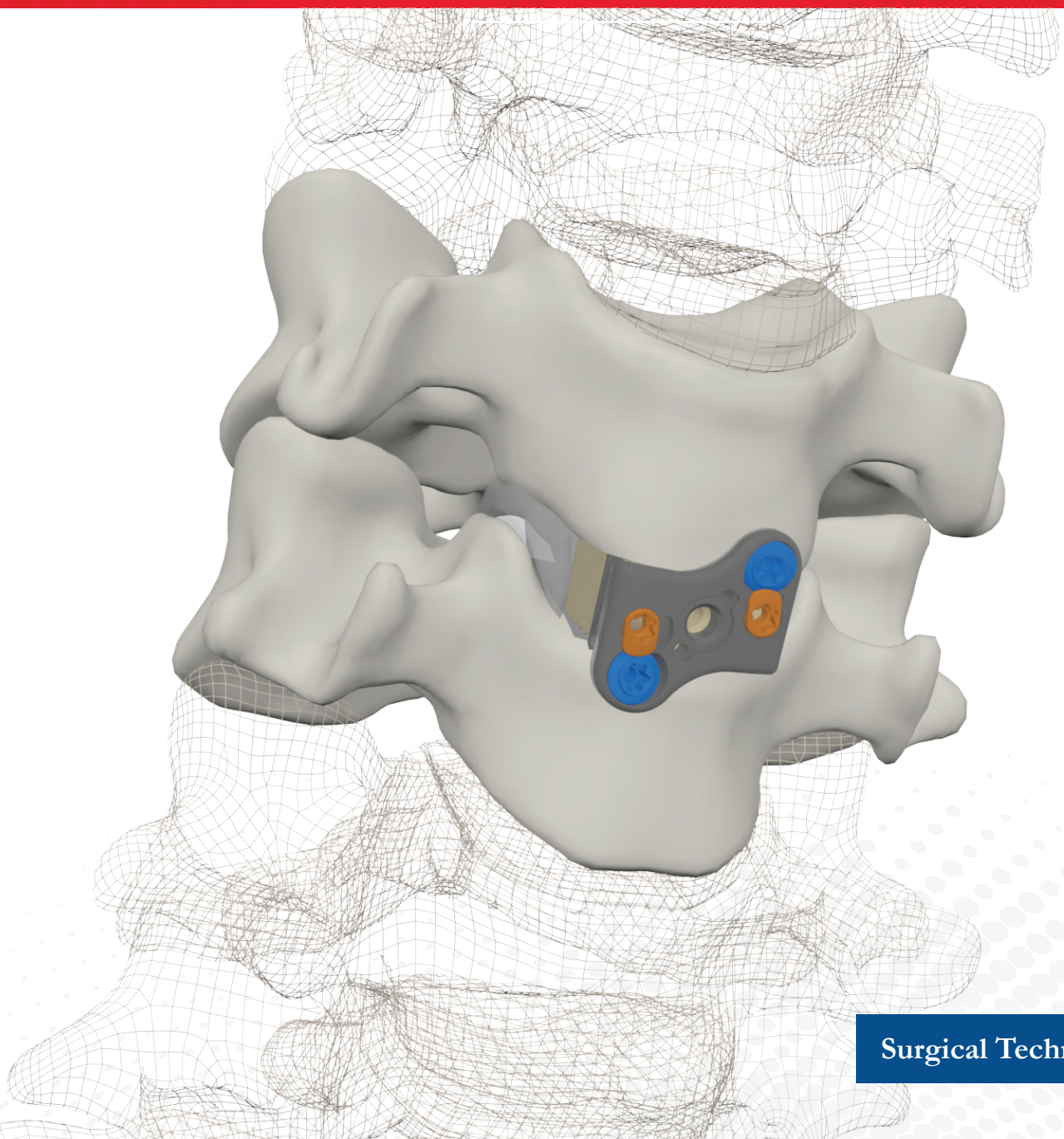
ZAVATION®

VARISYNC®

Stand-alone Cervical System & Anterior Cervical Interbodies



Surgical Technique Guide

THE VARISYNC® DIFFERENCE

The Varisync Cervical System is adaptable to surgeon technique and preference with its **robust implant and instrumentation offering**. The system includes a modular plate and cage offering for creating a **stand-alone construct** or for individual plate and cage insertion.

If a stand-alone construct is not preferred, our **cervical interbody portfolio** features five additional cages that can be used with this system's instrumentation.

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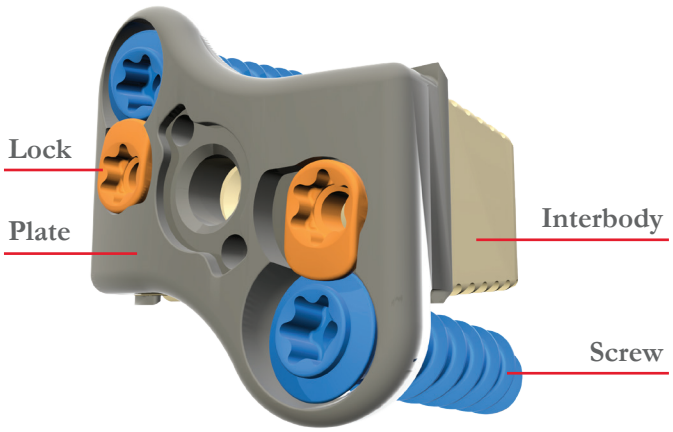
SYSTEM OVERVIEW

The **Varisync Cervical System** is comprised of a plate, screws, and interbody. The plate offering includes 2-hole or 4-hole, and the PEEK interbody comes in two standard footprints.

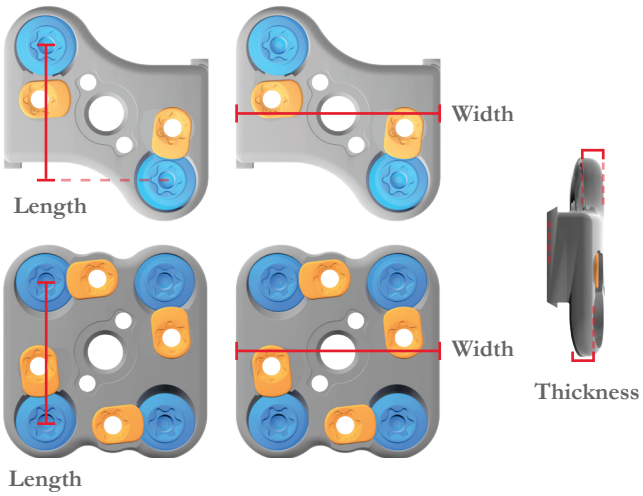
This **integrated system** utilizes a quick-connect assembly between the Varisync Plate and Varisync PEEK Interbody.



Varisync Plate

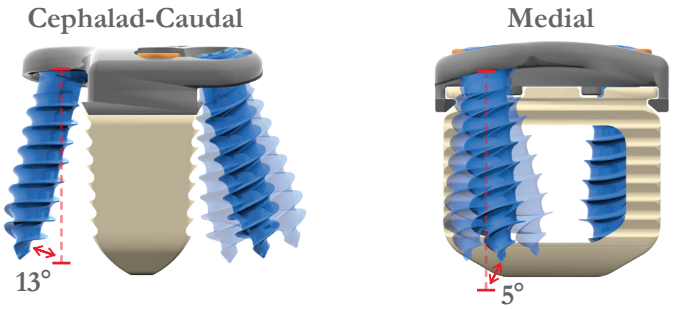
Specifications

- **Width:** 17.3mm
- **Lengths:** 6mm-12mm
- **Thickness:** 1.8mm
- 13° caudal and cephalad biased angles
- 5° midline biased angle
- ±10° variable angle



Features

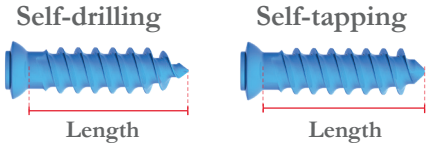
- 2-hole and 4-hole options available
- Titanium
- Quarter-turn locking mechanisms
- Locks use same driver as screw insertion
- Attaches to Varisync Interbody for stand-alone construct
- Compatible with all Zavation cages



Screws

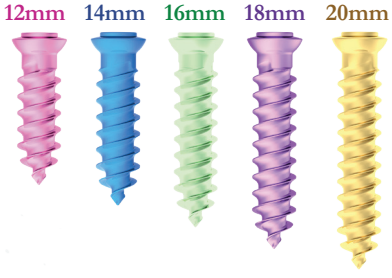
Specifications

- **Lengths:** 12mm-18mm (2mm increments)
- **Diameters:** 4.0m, 4.5mm (rescue)



Features

- Variable or Fixed angulation
- Titanium
- Sharp self-drilling and blunt self-tapping
- **Color-Coded by Length:**
  12mm Magenta, 14mm Dark Blue,
  16mm Green, 18mm Purple, 20mm Bronze



SYSTEM OVERVIEW (Continued)

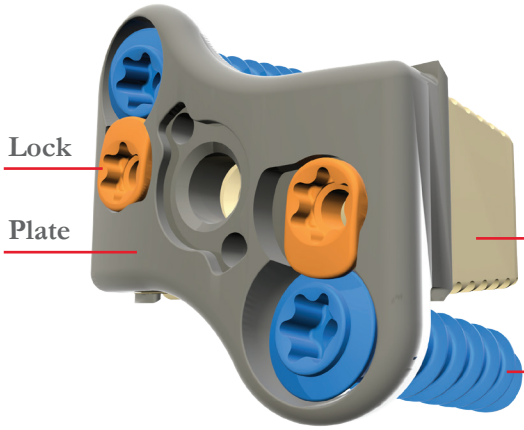
Varisync Interbody

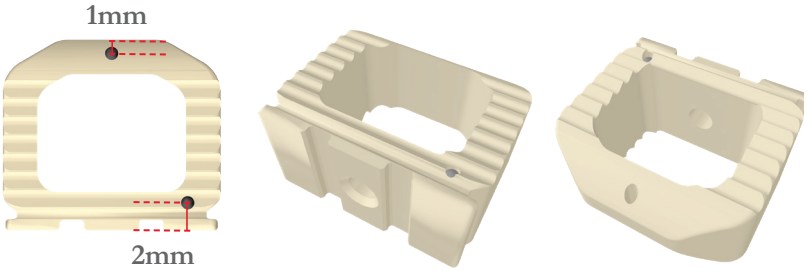
Specifications

- **Standard Footprints** (Width x Depth):
  - 14mm x 12mm
  - 16mm x 14mm
- **Heights:** 6mm-12mm (Top of serrations)
- **Lordosis:** 6°, 10°

Features

- Bulleted insertion end
- PEEK with 1mm Tantalum marker on distal end, 1mm from posterior edge, and 2mm from anterior edge.
- Attaches to Varisync Plate for stand-alone construct



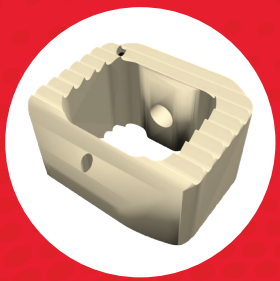


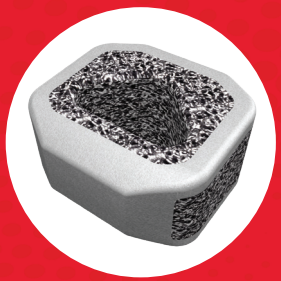
ADDITIONAL CERVICAL INTERBODY OPTIONS

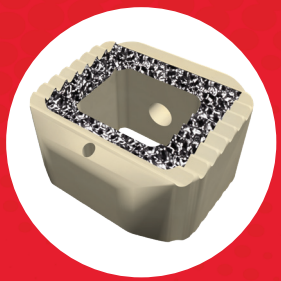
If the Varisync Interbody is not preferred, our cervical interbody portfolio includes IBF, Ti3Z, Whitney, Labyrinth, and F3D-Z with Mimetic Metal® technology.

The standard Varisync Cervical set includes inserters that can be used with any of these cages.

