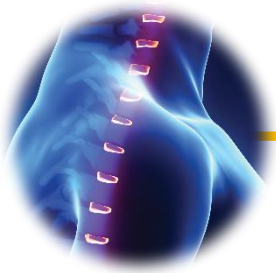

SURGICAL TECHNIQUE

PRECISION SPINE

SLIMPLICITY®

ANTERIOR CERVICAL PLATING SYSTEM

PRECISION SPINE®

Discover the Difference

Made in the USA

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PRECISION SPINE
SLIMPLICITY®
ANTERIOR CERVICAL PLATING SYSTEM

Slimplicity® Anterior Cervical Plate System

OVERVIEW

The Slimplicity® Anterior Cervical Plate System offers one of the slimmest plates available with an easy to use locking mechanism that facilitates visual locking confirmation.

Large graft windows have been incorporated to provide unimpeded graft site and end plate visualization. The large array of variable and fixed screw options accommodate semi-constrained, constrained and hybrid philosophies, while the plates are pre-contoured to address varying patient anatomy in single and multi-level constructs.

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: 120mm

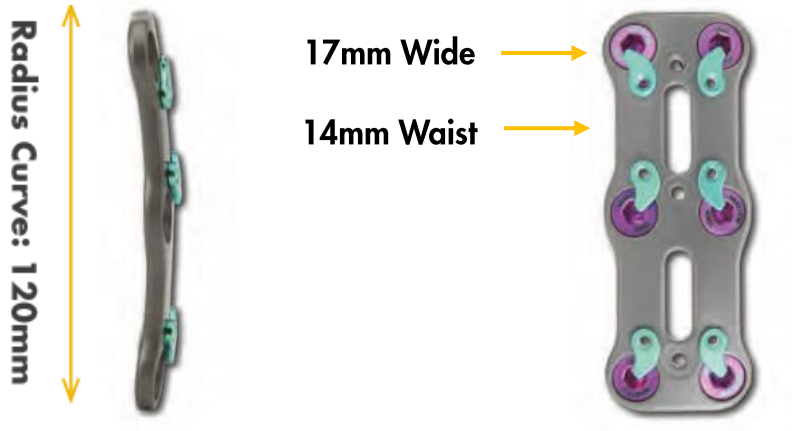


PLATE SIZES

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

Level 1 Lengths
18mm*
20mm
22mm
24mm
26mm
28mm
30mm
32mm
34mm*

Level 2 Lengths
33mm*
35mm*
37mm
40mm
43mm
46mm
49mm
52mm
55mm

Level 3 Lengths
51mm*
54mm
57mm
60mm
63mm
66mm
69mm
72mm
75mm

Level 4 Lengths
65mm*
69mm
73mm
77mm
81mm
85mm
89mm

FIXED & VARIABLE BONE SCREW SIZES

- Hex 2.5mm

4.0mm Diameter

Lengths
12mm
14mm
16mm
