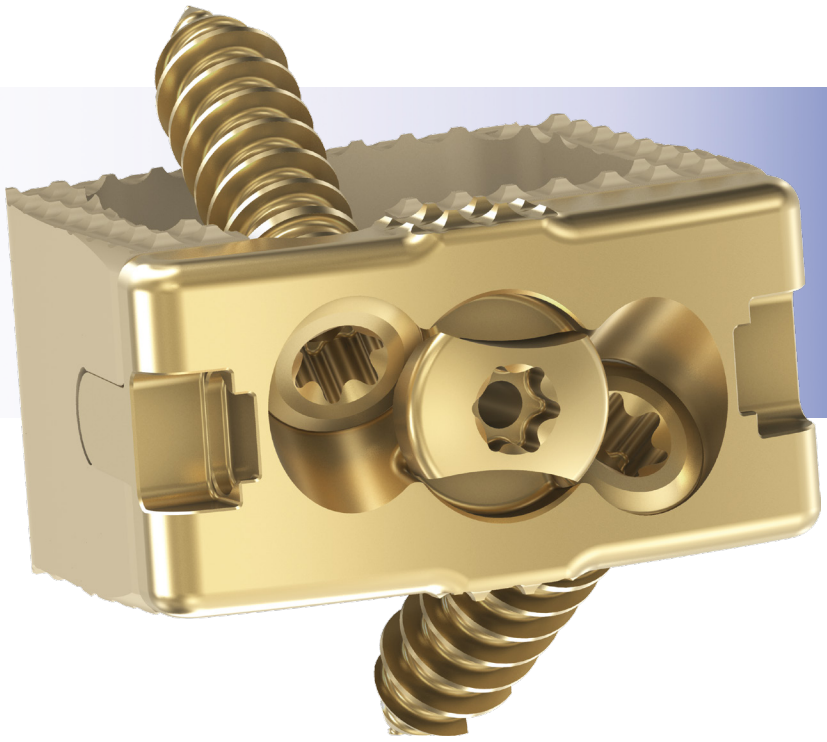
PRECISION SPINE™



PRECISION SPINE

VAULT™ C

ACDF SYSTEM

Surgical Technique

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Vault™ C ACDF System Overview

The Vault™ C Anterior Cervical Discectomy Fusion (ACDF) System implants are available in various heights and geometric footprints to accommodate individual patient anatomy and graft material size. Vault C interbody devices are provided as a modular plate and cage that are inserted through an anterior cervical approach and packed with autogenous bone graft to facilitate fusion. Serrations on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebral bodies to aid in expulsion resistance, while screws are inserted through the anterior titanium portion of the implant for bone fixation. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved.

The Vault C posterior cage component is manufactured from medical grade polyetheretherketone (PEEK-OPTIMA®, LT1) and assembled with marker rods manufactured from Tantalum per ASTM F560. The anterior plate components and fixation bone screws are manufactured from titanium alloy per ASTM F136. The products are supplied clean and "NON-STERILE".

Indications

The Vault C Anterior Cervical Discectomy Fusion (ACDF) System is a standalone cervical interbody device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The Vault C implants are used with two titanium alloy screws and filled with autogenous bone graft material to facilitate fusion in the cervical spine. The device is placed via an anterior approach at the C3 to T1 disc levels. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device.

Please refer to Vault C Anterior Cervical Discectomy Fusion (ACDF) System Instructions For Use (IFU) (LBL-IFU-015) for complete system description, indications and warnings.

Implant Features

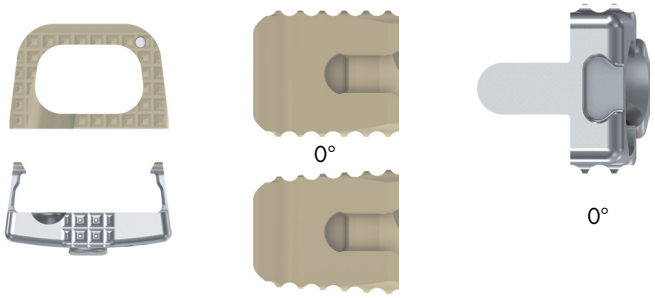
Modular Plate and Cage

- Tactile and audible assembly

14mm 16mm 18mm

Three Geometric Footprints, Anodized per Width

- 14x12mm; Natural
- 16x14mm; Dark Blue
- 18x15mm; Gold



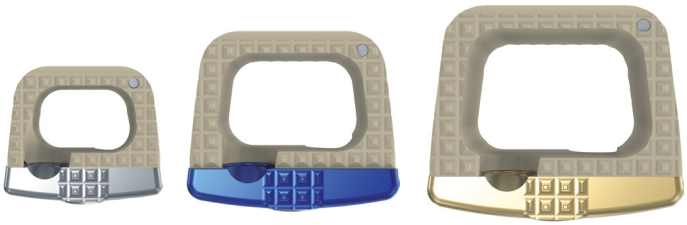
0° 0° 7°

2x Lateral Posterior Markers

- Indicate posterior height, width, depth

Two Saggital Profiles

- 0° Lordosis
- 7° Lordosis



14x12mm 16x14mm 18x15mm
Available by request

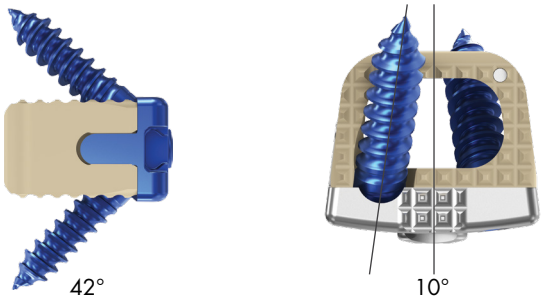
Heights

- 6mm-12mm; 1mm Increments

Screw Trajectory

35° Cephalad/Caudal x 10° Medial

- 42° Maximum angle



42° 10°

Implant Features

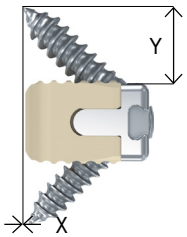
Self-drilling, Self-tapping Bone Screws

- Standard, Ø3.5mm
- Rescue, Ø4.0mm
- Anodized per 12, 14, 15, 17mm lengths
- Align with posterior aspect of common implant depth

Blunt-tip, Self-tapping Bone Screws

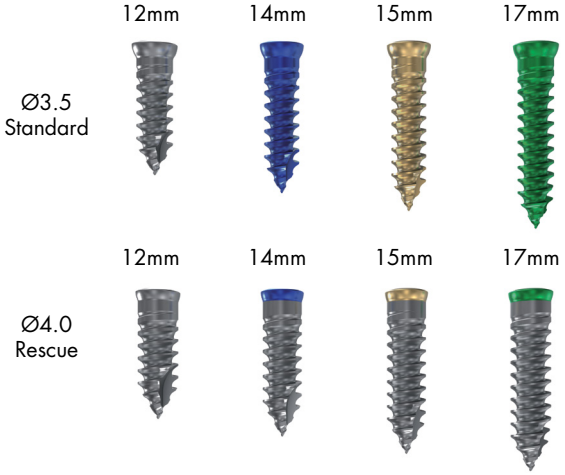
- Standard, Ø3.5mm
- Rescue, Ø4.0mm
- Anodized per 12, 14, 15, 17mm lengths
- Align with posterior aspect of common implant depth

