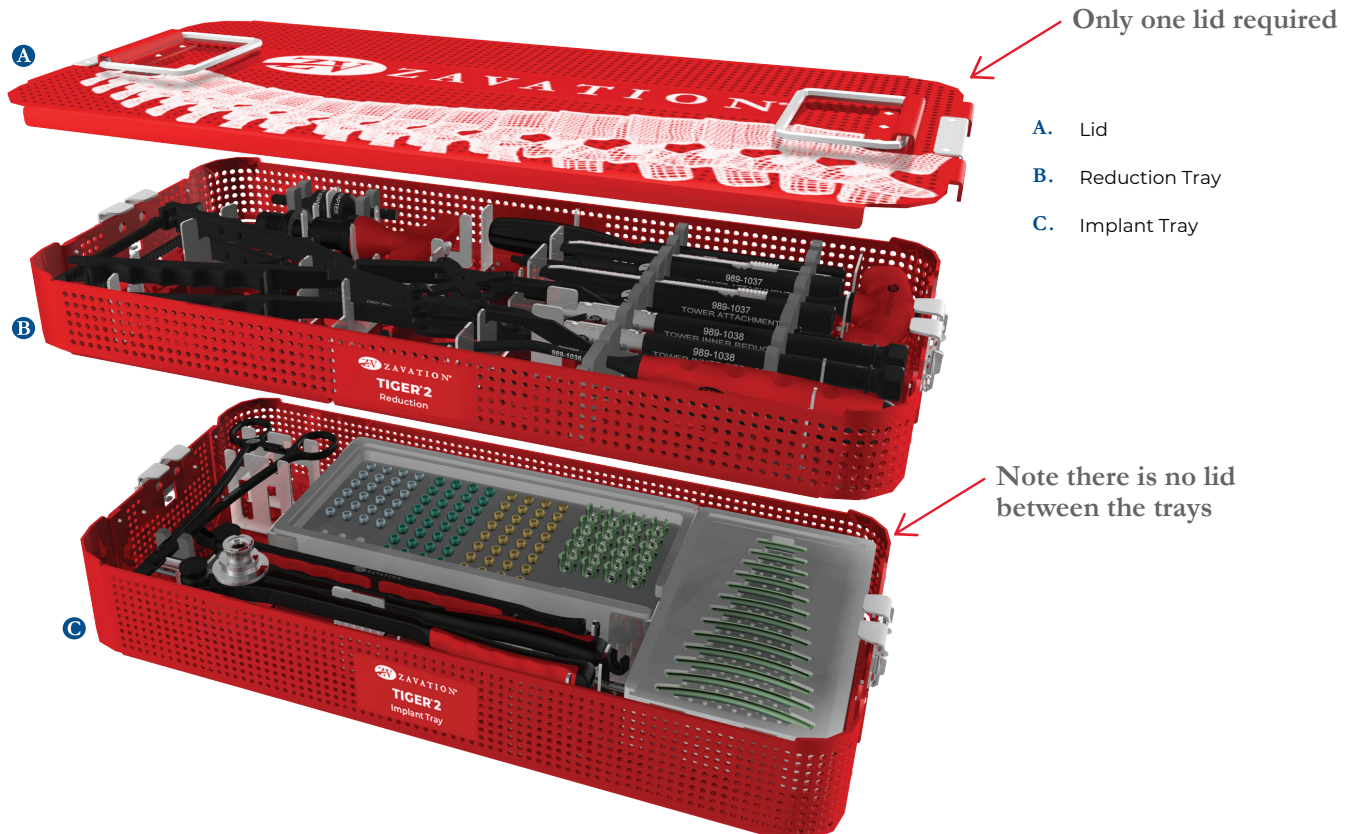
NOTE: Only one lid is required per stacked construct.

Each tray has latching features designed to snap onto the connecting tray or lid, so a lid is NOT needed for each individual tray level.



Tray Latch

Assembly Example:

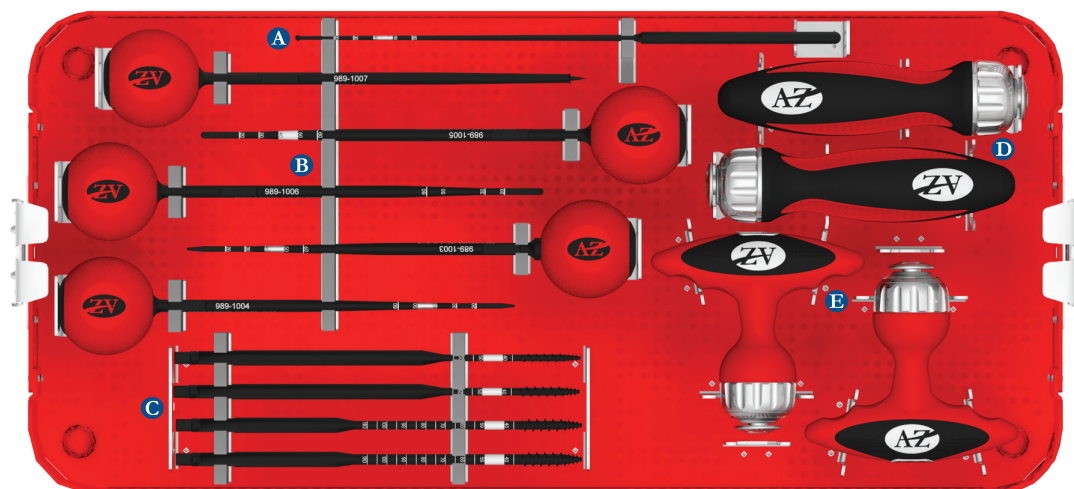


STANDARD TIGER® 2 PRODUCT LISTING & TRAY LAYOUT

Pedicle Prep Tray 1

Kit #KTG001

Catalog No.	Description	Qty
14G00733	Tray, Pedicle Prep	1
14G00737	Inner Lid	1
989-1002	Ball Tip Probe, SS	1
989-1003	Pedicle Probe, Straight Lenke	1
989-1004	Pedicle Probe, Curved Lenke	1
989-1005	Pedicle Probe, Straight Steffee	1
989-1006	Pedicle Probe, Curved Steffee	1
989-1007	Pedicle Awl, Awl Stop 4-sided Tip	1
989-1010-45	Modular Pedicle Screw Tap, Ø 4.5mm	1
989-1010-55	Modular Pedicle Screw Tap, Ø 5.5mm	1
989-1010-65	Modular Pedicle Screw Tap, Ø 6.5mm	1
989-1010-75	Modular Pedicle Screw Tap, Ø 7.5mm	1
Z-1057	Axial Ratcheting 1/4" Drive	2
Z-1058	T-Ratcheting 1/4" Drive	2



- A. Ball Tip Probe, SS
- B. Pedicle Probes
- C. Modular Pedicle Screw Taps
- D. Axial Ratcheting 1/4" Drive, Qty 2
- E. T-Ratcheting 1/4" Drive, Qty 2

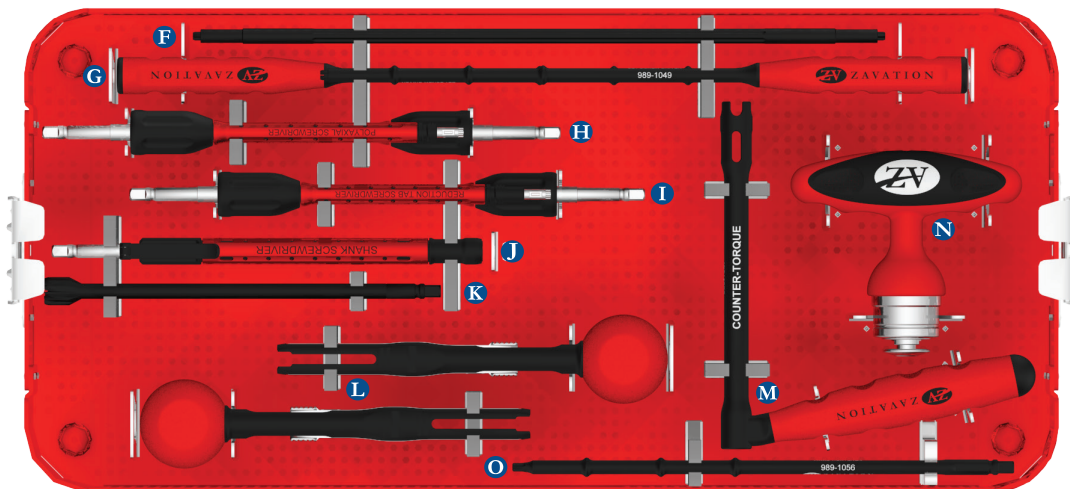
STANDARD TIGER® 2

PRODUCT LISTING & TRAY LAYOUT (Continued)

