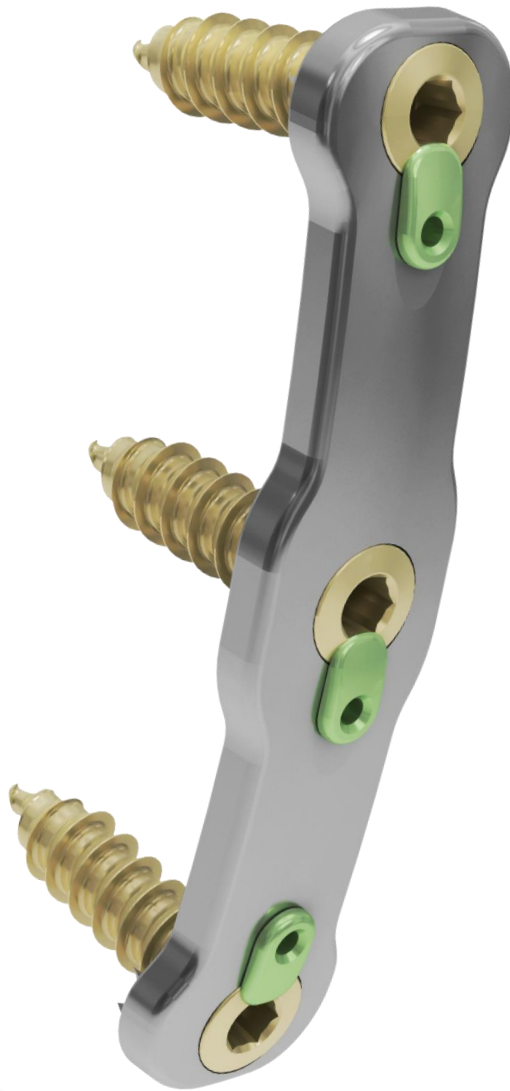


SURGICAL TECHNIQUE



PRECISION  SPINE® SOLO
SLIMPLICITY®
ANTERIOR CERVICAL PLATING SYSTEM

TABLE OF CONTENTS

Slimplicity® SOLO Anterior Cervical Plating System

OVERVIEW	3
PLATE OPTIONS	4
SCREW OPTIONS	4
TRAY IMAGES & CONTENTS	5
<i>Implants</i>	<i>5</i>
<i>Instruments</i>	<i>6</i>
SURGICAL TECHNIQUE	7
<i>Patient Positioning</i>	<i>7</i>
<i>Plate Selection</i>	<i>7</i>
<i>Plate Contouring</i>	<i>7</i>
<i>Plate Positioning</i>	<i>8</i>
<i>Temporary Pin Placement</i>	<i>8</i>
<i>Screw Preparation</i>	<i>9</i>
<i>Screw Insertion</i>	<i>10</i>
<i>Screw Removal</i>	<i>11</i>
<i>Closure</i>	<i>11</i>
ORDERING INFORMATION	12
INDICATIONS, CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS	13

Slimplicity® SOLO OVERVIEW

The Slimplicity® Solo Anterior Cervical Plate System is composed of the following components: Plates with rivets pre-assembled, and bone screws, which can be assembled with associated instruments to provide immobilization of the cervical spine. All implantable components are made from medical grade titanium or titanium alloy described by such standards as ASTM F136 or ISO 5832-3. The products are supplied clean and "NON-STERILE".

PRODUCT HIGHLIGHTS

- Ultra-slim Low Profile Plate minimizes tissue disruption and post-op discomfort
- Intuitive Single Step Locking Mechanism assists secure application
- Strategically Positioned Cleats increase torsional stability
- Fixed and Variable Screw Options assists in optimal screw placement
- Variable Screws have 10° of Angulation to optimize fixation

INDICATIONS

The Slimplicity Solo Anterior Cervical Plate System is intended for anterior cervical fixation to the cervical spine C2 – C7 for the following indications: degenerative disc disease (DDD) (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures, tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

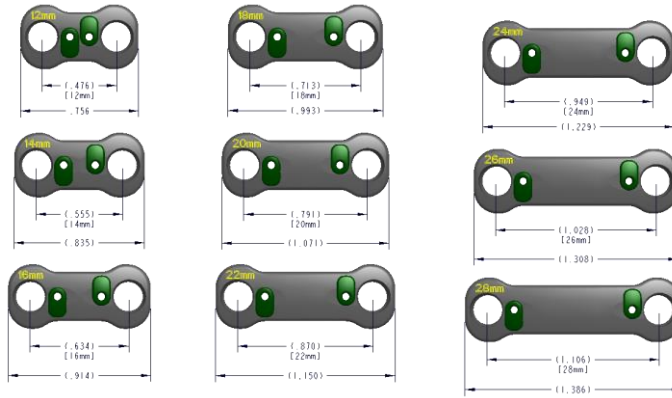
Please refer to package insert (LBL-IFU-014) for complete system description, indications and warnings.