	14x12mm		16x14mm		18x15mm	
Screw Length	**X**	**Y**	**X**	**Y**	**X**	**Y**
12mm	Flush	4.3	-1.6	4.3	-3.2	4.3
14mm	1.4	5.3	Flush	5.3	-1.6	5.3
15mm	2.9	6.4	1.4	6.4	Flush	6.4
17mm	4.4	7.4	2.9	7.4	1.4	7.4



Self-drilling, Self-tapping

Blunt-tip, Self-tapping



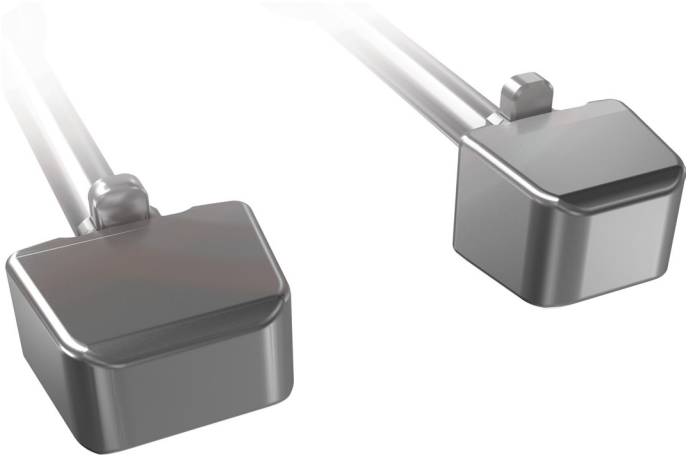
Implant Height	Color
6mm	Natural
7mm	Dark Blue
8mm	Gold
9mm	Green
10mm	Dark Purple
11mm	Seafoam
12mm	Magenta

Implant Depth	Screw Length	Color
12mm	12mm	Natural
14mm	14mm	Dark Blue
15mm	15mm	Gold
N/A	17mm	Green

Instruments

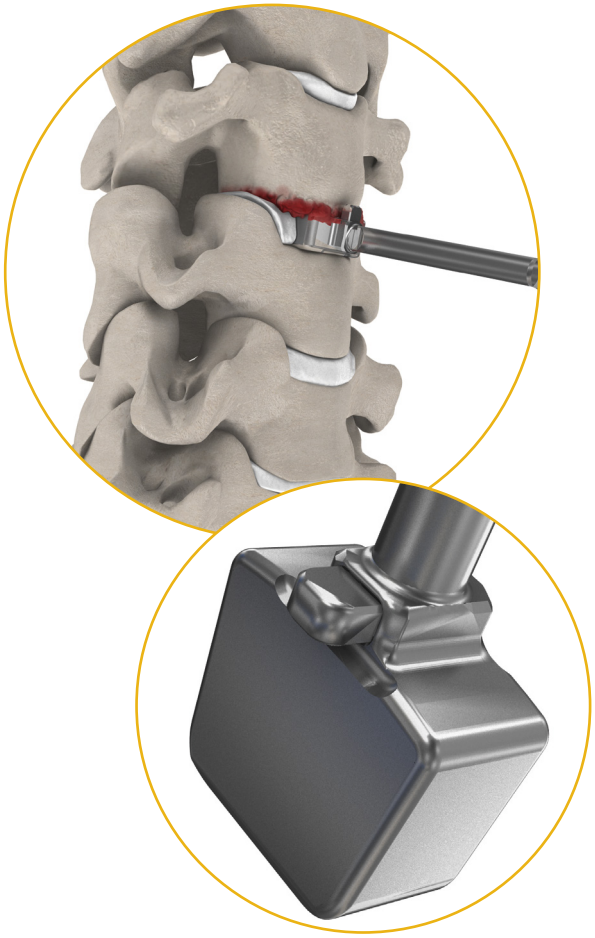
Trials 0° Lordosis

- 14x12 - 5/6mm - 37-TN-0406
- 14x12 - 7/8mm - 37-TN-0408
- 14x12 - 9/10mm - 37-TN-0410
- 14x12 - 11/12mm - 37-TN-0412
- 16x14 - 5/6mm - 37-TN-0606
- 16x14 - 7/8mm - 37-TN-0608
- 16x14 - 9/10mm - 37-TN-0610
- 16x14 - 11/12mm - 37-TN-0612
- **18x15 - 5/6mm - 37-TN-0806***
- **18x15 - 7/8mm - 37-TN-0808***
- **18x15 - 9/10mm - 37-TN-0810***
- **18x15 - 11/12mm - 37-TN-0812***



Trials 7° Lordosis

- 14x12 - 5/6mm - 37-TN-7406
- 14x12 - 7/8mm - 37-TN-7408
- 14x12 - 9/10mm - 37-TN-7410
- 14x12 - 11/12mm - 37-TN-7412
- 16x14 - 5/6mm - 37-TN-7606
- 16x14 - 7/8mm - 37-TN-7608
- 16x14 - 9/10mm - 37-TN-7610
- 16x14 - 11/12mm - 37-TN-7612
- **18x15 - 5/6mm - 37-TN-7806***
- **18x15 - 7/8mm - 37-TN-7808***
- **18x15 - 9/10mm - 37-TN-7810***
- **18x15 - 11/12mm - 37-TN-7812***



- Line-to-line anterior depth stop
- Match implant geometry
- Double sided, color coded per height

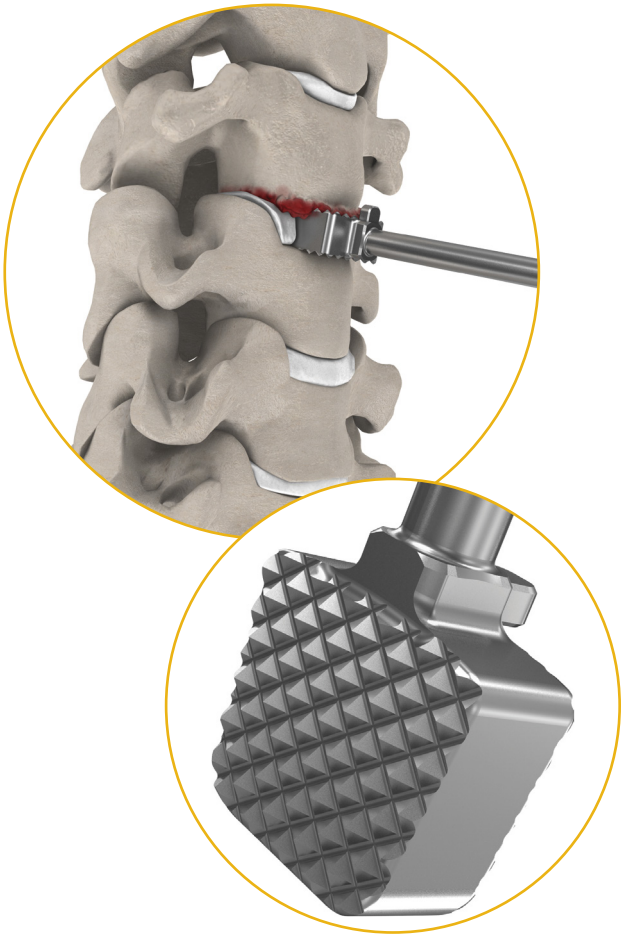
*** Special Order**

Rasp 0° Lordosis

- 14x12 - 5/6mm - 37-RS-0406
- 14x12 - 7/8mm - 37-RS-0408
- 14x12 - 9/10mm - 37-RS-0410
- 14x12 - 11/12mm - 37-RS-0412
- 16x14 - 5/6mm - 37-RS-0606
- 16x14 - 7/8mm - 37-RS-0608
- 16x14 - 9/10mm - 37-RS-0610
- 16x14 - 11/12mm - 37-RS-0612
- **18x15 - 5/6mm - 37-RS-0806***
- **18x15 - 7/8mm - 37-RS-0808***
- **18x15 - 9/10mm - 37-RS-0810***
- **18x15 - 11/12mm - 37-RS-0812***

