

SURGICAL TECHNIQUE



PRECISION SPINE
Vault[®] C
ACDF SYSTEM

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Vault® C ACDF System

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VAULT® C OVERVIEW

DEVICE DESCRIPTION

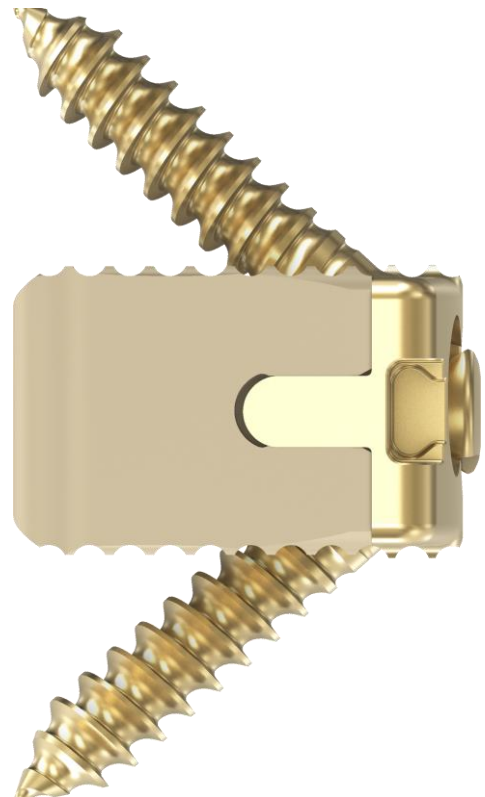
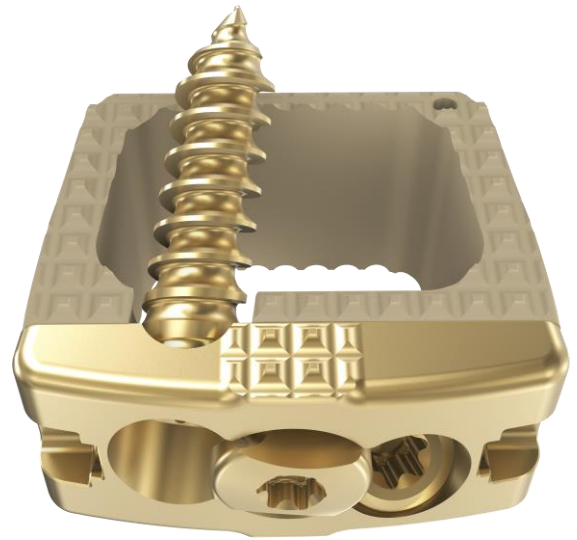
The Vault C ACDF System implants are available in various heights and geometric footprints to accommodate individual patient anatomy and graft material size. Vault C Interbody devices are inserted through an anterior cervical approach and packed with autogenous bone graft to facilitate fusion. Serrations 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 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 C-3 to T-1 disc levels. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device.

Please refer to package insert (LBL-IFU-015) for complete system description, indications and warnings.



IMPLANT FEATURES

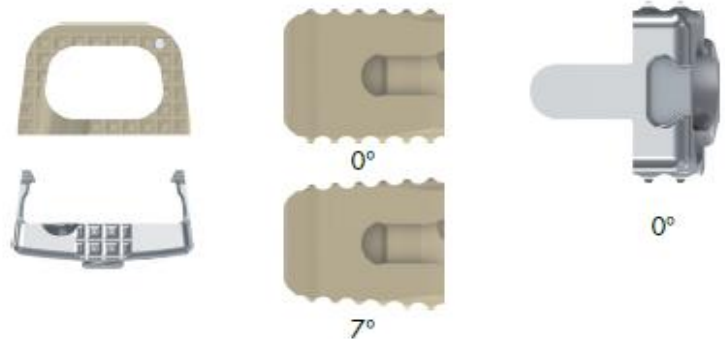
MODULAR PLATE AND CAGE

- Tactile and audible assembly



THREE GEOMETRIC FOOTPRINTS, ANODIZED PER WIDTH

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



2X LATERAL POSTERIOR MARKERS

- Indicate posterior height, width, depth

TWO SAGITTAL PROFILES

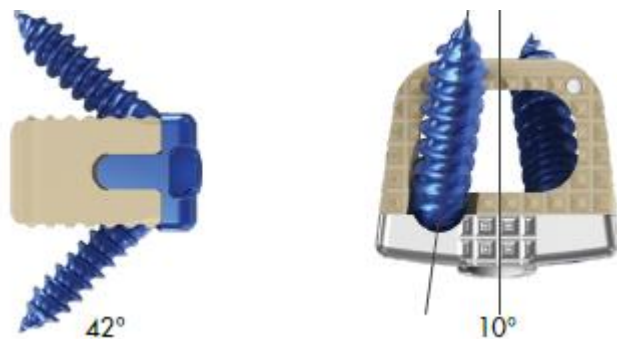
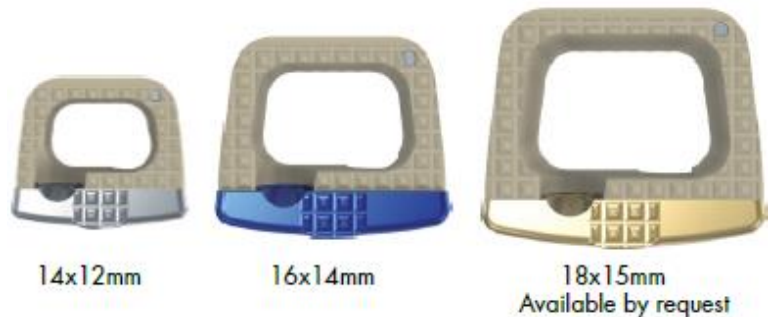
- 0° Lordosis
- 7° Lordosis

HEIGHTS

- 6mm-12mm; 1mm Increments

SCREW TRAJECTORY

- 35° Cephalad/Caudal x 10° Medial
- 42° Maximum angle



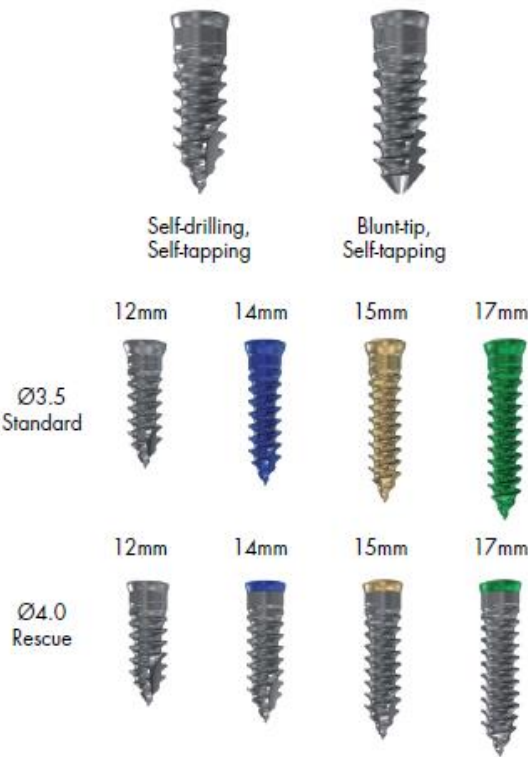
IMPLANT FEATURES

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

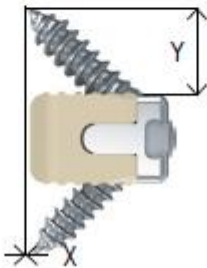
- Standard, Ø3.5mm
- Rescue, Ø4.0mm
- Anodized per 12, 14, 15, 17mm lengths
- Align with posterior aspect of common implant depth



