PRECISION SPINE

VAULT®

ALIF SYSTEM

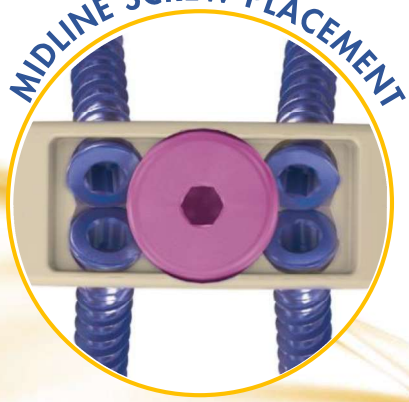
SUPERIOR ENGINEERING DESIGN

Vault® is a zero profile, ALIF system offering midline screw placement to enable easier access, reduced retraction of the neural elements and precise screw placement.

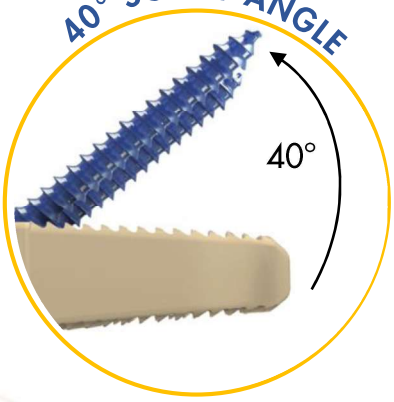
The modular plate and cage construct offers two footprints with 8° and 15° lordotic angles to assist in reproducing the patient's sagittal profile while providing anterior column support.

The system features four points of divergent, lag screw fixation to allow for compression of the interbody along with a large bone graft window to promote fusion.

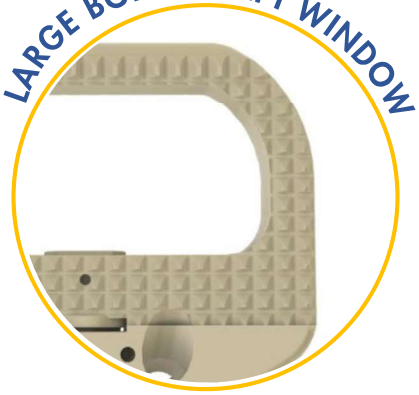
MIDLINE SCREW PLACEMENT



40° SCREW ANGLE



LARGE BONE GRAFT WINDOW

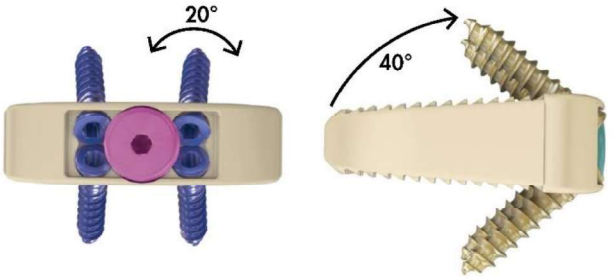


PRECISION SPINE®

Discover the Difference

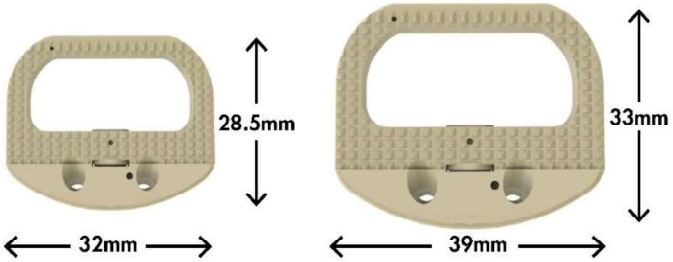
Made in the USA

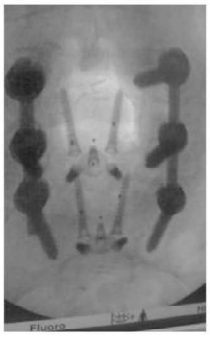
VAULT® ALIF SYSTEM



Midline Screw Placement with ±10° angulation, aids optimal access and solid fixation.
Single Step Locking Cap reduces the risk of screw back-out.
40° Screw Angle resists expulsion forces.