18mm

4.5mm Diameter

Lengths
12mm
14mm
16mm
18mm

FIXATION PIN

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

*By Request

PRECISION SPINE®

SYSTEM FEATURES

VARIABLE SCREW ANGULATION

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

4.0mm - 20˚

4.5mm - 14˚

FIXED SCREW ANGULATION

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

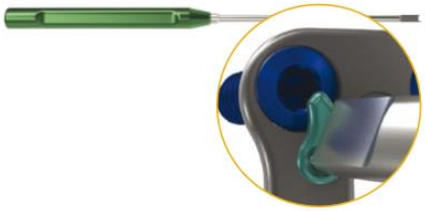
PLATE BENDER

Kyphosis

Lordosis

LOCKING TOOL

Lock/Unlock Tool



Dual Locking Tool

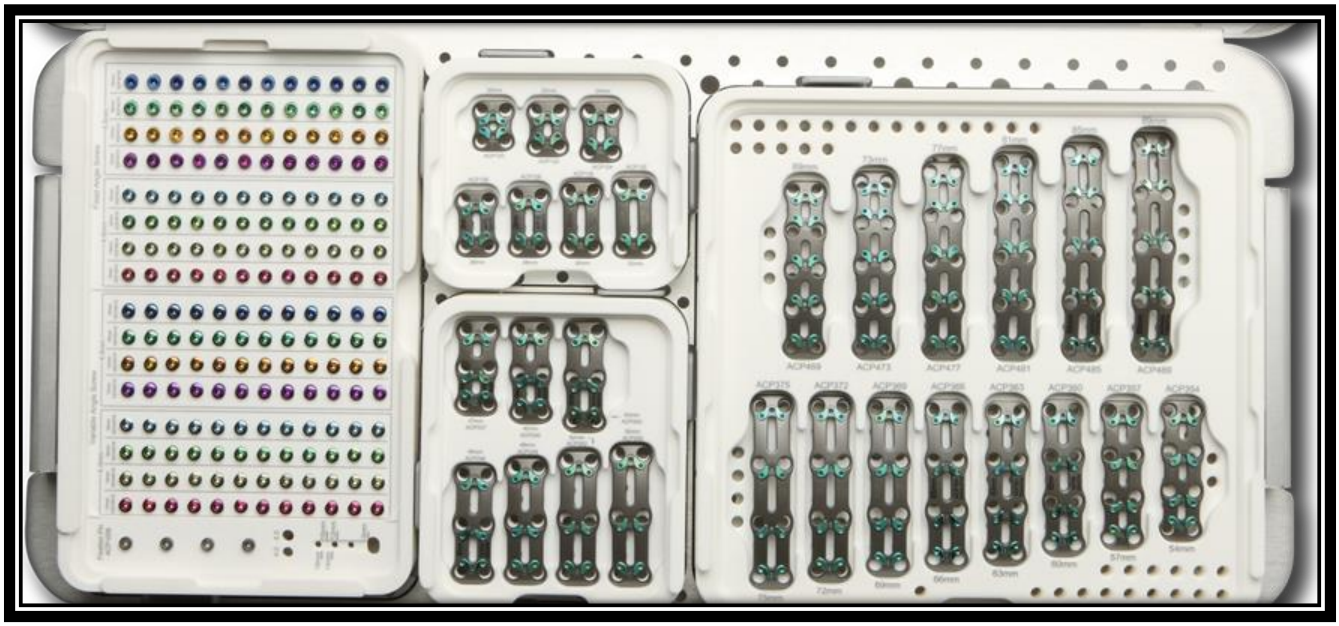
DRILL GUIDE (FIXED & VARIABLE)

Fixed

Variable

IMPLANTS – TOP TRAY

TRAY NUMBER 21-1015-CA



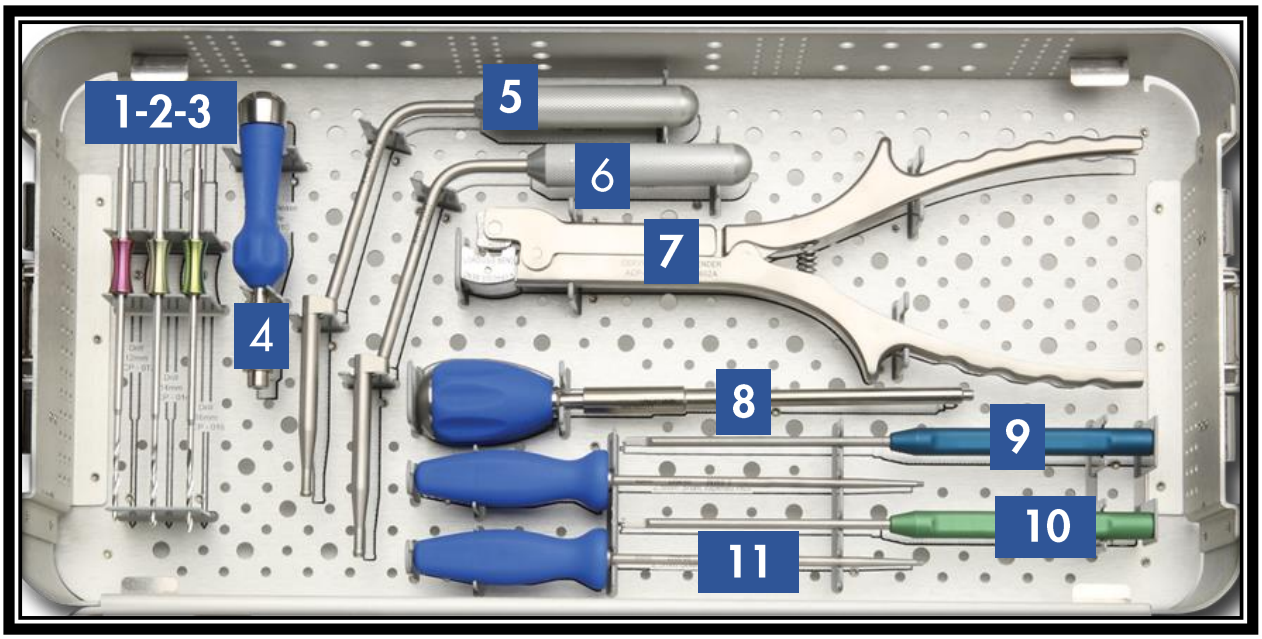
Item No.	Description	Qty
SDF4012	4.0mm x 12mm SD Fixed Screw	12
SDF4014	4.0mm x 14mm SD Fixed Screw	12
SDF4016	4.0mm x 16mm SD Fixed Screw	12
SDF4018	4.0mm x 18mm SD Fixed Screw	12
SDF4512	4.5mm x 12mm SD Fixed Screw	12
SDF4514	4.5mm x 14mm SD Fixed Screw	12
SDF4516	4.5mm x 16mm SD Fixed Screw	12
SDF4518	4.5mm x 18mm SD Fixed Screw	12
SDV4012	4.0mm x 12mm SD Variable Screw	12
SDV4014	4.0mm x 14mm SD Variable Screw	12
SDV4016	4.0mm x 16mm SD Variable Screw	12
SDV4018	4.0mm x 18mm SD Variable Screw	12
SDV4512	4.5mm x 12mm SD Variable Screw	12
SDV4514	4.5mm x 14mm SD Variable Screw	12
SDV4516	4.5mm x 16mm SD Variable Screw	12
SDV4518	4.5mm x 18mm SD Variable Screw	12
ACP-009	ACP Fixation Pin, 2.5mm Hex	4