Screw Placement Tray 2

Kit #KTG002

Catalog No.	Description	Qty
14G00734	Tray, Screw Placement	1
989-1016-SP	Shank Driver 8.5" Powerease	2
989-1017-SP	Polyaxial Screwdriver 8.5" Powerease	2
989-1017-SPR	Reduction Screwdriver 8.5" Powerease	2
389-1012-S	Decorticator	1
989-1021	Head Inserter	2
989-1047	Counter Torque Wrench	1
Z-1059	T-Torque Limiting 1/4" Drive	1
989-1049	Provisional Set Screw Driver	2
989-1052	Provisional Double-Ended Set Screw Driver	2
989-1056	Final Tightener	2



- F. Provisional Double-Ended Set Screw Driver
- G. Provisional Set Screw Driver
- H. Polyaxial Screwdriver
- I. Reduction Screwdriver
- J. Shank Driver
- K. Decorticator
- L. Head Inserter
- M. Counter Torque Wrench
- N. T-Torque Limiting 1/4" Drive
- O. Final Tightener

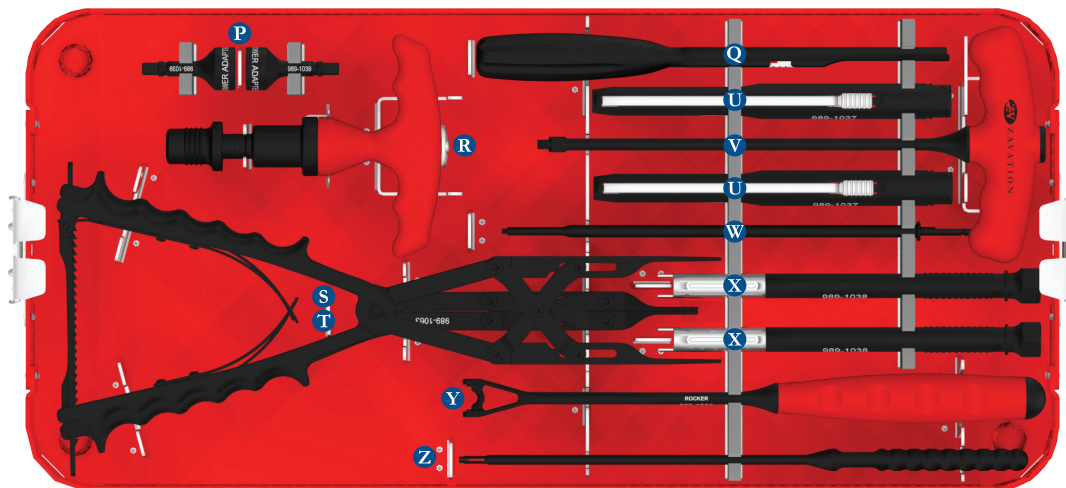
STANDARD TIGER® 2

PRODUCT LISTING & TRAY LAYOUT (Continued)

Reduction Tray 3

Kit #KTG003

Catalog No.	Description	Qty
14G00735	Tray, Rod Reduction & Locking	1
989-1023	Tab Breaker	1
989-1036	Rod Rocker	1
989-1037	Tower	2
989-1038	Inner Reducer	2
989-1039	Tower Adapter Socket	2
989-1063	Compressor Parallel	1
989-1064	Distractor Parallel	1
Z-1056	T-Handle, Torque Limiting, 45in/lbs Connector	1
989-1054	Height Adjuster / Head Adjuster	1
880-1013	Provisional Connector Driver	1
880-1014	Final Locking Connector Driver	1



- P.** Tower Adapter Socket
- Q.** Tab Breaker
- R.** T-Handle, Torque Limiting, 45in/lbs Connector
- S.** Distractor Parallel (top)
- T.** Compressor Parallel (below)
- U.** Tower Attachment
- V.** Height Adjuster / Head Adjuster
- W.** Final Locking Connector Driver
- X.** Tower Inner Reducer
- Y.** Rod Rocker
- Z.** Provisional Connector Driver

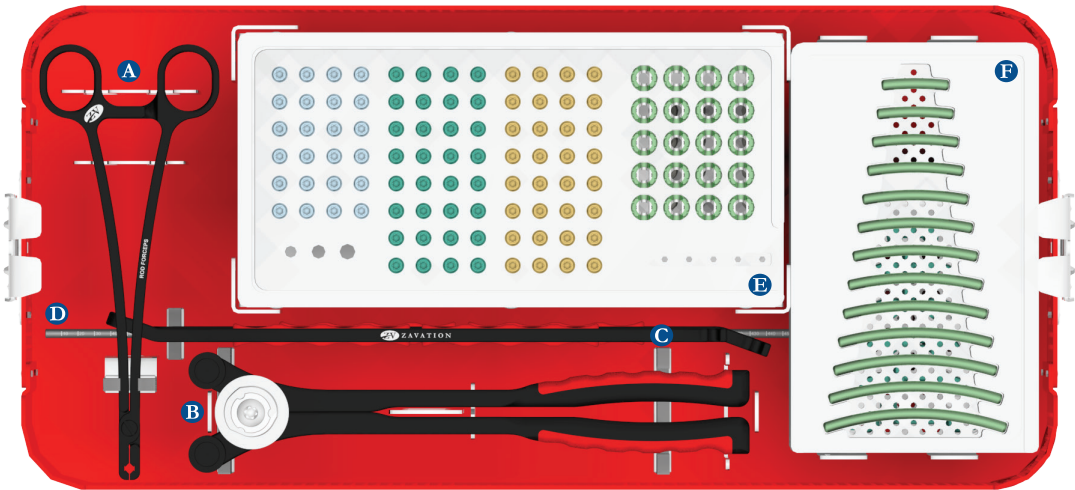
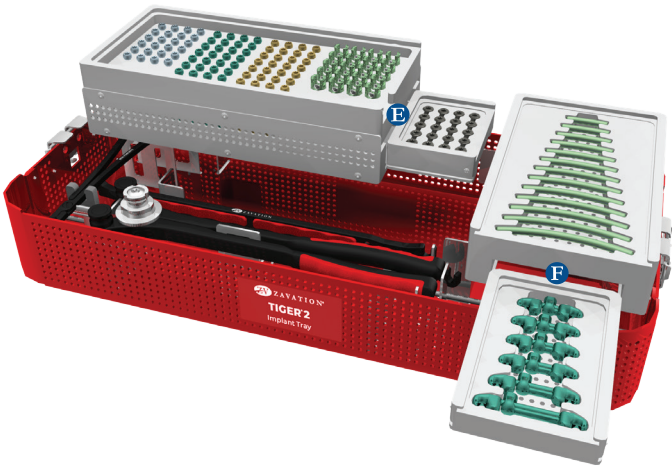
STANDARD TIGER[®] 2

PRODUCT LISTING & TRAY LAYOUT (Continued)

Implant Tray

Kit #KTG005 (Cannulated: #KTG046)

Catalog No.	Description	Qty
14G00738	Tray, Implants	1
14G00737	Inner Lid	1
14G00741	Caddy, Standard Shanks, Tulips, & Set Screws	1
14G00829	Caddy, $\varnothing$ 5.5mm Pre-Lordosed Rods, & Rod Connectors	1
989-1026	Rod Template, 600mm	1
989-1027	Screw Size Tool	1
989-1028-L	In situ Bender, Left	1
989-1028-R	In situ Bender, Right	1
989-1030	French Bender	1
989-1031	Rod Forceps	1



- A. Rod Forceps
- B. French Bender
- C. In situ Benders (Left & Right)
- D. Rod Template
- E. Standard Solid Shanks, Tulips, and Set Screws Caddy
- F. 5.5mm Pre-Lordosed Rods and Rod Connectors Caddy