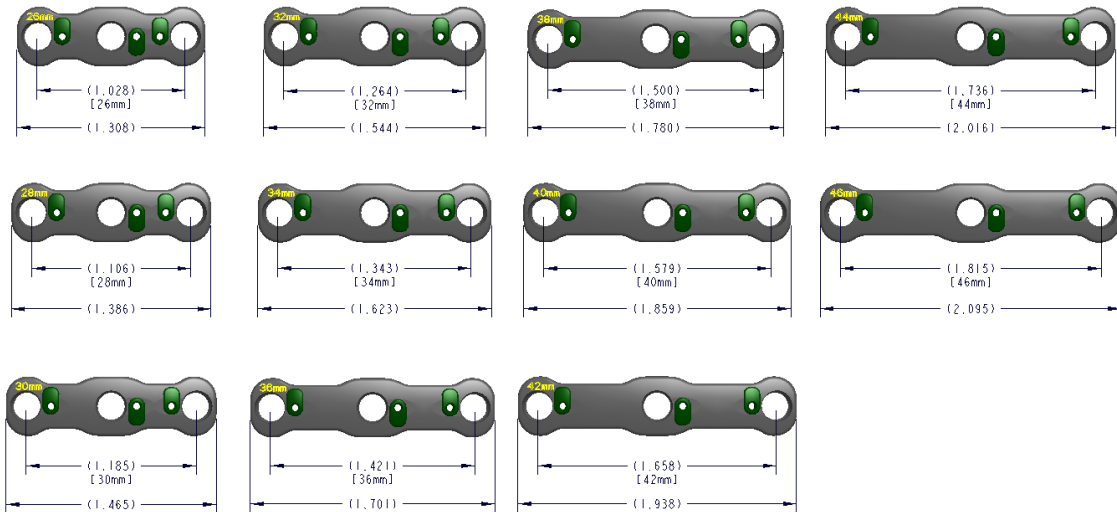
PLATE OPTIONS

- Size Options (Measurement is from hole to hole)
- Add 7mm to plate length for end to end plate length