Item No.	Description	Qty
ACP120	Anterior Cervical Plate, 1-Level, 20mm	1
ACP122	Anterior Cervical Plate, 1-Level, 22mm	1
ACP124	Anterior Cervical Plate, 1-Level, 24mm	1
ACP126	Anterior Cervical Plate, 1-Level, 26mm	1
ACP128	Anterior Cervical Plate, 1-Level, 28mm	1
ACP130	Anterior Cervical Plate, 1-Level, 30mm	1
ACP132	Anterior Cervical Plate, 1-Level, 32mm	1
ACP237	Anterior Cervical Plate, 2-Level, 37mm	1
ACP240	Anterior Cervical Plate, 2-Level, 40mm	1
ACP243	Anterior Cervical Plate, 2-Level, 43mm	1
ACP246	Anterior Cervical Plate, 2-Level, 46mm	1
ACP249	Anterior Cervical Plate, 2-Level, 49mm	1
ACP252	Anterior Cervical Plate, 2-Level, 52mm	1
ACP255	Anterior Cervical Plate, 2-Level, 55mm	1
ACP354	Anterior Cervical Plate, 3-Level, 54mm	1
ACP357	Anterior Cervical Plate, 3-Level, 57mm	1
ACP360	Anterior Cervical Plate, 3-Level, 60mm	1
ACP363	Anterior Cervical Plate, 3-Level, 63mm	1
ACP366	Anterior Cervical Plate, 3-Level, 66mm	1
ACP369	Anterior Cervical Plate, 3-Level, 69mm	1
ACP372	Anterior Cervical Plate, 3-Level, 72mm	1
ACP375	Anterior Cervical Plate, 3-Level, 75mm	1
ACP469	Anterior Cervical Plate, 4-Level, 69mm	1
ACP473	Anterior Cervical Plate, 4-Level, 73mm	1
ACP477	Anterior Cervical Plate, 4-Level, 77mm	1
ACP481	Anterior Cervical Plate, 4-Level, 81mm	1
ACP485	Anterior Cervical Plate, 4-Level, 85mm	1
ACP489	Anterior Cervical Plate, 4-Level, 89mm	1

* Please see Page 4 for additional by request plate sizes

INSTRUMENTS – BOTTOM TRAY

TRAY NUMBER 21-1015-CA



#	Item No.	Description	Qty
1	ACP-012	ACP Drill – 3mm x 12mm	1
2	ACP-014	ACP Drill – 3mm x 14mm	1
3	ACP-016	ACP Drill – 3mm x 16mm	1
4	04-9024	ACP Straight Handle	1
5	ACP-005V	ACP Variable Drill Guide	1
6	ACP-005F	ACP Fixed Drill Guide	1
7	ACP-003	ACP Plate Bender	1
8	ACP-006	ACP Bone Awl (2.3mm x 10mm)	1
9	00-9021	ACP Locking Tool	1
10	00-9023	ACP Lock/Unlock Tool	1
11	00-9027	ACP 2.5mm Hex Driver	2

SURGICAL TECHNIQUE

1 PATIENT POSITIONING AND APPROACH

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 (Figure 1), it is important to know that the length of the Plate is based on the distance between the ends of the Plate. The Plate should not extend over the adjacent disc spaces.

Figure 1

3 PLATE CONTOURING

The Slimplicity® Anterior Cervical Plate is pre-contoured with lordotic curvature to minimize intraoperative contouring (Figure 2). If the lordotic curvature of the plate needs to be modified, the Plate Bender (ACP-003) may be used for contouring.

The Plate should not be contoured through the locking mechanism as it could become damaged (Figure 2a).

