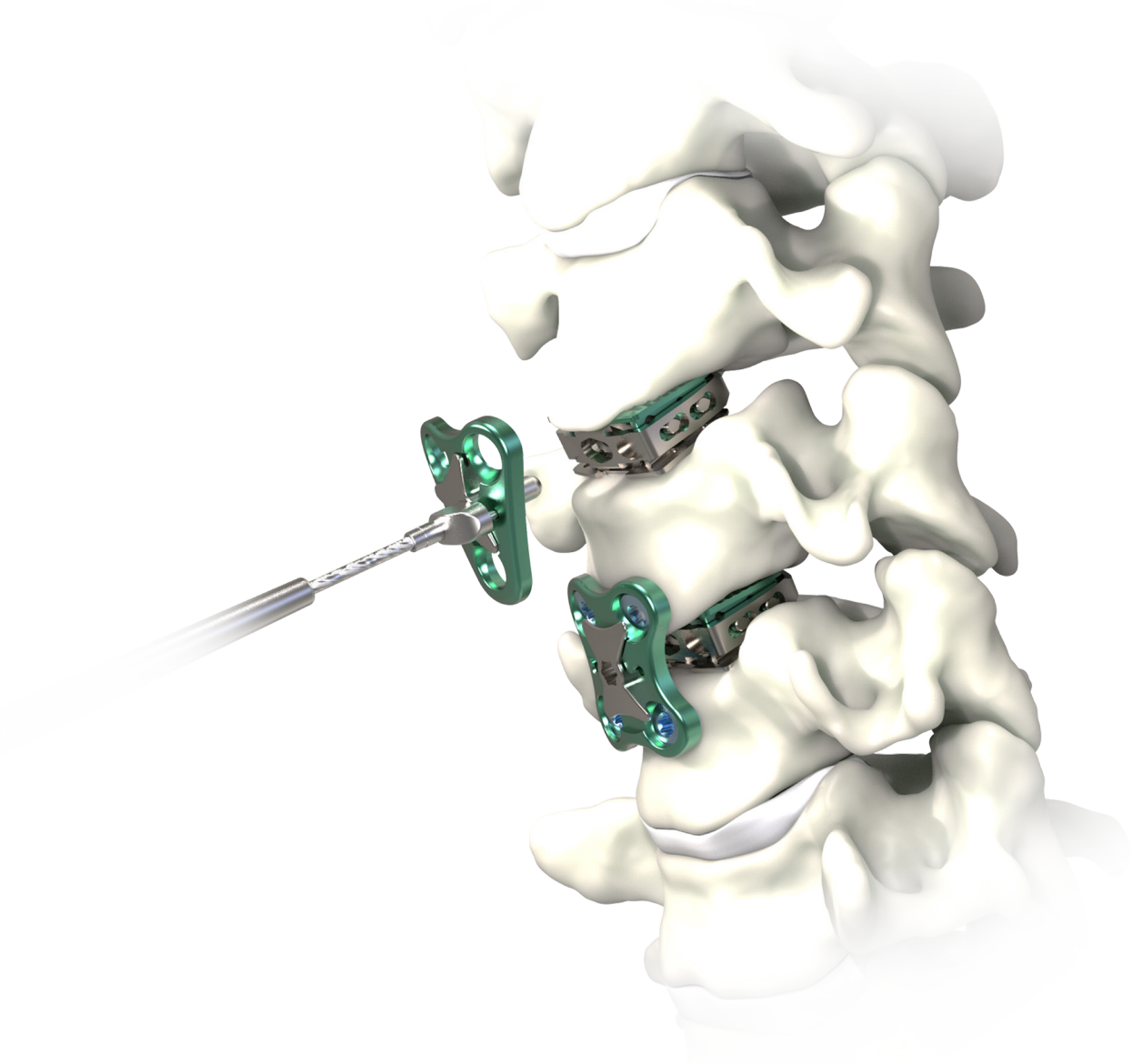
V3

SEGMENTAL PLATING SYSTEM

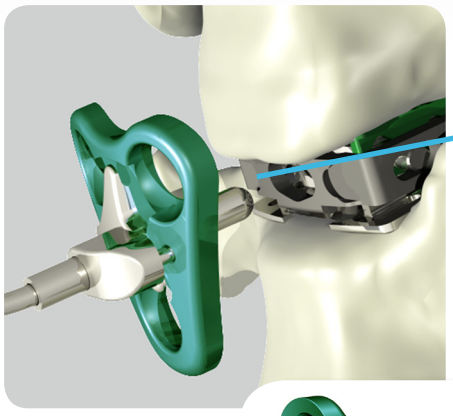
SURGICAL TECHNIQUE



ATLAS spine

Fusing Science With Simplicity

The V3 Guided Segmental Plating System represents a progressive technique in cervical plating by giving surgeons the opportunity to treat each segment individually. This emerging approach combines the technical simplicity of "stand-alone" type devices with the benefits and integrity of conventional plate/cage constructs.