Install Guide Block facilitates easier vertebral body access for simple, precise screw placement.





Large Bone Graft Window features a significant crosssectional area for placement of bone graft material.

Vault System with adjunctive **SureLOK™ Pedicle Screw System.**

8° and 15° Lordotic Options address anatomical requirements.

Vault Implant Sizing

Plate and Cage	Heights	Lordotic Angles	Screw Sizes
32 x 28.5mm	11mm	8°	25mm
39 x 33mm	13mm	15°	30mm
	15mm		35mm
	17mm		
	19mm		

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VAULT®

ALIF SYSTEM

Surgical Technique

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VAULT® ALIF SYSTEM OVERVIEW

The Vault ALIF (Anterior Lumbar Interbody Fusion) System is an innovative PEEK interbody fusion implant. The Vault System comes in various sizes to fit individual disc spaces along with incorporating titanium screws to provide stability while maintaining a zero profile implant.

Product Highlights:

- Unique combination of ALIF PEEK Cage and PEEK Plate design
- Large bone graft window allowing for extensive bone growth
- Radiolucent with tantalum markers for positioning
- Four divergent screws provides strong stable fixation
- Midline screw access
- Locking screw prevents bone screw back out
- Implant provided in various widths and heights with parallel and lordotic angles

The Vault System's design qualities represent modern architecture along with cutting edge technology and versatility for anterior lumbar interbody procedures. The Vault Cage design allows significant open cross sectional area for placement of bone graft material. The Vault Plate design allows for excellent visualization and has a favorable modulus of elasticity.

Indications:

The Vault System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device is designed for use with bone graft material to facilitate fusion. One device is used per intervertebral space.

The Vault System is 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 1 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 to be used with bone graft material. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.

The Vault System is intended to be used with the bone screws provided and requires no additional supplementary fixations.

Please refer to package insert (LBL-IFU-007) for complete system description, indications and warnings.

Implant Features

Vault® Bone Screw

- Titanium
- Self-Drilling
- 4mm Major Diameter
- 2.7mm Minor Diameter
- Hex head screw
- Available in lengths 25mm, 30mm, and 35mm
- Part Numbers: 10-4025, 4030, 4035

Vault PEEK Cage

- Intervertebral body fusion device
- Available in widths 32mm and 39mm
- Available in heights 11mm, 13mm, 15mm, 17mm, and 19mm
- Available with lordotic angles 8° and 15°
- Part Numbers: 10-C3208, 3215, 3908, 3915

Vault Plate

- Recessed plate implant
- Available in widths 32mm and 39mm
- Available in heights 11mm, 13mm, 15mm, 17mm, and 19mm
- Available with lordotic angles 8° and 15°
- Part Numbers: 10-P3208, 3215, 3908, 3915

Vault Locking Cap

- Implanted to prevent disengagement/back out of Bone Screws
- Available in heights 11mm, 13mm, 15mm, 17mm and 19mm
- Color coded with the implant insertion blocks and matching the Vault Plate height description
- Part Number: 10-1002

Vault Set Screw

- Attaches Vault Plate to the Vault PEEK Cage
- Part Number: 10-1001

Instrument Features

Universal Screwdriver

- 2.5 Tapered hex head to secure Bone Screw for insertion
- Universal joint allows for driver use at multiple angles
- Part Number: 10-1003

Cage Tool

- For use with the Vault® Cage
- Connects to the Vault Cage
- Part Number: 10-1017