SPECIAL ORDER TIGER® 2 PRODUCT LISTING

Implant Caddies

Kit #KTG009

Standard Solid Shanks, Tulips, & Set Screws Caddy		
Catalog No.	Description	Qty
980-2000	Modular Head Assembly	20
980-2003	Modular Set Screw	20
380-5540-S	Screw, Solid Cortical-Cancellous, 5.5mm x 40mm	8
380-5545-S	Screw, Solid Cortical-Cancellous, 5.5mm x 45mm	8
380-5550-S	Screw, Solid Cortical-Cancellous, 5.5mm x 50mm	8
380-6540-S	Screw, Solid Cortical-Cancellous, 6.5mm x 40mm	8
380-6545-S	Screw, Solid Cortical-Cancellous, 6.5mm x 45mm	8
380-6550-S	Screw, Solid Cortical-Cancellous, 6.5mm x 50mm	8
380-6555-S	Screw, Solid Cortical-Cancellous, 6.5mm x 55mm	8
380-7540-S	Screw, Solid Cortical-Cancellous, 7.5mm x 40mm	8
380-7545-S	Screw, Solid Cortical-Cancellous, 7.5mm x 45mm	8
380-7550-S	Screw, Solid Cortical-Cancellous, 7.5mm x 50mm	8
380-7555-S	Screw, Solid Cortical-Cancellous, 7.5mm x 55mm	8

Kit #KTG012

Ø 5.5mm Pre-Lordosed Rods & Rod Connectors Caddy		
Catalog No.	Description	Qty
380-C035	Pre-Lordosed Rod, 5.5mm x 35mm	2
380-C040	Pre-Lordosed Rod, 5.5mm x 40mm	2
380-C045	Pre-Lordosed Rod, 5.5mm x 45mm	2
380-C050	Pre-Lordosed Rod, 5.5mm x 50mm	2
380-C055	Pre-Lordosed Rod, 5.5mm x 55mm	2
380-C060	Pre-Lordosed Rod, 5.5mm x 60mm	2
380-C065	Pre-Lordosed Rod, 5.5mm x 65mm	2
380-C070	Pre-Lordosed Rod, 5.5mm x 70mm	2
380-C075	Pre-Lordosed Rod, 5.5mm x 75mm	2
380-C080	Pre-Lordosed Rod, 5.5mm x 80mm	2
380-C085	Pre-Lordosed Rod, 5.5mm x 85mm	2
380-C090	Pre-Lordosed Rod, 5.5mm x 90mm	2
380-C095	Pre-Lordosed Rod, 5.5mm x 95mm	2
980-33	Rod Connector, 5.5mm, 32-33mm	1
980-35	Rod Connector, 5.5mm, 33-35mm	1
980-38	Rod Connector, 5.5mm, 35-38mm	1
980-44	Rod Connector, 5.5mm, 38-44mm	1
980-56	Rod Connector, 5.5mm, 44-56mm	1
980-80	Rod Connector, 5.5mm, 56-80mm	1

NOTE: The Standard Solid Shanks, Tulips & Set Screws Caddy and the Ø 5.5mm Pre-Lordosed Rods and Rod Connectors Caddy come standard in the Implant Tray, as listed on page 35. If you require 6.0mm rod compatibility, fenestrated screws, or more than 1 of each caddy—they can be special ordered using the Implant Caddies kit numbers listed above.

SPECIAL ORDER TIGER® 2

PRODUCT LISTING (Continued)

Auxiliary Reducers Tray 4

Kit #KTG004

Catalog No.	Description	Qty
14G00736	Tray, Auxiliary Reducers	1
14G00737	Inner Lid	1
989-1041	Pistol Grip Reducer	1
989-1042	Axial Reducer	1
989-1043	Dial-Down Reducer	2
989-1051	Provisional Set Screw Driver Beale	1

Auxiliary Implant Tray

Kit #KTG006

Catalog No.	Description	Qty
14G00739	Tray, Screw Shank Caddies	1
14G00737	Inner Lid	1
14G00743	Caddy, ø 4.5mm Screw Shanks	1
14G00744	Caddy, ø 5.5mm Screw Shanks	1
14G00745	Caddy, ø 6.5mm Screw Shanks	1
14G00746	Caddy, ø 7.5mm Screw Shanks	1
14G00747	Caddy, ø 8.5mm Screw Shanks	1

SPECIAL ORDER TIGER® 2 PRODUCT LISTING (Continued)

Auxiliary Implant Caddies

Kit #KTG017

Ø 4.5mm		
Catalog No.	Description	Qty
380-4535-S	Solid Cortical-Cancellous, 4.5mm x 35mm	8
380-4540-S	Solid Cortical-Cancellous, 4.5mm x 40mm	8
380-4545-S	Solid Cortical-Cancellous, 4.5mm x 45mm	8
380-4550-S	Solid Cortical-Cancellous, 4.5mm x 50mm	8
380-4555-S	Solid Cortical-Cancellous, 4.5mm x 55mm	8
380-4560-S	Solid Cortical-Cancellous, 4.5mm x 60mm	8

Kit #KTG018

Ø 5.5mm		
Catalog No.	Description	Qty
380-5535-S	Solid Cortical-Cancellous, 5.5mm x 35mm	8
380-5540-S	Solid Cortical-Cancellous, 5.5mm x 40mm	8
380-5545-S	Solid Cortical-Cancellous, 5.5mm x 45mm	8
380-5550-S	Solid Cortical-Cancellous, 5.5mm x 50mm	8
380-5555-S	Solid Cortical-Cancellous, 5.5mm x 55mm	8
380-5560-S	Solid Cortical-Cancellous, 5.5mm x 60mm	8

Kit #KTG019

Ø 6.5mm		
Catalog No.	Description	Qty
380-6535-S	Solid Cortical-Cancellous, 6.5mm x 35mm	8
380-6540-S	Solid Cortical-Cancellous, 6.5mm x 40mm	8
380-6545-S	Solid Cortical-Cancellous, 6.5mm x 45mm	8
380-6550-S	Solid Cortical-Cancellous, 6.5mm x 50mm	8
380-6555-S	Solid Cortical-Cancellous, 6.5mm x 55mm	8
380-6560-S	Solid Cortical-Cancellous, 6.5mm x 60mm	8

Kit #KTG020

Ø 7.5mm		
Catalog No.	Description	Qty
380-7535-S	Solid Cortical-Cancellous, 7.5mm x 35mm	8
380-7540-S	Solid Cortical-Cancellous, 7.5mm x 40mm	8
380-7545-S	Solid Cortical-Cancellous, 7.5mm x 45mm	8
380-7550-S	Solid Cortical-Cancellous, 7.5mm x 50mm	8
380-7555-S	Solid Cortical-Cancellous, 7.5mm x 55mm	8
380-7560-S	Solid Cortical-Cancellous, 7.5mm x 60mm	8

Kit #KTG021

Ø 8.5mm		
Catalog No.	Description	Qty
380-8535-S	Solid Cortical-Cancellous, 8.5mm x 35mm	8
380-8540-S	Solid Cortical-Cancellous, 8.5mm x 40mm	8
380-8545-S	Solid Cortical-Cancellous, 8.5mm x 45mm	8
380-8550-S	Solid Cortical-Cancellous, 8.5mm x 50mm	8
380-8555-S	Solid Cortical-Cancellous, 8.5mm x 55mm	8
380-8560-S	Solid Cortical-Cancellous, 8.5mm x 60mm	8

Kit #KTG022

Ø 9.5mm		
Catalog No.	Description	Qty
380-9535-S	Solid Cortical-Cancellous, 9.5mm x 35mm	8
380-9540-S	Solid Cortical-Cancellous, 9.5mm x 40mm	8
380-9545-S	Solid Cortical-Cancellous, 9.5mm x 45mm	8
380-9550-S	Solid Cortical-Cancellous, 9.5mm x 50mm	8
380-9555-S	Solid Cortical-Cancellous, 9.5mm x 55mm	8
380-9560-S	Solid Cortical-Cancellous, 9.5mm x 60mm	8

NOTE: The Ø 4.5mm, 5.5mm, 6.5mm, 7.5mm, and 8.5mm Screw Shank Caddies come in the Auxiliary Implant Tray, as listed on page 37. (The 9.5mm Screw Shanks Caddy does not.)

If you require more than 1 of any caddy, or you require the 9.5mm Caddy, they can be special ordered using the kit numbers listed above.

