

**SURGICAL
TECHNIQUE**

PRECISION SPINE
SIMPLICITY[®]
PLUS
ACDF SYSTEM



PRECISION SPINE[®]
Discover the Difference



TABLE OF CONTENTS



OVERVIEW	3
SYSTEM FEATURES	4
IMPLANT TRAY	6
INSTRUMENT TRAY	7
SURGICAL TECHNIQUE	8
Patient Positioning	8
Plate Selection	8
Plate Positioning	8
Plate Contouring	9
Temporary Pin Placement	10
Preparing the Screw Hole	10
Screw Insertion	11
Locking Mechanism	11
Closure	12
Screw Removal	12
INDICATIONS, CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS	13

Slimplicity® PLUS Anterior Cervical Plate System

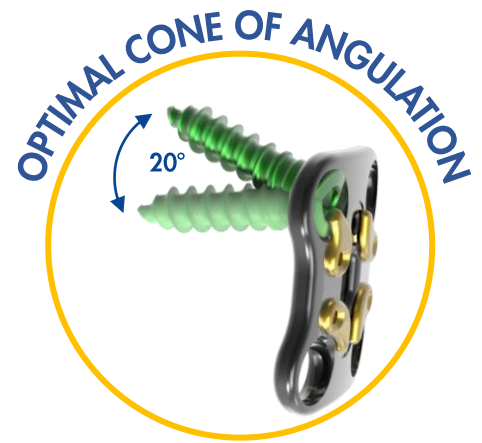
OVERVIEW

The Slimplicity® PLUS Anterior Cervical Plate offers one of the thinnest plates available, with an easy-to-use locking mechanism that facilitates visual locking confirmation. Large graft windows have been incorporated to provide an unimpeded graft site and end plate visualization. To optimize bone purchase, a generous 20° screw angulation is provided. The large array of variable and fixed screw options accommodates semi-constrained, constrained and hybrid philosophies.

INDICATIONS

The Slimplicity Anterior Cervical Plate System is indicated for use in temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with: degenerative disc disease (DDD) (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (including fractures or dislocations); spinal tumors; spinal stenosis; pseudoarthrosis; and failed previous fusions.

Please refer to Instructions For Use (IFU) (LBL-IFU-005) for complete system description, indications and warnings.



SYSTEM FEATURES

PLATES (Titanium)

- Low Profile Plate (2mm) designed to minimize tissue disruption and post-op discomfort
- Pre-Contoured to address patient anatomy
- Central Graft Windows facilitate unimpeded graft visualization
- Intuitive Single Step Locking Mechanism facilitates secure application
- Width: 17mm Waist 14mm
- Radius Curvature: 190mm – 1&2 level
390mm – 3&4 level

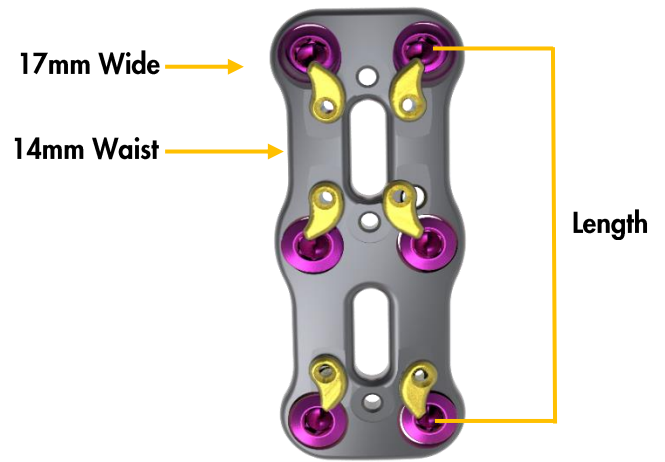


PLATE SIZES

- Size Options (Measurement is from hole to hole)
- Add 8mm to plate length for end to end plate length