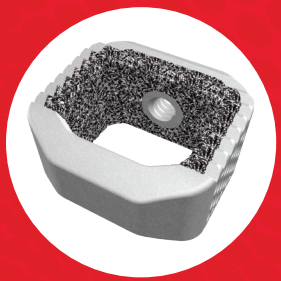
NOTE: These interbody options cannot be assembled to the plate for a stand-alone construct. However, they *can* be inserted simultaneously via the pin inserter, shown on page 7.


IBF


Ti3Z®


Whitney®


Labyrinth®


F3D-Z
with Mimetic Metal®

STAND-ALONE CONSTRUCT SCREW LENGTH GUIDE

Varisync Interbody Depth and Screw Length Comparison

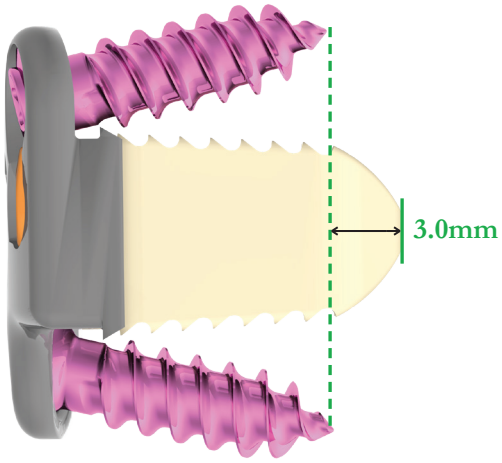
The measurements in the table show the distance of the screw tip in reference to the posterior edge of the Varisync cage. Measurements are calculated with screws at nominal screw angle.

NOTE: These apply to the stand-alone Varisync Interbody and Varisync Plate construct only.

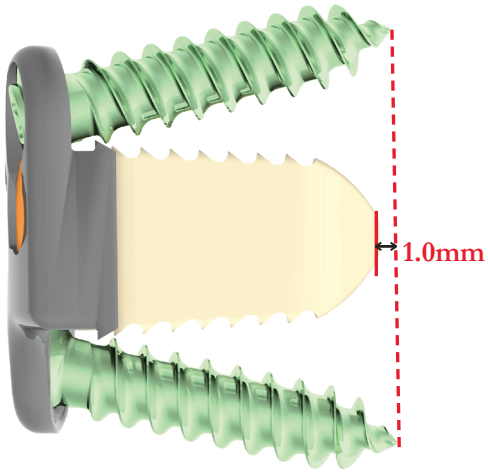
Red measurements indicate screw tip sits *past* the posterior edge of the cage at nominal angle.
Green measurements mean the screw will *not* extend past the posterior edge of the cage.

Distance from Screw Tip to Posterior End of Cage				
Footprint W x D	12mm Screw	14mm Screw	16mm Screw	18mm Screw
14mm x 12mm	1.0mm	1.0mm	3.0mm	5.0mm
16mm x 14mm	3.0mm	1.0mm	1.0mm	3.0mm

Examples:



16mm x 14mm cage with 12mm screws



16mm x 14mm cage with 16mm screws

PATIENT APPROACH & PREPARATION

Patient Positioning

The patient is put under anesthesia and placed in the supine position. The operative area is then prepped and draped in the standard fashion, and 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).

Distraction

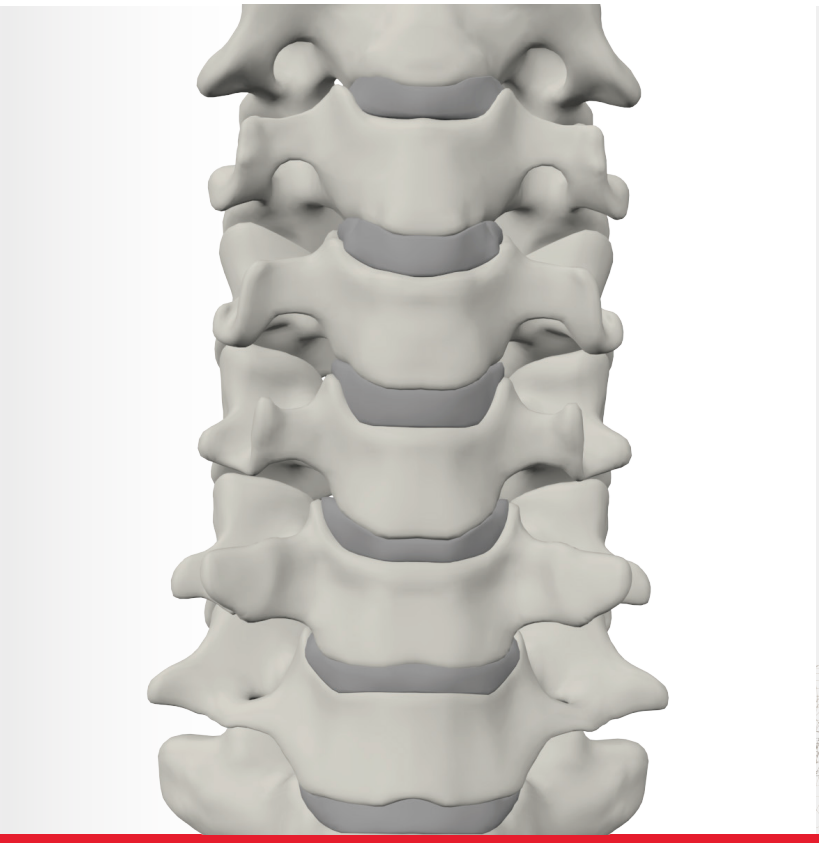
Distraction of the vertebral bodies may be accomplished using standard methods.

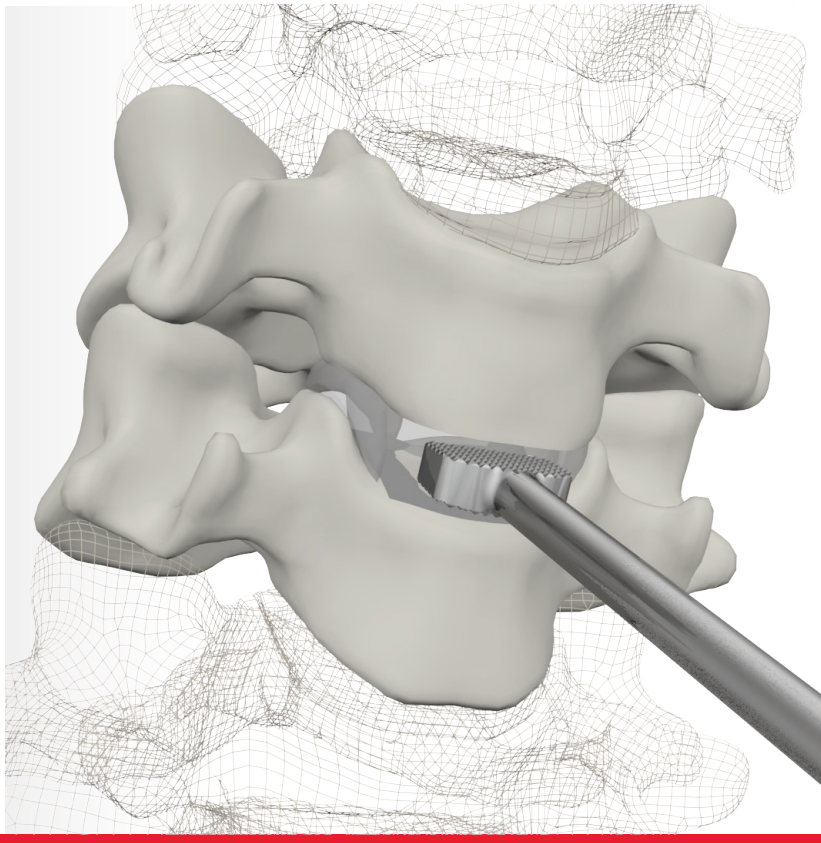
Distraction pins are available in lengths of 12mm, 14mm, and 16mm as a special order through customer service.

Discectomy & Endplate Prep

Remove the intervertebral disc and osteophytes as needed, leaving the lateral annulus intact.

Cervical rasps (20-2001) in heights 5mm-12mm are available to reveal the cartilaginous endplates and prep the disc space for fusion.





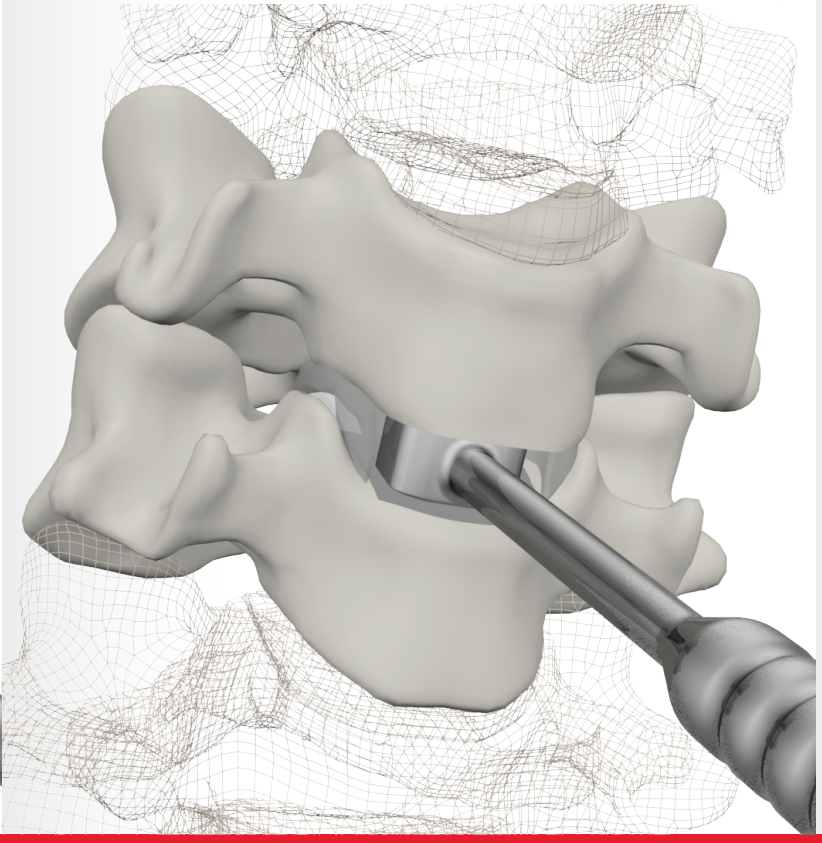
IMPLANT SIZING

Trialing

Introduce the various sized trials (20-2000-XX or 22-2000-XX) into the intervertebral space to determine the height and degree of the implant.

A secure fit is desirable in order to maintain disc height and promote fusion. Radiographic images may be used to verify implant size.

NOTE: Trials are line to line and not undersized.



IMPLANT ASSEMBLY

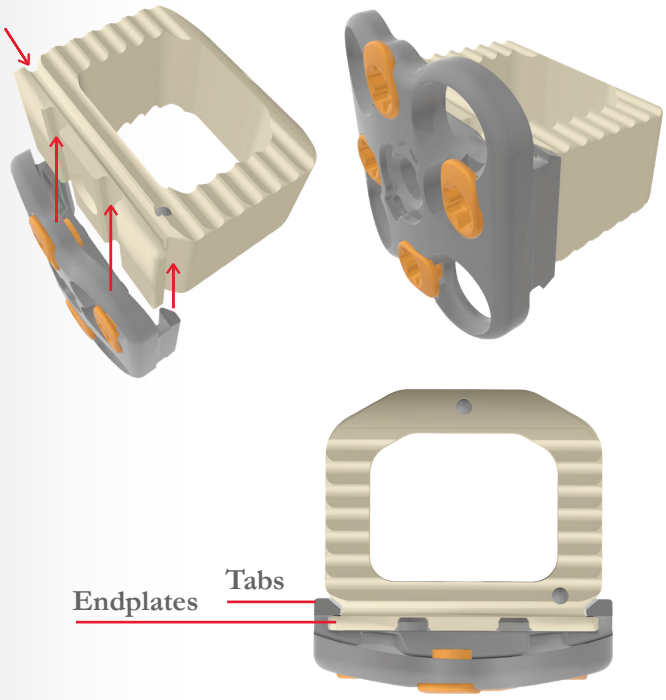
Stand-alone System

NOTE: If you do not wish to use the Varisync cage and plate as a stand-alone, or prefer to use IBF, Ti3Z, Whitney, Labyrinth, or F3D-Z interbodies—skip to the next step on page 7.