1 Level

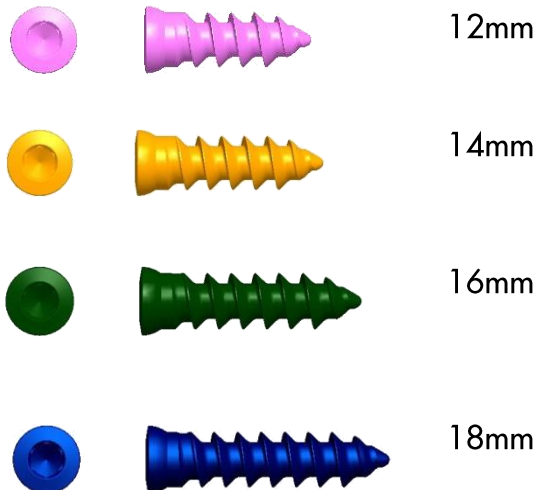


2 Level



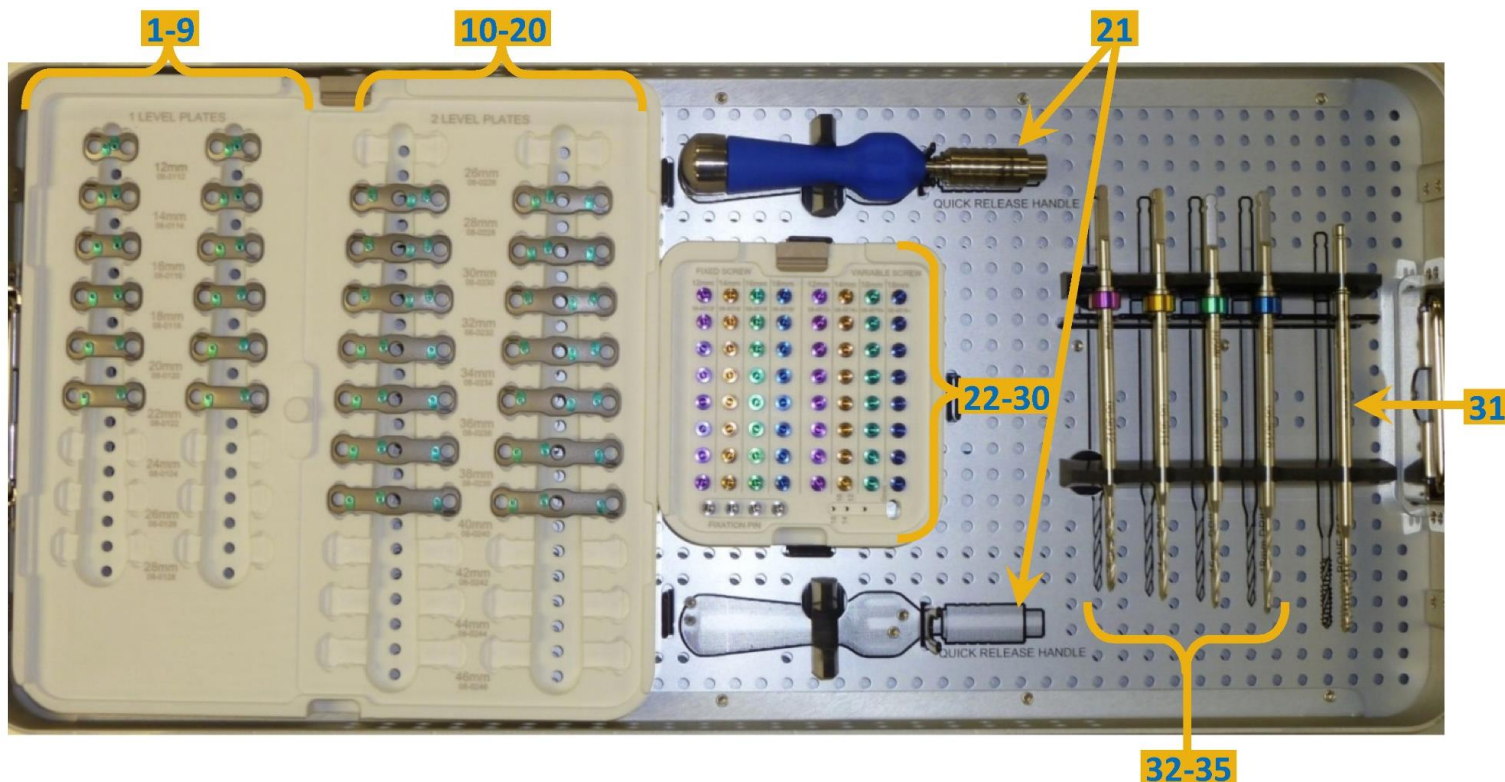
SCREW OPTIONS

- 2.5mm Hex Drive
- Available in Lengths of 12mm, 14mm, 16mm, and 18mm
- 4.5mm & 5.0mm Variable or Fixed Screw Options
- Self Drilling Tip
- Color Anodized for Length Identification