TEMPORARY ALIGNMENT PIN

V3 vs. CONVENTIONAL PLATING

THE GUIDED PLATE HOLDER

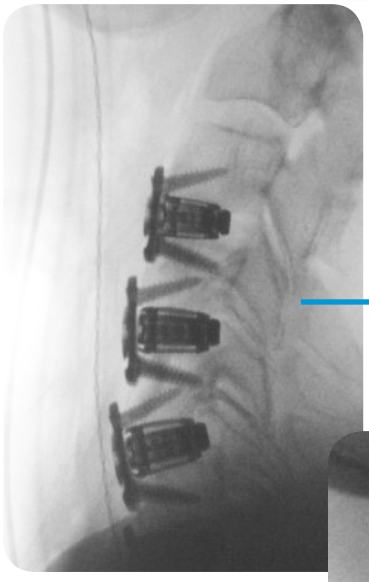
- ELIMINATES THE "FIDDLE" OF CHASING A PLATE
- SIMPLIFIES ALIGNMENT FOR MULTI-LEVEL CONSTRUCTS
- OPTIMIZES PLATE LENGTH TO AVOID ADJACENT LEVELS

THE SEGMENTAL PLATING PHILOSOPHY

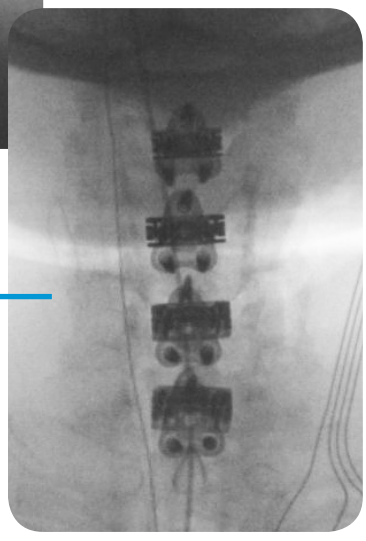
- ENSURES LOAD SHARING vs. STRESS SHIELDING
- MINIMIZES RETRACTION FOR MULTI - LEVEL CONSTRUCTS
- ELIMINATES PLATE BENDING. SEGMENTAL PLATES CONFORM TO THE SPINE TO PRESERVE THE NATURAL LORDOSIS VS. THE SPINE CONFORMING TO THE PLATE'S DESIGNED LORDOSIS

V3 vs. STAND -ALONE DEVICES

- BETTER BONE PURCHASE AND STABILITY*
- NO SCREW SKIVING INTO ENDPLATES
- NO "FIDDLE" WITH DIFFICULT SCREW ANGLES
- SCREWS DON'T VIOLATE THE GRAFT AREA
- A CLEAR REIMBURSEMENT PATHWAY



Segmental Lordotic Preservation



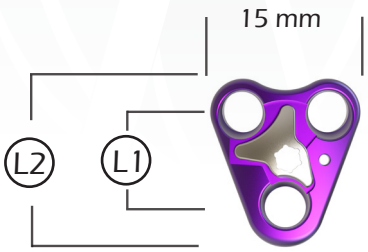
Automatic Coronal Alignment

Images From; "Multi-Level Anterior Cervical Discectomy and Fusion (ACDF) with Segmental Plating: Case Study and Clinical Rationale" K. Brandon Strenge MD, Vicky Zhang BS, Brett Zarda MS

Study available upon request.

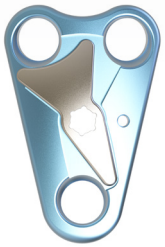
* Data on file 100 - VV - 021

PRODUCT OFFERING



L1 - 9mm
L2 - 16mm

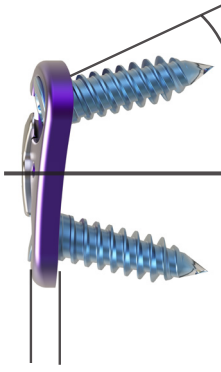
L1 - 11mm
L2 - 18mm



L1 - 13mm
L2 - 20mm

L1 - 15mm
L2 - 22mm

L1 - 17mm
L2 - 24mm



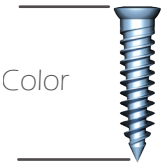
Up to 25° of cephalad/caudal screw angulation (10° convergent)