Rasp 7° Lordosis

- 14x12 - 5/6mm - 37-RS-7406
- 14x12 - 7/8mm - 37-RS-7408
- 14x12 - 9/10mm - 37-RS-7410
- 14x12 - 11/12mm - 37-RS-7412
- 16x14 - 5/6mm - 37-RS-7606
- 16x14 - 7/8mm - 37-RS-7608
- 16x14 - 9/10mm - 37-RS-7610
- 16x14 - 11/12mm - 37-RS-7612
- **18x15 - 5/6mm - 37-RS-7806***
- **18x15 - 7/8mm - 37-RS-7808***
- **18x15 - 9/10mm - 37-RS-7810***
- **18x15 - 11/12mm - 37-RS-7812***



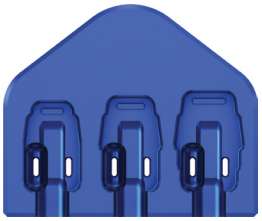
- Line-to-line anterior depth stop
- Match implant geometry
- Double sided, color coded per height

*** Special Order**

Instruments

Implant Assembly Block

- Part Number - 37-IN-0070



Bone Graft Compactor

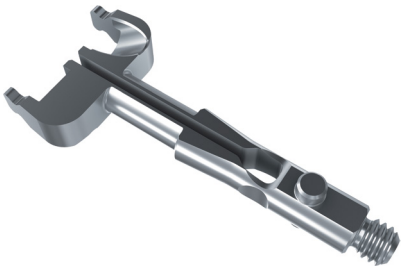
- Part Number - 37-IN-0072

Implant Insertion Handle

- Part Number - 37-IN-0010

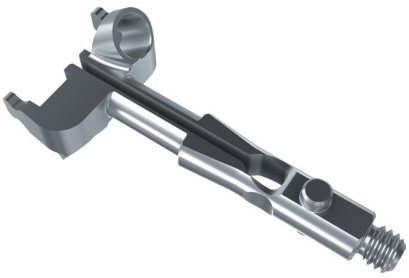
Streamline Insertion Tip

- Partial guidance for 6-8mm sizes
- Part Number - 37-IN-0428



Guided Insertion Tip

- 6mm - Part Number - 37-IN-0406
- 7mm - Part Number - 37-IN-0407
- 8mm - Part Number - 37-IN-0408
- 9mm - Part Number - 37-IN-0409
- 10mm - Part Number - 37-IN-0410
- 11mm - Part Number - 37-IN-0411
- 12mm - Part Number - 37-IN-0412



Implant Insertion Tamp

- Part Number - 37-IN-0050

Self-Retaining Driver

- Part Number - 37-IN-0060

Instruments

Angled Self-Retaining Driver

- Part Number - 37-HP-0400

Straight Awl

- Part Number - 37-HP-0010

Angled Awl

- Part Number - 37-HP-0020

Bone Drill

- 12mm - Part Number - 37-HP-0212
- 14mm - Part Number - 37-HP-0214
- 15mm - Part Number - 37-HP-0215

Angled Bone Drill

12mm - Part Number - 37-HP-0410

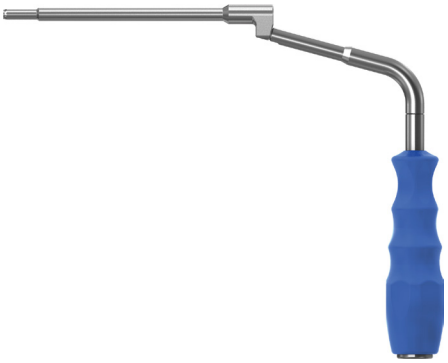
Freehand Drill Guide

- Part Number - 37-HP-0015

Instruments

Drill Guide

- Part Number - 37-HP-0030



Bone Tap

- 12mm - Part Number - 37-HP-0312

Implant Extraction Hook

- Securely retains anterior and posterior implant components during removal
- Part Number - 37-IN-0080

Modular Driver Handle

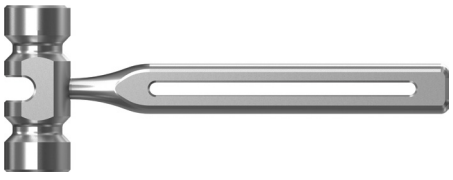
- Part Number - 37-CH-0024

Torque Locking Handle

- Used for definitive locking confirmation
- Part Number - 37-CH-0023

Impaction/Extraction Mallet

- Part Number - 37-IN-0084



1. Preoperative Planning

a. The surgeon should only consider utilizing the Vault™ C Anterior Cervical Discectomy Fusion System with those patients who meet the criteria described in the indications.

b. The surgeon should avoid utilizing this device with those patients who meet the criteria described in the listed contraindications.

c. The surgeon should make sure that all implants and instruments are unpacked, sterilized, and available prior to surgery.

d. The implant and instruments are provided non-sterile and must be cleaned and sterilized prior to use.

e. Implants and instruments should be inspected for surface flaws and scratches and should not be used in the presence thereof. If such instruments will not function optimally, they should be returned to Precision Spine for replacement.

f. The surgeon should have a complete understanding of the surgical technique, design rationale, indications and contraindications.

g. The surgeon should have a complete understanding of the surgical technique guide.

2. Disc Preparation and Implant Sizing

a. After preparation of the disc space is complete, insert a trial (37-TN-XXXX) to determine the preferred implant footprint and height (Figure 1).

b. Use a Rasp (37-RS-XXXX) to further prepare the endplates (Figure 2).

NOTE: 18 x 15mm trials and rasps are special order.

Figure 1

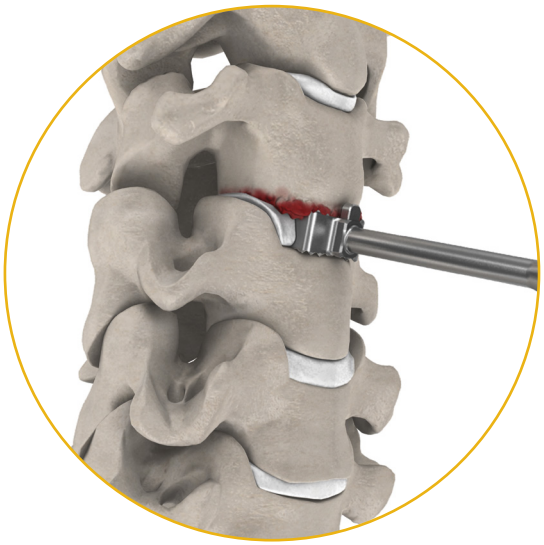
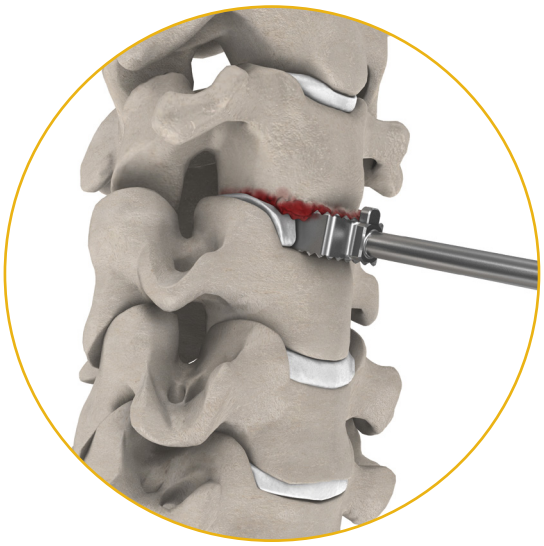