SPECIAL ORDER TIGER® 2 PRODUCT LISTING (Continued)

Ø 5.5mm Pre-Lordosed Long Ti Rods

Kit #KTG013

Ø 5.5mm		
Catalog No.	Description	Qty
380-C100	Pre-Lordosed Rod, 5.5mm x 100mm	2
380-C110	Pre-Lordosed Rod, 5.5mm x 110mm	2
380-C120	Pre-Lordosed Rod, 5.5mm x 120mm	2
380-C130	Pre-Lordosed Rod, 5.5mm x 130mm	2
380-C140	Pre-Lordosed Rod, 5.5mm x 140mm	2
380-C150	Pre-Lordosed Rod, 5.5mm x 150mm	2
380-C160	Pre-Lordosed Rod, 5.5mm x 160mm	2
380-C170	Pre-Lordosed Rod, 5.5mm x 170mm	2
380-C180	Pre-Lordosed Rod, 5.5mm x 180mm	2
380-C190	Pre-Lordosed Rod, 5.5mm x 190mm	2

Ø 5.5mm Straight Ti Rods

Kit #KTG014

Ø 5.5mm		
Catalog No.	Description	Qty
380-S035	Straight Rod, 5.5mm x 35mm	2
380-S040	Straight Rod, 5.5mm x 40mm	2
380-S045	Straight Rod, 5.5mm x 45mm	2
380-S050	Straight Rod, 5.5mm x 50mm	2
380-S055	Straight Rod, 5.5mm x 55mm	2
380-S060	Straight Rod, 5.5mm x 60mm	2
380-S065	Straight Rod, 5.5mm x 65mm	2
380-S070	Straight Rod, 5.5mm x 70mm	2
380-S075	Straight Rod, 5.5mm x 75mm	2
380-S080	Straight Rod, 5.5mm x 80mm	2
380-S085	Straight Rod, 5.5mm x 85mm	2
380-S090	Straight Rod, 5.5mm x 90mm	2
380-S095	Straight Rod, 5.5mm x 95mm	2
380-S100	Straight Rod, 5.5mm x 100mm	2
380-S105	Straight Rod, 5.5mm x 105mm	2
380-S110	Straight Rod, 5.5mm x 110mm	2
380-S115	Straight Rod, 5.5mm x 115mm	2
380-S120	Straight Rod, 5.5mm x 120mm	2
380-S130	Straight Rod, 5.5mm x 130mm	2
380-S140	Straight Rod, 5.5mm x 140mm	2
380-S150	Straight Rod, 5.5mm x 150mm	2
380-S200	Straight Rod, 5.5mm x 200mm	2

SPECIAL ORDER TIGER® 2 PRODUCT LISTING (Continued)

Ø 5.5mm Pre-Lordosed Long Cobalt Chrome (CoCrMo) Rods

Special Order

Ø 5.5mm		
Catalog No.	Description	Qty
350-C100	Pre-Lordosed Rod, 5.5mm x 100mm	2
350-C110	Pre-Lordosed Rod, 5.5mm x 110mm	2
350-C120	Pre-Lordosed Rod, 5.5mm x 120mm	2
350-C130	Pre-Lordosed Rod, 5.5mm x 130mm	2
350-C140	Pre-Lordosed Rod, 5.5mm x 140mm	2
350-C150	Pre-Lordosed Rod, 5.5mm x 150mm	2
350-C160	Pre-Lordosed Rod, 5.5mm x 160mm	2
350-C170	Pre-Lordosed Rod, 5.5mm x 170mm	2
350-C180	Pre-Lordosed Rod, 5.5mm x 180mm	2
350-C190	Pre-Lordosed Rod, 5.5mm x 190mm	2
350-C200	Pre-Lordosed Rod, 5.5mm x 200mm	2

Ø 5.5mm Deformity Rods

Kit #KTG042

Ø 5.5mm		
Catalog No.	Description	Qty
R5528-300	"S" Titanium Rod, 5.5mm x 300mm	2
R5528-400	"S" Titanium Rod, 5.5mm x 400mm	2
R5528-500	"S" Titanium Rod, 5.5mm x 500mm	2
R5527-300	"S" Cobalt Chrome Rod, 5.5mm x 300mm	2
R5527-400	"S" Cobalt Chrome Rod, 5.5mm x 400mm	2
R5527-500	"S" Cobalt Chrome Rod, 5.5mm x 500mm	2
380-S300	Titanium Rod, 5.5mm x 300mm	2
380-S400	Titanium Rod, 5.5mm x 400mm	2
380-S500	Titanium Rod, 5.5mm x 500mm	2
350-S300	Cobalt Chrome Rod, 5.5mm x 300mm	2
350-S400	Cobalt Chrome Rod, 5.5mm x 400mm	2
350-S500	Cobalt Chrome Rod, 5.5mm x 500mm	2

Ø 6.0mm Pre-Lordosed Ti Rods

Kit #KTG015

Ø 6.0mm		
Catalog No.	Description	Qty
381-C035	Pre-Lordosed Rod, 6.0mm x 35mm	2
381-C040	Pre-Lordosed Rod, 6.0mm x 40mm	2
381-C045	Pre-Lordosed Rod, 6.0mm x 45mm	2
381-C050	Pre-Lordosed Rod, 6.0mm x 50mm	2
381-C055	Pre-Lordosed Rod, 6.0mm x 55mm	2
381-C060	Pre-Lordosed Rod, 6.0mm x 60mm	2
381-C065	Pre-Lordosed Rod, 6.0mm x 65mm	2
381-C070	Pre-Lordosed Rod, 6.0mm x 70mm	2
381-C075	Pre-Lordosed Rod, 6.0mm x 75mm	2
381-C080	Pre-Lordosed Rod, 6.0mm x 80mm	2
381-C085	Pre-Lordosed Rod, 6.0mm x 85mm	2
381-C090	Pre-Lordosed Rod, 6.0mm x 90mm	2
381-C095	Pre-Lordosed Rod, 6.0mm x 95mm	2

Ø 6.0mm Long Ti Rods

Kit #KTG016

Ø 6.0mm		
Catalog No.	Description	Qty
381-C100	Pre-Lordosed Rod, 6.0mm x 100mm	2
381-C110	Pre-Lordosed Rod, 6.0mm x 110mm	2
381-C120	Pre-Lordosed Rod, 6.0mm x 120mm	2
381-C130	Pre-Lordosed Rod, 6.0mm x 130mm	2
381-C140	Pre-Lordosed Rod, 6.0mm x 140mm	2
381-C150	Pre-Lordosed Rod, 6.0mm x 150mm	2
381-C160	Pre-Lordosed Rod, 6.0mm x 160mm	2
381-C170	Pre-Lordosed Rod, 6.0mm x 170mm	2
381-C180	Pre-Lordosed Rod, 6.0mm x 180mm	2
381-C190	Pre-Lordosed Rod, 6.0mm x 190mm	2

SPECIAL ORDER TIGER® 2

PRODUCT LISTING (Continued)

Reduction Implants

Kit #KTG010

Catalog No.	Description	Qty
980-2001	Modular Reduction Head	20
980-2003	Modular Set Screw	20
380-5540-S	Screw, Solid Cortical-Cancellous, 5.5mm x 40mm	8
380-5545-S	Screw, Solid Cortical-Cancellous, 5.5mm x 45mm	8
380-5550-S	Screw, Solid Cortical-Cancellous, 5.5mm x 50mm	8
380-6540-S	Screw, Solid Cortical-Cancellous, 6.5mm x 40mm	8
380-6545-S	Screw, Solid Cortical-Cancellous, 6.5mm x 45mm	8
380-6550-S	Screw, Solid Cortical-Cancellous, 6.5mm x 50mm	8
380-6555-S	Screw, Solid Cortical-Cancellous, 6.5mm x 55mm	8
380-7540-S	Screw, Solid Cortical-Cancellous, 7.5mm x 40mm	8
380-7545-S	Screw, Solid Cortical-Cancellous, 7.5mm x 45mm	8
380-7550-S	Screw, Solid Cortical-Cancellous, 7.5mm x 50mm	8
380-7555-S	Screw, Solid Cortical-Cancellous, 7.5mm x 55mm	8

Fenestrated Screws

Kit #KTG011

Catalog No.	Description	Qty
980-2000	Modular Head Assembly	20
980-2003	Modular Set Screw	20
380-5540-F	Fenestrated, 5.5mm x 40mm	8
380-5545-F	Fenestrated, 5.5mm x 45mm	8
380-5550-F	Fenestrated, 5.5mm x 50mm	8
380-6540-F	Fenestrated, 6.5mm x 40mm	8
380-6545-F	Fenestrated, 6.5mm x 45mm	8
380-6550-F	Fenestrated, 6.5mm x 50mm	8
380-6555-F	Fenestrated, 6.5mm x 55mm	8
380-7540-F	Fenestrated, 7.5mm x 40mm	8
380-7545-F	Fenestrated, 7.5mm x 45mm	8
380-7550-F	Fenestrated, 7.5mm x 50mm	8
380-7555-F	Fenestrated, 7.5mm x 55mm	8

