Surgical Technique
The V2F Anterior Fixation System has been designed for use in the treatment of thoracolumbar burst fractures, tumors, disc degeneration and other unstable pathologies of the anterior spine. The V2F System consists of a wide range of plates and screws designed to accommodate the varying anatomy of the thoracolumbar spine. The system provides surgeons the ability to rigidly fixate the screw to the plate using a Fixed Cap Screw or semi-constrain the screw to the plate using a Variable Cap Screw. The combination of features, technique options and the wide range of instruments and implants make the Zimmer V2F Anterior Fixation System one of the most versatile and comprehensive systems on the market.
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Indications

The V2F Anterior Fixation System is indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.
Contraindications

Contraindications for use of the V2F Anterior Fixation System include:

• Use in the cervical spine
• Active systemic or local infection
• Local inflammation, with or without fever or leukocytosis
• Pregnancy
• Diseases or conditions other than those specifically described in the Indications section
• Use in the posterior elements (pedicles) of the cervical, thoracic, or lumbar vertebrae
• Where attempted correction exceeds the limits of physiological conditions
• Uncooperative patient or patient with neurologic disorders rendering the patient incapable of following instructions
• Metabolic disorders that may impair bone formation
• Inadequate bone stock to support the device
• Inability to restrict high activity level
• Suspected or documented metal allergy or intolerance
• Any medical or surgical condition that would preclude the potential benefit of spinal implant surgery or prevent secure component fixation that has the potential to decrease the useful life of the device, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
• Any patient with inadequate tissue coverage over the operative site, or inadequate bone stock or bone quality such as in the sacrum
• Any time implant utilization would interfere with anatomical structures or expected physiological performance
• Obesity
• Poor prognosis for good wound healing (e.g. decubitis ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition)
V2F Implants

**Cap Screws**
Fixed (Gold) 07.01660.001
Variable (Green) 07.01661.001

**Screws**
6mm (Aquamarine) 07.01658.001-007
7mm (Magenta) 07.01659.001-007
30-60mm in 5mm increments

**Thoracolumbar Plates**
07.01657.001-021
30-130mm in 5mm increments
V2F Instruments

**Torque Wrench**  
07.01669.001  
Used in conjunction with the Cap Screw Driver for final tightening of Cap Screws, ¼ in. square drive. 50 in/lbs.

**Ratcheting T-Handle**  
07.01736.001  
Connects to Drills, Tap, Screw Driver, and Cap Screw Driver, ¼ in. square drive.

**Ratcheting Inline Handle**  
07.01667.001  
Connects to Drills, Tap, Screw Driver and Cap Screw Driver, ¼ in. square drive.

**Plate Holder**  
07.01664.001  
Used alone or in conjunction with Plate Holder Handle to assist with initial plate placement.

**Screw Driver**  
07.01670.001  
Used to drive screw and also tighten or loosen ATO Guides to plate, incorporates retention spring technology to hold screw, 4.5mm Hex.

**Cap Screw Driver**  
07.01670.001  
Used to insert Cap Screw incorporates retention feature to hold Cap Screws, T25 – Hexalobe.

**6.0mm Tap**  
07.01674.001  
Optional instrument for tapping screw hole prior to screw placement. Length is 61mm, laser marked lines on distal end represent 10mm increments.

**60mm Drill**  
07.01671.002  
Used for drilling screw hole prior to screw placement. Length is 60mm, laser marked lines on distal end represent 10mm increments.
25mm Drill
07.01671.001
Used for drilling screw hole prior to screw placement. Length is 25mm, laser marked lines on distal end represent 10mm increments.

ATO Guide Handle
07.01665.001
Connects to ATO Holder, can be attached in 6 different positions to facilitate screw prep and placement through ATO Guides.

All-Through-One (ATO) Holder
07.01735.001
Connects to ATO Guide, can be used to attach ATO Guide to plate in-situ or prior to plate placement, can also be used as plate holder in conjunction with ATO Guide Handle.

All-Through-One (ATO) Guides
07.01662.001 (superior)
07.01663.001 (inferior)
All-Though-One Guides attach to plates and provide controlled trajectory for screw preparation and placement.

Awl
07.01676.001
Awl can be used through ATO Guides or in a freehand approach. Can also be used as temporary fixation device when through ATO Guides. Awl length is 25mm.