Figure 2

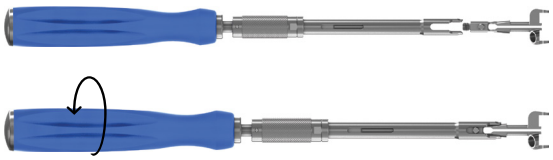


3. Implant Assembly

a. After the preferred implant size is determined, place the sized Posterior Cage within the appropriate footprint of the implant Assembly Block (37-IN-0070). Each side of the assembled block is labeled for the appropriate lordosis.

b. Select the preferred Implant Insertion Tip (37-IN-04XX) and assemble the Implant Inserter Handle (37-IN-0010). (See below), (Figures 3 and 3a).

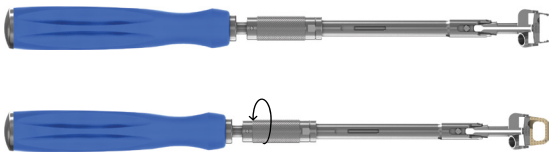
Insertion Handle Assembly:



1. Insert preferred insertion tip as shown
2. Rotate blue silicone handle clockwise to assemble

c. Assemble the appropriate Anterior Plate to the Implant Inserter Assembly and assemble the Anterior Plate and Posterior Cage to create the Implant Construct (Figure 4).

Insertion Handle Assembly w/ Implant:



1. Assemble preferred titanium plate as shown
2. Rotate knurled thumb wheel clockwise to lock

d. Insert bone graft into the Implant Construct and compress utilizing the Bone Graft Compactor, (37-IN-0072) (Figure 5).

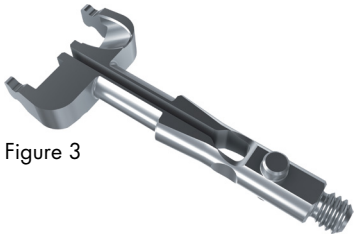


Figure 3

Streamline Insertion Tip

- Partial guidance for 6-8mm sizes
- Part Number - 37-IN-0428

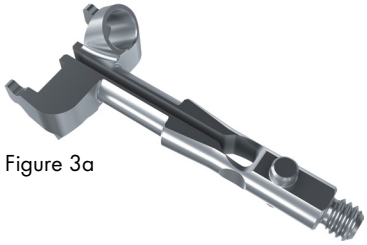
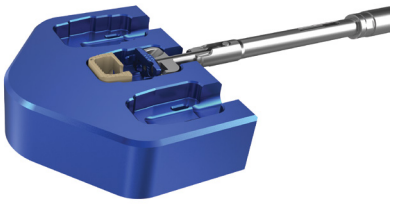


Figure 3a

Guided Insertion Tip

- 6mm - Part Number - 37-IN-0406
- 7mm - Part Number - 37-IN-0407
- 8mm - Part Number - 37-IN-0408
- 9mm - Part Number - 37-IN-0409
- 10mm - Part Number - 37-IN-0410
- 11mm - Part Number - 37-IN-0411
- 12mm - Part Number - 37-IN-0412



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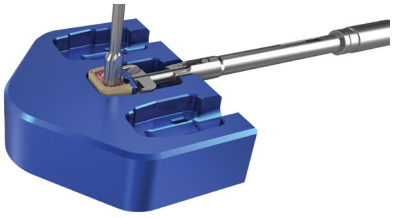


Figu

4. Implant Insertion

Insert the Implant Construct into the disc space.

5. Screw Hole Preparation

Prepare the screw holes using one of the following methods, which may be performed with or without the Implant Insertion Assembly in place.

Straight Preparation

a. **Straight Awl** (37-HP-0010)
Using the implant as a guide, align the Awl assembly within the corresponding hole on the implant and prepare the screw entry hole (Figure 6).

b. **Straight Drill & Drill Guide** (37-HP-021X & 37-HP-0030)
Align the Drill Guide within the corresponding hole on the implant.

Insert the appropriate length drill within the Drill Guide and prepare the hole until the drill depth stop seats on the Drill Guide (Figure 7).

An optional Freehand Drill Guide (37-HP-0015) can be used in place of the Standard Drill Guide to control depth (Figure 8).

c. **Screw Tap** (37-HP-0312)
Align the tap within the corresponding hole and prepare the hole (Figure 9).

Figure 6

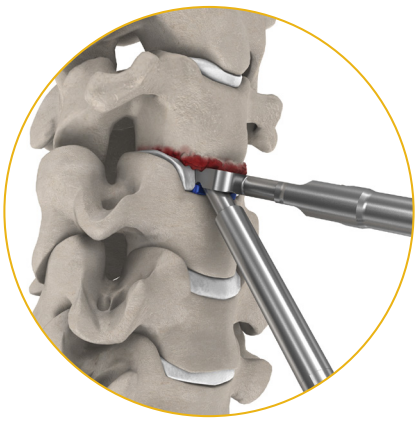


Figure 7

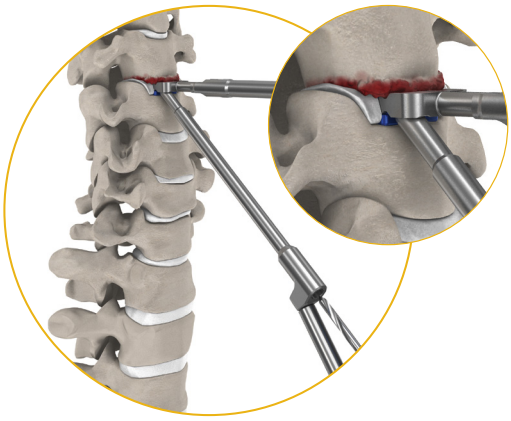


Figure 8

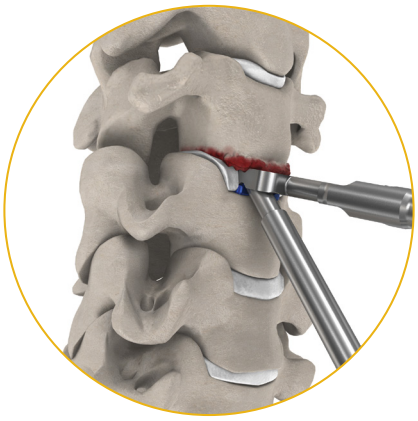
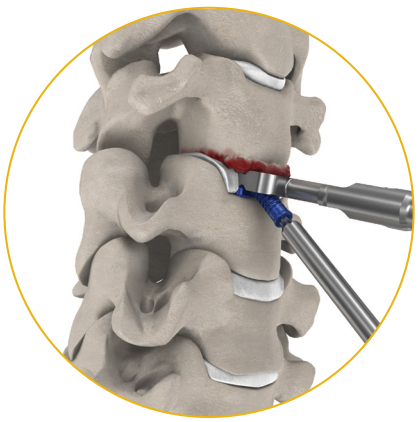


Figure 9



Angled Preparation

a. **Angled Awl**
Using the implant as a guide, align the Awl (37-HP-0020) within the corresponding hole on the implant and prepare the screw entry hole (Figure 10).

b. **Angled Drill**
Align the Angled Drill (37-HP-0410) within the corresponding hole on the implant and prepare the hole until the drill contacts the implant (Figure 11).