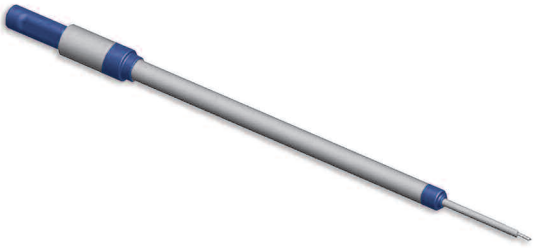
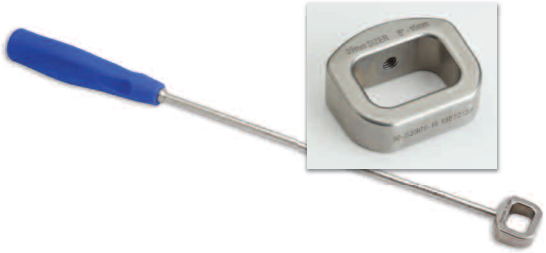


Plate Inserter

- Used to place the Vault Plate in intervertebral space
- Connects Install Guide Block to the Vault Plate
- Part Number: 10-1004

Sizer and Sizer Inserter

- Used to determine proper implant size
- Available in heights 11mm, 13mm, 15mm, 17mm and 19mm
- Available with lordotic angles 8° and 15°
- Available in widths 32mm and 39mm
- Part Number: 10-1006



Fixed Awl

- Bone Awl with a fixed 30° angle tip
- Part Number: 10-1007

Universal Awl

- Bone Awl attached to a universal joint allows for multiple angles of insertion
- Part Number: 10-1008

Install Guide Block

- Attaches to the Vault® Plate to act as guide for the Awl and Bone Screws
- Designed to absorb and distribute force during implant insertion
- Available in heights 11mm, 13mm, 15mm, 17mm and 19mm
- Color coded with the Vault Locking Screw
- Part Number: 10-IB30

11mm 13mm 15mm 17mm 19mm

Ratcheting Straight Handle

- Used with Universal and Fixed Awl
- Part Number: PSSRS

Torque Driver

- Consists of 10-1014 Straight Driver, with 10-1013 Torque Driver Handle
- Preset for a maximum of 10 in-lb
- Used to insert the Vault Locking Screw and Set Screw.

Slap Hammer (not shown)

- Used to apply force as necessary to assist implant insertion
- Part Number: 10-1019

Vault ALIF T8 Tapered Screwdriver (not shown)

- Used to tighten or remove Set Screw (Part Number 10-1001)
- Part Number: 10-1021
- To be used with Torque Driver Handle 10-1013

1. Patient Positioning:

The patient is positioned supine with appropriate padding to protect pressure points and peripheral nerves. A bolster or lift may be placed beneath the mid-lumbar spine to increase lordosis, if desired. Fluoroscopy may be utilized to identify anatomical landmarks for precise placement of the abdominal incision. Careful dissection should be undertaken to protect major vessels during the approach with adequate mobility achieved for safe retraction to properly expose the operative intervertebral spaces. The discectomy is then performed to remove the operative disc. The disc space is prepared for implant insertion.

2. Sizing:

The implant sizers are used to determine the correct implant size. The sizers are inserted into the intervertebral space using the Sizer Inserter (10-1006) (Figure 1).

Note: Do not implant sizers as they are only used to determine the correct implant size.

Figure 1: Sizer tool is inserted into the disc space to determine the implant size required.

3. Implant design and construct review:

A. Once the correct size is determined by utilizing the implant sizers, the Vault® system implants are chosen using the corresponding implant sizes. The Vault Cage and Plate height, width and lordotic angle should all match. (see below)

a. Heights available -
11mm, 13mm, 15mm, 17mm, 19mm

b. Widths available - 32mm, 39mm

c. Lordotic angles available - 8°, 15°

B. Fill the center opening of the Vault® PEEK Cage with the desired amount of bone graft.

Vault ALIF System					
Size	Part No.	Lordotic Angle (deg)	Height (mm)	Bone Growth Opening	
				Area (cm^2)	Volume (cm^3)
32mm	10-C3208-11	8	11	2.4	2.1
	10-C3208-13		13		2.6
	10-C3208-15		15		3.1
	10-C3208-17		17		3.6
	10-C3208-19		19		4.1
	10-C3215-11	15	11		1.7
	10-C3215-13		13		2.2
	10-C3215-15		15		2.7
	10-C3215-17		17		3.1
	10-C3215-19		19		3.6
39mm	10-C3908-11	8	11	4.3	3.6
	10-C3908-13		13		4.5
	10-C3908-15		15		5.3
	10-C3908-17		17		6.2
	10-C3908-19		19		7.1
	10-C3915-11	15	11		2.7
	10-C3915-13		13		3.5
	10-C3915-15		15		4.4
	10-C3915-17		17		5.2
	10-C3915-19		19		6.1