Compressor
07.01681.001
Compressor used with compressor tips and compression pin to provide compression on a VBR device.
Compression Tips
07.01682.001 - Compression Tip Superior
07.01683.001 – Short Compression Tip Inferior
07.01685.001 - Medium Compression Tip Inferior
07.01687.001 – Large Compression Tip Inferior

Compression Tips are used in conjunction with the compressor to provide compression on a VBR device.

Templating Caliper
07.01666.001
Assists in determining the appropriate length plate. Note: Plate length is measured from center of the closest holes on the plate.

Temporary Fixation Pin
07.01678.001 (Single Use)
Used through the screw hole in the plate to provide temporary fixation.

Compression Pin
07.01679.001 (Single Use)
Used adjacent to the plate to provide anchor for compression technique.

Temporary Fixation Pin Inserter
07.01680.001
Attaches to Ratcheting Inline or T-Handle to and used to insert Temporary fixation pin or Compression Pin.

Depth Gauge
07.01673.001
Used to measure depth of prepared hole and select appropriate length screw.
Standard Technique

Step 1

Corpectomy
Complete corpectomy procedure. Remove any osteophytes or boney protrusions that prevent the plate from sitting flush on the vertebral body.

Step 2

Plate Selection
Use calipers to determine plate length.

The labeled plate length is measured from the center of the screw holes closest to endplates.
**Step 3**

*Attach ATO Guides and Plate Holder*
Thread superior and inferior ATO Guides into plate. Thread Plate Holder into plate and connect Plate Holder Handle to Plate Holder. ATO Holder can be used to help attach ATO Guides to the plate.

*Note: ATO Guides are not compatible with the 30mm length plate.*

*Note: If using 35mm or 40mm plate, Plate Holder Handle and ATO Holder connected to ATO Guide will be used as plate holder.*

*Note: Fluoroscopy should be used during each step to ensure proper screw preparation and placement.*

**Step 4**

*Position Plate*
Position plate on lateral aspect of spine confirming the plate is in the desired position.

*Note: Excessive force should not be applied to Plate Holder Handle.*

**Step 5**

*Temporary Fixation (Optional)*
When using the ATO Guides, the Awl can be used to hold the plate in position. Insert Awl through ATO Guide Tube on the opposite end of the plate that you will be inserting your first screws.
Step 6
Prepare Bone Screw Hole
There are two options that can be used for preparing the screw hole.

Option 1: The Bone Awl can be used to penetrate the cortex of the vertebral body and create a pilot hole for the screw. The Awl has a positive stop at 25mm.

Note: When using the Bone Awl, caution should be taken to ensure that the spinal canal is not violated. Fluoroscopy is recommended during this step.

Option 2: A 25mm and 60mm Drill is provided as an alternative for preparing a screw hole. To use drill, attach Ratcheting Inline Handle, advance clockwise until appropriate drill depth is reached (confirm drill depth using flouro). Laser marked lines on the Drills identify the depth of drill engagement in bone.

An optional 5.5mm Tap is provided if needed. To use Tap, attach Ratcheting Inline Handle, advance clockwise until appropriate depth is reached (confirm depth using flouro). Laser marked lines on the Tap identify the depth of Tap engagement in bone. Rotate counter-clockwise to remove.

Note: When using the Drill or Tap caution should be taken to ensure that the spinal canal is not violated. Fluoroscopy is recommended during each of these steps.

Note: The Drills have a positive stop at 25mm and 60mm. The positive stop for the Tap is 61mm.
Step 7

Bone Screw Selection
Screw length should be based off depth of drilling or tapping. If it’s desired to use Depth Gauge to confirm screw length, remove ATO guide to use Depth Gauge. Depth Gauge may need to be pushed through the cancellous bone to the desired depth. The lines on the Depth Gauge will represent the appropriate screw length.

The V2F Anterior Fixation System offers dual-lead cortical/cancellous screws available in 6.0mm and 7.0mm diameters. Choose the appropriate length and diameter screw. Screw lengths are measured from the base of the screw head to the tip of the screw.
**Step 8**

**Bone Screw Insertion**
Connect the Screw Driver to either the Inline or Ratcheting T-Handle.

Attach screw onto Screw Driver and insert into prepared screw hole. While ensuring Screw Driver is fully seated in screw, advance until line on Screw Driver meets top of ATO Guide. This position represents provisionally tightened screws. Remove Screw Driver. Repeat steps 6-8 for adjacent screw hole.

