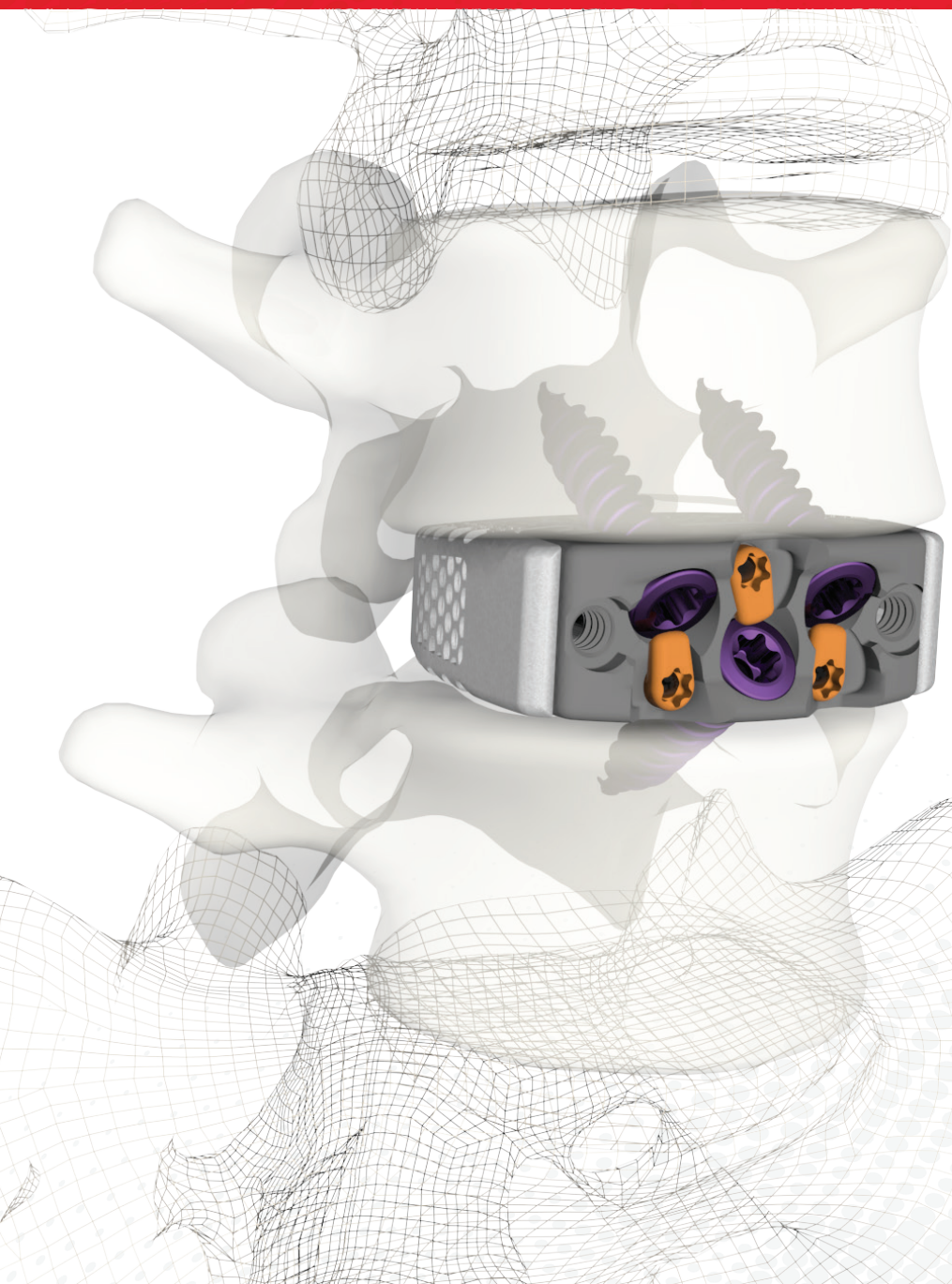
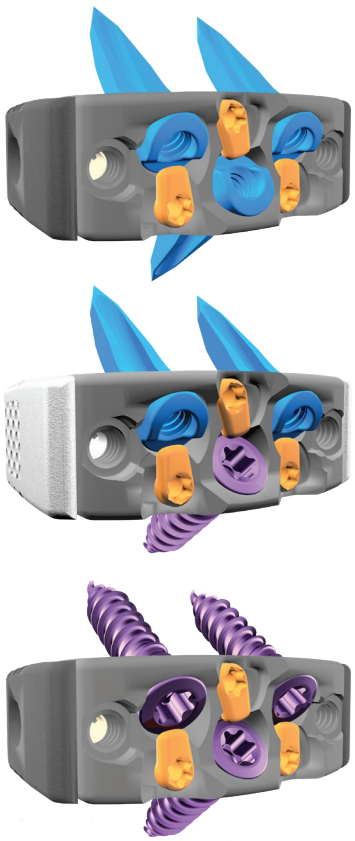
ZAVATION®

VARISYNC®

ALIF System



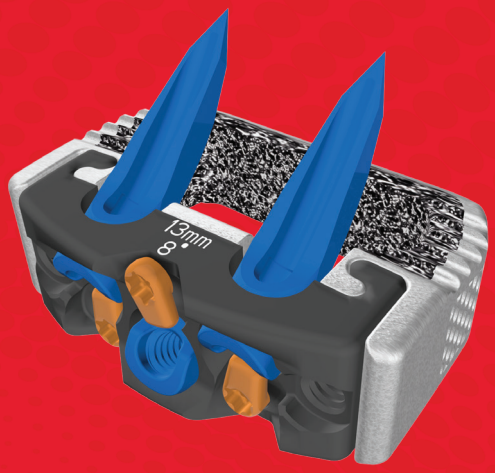


Surgical Technique Guide

THE VARISYNC DIFFERENCE

The Zavation® Varisync® ALIF System is an **integrated lumbar spacer** designed to deliver **screw** or **anchor** fixation in fewer procedural steps through a **less invasive** surgical corridor than traditional integrated cages.

The system features **versatile cage fixation** options, **innovative instruments** that streamline implantation at the most challenging levels, and the biocompatible benefits of **Mimetic Metal®** and **NanoPrime™** Titanium Ion Bond Technology.



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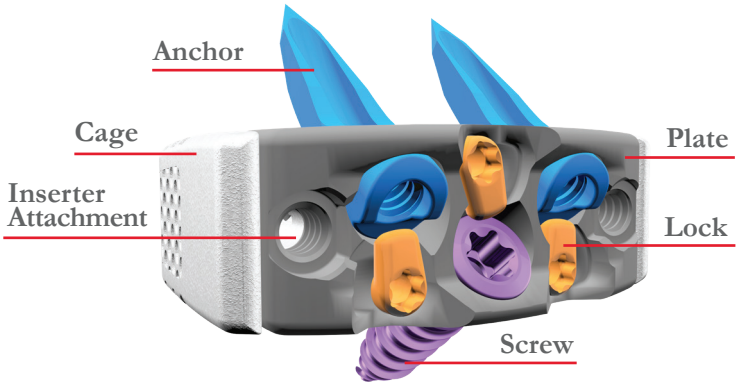
SYSTEM OVERVIEW

The **Zavation Varisync ALIF System** is comprised of a plate, cage, and fixation anchors and/or screws. The integrated fixation features a quick-connect assembly between the plate and cage.



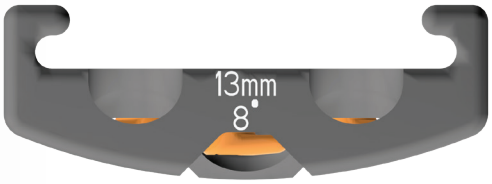
VARISYNC ALIF RECESSED PLATE

Specifications

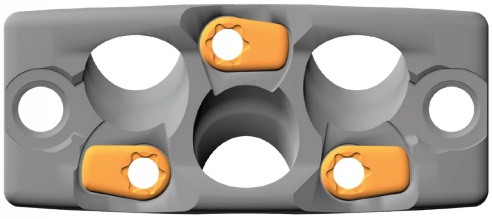
- Plate selection is based on the cage height and lordotic angle.
- The same plate fits all cage footprints of the same height and lordosis.

Features

- Integrated fixation within the cage
- Three fixation points with anti-backout camlocks
- Accepts screws or anchors
- Steam sterilized
- Bi-directional construct design



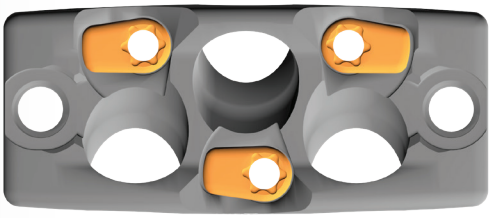
Top View



Front View

Bi-directional Recessed Plate Design
2-up, 1-down

Top View



Front View

Bi-directional Recessed Plate Design
1-up, 2-down

VARISYNC ALIF CAGE OPTIONS

NanoPrime™ IBF Cage

Specifications

- **Standard Footprints** (Depth x Width):
  - 24mm x 30mm
  - 26mm x 35mm
  - 28mm x 40mm
- **Heights**: 11mm-15mm, 17mm
  - Special Order: 19mm, 21mm
- **Lordosis**: 8°, 15°
  - Special Order: 20°
- **Coating Thickness**: 0.4 microns

Features

- Proprietary thin layer deposit of titanium to a PEEK cage, combining the proven advantages of PEEK with the clinical benefits of titanium.
- Maintains native benefits of PEEK IBF cage.
- Designed to improve surface functionality.
- Steam sterilized

F3D-Z Cage

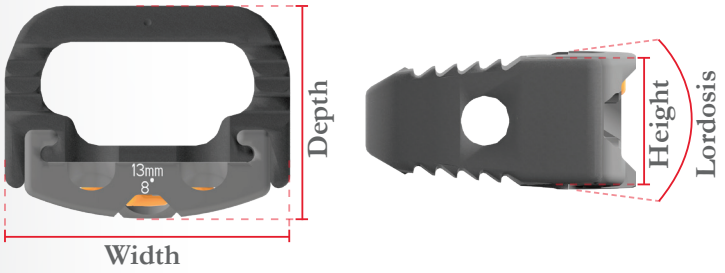
Specifications

- **Standard Footprints** (Depth x Width):
  - 24mm x 30mm
  - 26mm x 35mm
  - 28mm x 40mm
- **Heights**: 11mm-15mm, 17mm
  - Special Order: 19mm, 21mm
- **Lordosis**: 8°, 15°
  - Special Order: 20°, 25°

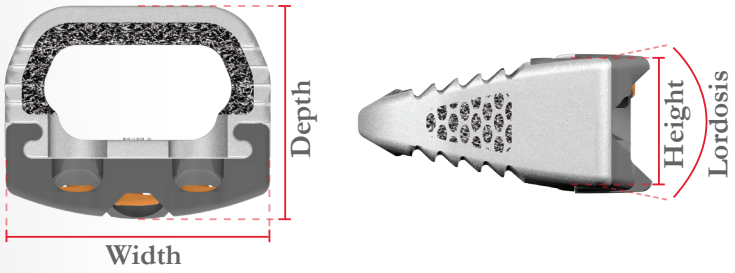
Features

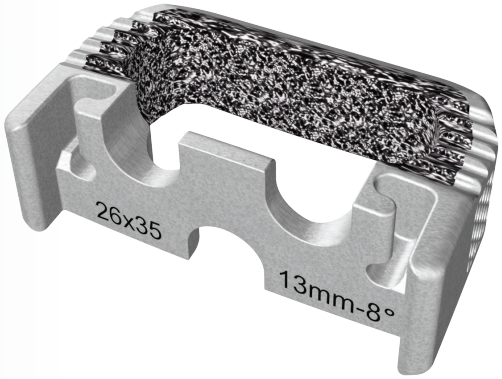
- Patented Mimetic Metal® technology designed to emulate key characteristics of natural bone to provide an optimal structure and environment for healing*.
- Porous structure optimized at 500 microns*.
- 3D-printed Titanium
- Prepackaged sterile

*Data on file.



PEEK Cage with NanoPrime technology





F3D-Z Cage with Mimetic Metal technology

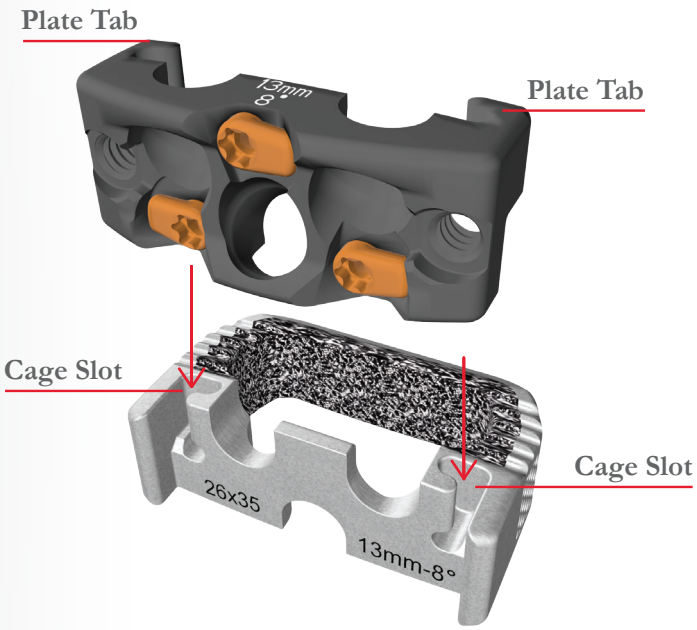
SYSTEM ASSEMBLY

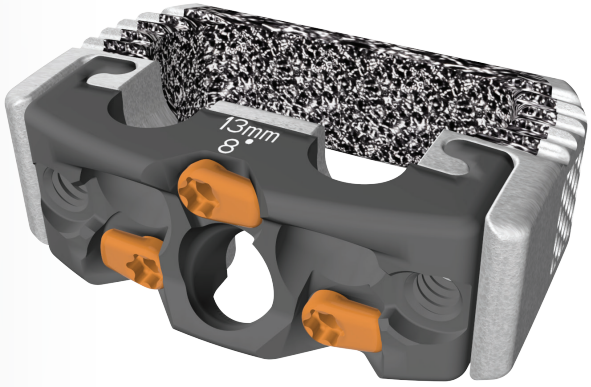
Cage & Plate Assembly

Assembly is the same whether you're using a NanoPrime IBF cage or F3D-Z cage. Align the slots and tabs of the cage and plate, and slide the plate onto the cage within the slot channel until the plate bottoms in the cage.

There is a slip-fit connection between the plate and cage until connected to the inserter.

Once the plate is assembled to the cage, the inserter is attached and retains assembly throughout the procedure.