Level 1 Lengths



- 10mm
- 12mm
- 14mm
- 16mm
- 18mm
- 20mm
- 24mm*
- 26mm*

Level 2 Lengths*



- 25mm
- 27mm
- 29mm
- 32mm
- 35mm
- 38mm
- 41mm
- 44mm*
- 47mm*

Level 3 Lengths



- 43mm
- 46mm
- 49mm
- 52mm
- 55mm
- 58mm
- 61mm
- 64mm*
- 67mm*

Level 4 Lengths



- 57mm*
- 61mm
- 65mm
- 69mm
- 73mm
- 77mm
- 81mm

FIXED & VARIABLE BONE SCREW SIZES

- Hex 2.5mm

4.0mm Diameter

Lengths

- 12mm
- 14mm
- 16mm
- 18mm



4.5mm Diameter

Lengths

- 12mm
- 14mm
- 16mm
- 18mm



Variable



Fixed



FIXATION PIN

- 10mm length
- Hex 2.5mm
- 2mm major diameter

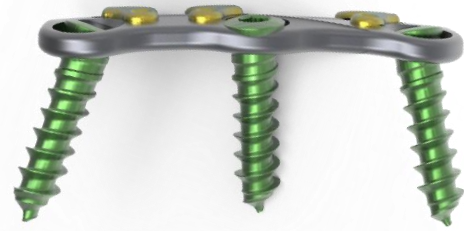


*Upon Request

SYSTEM FEATURES

VARIABLE SCREW ANGLUATION

- 20° Angulation 4.0mm Variable Screws
- 14° Angulation 4.5mm Variable Screws



4.0mm - 20°

4.5mm - 14°

FIXED SCREW ANGLUATION

- 10° Angulation Cephalad/Caudal Screws
- 0° Angulation Intermediate Screws

PLATE BENDER



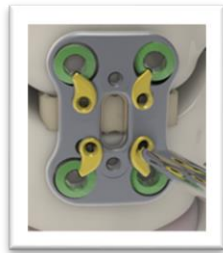
Kyphosis



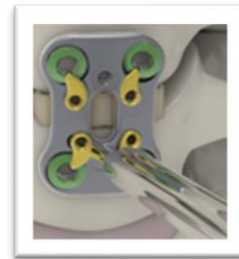
Lordosis

LOCKING TOOL

Lock/Unlock Tool



Dual Locking Tool



DRILL GUIDE (FIXED & VARIABLE)