C. The Vault PEEK Cage and Vault Plate are inserted under fluoroscopy. The tantalum markers will assist in determining positioning of the cage. (Figure 2)

D. The Vault Plate is connected to the Vault PEEK Cage using the Vault Set Screw (10-1001). (Figure 3a & 3b)

NOTE: Not intended to be disassembled

E. The Install Guide Block (10-IB30) is attached to the Plate Inserter (10-1004) (Figure 4). Once attached, the Inserter and the Install Guide Block mate with the anterior surface of the Vault Plate (Figure 5).

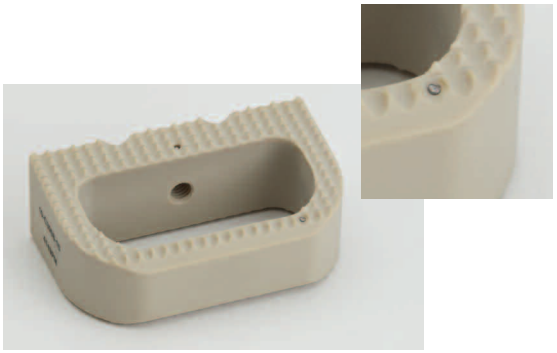


Figure 2: Tantalum markers assist in positioning implant

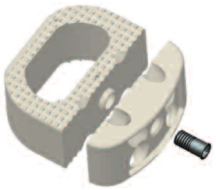


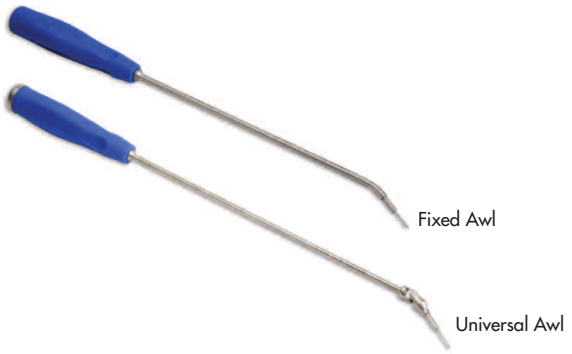
Figure 3a: Exploded view: Vault PEEK Cage, Vault Plate, Set Screw

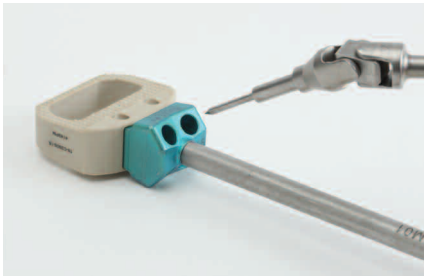
Figure 3b: The Vault Plate is placed on the anterior face of the Vault PEEK Cage and secured in place with the Vault Set Screw using Torque Driver Handle and Vault ALIF T8 Tapered Screwdriver

Figure 4: The Install Guide Block attaches to the end of the Inserter Tool and acts as a guide for the Awl and Bone Screws.

Figure 5: The Install Guide Block and Inserter are locked onto the Vault ALIF System

F. Place the Vault® PEEK Cage and Vault Plate in the desired position. Use the Slap Hammer (10-1019) to assist with insertion if necessary. Use the Fixed Awl (10-1007) or the Universal Awl (10-1008) to create screw holes for the Bone Screws (Figure 6). A constant depth is ensured by the Awl bottoming out against the Install Guide Block (10-IB30). Fluoroscopy is used to locate the four embedded tantalum markers on the implant to verify proper implant positioning in the intervertebral space.