**Step 9**

**Bone Screw Insertion**
If Awl was used to fixate plate, remove and follow steps 7-8 for screw placement.
Step 10

Bone Screw Insertion
Follow steps 6-8 for screw placement in the remaining holes.

Step 11

Remove Plate Holder and ATO Guides
Remove Plate holder, then insert hex tip of ATO Holder into ATO Guide. Turn sleeve clockwise to engage threaded post on ATO Guide. Rotate top of ATO Holder counter clockwise to remove ATO Guide from plate.
Step 12

Final Tighten Bone Screws
Fully seat Screw Driver in screw and final tighten all screws in a star pattern to ensure plate seats evenly on vertebral bodies.

Note: Bone Screws must be fully seated to ensure Cap Screws engage appropriately.

Step 13

Insertion of Locking Caps
Select either the Fixed (Gold) or Variable (Green) Cap Screw. The Fixed Cap Screw will lock the screw in a fixed position relative to the plate. The Variable Cap Screw will accommodate controlled movement of the screw relative to the plate, allowing for load sharing.

Attach the appropriate Cap Screw to the Cap Screw Driver and insert into one of the positions on plate. Advance until provisionally tight, repeat for remaining Cap Screws

Note: Cap Screw should engage plate without resistance; any resistance might signal Cap Screw cross threading with plate.

Step 14

Final Tightening Cap Screws
Attach Cap Screw Driver to Torque Limiting T-Handle. Fully seat Cap Screw Driver into one of the provisionally tightened Cap Screws, and turn clockwise until Torque Limiting T-Handle snaps. Repeat step for remaining Cap Screws.

Note: 50 in lb. Torque Wrench must be used for final tightening of Cap Screws
**Step 15**

Final Construct

**Compression Technique**

If compression is required, the V2F Anterior Fixation System offers instrumentation to accomplish this. The technique requires you to fix one end of the plate to the vertebral body and then translate the opposite vertebral body which provides compression across vertebral body replacement device.

**Step 1**

**Corpectomy**

Complete corpectomy procedure. Remove any osteophytes or boney protrusions that prevent the plate from sitting flush on the vertebral body.
**Step 2**

Plate Selection
Use calipers to determine plate length.

The labeled plate length is measured from the center of the screw holes closest to endplates.

**Step 3**

Attach ATO Guides and Plate Holder
Thread superior and inferior ATO Guides into plate. Thread Plate Holder into plate and connect Plate Holder Handle to Plate Holder. ATO Holder can be used to help attach ATO Guides to the plate.

*Note:* ATO Guides are not compatible with the 30mm length plate.

*Note:* If using 35mm or 40mm plate, Plate Holder Handle and ATO Holder connected to ATO Guide will be used as plate holder.

*Note:* Fluoroscopy should be used during each step to ensure proper screw preparation and placement.
**Step 4**

**Position Plate**
Position plate on lateral aspect of spine confirming the plate is in the desired position.

*Note: Excessive force should not be applied to Plate Holder Handle.*

---

**Step 5**

**Temporary Fixation (Optional)**
When using the ATO Guides the Awl can be used to hold the plate in position. When using compression technique, insert Awl through ATO Guide Tube on the end of the plate that you will be inserting your first screws.

*Note: Awl should not be used on opposite end of plate that you are inserting screws; this could cause issues when trying to prepare screw holes after compression has been applied.*
Step 6

Prepare Inferior Bone Screw Holes

There are two options that can be used for preparing the screw hole.

Option 1: The Bone Awl can be used to penetrate the cortex of the vertebral body and create a pilot hole for the screw. The Awl has a positive stop at 25mm.

Note: When using the Bone Awl, caution should be taken to ensure that the spinal canal is not violated. Fluoroscopy is recommended during this step. Threading with plate.

Option 2: A 25mm and 60mm drill is provided as an alternative for preparing a screw hole. To use Drill, attach Ratcheting Inline Handle, advance clockwise until appropriate drill depth is reached (confirm drill depth using flouro). Laser marked lines on the Drills identify the depth of drill engagement in bone.

An optional 5.5mm Tap is provided if needed. To use Tap, attach Ratcheting Inline Handle, advance clockwise until appropriate depth is reached (confirm depth using flouro). Laser marked lines on the Tap identify the depth of Tap engagement in bone. Rotate counter-clockwise to remove.