1.5 mm
Plate Thickness

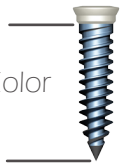
SCREW STYLES

SCREW OPTIONS IN 12, 14, AND 16MM LENGTHS

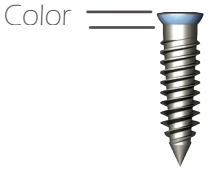
VARIABLE
3.4 mm Ø



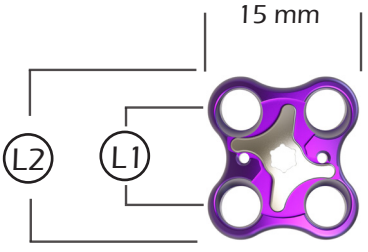
FIXED
3.4 mm Ø



RESCUE
3.9 mm Ø



4 Hole Option



L1 - 9mm
L2 - 16mm

L1 - 11mm
L2 - 18mm

L1 - 13mm
L2 - 20mm

L1 - 15mm
L2 - 22mm

L1 - 17mm
L2 - 24mm

INSTRUMENTATION APPLICATION

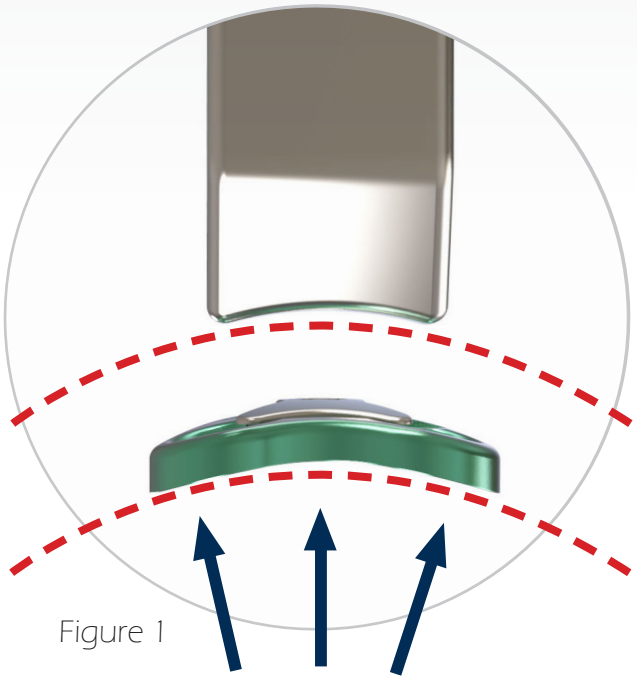


Figure 1

STEP 1: BONE PREPARATION (Optional Instrument)

The V3 system offers a unique Osteophyte Rongeur for precise removal of osteophytes and other bony irregularities. The rongeur's cutting edge matches the axial contour of the plate to optimize the plate-to-bone interface (Fig 1).

Place the flat surface of the rongeur against the endplate and the contoured cutting edge against the vertebral surface and squeeze handles to groom the surface.

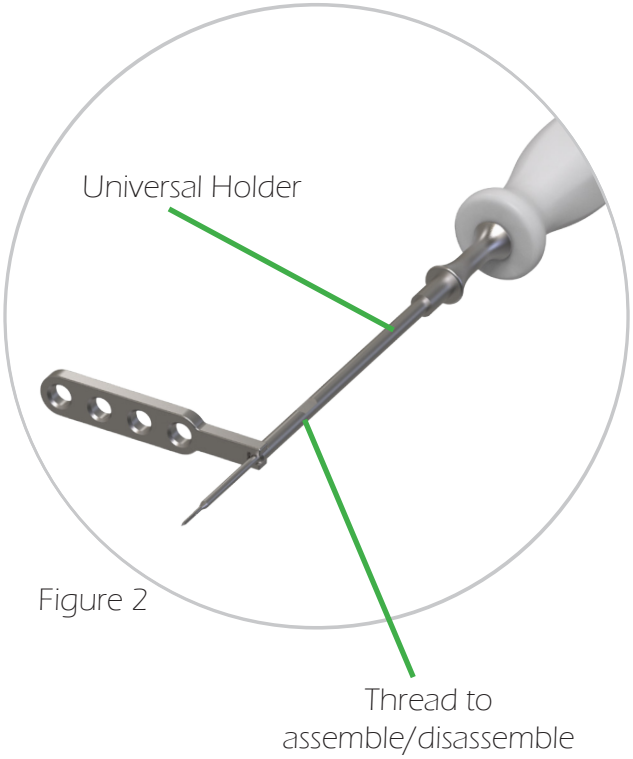


Figure 2

STEP 2: SCREW HOLE PREPARATION

The V3 system provides two options for screw hole preparation. A "Hybrid Drill" for osteoporotic bone and a "Drill" for more dense bone. To change drill bits, use the Instrument Wrench shown in figure 2 for removal and installation.

Note: The V3 screw has a unique design. Only use the hole prep instruments provided in the set to ensure appropriate purchase.

Note: The plate length and position of the midline screw should consider the Caspar pin hole. Attempt to avoid interference with the Caspar pin hole.