IMPLANTS – TOP TRAY

TRAY NUMBER 21-1080-CA



#	Part No.	Description	Qty
1.	08-0112	Simplicity SOLO, 1-Level 12mm	2
2.	08-0114	Simplicity SOLO, 1-Level, 14mm	2
3.	08-0116	Simplicity SOLO, 1-Level, 16mm	2
4.	08-0118	Simplicity SOLO, 1-Level, 18mm	2
5.	08-0120	Simplicity SOLO, 1-Level, 20mm	2
6.	08-0122	Simplicity SOLO, 1-Level, 22mm	2
7.	08-0124	Simplicity SOLO, 1-Level, 24mm	0*
8.	08-0126	Simplicity SOLO, 1-Level, 26mm	0*
9.	08-0128	Simplicity SOLO, 1-Level, 28mm	0*
10.	08-0226	Simplicity SOLO, 2-Level, 26mm	0*
11.	08-0228	Simplicity SOLO, 2-Level, 28mm	2
12.	08-0230	Simplicity SOLO, 2-Level, 30mm	2
13.	08-0232	Simplicity SOLO, 2-Level, 32mm	2
14.	08-0234	Simplicity SOLO, 2-Level, 34mm	2
15.	08-0236	Simplicity SOLO, 2-Level, 36mm	2
16.	08-0238	Simplicity SOLO, 2-Level, 38mm	2
17.	08-0240	Simplicity SOLO, 2-Level, 40mm	2
18.	08-0242	Simplicity SOLO, 2-Level, 42mm	0*
19.	08-0244	Simplicity SOLO, 2-Level, 44mm	0*
20.	08-0246	Simplicity SOLO, 2-Level, 46mm	0*
21.	04-9024	Universal Straight Handle, AO	2
22.	08-4512f	4.5mm x 12mm Self-Drilling Fixed Screws	8
23.	08-4514f	4.5mm x 14mm Self-Drilling Fixed Screws	8
24.	08-4516f	4.5mm x 16mm Self-Drilling Fixed Screws	8
25.	08-4518f	4.5mm x 18mm Self-Drilling Fixed Screws	8
26.	08-4512v	4.5mm x 12mm Self-Drilling Variable Screws	8
27.	08-4514v	4.5mm x 14mm Self-Drilling Variable Screws	8
28.	08-4516v	4.5mm x 16mm Self-Drilling Variable Screws	8
29.	08-4518v	4.5mm x 18mm Self-Drilling Variable Screws	8

#	Part No.	Description	Qty
30.	ACP-009	Fixation Pin 2.5mm Hex (2mm x 10mm)	4
31.	08-9003	4.0mm Bone Tap	1
32.	08-9012	2.7mm x 12mm Drill	1
33.	08-9014	2.7mm x 14mm Drill	1
34.	08-9016	2.7mm x 16mm Drill	1
35.	08-9018	2.7mm x 18mm Drill	1

CONTAINED IN TRAY BUT NOT VISIBLE IN IMAGE ABOVE

Part No.	Description	Qty
08-5012f	5.0mm x 12mm Self-Drilling Fixed Screws	8
08-5014f	5.0mm x 14mm Self-Drilling Fixed Screws	8
08-5016f	5.0mm x 16mm Self-Drilling Fixed Screws	8
08-5018f	5.0mm x 18mm Self-Drilling Fixed Screws	8
08-5012v	5.0mm x 12mm Self-Drilling Variable Screws	8
08-5014v	5.0mm x 14mm Self-Drilling Variable Screws	8
08-5016v	5.0mm x 16mm Self-Drilling Variable Screws	8
08-5018v	5.0mm x 18mm Self-Drilling Variable Screws	8

* Special Order

INSTRUMENTS – BOTTOM TRAY

TRAY NUMBER 21-1080-CA



#	Part No.	Description	Qty
1.	08-9026	Variable Drill Guide	1
2.	08-9025	Fixed Drill Guide	1
3.	08-9020	All-in-One Plate Holder	1
4.	08-9021	Depth Gauge	1
5.	08-9001	Lock/Unlock Tool	2
6.	08-9024	2.5mm Screw Driver	2
7.	08-9002	Plate Bender	1
8.	08-9004	Bone Awl (2.7mm x 10mm)	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 proximal and distal center holes of the plate. The plate should not extend over the adjacent disc spaces.



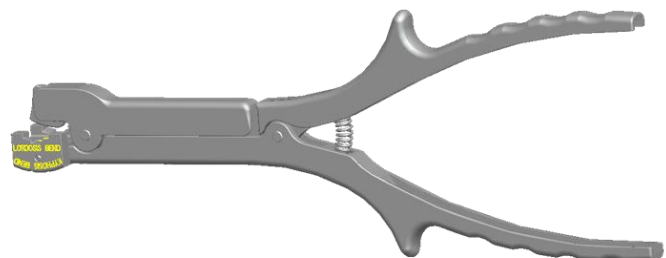
Plate size based on center hole to center hole distance

3

PLATE CONTOURING

The Simplicity® Solo Anterior Cervical Plate is pre-contoured with lordotic curvature to minimize intra-operative contouring. If the lordotic curvature of the plate needs to be modified, the Plate Bender (08-9002) may be used for contouring.

The plate should not be contoured through the locking mechanism as it could become damaged.



SURGICAL TECHNIQUE

4

PLATE POSITIONING

Position the plate over the vertebral bodies to be instrumented using the Plate Holder (08-9020) (Figure 1).

Plate alignment pin inserts into locking tab hole (Figure 2). Groove provides spring clamping load.

Press to rotate handle in 45° increments (Figure 3).