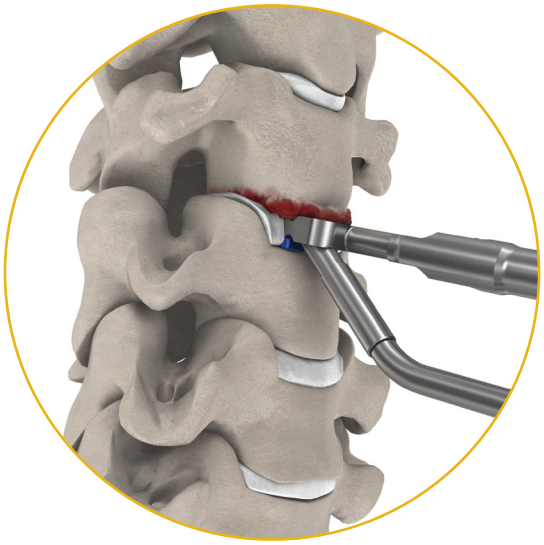


Figure 10

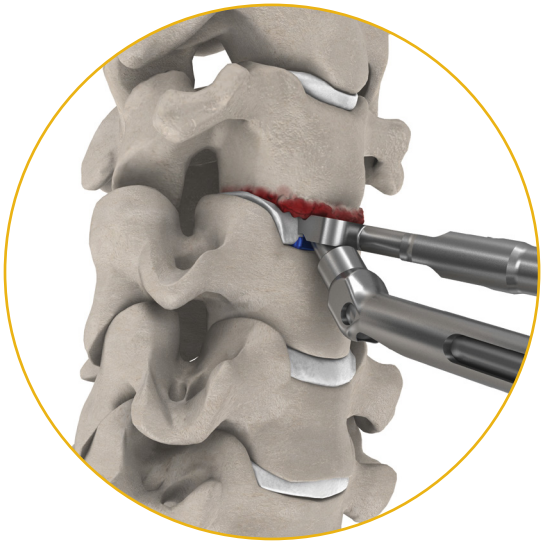


Figure 11

6. Screw Insertion

a. Insert the Screw using either the Straight Self-Retaining Driver (37-IN-0060) (Figure 12) or the Angled Self-Retaining Driver (37-HP-0400) (Figure 13).

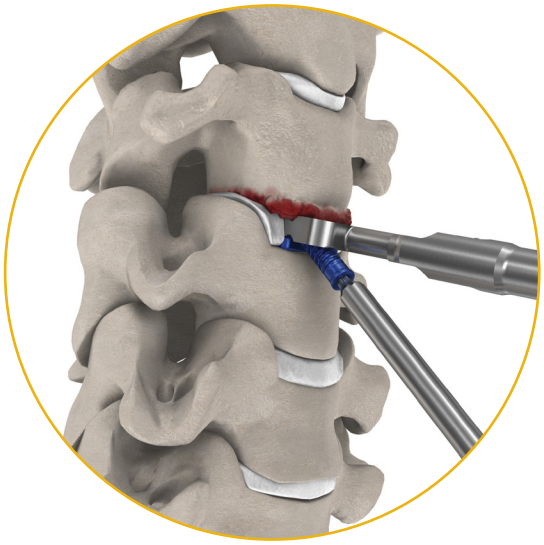


Figure 12

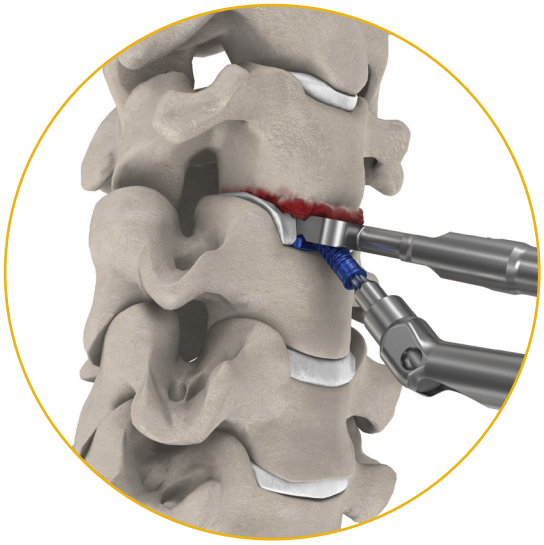


Figure 13

7. Screw Locking

a. Remove the Implant Insertion Assembly from the Implant Construct. A slight cephalad/caudal toggle may be required to release the inserter from the implant.

b. Rotate the Retention Rivet with the Straight Driver (37-IN-0060) to approximately 90° clockwise to lock the Screws into the Implant Assembly (Figure 14).

OPTIONAL: Rotate the Retention Rivet using the Torque Locking Handle (37-CH-0023) attached to the Straight Driver (37-IN-0060) until the torque limit of 2.5 in-lbs is reached, approximately 90° clockwise, to facilitate definitive screw locking (Figure 14).

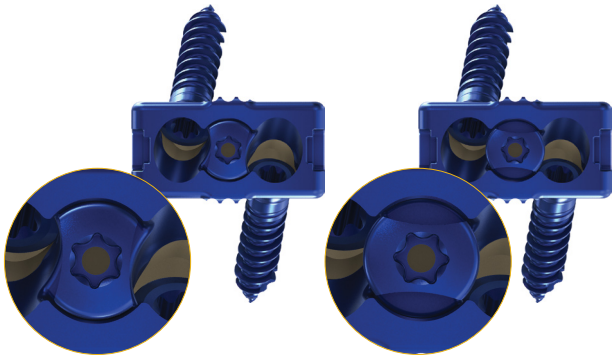


Figure 14

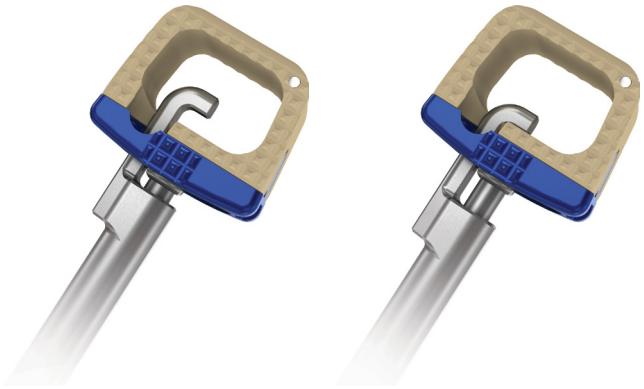
Unlocked Locked

8. System Removal

a. Unlock the Retention Rivet by rotating the Rivet counter-clockwise approximately 90°, until the Screws are no longer retained.

b. After the Screw removal (Figure 15) insert the Implant Extraction Hook (37-IN-0080) and tighten to retain the implant.

c. Remove the Implant Assembly from the disc space, using the Impaction/Extraction Mallet (37-IN-0084) for added control (Figure 16).