Note: When using the Drill or Tap caution should be taken to ensure that the spinal canal is not violated. Fluoroscopy is recommended during each of these steps.

Note: The Drills have a positive stop at 25mm and 60mm. The positive stop for the Tap is 61mm.
**Step 7**

**Bone Screw Selection**

Screw length should be based off depth of drilling or tapping. If it is desired to use Depth Gauge to confirm screw length, remove ATO guide to use Depth Gauge. Depth Gauge may need to be pushed through the cancellous bone to the desired depth. The lines on the Depth Gauge will represent the appropriate screw length.

The V2F Anterior Fixation System offers dual-lead cortical/cancellous screws available in 6.0mm and 7.0mm diameters. Choose the appropriate length and diameter screw. Screw lengths are measured from the base of the screw head to the tip of the screw.
**Step 8**

**Bone Screw Insertion**
Connect the Screwdriver to either the Inline or Ratcheting T-Handle.

**Step 9**

**Bone Screw Insertion**
Attach screw onto Screw Driver and insert into prepared screw hole. While ensuring Screw Driver is fully seated in screw, advance until line on Screw Driver meets top of ATO Guide. This position represents provisionally tightened screws. Remove Screw Driver.

If Awl was used to fixate plate, remove and follow steps 7-8 for screw placement, if not repeat steps 6-8 for adjacent screw hole in Inferior Guide Tube.

**Remove Plate Holder and Inferior ATO Guide**
Remove Plate Holder and use ATO Holder to remove ATO Guide from plate. Insert hex tip of ATO Holder into ATO Guide. Turn sleeve clockwise to engage threaded post on ATO Guide. Rotate top of ATO Holder counter clockwise to remove ATO Guide from plate.
Tighten Inferior Screws
Fully seat Screw Driver in screw and final tighten inferior screws.

*Note: Bone Screws must be fully seated to ensure Cap Screws engage appropriately.*

Insert Locking Caps
Fixed Locking Caps should be used to secure the inferior screws in the plate prior to applying compression. Attach the Fixed Cap Screw to the Cap Screw Driver and insert into one of the positions on caudal end of plate. Advance until provisionally tight, repeat for remaining Cap Screw on plate.

*Note: Cap Screw should engage plate without resistance; any resistance might signal Cap Screw cross threading with plate.*

Compression Tool Assembly
Attach appropriate Compressor Arms based on plate length onto compressor. Ensure laser marking on Compressor Arm matches the marking on the Compressor.

*Plate length:*
- 30mm – 70mm = SMALL
- 75mm – 100mm = MEDIUM
- 105mm -130mm = LARGE
**Step 13**

Insert Compression Pin
Insert compression pin into non-fixed vertebral body above the plate; ensuring the gap between the pin and the plate is equal to the desired compression.

**Step 14**

Compression
Use the compressor to compress the cephalad vertebral body relative to the plate using the compression pin.
Step 15
Prepare Superior Bone Screw Holes
With compression maintained by the compression instrument proceed to preparing Bone Screw holes. There are two options that can be used for preparing the screw hole.

Option 1: The Bone Awl can be used to penetrate the cortex of the vertebral body and create a pilot hole for the screw. Place Awl into ATO Guide and advance into bone.

Note: When using the Bone Awl caution should be taken to ensure that the spinal canal is not violated. Fluoroscopy is recommended during this step.

Option 2: A 25mm and 60mm Drill is provided as an alternative for preparing a screw hole. To use Drill, attach Ratcheting Inline Handle, insert into ATO Guide and advance clockwise until appropriate drill depth is reached (confirm drill depth using flouro). Laser marked lines on the Drills identify the depth of drill engagement in bone.

An optional 5.5mm Tap is provided if needed. To use Tap, attach Ratcheting Inline Handle, insert into ATO Guide on opposite side from Fixation Pin and advance clockwise until appropriate depth is reached (confirm depth using flouro). Laser marked lines on the Tap identify the depth of Tap engagement in bone. Rotate counter-clockwise to remove.

Note: When using the Drill or Tap caution should be taken to ensure that the spinal canal is not violated. Fluoroscopy is recommended during each of these steps.

Note: The Drills have a positive stop at 25mm and 60mm. The Tap has a positive stop at 61mm.
Step 16

Bone Screw Selection
Screw length should be based off depth of drilling or tapping. If it’s desired to use Depth Gauge to confirm screw length, remove ATO guide to use Depth Gauge. Depth Gauge may need to be pushed through the cancellous bone to the desired depth. The lines on the Depth Gauge will represent the appropriate screw length.