	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

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



TRIALS

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*

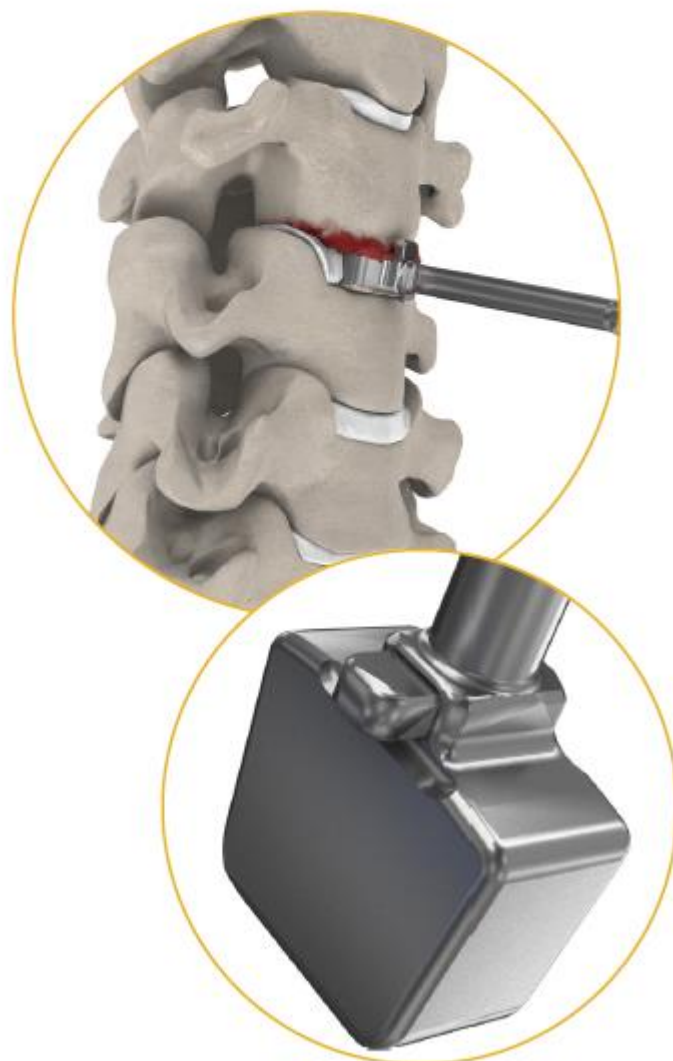
TRIALS 7° LORDOSIS

- 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

RASPS

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

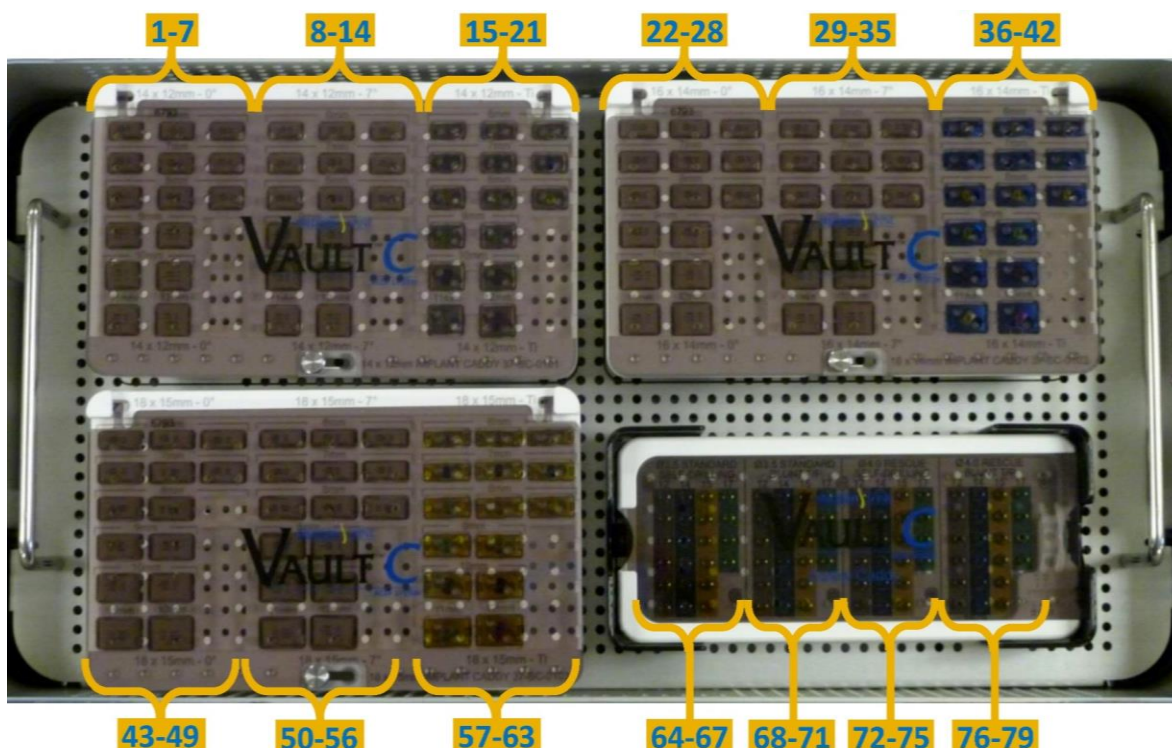
Double sided, color coded per height



* Special Order

VAULT® C – IMPLANTS – TOP TRAY

TRAY NUMBER 37-BK-01XX



#	Part No.	Description	Qty
1.	37-CP-4206	14 x 12 x 06mm 0° Posterior Cage	3
2.	37-CP-4207	14 x 12 x 07mm 0° Posterior Cage	3
3.	37-CP-4208	14 x 12 x 08mm 0° Posterior Cage	3
4.	37-CP-4209	14 x 12 x 09mm 0° Posterior Cage	2
5.	37-CP-4210	14 x 12 x 10mm 0° Posterior Cage	2
6.	37-CP-4211	14 x 12 x 11mm 0° Posterior Cage	1
7.	37-CP-4212	14 x 12 x 12mm 0° Posterior Cage	1
8.	37-CL-4206	14 x 12 x 06mm 7° Posterior Cage	3
9.	37-CL-4207	14 x 12 x 07mm 7° Posterior Cage	3
10.	37-CL-4208	14 x 12 x 08mm 7° Posterior Cage	3
11.	37-CL-4209	14 x 12 x 09mm 7° Posterior Cage	2
12.	37-CL-4210	14 x 12 x 10mm 7° Posterior Cage	2
13.	37-CL-4211	14 x 12 x 11mm 7° Posterior Cage	1
14.	37-CL-4212	14 x 12 x 12mm 7° Posterior Cage	1
15.	37-PA-4206	14 x 12 x 06mm Anterior Plate	3
16.	37-PA-4207	14 x 12 x 07mm Anterior Plate	3
17.	37-PA-4208	14 x 12 x 08mm Anterior Plate	3
18.	37-PA-4209	14 x 12 x 09mm Anterior Plate	2
19.	37-PA-4210	14 x 12 x 10mm Anterior Plate	2
20.	37-PA-4211	14 x 12 x 11mm Anterior Plate	1
21.	37-PA-4212	14 x 12 x 12mm Anterior Plate	1
22.	37-CP-6406	16 x 14 x 06mm 0° Posterior Cage	3
23.	37-CP-6407	16 x 14 x 07mm 0° Posterior Cage	3
24.	37-CP-6408	16 x 14 x 08mm 0° Posterior Cage	3
25.	37-CP-6409	16 x 14 x 09mm 0° Posterior Cage	2
26.	37-CP-6410	16 x 14 x 10mm 0° Posterior Cage	2
27.	37-CP-6411	16 x 14 x 11mm 0° Posterior Cage	1
28.	37-CP-6412	16 x 14 x 12mm 0° Posterior Cage	1
29.	37-CL-6406	16 x 14 x 06mm 7° Posterior Cage	3
30.	37-CL-6407	16 x 14 x 07mm 7° Posterior Cage	3
31.	37-CL-6408	16 x 14 x 08mm 7° Posterior Cage	3
32.	37-CL-6409	16 x 14 x 09mm 7° Posterior Cage	2
33.	37-CL-6410	16 x 14 x 10mm 7° Posterior Cage	2
34.	37-CL-6411	16 x 14 x 11mm 7° Posterior Cage	1