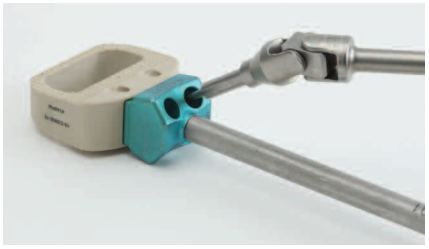
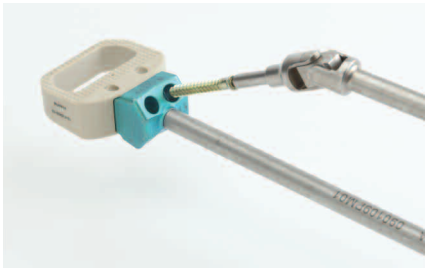


Figure 6: The Universal Awl or Fixed Awl is inserted into the guide holes until it bottoms out against the Install Block to create holes for the Bone Screw.

4. Bone Screw Insertion:

Upon correct positioning, Bone Screws (10-4025, 4030 or 4035) are inserted using the Universal Screwdriver (10-1003). The Universal Screwdriver uses a 2.5mm tapered hex to hold the Bone Screw to the driver during insertion. The Bone Screws are driven into the vertebrae until the Universal Driver bottoms out against the Install Block (Figure 7).



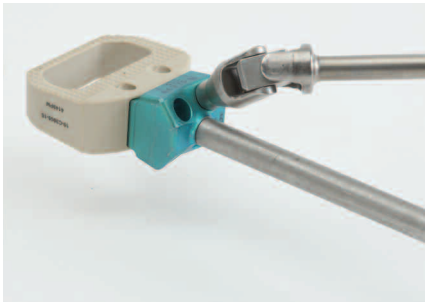


Figure 7: The Bone Screws are inserted into the guide holes of the Install Guide Block and are inserted until the Universal Driver contacts the Install Guide Block.

5. Locking Screw:

Upon insertion of the Bone Screws, the Install Guide Block (10-IB30) is removed. To prevent post-operative-backout of the Bone Screws, the Vault® Locking Cap (10-1002) is placed on the anterior surface of the Vault Plate using a Straight 2.5mm tapered Hex Driver (10-1014). The Torque Driver (10-1014 with 10-1013) is pre-set to tighten the screw until maximum torque is reached, and will break away after torque exceeds maximum setting. The Locking Cap's head will cover the path of the Bone Screws to prevent movement (Figure 8).

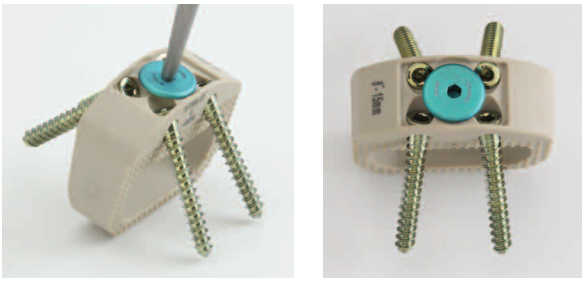


Figure 8: The Locking Cap is applied using a Straight 2.5mm Tapered Hex Driver (10-1014) with Torque Driver Handle (10-1013). The Locking Cap is inserted until it contacts the Vault Plate and is tightened to the preset torque with the torque driver handle.

6. Adjunctive Posterior Stabilization:

When indicated, adjunctive posterior stabilization may be achieved utilizing the Reform® or SureLOK™ Pedicle Screw System from Precision Spine (Figures 9 & 10).

SureLOK technology offers: a low profile anatomical design while providing the surgical advantages of square threaded, self tapping screws, friction fit head, enhanced locking and intuitive, logical instrumentation. For more information on the SureLOK System, visit www.precisionspineinc.com.

Figure 9: Reform Pedicle Screw

Figure 10: SureLOK Pedicle Screw

7. Implant Removal/Revision

Should it become necessary to remove the Vault® System, the following guidelines should be observed:

A. Soft tissue on the anterior portion of the implant should be removed for sufficient screw visualization.

B. The Locking Cap (10-1002) is removed by turning counter clockwise with the Straight 2.5mm Hex Driver (10-1014) allowing access to the Bone Screws (Figure 10).