The V2F Anterior Fixation System offers 6.0mm and 7.0mm screw diameters choose appropriate length and diameter screw.
Bone Screw Insertion
Connect the Screwdriver to either the Inline or Ratcheting T-Handle.

Attach screw onto Screw Driver and insert into prepared screw hole. While ensuring Screw Driver is fully seated in screw, advance until line on Screw Driver meets top of ATO Guide. This position represents provisionally tightened screws. Remove Screw Driver. Repeat steps 15-17 for adjacent screw hole.
Step 18

Remove ATO Guide
With Compressor still in place remove Superior ATO Guide.

Use ATO Holder to remove ATO Guide from plate. Insert hex tip of ATO Holder into ATO Guide. Turn sleeve clockwise to engage threaded post on ATO Guide. Rotate top of ATO Holder counter clockwise to remove ATO Guide from plate.

Step 19

Final Tighten Bone Screws
Fully seat Screw Driver in screw and final tighten, repeat for remaining screw.

Step 20
Insertion of Locking Caps
Select the Fixed (Gold) Cap Screw and attach to the Cap Screw Driver and insert into one of the positions on plate. Advance until provisionally tight, repeat for remaining Cap Screw.

*Note:* Cap Screw should engage plate without resistance; any resistance might signal Cap Screw cross threading with plate.

Remove Compressor and Compression Pin
Use Compression Pin Inserter to remove Compression Pin by turning it counter clockwise.

Step 21
Step 22

Final Tightening Cap Screws
Attach Cap Screw Driver to Torque Limiting T-Handle. Fully seat Cap Screw Driver into one of the provisionally tightened Cap Screws, and turn clockwise until Torque Limiting T-Handle snaps. Repeat step for remaining Cap Screws.

Note: 50 in lb. Torque Wrench must be used for final tightening of Cap Screws

Step 23

Final Construct
Free Hand Technique

The V2F Anterior Fixation Systems is designed to support a free hand insertion technique.

Step 1

Corpectomy
Complete corpectomy procedure. Remove any osteophytes or boney protrusions that prevent the plate from sitting flush on the vertebral body.

Step 2

Plate Selection
Use calipers to determine plate length.
Step 3

Attach Plate Holder
Thread Plate Holder into plate and connect Plate Holder Handle to Plate Holder.

The labeled plate length is measured from the center of the screw holes closest to endplates.
Step 4

Position Plate
Position plate on lateral aspect of spine confirming the plate is in the desired position.

*Note: Excessive force should not be applied to Plate Holder Handle.*

Step 5

Temporary Fixation (Optional)
Fixate the plate in position using Temporary Fixation Pins. Insert Fixation Pin into Pin Inserter and place through screw hole in opposite end of the plate that you will be inserting your first screws. Turn clockwise to advance the pin into the bone.

The Bone Awl can also be used as a temporary fixation device. If this option is used follow Step 6, option 1, and then repeat on opposite corner of plate using second Awl or 25 or 60mm Drill. You can then proceed directly to Step 8 for Bone Screw Insertion.
**Step 6**

**Prepare Bone Screw Holes**

The Bone Screws can be inserted in a 30 degree cone relative to the plate. This 30 degree range cannot be exceeded in order to guarantee Screws will seat completely within screw pocket of plate and allow for Cap Screw insertion.  

*Note: Care should be taken to ensure trajectory provides a safe screw placement relative to spinal canal and adjacent discs.*

There are two options that can be used for preparing the screw hole.

**Option 1:** The Bone Awl can be used to penetrate the cortex of the vertebral body and create a pilot hole for the screw. Place Awl on opposite side from Fixation Pin and advance into bone. The Awl has a positive stop at 25mm.  

*Note: When using the Bone Awl, caution should be taken to ensure that the spinal canal is not violated. Fluoroscopy is recommended during this step.*

**Option 2:** A 25mm and 60mm Drill is provided as an alternative for preparing a screw hole. To use Drill, attach Ratcheting Inline Handle, insert on opposite side from Fixation Pin and advance clockwise until appropriate drill depth is reached (confirm drill depth using fluoro). Laser marked lines on the Drills identify the depth of drill engagement in bone. An optional 5.5mm Tap is provided if needed. To use Tap, attach Ratcheting Inline Handle, insert on opposite side from Fixation Pin and advance clockwise until appropriate depth is reached (confirm depth using fluoro). Laser marked lines on the Tap identify the depth of Tap engagement in bone. Rotate counterclockwise to remove.  