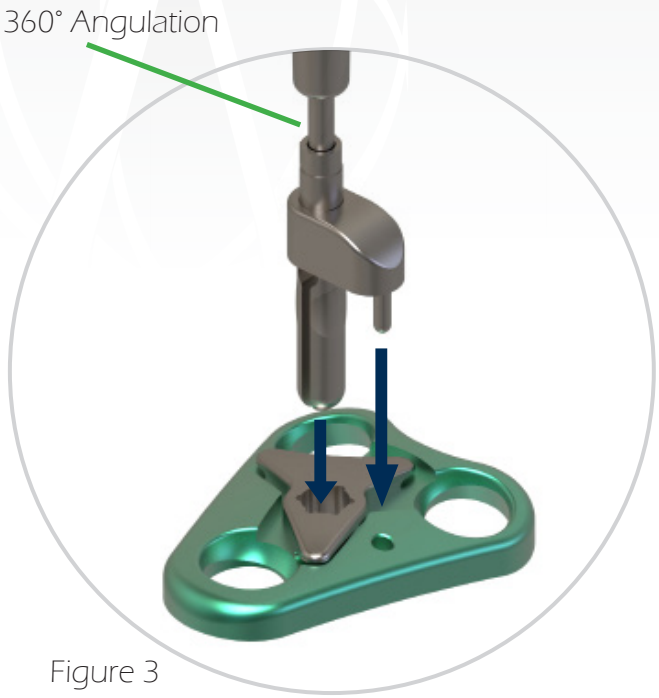


Figure 3

STEP 3: PLATE HOLDER

The Plate Holder has a flexible stem allowing angulation to gain clearance for prep instruments and screw placement.
Attach the Plate Holder by engaging the alignment pin through the plate.

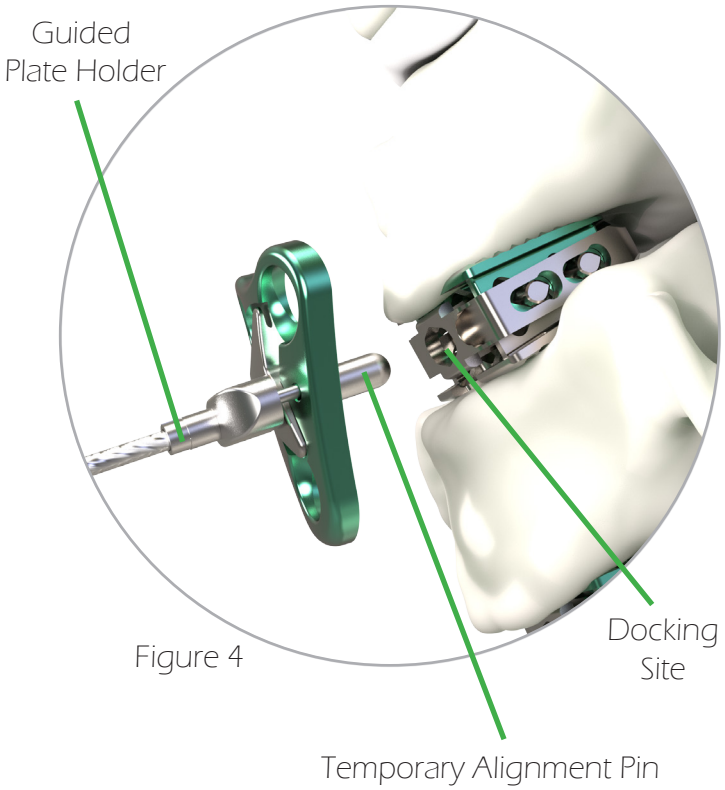


Figure 4

STEP 4: GUIDED PLATING

The Plate Holder and Fixed Plate Holder have an alignment pin that can temporarily dock onto the face of the HiJAK AC expandable cage. The pin eliminates the "fiddle" of chasing a plate, simplifies alignment for multi-level constructs and assists in optimization of plate length.

Note: For multi-level procedures, pre-operative planning should verify adequate vertebral body length for a segmental approach. All plate lengths should be determined prior to fixation. The V3 plate can be implanted with two screws cephalad or caudal at surgeon discretion. The V3 plates should not be bent.