35.	37-CL-6412	16 x 14 x 12mm 7° Posterior Cage	1
36.	37-PA-6406	16 x 14 x 06mm Anterior Plate	3
37.	37-PA-6407	16 x 14 x 07mm Anterior Plate	3
38.	37-PA-6408	16 x 14 x 08mm Anterior Plate	3
39.	37-PA-6409	16 x 14 x 09mm Anterior Plate	2
40.	37-PA-6410	16 x 14 x 10mm Anterior Plate	2

#	Part No.	Description	Qty
41.	37-PA-6411	16 x 14 x 11mm Anterior Plate	1
42.	37-PA-6412	16 x 14 x 12mm Anterior Plate	1
43.	37-CP-8506	18 x 15 x 06mm 0° Posterior Cage	0
44.	37-CP-8507	18 x 15 x 07mm 0° Posterior Cage	0
45.	37-CP-8508	18 x 15 x 08mm 0° Posterior Cage	0
46.	37-CP-8509	18 x 15 x 09mm 0° Posterior Cage	0
47.	37-CP-8510	18 x 15 x 10mm 0° Posterior Cage	0
48.	37-CP-8511	18 x 15 x 11mm 0° Posterior Cage	0
49.	37-CP-8512	18 x 15 x 12mm 0° Posterior Cage	0
50.	37-CL-8506	18 x 15 x 06mm 7° Posterior Cage	0
51.	37-CL-8507	18 x 15 x 07mm 7° Posterior Cage	0
52.	37-CL-8508	18 x 15 x 08mm 7° Posterior Cage	0
53.	37-CL-8509	18 x 15 x 09mm 7° Posterior Cage	0
54.	37-CL-8510	18 x 15 x 10mm 7° Posterior Cage	0
55.	37-CL-8511	18 x 15 x 11mm 7° Posterior Cage	0
56.	37-CL-8512	18 x 15 x 12mm 7° Posterior Cage	0
57.	37-PA-8506	18 x 15 x 06mm Anterior Plate	0
58.	37-PA-8507	18 x 15 x 07mm Anterior Plate	0
59.	37-PA-8508	18 x 15 x 08mm Anterior Plate	0
60.	37-PA-8509	18 x 15 x 09mm Anterior Plate	0
61.	37-PA-8510	18 x 15 x 10mm Anterior Plate	0
62.	37-PA-8511	18 x 15 x 11mm Anterior Plate	0
63.	37-PA-8512	18 x 15 x 12mm Anterior Plate	0
64.	37-SD-3512	3.5 x 12mm Self-Drilling Screw	6
65.	37-SD-3514	3.5 x 14mm Self-Drilling Screw	6
66.	37-SD-3515	3.5 x 15mm Self-Drilling Screw	6
67.	37-SD-3517	3.5 x 17mm Self-Drilling Screw	4
68.	37-SB-3512	3.5 x 12mm Blunt Tip Screw	6
69.	37-SB-3514	3.5 x 14mm Blunt Tip Screw	6
70.	37-SB-3515	3.5 x 15mm Blunt Tip Screw	6
71.	37-SD-3517	3.5 x 17mm Blunt Tip Screw	4
72.	37-SD-4012	4.0 x 12mm Rescue Self-Drilling Screw	6
73.	37-SD-4014	4.0 x 14mm Rescue Self-Drilling Screw	6
74.	37-SD-4015	4.0 x 15mm Rescue Self-Drilling Screw	6
75.	37-SD-4017	4.0 x 17mm Rescue Self-Drilling Screw	4
76.	37-SB-4012	4.0 x 12mm Rescue Blunt Tip Screw	6
77.	37-SB-4014	4.0 x 14mm Rescue Blunt Tip Screw	6
78.	37-SB-4015	4.0 x 15mm Rescue Blunt Tip Screw	6
79.	37-SB-4017	4.0 x 17mm Rescue Blunt Tip Screw	4