Fixed

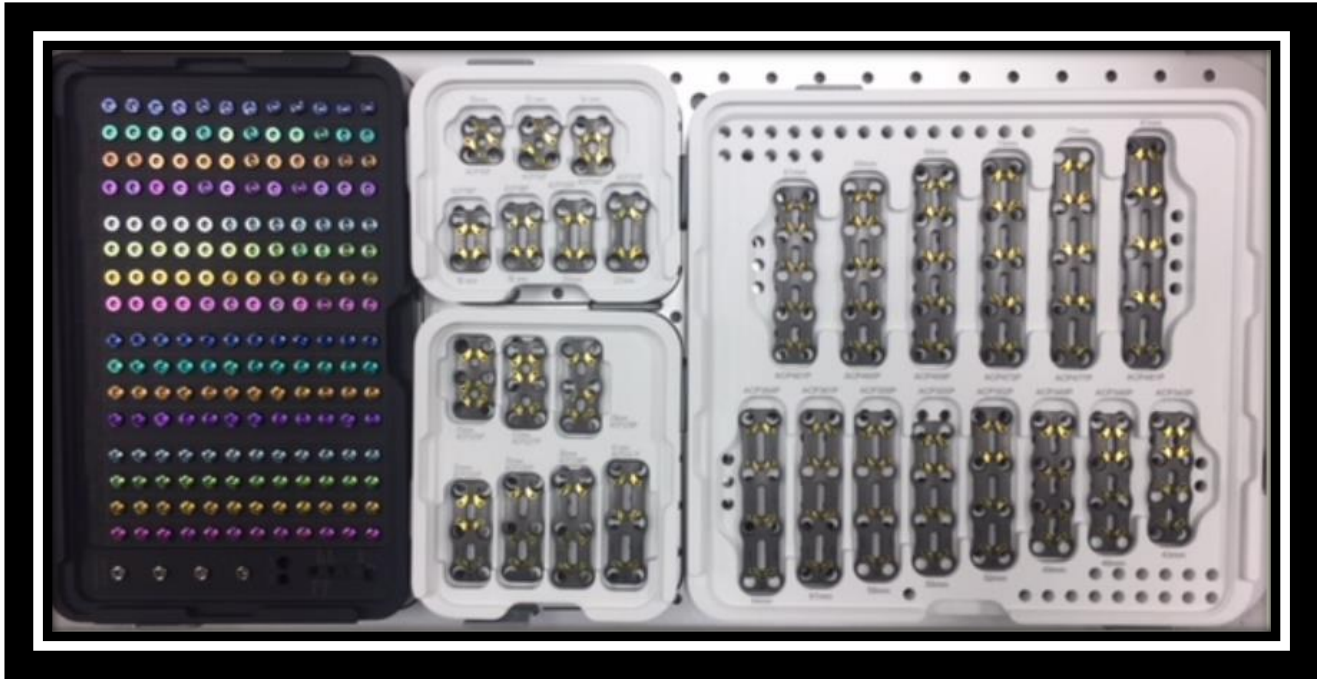


Variable



IMPLANTS – TOP TRAY

TRAY NUMBER 61-BK-0101

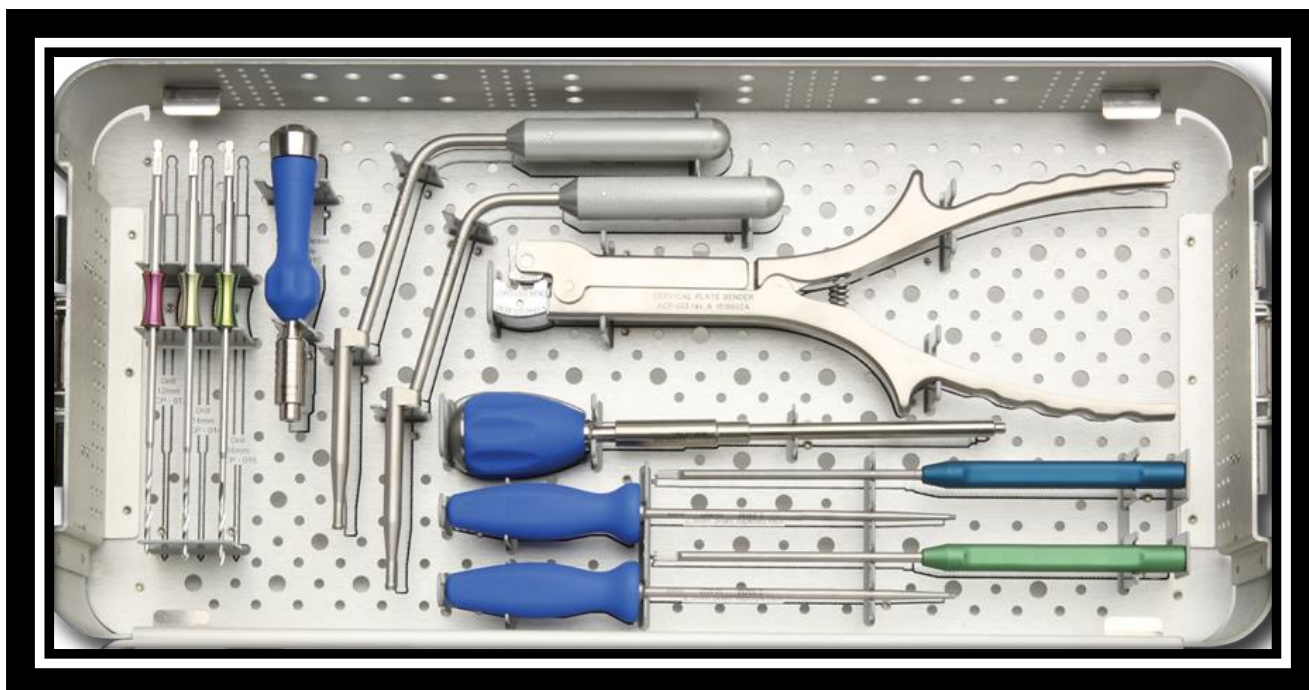


Item No.	Description	Qty	Item No.	Description	Qty
66-SF-4012	4.0mm x 12mm SD Fixed Screw	12	ACP110P	Anterior Cervical Plate, 1-Level, 10mm	1
66-SF-4014	4.0mm x 14mm SD Fixed Screw	12	ACP112P	Anterior Cervical Plate, 1-Level, 12mm	1
66-SF-4016	4.0mm x 16mm SD Fixed Screw	12	ACP114P	Anterior Cervical Plate, 1-Level, 14mm	1
66-SF-4018	4.0mm x 18mm SD Fixed Screw	12	ACP116P	Anterior Cervical Plate, 1-Level, 16mm	1
			ACP118P	Anterior Cervical Plate, 1-Level, 18mm	1
66-SF-4512	4.5mm x 12mm SD Fixed Screw	12	ACP120P	Anterior Cervical Plate, 1-Level, 20mm	1
66-SF-4514	4.5mm x 14mm SD Fixed Screw	12	ACP122P	Anterior Cervical Plate, 1-Level, 22mm	1
66-SF-4516	4.5mm x 16mm SD Fixed Screw	12	ACP225P	Anterior Cervical Plate, 2-Level, 25mm	1
66-SF-4518	4.5mm x 18mm SD Fixed Screw	12	ACP227P	Anterior Cervical Plate, 2-Level, 27mm	1
			ACP229P	Anterior Cervical Plate, 2-Level, 29mm	1
66-SV-4012	4.0mm x 12mm SD Variable Screw	12	ACP232P	Anterior Cervical Plate, 2-Level, 32mm	1
66-SV-4014	4.0mm x 14mm SD Variable Screw	12	ACP235P	Anterior Cervical Plate, 2-Level, 35mm	1
66-SV-4016	4.0mm x 16mm SD Variable Screw	12	ACP238P	Anterior Cervical Plate, 2-Level, 38mm	1
66-SV-4018	4.0mm x 18mm SD Variable Screw	12	ACP241P	Anterior Cervical Plate, 2-Level, 41mm	1
			ACP343P	Anterior Cervical Plate, 3-Level, 43mm	1
66-SV-4512	4.5mm x 12mm SD Variable Screw	12	ACP346P	Anterior Cervical Plate, 3-Level, 46mm	1
66-SV-4514	4.5mm x 14mm SD Variable Screw	12	ACP349P	Anterior Cervical Plate, 3-Level, 49mm	1