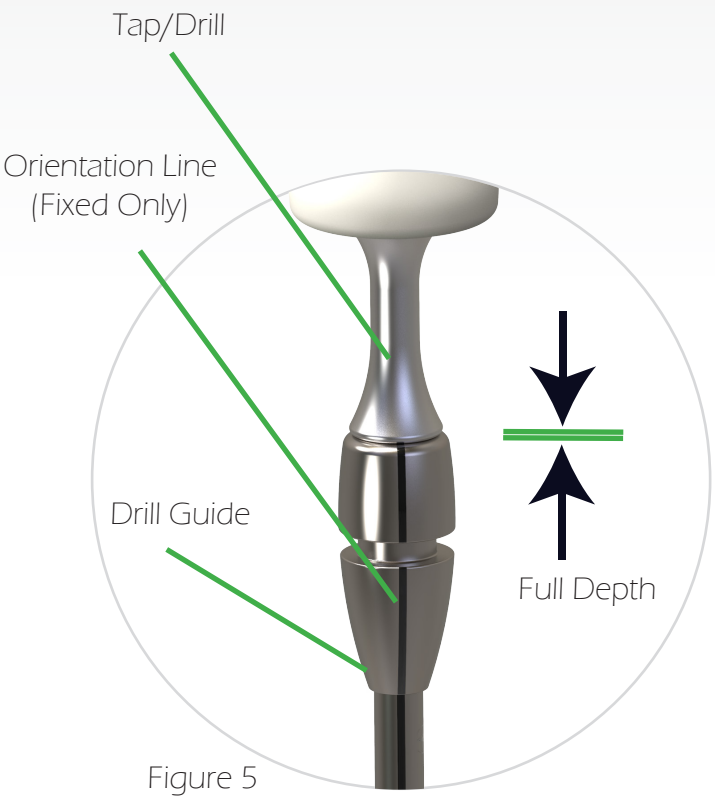


Figure 5

STEP 5: DRILL GUIDE

Pre-assemble the Fixed or Variable Drill Guide by placing the Universal Holder through the guide. The guides are spring loaded for soft tissue protection. Fully seat the distal tip of the guide into the plate screw hole until there is tactile feedback of engagement with the plate.

Both Drill Guides allow for hole preparation up to 10mm in depth. Full depth is reached when the assembly contacts the proximal end of the drill guide (Fig 5).

Note: The Drill Guides do not allow for screw insertion.

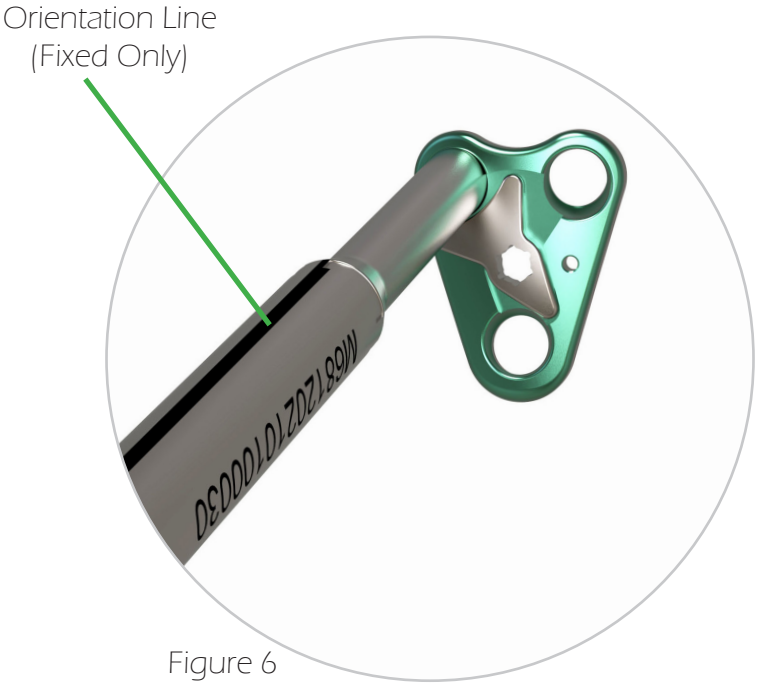


Figure 6

The Fixed Drill Guide has a marking along its shaft indicating correct orientation when docking into the plate (cephalad for superior screws, caudal for inferior screws) (Fig 6).

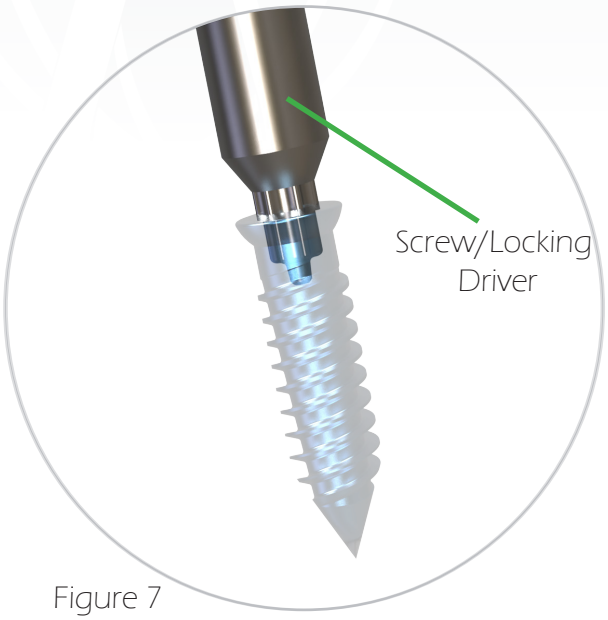


Figure 7

STEP 6: SCREW SELECTION AND INSERTION

The V3 System offers a variety of screw options. Variable and Fixed trajectory screws are all available in 3.4mm diameter by 12, 14, 16 mm lengths. Rescue screws at 3.9mm diameter are available in the same lengths. Load the screw on the Screw/Locking Driver by pressing down firmly into the screw head. The tapered pin on the tip of the Screw/Locking Driver provides self-retention of the screw.