* Special Order

VAULT® C – IMPLANTS – BOTTOM TRAY

TRAY NUMBER 37-BK-01XX

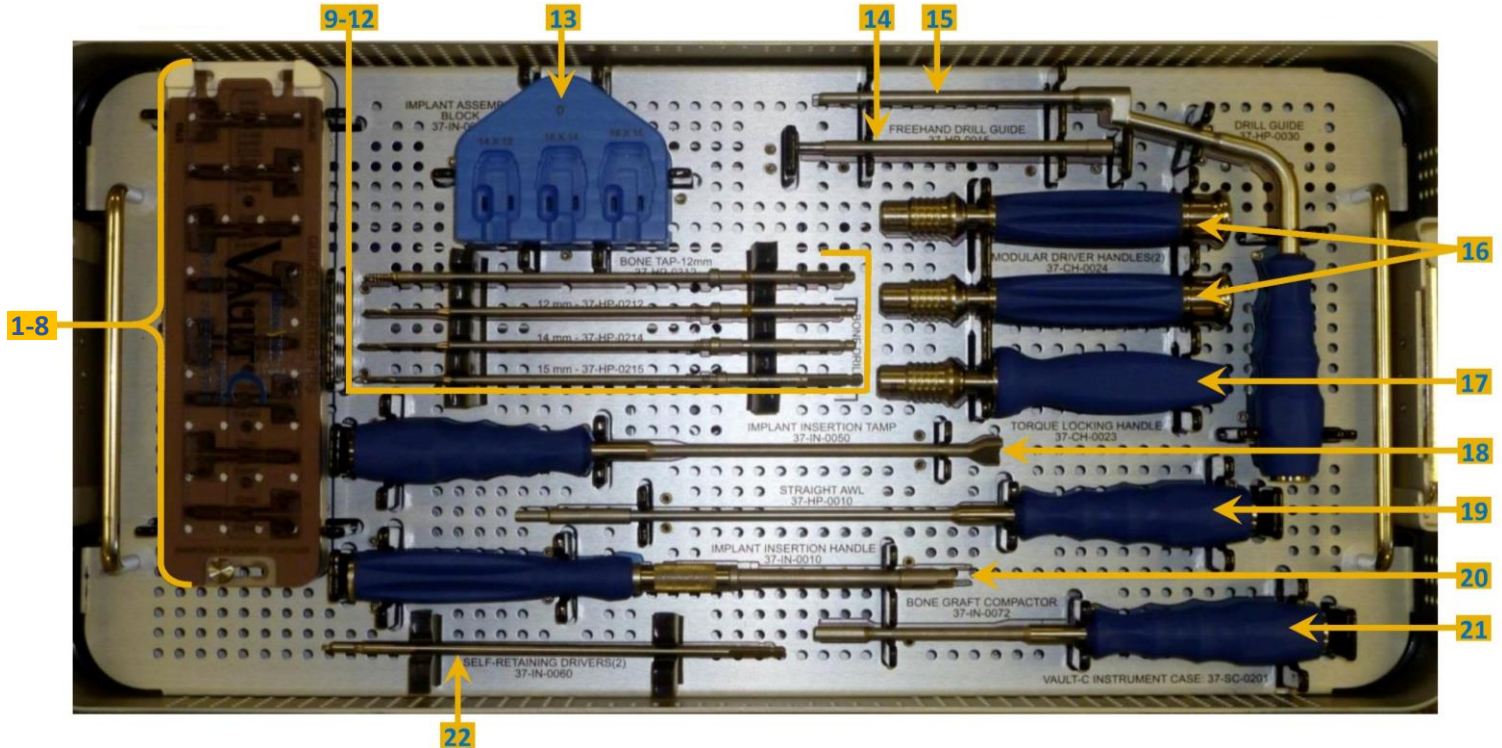


#	Part No.	Description	Qty	#	Part No.	Description	Qty
1.	37-TN-0406	Trial, 0° Lordosis, 14x12 – 5/6mm	1	13.	37-TN-7406	Trial, 7° Lordosis, 14x12 – 5/6mm	1
2.	37-TN-0408	Trial, 0° Lordosis, 14x12 – 7/8mm	1	14.	37-TN-7408	Trial, 7° Lordosis, 14x12 – 7/8mm	1
3.	37-TN-0410	Trial, 0° Lordosis, 14x12 – 9/10mm	1	15.	37-TN-7410	Trial, 7° Lordosis, 14x12 – 9/10mm	1
4.	37-TN-0412	Trial, 0° Lordosis, 14x12 – 11/12mm	1	16.	37-TN-7412	Trial, 7° Lordosis, 14x12 – 11/12mm	1
5.	37-TN-0806	Trial, 0° Lordosis, 18x15 – 5/6mm	0	17.	37-TN-7806	Trial, 7° Lordosis, 18x15 – 5/6mm	0
6.	37-TN-0808	Trial, 0° Lordosis, 18x15 – 7/8mm	0	18.	37-TN-7808	Trial, 7° Lordosis, 18x15 – 7/8mm	0
7.	37-TN-0810	Trial, 0° Lordosis, 18x15 – 9/10mm	0	19.	37-TN-7810	Trial, 7° Lordosis, 18x15 – 9/10mm	0
8.	37-TN-0812	Trial, 0° Lordosis, 18x15 – 11/12mm	0	20.	37-TN-7812	Trial, 7° Lordosis, 18x15 – 11/12mm	0
9.	37-TN-0606	Trial, 0° Lordosis, 16x14 – 5/6mm	1	21.	37-TN-7606	Trial, 7° Lordosis, 16x14 – 5/6mm	1
10.	37-TN-0608	Trial, 0° Lordosis, 16x14 – 7/8mm	1	22.	37-TN-7608	Trial, 7° Lordosis, 16x14 – 7/8mm	1
11.	37-TN-0610	Trial, 0° Lordosis, 16x14 – 9/10mm	1	23.	37-TN-7610	Trial, 7° Lordosis, 16x14 – 9/10mm	1
12.	37-TN-0612	Trial, 0° Lordosis, 16x14 – 11/12mm	1	24.	37-TN-7612	Trial, 7° Lordosis, 16x14 – 11/12mm	1