*Note: When using the Drill or Tap caution should be taken to ensure that the spinal canal is not violated. Fluoroscopy is recommended during each of these steps.*

*Note: The Drills have a positive stop at 25mm and 60mm. The positive stop for the Tap is 61mm.*
Step 7

Bone Screw Selection
Insert the Depth Gauge through the prepared screw hole, the gauge may need to be pushed through the cancellous bone to the desired depth. The lines on the Depth Gauge will represent the appropriate screw length.

Step 8

Bone Screw Insertion
Connect the Screw Driver to either the Inline or Ratcheting T-Handle.

The V2F Anterior Fixation System offers dual-lead cortical/cancellous screws available in 6.0mm and 7.0mm diameters. Choose the appropriate length and diameter screw. Screw lengths are measured from the base of the screw head to the tip of the screw.
Attach screw onto Screw Driver and insert into prepared screw hole ensuring Screw Driver is fully seated in screw. Remove Screw Driver. Repeat steps 6-8 for adjacent screw hole.

Step 9

Remove Temporary Fixation Pin
Follow steps 6-8 for screw placement in the remaining holes.

Step 10

Final Tighten Bone Screws
Fully seat Screw Driver in screw and final tighten all screws in a star pattern to ensure plate seats evenly on vertebral bodies. Remove Plate Holder.

Note: Bone Screws must be fully seated to ensure Cap Screws engage appropriately.
Step 11

Insertion of Locking Caps
Select either the Fixed or Variable Cap Screw. The Fixed Cap Screw will lock the screw in a fixed position relative to the plate. The Variable Cap Screw will allow the screw to accommodate subsidence of the vertebral body. Attach the appropriate Cap Screw to the Cap Screw Driver and insert into one of the positions on plate. Advance until provisionally tight, repeat for remaining Cap Screws.

*Note: Cap Screw should engage plate without resistance; any resistance might signal Cap Screw cross threading with plate.*

Step 12

Final Tightening Cap Screws
Attach Cap Screw Driver to Torque Limiting T-Handle. Fully seat Cap Screw Driver into one of the provisionally tightened Cap Screws, and turn clockwise until Torque Limiting T-Handle snaps. Repeat step for remaining Cap Screws.

*Note: 50 in lb. Torque Wrench must be used for final tightening of Cap Screws*
Removal

The following outlines the suggested steps for removing the V2F Anterior Fixation System.

1. Attach Cap Screw Driver to either Ratcheting Inline or T-Handle.

2. Insert Cap Screw Driver into Cap Screw and rotate counter-clockwise to remove, repeat for all four Cap Screws.

3. Attach Bone Screw Driver to either Ratcheting Inline or T-Handle.

4. Insert Bone Screw Driver into hex on top of Bone Screw and rotate counter-clockwise to remove, repeat for all four Bone Screws.

5. Remove plate.
# V2F Kit Contents

## Implant Tray

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<th>Description</th>
<th>Standard Kit Quantity</th>
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<td>07.01845.001</td>
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## Implant Tray continued

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<td>07.01661.001</td>
<td>V2F, Variable Cap Screw</td>
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<td>07.01839.001</td>
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<td>07.01844.001</td>
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## Instrument Tray

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<td>07.01662.001</td>
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<td>07.01663.001</td>
<td>ATO Guide, Inferior</td>
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<td>07.01664.001</td>
<td>Plate Holder</td>
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<td>07.01665.001</td>
<td>ATO Guide Handle</td>
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<td>07.01735.001</td>
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<td>07.01666.001</td>
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<td>07.01736.001</td>
<td>Ratcheting T-Handle</td>
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<td>07.01669.001</td>
<td>V2F, Driver Handle, Torque-Limiting</td>
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<td>07.01692.001</td>
<td>Cap Screw Driver</td>
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<td>07.01670.001</td>
<td>Screw Driver</td>
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<td>07.01671.001</td>
<td>Drill, 25mm Length</td>
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<td>Drill, 60mm Length</td>
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<td>07.01673.001</td>
<td>Depth Gauge</td>
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<td>07.01679.001</td>
<td>Compression Pin</td>
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<td>07.01680.001</td>
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<td>07.01847.001</td>
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<td>V2F, Inner Instrument Tray</td>
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## Compression Set