Confirm the plate is properly aligned in mediolateral and caudocranial position.



Figure 1



Figure 2



Figure 3

5

TEMPORARY PIN PLACEMENT

Plate position can be temporarily fixed using the Fixation Pin (ACP-009) (Figure 4) and the Screw Driver (08-9024) (Figure 5). The temporary Pin can be inserted through any of the screw holes in the plate and provides stability during screw placement.



Figure 4



Figure 5

SURGICAL TECHNIQUE

6

SCREW PREPARATION

In preparing the screw hole, the Awl (08-9004) may be used to create a pilot hole. The Awl can be placed through the Plate Holder and in the desired screw hole position with up to 5° of angulation (10° total) (Figure 6). Press and rotate the Awl through the plate and into the bone until the depth has bottomed out against the plate (Figure 6A). The Awl will provide a pilot hole up to a depth of 10mm.

Either the Plate Holder or the Drill Guide, Fixed (08-9025) or Variable (08-9026) depending on screw choice, and appropriate Drill can also be used to create the screw hole.

If using the Drill Guide, 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, 16 and 18mm lengths. When used in conjunction with the drill guides, there is a positive stop on the drill bits to prevent over-drilling.

The colors of the drill depth stop correspond to their respective screw length colors.



Figure 6

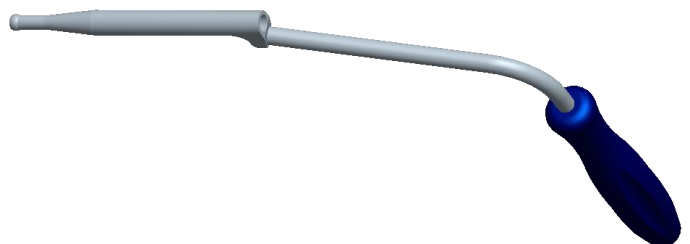


Figure 6A

Fixed Drill Guide
P/N 08-9025



Variable Drill Guide
P/N 08-9026



Color-Coded
Depth Stop

SURGICAL TECHNIQUE

7

SCREW INSERTION

The self-drilling bone screws are available in 12, 14, 16, and 18mm lengths in 4.5mm and 5.0mm diameters and in a fixed and variable head design.

The Bone Screw Driver (08-9024) (Figures 7, 7A) 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 vertebra to be instrumented until it rests firmly and flush inside the plate screw hole. This will enable the locking mechanism to be engaged. Repeat the screw insertion procedure for each screw hole position within the plate.

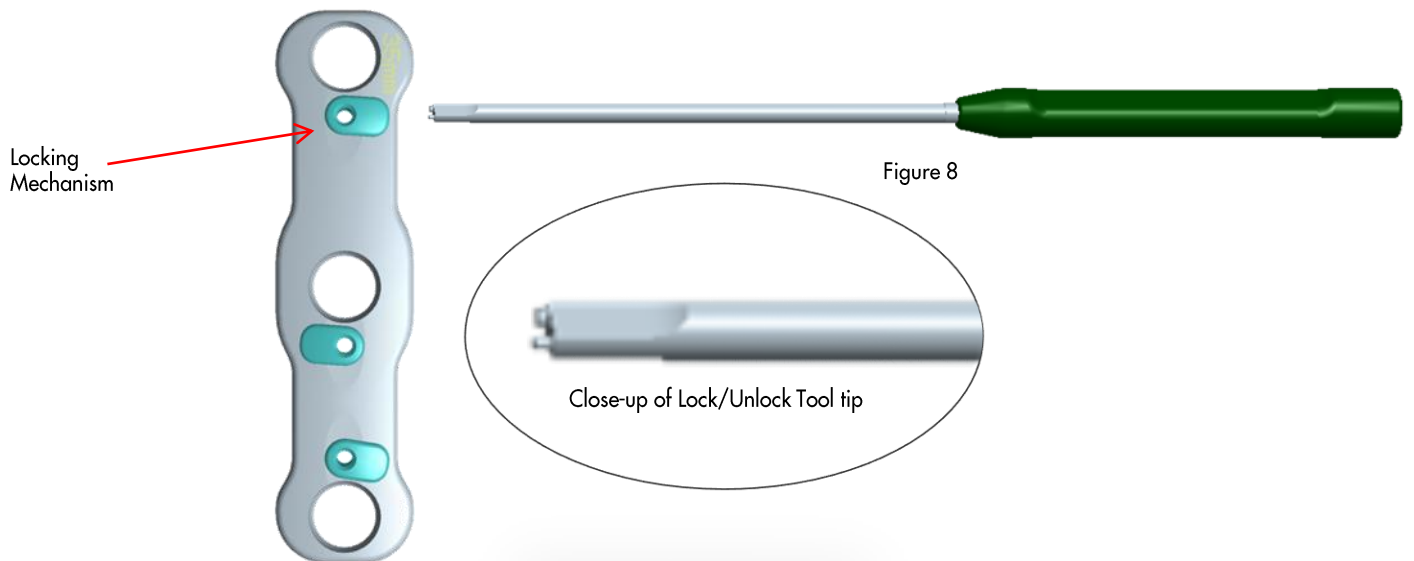
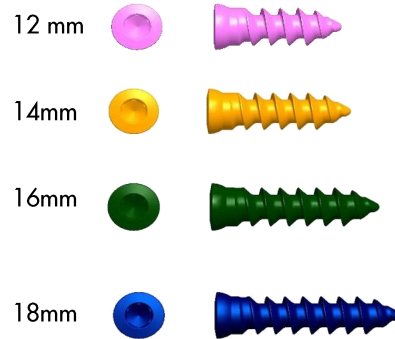
Once the bone screws have been properly seated, positioned, and tightened, the locking mechanism can be rotated to secure the seated bone screws within the construct. Securely insert the Lock/Unlock Tool (08-9001) (Figure 8) into the locking mechanism and rotate until the rivet covers the screw head. Do not rotate rivets more than once as this will weaken the locking mechanism. Secure all bone screws with the locking mechanism.