Assembly of the Varisync cage and Varisync plate allow for simultaneous implantation as a stand-alone system.

Select the Varisync plate for the chosen Varisync cage height. Plate caddies are labeled with height information. After choosing the appropriate cage height and plate, assemble by sliding the tabs on the underside of the plate along the retention track of the interbody.

Visually confirm the tabs are flush, this means the system is fully assembled. Next, assemble to the appropriate inserter based on surgeon technique.



INSERTER OPTIONS

The Varisync Cervical System offers four inserter options to accommodate surgeon technique or preference. Assemble plate and/or interbody to inserter of choice by threading the stylus into the center hole(s) of the interbody.

DTS Screw Guide Inserter

Stand-alone Construct Guided Technique

The system includes a fixed angle DTS guide with compatible drills, awls, and screwdriver for surgeons who prefer a guided technique.

Assemble DTS inserter (690-1000-XX) by inserting the plate stylus (690-1000-2) into the proximal end of the DTS inserter. Then, assemble cage to inserter by aligning the center hole of the interbody to the threaded stylus. Rotate the stylus knob to secure connection. **NOTE:** DTS inserters are height specific to the plate. Ensure the correct DTS guide is chosen based on plate length.

In-Line Inserter

Stand-alone Construct Freehand Technique

The in-line inserter allows for placement of the Varisync plate and Varisync cage construct via a freehand approach.

Fixed and variable angle drill guides/awls are available when the in-line inserter is used, as shown on page 10.

Assemble the in-line inserter (690-1009) by inserting the plate stylus (690-1000-2) into the proximal end of the in-line inserter. Rotate the stylus knob to secure connection.

INSERTER OPTIONS (Continued)

Plate Pin Inserter

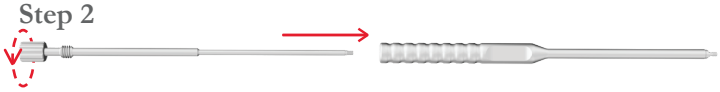
Simultaneous Insertion of Varisync Plate with Non-Varisync Cervical Interbody (IBF, Ti3Z, Whitney, Labyrinth, or F3D-Z)

After choosing the appropriate cage size, select the corresponding Varisync plate as labeled on the implant caddy. A plate pin (690-1007) located in the screw caddy will be needed for assembly.

Step 1: Assemble the plate pin inserter (690-1006) by inserting the plate pin into the distal end of the inserter. Hold it firmly in place throughout step 2.
Step 2: Thread the stylus (690-1000-2) into the proximal end of the plate pin inserter. Rotate the stylus knob to secure connection.
Step 3: Align threaded hole of cage to threaded hole of plate, and thread in the plate pin inserter.

Step 1

Step 2



Step 3

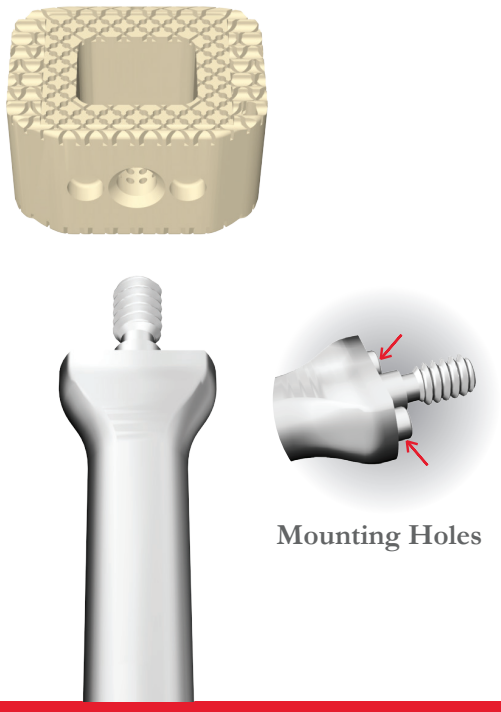
Interbody Inserter

Insertion of Non-Varisync Cervical Interbody Only (IBF, Ti3Z, Whitney, Labyrinth, or F3D-Z)

Choose the appropriate cage size.

Align the mounting holes on the spacer to the interbody inserter (20-2002-1).

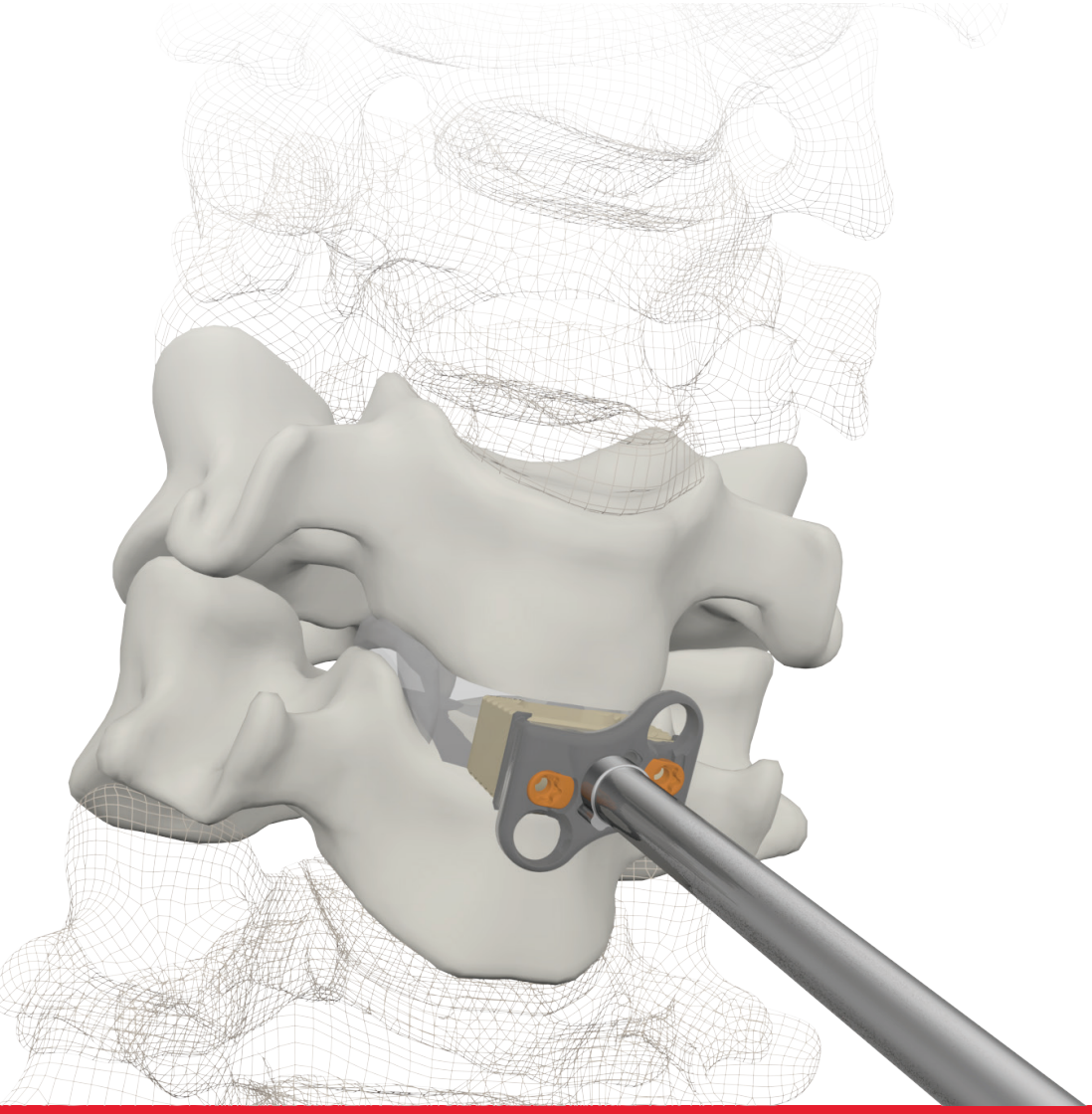
Thread the stylus (20-2002-2) through the proximal end of the inserter until it has captured the threaded hole on the cage. Rotate the stylus knob to secure connection.



IMPLANT INSERTION

With the implant mounted on the insertion instrument, gently insert into the disc space toward its final position.

Verify the final implant position relative to the vertebral bodies using fluoroscopy.



SCREW HOLE PREPARATION

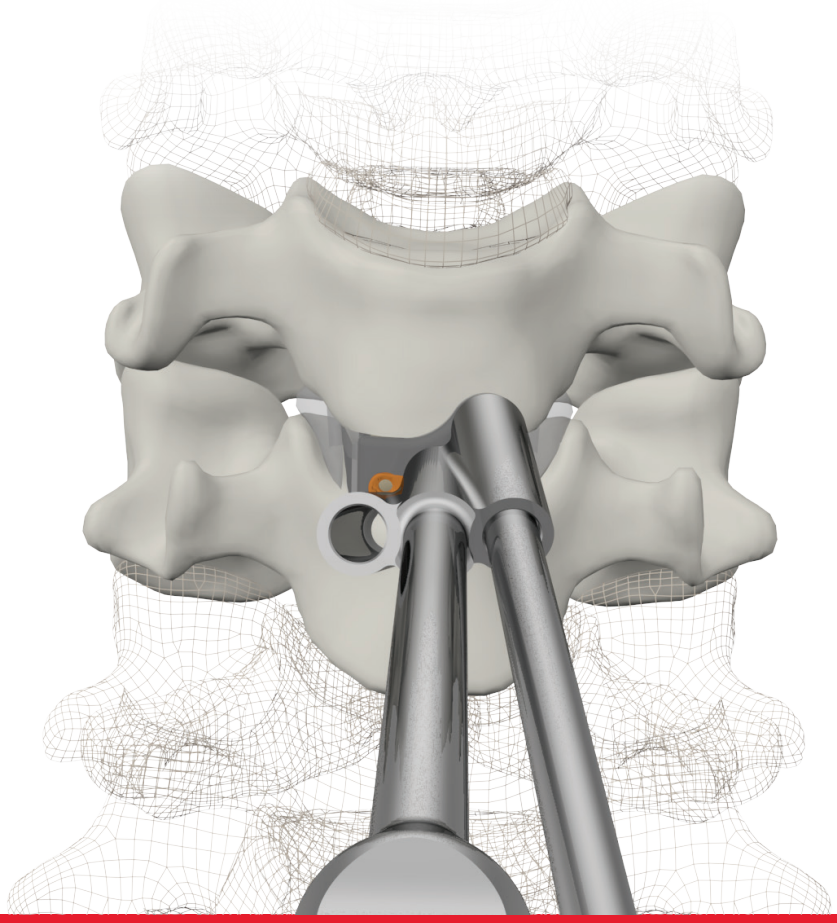
With DTS Screw Guide Inserter

Drilling, awling, and screw insertion can all be done through the DTS inserter.

The DTS awl (690-1002) can be used by attaching the jeweler handle (Z-1023) with the quick release. Advance the awl through plate hole at appropriate angle until the awl is seated in the screw hole.

NOTE: The DTS awl protrudes 11mm past the plate.

Drills (690-1003-XX) are 2.5mm in diameter and available in 12mm, 14mm, 16mm, and 18mm lengths. If using the drill, select the drill that corresponds to the screw length and attach to the jeweler handle with the quick release. Both the drill and awl should be advanced until they stop on the drill guide to achieve the depth specified.



SCREW HOLE PREPARATION (Continued)

With In-line Inserter, Plate Pin Inserter, or Interbody Inserter

Drills

Fixed and variable angle drill guides are available when using the in-line, plate pin, or interbody inserters. Drills are 2.5mm in diameter and available in 12mm, 14mm, 16mm, and 18mm lengths.