SPECIAL ORDER TIGER® 2 PRODUCT LISTING (Continued)

Fenestrated Screws

Kit #KTG031

Ø 5.5mm		
Catalog No.	Description	Qty
380-5535-F	Fenestrated Cortical-Cancellous, 5.5mm x 35mm	8
380-5540-F	Fenestrated Cortical-Cancellous, 5.5mm x 40mm	8
380-5545-F	Fenestrated Cortical-Cancellous, 5.5mm x 45mm	8
380-5550-F	Fenestrated Cortical-Cancellous, 5.5mm x 50mm	8
380-5555-F	Fenestrated Cortical-Cancellous, 5.5mm x 55mm	8
380-5560-F	Fenestrated Cortical-Cancellous, 5.5mm x 60mm	8

Kit #KTG032

Ø 6.5mm		
Catalog No.	Description	Qty
380-6535-F	Fenestrated Cortical-Cancellous, 6.5mm x 35mm	8
380-6540-F	Fenestrated Cortical-Cancellous, 6.5mm x 40mm	8
380-6545-F	Fenestrated Cortical-Cancellous, 6.5mm x 45mm	8
380-6550-F	Fenestrated Cortical-Cancellous, 6.5mm x 50mm	8
380-6555-F	Fenestrated Cortical-Cancellous, 6.5mm x 55mm	8
380-6560-F	Fenestrated Cortical-Cancellous, 6.5mm x 60mm	8

Kit #KTG033

Ø 7.5mm		
Catalog No.	Description	Qty
380-7535-F	Fenestrated Cortical-Cancellous, 7.5mm x 35mm	8
380-7540-F	Fenestrated Cortical-Cancellous, 7.5mm x 40mm	8
380-7545-F	Fenestrated Cortical-Cancellous, 7.5mm x 45mm	8
380-7550-F	Fenestrated Cortical-Cancellous, 7.5mm x 50mm	8
380-7555-F	Fenestrated Cortical-Cancellous, 7.5mm x 55mm	8
380-7560-F	Fenestrated Cortical-Cancellous, 7.5mm x 60mm	8

Kit #KTG034

Ø 8.5mm		
Catalog No.	Description	Qty
380-8535-F	Fenestrated Cortical-Cancellous, 8.5mm x 35mm	8
380-8540-F	Fenestrated Cortical-Cancellous, 8.5mm x 40mm	8
380-8545-F	Fenestrated Cortical-Cancellous, 8.5mm x 45mm	8
380-8550-F	Fenestrated Cortical-Cancellous, 8.5mm x 50mm	8
380-8555-F	Fenestrated Cortical-Cancellous, 8.5mm x 55mm	8
380-8560-F	Fenestrated Cortical-Cancellous, 8.5mm x 60mm	8

SPECIAL ORDER TIGER® 2

PRODUCT LISTING (Continued)

Sacroiliac Fenestrated Screws

Kit #KTG035

Ø 7.5mm		
Catalog No.	Description	Qty
383-7560-F	Fenestrated Standard, 7.5mm x 60mm	2
383-7565-F	Fenestrated Standard, 7.5mm x 65mm	2
383-7570-F	Fenestrated Standard, 7.5mm x 70mm	2
383-7575-F	Fenestrated Standard, 7.5mm x 75mm	2
383-7580-F	Fenestrated Standard, 7.5mm x 80mm	2
383-7585-F	Fenestrated Standard, 7.5mm x 85mm	2
383-7590-F	Fenestrated Standard, 7.5mm x 90mm	2
383-7595-F	Fenestrated Standard, 7.5mm x 95mm	2
383-75100-F	Fenestrated Standard, 7.5mm x 100mm	2
383-75105-F	Fenestrated Standard, 7.5mm x 105mm	2
383-75110-F	Fenestrated Standard, 7.5mm x 110mm	2
Ø 8.5mm		
Catalog No.	Description	Qty
383-8560-F	Fenestrated Standard, 8.5mm x 60mm	2
383-8565-F	Fenestrated Standard, 8.5mm x 65mm	2
383-8570-F	Fenestrated Standard, 8.5mm x 70mm	2
383-8575-F	Fenestrated Standard, 8.5mm x 75mm	2
383-8580-F	Fenestrated Standard, 8.5mm x 80mm	2
383-8585-F	Fenestrated Standard, 8.5mm x 85mm	2
383-8590-F	Fenestrated Standard, 8.5mm x 90mm	2
383-8595-F	Fenestrated Standard, 8.5mm x 95mm	2
383-85100-F	Fenestrated Standard, 8.5mm x 100mm	2
383-85105-F	Fenestrated Standard, 8.5mm x 105mm	2
383-85110-F	Fenestrated Standard, 8.5mm x 110mm	2

Ø 9.5mm		
Catalog No.	Description	Qty
383-9560-F	Fenestrated Standard, 9.5mm x 60mm	2
383-9565-F	Fenestrated Standard, 9.5mm x 65mm	2
383-9570-F	Fenestrated Standard, 9.5mm x 70mm	2
383-9575-F	Fenestrated Standard, 9.5mm x 75mm	2
383-9580-F	Fenestrated Standard, 9.5mm x 80mm	2
383-9585-F	Fenestrated Standard, 9.5mm x 85mm	2
383-9590-F	Fenestrated Standard, 9.5mm x 90mm	2
383-9595-F	Fenestrated Standard, 9.5mm x 95mm	2
383-95100-F	Fenestrated Standard, 9.5mm x 100mm	2
383-95105-F	Fenestrated Standard, 9.5mm x 105mm	2
383-95110-F	Fenestrated Standard, 9.5mm x 110mm	2
Ø 10.5mm		
Catalog No.	Description	Qty
383-10560-F	Fenestrated Standard, 10.5mm x 60mm	2
383-10565-F	Fenestrated Standard, 10.5mm x 65mm	2
383-10570-F	Fenestrated Standard, 10.5mm x 70mm	2
383-10575-F	Fenestrated Standard, 10.5mm x 75mm	2
383-10580-F	Fenestrated Standard, 10.5mm x 80mm	2
383-10585-F	Fenestrated Standard, 10.5mm x 85mm	2
383-10590-F	Fenestrated Standard, 10.5mm x 90mm	2
383-10595-F	Fenestrated Standard, 10.5mm x 95mm	2
383-105100-F	Fenestrated Standard, 10.5mm x 100mm	2
383-105105-F	Fenestrated Standard, 10.5mm x 105mm	2
383-105110-F	Fenestrated Standard, 10.5mm x 110mm	2

SPECIAL ORDER TIGER® 2 PRODUCT LISTING (Continued)

Sacroiliac Screws

Kit #KTG023

ø 7.5mm		
Catalog No.	Description	Qty
383-7560-S	Solid Standard, 7.5mm x 60mm	2
383-7565-S	Solid Standard, 7.5mm x 65mm	2
383-7570-S	Solid Standard, 7.5mm x 70mm	2
383-7575-S	Solid Standard, 7.5mm x 75mm	2
383-7580-S	Solid Standard, 7.5mm x 80mm	2
383-7585-S	Solid Standard, 7.5mm x 85mm	2
383-7590-S	Solid Standard, 7.5mm x 90mm	2
383-7595-S	Solid Standard, 7.5mm x 95mm	2
383-75100-S	Solid Standard, 7.5mm x 100mm	2
383-75105-S	Solid Standard, 7.5mm x 105mm	2
383-75110-S	Solid Standard, 7.5mm x 110mm	2
ø 8.5mm		
Catalog No.	Description	Qty
383-8560-S	Solid Standard, 8.5mm x 60mm	2
383-8565-S	Solid Standard, 8.5mm x 65mm	2
383-8570-S	Solid Standard, 8.5mm x 70mm	2
383-8575-S	Solid Standard, 8.5mm x 75mm	2
383-8580-S	Solid Standard, 8.5mm x 80mm	2
383-8585-S	Solid Standard, 8.5mm x 85mm	2
383-8590-S	Solid Standard, 8.5mm x 90mm	2
383-8595-S	Solid Standard, 8.5mm x 95mm	2
383-85100-S	Solid Standard, 8.5mm x 100mm	2
383-85105-S	Solid Standard, 8.5mm x 105mm	2
383-85110-S	Solid Standard, 8.5mm x 110mm	2