* Special Order

VAULT® C – INSTRUMENTS – TOP TRAY

TRAY NUMBER 37-BK-0201

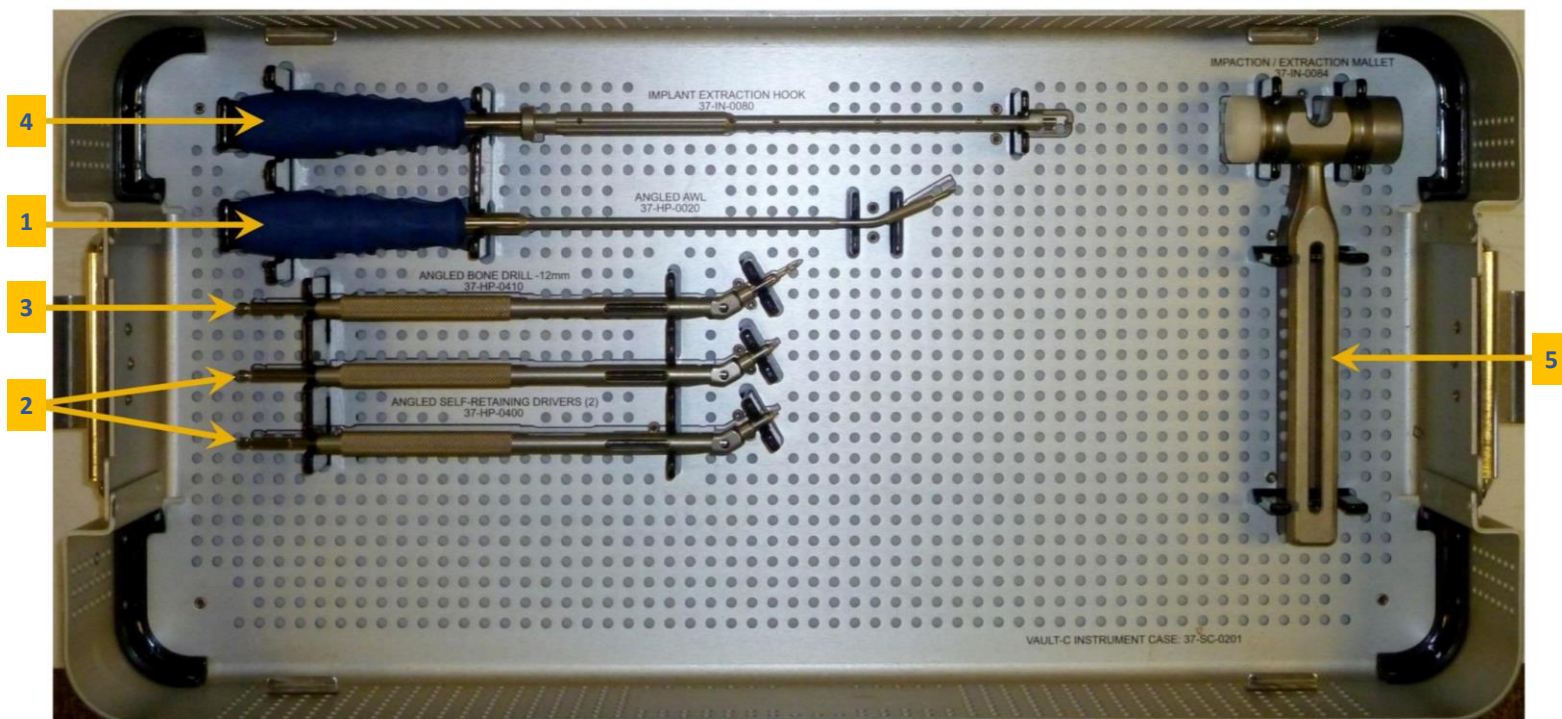


#	Part No.	Description	Qty	#	Part No.	Description	Qty
1.	37-IN-0406	Guided Insertion Tip – 06mm	1	13.	37-IN-0070	Implant Assembly Block (0° & 7° on Front & Back)	1
2.	37-IN-0407	Guided Insertion Tip – 07mm	1	14.	37-HP-0015	Freehand Drill Guide (Threads Directly onto Drill)	1
3.	37-IN-0408	Guided Insertion Tip – 08mm	1	15.	37-HP-0030	Drill Guide	1
4.	37-IN-0409	Guided Insertion Tip – 09mm	1	16.	37-CH-0024	Modular Driver Handle	2
5.	37-IN-0410	Guided Insertion Tip – 10mm	1	17.	37-CH-0023	Torque Locking Handle	1
6.	37-IN-0411	Guided Insertion Tip – 11mm	1	18.	37-IN-0050	Implant Insertion Tamp	1
7.	37-IN-0412	Guided Insertion Tip – 121mm	1	19.	37-HP-0010	Straight Awl (Retractable with End-Stop)	1
8.	37-IN-0428	Streamline Insertion Tip*	1	20.	37-IN-0010	Implant Insertion Handle	1
9.	37-HP-0312	Bone Tap – 12mm (.5mm Undersized)	1	21.	37-IN-0072	Bone Graft Compactor	1
10.	37-HP-0212	Bone Drill – 12mm (1.5mm Undersized)	1	22.	37-IN-0060	Self-Retaining Straight Drivers (used with Screws & Locking Rivets)	2
11.	37-HP-0214	Bone Drill – 14mm (1.5mm Undersized)	1				
12.	37-HP-0215	Bone Drill – 15mm (1.5mm Undersized)	1				

*Will pass instruments when assembled to 6mm, 7mm and 8mm height implants

VAULT® C – INSTRUMENTS – BOTTOM TRAY

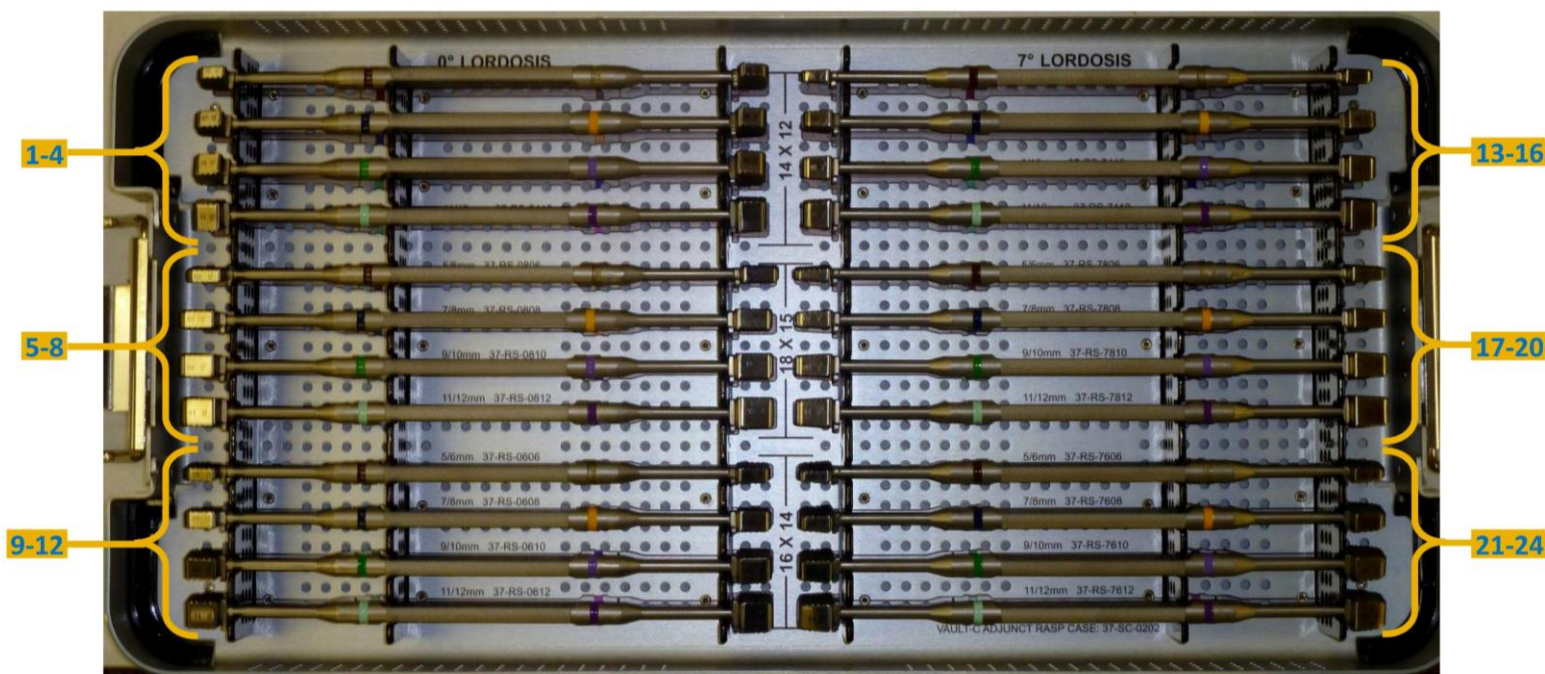
TRAY NUMBER 37-BK-0201



#	Part No.	Description	Qty
1.	37-HP-0020	Angled Awl (35° Angle; 2mm Diameter; 4mm Length; Retractable with End-Stop)	1
2.	37-HP-0400	Angled Self-Retaining Drivers (35° Fixed-Angle)	2
3.	37-HP-0410	Angled Bone Drill – 12mm (35° Fixed Angle; Reusable; 1.5mm Undersized)	1
4.	37-IN-0080	Implant Extraction Hook (Secures Plate and Cage)	1
5.	37-IN-0084	Implant/Extraction Mallet	1