Assembled Construct shown with F3D-Z Cage and Varisync Recessed ALIF Plate

SCREW FIXATION OVERVIEW

Screws

Specifications

- **Style**: Fixed and Variable
- **Tip**: Self-drilling and Self-tapping
- **Diameter**: 5.0mm, 6.0mm (rescue)
- **Lengths**: 20mm, 25mm
- **Material**: Titanium

Fixed Angulation

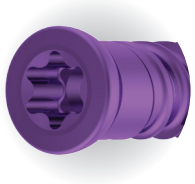
- 0° axial
- 35° cephalad/caudal

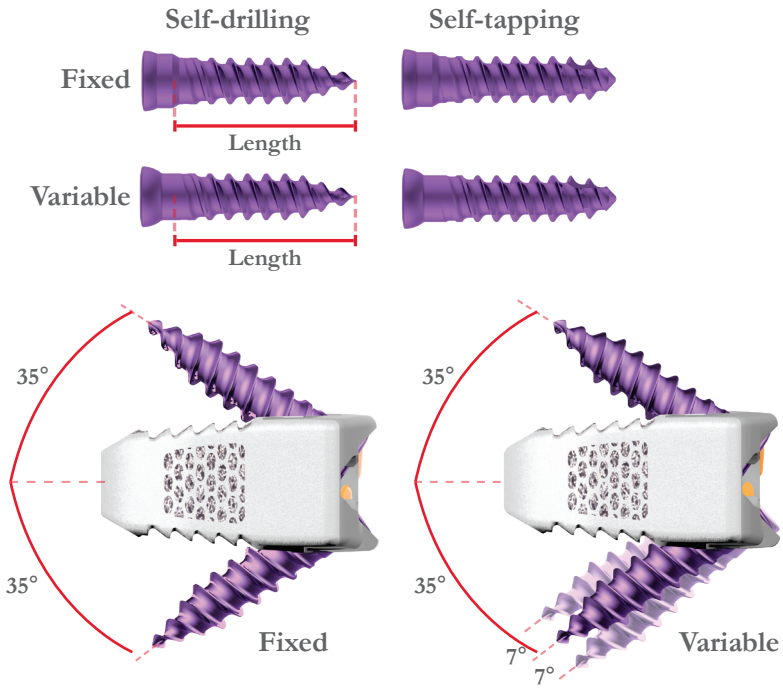
Variable Angulation

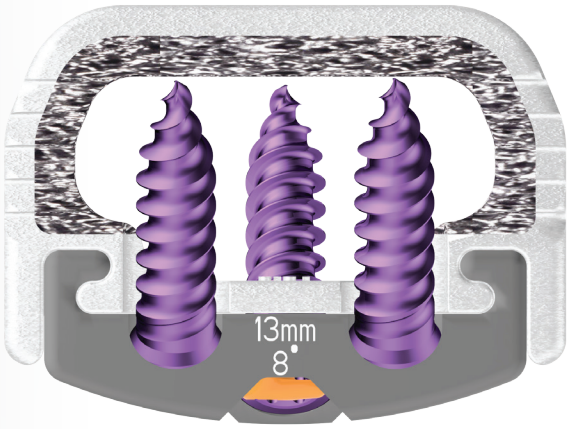
- 0° axial, +/- 7°
- 35° cephalad/caudal, +/- 7°

Features

- T20 Torx drive





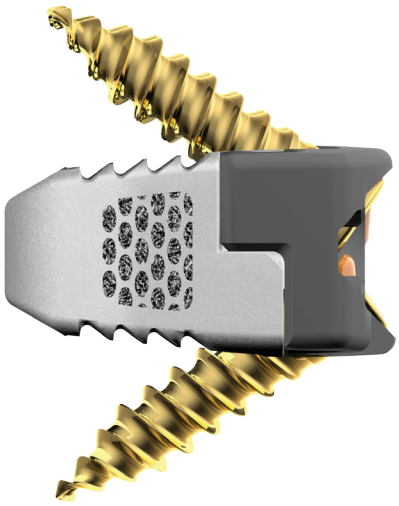


SCREW LENGTH GUIDE

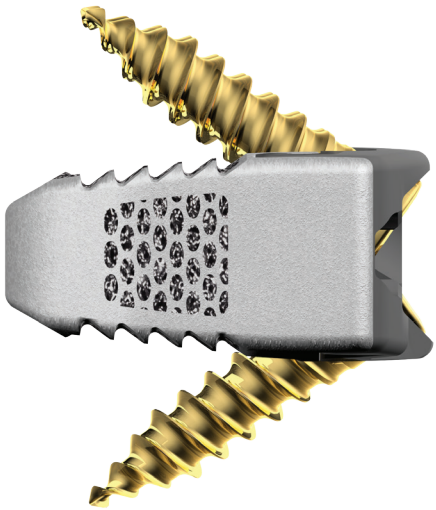
Depending on the footprint of your cage, certain screw lengths are recommended. Reference the information below.

NOTE: When using a variable screw, be aware that at the shallow 35° +/- 7° cephalad/caudal angle, the screw will project longer than at the nominal angle.

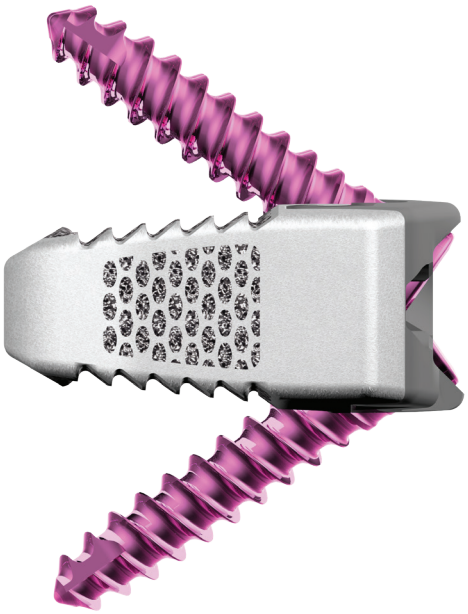
Cage Footprint	Recommended Screw Length
24mm x 30mm	20mm
26mm x 35mm	20mm or 25mm
28mm x 40mm	20mm or 25mm



24mm x 30mm Cage with 20mm Screws



26mm x 35mm Cage with 20mm Screws



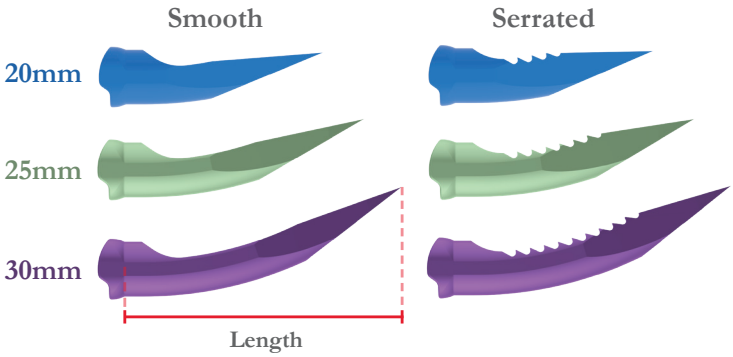
28mm x 40mm Cage with 25mm Screws

ANCHOR FIXATION OVERVIEW

Anchors

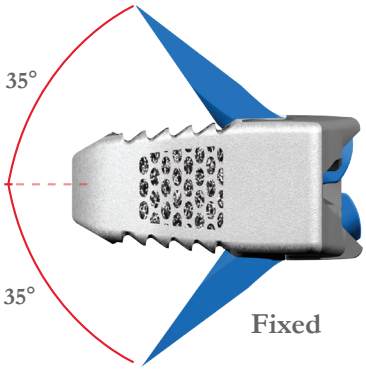
Specifications

- **Style**: Smooth with fixed angle design
  - **Special Order:** Serrated with fixed angle
- **Diameter**: 6.0mm
- **Lengths**: 20mm, 25mm, 30mm
- **Material**: Titanium



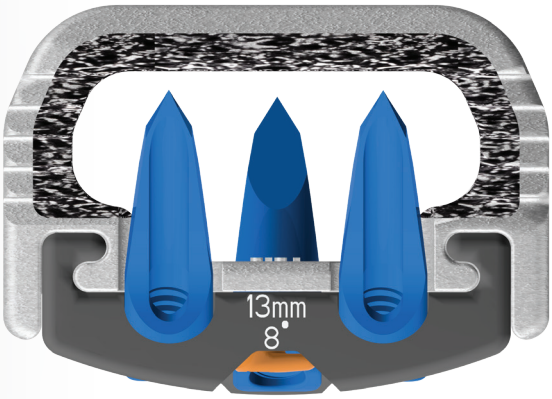
Fixed Angulation

- 0° axial
- 35° cephalad/caudal



Features

- Internal threads for removal



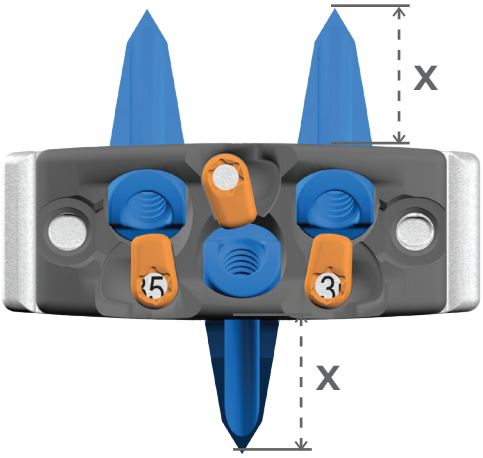
ANCHOR LENGTH GUIDE

The measurements below show distances **X**, **Y**, and **Z** from cage endplate to anchor tip. The measurements are the same whether you're using a NanoPrime IBF cage or F3D-Z cage.

NOTE: Measurements vary depending on orientation of the construct—2 anchor side or 1 anchor side.

2 Anchor & 1 Anchor Sides, X Distance

Cage Height	20mm Anchor	25mm Anchor	30mm Anchor
11mm	12.2mm	17.1mm	22.2mm
12mm	11.7mm	16.6mm	21.7mm
13mm	10.5mm	15.3mm	20.4mm
14mm, 15mm, 17mm, 19mm, 21mm	10.0mm	14.8mm	19.9mm

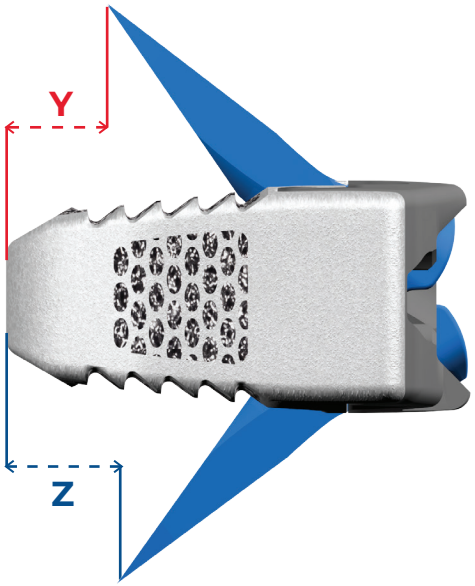


2 Anchor Side, Y Distance

Cage Depth	20mm Anchor	25mm Anchor	30mm Anchor
24mm	4.4mm	2.3mm	0.9mm
26mm	6.4mm	4.3mm	2.9mm
28mm	8.4mm	6.3mm	4.9mm

1 Anchor Side, Z Distance

Cage Depth	20mm Anchor	25mm Anchor	30mm Anchor
24mm	5.1mm	3.0mm	1.6mm
26mm	7.1mm	5.0mm	3.6mm
28mm	9.1mm	7.0mm	5.6mm



PATIENT POSITIONING & APPROACH

Patient Prep

The patient is put under anesthesia and positioned supine. The operative area is prepared and draped in the standard fashion.

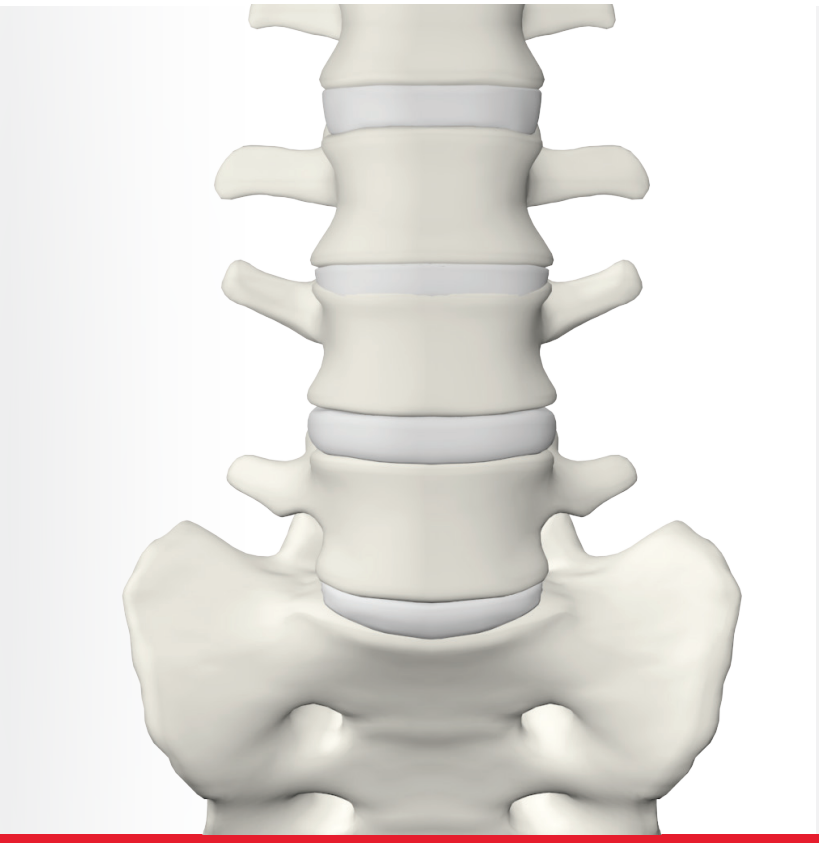
An incision is made at the appropriate level(s). Radiographic guidance, such as C-arm fluoroscopy, should be considered throughout the procedure to ensure correct placement of the implant(s).

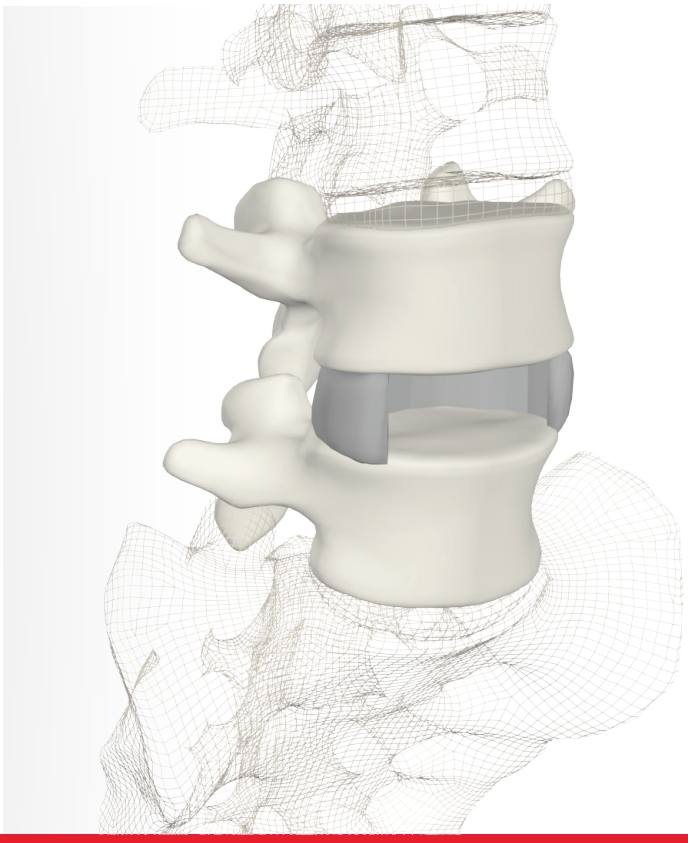
DISCECTOMY & ENDPLATE PREP

Disc Prep

Remove the intervertebral disc and osteophytes as needed.

A variety of disc preparation instruments are provided to help decorticate the endplates.





IMPLANT SIZING & SELECTION

Trialing

The modular, smooth trials (869-1008-XXXX-XX-R) are line-to-line dimensionally with the cage.

The trials must be used to determine the height of the cage that will best fit the prepared intervertebral space. A secure fit is desirable to maintain height and promote fusion. Radiographic images must be used to verify proper fit.

To use, thread the trial onto the trial inserter (869-1007) and insert the trial into the desired disc space. Repeat the process with incrementally taller trials until the appropriate fit has been achieved.

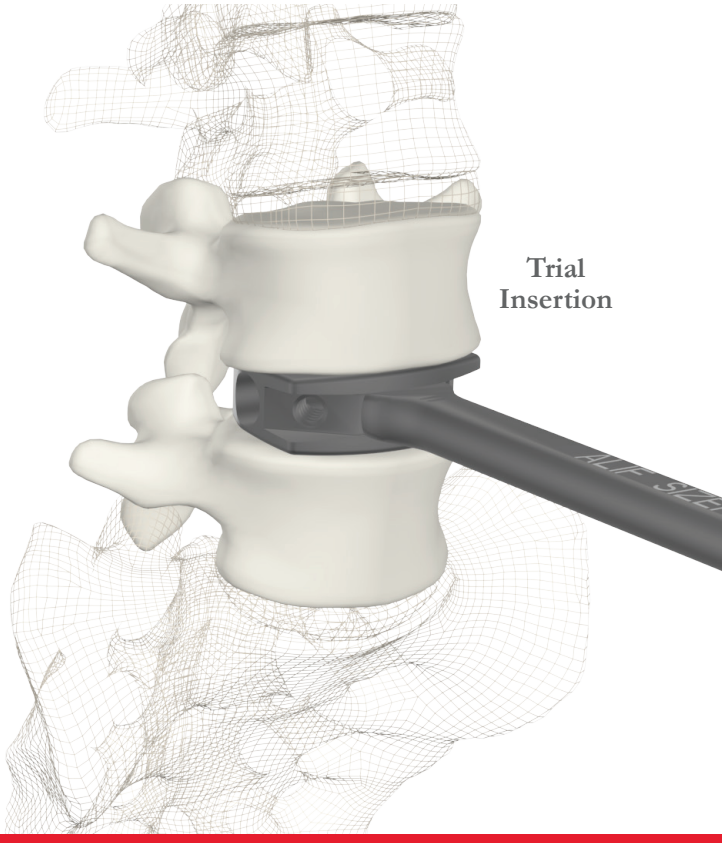
If necessary, the slap hammer (Z-1050) may be used to remove the trial from the disc space.