Fixed angle drill guides (690-1004) align to screw holes with small pilot diameter on drill guide tip.

Variable angle drill guides (690-1005) allow for freehand angle selection. Ensure angle of the guide relative to the biased angle of the hole does not exceed 10°.

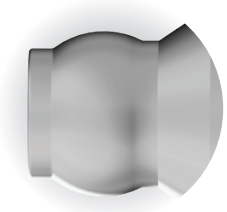
Awls

Sleeved awls are available for use when using the inline, pin, or interbody inserter. Advance the awl through plate hole at appropriate angle until the awl is seated in the screw hole of the plate.

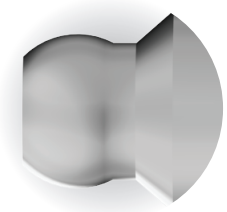
NOTE: The awl tip protrudes 10mm past the plate when fully extended.

Fixed angle awls (690-1010-1) align to screw holes with small pilot diameter on awl tip.

Variable angle awls (690-1010-2) allow for freehand angle selection. Ensure angle of the awl relative to the biased angle of the hole does not exceed 10°.

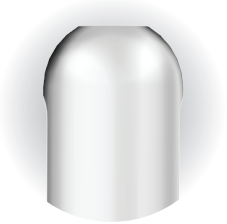


Fixed Guide Tip

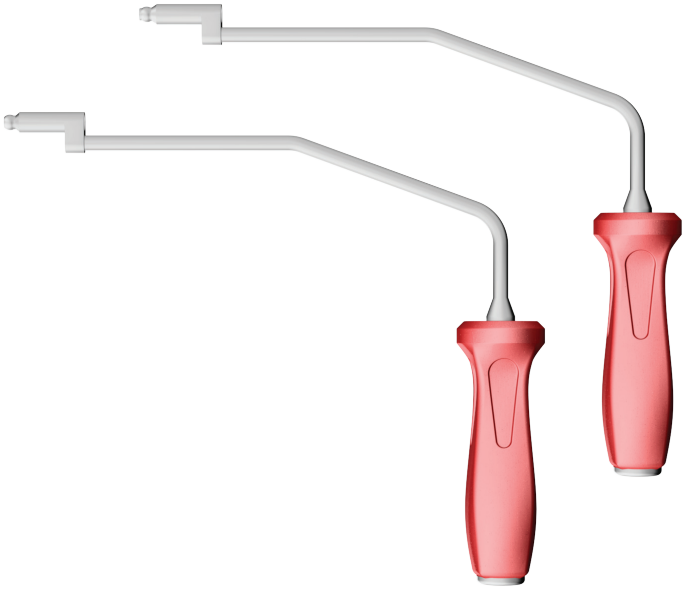


Variable Guide Tip

Fixed Awl Tip



Variable Awl Tip

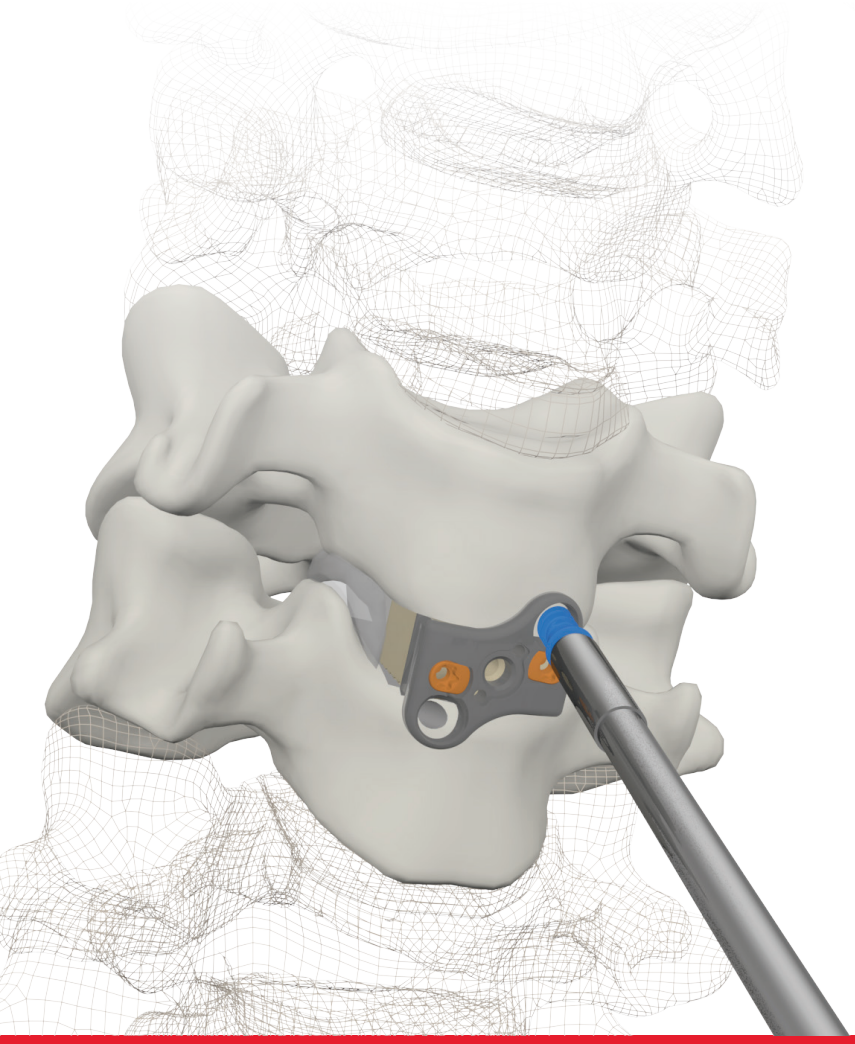


SCREW INSERTION

Attach selected driver to the jeweler handle (Z-1023). Load the appropriate length screw on the standard screwdriver (690-1001) or the universal driver (690-1008).

The screwdriver has a self-retaining post at tip to hold the screw during insertion.

Advance screw until it seats firmly inside the pocket in the interbody plate. Screws must be seated completely to allow screw locks to engage.

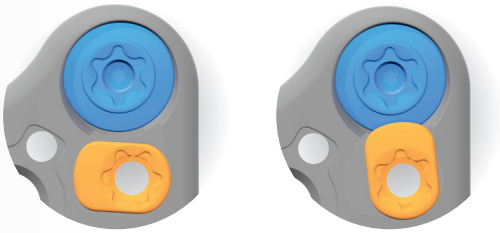


NOTE: It is important to keep the screwdriver and screw at the same axis. Do not misalign the screwdriver in relation to the screw, as this action could damage the driver.

Correct Incorrect

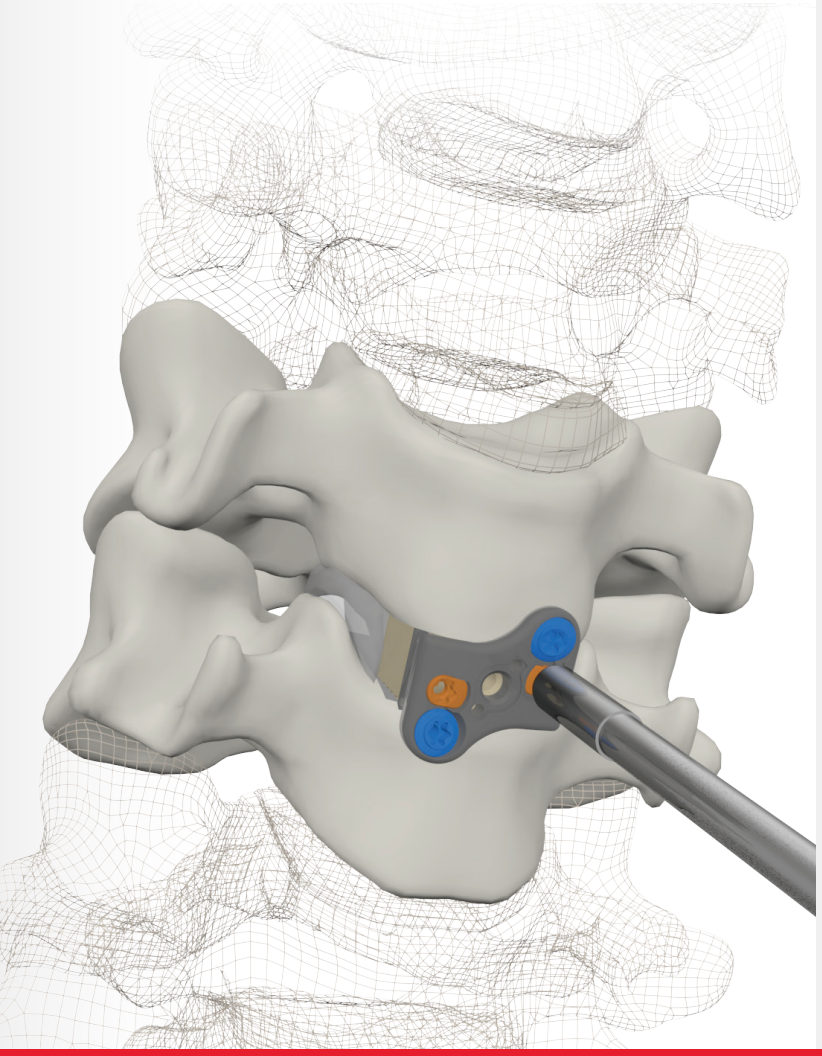
LOCKING MECHANISM

Each screw is locked by rotating the screw lock a quarter turn using the same T-10 driver (690-1001) that's used for screw insertion.



Not Locked Locked

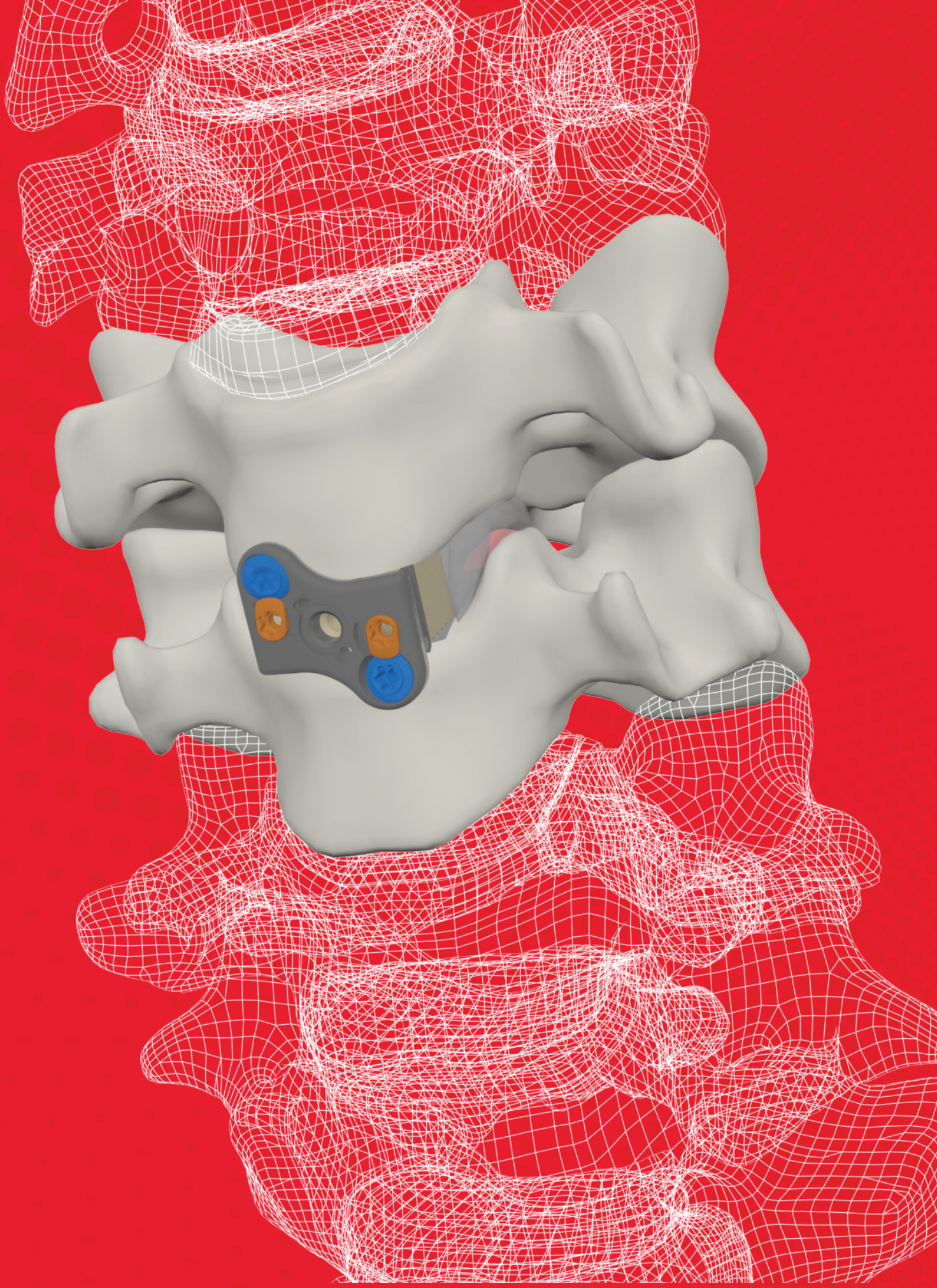
NOTE: It is recommended not to rotate the lock more than 2 times.