C. The Universal Screwdriver (10-1003) with 2.5mm tapered hex is utilized turning counter clockwise to remove Bone Screws (Figure 11).

D. The Vault Stabilizer Set Screw (10-1001) and Plate can be removed once all Bone Screws have been removed from the device. The Vault ALIF T8 Tapered Screwdriver is turned counter clockwise to remove the Set Screw (Figure 12).

E. The Cage Tool (10-1017) can now be used to remove the implant from the vertebral space.

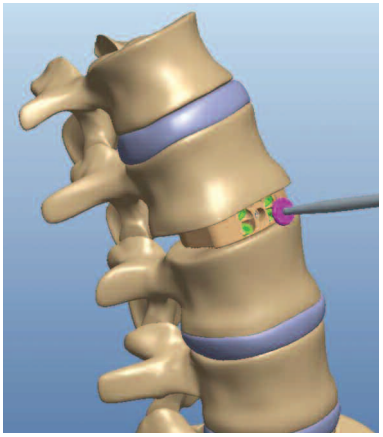


Figure 10: Remove Locking Screw

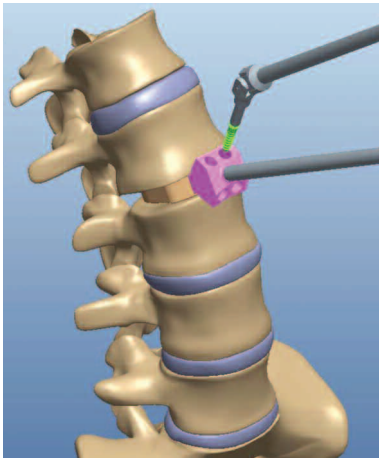


Figure 11: Remove Bone Screws

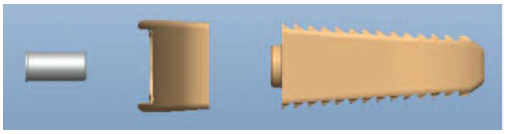


Figure 12: Remove Set Screw and Plate

INDICATIONS

Contraindications:

The Vault® ALIF System contraindications include, but not limited to:

1. Prior fusion at the level(s) to be reated
2. Any condition not described in the indications for use
3. Previous vascular approach
4. Iliofemoral arteriosclerosis
5. Morbid obesity
6. Mental illness
7. Pregnancy
8. Local infection or inflammation
9. Any case needing to mix metals from different components
10. Any patient unwilling to cooperate with postoerative instructions
11. All cases not stated in the indications
12. Reuse, or multiple use

Potetntial Adverse Effects:

The following potential adverse effects associated with the procedure have been shown to occur with the use of similar spinal systems. All cerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects. The following are potential adverse effects, but not limited to:

1. Loss of proper spinal curvature, correction, height, and/or reduction
2. Infection
3. Non-Union or delayed union
4. Foreign body reaction to the implants
5. Hemorrhaging
6. Loss of neurological function, dural tear, pain, and/or discomfort
7. Bone graft fracture, vertebral body fracture or discontinued growth of fused at, above and/or below the surgery level
8. Bending, loosening, fracture, disassembly, slippage and/or migration of the components
9. Pain or discomfort
10. Change in mental status
11. Bursitis. Bone loss and/or bone fracture due to stress shielding
12. Inability to resume activities of normal daily activities
13. Revision surgery
14. Death

Warnings:

The following are warnings for this device.