Cage & Plate Assembly

After trialing, open the appropriate cage—861-F3D-XXXX-XX or 970-XXXX-XX from the NanoPrime ALIF cage caddy.

Plate selection is based on the cage height and lordotic angle. The same plate fits all cage footprints of the same height and lordotic angle. The recessed plates (860-XX-XX) can be found in a caddy in the screw fixation tray.

To assemble the plate, align the slots and tabs of the plate and cage and slide the plate onto the cage until the plate bottoms in the cage. See page 3 for image of assembly.



INSERTER OPTIONS

The Zavation Varisync ALIF System includes three inserter options to accommodate surgeon technique or preference—the screw guide inserter (869-1003-XX) , anchor guide inserter (869-1001-XX), and universal freehand inserter (869-1036).

Screw Guide Inserter

For Guided Technique with Screw Fixation

Anchor Guide Inserter

For Guided Technique with Anchor Fixation

Universal Freehand Inserter

For Freehand Technique

INSERTER OPTIONS (Continued)

Height Selection

The anchor guide and screw guide inserters are cage-height specific. The universal freehand inserter can be used across all cage heights. All inserters retain the construct connection during the entire procedure. Attach the correct height inserter with its respective cage.

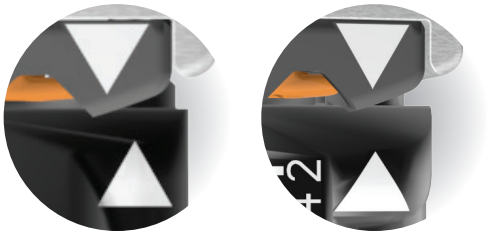
NOTE: All inserters are laser marked on their side with the compatible cage height(s) for identification, as shown below.

Example of Laser Etching

Arrow Alignment

To ensure proper alignment between the guide and cage holes, every plate has one small arrow that must align with the arrow on the distal tip of the inserter. **NOTE:** It is normal if the arrows don't perfectly align tip-to-tip.

WARNING: The guide will not function properly if arrows are not aligned.



Examples of Correct Arrow Alignment

IMPLANT INSERTION WITH SCREW GUIDE INSERTER

Implant & Inserter Connection

Threaded Stylus

After confirming proper alignment, thread the stylus near the etched arrow on the inserter into the implant. Next, thread the other stylus into the cage.

Complete Connection

Verify both styluses are completely threaded into the construct with no gaps between the inserter and construct.

Cage & Inserter with No Gap

Looking for anchor insertion? Skip to page 22.

Insertion into the Disc Space

Packing Autograft

With the selected cage and plate attached to the inserter, fill the cage with autograft.

IMPLANT INSERTION WITH SCREW GUIDE INSERTER (Continued)

Insertion into the Disc Space

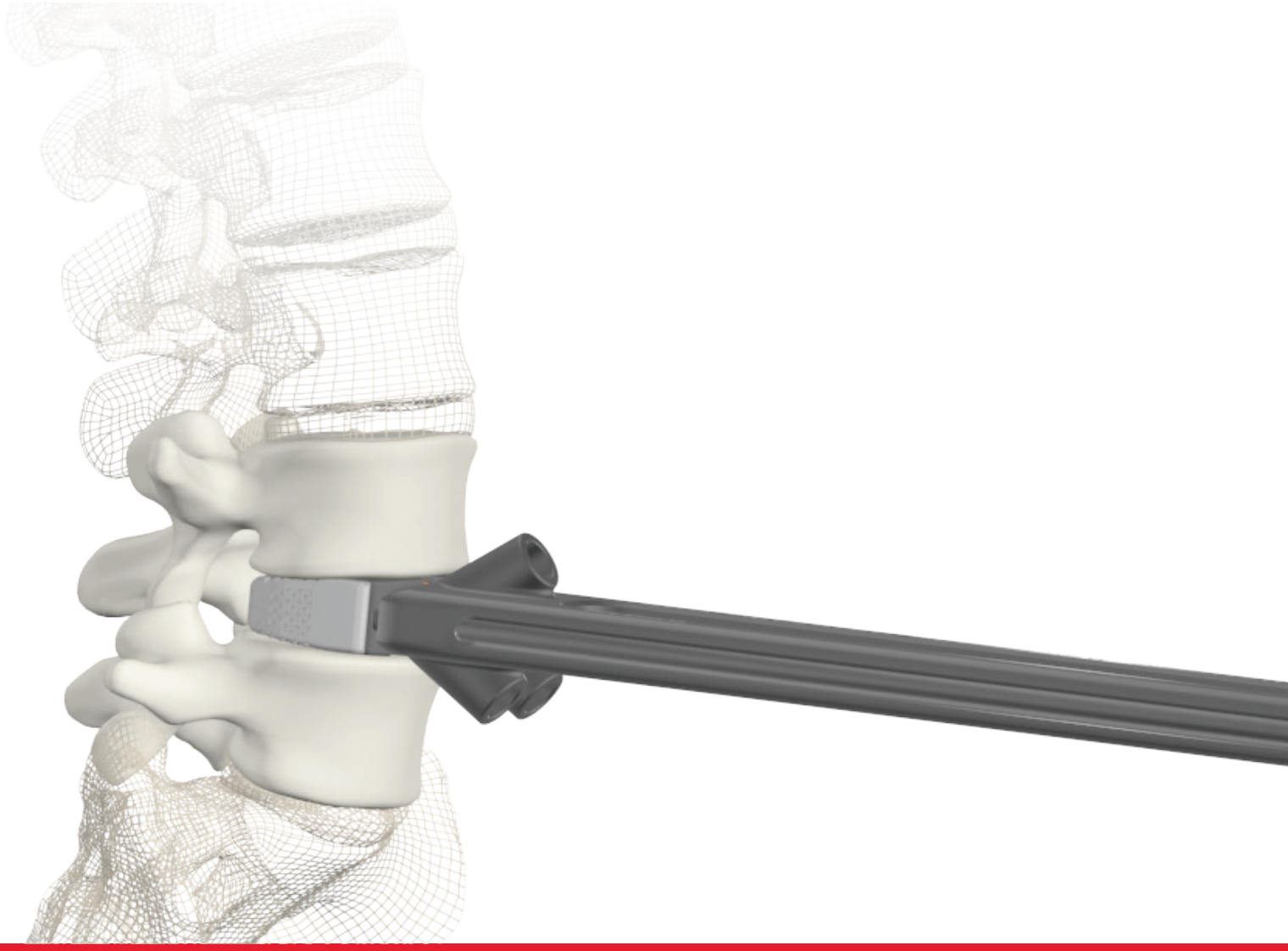
Screw Guide Insertion

When the construct and inserter are assembled correctly, the etched arrow on the distal end of the inserter indicates the directionality of the one screw side of the construct. See page 11 for image. The arrow on the guide should align with the arrow on the plate.

NOTE: Keep the inserter attached to the cage during instrumentation steps. The barrels on the screw guide will serve as a stop mechanism.

Fluoroscopy

Under fluoroscopy, with the implant attached to the chosen inserter, gently insert into the disc space toward its final position.



SCREW HOLE PREPARATION

With Screw Guide Inserter

Universal Awl & Drill

The pilot hole can be created with the awl or drill instruments. The awls and drills are guided by the holes in the guide inserter. Awls and drills have a ¼" drive connection and should be used with the straight axial handles.

Use the awl or drills to sequentially create a pilot hole and insert the screw one at a time.
This will prevent cage migration and misalignment between the pilot hole and the screw path.

Universal Awl Tip

Universal Drill Tip

Universal Awl

Universal Drill

With Screw Guide Inserter

Universal Guide

There is a universal guide (869-1016) in the system that is compatible with the universal awl (869-1011) and universal drill (869-1013).

The shaft angle can be adjusted by pulling back on the instrument collar.

Instrument Collar

Universal Guide

SCREW HOLE PREPARATION (Continued)

With Screw Guide Inserter

Sleeved Universal Awl

The sleeved universal jointed instruments are compatible with a universal joint cover (869-1017) to prevent tissue impingement.

To attach the joint cover, slide cover proximal end of the shaft until joint is covered. Click cover into place. Attach axial handle (Z-1064) as final assembly step.

The cover will work with all universal jointed instruments, including the sleeved and no-sleeve awls and drills, and will not impede their use with the screw guides.

NOTE: Slotted teeth end should be pointed toward proximal end of instrument. Force is necessary for both joint cover assembly and disassembly. Take care not to pinch fingers during disassembly.

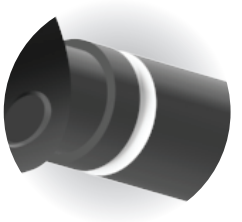
Sleeved Universal Awl with Joint Cover

SCREW HOLE PREPARATION (Continued)

With Screw Guide Inserter

The grooved line around the awl shaft should be aligned with the top of the screw guide barrel when the awl is completely seated.

The grooved line shows complete puncture depth (15mm or 20mm depending on instrument).



In addition, the sleeved universal awl (869-1025-XX) can be used with the single barrel awl guide.

SCREW HOLE PREPARATION (Continued)

With Screw Guide Inserter

Drills

The drill instruments are available in 15mm straight (869-1012), 15mm universal (869-1013), 15mm sleeved universal (869-1026-15), and 20mm sleeved universal (869-1026-20).

NOTE: Every drill is compatible with the screw guide inserter. In addition, the sleeved universal guide can be used with the single barrel guide.

Straight Drill

Universal Drill

Sleeved Universal Drill

With Screw Guide Inserter

Awls

The awl instruments are available in 15mm straight (869-1033), 15mm angled (869-1010), 15mm universal (869-1011), 15mm sleeved universal (869-1025-15), and 20mm sleeved universal (860-1025-20).

NOTE: Every awl is compatible with the screw guide inserter.

Straight Awl

Angled Awl

Universal Awl

Sleeved Universal Awl

SCREW INSERTION

Screwdrivers

The screwdriver instruments are available in straight (869-1014), universal (869-1015), short universal (869-1023), and fixed angle (Z-1051-0 / Z-1051-01).

All screwdrivers have a T20 drive.

The straight, universal, long bit and fixed angled drivers can be used with the screw guide inserter.

The short universal, short bit and fixed angled drivers will need to be used in a freehand fashion.

Straight Driver

Universal Driver

Short Universal Driver

Fixed Angle Driver

NOTE: Screws can be loaded onto the drivers from the screw caddy. Press driver tip down firmly into screw head for solid screw connection.

Fixed Angle Instrument

Fixed Angle Instrument Assembly

Insert the inner shaft into the outer sleeve and dial down until a tight connection is complete.

Attach ratcheting straight handle or T-handle to the proximal end of the inner drive shaft. Set the handle to "lock" or "forward ratchet" to advance.

SCREW INSERTION (Continued)

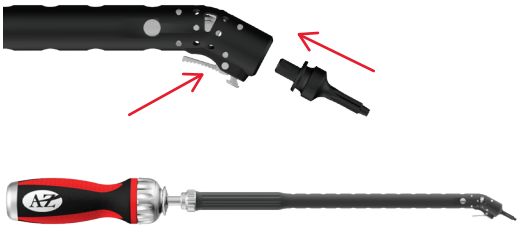
Fixed Angle Instrument

Fixed Angle Instrument Assembly

There are two screwdriver bits available for the fixed angle driver: a short bit (Z-1053-S) and a long bit (Z-1053-L).

NOTE: Only the long bit can be used through the screw guide inserter; the short bit cannot.

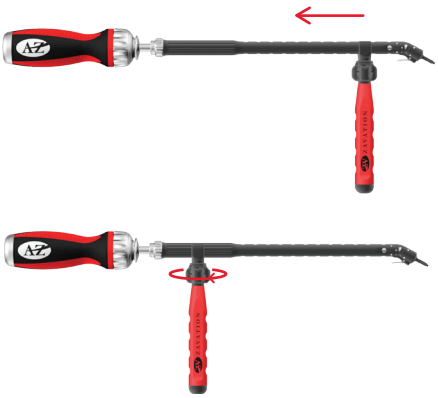
Insert the bit into the outer sleeve opening as shown below, while pressing the button on the underside of the sleeve. Release the button and confirm bit is secure.



If additional stability is needed, the system includes a support handle (Z-1052) for the fixed angle driver.

To attach, slide the C-shaped handle end up the smooth portion of the shaft, and align with the ridges on the upper shaft.

Rotate knob clockwise to lock handle on ridged shaft.

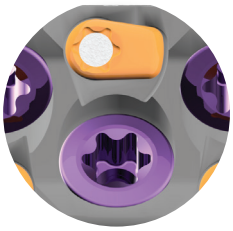


SCREW LOCKING MECHANISM

Remove the inserter instrument from the cage/plate by unthreading the two styluses.

Using the long lock driver (869-1018) or the short lock driver (869-1034) with AO Handle (Z-1048), turn the locking mechanism until the screw heads are covered.

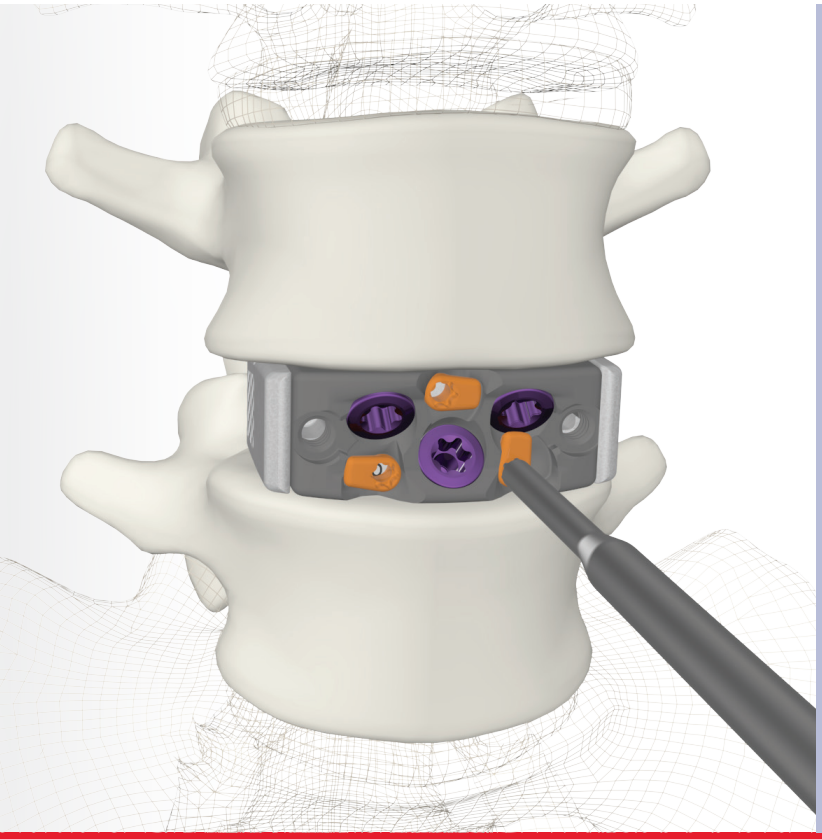
NOTE: The locks have a positive stop to prevent overturning.