66-SV-4516	4.5mm x 16mm SD Variable Screw	12	ACP352P	Anterior Cervical Plate, 3-Level, 52mm	1
66-SV-4518	4.5mm x 18mm SD Variable Screw	12	ACP355P	Anterior Cervical Plate, 3-Level, 55mm	1
			ACP358P	Anterior Cervical Plate, 3-Level, 58mm	1
ACP-009	ACP Fixation Pin, 2.5mm Hex	4	ACP361P	Anterior Cervical Plate, 3-Level, 61mm	1
			ACP364P	Anterior Cervical Plate, 3-Level, 64mm	1
			ACP461P	Anterior Cervical Plate, 4-Level, 61mm	1
			ACP465P	Anterior Cervical Plate, 4-Level, 65mm	1
			ACP469P	Anterior Cervical Plate, 4-Level, 69mm	1
			ACP473P	Anterior Cervical Plate, 4-Level, 73mm	1
			ACP477P	Anterior Cervical Plate, 4-Level, 77mm	1
			ACP481P	Anterior Cervical Plate, 4-Level, 81mm	1

* Please see Page 4 for additional by request plate sizes

INSTRUMENTS – BOTTOM TRAY

TRAY NUMBER 61-BK-0101



Item No.	Description	Qty
66-PB-0010	ACP Plate Bender	1
ACP-006	ACP Bone Awl (2.3mm x 10mm)	1
ACP-005F	ACP Fixed Drill Guide	1
ACP-005V	ACP Variable Drill Guide	1
04-9024	Universal Straight Handle, AO	1
66-DR-0012	ACP Drill – 3mm x 12mm	1
66-DR-0014	ACP Drill – 3mm x 14mm	1
66-DR-0016	ACP Drill – 3mm x 16mm	1
00-9027	ACP 2.5mm Tapered Hex Driver	2
00-9021	ACP Locking Tool	1
00-9023	ACP Lock/Unlock Tool	1
66-PB-0021	Small Insert (Not Shown)	1
66-PB-0022	Large Insert (Not Shown)	1

SURGICAL TECHNIQUE

1

PATIENT POSITIONING

The patient is placed on the operating room table in the supine position with the head in slight extension and slight rotation opposite the side of incision. After decompression and interbody grafting procedures have been completed, remove all anterior osteophytes to provide a contoured contact surface for optimum plate positioning.