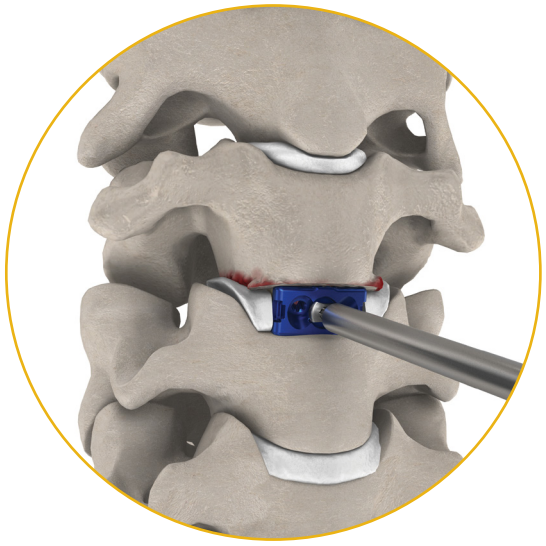


Figure 15

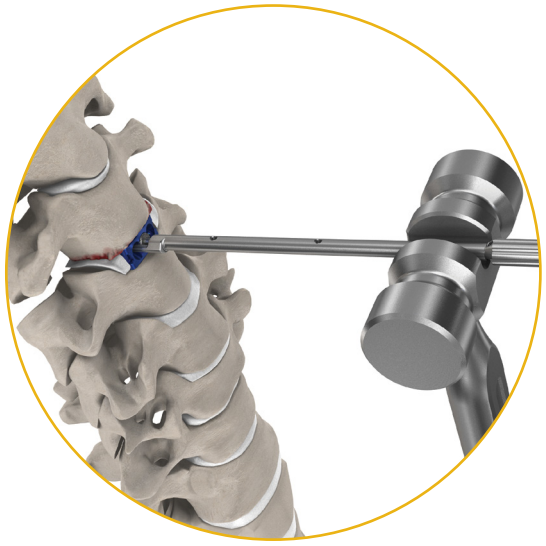


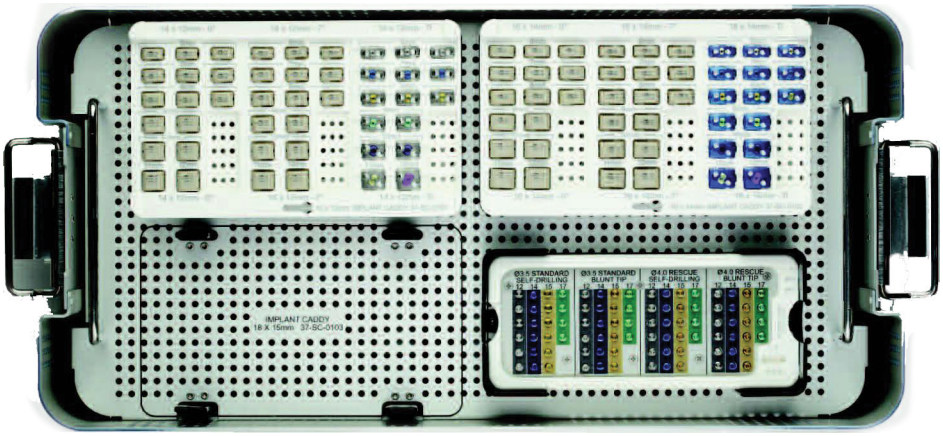
Figure 16

VAULT™ C SYSTEM IMPLANTS

Vault C Anterior Cervical Discectomy Fusion (ACDF) System

Item No.	Description
Anterior Plate	
37-PA-4206	14 x 12 x 06mm Anterior Plate
37-PA-4207	14 x 12 x 07mm Anterior Plate
37-PA-4208	14 x 12 x 08mm Anterior Plate
37-PA-4209	14 x 12 x 09mm Anterior Plate
37-PA-4210	14 x 12 x 10mm Anterior Plate
37-PA-4211	14 x 12 x 11mm Anterior Plate
37-PA-4212	14 x 12 x 12mm Anterior Plate
37-PA-6406	16 x 14 x 06mm Anterior Plate
37-PA-6407	16 x 14 x 07mm Anterior Plate
37-PA-6408	16 x 14 x 08mm Anterior Plate
37-PA-6409	16 x 14 x 09mm Anterior Plate
37-PA-6410	16 x 14 x 10mm Anterior Plate
37-PA-6411	16 x 14 x 11mm Anterior Plate
37-PA-6412	16 x 14 x 12mm Anterior Plate
37-PA-8506	**18 x 15 x 06mm Anterior Plate***
37-PA-8507	**18 x 15 x 07mm Anterior Plate***
37-PA-8508	**18 x 15 x 08mm Anterior Plate***
37-PA-8509	**18 x 15 x 09mm Anterior Plate***
37-PA-8510	**18 x 15 x 10mm Anterior Plate***
37-PA-8511	**18 x 15 x 11mm Anterior Plate***
37-PA-8512	**18 x 15 x 12mm Anterior Plate***

Item No.	Description
Self-Tapping, Self-Drilling Screw	
37-SD-3512	Ø3.5 x 12mm Standard Self-Drilling Screw
37-SD-3514	Ø3.5 x 14mm Standard Self-Drilling Screw
37-SD-3515	Ø3.5 x 15mm Standard Self-Drilling Screw
37-SD-3517	Ø3.5 x 17mm Standard Self-Drilling Screw
37-SD-4012	Ø4.0 x 12mm Rescue Self-Drilling Screw
37-SD-4014	Ø4.0 x 14mm Rescue Self-Drilling Screw
37-SD-4015	Ø4.0 x 15mm Rescue Self Drilling Screw
37-SD-4017	Ø4.0 x 17mm Rescue Self Drilling Screw
Self-Tapping, Blunt Tip Screw	
37-SB-3512	Ø3.5 x 12mm Standard Blunt Tip Screw
37-SB-3514	Ø3.5 x 14mm Standard Blunt Tip Screw
37-SB-3515	Ø3.5 x 15mm Standard Blunt Tip Screw
37-SB-3517	Ø3.5 x 17mm Standard Blunt Tip Screw
37-SB-4012	Ø4.0 x 12mm Rescue Blunt Tip Screw
37-SB-4014	Ø4.0 x 14mm Rescue Blunt Tip Screw
37-SB-4015	Ø4.0 x 15mm Rescue Blunt Tip Screw
37-SB-4017	Ø4.0 x 17mm Rescue Blunt Tip Screw