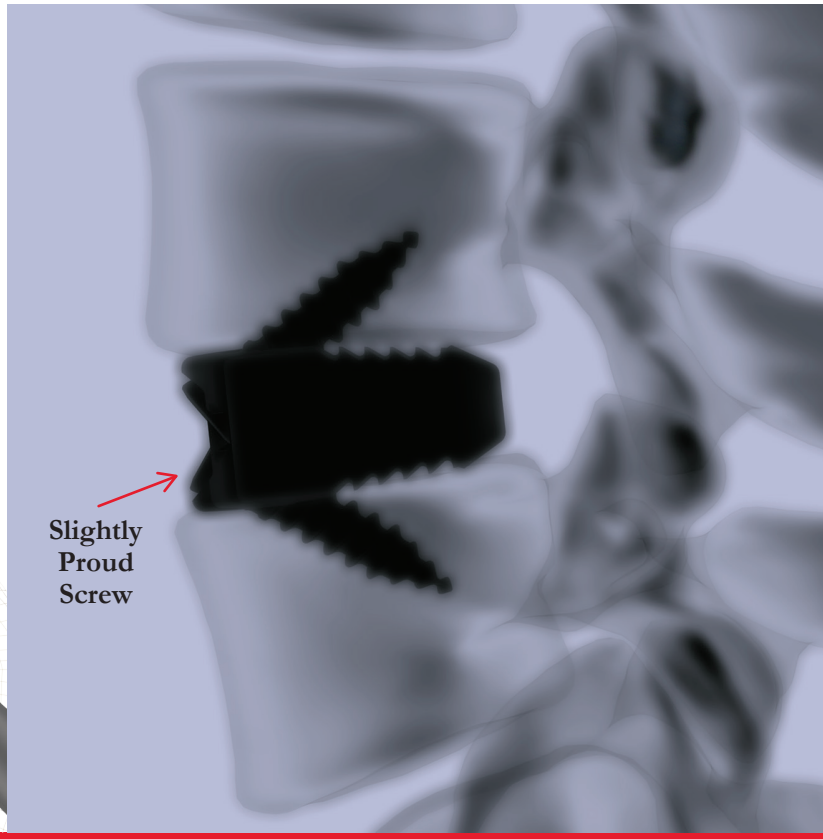


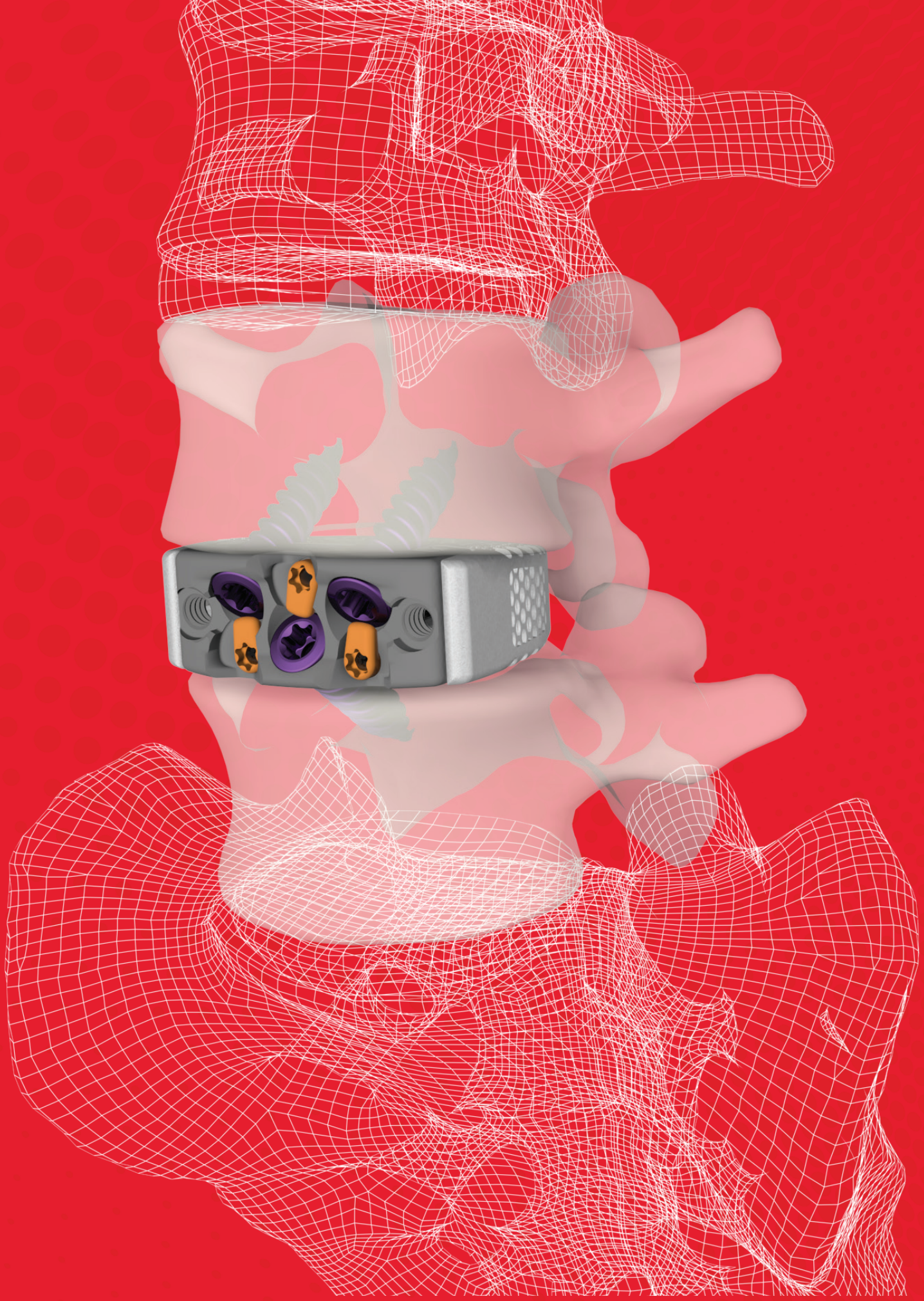
Not Locked

Locked

NOTE: The screw head may appear slightly proud in lateral fluoro image. If the camlock covers the screw head, then the anti-backout lock is engaged.







ANCHOR FIXATION PREPARATION

Implant & Inserter Connection

Assembly

First, follow the cage assembly steps on page 3. Attach pre-assembled cage to correct anchor guide inserter. Tightly hold plate and cage together during assembly. Refer to page 9 for details.

Be mindful to align the arrow etching on the plate and inserter during assembly. See page 11.

Threaded Stylus

After confirming proper alignment, thread the stylus near the etched arrow on the inserter into the implant. Next, thread the other stylus into the cage.

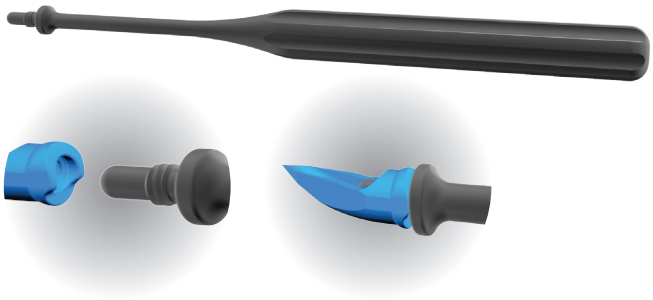
Complete Connection

Verify both styluses are completely threaded into the construct with no gaps between the inserter and construct.

Anchor Prep

Anchor Loader Instrument

Thread each anchor onto the anchor loader instrument (869-1028).



Carriage Retraction

NOTE: Prior to loading anchors, pull the anchor guide carriage back so the etched lines are aligned with markings on the anchor guide frame. Once the anchors have been deployed, the proximal etched lines will be aligned, as seen on page 25.

ANCHOR FIXATION PREPARATION (Continued)

Loading Anchors

Anchor Loading Channels

When loading anchors, use a pencil grip with anchor inserter's proximal end against palm (area between the thumb and index finger).

Apply strong force to bypass spring clips.

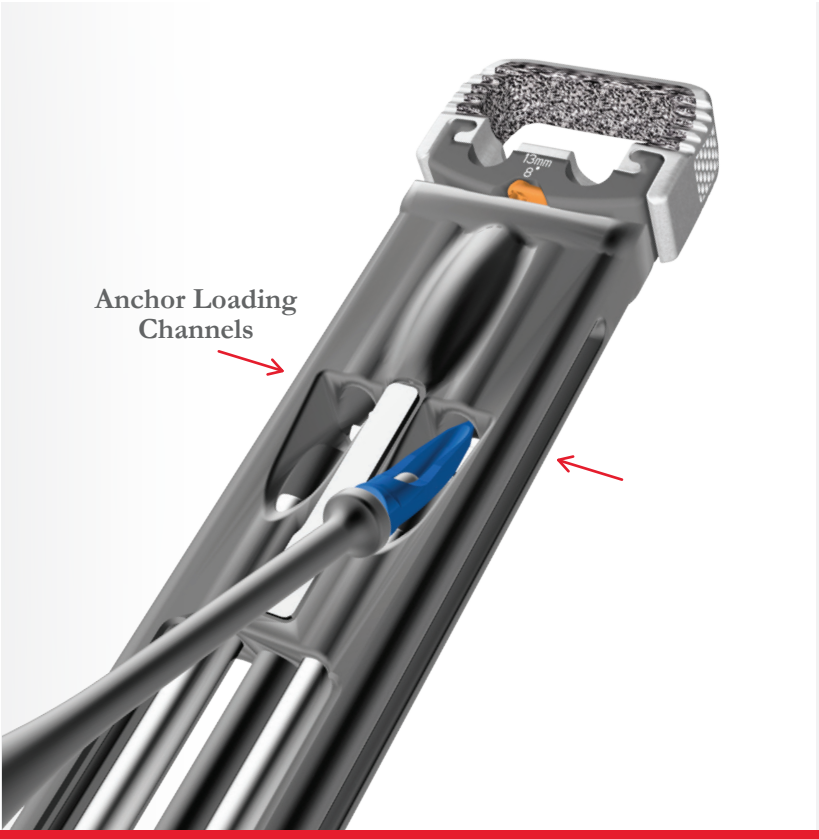
Spring Clips

Each anchor loading channel on the inserter has a spring clip that retains the anchor while implanting into the disc space.

The spring clip provides a tactile, audible, and visual confirmation when seating the anchor into the guide.

Unthread the anchor loader instrument from the anchor once it is properly seated into the guide.

Repeat loading steps for additional anchors.



ANCHOR FIXATION PREPARATION (Continued)

Stop Adjustment

Before Insertion into the Disc Space

On the anchor guide inserter, the stop can be adjusted with the long lock driver (869-1018) or short lock driver (869-1034).

Prior to insertion into the disc space, make sure the stop is at the 0mm (flush) position.

After Insertion into the Disc Space

Once in the disc space, the position of the cage can be recessed if needed.

Adjust the stop to recess the cage up to 6mm.

Stop at Flush (0mm) Position

Stop at Recessed (6mm) Position

IMPLANT INSERTION WITH ANCHOR GUIDE INSERTER

Insertion into the Disc Space

Packing Autograft

With the selected cage and plate attached to the inserter, fill the cage with autograft.

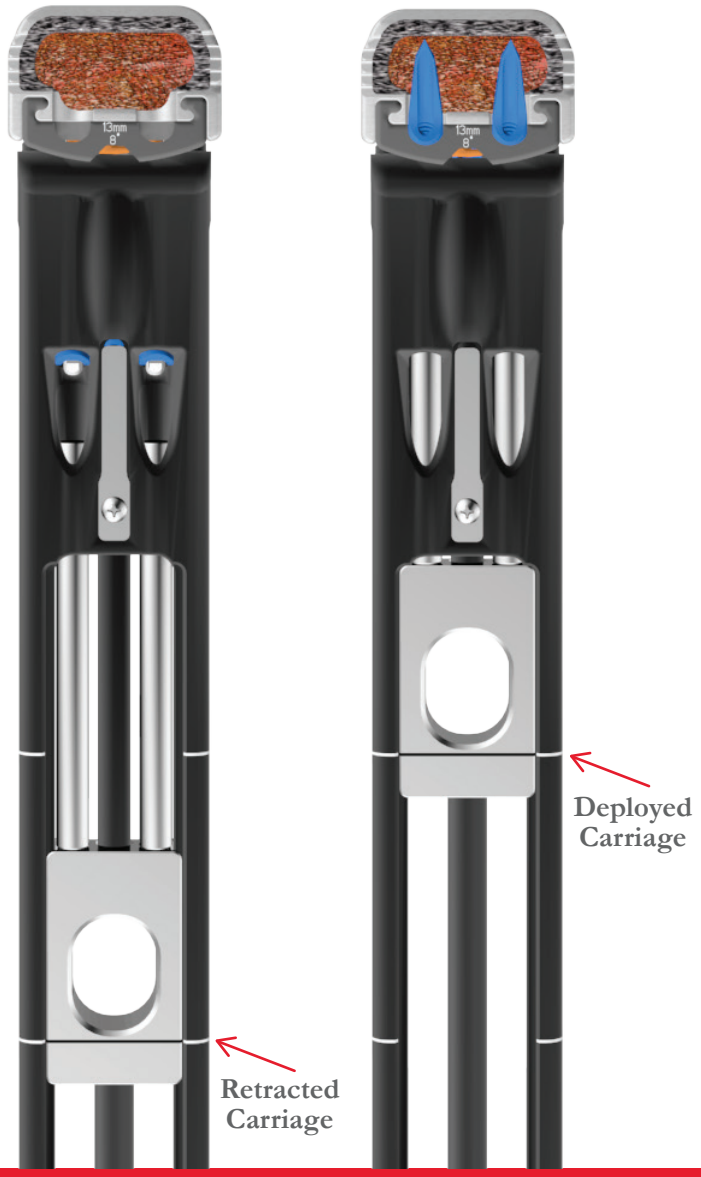
Anchor Guide Insertion

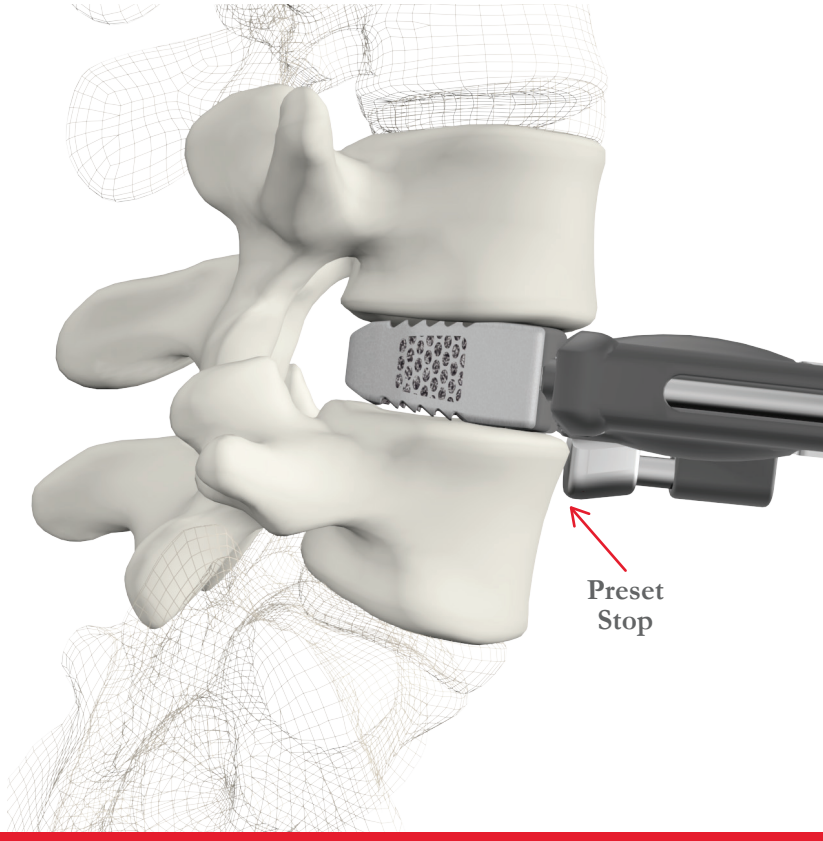
REMINDER: Prior to cage insertion, make sure the anchor guide carriage is retracted. There are etched lines on the carriage and inserter frame that must be aligned prior to cage insertion.

Fluoroscopy

Under fluoroscopy, with the implant attached to the inserter instrument, gently insert into the disc space until the preset stop rests against the vertebral body.

Adjust stop to recess the cage if necessary.