Figure 2

Figure 2a

4 PLATE POSITIONING

Position the Plate over the vertebral bodies to be instrumented. Confirm the Plate is properly aligned in mediolateral and caudocranial position (Figure 3).

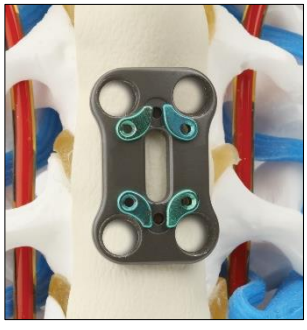


Figure 3

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

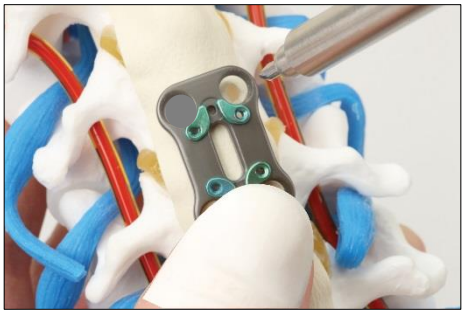


Figure 6

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 (ACP-012, 014 or 016) can be used to create the screw hole.

Securely 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 and 7a).

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

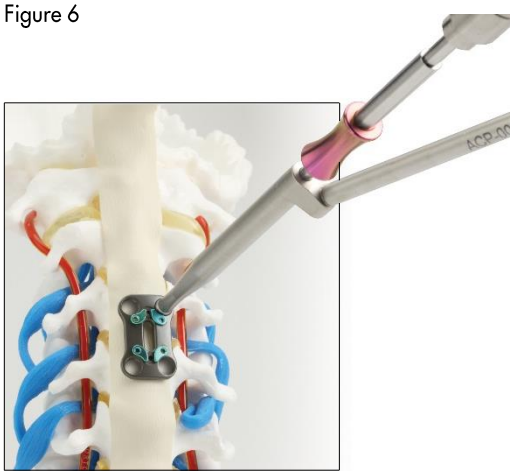


Figure 7

Figure 7a

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.

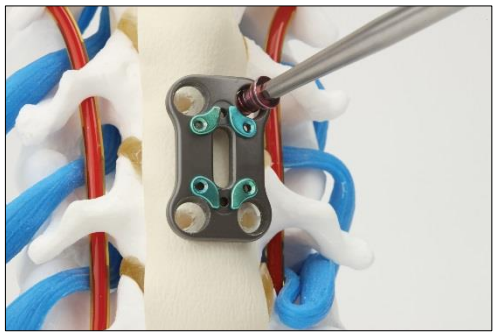


Figure 8

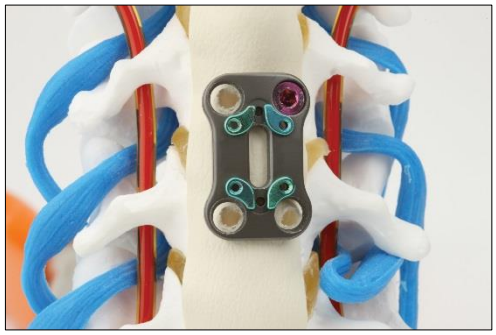


Figure 9

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 green 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 green rivets individually. Turn the rivet until it is fully engaged and covering the bone screw (Figure 11).

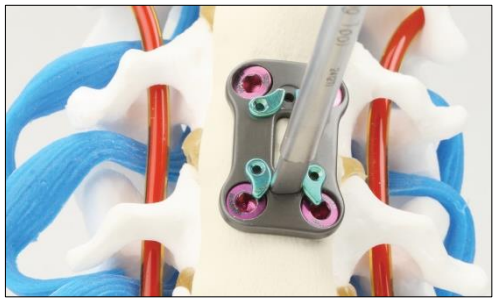


Figure 10

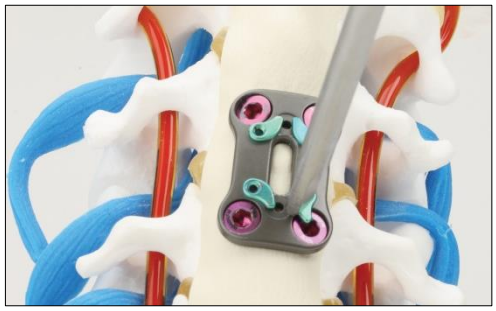


Figure 11

SURGICAL TECHNIQUE

9 CLOSURE

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

The Slimplicity® Anterior Cervical Plate System surgical technique is a general guide for instrumentation. The surgeon should be familiar with anterior cervical fusion.

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 **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.

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

PRECAUTIONS
The **Slimplicity** 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 **Slimplicity** 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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