ø 9.5mm		
Catalog No.	Description	Qty
383-9560-S	Solid Standard, 9.5mm x 60mm	2
383-9565-S	Solid Standard, 9.5mm x 65mm	2
383-9570-S	Solid Standard, 9.5mm x 70mm	2
383-9575-S	Solid Standard, 9.5mm x 75mm	2
383-9580-S	Solid Standard, 9.5mm x 80mm	2
383-9585-S	Solid Standard, 9.5mm x 85mm	2
383-9590-S	Solid Standard, 9.5mm x 90mm	2
383-9595-S	Solid Standard, 9.5mm x 95mm	2
383-95100-S	Solid Standard, 9.5mm x 100mm	2
383-95105-S	Solid Standard, 9.5mm x 105mm	2
383-95110-S	Solid Standard, 9.5mm x 110mm	2
ø 10.5mm		
Catalog No.	Description	Qty
383-10560-S	Solid Standard, 10.5mm x 60mm	2
383-10565-S	Solid Standard, 10.5mm x 65mm	2
383-10570-S	Solid Standard, 10.5mm x 70mm	2
383-10575-S	Solid Standard, 10.5mm x 75mm	2
383-10580-S	Solid Standard, 10.5mm x 80mm	2
383-10585-S	Solid Standard, 10.5mm x 85mm	2
383-10590-S	Solid Standard, 10.5mm x 90mm	2
383-10595-S	Solid Standard, 10.5mm x 95mm	2
383-105100-S	Solid Standard, 10.5mm x 100mm	2
383-105105-S	Solid Standard, 10.5mm x 105mm	2
383-105110-S	Solid Standard, 10.5mm x 110mm	2

SPECIAL ORDER TIGER® 2

PRODUCT LISTING (Continued)

Cannulated Screws

Kit #KTG024

Ø 4.5mm		
Catalog No.	Description	Qty
380-4535-C	Cannulated Cortical-Cancellous, 4.5mm x 35mm	8
380-4540-C	Cannulated Cortical-Cancellous, 4.5mm x 40mm	8
380-4545-C	Cannulated Cortical-Cancellous, 4.5mm x 45mm	8
380-4550-C	Cannulated Cortical-Cancellous, 4.5mm x 50mm	8
380-4555-C	Cannulated Cortical-Cancellous, 4.5mm x 55mm	8
380-4560-C	Cannulated Cortical-Cancellous, 4.5mm x 60mm	8

Kit #KTG025

Ø 5.5mm		
Catalog No.	Description	Qty
380-5535-C	Cannulated Cortical-Cancellous, 5.5mm x 35mm	8
380-5540-C	Cannulated Cortical-Cancellous, 5.5mm x 40mm	8
380-5545-C	Cannulated Cortical-Cancellous, 5.5mm x 45mm	8
380-5550-C	Cannulated Cortical-Cancellous, 5.5mm x 50mm	8
380-5555-C	Cannulated Cortical-Cancellous, 5.5mm x 55mm	8
380-5560-C	Cannulated Cortical-Cancellous, 5.5mm x 60mm	8

Kit #KTG026

Ø 6.5mm		
Catalog No.	Description	Qty
380-6535-C	Cannulated Cortical-Cancellous, 6.5mm x 35mm	8
380-6540-C	Cannulated Cortical-Cancellous, 6.5mm x 40mm	8
380-6545-C	Cannulated Cortical-Cancellous, 6.5mm x 45mm	8
380-6550-C	Cannulated Cortical-Cancellous, 6.5mm x 50mm	8
380-6555-C	Cannulated Cortical-Cancellous, 6.5mm x 55mm	8
380-6560-C	Cannulated Cortical-Cancellous, 6.5mm x 60mm	8

Kit #KTG027

Ø 7.5mm		
Catalog No.	Description	Qty
380-7535-C	Cannulated Cortical-Cancellous, 7.5mm x 35mm	8
380-7540-C	Cannulated Cortical-Cancellous, 7.5mm x 40mm	8
380-7545-C	Cannulated Cortical-Cancellous, 7.5mm x 45mm	8
380-7550-C	Cannulated Cortical-Cancellous, 7.5mm x 50mm	8
380-7555-C	Cannulated Cortical-Cancellous, 7.5mm x 55mm	8
380-7560-C	Cannulated Cortical-Cancellous, 7.5mm x 60mm	8

Kit #KTG028

Ø 8.5mm		
Catalog No.	Description	Qty
380-8535-C	Cannulated Cortical-Cancellous, 8.5mm x 35mm	8
380-8540-C	Cannulated Cortical-Cancellous, 8.5mm x 40mm	8
380-8545-C	Cannulated Cortical-Cancellous, 8.5mm x 45mm	8
380-8550-C	Cannulated Cortical-Cancellous, 8.5mm x 50mm	8
380-8555-C	Cannulated Cortical-Cancellous, 8.5mm x 55mm	8
380-8560-C	Cannulated Cortical-Cancellous, 8.5mm x 60mm	8

Kit #KTG029

Ø 9.5mm		
Catalog No.	Description	Qty
380-9535-C	Cannulated Cortical-Cancellous, 9.5mm x 35mm	8
380-9540-C	Cannulated Cortical-Cancellous, 9.5mm x 40mm	8
380-9545-C	Cannulated Cortical-Cancellous, 9.5mm x 45mm	8
380-9550-C	Cannulated Cortical-Cancellous, 9.5mm x 50mm	8
380-9555-C	Cannulated Cortical-Cancellous, 9.5mm x 55mm	8
380-9560-C	Cannulated Cortical-Cancellous, 9.5mm x 60mm	8

SPECIAL ORDER TIGER® 2 PRODUCT LISTING (Continued)

Sacroiliac Cannulated Screws

Kit #KTG030

ø 7.5mm		
Catalog No.	Description	Qty
383-7560-C	Cannulated Standard, 7.5mm x 60mm	2
383-7565-C	Cannulated Standard, 7.5mm x 65mm	2
383-7570-C	Cannulated Standard, 7.5mm x 70mm	2
383-7575-C	Cannulated Standard, 7.5mm x 75mm	2
383-7580-C	Cannulated Standard, 7.5mm x 80mm	2
383-7585-C	Cannulated Standard, 7.5mm x 85mm	2
383-7590-C	Cannulated Standard, 7.5mm x 90mm	2
383-7595-C	Cannulated Standard, 7.5mm x 95mm	2
383-75100-C	Cannulated Standard, 7.5mm x 100mm	2
383-75105-C	Cannulated Standard, 7.5mm x 105mm	2
383-75110-C	Cannulated Standard, 7.5mm x 110mm	2
ø 8.5mm		
Catalog No.	Description	Qty
383-8560-C	Cannulated Standard, 8.5mm x 60mm	2
383-8565-C	Cannulated Standard, 8.5mm x 65mm	2
383-8570-C	Cannulated Standard, 8.5mm x 70mm	2
383-8575-C	Cannulated Standard, 8.5mm x 75mm	2
383-8580-C	Cannulated Standard, 8.5mm x 80mm	2
383-8585-C	Cannulated Standard, 8.5mm x 85mm	2
383-8590-C	Cannulated Standard, 8.5mm x 90mm	2
383-8595-C	Cannulated Standard, 8.5mm x 95mm	2
383-85100-C	Cannulated Standard, 8.5mm x 100mm	2
383-85105-C	Cannulated Standard, 8.5mm x 105mm	2
383-85110-C	Cannulated Standard, 8.5mm x 110mm	2