After screw insertion, remove the driver by pulling straight up to overcome the friction fit.

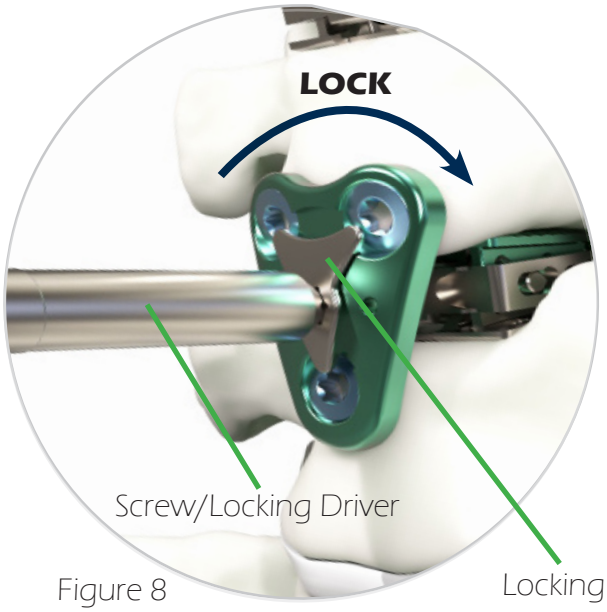


Figure 8

STEP 7: SYSTEM LOCKING/UNLOCKING

After screws are completely seated, use the Screw/Locking Driver to rotate the locking tab over the screw heads. The edges of the locking tab should be visible over screw heads. To unlock, rotate the locking tab back to its home position.

Note: If resistance is felt at final lockup ensure screws are fully seated.