VAULT® C – INSTRUMENTS – RASP TRAY

TRAY NUMBER 37-BK-021X



#	Part No.	Description	Qty	#	Part No.	Description	Qty
1.	37-RS-0406	Rasp, 0° Lordosis, 14x12 – 5/6mm	1	13.	37-RS-7406	Rasp, 7° Lordosis, 14x12 – 5/6mm	1
2.	37-RS-0408	Rasp, 0° Lordosis, 14x12 – 7/8mm	1	14.	37-RS-7408	Rasp, 7° Lordosis, 14x12 – 7/8mm	1
3.	37-RS-0410	Rasp, 0° Lordosis, 14x12 – 9/10mm	1	15.	37-RS-7410	Rasp, 7° Lordosis, 14x12 – 9/10mm	1
4.	37-RS-0412	Rasp, 0° Lordosis, 14x12 – 11/12mm	1	16.	37-RS-7412	Rasp, 7° Lordosis, 14x12 – 11/12mm	1
5.	37-RS-0806	Rasp, 0° Lordosis, 18x15 – 5/6mm	0	17.	37-RS-7806	Rasp, 7° Lordosis, 18x15 – 5/6mm	0
6.	37-RS-0808	Rasp, 0° Lordosis, 18x15 – 7/8mm	0	18.	37-RS-7808	Rasp, 7° Lordosis, 18x15 – 7/8mm	0
7.	37-RS-0810	Rasp, 0° Lordosis, 18x15 – 9/10mm	0	19.	37-RS-7810	Rasp, 7° Lordosis, 18x15 – 9/10mm	0
8.	37-RS-0812	Rasp, 0° Lordosis, 18x15 – 11/12mm	0	20.	37-RS-7812	Rasp, 7° Lordosis, 18x15 – 11/12mm	0
9.	37-RS-0606	Rasp, 0° Lordosis, 16x14 – 5/6mm	1	21.	37-RS-7606	Rasp, 7° Lordosis, 16x14 – 5/6mm	1
10.	37-RS-0608	Rasp, 0° Lordosis, 16x14 – 7/8mm	1	22.	37-RS-7608	Rasp, 7° Lordosis, 16x14 – 7/8mm	1
11.	37-RS-0610	Rasp, 0° Lordosis, 16x14 – 9/10mm	1	23.	37-RS-7610	Rasp, 7° Lordosis, 16x14 – 9/10mm	1
12.	37-RS-0612	Rasp, 0° Lordosis, 16x14 – 11/12mm	1	24.	37-RS-7612	Rasp, 7° Lordosis, 16x14 – 11/12mm	1

* Special Order

SURGICAL TECHNIQUE

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.

Figure 1



2

DISC PREPARATION & 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).

Figure 2



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

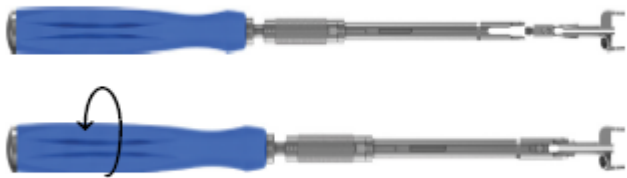
SURGICAL TECHNIQUE

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 assembly 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 and Figures 3 and 3a).

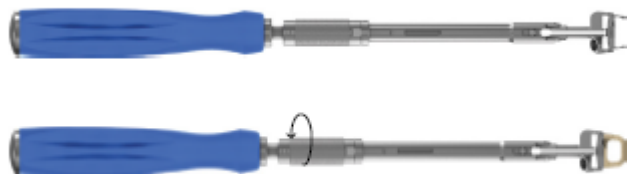
Insertion Handle Assembly:



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



Figure 3a



Figure 4



Figure 5

SURGICAL TECHNIQUE

4

IMPLANT INSERTION

Insert the Implant Construct into the disc space.

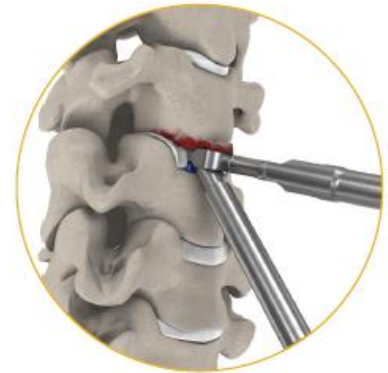


Figure 6

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 (Figure 9) within the corresponding hole and prepare the hole.

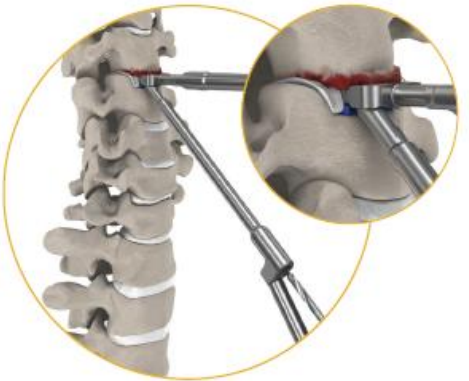


Figure 7



Figure 8



Figure 9

SURGICAL TECHNIQUE

5

SCREW HOLE PREPARATION (cont.)

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

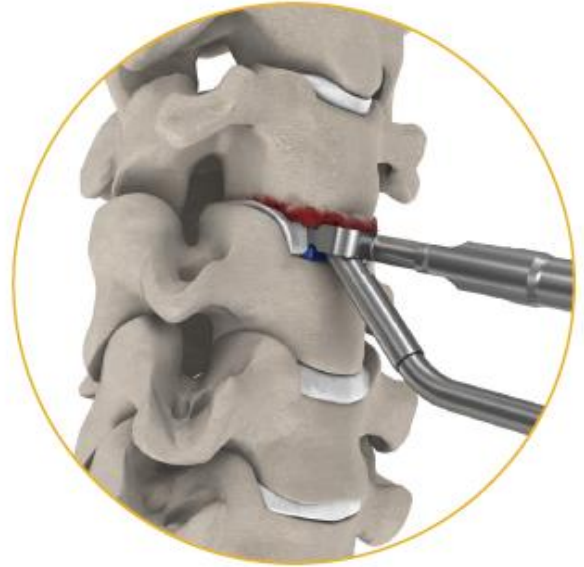
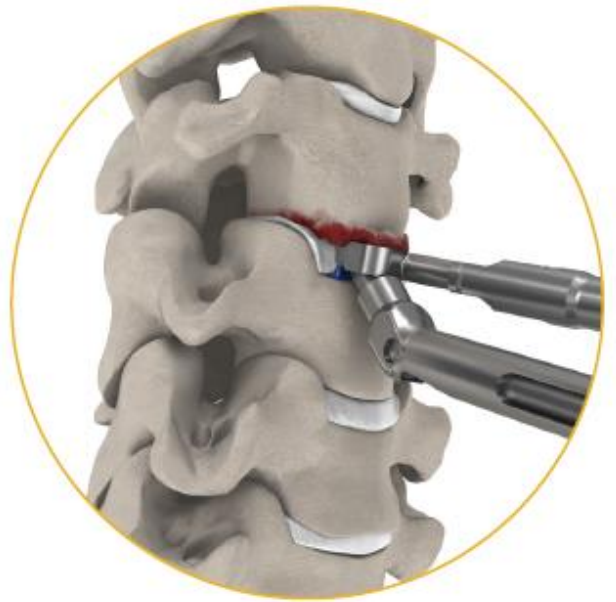


Figure 11



SURGICAL TECHNIQUE

6

SCREW INSERTION

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

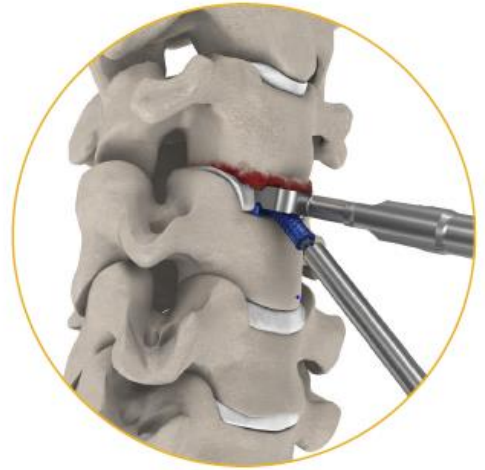
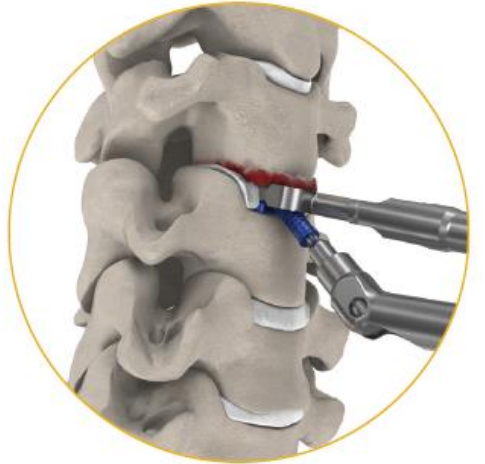