2

PLATE SELECTION

When selecting the Plate size that best fits the anatomy, it is important to know that the length of the Plate is based on the distance between the holes of the Plate (Figure 1). The Plate should not extend over the adjacent disc spaces.

Hole to Hole

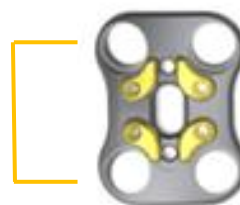


Figure 1

3

PLATE POSITIONING

Position the Plate over the vertebral bodies to be instrumented. Confirm the Plate is properly aligned in mediolateral and caudocranial position (Figure 2).



Figure 2

SURGICAL TECHNIQUE

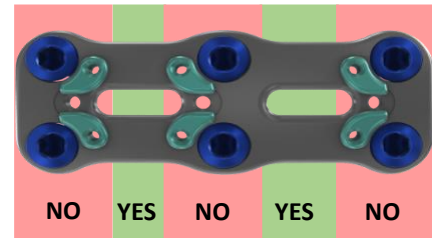
3

PLATE CONTOURING

The Simplicity® PLUS Anterior Cervical Plate is pre-contoured with lordotic curvature to minimize intraoperative contouring (Figure 3). If the lordotic curvature of the plate needs to be modified, the Plate Bender (66-PB-0010) may be used for contouring. The Plate should not be contoured through the locking mechanism as it could become damaged.



Figure 3



DO NOT BEND PLATE ON OR NEAR THE LOCKING RIVETS AND SCREW HOLES. Bending in these regions may weaken the plate and/or prevent proper functionality of the locking mechanism.

Increase Lordosis

1. Choose the appropriate insert type based on the exact system and plate size (See Chart Below)
2. Attach the appropriate insert, **SMALL** (66-PB-0021) or **LARGE** (66-PB-0022), to plate bender with the insert tab facing up (Figure 3A)
3. Adjust bender's hammer so the convex portion is facing the insert tab
4. Insert plate into the bender so the posterior surface is facing the hammer. **THE INSERT TAB MUST BE SEATED WITHIN THE PLATE SLOT**
5. Once securely positioned, squeeze the handle to obtain the desired curvature

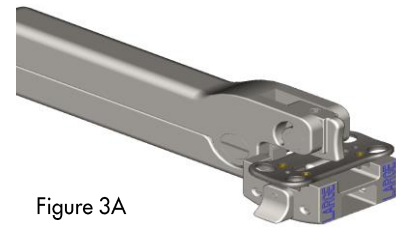


Figure 3A

Decrease Lordosis

1. Attach either insert, **SMALL or LARGE**, to plate bender with the insert tab facing down
2. Adjust bender's hammer so the concave portion is facing down (Figure 3B)
3. Insert plate into the bender so the anterior surface is facing the hammer.
4. While holding the plate in position, squeeze the handle to obtain the desired curvature

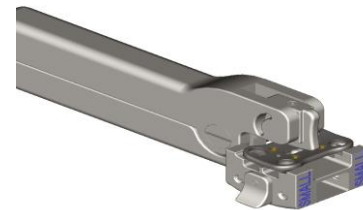
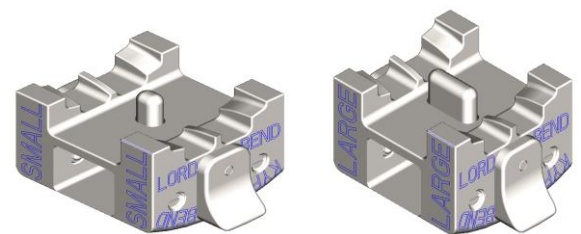


Figure 3B

SLIMPLICITY PLUS			
Plate Level	Plate Sizes (measured hole to hole)	Small Insert	Large Insert
1	10 - 12mm	Not applicable	
	14 - 16mm	x	
	18 - 26mm		x
2	25 - 32mm	x	
	35 - 47mm		x
3	43 - 49mm	x	
	52 - 67mm		x
4	57 - 65mm	x	
	69 - 81mm		x



Small Insert

Large Insert

SURGICAL TECHNIQUE

5

TEMPORARY PIN PLACEMENT

Plate position can be temporarily fixed using the ACP Fixation Pin (ACP-009) and the ACP Bone Screw Driver (00-9027). The Temporary Pin can be inserted through any of the screw holes in the Plate and provides stability during Screw placement (Figure 5).