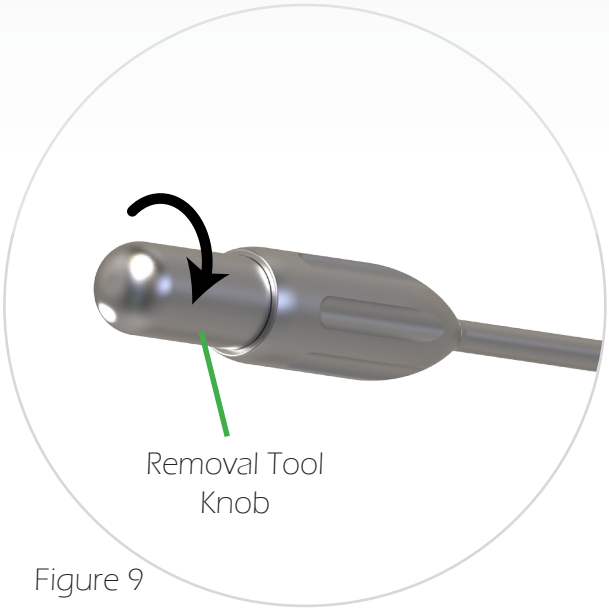


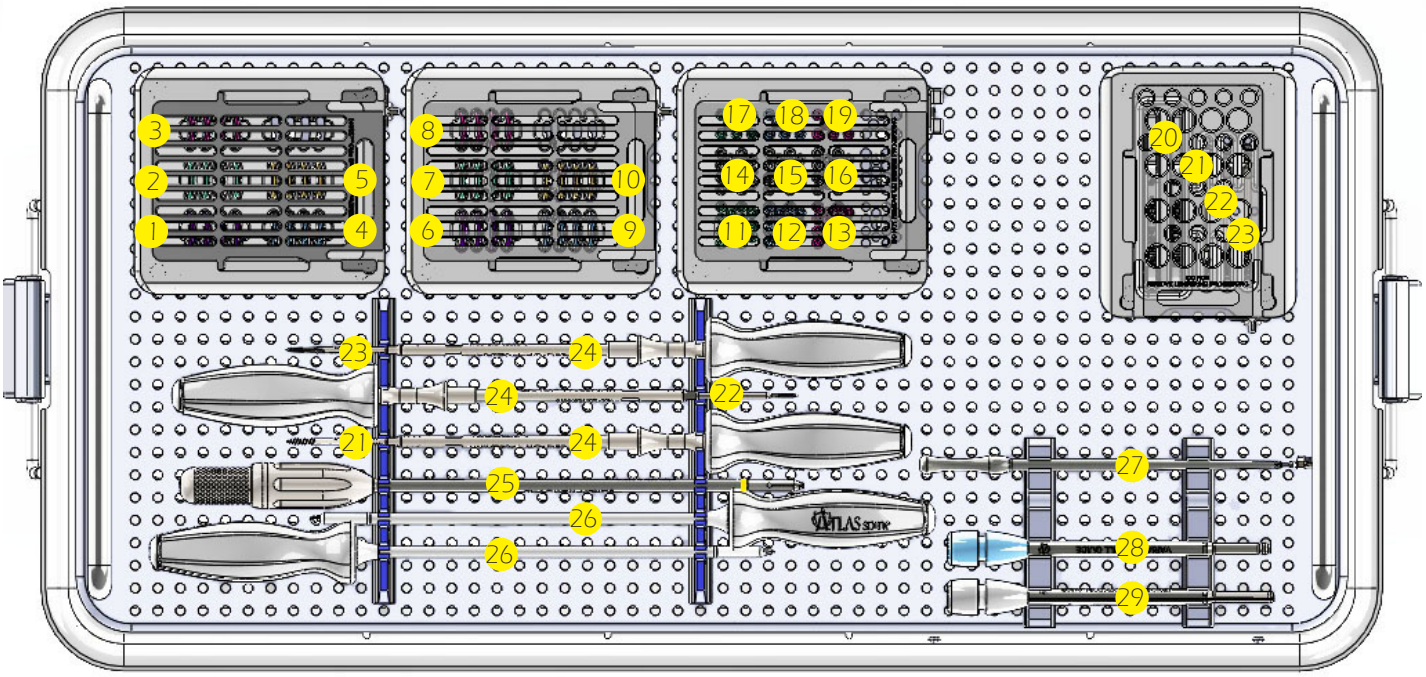
Figure 9

STEP 8: SCREW REMOVAL

The Removal Tool can be used to remove screws that have become stripped in the bone. Insert the Removal Tool into the screw head and turn the distal knob clockwise to attach to the screw (Fig 9).

Note: Removal Tool is not intended for insertion. The retention tip may not withstand the required torque.

TRAY LAYOUT
INSTRUMENTS AND IMPLANTS



1	1121-01-0009	9mm Plate Assembly
2	1121-01-0011	11mm Plate Assembly
3	1121-01-0013	13mm Plate Assembly
4	1121-01-0015	15mm Plate Assembly
5	1121-01-0017	17mm Plate Assembly
6	1121-05-0009	9mm Four Hole Plate
7	1121-05-0011	11mm Four Hole Plate
8	1121-05-0013	13mm Four Hole Plate
9	1121-05-0015	15mm Four Hole Plate
10	1121-05-0017	17mm Four Hole Plate
11	1121-02-0012	12mm Variable Screw
12	1121-02-0014	14mm Variable Screw
13	1121-02-0016	16mm Variable Screw
14	1121-03-0012	12mm Fixed Screw
15	1121-03-0014	14mm Fixed Screw
16	1121-03-0016	16mm Fixed Screw
17	1121-04-0012	12mm Rescue Screw
18	1121-04-0014	14mm Rescue Screw
19	1121-04-0016	16mm Rescue Screw
20	IGW-001-000	Instrument Wrench
21	2021-01-0006	Tap Bit
22	2021-01-0015	Hybrid Drill Bit
23	2021-01-0008	Drill Bit
24	2021-02-0001	Universal Holder
25	2021-01-0000	Removal Tool
26	2021-01-0004	Screw/Locking Driver
27	2021-01-0005	Plate Holder
28	2021-01-0002	Variable Drill Guide
29	2021-01-0003	Fixed Trajectory Drill Guide

Available Upon Request:

IVR-001-000	Osteophyte Rongeur

INSTRUCTIONS FOR USE

V3™ Segmental Plating System

Description:

The V3™ Segmental Plating System is comprised of titanium alloy (Ti6Al4V ELI per ASTM F136) plates and screw implants. The titanium plates and screws are available in a variety of lengths to address varying patient anatomy. The plates contain an integrated locking mechanism which interfaces with fixed and variable angle screws of various diameters and lengths, to accommodate anatomical variation when securing the plate-screw construct to the anterior cervical vertebral bodies. The system is intended to provide mechanical support to the implanted level(s) until fusion is achieved. To accommodate normal cervical spine lordosis, and at the same time eliminate the need for additional plate contouring, the V3™ Segmental Plating System come with a pre-lordosed curve. Various instruments are available to facilitate the implantation of the device.

Indications for Use:

The V3™ Segmental Plating System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (i.e., fractures or dislocation), 3) tumors, 4) spinal stenosis, 5) spondylolisthesis, 6) deformity or curvatures (i.e., kyphosis and/or lordosis, or scoliosis), 7) pseudoarthrosis, and/or 8) failed previous fusions.

Contraindications:

The V3™ Segmental Plating System, as with other orthopedic implants, is contraindicated for use in patients with:

1. Active infections in which the use of an implant could preclude adequate and appropriate treatment of the infection.
2. Rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis which may prevent adequate fixation.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity, pregnancy or degenerative diseases. The decision to use this system in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Any circumstances not listed under the heading indications.