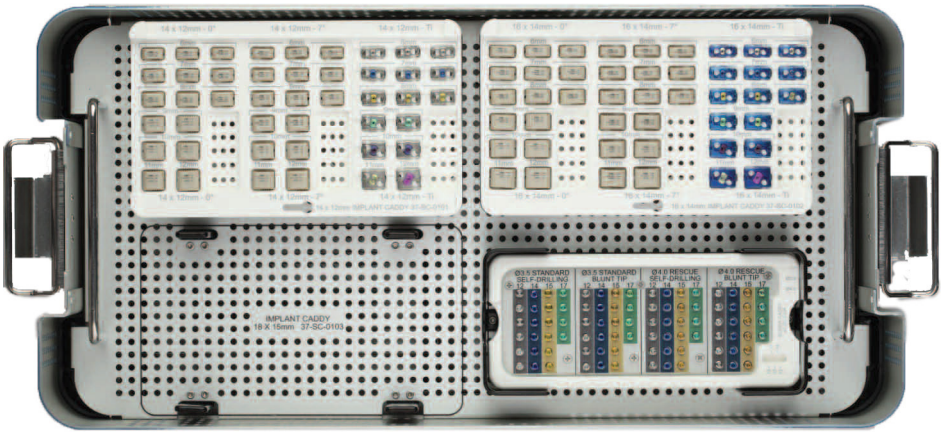


*** Special Order**

VAULT™ C SYSTEM IMPLANTS

Item No.	Description
Posterior Cage	
37-CL-4206	14 x 12 x 06mm 7° Posterior Cage
37-CL-4207	14 x 12 x 07mm 7° Posterior Cage
37-CL-4208	14 x 12 x 08mm 7° Posterior Cage
37-CL-4209	14 x 12 x 09mm 7° Posterior Cage
37-CL-4210	14 x 12 x 10mm 7° Posterior Cage
37-CL-4211	14 x 12 x 11mm 7° Posterior Cage
37-CL-4212	14 x 12 x 12mm 7° Posterior Cage
37-CL-6406	16 x 14 x 06mm 7° Posterior Cage
37-CL-6407	16 x 14 x 07mm 7° Posterior Cage
37-CL-6408	16 x 14 x 08mm 7° Posterior Cage
37-CL-6409	16 x 14 x 09mm 7° Posterior Cage
37-CL-6410	16 x 14 x 10mm 7° Posterior Cage
37-CL-6411	16 x 14 x 11mm 7° Posterior Cage
37-CL-6412	16 x 14 x 12mm 7° Posterior Cage
37-CL-8506	**18 x 15 x 06mm 7° Posterior Cage***
37-CL-8507	**18 x 15 x 07mm 7° Posterior Cage***
37-CL-8508	**18 x 15 x 08mm 7° Posterior Cage***
37-CL-8509	**18 x 15 x 09mm 7° Posterior Cage***
37-CL-8510	**18 x 15 x 10mm 7° Posterior Cage***
37-CL-8511	**18 x 15 x 11mm 7° Posterior Cage***
37-CL-8512	**18 x 15 x 12mm 7° Posterior Cage***

Item No.	Description
37-CP-4206	14 x 12 x 06mm 0° Posterior Cage
37-CP-4207	14 x 12 x 07mm 0° Posterior Cage
37-CP-4208	14 x 12 x 08mm 0° Posterior Cage
37-CP-4209	14 x 12 x 09mm 0° Posterior Cage
37-CP-4210	14 x 12 x 10mm 0° Posterior Cage
37-CP-4211	14 x 12 x 11mm 0° Posterior Cage
37-CP-4212	14 x 12 x 12mm 0° Posterior Cage
37-CP-6406	16 x 14 x 06mm 0° Posterior Cage
37-CP-6407	16 x 14 x 07mm 0° Posterior Cage
37-CP-6408	16 x 14 x 08mm 0° Posterior Cage
37-CP-6409	16 x 14 x 09mm 0° Posterior Cage
37-CP-6410	16 x 14 x 10mm 0° Posterior Cage
37-CP-6411	16 x 14 x 11mm 0° Posterior Cage
37-CP-6412	16 x 14 x 12mm 0° Posterior Cage
37-CP-8506	**18 x 15 x 06mm 0° Posterior Cage***
37-CP-8507	**18 x 15 x 07mm 0° Posterior Cage***
37-CP-8508	**18 x 15 x 08mm 0° Posterior Cage***
37-CP-8509	**18 x 15 x 09mm 0° Posterior Cage***
37-CP-8510	**18 x 15 x 10mm 0° Posterior Cage***
37-CP-8511	**18 x 15 x 11mm 0° Posterior Cage***
37-CP-8512	**18 x 15 x 12mm 0° Posterior Cage***



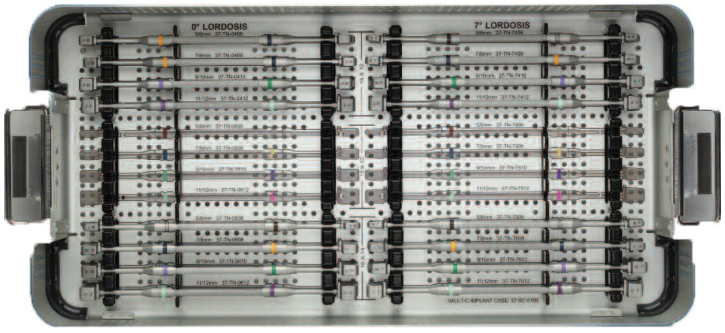
* Special Order

VAULT™ C SYSTEM INSTRUMENTS

Vault *C* Anterior Cervical Discectomy Fusion (ACDF) System

Item No.	Description
Trial	
37-TN-0406	Trial, 0° Lordosis, 14 x 12 – 5/6mm
37-TN-0408	Trial, 0° Lordosis, 14 x 12 – 7/8mm
37-TN-0410	Trial, 0° Lordosis, 14 x 12 – 9/10mm
37-TN-0412	Trial, 0° Lordosis, 14 x 12 – 11/12mm
37-TN-0606	Trial, 0° Lordosis, 16 x 14 – 5/6mm
37-TN-0608	Trial, 0° Lordosis, 16 x 14 – 7/8mm
37-TN-0610	Trial, 0° Lordosis, 16 x 14 – 9/10mm
37-TN-0612	Trial, 0° Lordosis, 16 x 14 – 11/12mm
37-TN-0806	**Trial, 0° Lordosis, 18 x 15 – 5/6mm***
37-TN-0808	**Trial, 0° Lordosis, 18 x 15 – 7/8mm***
37-TN-0810	**Trial, 0° Lordosis, 18 x 15 – 9/10mm***
37-TN-0812	**Trial, 0° Lordosis, 18 x 15 – 11/12mm***
37-TN-7406	Trial, 7° Lordosis, 14 x 12 – 5/6mm
37-TN-7408	Trial, 7° Lordosis, 14 x 12 – 7/8mm
37-TN-7410	Trial, 7° Lordosis, 14 x 12 – 9/10mm
37-TN-7412	Trial, 7° Lordosis, 14 x 12 – 11/12mm
37-TN-7606	Trial, 7° Lordosis, 16 x 14 – 5/6mm
37-TN-7608	Trial, 7° Lordosis, 16 x 14 – 7/8mm
37-TN-7610	Trial, 7° Lordosis, 16 x 14 – 9/10mm
37-TN-7612	Trial, 7° Lordosis, 16 x 14 – 11/12mm
37-TN-7806	**Trial, 7° Lordosis, 18 x 15 – 5/6mm***
37-TN-7808	**Trial, 7° Lordosis, 18 x 15 – 7/8mm***
37-TN-7810	**Trial, 7° Lordosis, 18 x 15 – 9/10mm***
37-TN-7812	**Trial, 7° Lordosis, 18 x 15 – 11/12mm***
Implant Kit	
37-BK-0101	Standard Implant Kit: Screws, 14x12, 16x14 implants and trials
37-BK-0102	Standard Implant Kit + 18x15 implants and trials
Instrument Kit	
37-BK-0201	Instrument Kit
Adjunct Rasp Kit*	
37-BK-0211	Standard Adjunct Rasp Kit: 14x12, 16x14 rasps
37-BK-0212	Standard Adjunct Rasp Kit + 18x15 rasps