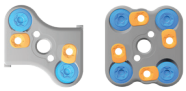
IMPLANT REMOVAL

Unlock each screw lock by using the T-10 driver. Remove each screw by using the T-10 driver or T-10 universal driver. Attach the inserter to the implant anteriorly, gently remove the implant from the disc space.

If the implant cannot be easily removed, a cobb elevator or osteotome should be used to loosen the bone to implant interface.



STANDARD VARISYNC PRODUCT LISTING

Varisync Cervical Plate 

2-Hole Plate, for 14mm x 12mm Cage				
Catalog Number	Cage Height	Plate Width	Plate Thickness	Qty
690-14-06	6mm	17.3mm	1.8mm	2
690-14-07	7mm	17.3mm	1.8mm	2
690-14-08	8mm	17.3mm	1.8mm	2
690-14-09	9mm	17.3mm	1.8mm	2
690-14-10	10mm	17.3mm	1.8mm	2
690-14-11	11mm	17.3mm	1.8mm	2
690-14-12	12mm	17.3mm	1.8mm	2
2-Hole Plate, for 16mm x 14mm Cage				
Catalog Number	Cage Height	Plate Width	Plate Thickness	Qty
690-16-06	6mm	17.3mm	1.8mm	2
690-16-07	7mm	17.3mm	1.8mm	2
690-16-08	8mm	17.3mm	1.8mm	2
690-16-09	9mm	17.3mm	1.8mm	2
690-16-10	10mm	17.3mm	1.8mm	2
690-16-11	11mm	17.3mm	1.8mm	2
690-16-12	12mm	17.3mm	1.8mm	2
4-Hole Plate, for 14mm x 12mm Cage				
Catalog Number	Cage Height	Plate Width	Plate Thickness	Qty
691-14-06	6mm	17.3mm	1.8mm	2
691-14-07	7mm	17.3mm	1.8mm	2
691-14-08	8mm	17.3mm	1.8mm	2
691-14-09	9mm	17.3mm	1.8mm	2
691-14-10	10mm	17.3mm	1.8mm	2
691-14-11	11mm	17.3mm	1.8mm	2
691-14-12	12mm	17.3mm	1.8mm	2
4-Hole Plate, for 16mm x 14mm Cage				
Catalog Number	Cage Height	Plate Width	Plate Thickness	Qty
691-16-06	6mm	17.3mm	1.8mm	2
691-16-07	7mm	17.3mm	1.8mm	2
691-16-08	8mm	17.3mm	1.8mm	2
691-16-09	9mm	17.3mm	1.8mm	2
691-16-10	10mm	17.3mm	1.8mm	2
691-16-11	11mm	17.3mm	1.8mm	2
691-16-12	12mm	17.3mm	1.8mm	2

Varisync Cervical Screws 

Variable, Self-Drilling Screw			
Catalog Number	Diameter	Length	Qty
693-4012	4.0mm	12mm	12
693-4014	4.0mm	14mm	12
693-4016	4.0mm	16mm	12
693-4018	4.0mm	18mm	12
Variable, Self-Tapping Screw			
Catalog Number	Diameter	Length	Qty
695-4012	4.0mm	12mm	12
695-4014	4.0mm	14mm	12
695-4016	4.0mm	16mm	12
695-4018	4.0mm	18mm	12
695-4512	4.5mm	12mm	6
695-4514	4.5mm	14mm	6
695-4516	4.5mm	16mm	6
695-4518	4.5mm	18mm	6
Fixed, Self-Drilling Screw			
Catalog Number	Diameter	Length	Qty
694-4012	4.0mm	12mm	12
694-4014	4.0mm	14mm	12
694-4016	4.0mm	16mm	12
694-4018	4.0mm	18mm	12
Fixed, Self-Tapping Screw			
Catalog Number	Diameter	Length	Qty
696-4012	4.0mm	12mm	12
696-4014	4.0mm	14mm	12
696-4016	4.0mm	16mm	12
696-4018	4.0mm	18mm	12
696-4512	4.5mm	12mm	6
696-4514	4.5mm	14mm	6
696-4516	4.5mm	16mm	6
696-4518	4.5mm	18mm	6

690-1007	Cervical Plate Pin	4

STANDARD VARISYNC PRODUCT LISTING

Varisync Cervical PEEK Interbody

14mm x 12mm, 6°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
690-061412-06	6mm	0.1mm	0.3cc	2
690-061412-07	7mm	0.2mm	0.4cc	2
690-061412-08	8mm	0.2mm	0.4cc	2
690-061412-09	9mm	0.2mm	0.5cc	2
690-061412-10	10mm	0.3mm	0.5cc	2
690-061412-11	11mm	0.3mm	0.6cc	2
690-061412-12	12mm	0.4mm	0.7cc	2

14mm x 12mm, 10°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
690-101412-06	6mm	0.1mm	0.3cc	2
690-101412-07	7mm	0.1mm	0.4cc	2
690-101412-08	8mm	0.2mm	0.4cc	2
690-101412-09	9mm	0.2mm	0.5cc	2
690-101412-10	10mm	0.2mm	0.5cc	2
690-101412-11	11mm	0.3mm	0.6cc	2
690-101412-12	12mm	0.3mm	0.7cc	2

Available Upon Request:

16mm x 14mm, 6°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
690-061614-06	6mm	0.1mm	0.5cc	2
690-061614-07	7mm	0.2mm	0.6cc	2
690-061614-08	8mm	0.2mm	0.7cc	2
690-061614-09	9mm	0.2mm	0.8cc	2
690-061614-10	10mm	0.3mm	0.8cc	2
690-061614-11	11mm	0.3mm	0.9cc	2
690-061614-12	12mm	0.4mm	1.1cc	2

16mm x 14mm, 10°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
690-101614-06	6mm	0.1mm	0.5cc	2
690-101614-07	7mm	0.1mm	0.6cc	2
690-101614-08	8mm	0.2mm	0.7cc	2
690-101614-09	9mm	0.2mm	0.8cc	2
690-101614-10	10mm	0.2mm	0.8cc	2
690-101614-11	11mm	0.3mm	0.9cc	2
690-101614-12	12mm	0.3mm	1.1cc	2

NOTE: Additional Cervical Interbody listing on page 17.

Interbody footprints listed as Width x Depth
Ant. Height = Anterior height of cage
Post. Height = Posterior height of cage

STANDARD VARISYNC PRODUCT LISTING

Varisync Cervical Instruments

Kit #KZ-VS001

Catalog Number	Description	Qty
690-1000-06	DTS Inserter, 6mm interbody height	1
690-1000-07	DTS Inserter, 7mm interbody height	1
690-1000-08	DTS Inserter, 8mm interbody height	1
690-1000-09	DTS Inserter, 9mm interbody height	1
690-1000-10	DTS Inserter, 10mm interbody height	1
690-1000-11	DTS Inserter, 11mm interbody height	1
690-1000-12	DTS Inserter, 12mm interbody height	1
690-1000-2	DTS Inserter Stylus, 6-32	2
690-1000-3	DTS Inserter Stylus, 4-40	2
690-1001	T10 Driver with AO Connection	2
690-1002	Awl with AO Connection	1
690-1003-12	Cervical Drill, Short, 12mm	1
690-1003-14	Cervical Drill, Short, 14mm	1
690-1003-16	Cervical Drill, Short, 16mm	1
690-1003-18	Cervical Drill, Short, 18mm	1
690-1004	Fixed Drill Guide	1
690-1005	Variable Drill Guide	1
690-1006-1	Plate Pin Inserter, Outer	1
690-1006-2	Plate Pin Inserter, Stylus	2
690-1008	Universal T10 Driver	1
170-2012	Universal Driver Handle	1
690-1009	In-line Inserter	1
690-1010-1	Sleeved Awl, Fixed	1
690-1010-2	Sleeved Awl, Variable	1
20-2001	Rasp	1
20-2002	Interbody Inserter	1

Catalog Number	Description	Qty
20-2000-01	6° Sizer, 5mm and 6mm, 14mm x 12mm	1
20-2000-02	6° Sizer, 7mm and 8mm, 14mm x 12mm	1
20-2000-03	6° Sizer, 9mm and 10mm, 14mm x 12mm	1
20-2000-04	6° Sizer, 11mm and 12mm, 14mm x 12mm	1
20-2000-05	10° Sizer, 5mm and 6mm, 14mm x 12mm	1
20-2000-06	10° Sizer, 7mm and 8mm, 14mm x 12mm	1
20-2000-07	10° Sizer, 9mm and 10mm, 14mm x 12mm	1
20-2000-08	10° Sizer, 11mm and 12mm, 14mm x 12mm	1
22-2000-01	6° Sizer, 5mm and 6mm, 16mm x 14mm	1
22-2000-02	6° Sizer, 7mm and 8mm, 16mm x 14mm	1
22-2000-03	6° Sizer, 9mm and 10mm, 16mm x 14mm	1
22-2000-04	6° Sizer, 11mm and 12mm, 16mm x 14mm	1
22-2000-05	10° Sizer, 5mm and 6mm, 16mm x 14mm	1
22-2000-06	10° Sizer, 7mm and 8mm, 16mm x 14mm	1
22-2000-07	10° Sizer, 9mm and 10mm, 16mm x 14mm	1
22-2000-08	10° Sizer, 11mm and 12mm, 16mm x 14mm	1
Z-1023	Jeweler Handle with AO Connection	2

NOTE: The interbody inserter (20-2002) is included in the Varisync kit only if additional cervical interbodies are requested.

SPECIAL ORDER PRODUCT LISTING

IBF PEEK Cervical Interbody

Kit #CZ-C0001

14mm x 12mm, 6°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
20-0605	5mm	0.7mm	0.2cc	3
20-0606	6mm	1.7mm	0.3cc	3
20-0607	7mm	2.7mm	0.4cc	3
20-0608	8mm	3.7mm	0.4cc	3
20-0609	9mm	4.7mm	0.5cc	3
20-0610	10mm	5.7mm	0.5cc	3
20-0611	11mm	6.7mm	0.6cc	3
20-0612	12mm	7.7mm	0.6cc	3
14mm x 12mm, 10°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
20-1005	5mm	0.7mm	0.2cc	3
20-1006	6mm	1.7mm	0.3cc	3
20-1007	7mm	2.7mm	0.3cc	3
20-1008	8mm	3.7mm	0.4cc	3
20-1009	9mm	4.7mm	0.4cc	3
20-1010	10mm	5.7mm	0.5cc	3
20-1011	11mm	6.7mm	0.6cc	3
20-1012	12mm	7.7mm	0.6cc	3

Ti3Z 3D-Printed Titanium Cervical Interbody

Kit #KZ-CT0001

14mm x 12mm, 6°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
220-0606	6mm	2.8mm	0.2cc	3
220-0607	7mm	3.8mm	0.3cc	3
220-0608	8mm	4.7mm	0.3cc	3
220-0609	9mm	5.7mm	0.3cc	3
220-0610	10mm	6.7mm	0.4cc	3
14mm x 12mm, 10°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
220-1006	6mm	2.1mm	0.2cc	3
220-1007	7mm	3.1mm	0.3cc	3
220-1008	8mm	4.1mm	0.3cc	3
220-1009	9mm	5.0mm	0.3cc	3
220-1010	10mm	6.0mm	0.4cc	3

Available Upon Request:

16mm x 14mm, 6°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
222-0606	6mm	2.8mm	0.3cc	3
222-0607	7mm	3.8mm	0.4cc	3
222-0608	8mm	4.7mm	0.4cc	3
222-0609	9mm	5.7mm	0.4cc	3
222-0610	10mm	6.7mm	0.5cc	3

NOTE: Varisync Cervical Interbody listing on page 15.