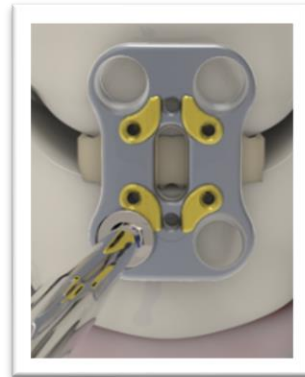


Figure 5

6

PREPARING THE SCREW HOLE

In preparing the screw hole, the Awl (ACP-006) may be used to create a pilot hole.

The Awl is placed in the desired screw hole position with up to 14° of angulation. Press and rotate the Awl through the Plate and into the bone until the depth has bottomed out against the Plate. The Awl will provide a pilot hole up to a depth of 10mm (Figure 6).

If preferred, the Drill Guide (ACP-005F or ACP-005V) (fixed or variable depending on Screw choice) and Drill (66-DR-0012, -0014, -0016) can be used to create the screw hole.

Attach the Drill Guide to the Plate and drill the screw hole (Fixed Drill Guide if Fixed Screws are desired or Variable Drill Guide if Variable Screws are desired).

The Drills are provided in 12, 14 and 16mm lengths with corresponding Drill Guides in both variable and fixed positions (Figures 7).

When used in conjunction with the drill guides, there is a positive stop on the drill bits to prevent over-drilling.

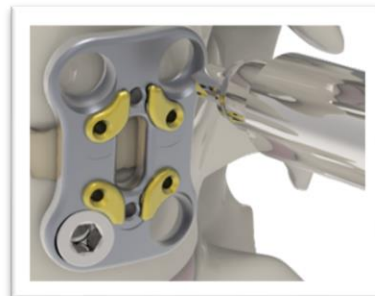


Figure 6



Figure 7

SURGICAL TECHNIQUE

7

SCREW INSERTION

The self-tapping, self-drilling Bone Screws are available in 12, 14, 16, and 18mm lengths in both 4 and 4.5mm diameters. All length and diameter Bone Screw options are available in a fixed and variable head design. Bone Screw lengths measure from under screw head to point.

The ACP Bone Screw Driver (00-9027) (Figure 8) is inserted firmly into the Bone Screws selected for implantation.

Note: The screw driver tip must be completely seated into hex of the bone screw during insertion to ensure proper placement.

Insert the Bone Screw into the vertebrae to be instrumented until it rests firmly and flush inside the plate screw hole (Figure 9). This will enable the Locking Mechanism to be engaged. Repeat the Screw insertion procedure for each screw hole position within the Plate.



Figure 8

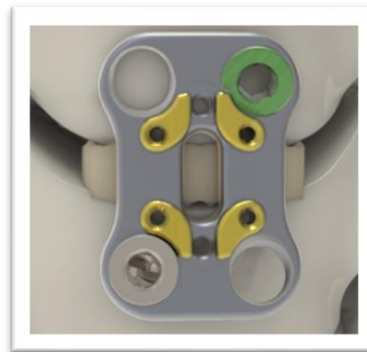


Figure 9

8

LOCKING MECHANISM

Once the Bone Screws have been properly seated, positioned, and tightened, the Locking Mechanism can be rotated to secure the seated Bone Screws within the construct. Securely insert the ACP Locking Tool (00-9021) between the two gold rivets and rotate 360° until the rivets cover both screw heads (Figure 10). Do not rotate rivets more than once as this will weaken the Locking Mechanism. Secure all Bone Screws with the Locking Mechanism (Figure 10). If desired the ACP Lock/Unlock tool (00-9023) can be used to lock the gold rivets individually. Turn the rivet until it is fully engaged and covering the bone screw (Figure 11).