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<td>07.01682.001</td>
<td>Compression Tip Superior</td>
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<td>07.01683.001</td>
<td>Short Compression Tip Inferior</td>
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<td>07.01685.001</td>
<td>Medium Compression Tip Inferior</td>
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<td>07.01687.001</td>
<td>Long Compression Tip Inferior</td>
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<td>07.01668.001</td>
<td>Extended Ratcheting Driver Handle, Inline</td>
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<td>07.01846.001</td>
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Warnings

Some metals, polymers, chemicals, and other materials utilized with orthopedic implants have been known to cause cancer and other adverse body reactions, or reports in the literature have suggested such causation. Any factor that causes chronic damage to tissues may be oncogenic. Cancer can metastasize from soft tissue sites (lung, breast, digestive system, and others) to bone, including areas adjacent to implants, or it can be seeded to these locations during operative and diagnostic procedures (such as biopsies). Paget’s disease has been reported to progress to cancer; surgical candidates suffering from this disease should be warned accordingly.

Implantation of foreign material in tissues can elicit an inflammatory reaction. Current literature suggests that wear debris (including metal, polyethylene, ceramic, and cement particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening.

Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitivities (nickel, cobalt, and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.

The V2F Lateral Plate System is a temporary internal fixation device. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and it is recommended that the device is removed. Implant removal, should be followed by adequate postoperative management to avoid fracture or refracture.
Precautions

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 implant 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. This may in turn result in further injury or the need to remove the device prematurely.

The V2F Anterior Fixation System instrumentation should only be used after the surgeon has had adequate training in this method of fixation and has become thoroughly knowledgeable about the spinal anatomy and biomechanics. A surgical technique for the V2F System is available upon request. This technique is not a substitute for training and is for general informational purposes only.

Components from other anterior thoracic and thoracolumbar plating systems must not be intermixed with the V2F System components since compatibility of the components is not known.

Do not use implants made from dissimilar metals (such as cobalt chromium-molybdenum alloy or stainless steel) in contact with components of the V2F System; otherwise, galvanic corrosion may occur.

If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant(s) surface. The plates must not be repeatedly or excessively bent. Do not reverse bend the plate.

All implants and some instruments are intended for single use only; refer to the product label to determine if the instrument is intended for single use only. Single use devices should not be re-used. Possible risks associated with re-use of single use devices include:

- Mechanical malfunction
- Transmission of infectious agents
Adverse Effects

- Early or late loosening of the components
- Implant migration
- Disassembly, bending, loosening, slippage, and/or breakage of any or all of the components or Instruments
- Foreign body reaction to the implants including possible tumor formation, autoimmune disease, metallosis, and/or scarring
- Pressure on the skin possibly resulting in skin breakdown from component parts where there is inadequate tissue coverage over the implant
- Implant or graft extrusion through the skin
- Wound complications
- Loss of proper spinal curvature, correction, height and/or reduction
- Infection
- Bone fracture or stress shielding at, above, or below the level of surgery
- Non-union (or pseudoarthrosis)
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain
- Neurovascular compromise including paralysis or other types of serious injury
- Cerebral spine fluid leakage
- Gastrointestinal, urological, and/or reproductive system compromise including sterility, impotency, and/or loss of consortium
- Hemorrhage of blood vessels and/or hematomas
- Cessation of growth of the fused portion of the spine
- Discitis, arachnoiditis, and/or other types of inflammation
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus
- Bone graft donor site pain
- Inability to resume activities of normal daily living
- Death

**NOTE:** Additional surgery may be necessary to correct some of these anticipated adverse reactions.
Unless otherwise specified in extended warranty plans or other Zimmer written materials pertaining to a particular product, Zimmer warrants to customer that products purchased from Zimmer conform to Zimmer’s published specifications and are free from defects in workmanship and material at the time of shipment. If, upon inspection within a reasonable time after delivery and before implantation or use, customer discovers a failure of a product to conform to specifications or a defect in material and workmanship, it must promptly notify Zimmer in writing. Within a reasonable time after such notification, Zimmer will correct any failure of the product to conform to the warranty by providing, at its option, repair of the product, a replacement unit, or a refund of the purchase price, if applicable. The aforementioned remedies are customer’s exclusive remedies for breach of warranty.

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Federal (USA) law restricts this device to sale by or on the order of a physician.

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