Interbody footprints listed as Width x Depth
Ant. Height = Anterior height of cage
Post. Height = Posterior height of cage

SPECIAL ORDER PRODUCT LISTING

Whitney® PEEK with Titanium Coating Cervical Interbody

Kit #CZ-C0001

14mm x 12mm, 6°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
490-0605	5mm	0.7mm	0.1cc	3
490-0606	6mm	1.7mm	0.2cc	3
490-0607	7mm	2.7mm	0.2cc	3
490-0608	8mm	3.7mm	0.2cc	3
490-0609	9mm	4.7mm	0.2cc	3
490-0610	10mm	5.7mm	0.3cc	3
14mm x 12mm, 10°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
490-1005	5mm	0.7mm	0.1cc	3
490-1006	6mm	1.7mm	0.2cc	3
490-1007	7mm	2.7mm	0.2cc	3
490-1008	8mm	3.7mm	0.2cc	3
490-1009	9mm	4.7mm	0.2cc	3
490-1010	10mm	5.7mm	0.3cc	3

Available Upon Request:

16mm x 14mm, 6°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
492-0605	5mm	0.7mm	0.3cc	3
492-0606	6mm	1.7mm	0.3cc	3
492-0607	7mm	2.7mm	0.4cc	3
492-0608	8mm	3.7mm	0.4cc	3
492-0609	9mm	4.7mm	0.5cc	3
492-0610	10mm	5.7mm	0.5cc	3

NOTE: Varisync Cervical Interbody listing on page 15.

Interbody footprints listed as Width x Depth
Ant. Height = Anterior height of cage
Post. Height = Posterior height of cage

SPECIAL ORDER PRODUCT LISTING

Labyrinth® Porous PEEK Cervical Interbody

Kit #KZ-CL0001

14mm x 12mm, 6°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
560-0605	5mm	2.3mm	0.1cc	3
560-0606	6mm	2.8mm	0.1cc	3
560-0607	7mm	3.8mm	1.1cc	3
560-0608	8mm	4.7mm	1.1cc	3
560-0609	9mm	5.7mm	2.1cc	3
560-0610	10mm	6.7mm	2.1cc	3
560-0611	11mm	7.6mm	3.1cc	3
560-0612	12mm	8.6mm	3.1cc	3
14mm x 12mm, 10°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
560-1005	5mm	1.6mm	0.1cc	3
560-1006	6mm	2.1mm	0.1cc	3
560-1007	7mm	3.1mm	1.1cc	3
560-1008	8mm	4.1mm	1.1cc	3
560-1009	9mm	5.0mm	2.1cc	3
560-1010	10mm	6.0mm	2.1cc	3
560-1011	11mm	7.0mm	3.1cc	3
560-1012	12mm	7.9mm	3.1cc	3

Available Upon Request:

16mm x 14mm, 6°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
562-0605	5mm	2.3mm	0.2cc	3
562-0606	6mm	2.8mm	0.3cc	3
562-0607	7mm	3.8mm	0.3cc	3
562-0608	8mm	4.7mm	0.4cc	3
562-0609	9mm	5.7mm	0.4cc	3
562-0610	10mm	6.7mm	0.5cc	3
562-0611	11mm	7.6mm	0.5cc	3
562-0612	12mm	8.6mm	0.5cc	3
16mm x 14mm, 10°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
562-1005	5mm	1.6mm	0.2cc	3
562-1006	6mm	2.1mm	0.3cc	3
562-1007	7mm	3.1mm	0.3cc	3
562-1008	8mm	4.1mm	0.4cc	3
562-1009	9mm	5.0mm	0.4cc	3
562-1010	10mm	6.0mm	0.5cc	3
562-1011	11mm	7.0mm	0.5cc	3
562-1012	12mm	7.9mm	0.5cc	3

NOTE: Varisync Cervical Interbody listing on page 15.

Interbody footprints listed as Width x Depth
Ant. Height = Anterior height of cage
Post. Height = Posterior height of cage

SPECIAL ORDER PRODUCT LISTING

F3D-Z 3D-Printed Titanium with Mimetic Metal® Cervical Interbody

14mm x 12mm, 6°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
910-0605	5mm	0.7mm	0.2cc	3
910-0606	6mm	1.7mm	0.3cc	3
910-0607	7mm	2.7mm	0.4cc	3
910-0608	8mm	3.7mm	0.4cc	3
910-0609	9mm	4.7mm	0.5cc	3
910-0610	10mm	5.7mm	0.5cc	3
910-0611	11mm	6.7mm	0.6cc	2
910-0612	12mm	7.7mm	0.6cc	2
14mm x 12mm, 10°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
910-1005	5mm	0.7mm	0.2cc	2
910-1006	6mm	1.7mm	0.3cc	2
910-1007	7mm	2.7mm	0.3cc	2
910-1008	8mm	3.7mm	0.4cc	2
910-1009	9mm	4.7mm	0.4cc	2
910-1010	10mm	5.7mm	0.5cc	1
910-1011	11mm	6.7mm	0.6cc	1
910-1012	12mm	7.7mm	0.6cc	1

Available Upon Request:

16mm x 14mm, 6°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
912-0605	5mm	0.7mm	0.4cc	3
912-0606	6mm	1.7mm	0.5cc	3
912-0607	7mm	2.7mm	0.6cc	3
912-0608	8mm	3.7mm	0.7cc	3
912-0609	9mm	4.7mm	0.8cc	3
912-0610	10mm	5.7mm	0.8cc	3
912-0611	11mm	6.7mm	0.9cc	2
912-0612	12mm	7.7mm	1.0cc	2
16mm x 14mm, 10°				
Catalog Number	Ant. Height	Post. Height	Graft Volume	Qty
912-1005	5mm	0.7mm	0.3cc	2
912-1006	6mm	1.7mm	0.4cc	2
912-1007	7mm	2.7mm	0.5cc	2
912-1008	8mm	3.7mm	0.6cc	2
912-1009	9mm	4.7mm	0.7cc	2
912-1010	10mm	5.7mm	0.8cc	1
912-1011	11mm	6.7mm	0.9cc	1
912-1012	12mm	7.7mm	1.0cc	1

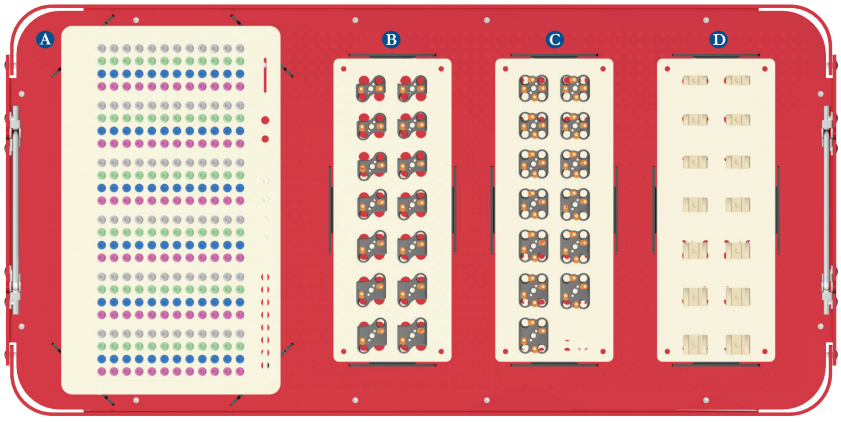
NOTE: Varisync Cervical Interbody listing on page 15.

Interbody footprints listed as Width x Depth
Ant. Height = Anterior height of cage
Post. Height = Posterior height of cage

TRAY LAYOUT

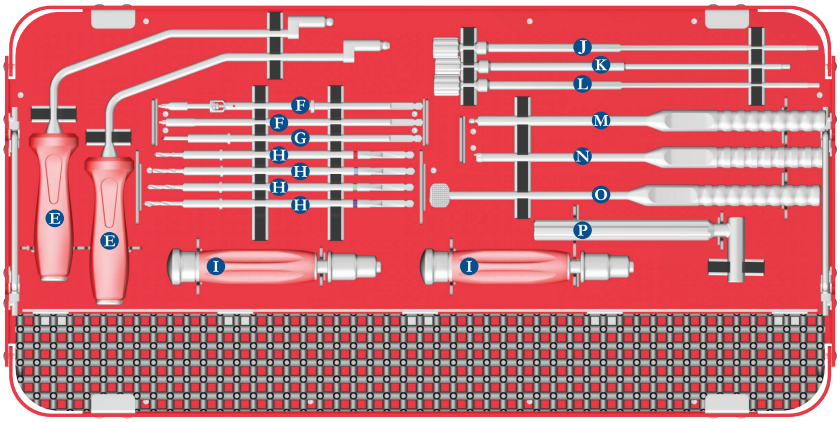
Kit #KZ-VS0001

Top Tray



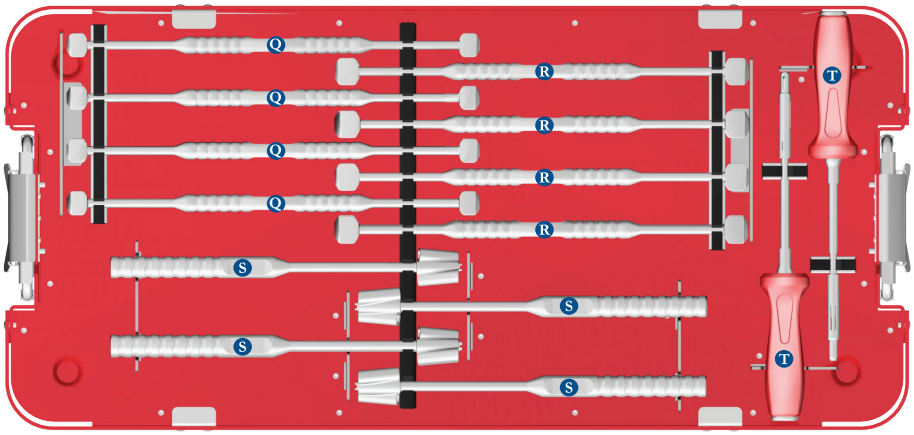
- **A.** Screw Caddy
- **B.** 2-Hole Plate Caddy
- **C.** 4-Hole Plate Caddy
- **D.** Varisync Cages

Middle Tray



- **E.** Drill Guides: Variable (left), Fixed (right)
- **F.** Screw Drivers
- **G.** DTS Awl
- **H.** Drills: 12mm-18mm
- **I.** Jeweler Handles
- **J.** Stylus: DTS and In-Line
- **K.** Stylus: Plate Pin
- **L.** Stylus: Interbody Inserter
- **M.** Pin Inserter
- **N.** In-Line Inserter
- **O.** Rasp
- **P.** Offset Handle

Bottom Tray



- **Q.** Trials: 16mm x 14mm
- **R.** Trials: 14mm x 12mm
- **S.** DTS Guides
- **T.** Sleeved Awl: Variable (left), Fixed (right)

NOTES

NOTES

INDICATIONS FOR USE

Zavation Varisync® Cervical System

Device Description

The Varisync Plate is a non-sterile anterior, cervical fixation device available in various heights and widths to fit the anatomical needs of a wide variety of patients. The plates are made from titanium alloy, as specified in ASTM F136. The Screws for use with the Varisync Plates are non-sterile and manufactured from titanium alloy, as specified in ASTM F136.