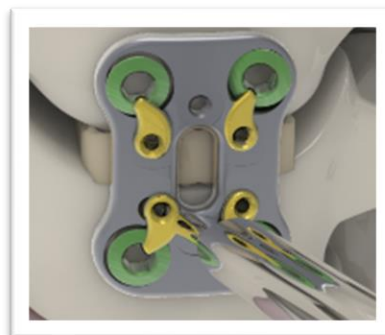


Figure 10

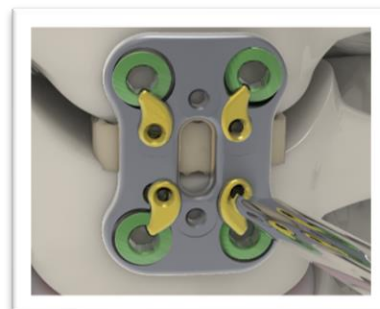


Figure 11

SURGICAL TECHNIQUE

9

CLOSURE

After visual and radiographic confirmation of Plate, Screw, and bone graft placement (Figure 12), the closure process can proceed.

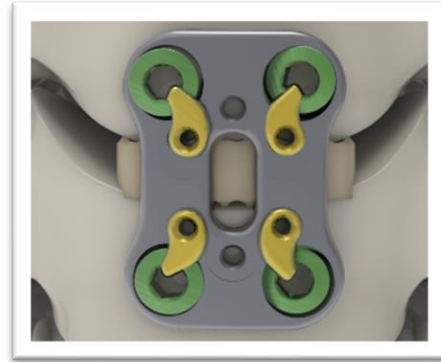


Figure 12

10

SCREW REMOVAL

If needed, the Bone Screws can be removed using the ACP Lock/Unlock Tool (00-9023). The Locking Mechanism is rotated back to its unlocked position. Once the rivet has been rotated the Screws can be removed from the construct.

Indications, Contraindications, Warnings, and Precautions

INDICATIONS

The **Simplicity** Anterior Cervical Plate System is indicated for use in temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with: degenerative disc disease (DDD) (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (including fractures or dislocations); spinal tumors; spinal stenosis; pseudoarthrosis; and failed previous fusions.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

PRECAUTIONS

The **Simplicity** Anterior Cervical Plate System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.

All system implants are single-use only. Reuse of the device may result in the following:

1. Infection
2. Loosening
3. Fracture / mechanical failure of the device
4. Inability to properly engage surgical instrumentation
5. Pyrogenic reaction

CONTRAINDICATIONS: The **Simplicity** Anterior Cervical Plate System contraindications include, but are not limited to:

1. Patients with infection in or adjacent to the spine or spinal structures
2. Inadequate tissue coverage over operative site
3. Patients with morbid obesity
4. Pregnancy
5. Bone absorption, rapid joint disease, osteomalacia, osteopenia, and/or osteoporosis
6. Any spinal surgery case not needing a fusion
7. Any reuse, or multiple use
8. Fever or leukocytosis
9. Any patient unwilling or resistant to following postoperative instructions
10. Mental illness
11. Cardiovascular complications
12. Allergic or other reaction to the metallic components and/or implants

POTENTIAL ADVERSE AFFECTS: The following potential adverse effects 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 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 fusion at, above and/or below the surgery level
8. Bending, loosening, fracture, disassembly, slippage and/or migration of the components
9. Revision surgery
10. Dysphagia
11. Bursitis
12. Bone loss and/or bone fracture due to stress shielding
13. Loss of bladder and/or bowel control
14. Injury to recurrent laryngeal nerve resulting in alteration of voice
15. Injury to esophagus and/or trachea
16. Death

WARNINGS: The following are warnings and precautions of this device.

1. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
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 fusion utilizing any cervical plating system 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. It is recommended that the locking rivets should only be engaged once, or disengaged once, if necessary.
7. The locking rivets should not be engaged until the surgeon has screwed and tightened all bone screws and is ready to close the soft tissues.
8. Failure to engage the locking rivet may increase the chances of screw back out from the plate if the screws become loose.
9. 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.
10. A successful result is not always achieved in every surgical case due to many extenuating circumstances. This device is intended for temporary immobilization of the cervical spine in order to obtain a solid fusion mass using a bone graft.
11. Only surgeons trained and experienced in spinal decompression and bone grafting techniques should use the cervical plate. 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.
12. 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. Reuse can potentially compromise device performance and patient safety.



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