IMPLANT INSERTION WITH ANCHOR GUIDE INSERTER (Continued)

Anchor Deployment

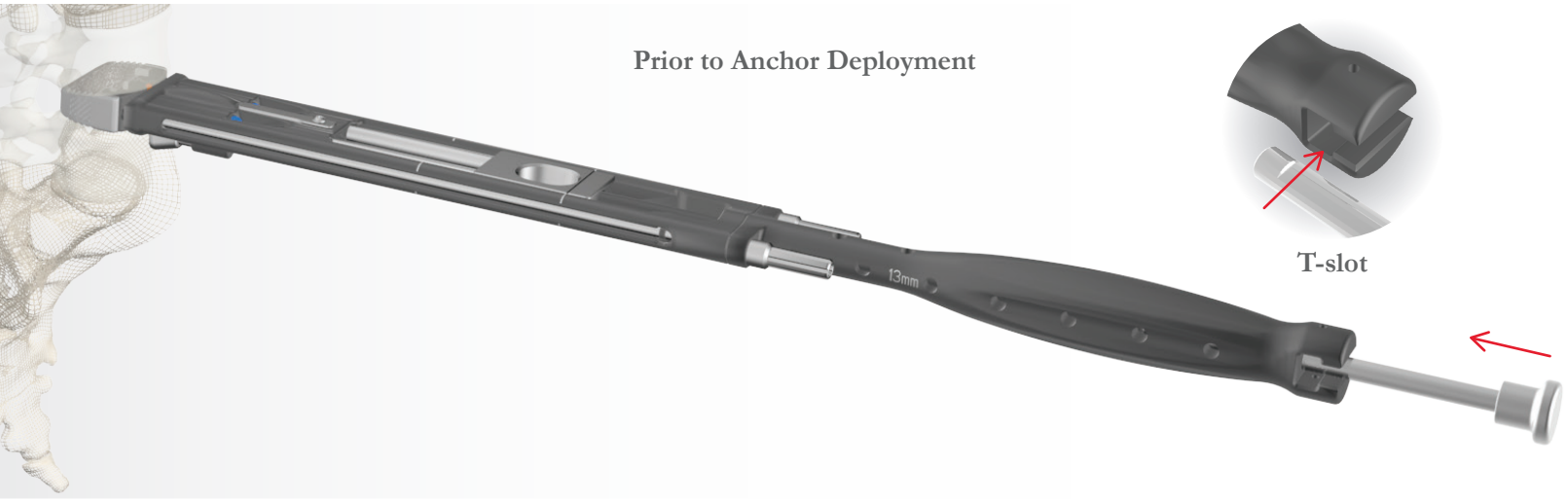
Impactor Instrument

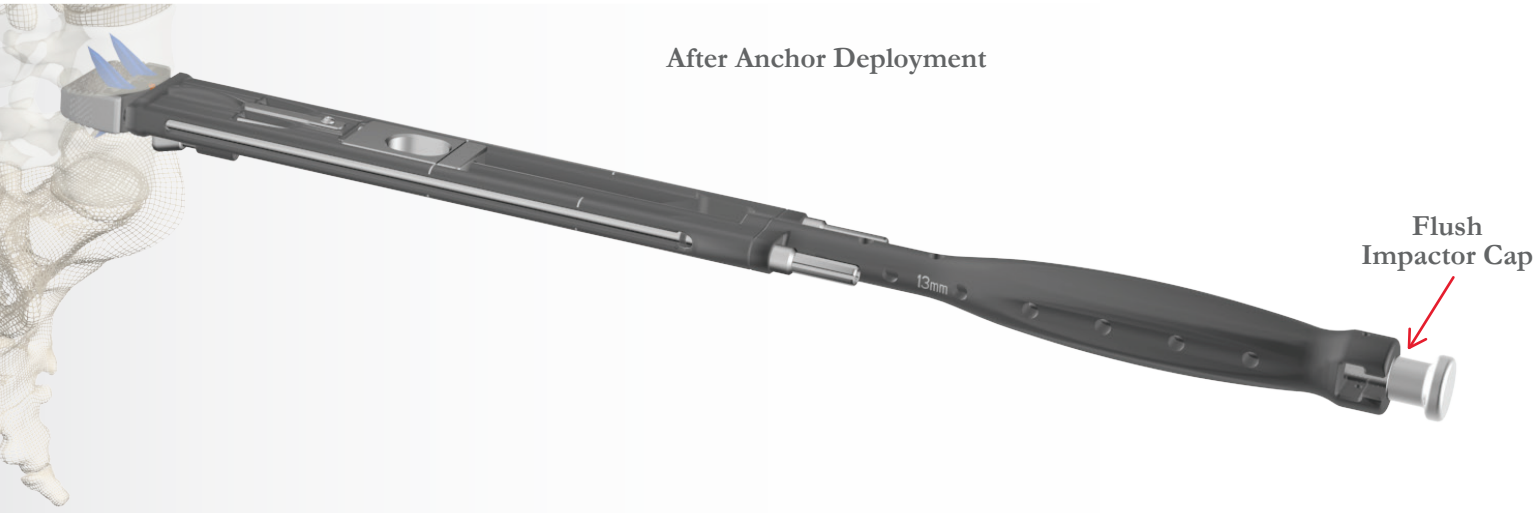
Align the flat sides of the impactor tool with the flat sides inside the Anchor Guide's T-slot. Slide impactor into T-Slot and gently slide the impactor down into the Guide body. Once ready to deploy the anchors, impact on the impactor instrument with the mallet.

All three anchors should deploy simultaneously. Monitor deployment with fluoroscopy throughout.

NOTE: When the anchors are deployed, the impactor cap will be flush with the proximal end of the anchor guide.

Additionally, refer to page 25 for visual confirmation of anchor and carriage deployment via the etched lines. Remove the inserter instrument from the construct by unthreading the two styluses.
To further seat the anchors, use the anchor tamp (869-1027) to seat anchor to the plate.





ANCHOR LOCKING MECHANISM

Remove the inserter instrument from the cage/plate by unthreading the two styluses.

Using the long lock driver (869-1018) or the short lock driver (869-1034) with AO Handle (Z-1048), turn the locking mechanism until the anchor heads are covered.

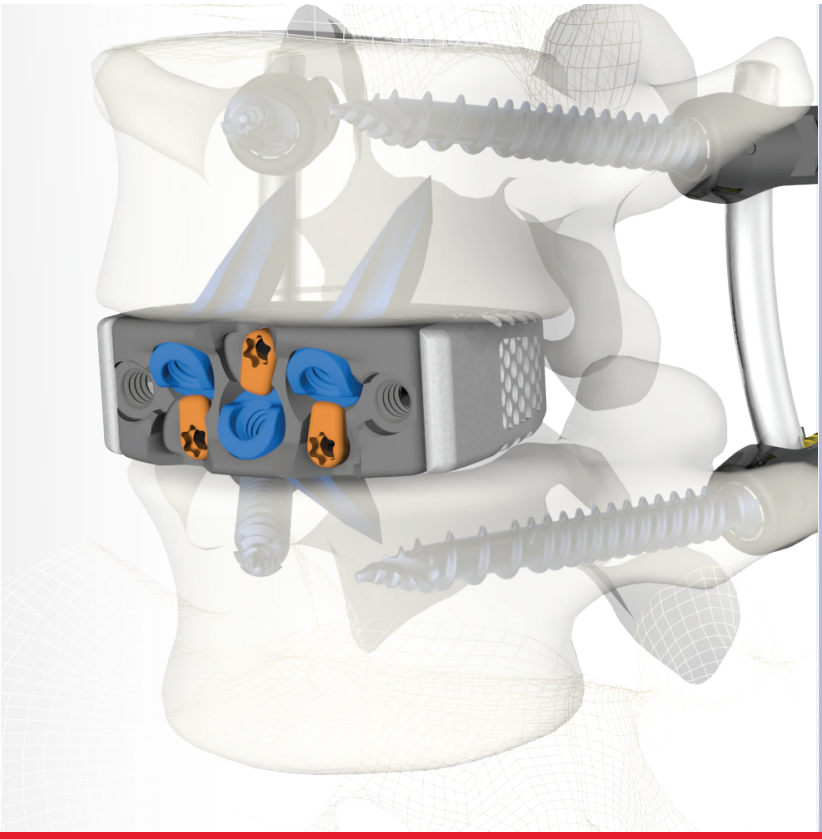
NOTE: The locks have a positive stop to prevent overturning.

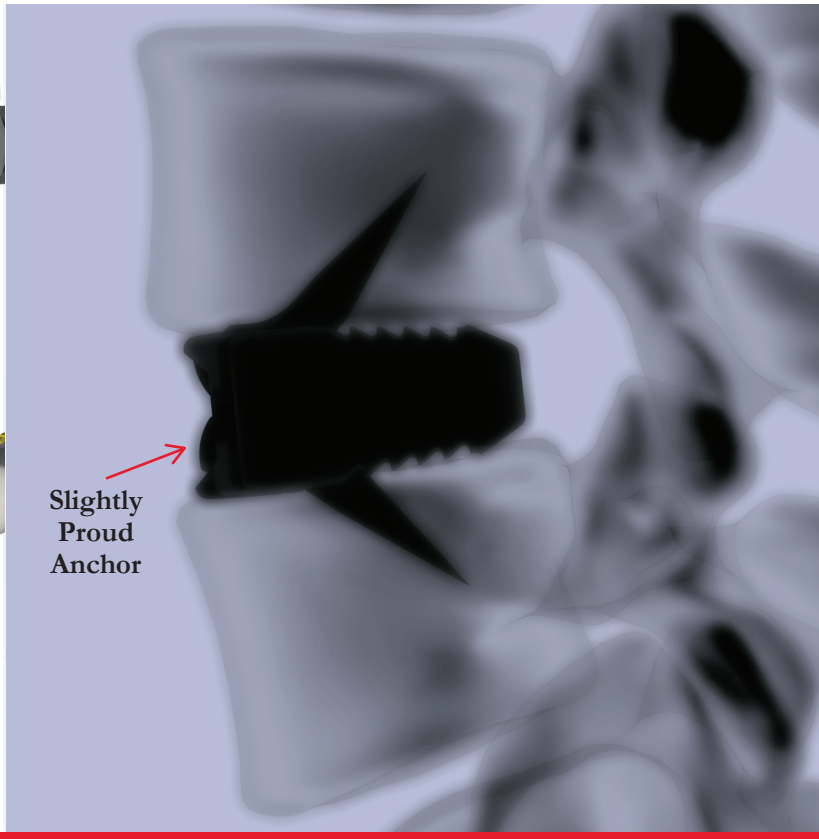
Not Locked

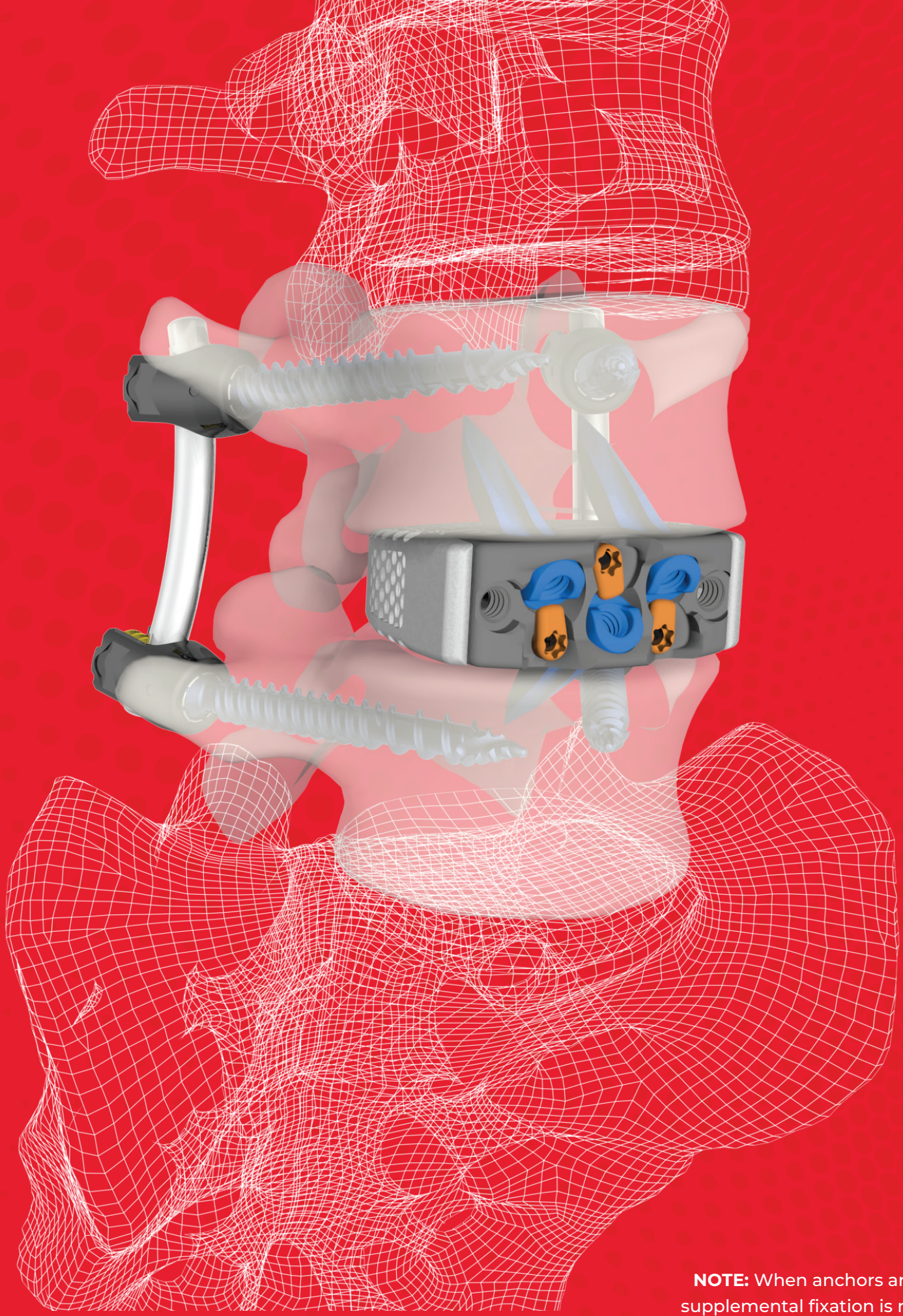
Locked

NOTE: The head of the single anchor side of the construct may appear slightly proud in lateral fluoro image. If the camlock covers the anchor head, then the anti-backout lock is engaged.

When anchors are in use, supplemental fixation is required.







NOTE: When anchors are in use, supplemental fixation is required.

IMPLANT REMOVAL

Using the lock screwdriver, turn the lock rivets to the unlocked position.

Screw Removal

When removing screws, simply back out the screws from the plate using one of the system's screwdrivers.

Anchor Removal

Thread the tip of the anchor removal tool (869-1035) into the target anchor. Attach the slap hammer to the anchor remover and remove the anchors.

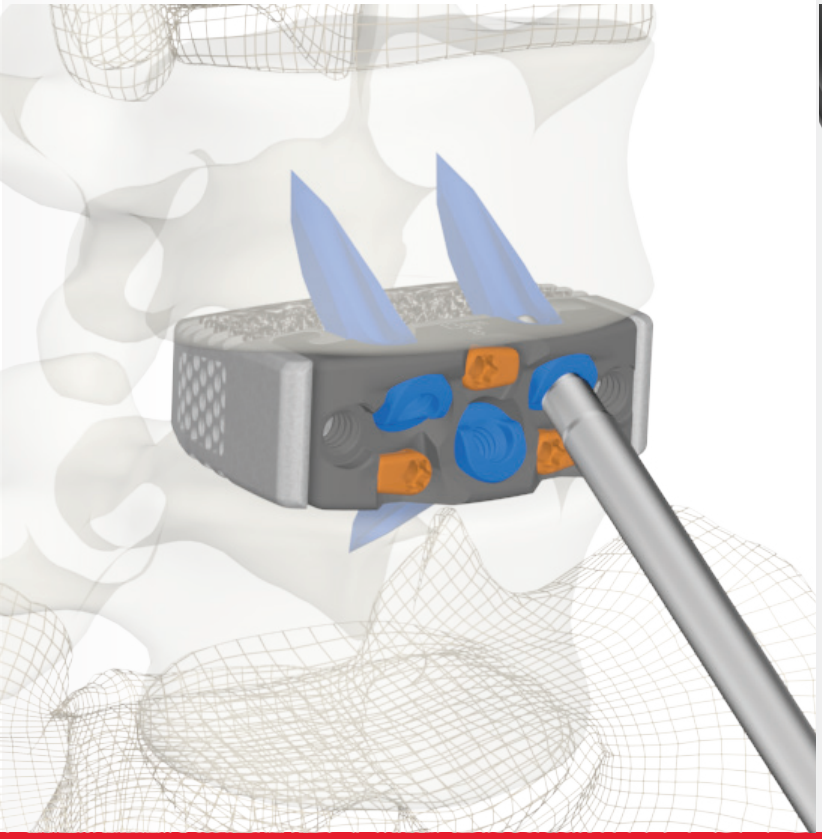
Cage Removal

Attach the inserter to the cage/plate, then attach the slap hammer to the inserter and remove construct.

CLEANING PROCEDURE

Mandatory Cleaning Step

WARNING: Prior to cleaning the anchor guide inserters, the carriage must be retracted so the anchor channels can be properly cleaned.