ø 9.5mm		
Catalog No.	Description	Qty
383-9560-C	Cannulated Standard, 9.5mm x 60mm	2
383-9565-C	Cannulated Standard, 9.5mm x 65mm	2
383-9570-C	Cannulated Standard, 9.5mm x 70mm	2
383-9575-C	Cannulated Standard, 9.5mm x 75mm	2
383-9580-C	Cannulated Standard, 9.5mm x 80mm	2
383-9585-C	Cannulated Standard, 9.5mm x 85mm	2
383-9590-C	Cannulated Standard, 9.5mm x 90mm	2
383-9595-C	Cannulated Standard, 9.5mm x 95mm	2
383-95100-C	Cannulated Standard, 9.5mm x 100mm	2
383-95105-C	Cannulated Standard, 9.5mm x 105mm	2
383-95110-C	Cannulated Standard, 9.5mm x 110mm	2
ø 10.5mm		
Catalog No.	Description	Qty
383-10560-C	Cannulated Standard, 10.5mm x 60mm	2
383-10565-C	Cannulated Standard, 10.5mm x 65mm	2
383-10570-C	Cannulated Standard, 10.5mm x 70mm	2
383-10575-C	Cannulated Standard, 10.5mm x 75mm	2
383-10580-C	Cannulated Standard, 10.5mm x 80mm	2
383-10585-C	Cannulated Standard, 10.5mm x 85mm	2
383-10590-C	Cannulated Standard, 10.5mm x 90mm	2
383-10595-C	Cannulated Standard, 10.5mm x 95mm	2
383-105100-C	Cannulated Standard, 10.5mm x 100mm	2
383-105105-C	Cannulated Standard, 10.5mm x 105mm	2
383-105110-C	Cannulated Standard, 10.5mm x 110mm	2

SPECIAL ORDER TIGER® 2

PRODUCT LISTING (Continued)

Pedicle Prep Cannulated

Kit #KTG044

Catalog No.	Description	Qty
14G00733	Tray, Pedicle Prep	1
14G00737	Inner Lid	1
989-1002	Ball Tip Probe, SS	1
989-1003	Pedicle Probe, Straight Lenke	1
989-1004	Pedicle Probe, Curved Lenke	1
989-1005	Pedicle Probe, Straight Steffee	1
989-1006	Pedicle Probe, Curved Steffee	1
989-1007	Pedicle Awl, Awl Stop 4-sided Tip	1
989-1011-45	Tap, 4.5mm Cannulated	1
989-1011-55	Tap, 5.5mm Cannulated	1
989-1011-65	Tap, 6.5mm Cannulated	1
989-1011-75	Tap, 7.5mm Cannulated	1
Z-1057	Axial Ratcheting, 1/4" Drive	2
Z-1058	T-Ratcheting, 1/4" Drive	2

Screw Placement Cannulated

Kit #KTG045

Catalog No.	Description	Qty
14G00734	Tray, Screw Placement	1
989-1016-CP	Shank Driver 8.5" Cannulated Powerease	2
989-1017-CP	Polyaxial 8.5" Powerease	2
989-1017-CPR	Reduction Tab 8.5" Cannulated Powerease	2
989-1020-C	Decorticator, Cannulated	1
989-1021	Head Inserter	2
989-1047	Counter Torque Wrench	1
Z-1059	T-Torque Limiting 1/4" Drive	1
989-1049	Provisional Set Screw Driver	2
989-1052	Provisional Double Ended Set Screw Driver	2
989-1056	Final Locking Final Tightener	2

SPECIAL ORDER TIGER® 2 PRODUCT LISTING (Continued)

Rods Connectors

Kit #KTG041

Rod Connectors		
Catalog No.	Description	Qty
880-60-0103	Rod Connector, U-Rod Left 5.5mm Rod, 5.5/6.0mm	1
880-60-0203	Rod Connector, U-Rod Right 5.5mm Rod, 5.5/6.0mm	1
880-70-0103	Rod Connector, Bypass Rod Single, Left 5.5mm Rod, 5.5/6.0mm	1
880-70-0203	Rod Connector, Bypass Rod Single, Right 5.5mm Rod, 5.5/6.0mm	1
880-80-0103	Rod Connector, Bypass Rod Double, Left 5.5mm Rod, 5.5/6.0mm	1
880-80-0203	Rod Connector, Bypass Rod Double, Right 5.5mm Rod, 5.5/6.0mm	1
880-45-03	Rod Connector, Rod with Connector 5.5mm Rod, 5.5/6.0mm	2
880-90-12	Rod Connector, Z-Rod 12mm Offset, 5.5mm Rod, 150x150	2
880-90-14	Rod Connector, Z-Rod 14mm Offset, 5.5mm Rod, 150x300	2

Top Loading		
Catalog No.	Description	Qty
880-3300-10	Rod Connector, Parallel Top Loading 10mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-3300-12	Rod Connector, Parallel Top Loading 12mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-3300-14	Rod Connector, Parallel Top Loading 14mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-3310	Rod Connector, Parallel Top Loading 10° Offset, 5.5/6.0mm x 5.5/6.0mm	2
880-3320	Rod Connector, Parallel Top Loading 20° Offset, 5.5/6.0mm x 5.5/6.0mm	2
880-3330	Rod Connector, Parallel Top Loading 30° Offset, 5.5/6.0mm x 5.5/6.0mm	2
Side Loading		
Catalog No.	Description	Qty
880-1233-10	Rod Connector, Parallel Side Loading/Closed 10mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-1233-12	Rod Connector, Parallel Side Loading/Closed 12mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-1233-14	Rod Connector, Parallel Side Loading/Closed 14mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-2233-10	Rod Connector, Parallel Side Loading 10mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-2233-12	Rod Connector, Parallel Side Loading 12mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-2233-14	Rod Connector, Parallel Side Loading 14mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
Closed		
Catalog No.	Description	Qty
880-1133-10	Rod Connector, Parallel Closed 10mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-1133-12	Rod Connector, Parallel Closed 12mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-1133-14	Rod Connector, Parallel Closed 14mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-4033	Rod Connector, Axial Closed 5.5/6.0mm x 5.5/6.0mm	2

SPECIAL ORDER TIGER® 2

PRODUCT LISTING (Continued)

Cross Connectors

Kit #KTG036

Catalog No.	Description	Qty
980-33	Rod Connector, 5.5mm, 32-33mm	1
980-35	Rod Connector, 5.5mm, 33-35mm	1
980-38	Rod Connector, 5.5mm, 35-38mm	1
980-44	Rod Connector, 5.5mm, 38-44mm	1
980-56	Rod Connector, 5.5mm, 44-56mm	1
980-80	Rod Connector, 5.5mm, 56-80mm	1

Top Loading Connectors

Kit #KTG037

Catalog No.	Description	Qty
880-3300-10	Rod Connector, Parallel Top Loading 10mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-3300-12	Rod Connector, Parallel Top Loading 12mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-3300-14	Rod Connector, Parallel Top Loading 14mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-3310	Rod Connector, Parallel Top Loading 10° Offset, 5.5/6.0mm x 5.5/6.0mm	2
880-3320	Rod Connector, Parallel Top Loading 20° Offset, 5.5/6.0mm x 5.5/6.0mm	2
880-3330	Rod Connector, Parallel Top Loading 30° Offset, 5.5/6.0mm x 5.5/6.0mm	2

SPECIAL ORDER TIGER® 2 PRODUCT LISTING (Continued)

Side Loading Connectors

Kit #KTG038

Catalog No.	Description	Qty
880-1233-10	Rod Connector, Parallel Side Loading/Closed 10mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-1233-12	Rod Connector, Parallel Side Loading/Closed 12mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-1233-14	Rod Connector, Parallel Side Loading/Closed 14mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-2233-10	Rod Connector, Parallel Side Loading 10mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-2233-12	Rod Connector, Parallel Side Loading 12mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-2233-14	Rod Connector, Parallel Side Loading 14mm Offset, 5.5/6.0mm x 5.5/6.0mm	4

Closed Connectors

Kit #KTG039

Catalog No.	Description	Qty
880-1133-10	Rod Connector, Parallel Closed 10mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-1133-12	Rod Connector, Parallel Closed 12mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-1133-14	Rod Connector, Parallel Closed 14mm Offset, 5.5/6.0mm x 5.5/6.0mm	4
880-4033	Rod Connector, Axial Closed 5.5/6.0mm x 5.5/6.0mm	2

SPECIAL ORDER TIGER® 2

PRODUCT LISTING (Continued)

Lateral Offset Connectors

Kit #KTG040

Catalog No.	Description	Qty
880-50-15	Rod Connector, Lateral Offset 15mm Neutral Offset, 5.5/6.0mm	2
880-50-30	Rod Connector, Lateral Offset 30mm Neutral Offset, 5.5/6.0mm	2
880-50-60	Rod Connector, Lateral Offset 60mm Neutral Offset, 5.5/6.0mm	2
880-51-15	Rod Connector, Lateral Offset 15mm 75° Offset, 5.5/6.0mm	1
880-51-30	Rod Connector, Lateral Offset 30mm 75° Offset, 5.5/6.0mm	1
880-51-60	Rod Connector, Lateral Offset 60mm 75° Offset, 5.5/6.0mm	1
880-52-15	Rod Connector, Lateral Offset 15mm 105° Offset, 5.5/6.0mm	1
880-52-30	Rod Connector, Lateral Offset 30mm 105° Offset, 5.5/6.0mm	1
880-52-60	Rod Connector, Lateral Offset 60mm 105° Offset, 5.5/6.0mm	1

INDICATIONS FOR USE

Zavation Tiger® 2 System

Device Description

The Zavation Tiger® 2 System is comprised of polyaxial pedicle screws, rods and crosslinks. The Zavation Tiger® 2 System can be used for single or multiple level fixations. The pedicle screws are available in various lengths and diameters. The rods are available in straight and pre-lordosed (curved) configurations. The system has variable length cross connectors. Subject instruments are intended for use only with Zavation pedicle or OCT screws.