Varisync Spacers are non-sterile, anterior cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The spacers are available in various heights and footprints to fit the anatomical needs of a wide variety of patients. These devices are to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. The Varisync Spacers are manufactured from radiolucent PEEK polymer, with tantalum markers, as specified in ASTM F2026 and F560.

Indications for Use

The Varisync Plate is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

The Varisync Spacer is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The Varisync Spacer is to be filled with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. These devices are intended to be used with supplemental fixation such as the Zavation Varisync Plate, Zavation Midline Plate, Zavation EZ Plate, or Zavation Cervical Plate Systems. When used with the Varisync Plate, the assembly takes on the indications of the Varisync Spacer, with the Varisync Plate acting as the supplemental fixation.

Materials

The spacer component is manufactured from medical grade PEEK Zeniva ZA-500 or Superior Polymers Magnolia PEEK (ASTM F2026) with a Tantalum alloy position marker (ASTM F560). The plate and screws are titanium alloy (ASTM F136).

Contraindications

- The Zavation Varisync® System is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, drug/alcohol abuse, mental illness, general neurologic conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity and patients who are unwilling to restrict activities or follow medical advice.
- Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
- This device is not intended for use except as indicated.
- Prior fusion at the level(s) to be treated.

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.
- Neurological injury, vascular or visceral injury.
- Death

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

Warnings and Precautions

- A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without autograft or in cases that do not develop a union will not be successful.
- Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.
- Non-sterile, the Zavation Varisync System implants are sold non-sterile, and therefore, must be sterilized before each use.
- Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
- Do not reuse implants; discard used, damaged, or otherwise suspect implants.
- Single use only.
- The Zavation Varisync System components should not be used with components of any other system or manufacturer.
- The Zavation Varisync System has not been evaluated for safety and compatibility in the MR environment. The Zavation Varisync 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.

INDICATIONS FOR USE (Continued)

- This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Do not use if package is opened or damaged or if expiration date has passed.

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

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 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 neurologic 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 of 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: Ensure that all instruments have been disassembled and placed in their dedicated locations in the sterilization tray after cleaning. Remove central stylus from plate inserters and place in appropriate tray locations. Disassemble removable handles that are left attached to the drill, awl and screw drivers. (note that these items are normally stored in the dedicated trays already disassembled). Plate inserters and removable handles should stay disassembled in appropriate tray locations after cleaning and sterilization until next use.

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

Manual

4.1 Manual Pre-Cleaning:

- Alcohol wipe
- 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 a 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.
- Refer to labeling of automated washer for detailed instructions of use.
- 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.
- Visually check instruments with long slender features for distortion.
- Visually inspect the devices for any cracking, pitting, or other signs of deterioration.
- If distortion or any signs of deterioration are found, discontinue use, return device to Zavation, and request a replacement device from Zavation Medical Products, LLC.

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

Sterilization: See sterilization procedure.

Storage: Control environment. Plate inserters and removable handles should stay disassembled in appropriate tray locations after cleaning and sterilization until next use.

INDICATIONS FOR USE (Continued)

Additional Information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded. Before next use, to reassemble inserter, thread inserter stylus down central shaft of inserter until stop is reached. To reassemble removable handles, pull back outer metal sleeve on handle, place desired instrument (tap or drill) in open slot and slide outer sleeve back over to original position to lock instrument in place.

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

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

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

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

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

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

INDICATIONS FOR USE

Zavation Cervical IBF Interbody and Zavation Whitney® Cervical Interbody

Device Description

The Zavation IBF implants offers a variety of heights, widths and lengths. There are six main configurations: ALIF, LLIF, TLIF, T-PLIF, PLIF and CIF. The different configurations allow for multiple surgical technique options. The implants are manufactured from medical grade PEEK (Polyetheretherketone) or titanium.

The Zavation IBF implants are available in a range of sizes, as well as parallel and lordotic angled implants, to accommodate variations in patients' anatomy. In addition, tantalum beads or pins are embedded in the implants as an option to help allow for radiographic visualization. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates.

Indications for Use

When used as a cervical intervertebral body fusion device, the Zavation IBF implants are indicated for spinal fusion procedures to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of nonoperative treatment.

When used as a lumbar intervertebral body fusion device, the Zavation IBF implants are indicated for spinal fusion procedures to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

For all the above indications the Zavation IBF implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Pedicle Screw System and Zavation Cervical Plate System.

Materials

The devices are manufactured from medical grade PEEK Zeniva ZA-500 or Magnolia PEEK (ASTM F2026) with tantalum alloy position markers (ASTM F560) or titanium per ASTM F136, or titanium coating per ASTM F1580.

Contraindications

- The Zavation IBF System is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, drug/alcohol abuse, mental illness, general neurologic conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity and patients who are unwilling to restrict activities or follow medical advice.
- Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
- This device is not intended for use except as indicated.
- Prior fusion at the level(s) to be treated.

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.
- Neurological injury, vascular or visceral injury.
- Death

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

Warnings and Precautions

- A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without autograft or in cases that do not develop a union will not be successful.
- Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.
- Unless clearly marked as sterile and presented in an unopened sterile package, the Zavation IBF implants are sold non-sterile, and therefore, must be sterilized before each use.
- For implants marked as sterile, do not use if sterile package is opened or damaged.
- Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
- Do not reuse implants; discard used, damaged, or otherwise suspect implants.
- Single use only.
- The Zavation IBF System components should not be used with components of any other system or manufacturer.
- The Zavation IBF System has not been evaluated for safety and compatibility in the MR environment. The Zavation IBF 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.

INDICATIONS FOR USE (Continued)

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

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. 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 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.
- Unless clearly marked as sterile and presented in an unopened sterile package, 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 neurologic 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 of 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 IBF System, the only instruments requiring disassembly would be the inserter. The inserter is disassembled and reassembled by sliding the stylus through the proximal end of the inserter. (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:

- Alcohol wipe
- 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.
- Refer to labeling of automated washer for detailed instructions of use.
- 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.
- Visually check instruments with long slender features for distortion.
- Visually 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.

INDICATIONS FOR USE (Continued)

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

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

Sterilization: Unless clearly marked as sterile and presented in an unopened sterile package, the Zavation IBF System components 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

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

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

INDICATIONS FOR USE

Zavation Ti3Z® Cervical Interbody

Device Description

The Zavation Ti3Z Cervical Interbody System implants are offered in two configurations: Ti3Z cervical implants are additively manufactured entirely from medical grade Titanium Ti64ELI powder by way of laser sintering (ASTM F3001); Ti3Z-PEEK cervical implants have an exterior that is manufactured from medical grade PEEK (polyetheretherketone) with tantalum beads or pins embedded in the implants to allow for radiographic visualization. Ti3Z-PEEK implants also contain an interior titanium insert manufactured by way of laser sintering (ASTM F3001). The ends of the Ti3Z-PEEK implants have machined teeth which are designed to engage with the vertebral body end plates.

The Zavation Ti3Z Cervical and Ti3Z-PEEK Cervical Interbody implants are available in a range of heights, widths, and lengths as well as parallel and lordotic angled implants, to accommodate variations in patients' anatomy. The internal body of both constructs have a porous structure while the external edges of the implants have a solid, roughened surface designed to engage with the vertebral body end plates. All implants will be provided sterile.

Indications for Use

When used as a cervical intervertebral body fusion device, the Zavation Ti3Z Cervical Interbody System implants are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The Ti3Z cervical implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

For all the above indications the Zavation Ti3Z Cervical Interbody implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Cervical Plate System.

Materials

Ti3Z Cervical devices are manufactured entirely from medical grade titanium (ASTM F3001-14). Ti3Z-PEEK Cervical devices have an exterior manufactured from medical grade PEEK with tantalum markers or pins embedded into the implant and an interior manufactured from medical grade titanium (ASTM F3001-14).

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.
- Neurological injury, vascular or visceral injury.
- Death

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

Warnings and Precautions

- The Zavation Ti3Z Cervical Interbody System has not been evaluated for safety and compatibility in the MR environment. The Zavation Ti3Z Cervical Interbody 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 instruments should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images.
- Do not re-sterilize and/or reuse. The instruments are for single use only. Reconditioning, refurbishing, repair, or re-sterilization of the device to enable further use is expressly prohibited.

Sterilization

The Ti3Z Cervical Interbody System implants will be received sterile in sealed sterile packaging.

INDICATIONS FOR USE (Continued)

Other preoperative, intraoperative and postoperative warnings are as follows:

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. Titanium 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 neurologic 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 of their limitations and taught to compensate for this permanent physical restriction in body motion.
- If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the implant. It is important that immobilization of the spinal segment be maintained until fusion has occurred.
- 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.

INDICATIONS FOR USE (Continued)

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 Ti3Z Cervical Interbody System, the only instruments requiring disassembly would be the inserter. The inserter is disassembled and reassembled by sliding the stylus through the proximal end of the inserter. (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:

- Alcohol wipe
- Prepare a pH neutral, enzymatic detergent soak with warm water (approximately 35-40°C) per the instructions of the enzymatic solution manufacturer.
- Soak the instrument for a minimum of 15 minutes. Actuate any mechanisms and slide moving parts to the extreme positions to ensure the cleaning solution contacts all the surfaces.
- Change the soak solution if the solution becomes visibly soiled.
- While still in the soak solution, use a soft brush to remove all exterior soil. Thoroughly scrub any grooves, slots, threads, teeth, ratchets, or hinges. Use an appropriate size cleaning brush to thoroughly brush the entire length of any internal lumens a minimum of five times per lumen.
- Rinse instruments thoroughly with 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.

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)

4.2 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.

4.2 Washer Disinfector 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:
  - 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.
- Visually check instruments with long slender features for distortion.
- Visually 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.

Sterilization: The Zavation Ti3Z Cervical Interbody 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

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

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

INDICATIONS FOR USE

Zavation Labyrinth® Cervical Interbody

Device Description

The Labyrinth implants offers a variety of heights, widths and lengths. There are six main configurations: ALIF, LLIF, TLIF, T-PLIF, PLIF and CIF. The different configurations allow for multiple surgical technique options. The implants are manufactured from medical grade PEEK (Polyetheretherketone).

The Labyrinth implants are available in a range of sizes, as well as parallel and lordotic angled implants, to accommodate variations in patients' anatomy. In addition, tantalum beads or pins are embedded in the implants as an option to help allow for radiographic visualization. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates. The LABYRINTH® device includes a porous structure on the endplate and through the device.

Indications for Use

When used as a cervical intervertebral body fusion device, the Labyrinth implants are indicated for spinal fusion procedures to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the Labyrinth implants are indicated for spinal fusion procedures to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

For all the above indications the Labyrinth implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Pedicle Screw System and Zavation Cervical Plate System.

Materials

The devices are manufactured from medical grade PEEK Zeniva ZA-500 or Magnolia PEEK (ASTM F2026) with Tantalum alloy position markers (ASTM F560).

Contraindications

- The Labyrinth devices are contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, drug/alcohol abuse, mental illness, general neurologic conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity and patients who are unwilling to restrict activities or follow medical advice.
- Biological factors such as smoking, use of non-steroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
- This device is not intended for use except as indicated.
- Prior fusion at the level(s) to be treated.

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

- A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without autograft or in cases that do not develop a union will not be successful.
- Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.
- For implants marked as sterile, do not use if sterile package is opened or damaged.
- Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
- Do not reuse implants; discard used, damaged, or otherwise suspect implants.
- Single use only
- Labyrinth components are identical to Zavation IBF System components
- Labyrinth components should not be used with components of any other manufacturer.
- Labyrinth devices have not been evaluated for safety and compatibility in the MR environment. Labyrinth devices have 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.

Sterilization

- Labyrinth implants will be provided sterile in sealed sterile packaging.