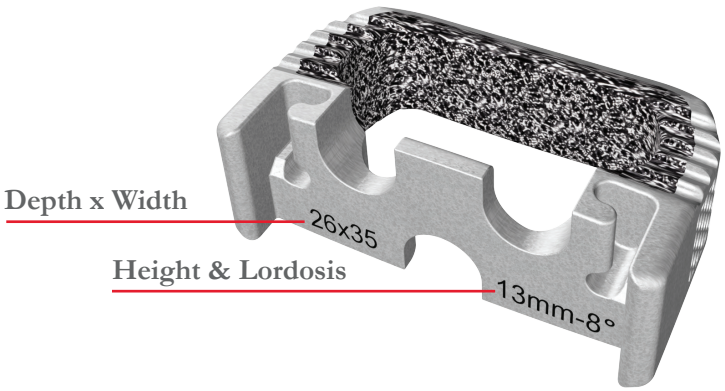
STANDARD—VARISYNC ALIF PRODUCT LISTING

F3D-Z Cages

Kit #KVA007 

24mm x 30mm, 8°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-0830-11	11mm	4.06mm	1.98cc	1
861-F3D-0830-12	12mm	5.08mm	2.18cc	1
861-F3D-0830-13	13mm	6.10mm	2.38cc	1
861-F3D-0830-14	14mm	7.11mm	2.58cc	1
861-F3D-0830-15	15mm	8.13mm	2.78cc	1
861-F3D-0830-17	17mm	10.16mm	3.18cc	1
24mm x 30mm, 15°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-1530-11	11mm	2.03mm	1.73cc	1
861-F3D-1530-12	12mm	3.05mm	1.93cc	1
861-F3D-1530-13	13mm	4.06mm	2.13cc	1
861-F3D-1530-14	14mm	5.08mm	2.33cc	1
861-F3D-1530-15	15mm	6.10mm	2.53cc	1
861-F3D-1530-17	17mm	8.13mm	2.93cc	1
26mm x 35mm, 8°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-0835-11	11mm	3.81mm	2.76cc	2
861-F3D-0835-12	12mm	4.83mm	3.05cc	2
861-F3D-0835-13	13mm	5.84mm	3.33cc	2
861-F3D-0835-14	14mm	6.86mm	3.62cc	2
861-F3D-0835-15	15mm	7.87mm	3.90cc	1
861-F3D-0835-17	17mm	9.91mm	4.47cc	1
26mm x 35mm, 15°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-1535-11	11mm	1.52mm	2.36cc	1
861-F3D-1535-12	12mm	2.54mm	2.65cc	1
861-F3D-1535-13	13mm	3.56mm	2.93cc	1
861-F3D-1535-14	14mm	4.57mm	3.22cc	1
861-F3D-1535-15	15mm	5.59mm	3.51cc	1
861-F3D-1535-17	17mm	7.37mm	4.07cc	1

28mm x 40mm, 8°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-0840-11	11mm	3.56mm	3.72cc	2
861-F3D-0840-12	12mm	4.57mm	4.12cc	2
861-F3D-0840-13	13mm	5.59mm	4.51cc	2
861-F3D-0840-14	14mm	6.60mm	4.90cc	2
861-F3D-0840-15	15mm	7.62mm	5.29cc	1
861-F3D-0840-17	17mm	9.65mm	6.07cc	1
28mm x 40mm, 15°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-1540-11	11mm	1.02mm	3.11cc	1
861-F3D-1540-12	12mm	2.03mm	3.51cc	1
861-F3D-1540-13	13mm	3.05mm	3.90cc	1
861-F3D-1540-14	14mm	4.06mm	4.29cc	1
861-F3D-1540-15	15mm	5.08mm	4.68cc	1
861-F3D-1540-17	17mm	7.11mm	5.46cc	1



SPECIAL ORDER—VARISYNC ALIF PRODUCT LISTING

F3D-Z Cages—Tall

Kit #KVA009 

24mm x 30mm, 8°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-0830-19	19mm	12.19mm	3.59cc	1
24mm x 30mm, 15°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-1530-19	19mm	9.91mm	3.33cc	1
26mm x 35mm, 8°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-0835-19	19mm	11.94mm	5.04cc	1
861-F3D-0835-21	21mm	13.97mm	5.61cc	1
26mm x 35mm, 15°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-1535-19	19mm	9.40mm	4.65cc	1
861-F3D-1535-21	21mm	11.43mm	5.22cc	1
28mm x 40mm, 8°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-0840-19	19mm	11.68mm	6.86cc	1
861-F3D-0840-21	21mm	13.72mm	7.64cc	1
28mm x 40mm, 15°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-1540-19	19mm	9.14mm	6.25cc	1
861-F3D-1540-21	21mm	11.18mm	7.03cc	1

STANDARD—VARISYNC ALIF PRODUCT LISTING

F3D-Z Cages—Hyperlordotic

Kit #KVA008 

24mm x 30mm, 20°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-2030-13	13mm	2.79mm	1.90cc	1
861-F3D-2030-14	14mm	3.81mm	2.10cc	1
861-F3D-2030-15	15mm	4.83mm	2.30cc	1
861-F3D-2030-17	17mm	6.86mm	2.70cc	1
861-F3D-2030-19	19mm	8.89mm	3.10cc	1
24mm x 30mm, 25°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-2530-15	15mm	3.30mm	2.07cc	1
861-F3D-2530-17	17mm	5.33mm	2.47cc	1
861-F3D-2530-19	19mm	7.37mm	2.87cc	1
861-F3D-2530-21	21mm	9.40mm	3.28cc	1
26mm x 35mm, 20°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-2035-13	13mm	2.03mm	2.57cc	2
861-F3D-2035-14	14mm	3.05mm	2.86cc	2
861-F3D-2035-15	15mm	4.06mm	3.14cc	2
861-F3D-2035-17	17mm	6.10mm	3.71cc	2
861-F3D-2035-19	19mm	8.13mm	4.28cc	1
861-F3D-2035-21	21mm	10.16mm	4.85cc	1
26mm x 35mm, 25°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-2535-15	15mm	2.54mm	2.77cc	1
861-F3D-2535-17	17mm	4.57mm	3.33cc	1
861-F3D-2535-19	19mm	6.35mm	3.91cc	1
861-F3D-2535-21	21mm	8.38mm	4.48cc	1

28mm x 40mm, 20°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-2040-15	15mm	3.30mm	4.14cc	1
861-F3D-2040-17	17mm	5.33mm	4.92cc	1
861-F3D-2040-19	19mm	7.37mm	5.71cc	1
861-F3D-2040-21	21mm	9.14mm	6.49cc	1
28mm x 40mm, 25°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
861-F3D-2540-17	17mm	3.56mm	4.39cc	1
861-F3D-2540-19	19mm	5.33mm	5.18cc	1
861-F3D-2540-21	21mm	7.37mm	5.96cc	1

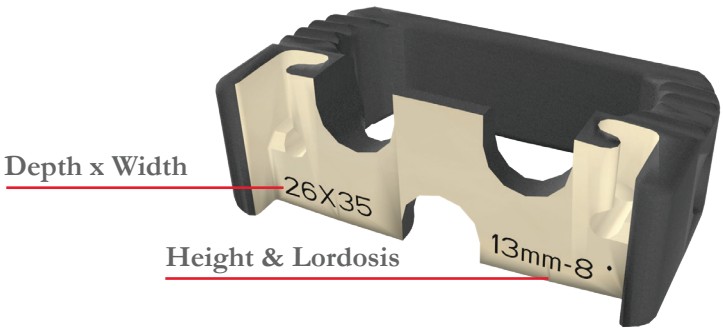
STANDARD—VARISYNC ALIF PRODUCT LISTING

NanoPrime™ IBF Cages

Kit #KVA018 

24mm x 30mm, 8°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-0830-11	11mm	4.06mm	1.98cc	1
970-0830-12	12mm	5.08mm	2.18cc	1
970-0830-13	13mm	6.10mm	2.38cc	1
970-0830-14	14mm	7.11mm	2.58cc	1
970-0830-15	15mm	8.13mm	2.78cc	1
970-0830-17	17mm	10.16mm	3.18cc	1
24mm x 30mm, 15°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-1530-11	11mm	2.03mm	1.73cc	1
970-1530-12	12mm	3.05mm	1.93cc	1
970-1530-13	13mm	4.06mm	2.13cc	1
970-1530-14	14mm	5.08mm	2.33cc	1
970-1530-15	15mm	6.10mm	2.53cc	1
970-1530-17	17mm	8.13mm	2.93cc	1
26mm x 35mm, 8°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-0835-11	11mm	3.81mm	2.76cc	2
970-0835-12	12mm	4.83mm	3.05cc	2
970-0835-13	13mm	5.84mm	3.33cc	2
970-0835-14	14mm	6.86mm	3.62cc	2
970-0835-15	15mm	7.87mm	3.90cc	1
970-0835-17	17mm	9.91mm	4.47cc	1
26mm x 35mm, 15°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-1535-11	11mm	1.52mm	2.36cc	1
970-1535-12	12mm	2.54mm	2.65cc	1
970-1535-13	13mm	3.56mm	2.93cc	1
970-1535-14	14mm	4.57mm	3.22cc	1
970-1535-15	15mm	5.59mm	3.51cc	1
970-1535-17	17mm	7.37mm	4.07cc	1

28mm x 40mm, 8°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-0840-11	11mm	3.56mm	3.72cc	2
970-0840-12	12mm	4.57mm	4.12cc	2
970-0840-13	13mm	5.59mm	4.51cc	2
970-0840-14	14mm	6.60mm	4.90cc	2
970-0840-15	15mm	7.62mm	5.29cc	1
970-0840-17	17mm	9.65mm	6.07cc	1
28mm x 40mm, 15°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-1540-11	11mm	1.02mm	3.11cc	1
970-1540-12	12mm	2.03mm	3.51cc	1
970-1540-13	13mm	3.05mm	3.90cc	1
970-1540-14	14mm	4.06mm	4.29cc	1
970-1540-15	15mm	5.08mm	4.68cc	1
970-1540-17	17mm	7.11mm	5.46cc	1



STANDARD—VARISYNC ALIF PRODUCT LISTING

NanoPrime™ IBF Cages—20°

Kit #KVA019 

24mm x 30mm, 20°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-2030-13	13mm	2.79mm	1.90cc	1
970-2030-14	14mm	3.81mm	2.10cc	1
970-2030-15	15mm	4.83mm	2.30cc	1
970-2030-17	17mm	6.86mm	2.70cc	1
26mm x 35mm, 20°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-2035-13	13mm	2.03mm	2.57cc	2
970-2035-14	14mm	3.05mm	2.86cc	2
970-2035-15	15mm	4.06mm	3.14cc	2
970-2035-17	17mm	6.10mm	3.71cc	2
28mm x 40mm, 20°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-2040-15	15mm	3.30mm	4.14cc	1
970-2040-17	17mm	5.33mm	4.92cc	1
970-2040-19	19mm	7.37mm	5.71cc	1
970-2040-21	21mm	9.14mm	6.49cc	1

NanoPrime™ IBF Cages—Tall

Kit #KVA020 

24mm x 30mm, 8°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-0830-19	19mm	12.19mm	3.59cc	1
24mm x 30mm, 15°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-1530-19	19mm	9.91mm	3.33cc	1
26mm x 35mm, 8°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-0835-19	19mm	11.94mm	5.04cc	1
970-0835-21	21mm	13.97mm	5.61cc	1
26mm x 35mm, 15°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-1535-19	19mm	9.40mm	4.65cc	1
970-1535-21	21mm	11.43mm	5.22cc	1
28mm x 40mm, 8°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-0840-19	19mm	11.68mm	6.86cc	1
970-0840-21	21mm	13.72mm	7.64cc	1
28mm x 40mm, 15°				
Catalog Number	Anterior Height	Posterior Height	Graft Window Volume	Qty
970-1540-19	19mm	9.14mm	6.25cc	1
970-1540-21	21mm	11.18mm	7.03cc	1

STANDARD—VARISYNC ALIF PRODUCT LISTING & TRAY LAYOUT

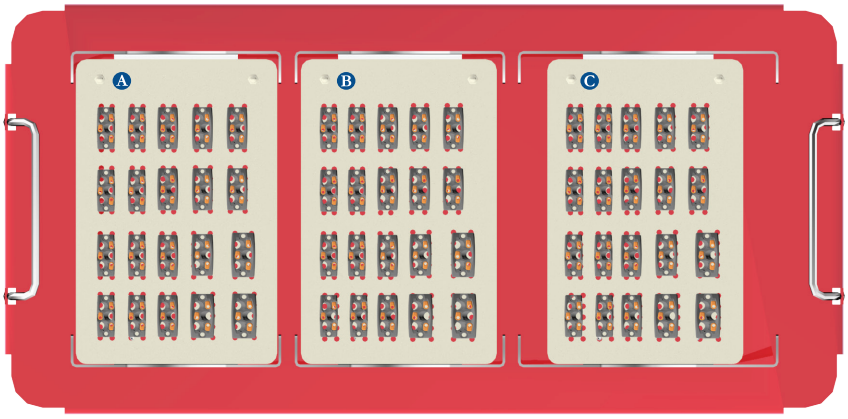
Screw Fixation Instrument Set—Top Tray

Kit #KVA001

8° Recessed Plate Caddy		
Catalog Number	Anterior Height	Qty
860-08-11	11mm x 8°	3
860-08-12	12mm x 8°	3
860-08-13	13mm x 8°	3
860-08-14	14mm x 8°	3
860-08-15	15mm x 8°	2
860-08-17	17mm x 8°	2
15° Recessed Plate Caddy		
Catalog Number	Anterior Height	Qty
860-15-11	11mm x 15°	2
860-15-12	12mm x 15°	2
860-15-13	13mm x 15°	2
860-15-14	14mm x 15°	2
860-15-15	15mm x 15°	2
860-15-17	17mm x 15°	2
Special Order Tall Recessed Plates		
Catalog Number	Anterior Height	Qty
860-08-19	19mm x 8°	
860-08-21	21mm x 8°	
860-15-19	19mm x 15°	
860-15-21	21mm x 15°	

Special Order Kit #KVA010

Hyperlordotic Recessed Plate Caddy		
Catalog Number	Anterior Height	Qty
860-20-13	13mm x 20°	2
860-20-14	14mm x 20°	2
860-20-15	15mm x 20°	2
860-20-17	17mm x 20°	2
860-20-19	19mm x 20°	2
860-20-21	21mm x 20°	2
860-25-15	15mm x 25°	2
860-25-17	17mm x 25°	2
860-25-19	19mm x 25°	2
860-25-21	21mm x 25°	2



A. 8° Recessed Plate Caddy

B. 15° Recessed Plate Caddy

C. **Special Order Caddy**
Hyperlordotic Recessed Plate Caddy

NOTE: When special orders, the Tall Recessed Plates are stored in the 8° and 15° Recessed Plate Caddies.

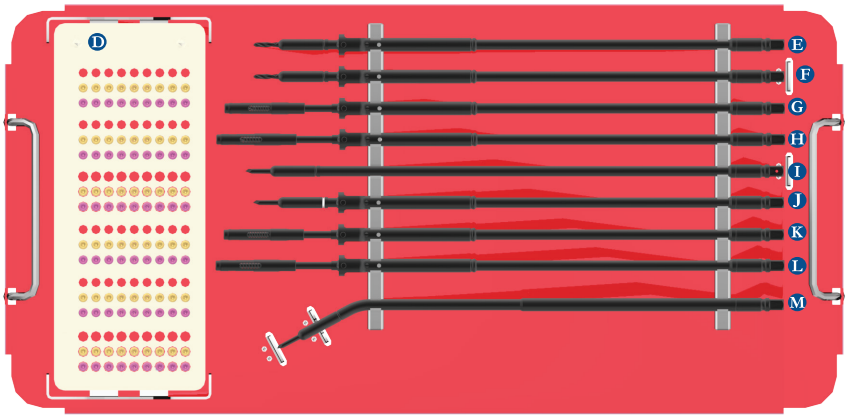
STANDARD—VARISYNC ALIF PRODUCT LISTING & TRAY LAYOUT

Screw Fixation Instrument Set—Middle Tray

Kit #KVA001 (Continued)

Screw Caddy				
Catalog Number	Description	Diameter	Length	Qty
863-5020V	Variable, Self-drilling	5.0mm	20mm	9
863-5025V	Variable, Self-drilling	5.0mm	25mm	9
864-5020V	Variable, Self-tapping	5.0mm	20mm	9
864-5025V	Variable, Self-tapping	5.0mm	25mm	9
863-5020F	Fixed, Self-drilling	5.0mm	20mm	9
863-5025F	Fixed, Self-drilling	5.0mm	25mm	9
863-6020F	Fixed, Self-drilling	6.0mm	20mm	9
863-6025F	Fixed, Self-drilling	6.0mm	25mm	9
864-5020F	Fixed, Self-tapping	5.0mm	20mm	9
864-5025F	Fixed, Self-tapping	5.0mm	25mm	9
864-6020F	Fixed, Self-tapping	6.0mm	20mm	9
864-6025F	Fixed, Self-tapping	6.0mm	25mm	9

Instruments		
Catalog Number	Description	Qty
869-1013	Universal Drill, 15mm	1
869-1012	Straight Drill, 15mm	1
869-1026-15	Sleeved Universal Drill, 15mm	1
869-1026-20	Sleeved Universal Drill, 20mm	1
869-1033	Straight Awl, 15mm	1
869-1011	Universal Awl, 15mm	1
869-1025-15	Sleeved Universal Awl, 15mm	1
869-1025-20	Sleeved Universal Awl, 20mm	1
869-1010	Angled Awl, 15mm	1