Figure 13



7

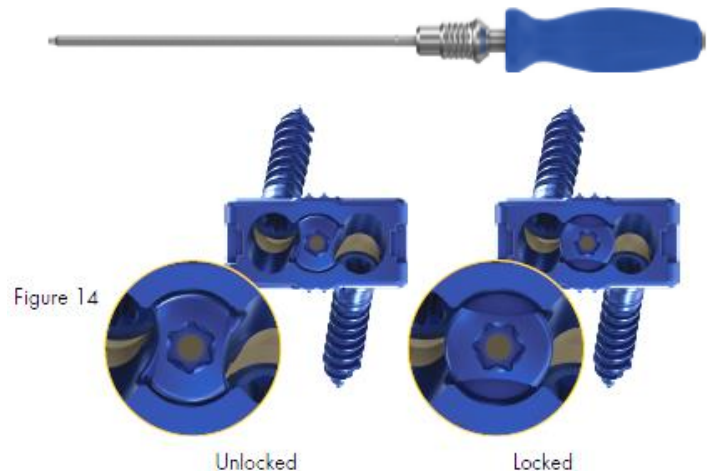
SCREW LOCKING

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

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).



SURGICAL TECHNIQUE

8

SYSTEM REMOVAL

Unlock the Retention Rivet by rotating the Rivet counterclockwise approximately 90°, until the Screws are no longer retained.

After the Screws are removed (Figure 15), insert the Implant Extraction Hook (37-IN-0080) and tighten by rotating the blue silicone handle clockwise to retain the implant.

Remove the Implant Assembly from the disc space, using the Impaction/Extraction Mallet (37-IN0084) for added control (Figure 16).

Figure 15

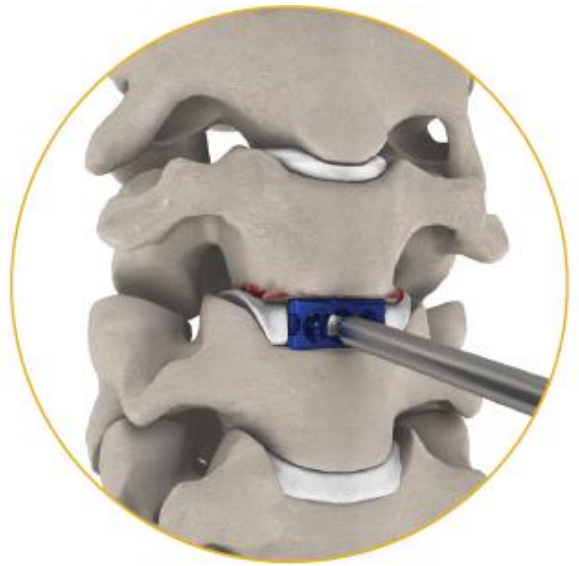


Figure 16



ORDERING INFORMATION – IMPLANTS

Part No.	Description	Part No.	Description
37-CP-4206	14 x 12 x 06mm 0° Posterior Cage	37-CP-8506	18 x 15 x 06mm 0° Posterior Cage*
37-CP-4207	14 x 12 x 07mm 0° Posterior Cage	37-CP-8507	18 x 15 x 07mm 0° Posterior Cage*
37-CP-4208	14 x 12 x 08mm 0° Posterior Cage	37-CP-8508	18 x 15 x 08mm 0° Posterior Cage*
37-CP-4209	14 x 12 x 09mm 0° Posterior Cage	37-CP-8509	18 x 15 x 09mm 0° Posterior Cage*
37-CP-4210	14 x 12 x 10mm 0° Posterior Cage	37-CP-8510	18 x 15 x 10mm 0° Posterior Cage*
37-CP-4211	14 x 12 x 11mm 0° Posterior Cage	37-CP-8511	18 x 15 x 11mm 0° Posterior Cage*
37-CP-4212	14 x 12 x 12mm 0° Posterior Cage	37-CP-8512	18 x 15 x 12mm 0° Posterior Cage*
37-CL-4206	14 x 12 x 06mm 7° Posterior Cage	37-CL-8506	18 x 15 x 06mm 7° Posterior Cage*
37-CL-4207	14 x 12 x 07mm 7° Posterior Cage	37-CL-8507	18 x 15 x 07mm 7° Posterior Cage*
37-CL-4208	14 x 12 x 08mm 7° Posterior Cage	37-CL-8508	18 x 15 x 08mm 7° Posterior Cage*
37-CL-4209	14 x 12 x 09mm 7° Posterior Cage	37-CL-8509	18 x 15 x 09mm 7° Posterior Cage*
37-CL-4210	14 x 12 x 10mm 7° Posterior Cage	37-CL-8510	18 x 15 x 10mm 7° Posterior Cage*
37-CL-4211	14 x 12 x 11mm 7° Posterior Cage	37-CL-8511	18 x 15 x 11mm 7° Posterior Cage*
37-CL-4212	14 x 12 x 12mm 7° Posterior Cage	37-CL-8512	18 x 15 x 12mm 7° Posterior Cage*
37-PA-4206	14 x 12 x 06mm Anterior Plate	37-PA-8506	18 x 15 x 06mm Anterior Plate*
37-PA-4207	14 x 12 x 07mm Anterior Plate	37-PA-8507	18 x 15 x 07mm Anterior Plate*
37-PA-4208	14 x 12 x 08mm Anterior Plate	37-PA-8508	18 x 15 x 08mm Anterior Plate*
37-PA-4209	14 x 12 x 09mm Anterior Plate	37-PA-8509	18 x 15 x 09mm Anterior Plate*
37-PA-4210	14 x 12 x 10mm Anterior Plate	37-PA-8510	18 x 15 x 10mm Anterior Plate*
37-PA-4211	14 x 12 x 11mm Anterior Plate	37-PA-8511	18 x 15 x 11mm Anterior Plate*
37-PA-4212	14 x 12 x 12mm Anterior Plate	37-PA-8512	18 x 15 x 12mm Anterior Plate*
37-CP-6406	16 x 14 x 06mm 0° Posterior Cage	37-SD-3512	3.5 x 12mm Self-Drilling Screw
37-CP-6407	16 x 14 x 07mm 0° Posterior Cage	37-SD-3514	3.5 x 14mm Self-Drilling Screw
37-CP-6408	16 x 14 x 08mm 0° Posterior Cage	37-SD-3515	3.5 x 15mm Self-Drilling Screw
37-CP-6409	16 x 14 x 09mm 0° Posterior Cage	37-SD-3517	3.5 x 17mm Self-Drilling Screw
37-CP-6410	16 x 14 x 10mm 0° Posterior Cage	37-SB-3512	3.5 x 12mm Blunt Tip Screw
37-CP-6411	16 x 14 x 11mm 0° Posterior Cage	37-SB-3514	3.5 x 14mm Blunt Tip Screw
37-CP-6412	16 x 14 x 12mm 0° Posterior Cage	37-SB-3515	3.5 x 15mm Blunt Tip Screw
37-CL-6406	16 x 14 x 06mm 7° Posterior Cage	37-SB-3517	3.5 x 17mm Blunt Tip Screw
37-CL-6407	16 x 14 x 07mm 7° Posterior Cage	37-SD-4012	4.0 x 12mm Rescue Self-Drilling Screw
37-CL-6408	16 x 14 x 08mm 7° Posterior Cage	37-SD-4014	4.0 x 14mm Rescue Self-Drilling Screw
37-CL-6409	16 x 14 x 09mm 7° Posterior Cage	37-SD-4015	4.0 x 15mm Rescue Self-Drilling Screw
37-CL-6410	16 x 14 x 10mm 7° Posterior Cage	37-SD-4017	4.0 x 17mm Rescue Self-Drilling Screw
37-CL-6411	16 x 14 x 11mm 7° Posterior Cage	37-SB-4012	4.0 x 12mm Rescue Blunt Tip Screw
37-CL-6412	16 x 14 x 12mm 7° Posterior Cage	37-SB-4014	4.0 x 14mm Rescue Blunt Tip Screw
37-PA-6406	16 x 14 x 06mm Anterior Plate	37-SB-4015	4.0 x 15mm Rescue Blunt Tip Screw
37-PA-6407	16 x 14 x 07mm Anterior Plate	37-SB-4017	4.0 x 17mm Rescue Blunt Tip Screw
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		