1. Patients with previous spinal surgery at the level(s) to be treated may have differentclinical outcomes compared to those without previous surgery.
2. Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, necrosis of the bone, neurological injury, and/or vascular or visceral injury.
3. The benefit of spinal fusions utilizing any interbody fusion device has not beenadequately established in patients with stable spines.
4. Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Patients who smoke or abuse alcohol are poor candidates for spinal fusion.
5. Patients who smoke should be advised of the consequences of the fact that anincreased incidence of non-union has been reported with patients who smoke.
6. The implants and instruments are provided non-sterile and must be cleaned andsterilized before use. Device components should be sterilized using one of the noted validated sterilization cycle parameters.
7. A successful result is not always achieved in every surgical case due to manyextenuating circumstances. This is especially true in spinal surgeries where other patient conditions may compromise the results.
8. Single use only. Do not reuse implants. Discard used, damaged, or otherwise suspect implants. **AN IMPLANT SHOULD NEVER BE REUSED.** Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. Reuse can potentially compromise device performance and patient safety.
9. This device is not intended to be the sole means of spinal support. The Vault™ALIF System must be used with additional anterior and/or posterior instrumentation to augment stability.
10. Only surgeons trained and experienced in spinal decompression and bone grafting techniques should use the Vault ALIF System. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are essential considerations in the utilization of this device.
11. Physician note: Although the physician is the learned intermediary, the important medical information given in this document should be conveyed to the patient.

VAULT® SYSTEM IMPLANTS/INSTRUMENTS

Implants

Item No.	Description
10-1001	Vault Set Screw
10-1002-11	Vault Locking Cap 11mm
10-1002-13	Vault Locking Cap 13mm
10-1002-15	Vault Locking Cap 15mm
10-1002-17	Vault Locking Cap 17mm
10-1002-19	Vault Locking Cap 19mm
10-4025	Vault ALIF Self Drilling Variable Screw 40mm X 25mm
10-4030	Vault ALIF Self Drilling Variable Screw 40mm X 30mm
10-4035	Vault ALIF Self Drilling Variable Screw 40mm X 35mm
10-C3208-11	Vault ALIF Peek Cage 32mm X 11mm 8° Lordosis
10-C3208-13	Vault ALIF Peek Cage 32mm X 13mm 8° Lordosis
10-C3208-15	Vault ALIF Peek Cage 32mm X 15mm 8° Lordosis
10-C3208-17	Vault ALIF Peek Cage 32mm X 17mm 8° Lordosis
10-C3208-19	Vault ALIF Peek Cage 32mm X 19mm 8° Lordosis
10-C3215-11	Vault ALIF Peek Cage 32mm X 11mm 15° Lordosis
10-C3215-13	Vault ALIF Peek Cage 32mm X 13mm 15° Lordosis
10-C3215-15	Vault ALIF Peek Cage 32mm X 15mm 15° Lordosis
10-C3215-17	Vault ALIF Peek Cage 32mm X 17mm 15° Lordosis
10-C3215-19	Vault ALIF Peek Cage 32mm X 19mm 15° Lordosis
10-C3908-11	Vault ALIF Peek Cage 39mm X 11mm 8° Lordosis
10-C3908-13	Vault ALIF Peek Cage 39mm X 13mm 8° Lordosis
10-C3908-15	Vault ALIF Peek Cage 39mm X 15mm 8° Lordosis
10-C3908-17	Vault ALIF Peek Cage 39mm X 17mm 8° Lordosis
10-C3908-19	Vault ALIF Peek Cage 39mm X 19mm 8° Lordosis
10-C3915-11	Vault ALIF Peek Cage 39mm X 11mm 15° Lordosis
10-C3915-13	Vault ALIF Peek Cage 39mm X 13mm 15° Lordosis
10-C3915-15	Vault ALIF Peek Cage 39mm X 15mm 15° Lordosis
10-C3915-17	Vault ALIF Peek Cage 39mm X 17mm 15° Lordosis
10-C3915-19	Vault ALIF Peek Cage 39mm X 19mm 15° Lordosis
10-P3208-11P	Vault ALIF Plate 32mm X 11mm 8° Lordosis
10-P3208-13P	Vault ALIF Plate 32mm X 13mm 8° Lordosis
10-P3208-15P	Vault ALIF Plate 32mm X 15mm 8° Lordosis
10-P3208-17P	Vault ALIF Plate 32mm X 17mm 8° Lordosis
10-P3208-19P	Vault ALIF Plate 32mm X 19mm 8° Lordosis
10-P3215-11P	Vault ALIF Plate 32mm X 11mm 15° Lordosis
10-P3215-13P	Vault ALIF Plate 32mm X 13mm 15° Lordosis
10-P3215-15P	Vault ALIF Plate 32mm X 15mm 15° Lordosis
10-P3215-17P	Vault ALIF Plate 32mm X 17mm 15° Lordosis
10-P3215-19P	Vault ALIF Plate 32mm X 19mm 15° Lordosis
10-P3908-11P	Vault ALIF Plate 39mm X 11mm 8° Lordosis
10-P3908-13P	Vault ALIF Plate 39mm X 13mm 8° Lordosis
10-P3908-15P	Vault ALIF Plate 39mm X 15mm 8° Lordosis
10-P3908-17P	Vault ALIF Plate 39mm X 17mm 8° Lordosis
10-P3908-19P	Vault ALIF Plate 39mm X 19mm 8° Lordosis
10-P3915-11P	Vault ALIF Plate 39mm X 11mm 15° Lordosis
10-P3915-13P	Vault ALIF Plate 39mm X 13mm 15° Lordosis
10-P3915-15P	Vault ALIF Plate 39mm X 15mm 15° Lordosis
10-P3915-17P	Vault ALIF Plate 39mm X 17mm 15° Lordosis
10-P3915-19P	Vault ALIF Plate 39mm X 19mm 15° Lordosis