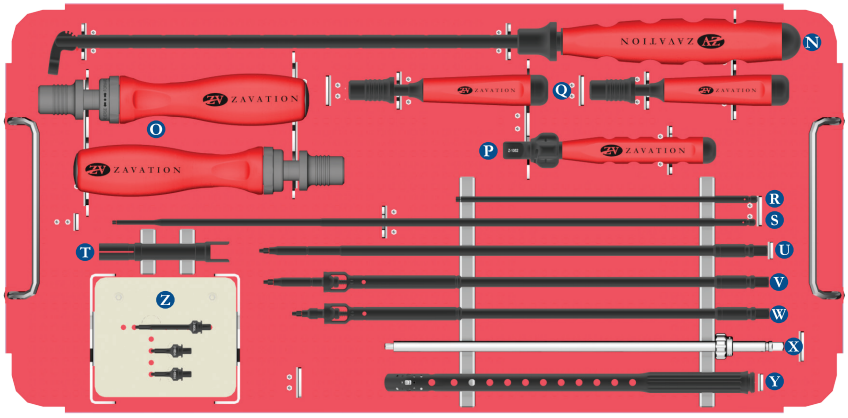
- **D.** Screw Caddy
- **E.** Universal Drill, 15mm
- **F.** Straight Drill, 15mm
- **G.** Sleeved Universal Drill, 15mm
- **H.** Sleeved Universal Drill, 20mm
- **I.** Straight Awl, 15mm
- **J.** Universal Awl, 15mm
- **K.** Sleeved Universal Awl, 15mm
- **L.** Sleeved Universal Awl, 20mm
- **M.** Angled Awl, 15mm

STANDARD—VARISYNC ALIF PRODUCT LISTING & TRAY LAYOUT

Screw Fixation Instrument Set—Bottom Tray

Kit #KVA001 (Continued)

Instruments		
Catalog Number	**Description**	**Qty**
869-1016	Universal Guide for Jointed Instruments	1
Z-1064	Straight Axial Handle, Ratcheting, 1/4" Drive, T20	2
Z-1052	Fixed Instrument Support Handle	1
Z-1048	AO Handle	2
869-1029	Inserter Attachment Driver, T15	2
869-1034	Short Lock Driver, T10 / Stop Adjustment Tool	1
869-1018	Long Lock Driver, T10 / Stop Adjustment Tool	1
869-1017	Universal Instrument Joint Cover	1
869-1014	Straight Screw Driver, T20	1
869-1015	Universal Screw Driver, T20	1
869-1023	Short Universal Screw Driver, T20	1
Z-1051-0	Fixed Angle Driver Inner Component	1
Z-1051-01	Fixed Angle Driver Outer Component	1
Fixed Angle Driver Bit Caddy		
Catalog Number	**Description**	**Qty**
Z-1053-S	Short Driver Bit, T20	2
Z-1053-L	Long Driver Bit, T20	1



N. Universal Guide for Jointed Instruments
O. Straight Axial Handle, Ratcheting, 1/4" Drive, T20 (qty 2)
P. Fixed Instrument Support Handle
Q. AO Handle (qty 2)
R. Inserter Attachment Driver, T15
S. Short Lock Driver, T10
Long Lock Driver, T10
T. Universal Instrument Joint Cover
U. Straight Screw Driver, T20
V. Universal Screw Driver, T20
W. Short Universal Screw Driver, T20
X. Fixed Angle Driver Inner Component
Y. Fixed Angle Driver Outer Component
Z. Fixed Angle Driver Bit Caddy

STANDARD—VARISYNC ALIF PRODUCT LISTING & TRAY LAYOUT

Anchor Fixation Instrument Set—Top Tray

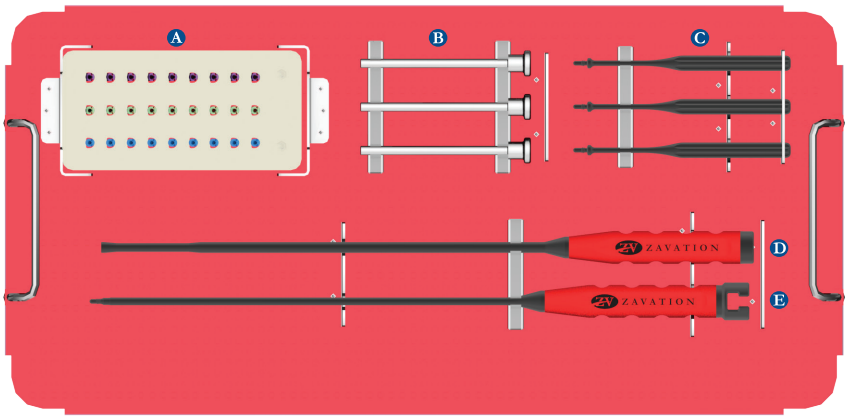
Kit #KVA002

Smooth Anchor Caddy				
Catalog Number	Description	Diameter	Length	Qty
862-20	Smooth Anchor	6.0mm	20mm	9
862-25	Smooth Anchor	6.0mm	25mm	9
862-30	Smooth Anchor	6.0mm	30mm	9

Instruments		
Catalog Number	Description	Qty
869-1001-10	Anchor Deployment Driver	3
869-1028	Anchor Loader	3
869-1027	Anchor Tamp	1
869-1035	Anchor Remover	1

Special Order Kit #KVA0012

Serrated Anchor Caddy				
Catalog Number	Description	Diameter	Length	Qty
865-20	Serrated Anchor	6.0mm	20mm	9
865-25	Serrated Anchor	6.0mm	25mm	9
865-30	Serrated Anchor	6.0mm	30mm	9



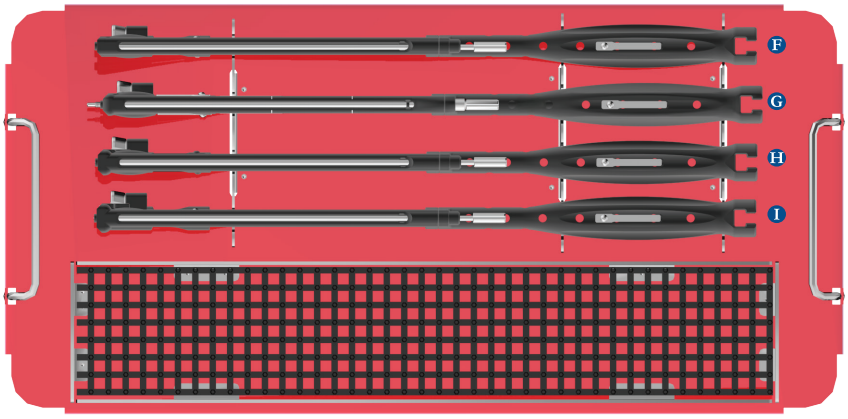
A. Smooth Anchor Caddy
B. Anchor Deployment Drivers (qty 3)
C. Anchor Loaders (qty 3)
D. Anchor Tamp
E. Anchor Remover

STANDARD—VARISYNC ALIF PRODUCT LISTING & TRAY LAYOUT

Anchor Fixation Instrument Set—Bottom Tray

Kit #KVA002 (Continued)

Instruments			
Catalog Number	Description	Cage Height	Qty
869-1001-11	Anchor Recessed Inserter	11mm / 12mm	1
869-1001-13	Anchor Recessed Inserter	13mm / 14mm	1
869-1001-15	Anchor Recessed Inserter	15mm	1
869-1001-17	Anchor Recessed Inserter	17mm	1



F. 11mm / 12mm Anchor Recessed Inserter
G. 13mm / 14mm Anchor Recessed Inserter
H. 15mm Anchor Recessed Inserter
I. 17mm Anchor Recessed Inserter

STANDARD—VARISYNC ALIF PRODUCT LISTING & TRAY LAYOUT

Disc Prep Instrument Set—Top Tray

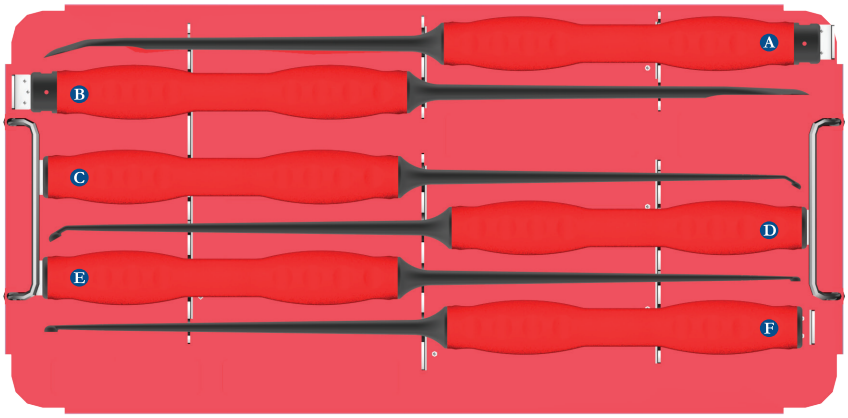
Kit #KVA006

Instruments		
Catalog Number	Description	Qty
09A00223	Angled Cobb Elevator, 22mm	1
09A00224	Straight Cobb Elevator, 22mm	1
04A00013	Angled Cup Curette, 15°, 4mm x 6mm Oval	1
04A00014	Angled Cup Curette, 15°, 6mm x 8mm Oval	1
04A00011	Straight Cup Curette, 4mm x 6mm Oval	1
04A00012	Straight Cup Curette, 6mm x 8mm Oval	1

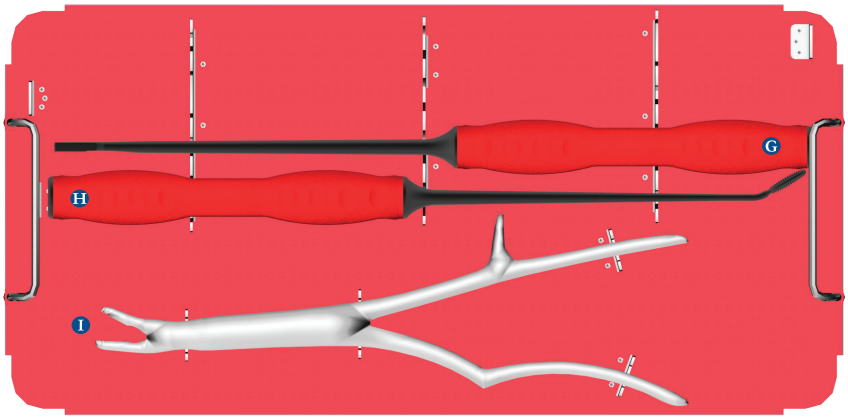
Disc Prep Instrument Set—Middle Tray

Kit #KVA006 (Continued)

Instruments		
Catalog Number	Description	Qty
03A00791	Flat Rectangular Rasp, Single-Sided, 12mm x 30mm	1
03A00792	Domed Rasp, Double-Sided, 30° Bend	1
7900-101	Double Action Rongeur, 14" with Teeth, 8mm	1



A. Angled Cobb Elevator, 22mm
B. Straight Cobb Elevator, 22mm
C. Cup Curette, 4mm x 6mm Oval, Angled 15°
D. Cup Curette, 6mm x 8mm Oval, Angled 15°
E. Cup Curette, 4mm x 6mm Oval, Straight
F. Cup Curette, 6mm x 8mm Oval, Straight



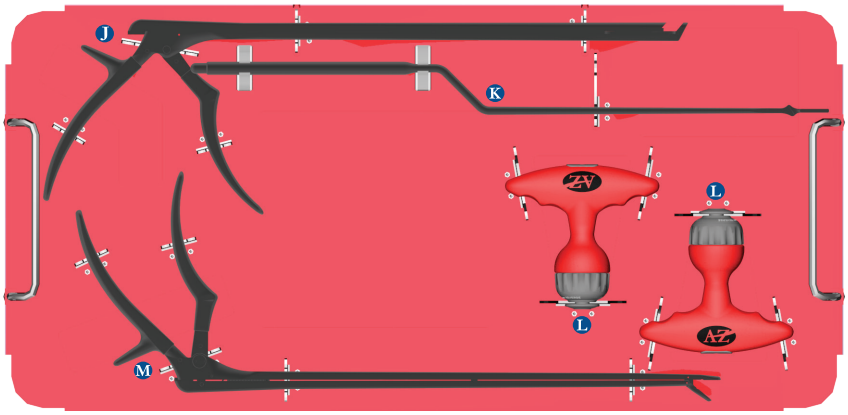
G. Flat Rectangular Rasp, Single-Sided, 12mm x 30mm
H. Domed Rasp, Double-Sided, 30° Bend
I. Double Action Rongeur, 14" with Teeth, 8mm

STANDARD—VARISYNC ALIF PRODUCT LISTING & TRAY LAYOUT

Disc Prep Instrument Set—Bottom Tray

Kit #KVA006 (Continued)

Instruments		
Catalog Number	Description	Qty
7803-602	Kerrison 325mm x 2mm, Straight	1
7803-604	Kerrison 325mm x 4mm, Straight	1
7803-606	Kerrison 325mm x 6mm, Straight	1
7815-006	Annulotomy Knife, Bayoneted	1
15G00009	T-Handle, 1/4" Quick Connect Driver, Cannulated	2
17A00013	Pituitary Ronguer, 325mm x 2mm, Straight	1
17A00014	Pituitary Ronguer, 325mm x 4mm, Straight	1
17A00015	Pituitary Ronguer, 325mm x 6mm, Straight	1



J. Kerrison, 325mm x 2mm, Straight
Kerrison, 325mm x 4mm, Straight
Kerrison, 325mm x 6mm, Straight

K. Annulotomy Knife, Bayoneted

L. T-Handle, 1/4" Quick Connect Driver, Cannulated

M. Pituitary Rongeur, 325mm x 2mm, Straight
Pituitary Rongeur, 325mm x 4mm, Straight
Pituitary Rongeur, 325mm x 6mm, Straight

STANDARD—VARISYNC ALIF PRODUCT LISTING & TRAY LAYOUT

Screw Guide and Freehand Inserters Instrument Set—Top Tray

Kit #KVA003

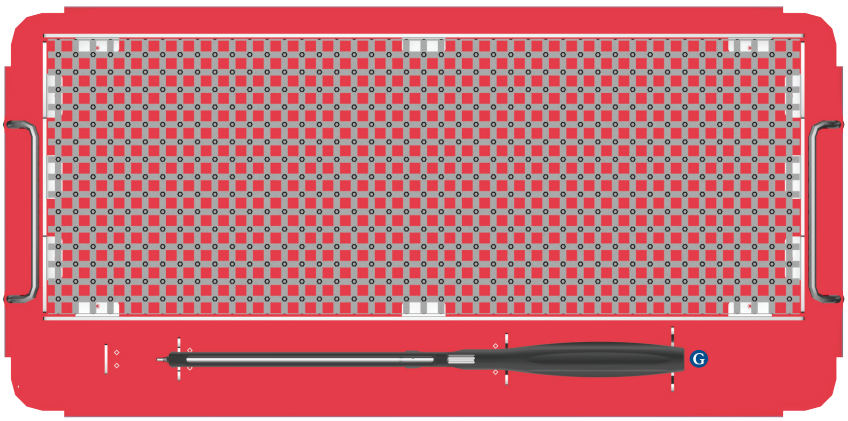
Instruments			
Catalog Number	Description	Cage Height	Qty
869-1003-11	Screw Guide Inserter	11mm / 12mm	1
869-1003-13	Screw Guide Inserter	13mm / 14mm	1
869-1003-15	Screw Guide Inserter	15mm	1
869-1003-17	Screw Guide Inserter	17mm	1
Special Order			
Catalog Number	Description	Cage Height	Qty
869-1003-19	Tall Cage Screw Guide Inserter	19mm	1
869-1003-21	Tall Cage Screw Guide Inserter	21mm	1

Screw Guide and Freehand Inserters Instrument Set—Bottom Tray

Kit #KVA003 (Continued)

Instruments		
Catalog Number	Description	Qty
869-1036	Universal Freehand Inserter	1

A. 11mm / 12mm Screw Guide Recessed Inserter
B. 13mm / 14mm Screw Guide Recessed Inserter
C. 15mm Screw Guide Recessed Inserter
D. 17mm Screw Guide Recessed Inserter
E. **Special Order** 19mm Screw Guide Recessed Inserter
F. **Special Order** 21mm Screw Guide Recessed Inserter



G. 869-1036 Universal Freehand Inserter

STANDARD—VARISYNC ALIF PRODUCT LISTING & TRAY LAYOUT

Trials Instrument Set—Top Tray

Kit #KVA004

Instruments		
Catalog Number	Description	Qty
869-1007	Trial Cage Inserter	2
869-1009	Tamp	1
Z-1050	Slap Hammer	1
Z-1049	Mallet	1