Item No.	Description
Rasp	
37-RS-0406	Rasp, 0° Lordosis, 14 x 12 – 5/6mm
37-RS-0408	Rasp, 0° Lordosis, 14 x 12 – 7/8mm
37-RS-0410	Rasp, 0° Lordosis, 14 x 12 – 9/10mm
37-RS-0412	Rasp, 0° Lordosis, 14 x 12 – 11/12mm
37-RS-0606	Rasp, 0° Lordosis, 16 x 14 – 5/6mm
37-RS-0608	Rasp, 0° Lordosis, 16 x 14 – 7/8mm
37-RS-0610	Rasp, 0° Lordosis, 16 x 14 – 9/10mm
37-RS-0612	Rasp, 0° Lordosis, 16 x 14 – 11/12mm
37-RS-0806	**Rasp, 0° Lordosis, 18 x 15 – 5/6mm***
37-RS-0808	**Rasp, 0° Lordosis, 18 x 15 – 7/8mm***
37-RS-0810	**Rasp, 0° Lordosis, 18 x 15 – 9/10mm***
37-RS 0812	**Rasp, 0° Lordosis, 18 x 15 – 11/12mm***
37-RS-7406	Rasp, 7° Lordosis, 14 x 12 – 5/6mm
37-RS-7408	Rasp, 7° Lordosis, 14 x 12 – 7/8mm
37-RS-7410	Rasp, 7° Lordosis, 14 x 12 – 9/10mm
37-RS-7412	Raps, 7° Lordosis, 14 x 12 – 11/12mm
37-RS-7606	Rasp, 7° Lordosis, 16 x 14 – 5/6mm
37-RS-7608	Rasp, 7° Lordosis, 16 x 14 – 7/8mm
37-RS-7610	Rasp, 7° Lordosis, 16 x 14 – 9/10mm
37-RS-7612	Rasp, 7° Lordosis, 16 x 14 – 11/12mm
37-RS-7806	**Rasp, 7° Lordosis, 18 x 15 – 5/6mm***
37-RS-7808	**Rasp, 7° Lordosis, 18 x 15 – 7/8mm***
37-RS-7810	**Rasp, 7° Lordosis, 18 x 15 – 9/10mm***
37-RS-7812	**Rasp, 7° Lordosis, 18 x 15 – 11/12mm***

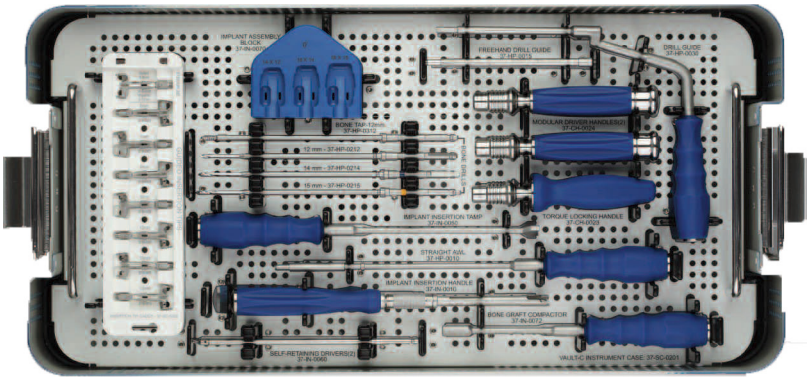


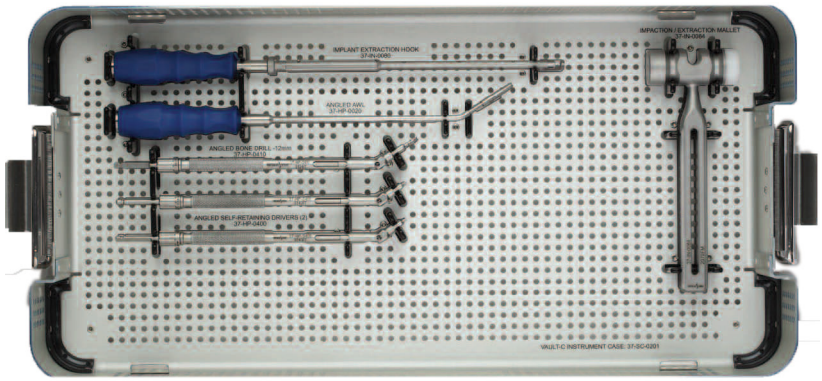
*** Special Order**

VAULT™ C SYSTEM INSTRUMENTS

Item No.	Description
37-IN-0010	Implant Insertion Handle
37-IN-0428	Streamline Insertion Tip
37-IN-0406	Guided Insertion Tip – 06mm
37-IN-0407	Guided Insertion Tip – 07mm
37-IN-0408	Guided Insertion Tip – 08mm
37-IN-0409	Guided Insertion Tip – 09mm
37-IN-0410	Guided Insertion Tip – 10mm
37-IN-0411	Guided Insertion Tip – 11mm
37-IN-0412	Guided Insertion Tip – 12mm
37-IN-0050	Implant Insertion Tamp
37-IN-0060	Self-Retaining Drivers (2)
37-IN-0070	Implant Assembly Block
37-IN-0072	Bone Graft Compactor
37-IN-0080	Implant Extraction Hook

Item No.	Description
37-IN-0084	Impaction/Extraction Mallet
37-HP-0010	Straight Awl
37-HP-0015	Freehand Drill Guide
37-HP-0020	Angled Awl
37-HP-0030	Drill Guide
37-HP-0212	Bone Drill – 12mm
37-HP-0214	Bone Drill – 14mm
37-HP-0215	Bone Drill – 15mm
37-HP-0312	Bone Tap – 12mm
37-HP-0400	Angled Self-Retaining Driver (2)
37-HP-0410	Angled Bone Drill – 12mm
37-CH-0023	Torque Locking Handle
37-CH-0024	Modular Driver Handle (2)





INDICATIONS

Contraindications:

The Vault™ C Anterior Cervical Discectomy Fusion (ACDF System contraindications include, but are not limited to:

1. Prior fusion at the level(s) to be treated
2. Any condition not described in the indication 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 requiring the use of different metals from components
10. Any patient unwilling or unable to follow postoperative care instructions
11. All cases not stated in the indications
12. Reuse, or multiple uses

Potential Adverse Effects/Surgical Risks:

The following potential adverse affects associated with the procedure have been shown to occur with the use of similar spinal systems. All patients considered candidates for fusion should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse affects. The following are potential adverse affects, 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
12. Bone loss and/or bone fracture due to stress shielding
13. Inability to resume activities of normal daily activities
14. Revision surgery
15. Death

Note: Additional surgery may be required to correct some of these potential adverse events.

Warnings:

The following are warnings for this device.

1. Patients with previous spinal surgery at the level(s) to be treated may have different clinical 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 been adequately 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 an increased incidence of non-union has been reported with patients who smoke.

6. The implants and instruments are provided non-sterile and must be cleaned and sterilized 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 many extenuating circumstances. This is especially true in spinal surgeries where other patient conditions may compromise the results.

8. Never reuse an internal fixation device under any circumstances. AN IMPLANT SHOULD NEVER BE RE-USED. 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. These Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.

9. Only surgeons trained and experienced in spinal decompression and bone grafting techniques should use the Vault C Anterior Cervical Discectomy Fusion (ACDF) 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.

10. Physician note: Although the physician is the learned intermediary, the important medical information given in this document should be conveyed to the patient.

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