Indications for Use

The Zavation Tiger® 2 System is a pedicle screw system 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 spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Zavation Tiger® 2 System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Zavation Tiger® 2 System when used as anterior thoracic/lumbar screw fixation systems, is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The Zavation Tiger® 2 System Fenestrated Screws are intended to be used with saline and radiopaque dye.

Materials

The Zavation Tiger® 2 System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136 and cobalt chrome alloy (Co-28Cr-6Mo) as described by ASTM F1537.

Contraindications

Contraindications include, but not limited to:

The Zavation Tiger® 2 System is contraindicated in patients with a systemic infection, with a local inflammation at the bone site, or with rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis. Do not use this system in patients with known or suspected metal allergies.

Use of the system is also contraindicated in patients with any other medical, surgical or psychological condition that would preclude potential benefits of internal fixation surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other disease, elevation of white blood cells or a marked shift in white blood cell differential count.

INDICATIONS FOR USE (Continued)

Potential Adverse Events

All the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

- Early or late loosening of any or disassembly, bending, and/or breakage of any or all of the components
- Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection
- Vertebral body fracture at, above, or below the level of surgery.
- Loss of neurological function, including paralysis (complete or incomplete).
- Non-union, delayed union.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Hemorrhage
- Cessation of any potential growth of the operated portion of the spine.
- Death

Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

Warnings and Precautions

- 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 (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
- Non-sterile, the screws, rods and instruments are sold non-sterile, and therefore, must be sterilized before each use
- Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct
- Do not reuse implants; discard used, damaged, or otherwise suspect implants
- Single use only
- The Zavation Tiger® 2 System components should not be used with components of any other system or manufacturer.
- The Zavation Tiger® 2 System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Zavation Tiger® 2 System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.
- The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). The device is intended only to be used with saline or radiopaque dye.

INDICATIONS FOR USE (Continued)

Precaution

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.

Implant Selection

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative

- Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- Carefully screen the patient, choosing only those that fit the indications described above.
- Care should be exercised in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Store away from corrosive environments.
- An adequate inventory should be available at surgery of those expected to be used.
- All components and instruments should be cleaned and sterilized prior to each use. Additional sterile components should be available in case of an unexpected need.

Intraoperative

- Instructions should be carefully followed.
- Extreme caution should be used around the spinal cord and nerve roots.
- The implant surface should not be scratched or notched since such actions may reduce the functional strength of the construct.
- The final operative procedure with the Zavation Tiger® 2 System must include tightening of all the set screws to the torque values indicated by the surgical technique with the instruments provided.

Postoperative

- Detailed instructions should be given to the patient regarding care and limitations, if any.
- To achieve maximum results, the patient should not be exposed to excessive mechanical vibrations. The patient should not smoke or consume alcohol during the healing process.
- The patient should be advised of their limitations and taught to compensate for this permanent physical restriction in body motion.
- If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the implant. It is important that immobilization of the spinal segment be maintained until fusion has occurred.
- The implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the spine during the normal healing process. After the spine is fused, the devices serve no functional purpose and should be removed.

INDICATIONS FOR USE (Continued)

Pre-Cleaning / Cleaning and Sterilization Procedure Recommended for Reusable Instruments (and Trays)

For safety reasons, reusable instruments must be pre-cleaned, cleaned and sterilized before use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following table.

Sterilization trays should be thoroughly cleaned using either the Automated or Manual procedure that is detailed below for instruments. It is acceptable to skip the ultrasonic cleaner step for the sterilization trays if the inspection criteria provided below are acceptable for the tray.

Cautions: Long, narrow cannulations and blind holes require particular attention during cleaning.

Limitations on Reprocessing: Repeated processing has minimal effect on these instruments.
End of life is determined by wear and damage due to use.

1. Point of Use: Remove all visual soil with disposable cloth/paper wipe. Soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be soaked immediately place a moist towel around them until they can be cleaned.

2. Containment and Transportation: Avoid damage and minimize time before cleaning.

3. Preparation for Cleaning: Dis-assemble instruments as required by the surgical technique guide.

4. Thoroughly clean instruments per one of the following: Manual or Automated

Manual

4.1 Manual Pre-Cleaning:

- Prepare a pH neutral, enzymatic detergent soak with warm water (approximately 35-40°C) per the instructions of the enzymatic solution manufacturer.
- Soak the instrument for a minimum of 15 minutes. Actuate any mechanisms and slide moving parts to the extreme positions to ensure the cleaning solution contacts all the surfaces.
- Change the soak solution if the solution becomes visibly soiled.
- While still in the soak solution, use a soft brush to remove all exterior soil. Thoroughly scrub any grooves, slots, threads, teeth, ratchets, or hinges. Use an appropriate size cleaning brush to thoroughly brush the entire length of any internal lumens a minimum of five times per lumen.
- Rinse instruments thoroughly with warm (approximately 35-40°C) critical water, such as reverse osmosis, distilled, and/or deionized water, taking care to flush all lumens or crevices, for at least one minute, until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until water runs clear.

Automated

4.1 Automated Pre-Cleaning:

- Automated washing shall be conducted in a validated washer-disinfector.
- An example of a validated cycle used for cleaning validation includes:
 - Wash 45°C 4 minutes dose pump 4 (detergent) 5mL
 - Wash 60°C 3 minutes
 - Rinse with unheated critical water, such as reverse osmosis, distilled, and/or deionized water for 1 minute.
 - Rinse 60°C 1 minute

INDICATIONS FOR USE (Continued)

4.2 Manual Cleaning:

- Prepare a fresh pH neutral enzymatic cleaning solution and sonicate the instruments and subassemblies for a minimum of 15 minutes in an ultrasonic bath. After sonication, rinse instruments again under clean running water for at least one minute until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until the water runs clear.
- Dry the exterior of the instruments with a clean, soft cloth. Use clean compressed air or 70% isopropyl to dry any lumens or crevices where water may become trapped.

Inspection:

- Visually inspect each device to ensure all visible blood and soil has been removed. If not visually clean repeat step 4 above until clean or appropriately dispose of device if unable to get visually clean.
- Check disassembled instruments with long slender features for distortion.
- Inspect the disassembled devices for any cracking, pitting, or other signs of deterioration

Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.

Sterilization: See sterilization procedure.

Storage: Control environment

Additional Information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

Manufacturer Contact: Contact local representative or call customer service at 601-919-1119.

Sterilization: The Zavation Tiger® 2 System should be sterilized by the hospital using the recommended cycle: Do not stack trays in the chamber.

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Gravity	270°F / 132°C	15 minutes	15 minutes
Steam	Pre-Vacuum	270°F / 132°C	4 minutes	30 minutes

4.2 Washer Disinfector Cleaning:

- Automated washing shall be conducted in a validated washer-disinfector.
- An example of a validated cycle used for cleaning validation includes:
 - Thermal Disinfection A0 93°C
 - A0 value: A03000
 - Dry 123°C air 14 minutes

INDICATIONS FOR USE (Continued)

Instrument Maintenance: Lubricate hinges, threads and other moving parts with a commercial water-based surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear. Follow lubricant manufacturer's instructions.

Product Complaints: Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Zavation Medical Products LLC, 3670 Flowood Drive, Flowood, MS 39232, USA, Telephone: 601-919-1119

Further Information: A recommended surgical technique for the use of this system is available upon request from Zavation Medical Products LLC, 3670 Flowood Drive, Flowood, MS 39232, USA, Telephone: 601-919-1119

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.



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