Trials Instrument Set—Bottom Tray

Kit #KVA004 (Continued)

24mm x 30mm Trial Caddy			
Catalog Number	Lordosis	Cage Height	Qty
869-1008-0830-11-R	8°	11mm	1
869-1008-0830-12-R	8°	12mm	1
869-1008-0830-13-R	8°	13mm	1
869-1008-0830-14-R	8°	14mm	1
869-1008-0830-15-R	8°	15mm	1
869-1008-0830-17-R	8°	17mm	1
869-1008-1530-11-R	15°	11mm	1
869-1008-1530-12-R	15°	12mm	1
869-1008-1530-13-R	15°	13mm	1
869-1008-1530-14-R	15°	14mm	1
869-1008-1530-15-R	15°	15mm	1
869-1008-1530-17-R	15°	17mm	1

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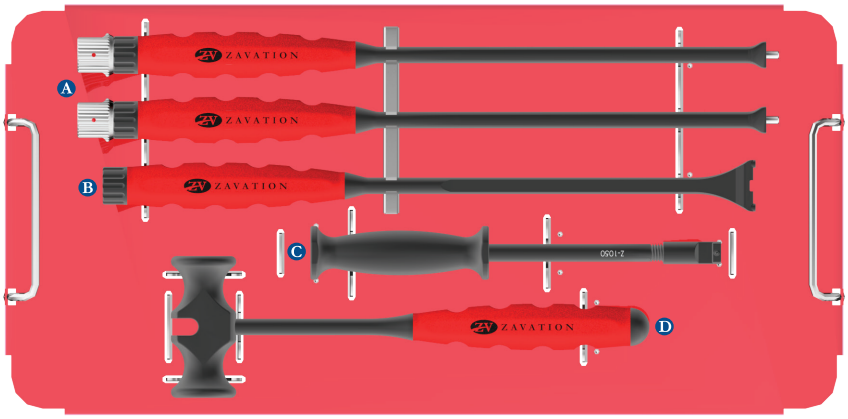
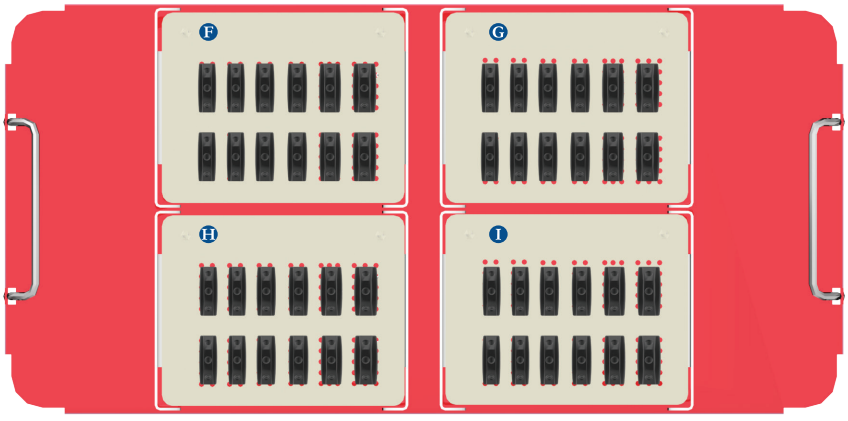


A. Trial Cage Inserters
B. Tamp
C. Slap Hammer
D. Mallet



F. 24mm x 30mm Trial Caddy
G. 26mm x 35mm Trial Caddy
H. 28mm x 40mm Trial Caddy
I. Special Order Tall Trial Caddy

STANDARD—VARISYNC ALIF PRODUCT LISTING & TRAY LAYOUT

Trials Instrument Set—Bottom Tray (Continued)

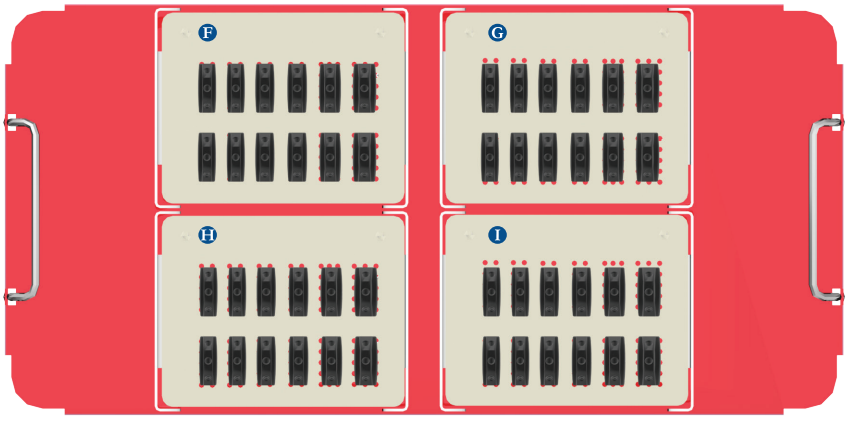
Kit #KVA004 (Continued)

26mm x 35mm Trial Caddy			
Catalog Number	Lordosis	Cage Height	Qty
869-1008-0835-11-R	8°	11mm	1
869-1008-0835-12-R	8°	12mm	1
869-1008-0835-13-R	8°	13mm	1
869-1008-0835-14-R	8°	14mm	1
869-1008-0835-15-R	8°	15mm	1
869-1008-0835-17-R	8°	17mm	1
869-1008-1535-11-R	15°	11mm	1
869-1008-1535-12-R	15°	12mm	1
869-1008-1535-13-R	15°	13mm	1
869-1008-1535-14-R	15°	14mm	1
869-1008-1535-15-R	15°	15mm	1
869-1008-1535-17-R	15°	17mm	1

28mm x 40mm Trial Caddy			
Catalog Number	Lordosis	Cage Height	Qty
869-1008-0840-11-R	8°	11mm	1
869-1008-0840-12-R	8°	12mm	1
869-1008-0840-13-R	8°	13mm	1
869-1008-0840-14-R	8°	14mm	1
869-1008-0840-15-R	8°	15mm	1
869-1008-0840-17-R	8°	17mm	1
869-1008-1540-11-R	15°	11mm	1
869-1008-1540-12-R	15°	12mm	1
869-1008-1540-13-R	15°	13mm	1
869-1008-1540-14-R	15°	14mm	1
869-1008-1540-15-R	15°	15mm	1
869-1008-1540-17-R	15°	17mm	1

Special Order Kit #KVA0011

Tall Trial Caddy				
Catalog Number	Footprint	Lordosis	Cage Height	Qty
869-1008-0830-19-R	24mm x 30mm	8°	19mm	1
869-1008-1530-19-R	24mm x 30mm	15°	19mm	1
869-1008-0835-19-R	26mm x 35mm	8°	19mm	1
869-1008-0835-21-R	26mm x 35mm	8°	21mm	1
869-1008-1535-19-R	26mm x 35mm	15°	19mm	1
869-1008-1535-21-R	26mm x 35mm	15°	21mm	1
869-1008-0840-19-R	28mm x 40mm	8°	19mm	1
869-1008-0840-21-R	28mm x 40mm	8°	21mm	1
869-1008-1540-19-R	28mm x 40mm	15°	19mm	1
869-1008-1540-21-R	28mm x 40mm	15°	21mm	1



F. 24mm x 30mm Trial Caddy
G. 26mm x 35mm Trial Caddy
H. 28mm x 40mm Trial Caddy
I. Special Order Tall Trial Caddy

SPECIAL ORDER—VARISYNC ALIF PRODUCT LISTING & TRAY LAYOUT

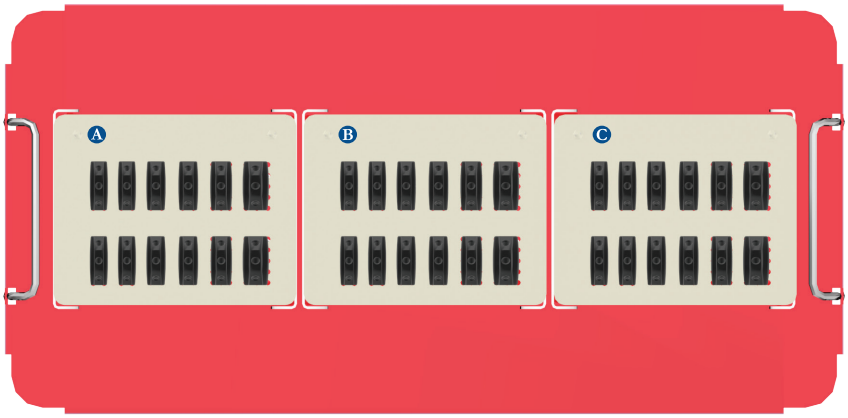
Hyperlordotic Trials Instrument Set—20° and 25°

Kit #KVA005

24mm x 30mm Hyperlordotic Trial Caddy			
Catalog Number	Lordosis	Cage Height	Qty
869-1008-2030-13-R	20°	13mm	1
869-1008-2030-14-R	20°	14mm	1
869-1008-2030-15-R	20°	15mm	1
869-1008-2030-17-R	20°	17mm	1
869-1008-2030-19-R	20°	19mm	1
869-1008-2530-15-R	25°	15mm	1
869-1008-2530-17-R	25°	17mm	1
869-1008-2530-19-R	25°	19mm	1
869-1008-2530-21-R	25°	21mm	1

26mm x 35mm Hyperlordotic Trial Caddy			
Catalog Number	Lordosis	Cage Height	Qty
869-1008-2035-13-R	20°	13mm	1
869-1008-2035-14-R	20°	14mm	1
869-1008-2035-15-R	20°	15mm	1
869-1008-2035-17-R	20°	17mm	1
869-1008-2035-19-R	20°	19mm	1
869-1008-2035-21-R	20°	21mm	1
869-1008-2535-15-R	25°	15mm	1
869-1008-2535-17-R	25°	17mm	1
869-1008-2535-19-R	25°	19mm	1
869-1008-2535-21-R	25°	21mm	1

28mm x 40mm Hyperlordotic Trial Caddy			
Catalog Number	Lordosis	Cage Height	Qty
869-1008-2040-15-R	20°	15mm	1
869-1008-2040-17-R	20°	17mm	1
869-1008-2040-19-R	20°	19mm	1
869-1008-2040-21-R	20°	21mm	1
869-1008-2540-17-R	25°	17mm	1
869-1008-2540-19-R	25°	19mm	1
869-1008-2540-21-R	25°	21mm	1



A. 24mm x 30mm Hyperlordotic Trial Caddy
B. 26mm x 35mm Hyperlordotic Trial Caddy
C. 28mm x 40mm Hyperlordotic Trial Caddy

NOTES

NOTES

INDICATIONS FOR USE

Zavation Varisync® ALIF System

Device Description

The Zavation Varisync ALIF System includes a spacer, plate, screws, and anchors. The spacer component is assembled to an interbody plate and implanted anteriorly. The spacer components are available in a variety of materials, depths, widths, and heights. The plate component includes three or four holes for inserting bone screws or anchors. The plate component also includes a lock at each hole. The bone screws are available in a variety of diameters and lengths. The anchors are available in a variety of lengths. The interbody plate components are available in a variety of heights.

Indications for Use

The Zavation Varisync ALIF System is a anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S 1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the Zavation Varisync ALIF System is to be filled with autogenous bone graft material.

The Zavation Varisync ALIF System spacer and plate assembly are an integrated fusion device intended for stand-alone use when used with screws. When used with anchors only the recessed plate may be used, and the assembly is intended for use with additional supplemental fixation that has been cleared by the FDA for use in the lumbar spine.

Hyperlordotic interbody devices (>20 degrees) must be used with supplemental fixation (e.g. posterior fixation) that has been cleared by the FDA for the use in the lumbar spine.

Materials

The Zavation Varisync ALIF System components are manufactured from medical grade titanium alloy Ti-6Al-4V ELi (ASTM F136 and ASTM F3001), OR medical grade PEEK Zeniva ZA-500 or Magnolia PEEK (ASTM F2026) with Tantalum (ASTM F560) alloy position markers. The PEEK implants are available with or without an ion beam assisted deposition (IBAD) coating. The (IBAD) coating is made from Grade 2 Commercially Pure Titanium coating that meets chemical composition requirements of (ASTM F67).

Contraindications

- Instability
- Infection
- Severe Bleeding
- Known allergies to bone cement
- Pregnancy

INDICATIONS FOR USE (Continued)

Potential Adverse Events

Potential adverse events include, but are not limited to:

- Pseudoarthrosis
- Early or late loosening of the components.
- Bending, and/or breakage of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, straining, tumor formation, and/or auto-immune disease.
- 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 Zavation Varisync ALIF System has not been evaluated for safety and compatibility in the MR environment. The Zavation Varisync ALIF System has not been tested for heating or migration in the MR environment.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Do not use if sterile package is opened or damaged.
- It is important to read the instructions for use, these precautions prior to device operation.
- Use the instrument kit prior to use by date noted on the package.
- Do not use damaged products. Before use, inspect the packaging to verify that no damage has occurred.
- Do not use this product if you have not been properly trained. Physicians using the device should be familiar with the physiology and pathology of the selected anatomy.
- The Zavation Varisync ALIF System should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images.
- Do not reuse. The Zavation Varisync ALIF System implants are for single use only. Reconditioning, refurbishing, or repair of the device to enable further use is expressly prohibited.
- Repacking or re-sterilization of sterile packed items is prohibited and must be returned to Zavation Medical for evaluation.

INDICATIONS FOR USE (Continued)

Other preoperative, intraoperative, and postoperative warnings are as followed:

Sterilization

The porous PEEK and porous Titanium spacers of the Zavation Varisync ALIF System will be received sterile. The solid PEEK and titanium coated PEEK spacers, all other implants and instruments will be received non-sterile.

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. Peek 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 peek 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.
- To assure proper fusion below and around the location of the fusion, autogenous bone graft should be used.
- Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurological damage and bone necrosis.

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 or their limitations and taught to compensate for this permanent physical restriction in body motion.

INDICATIONS FOR USE (Continued)

- 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.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

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 as long as 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 confirmed by visual inspection of each instrument.

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. For the Zavation Varisync ALIF System, the only instruments requiring disassembly would be to remove the Universal Drive Sleeve from all Universal Instruments. The Universal Drive Sleeve is removed by sliding the sleeve over the square drive end of the Universal Instruments. (Note that these items are normally stored in the dedicated trays already disassembled).

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.

Automated

4.1 Automated Pre-Cleaning:

- Automated washing shall be conducted in a validated washer-disinfector.
- Refer to labeling of automated washer for detailed instructions of use.
- 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 water 1 minute
  - Rinse 60°C 1 minute

INDICATIONS FOR USE (Continued)

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

Manual (Continued)

4.1 Manual Pre-Cleaning:

- 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 clean warm 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.

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.

Automated (Continued)

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

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 instruments with long slender features for distortion.
- Inspect the 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.

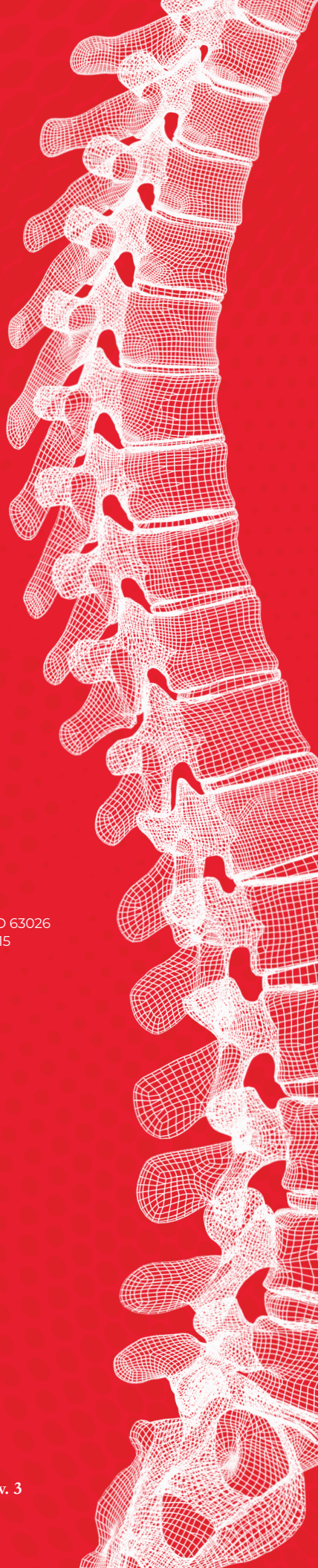
INDICATIONS FOR USE (Continued)

Sterilization: The Zavation Varisync ALIF System instruments 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

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

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



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