Instruments

Item No.	Description
10-1003-2	Vault Universal Driver 2.5mm
10-1004-2	Vault ALIF Plate Inserter
10-1006-2	Vault ALIF Sizer Inserter
10-1007-2	Vault Fixed Awl 30°
10-1008-2	Vault Universal Awl
PSSRS	Ratcheting Straight Handle
10-1013	Torque Driver Handle
10-1014	Screw Driver 2.5mm Hex
10-1017	Cage Tool
10-IB30-11	Vault/Plate Install Block 30 x 11
10-IB30-13	Vault/Plate Install Block 30 x 13
10-IB30-15	Vault/Plate Install Block 30 x 15
10-IB30-17	Vault/Plate Install Block 30 x 17
10-IB30-19	Vault/Plate Install Block 30 x 19
10-S3208-11	Vault Cage Sizer 8° 32mm x 11mm
10-S3208-13	Vault Cage Sizer 8° 32mm x 13mm
10-S3208-15	Vault Cage Sizer 8° 32mm x 15mm
10-S3208-17	Vault Cage Sizer 8° 32mm x 17mm
10-S3208-19	Vault Cage Sizer 8° 32mm x 19mm
10-S3215-11	Vault Cage Sizer 15° 32mm x 11mm
10-S3215-13	Vault Cage Sizer 15° 32mm x 13mm
10-S3215-15	Vault Cage Sizer 15° 32mm x 15mm
10-S3215-17	Vault Cage Sizer 15° 32mm x 17mm
10-S3215-19	Vault Cage Sizer 15° 32mm x 19mm
10-S3908-11	Vault Cage Sizer 8° 39mm x 11mm
10-S3908-13	Vault Cage Sizer 8° 39mm x 13mm
10-S3908-15	Vault Cage Sizer 8° 39mm x 15mm
10-S3908-17	Vault Cage Sizer 8° 39mm x 17mm
10-S3908-19	Vault Cage Sizer 8° 39mm x 19mm
10-S3915-11	Vault Cage Sizer 15° 39mm x 11mm
10-S3915-13	Vault Cage Sizer 15° 39mm x 13mm
10-S3915-15	Vault Cage Sizer 15° 39mm x 15mm
10-S3915-17	Vault Cage Sizer 15° 39mm x 17mm
10-S3915-19	Vault Cage Sizer 15° 39mm x 19mm
10-1019	Slap Hammer
10-1021	Vault ALIF T8 Tapered Screwdriver

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

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