INDICATIONS FOR USE (Continued)

Other preoperative, intraoperative and postoperative warnings are as follows:

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. 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 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.
- Unless clearly marked as sterile and presented in an unopened sterile package, 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 neurologic 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 of their limitations and taught to compensate for this permanent physical restriction in body motion.
- If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the implant. It is important that immobilization of the spinal segment be maintained until fusion has occurred.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

INDICATIONS FOR USE (Continued)

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

For safety reasons, reusable instruments must be pre-cleaned, cleaned and sterilized before use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following table. Sterilization trays should be thoroughly cleaned using either the Automated or Manual procedure that is detailed below for instruments. It is acceptable to skip the ultrasonic cleaner step for the sterilization trays 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 Labyrinth System, the only instruments requiring disassembly would be the inserter. The inserter is disassembled and reassembled by sliding the stylus through the proximal end of the inserter. (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:

- Alcohol wipe
- Prepare a pH neutral, enzymatic detergent soak with warm water (approximately 35-40°C) per the instructions of the enzymatic solution manufacturer.
- Soak the instrument for a minimum of 15 minutes. Actuate any mechanisms and slide moving parts to the extreme positions to ensure the cleaning solution contacts all the surfaces.
- Change the soak solution if the solution becomes visibly soiled.
- While still in the soak solution, use a soft brush to remove all exterior soil. Thoroughly scrub any grooves, slots, threads, teeth, ratchets, or hinges. Use an appropriate size cleaning brush to thoroughly brush the entire length of any internal lumens a minimum of five times per lumen.
- Rinse instruments thoroughly with 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.

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)

4.2 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.

4.2 Washer Disinfector 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:
  - 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.
- Visually check instruments with long slender features for distortion.
- Visually 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.

Sterilization: Unless clearly marked as sterile and presented in an unopened sterile package, the Labyrinth System components 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

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

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

INDICATIONS FOR USE

Zavation F3D-Z Cervical Interbody

Device Description

The Zavation F3D-Z Cervical Interbody System implants are additively manufactured entirely from medical grade Titanium Ti64ELI powder by way of laser sintering (ASTM F3001).

The Zavation F3D-Z Cervical Interbody implants are available in a range of heights, widths, and lengths as well as parallel and lordotic angled implants, to accommodate variations in patients' anatomy. The internal body has a porous structure while the external edges of the implants have a solid, roughened surface designed to engage with the vertebral body end plates. All implants will be provided sterile.

Indications for Use

When used as a cervical intervertebral body fusion device, the Zavation F3D-Z Cervical Interbody System implants are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The F3D-Z cervical implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

For all the above indications the Zavation F3D-Z Cervical Interbody implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Cervical Plate System.

Contraindications

- Instability
- Infection
- Severe Bleeding
- Pregnancy

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

INDICATIONS FOR USE (Continued)

- Herniated nucleus pulposus, disc disruption or disc degeneration at, above or below the level of surgery.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of sensory and/or motor function including paralysis (complete/incomplete), dysesthesia, hyperesthesia, paresthesia, radiculopathy, pain, numbness, spasms, sensory loss, tingling sensation and/or visual deficit.
- Neuropathy, paraplegia, paraparesis, reflex deficit, irritation, neurological deficit (transient or permanent) and/or muscle loss.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Decrease in bone density potentially caused by stress shielding.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Limited ability to perform daily activities.
- Continuation of symptoms that were to be treated for by the implantation.
- Change in mental status.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.

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

Warnings and Precautions

- The Zavation F3D-Z Cervical Interbody System has not been evaluated for safety and compatibility in the MR environment. The Zavation F3D-Z Cervical Interbody 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 instruments should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images.
- Do not re-sterilize and/or reuse. The instruments are for single use only. Reconditioning, refurbishing, repair, or re-sterilization of the device to enable further use is expressly prohibited.
- The safety and effectiveness of Cervical Interbody Fusion Device System have been established only for spinal conditions with acute and chronic instabilities or deformities of the Cervical spine (C2-T1): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion pseudarthrosis. The safety and effectiveness of these devices for any other conditions are unknown.

INDICATIONS FOR USE (Continued)

- Patients must be informed that implants cannot be made to last indefinitely, and the purpose of the implant is to provide temporary internal support while the fusion mass about the implant is developing. Without solid biological support provided by sufficient fusion mass, the implants will fail in any of several modes. These modes may include bone-implant interface failure, implant fracture, or bone failure. Spinal implants of this type are more likely to fail if no bone graft is used, if pseudarthrosis develops, or if patients have severe or multiple preoperative curves.
- Spinal implants, like other implants or temporary internal fixation devices, have a limited life. The life of the implant is directly impacted by the level of activity of the patient. Inform the patient that any activity increases the risk that the implant components may become loose, bend, or break. Instruct patients about restrictions to their activity levels in the postoperative period. Examine patients postoperatively to evaluate the condition of implant components and the development of the fusion mass about the implant components. Instruct the patient that implant components may bend, break, or loosen even though restrictions in activity are followed and even if fusion mass about the implant component sufficiently develops.
- This device is not intended or expected to be the only mechanism of support of the spine. Regardless of the spinal pathology for which implantation of this device was chosen, solid biological support is anticipated but is not always obtained. Without solid biological support provided by bony fusion, the device cannot be expected to support the spine indefinitely and will lose effectiveness.
- Potential risks associated with the use of this system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, vascular or visceral injury, neurological complications, over-distraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudarthrosis, disc height loss, adjacent level disc degeneration, allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, and expulsion. Risks and potential benefits must be provided to patients for whom this treatment modality is suggested. The decision to remove a broken implant must be made by the physician who must consider the risks associated with the presence of the broken implant and the condition of the patient.
- Altering an implant may reduce its strength from fatigue and cause its fracture or deformation. If spinal implants are damaged during insertion or adjustment, they may not remain implanted and must be replaced. Refer to the F3D-Z Ti3Z Cervical Series Interbody System surgical technique manual for descriptions of appropriate implant handling and insertion techniques.
- Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant fracture or deformation may result.

In addition to the warnings and precautions discussed above, patients must be informed about general surgical risks prior to surgery.

The implantation of the F3D-Z Ti3Z Cervical Series of intervertebral body fusion devices is a technically demanding procedure that presents a risk of serious injury to the patient. Accordingly, such a procedure must be performed only by experienced spinal surgeons with specific training in the use of this intervertebral body fusion device system. The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant procedure, and the surgeon must be thoroughly knowledgeable of the mechanical and metallurgical limitations of the implant. It is the surgeon's responsibility to ensure that the operating procedure is performed correctly. The Surgical Technique can be requested from Zavation by calling the phone number at the end of this document. No manufacturer can be responsible for complications resulting in erroneous indication, wrong choice of implant size, incorrect operating procedure, and incorrect implant component combination. Internal fixation devices such as the F3D-Z Ti3Z Cervical Series Interbody System rely upon individual patient physiological response, and proper use of the device does not guarantee any result.

INDICATIONS FOR USE (Continued)

Sterilization

The F3D-Z Cervical Interbody System implants will be received sterile in sealed sterile packaging.

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. Titanium 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 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 than 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.
- The implants of the F3D-Z Ti3Z Cervical Series Interbody System are provided sterile. The surgical instruments provided with the F3D-Z Ti3Z Cervical Series Interbody System are supplied non-sterile and must be thoroughly decontaminated, cleaned, and sterilized prior to surgical use.
- Instruments must be cleaned using validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization.
- Remove all packaging that individual instruments may be provided prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container.
- Some instruments must be disassembled to facilitate cleaning. All instruments should be reassembled following cleaning, prior to sterilization.
- Prior to use, instruments must be inspected for signs of wear, damage, and proper function. If an instrument is suspected to be damaged, please contact Zavation for a replacement

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.

Postoperative

- Detailed instructions should be given to the patient regarding care and limitations, if any.
- To achieve maximum results, the patient should not be exposed to excessive mechanical vibrations. The patient should not smoke or consume alcohol during the healing process.
- The patient should be advised of their limitations and taught to compensate for this permanent physical restriction in body motion.

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 tables in sections 4.1 and 4.2.

The implants of the F3D-Z Ti3Z Cervical Series Interbody System are provided sterile. The surgical instruments provided with the F3D-Z Ti3Z Cervical Series Interbody System are supplied non-sterile and must be thoroughly decontaminated, cleaned, and sterilized prior to surgical use.

Instruments must be cleaned using validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization.

Remove all packaging that individual instruments may be provided prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container.

Some instruments must be disassembled to facilitate cleaning. All instruments should be reassembled following cleaning, prior to sterilization.

Prior to use, instruments must be inspected for signs of wear, damage and proper function. If an instrument is suspected to be damaged, please contact Zavation for a replacement. Sterilization trays should be thoroughly cleaned using either the Automated or Manual procedure that is detailed below for instruments. It is acceptable to skip the ultrasonic cleaner step for the sterilization trays if the inspection criteria provided below are acceptable for the tray.

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

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

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

2. The maximum recommended time between use and cleaning is 4 hours:

- A. Instruments should not be exposed to elevated air temperatures (>100 °F).
- B. Certain cleaning solutions such as those containing fixatives, alcohols, aldehydes, chlorides, and/or excessive amounts of basic detergents can cause degradation of stainless-steel surfaces and laser marking. Use a cleaning and disinfecting agent that is compatible with aluminum, stainless steel, plastics, and silicone according to the manufacturer's instructions.

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

4. Preparation for Cleaning: Dis-assemble instruments as required. For the Zavation F3D-Z Cervical Interbody System, the only instruments requiring disassembly would be the inserter. The inserter is disassembled and reassembled by sliding the stylus through the proximal end of the inserter. (Note that these items are normally stored in the dedicated trays already disassembled).

INDICATIONS FOR USE (Continued)

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

Manual

5.1.1 Manual Pre-Cleaning:

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

Automated

5.1.2 Automated Pre-Cleaning:

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

5.2.1 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 running critical water, such as reverse osmosis, distilled, and/or deionized 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 alcohol to dry any lumens or crevices where water may become trapped.

5.2.2 Washer Disinfector 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:
  - Thermal Disinfection A0 93°C
  - A0 value: A03000
  - Dry 123°C air 14 minutes

Inspection:

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

INDICATIONS FOR USE (Continued)

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

Sterilization: See sterilization procedure.

Storage: Control environment.

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

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

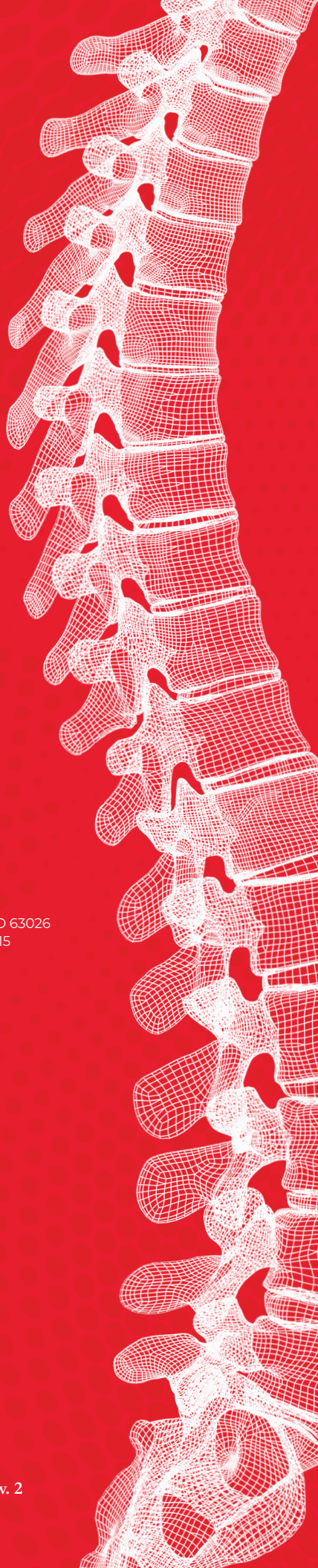
Sterilization: The Zavation F3D-Z Cervical Interbody System instruments should be sterilized by the hospital using the recommended cycle:
Do not stack trays in the chamber.

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

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

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



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