* Special Order

ORDERING INFORMATION – INSTRUMENTS

Part No.	Description
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-0428	Streamline Insertion Tip
37-HP-0312	Bone Tap – 12mm (.5mm Undersized)
37-HP-0212	Bone Drill – 12mm (1.5mm Undersized)
37-HP-0214	Bone Drill – 14mm (1.5mm Undersized)
37-HP-0215	Bone Drill – 15mm (1.5mm Undersized)
37-IN-0070	Implant Assembly Block
37-HP-0015	Freehand Drill Guide
37-HP-0030	Drill Guide
37-CH-0024	Modular Driver Handle
37-CH-0023	Torque Locking Handle
37-IN-0050	Implant Insertion Tamp
37-HP-0010	Straight Awl
37-IN-0010	Implant Insertion Handle
37-IN-0072	Bone Graft Compactor
37-IN-0060	Self-Retaining Straight Driver
37-HP-0020	Angled Awl
37-HP-0400	Angled Self-Retaining Driver
37-HP-0410	Angled Bone Drill – 12mm
37-IN-0080	Implant Extraction Hook
37-IN-0084	Implant/Extraction Mallet

Part No.	Description
37-RS-0406	Rasp, 0° Lordosis, 14x12 – 5/6mm
37-RS-0408	Rasp 0° Lordosis, 14x12 – 7/8mm
37-RS-0410	Rasp, 0° Lordosis, 14x12 – 9/10mm
37-RS-0412	Rasp 0° Lordosis, 14x12 – 11/12mm
37-RS-0606	Rasp, 0° Lordosis, 16x14– 5/6mm
37-RS-0608	Rasp, 0° Lordosis, 16x14 – 7/8mm
37-RS-0610	Rasp, 0° Lordosis, 16x14 – 9/10mm
37-RS-0612	Rasp, 0° Lordosis, 16x14 – 11/12mm
37-RS-0806	Rasp, 0° Lordosis, 18x15 – 5/6mm*
37-RS-0808	Rasp, 0° Lordosis, 18x15 – 7/8mm*
37-RS-0810	Rasp, 0° Lordosis, 18x15 – 9/10mm*
37-RS-0812	Rasp, 0° Lordosis, 18x15 – 11/12mm*
37-RS-7406	Rasp, 7° Lordosis, 14x12 – 5/6mm
37-RS-7408	Rasp, 7° Lordosis, 14x12 – 7/8mm
37-RS-7410	Rasp, 7° Lordosis, 14x12 – 9/10mm
37-RS-7412	Rasp, 7° Lordosis, 14x12 – 11/12mm
37-RS-7606	Rasp, 7° Lordosis, 16x14– 5/6mm
37-RS-7608	Rasp, 7° Lordosis, 16x14 – 7/8mm
37-RS-7610	Rasp, 7° Lordosis, 16x14 – 9/10mm
37-RS-7612	Rasp, 7° Lordosis, 16x14 – 11/12mm
37-RS-7806	Rasp, 7° Lordosis, 18x15 – 5/6mm*
37-RS-7808	Rasp, 7° Lordosis, 18x15 – 7/8mm*
37-RS-7810	Rasp, 7° Lordosis, 18x15 – 9/10mm*
37-RS-7812	Rasp, 7° Lordosis, 18x15 – 11/12mm*
37-TN-0406	Trial, 0° Lordosis, 14x12 – 5/6mm
37-TN-0408	Trial, 0° Lordosis, 14x12 – 7/8mm
37-TN-0410	Trial, 0° Lordosis, 14x12 – 9/10mm
37-TN-0412	Trial, 0° Lordosis, 14x12 – 11/12mm
37-TN-0606	Trial, 0° Lordosis, 16x14– 5/6mm
37-TN-0608	Trial, 0° Lordosis, 16x14 – 7/8mm
37-TN-0610	Trial, 0° Lordosis, 16x14 – 9/10mm
37-TN-0612	Trial, 0° Lordosis, 16x14 – 11/12mm
37-TN-0806	Trial, 0° Lordosis, 18x15 – 5/6mm*
37-TN-0808	Trial, 0° Lordosis, 18x15 – 7/8mm*
37-TN-0810	Trial, 0° Lordosis, 18x15 – 9/10mm*
37-TN-0812	Trial, 0° Lordosis, 18x15 – 11/12mm*
37-TN-7406	Trial, 7° Lordosis, 14x12 – 5/6mm
37-TN-7408	Trial, 7° Lordosis, 14x12 – 7/8mm
37-TN-7410	Trial, 7° Lordosis, 14x12 – 9/10mm
37-TN-7412	Trial, 7° Lordosis, 14x12 – 11/12mm
37-TN-7606	Trial, 7° Lordosis, 16x14– 5/6mm
37-TN-7608	Trial, 7° Lordosis, 16x14 – 7/8mm
37-TN-7610	Trial, 7° Lordosis, 16x14 – 9/10mm
37-TN-7612	Trial, 7° Lordosis, 16x14 – 11/12mm
37-TN-7806	Trial, 7° Lordosis, 18x15 – 5/6mm*
37-TN-7808	Trial, 7° Lordosis, 18x15 – 7/8mm*
37-TN-7810	Trial, 7° Lordosis, 18x15 – 9/10mm*
37-TN-7812	Trial, 7° Lordosis, 18x15 – 11/12mm*

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:

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. Only surgeons trained and experienced in spinal decompression and bone grafting techniques should use the Vault C 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.
9. Physician note: Although the physician is the learned intermediary, the important medical information given in this document should be conveyed to the patient.
10. Do not reuse implants. Discard used, damaged, or otherwise suspect implants. **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.



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