Potential Adverse Events:

Potential adverse events include, but are not limited to:

1. Failure of the device to provide adequate mechanical stability.
2. Loss of fixation of the implant.
3. Device component failure.
4. Migration or bending of the device.
5. Loss of bony alignment.
6. Non-union.
7. Fracture of bony structures.
8. Immunogenic response to the implant materials.

Note: As with any major surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, permanent pain and/or deformity. Rarely, some complications may be fatal.

Warnings and Precautions:

The surgeon should be aware of the following when using implants:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape, and design of the implant. No implant can be expected to withstand the unsupported stresses of full weight bearing. The size, shape and condition of human bones are also contributing factors to the success of the surgery.
2. Do not use damaged implants. The correct handling of the implant is extremely important. Implants should not be bent, notched or scratched. These operations can produce defects in surface finish and may cause internal stress concentrations which may become the focal point for eventual failure of the device.
3. Non-sterile; the V3™ Segmental Plating System implants and instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized prior to each use.
4. Single use only. V3™ Segmental Plating System implants are intended for SINGLE USE ONLY. No surgical implants should be reused. Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Any implant once used should be discarded. Even though the device appears undamaged, it may already have small defects and internal stress patterns that may lead to fatigue failure.
5. Do not re-sterilize single-use implants that come in contact with body fluids.
6. Postoperative care is important. The patient should be instructed in the limitations of the implant and should be cautioned regarding weight bearing and body stress on the device prior to secure bone healing.
7. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fusion device.
8. The implantation of the intervertebral body fusion device should be per formed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure pre senting a risk of serious injury to the patient.
9. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

MRI Compatibility Information:

The V3™ Segmental Plating System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the V3™ Segmental Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Cleaning and Decontamination:

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.

Atlas Spine rigid instrument cases may be washed and/or disinfected by using an automated washer-disinfection unit utilizing thermal disinfection. Temperatures, cycles, and disinfectant type used as instructed by manufacturer of washer-disinfection unit.

1. **Decontamination:** Saturate the surface completely with full strength disinfectant/cleaner* (e.g. Cavicide) and allow to remain in contact with devices for 5 minutes.
2. **Pre-Cleaning:** Remove gross contaminants by immersing the devices in room temperature neutral pH enzymatic cleaner*

   (e.g. Metrizyme) and disassemble instruments per instructions provided in the following pages. The majority of the surgical instruments and trial de vices are simply constructed and will not require disassembly. However, some of the more complex instruments are made of several components and these should be disassembled into their individual parts prior to decon tamination. Scrub with the appropriate soft bristle brush until visibly clean.
3. **Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. Metrizyme) and sonicate for 10 minutes. For ultrasonic cleaning follow the manufacturer's specifica tions for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place, and do not touch or overlap.

   * Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures.

4. **Rinsing:** Thoroughly rinse the devices with deionized or distilled water. For example, a minimum of 2 minutes three (3) times.
5. **Drying:** Allow devices to air dry a minimum of 30 minutes prior to inspection and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored.

Preparation and Assembly: After cleaning/disinfection, the disassembled instruments should be reassembled and visually inspected. Check for misalignment, burrs, bent, or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Place instruments into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines.

Note: Visually inspect instruments after cleaning and prior to each use. Discard or return to Atlas any instruments that are broken, discolored, corroded, have cracked components, pits, gouges, or are otherwise found defective. Do not use defective instruments.

Sterilization:

The V3™ Segmental Plating System instruments and implants are supplied NON-STERILE. Prior to use, all instruments and implants should be placed in the appropriate Atlas Spine case which will be wrapped in a FDA cleared sterilization wrap and placed in the autoclave for sterilization by the hospital using the following recommended cycle:

Method: Steam
Cycle: Pre-vac
Temperature: 270°F (132°C)
Preconditioning: Per manufacturer's settings
Exposure time: 4 minutes
Drying time: 30 minutes
Double wrapped (FDA cleared wrap)

Packaging:

Packages for each of the components should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage prior to use. Damaged packages or products should not be used and should be returned to Atlas Spine.

The V3™ Segmental Plating System instruments and implants are provided in a modular case specifically intended to contain and organize the system's components. The system's instruments are organized into trays within each modular case for easy retrieval during surgery. These trays also provide protection to the system components during shipping. Additionally, individual instruments and implants are provided in sealed poly bags with individual product labels.

Product Complaints:

Any Health Care Professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction with the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Atlas Spine Inc., 1555 Jupiter Park Dr., Suite 1, Jupiter, FL 33458, USA, by telephone at 1-561-741-1108.

Further Information:

A recommended operative technique for the use of this system is available upon request from Atlas Spine at the phone numbers provided above.

Latex Information:

The implants, instruments and/or packaging material for the V3™ Segmental Plating System are not formulated with and do not contain natural rubber. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

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

Atlas Spine Inc., 1555 Jupiter Park Drive, Suite 1 Jupiter, FL 33458 www.atlasspine.com Ph. 561-741-1108 Fx. 561-741-1870