Figure 7



Figure 7A



SURGICAL TECHNIQUE

8

SCREW REMOVAL

If needed, the bone screws can be removed using the Lock/Unlock Tool (08-9001) (Figure 9). The locking mechanism is rotated back to its unlocked position. Once the rivet has been rotated the screws can be removed from the construct.

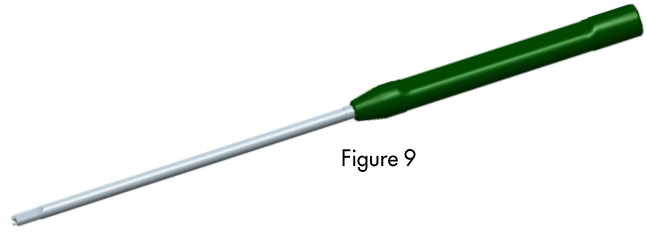


Figure 9

9

CLOSURE

After visual and radiographic confirmation of plate, screw, and bone graft placement, the closure process can proceed.

ORDERING INFORMATION

Implants

Part No.	Description
08-0112	Slimplicity SOLO, 1-Level, 12mm
08-0114	Slimplicity SOLO, 1-Level, 14mm
08-0116	Slimplicity SOLO, 1-Level, 16mm
08-0118	Slimplicity SOLO, 1-Level, 18mm
08-0120	Slimplicity SOLO, 1-Level, 20mm
08-0122	Slimplicity SOLO, 1-Level, 22mm
08-0124	Slimplicity SOLO, 1-Level, 24mm*
08-0126	Slimplicity SOLO, 1-Level, 26mm*
08-0128	Slimplicity SOLO, 1-Level, 28mm*
08-0226	Slimplicity SOLO, 2-Level, 26mm*
08-0228	Slimplicity SOLO, 2-Level, 28mm
08-0230	Slimplicity SOLO, 2-Level, 30mm
08-0232	Slimplicity SOLO, 2-Level, 32mm
08-0234	Slimplicity SOLO, 2-Level, 34mm
08-0236	Slimplicity SOLO, 2-Level, 36mm
08-0238	Slimplicity SOLO, 2-Level, 38mm
08-0240	Slimplicity SOLO, 2-Level, 40mm
08-0242	Slimplicity SOLO, 2-Level, 42mm*
08-0244	Slimplicity SOLO, 2-Level, 44mm*
08-0246	Slimplicity SOLO, 2-Level, 46mm*
04-9024	Universal Straight Handle, AO
08-4512f	4.5mm x 12mm Self-Drilling Fixed Screw
08-4514f	4.5mm x 14mm Self-Drilling Fixed Screw
08-4516f	4.5mm x 16mm Self-Drilling Fixed Screw
08-4518f	4.5mm x 18mm Self-Drilling Fixed Screw
08-4512v	4.5mm x 12mm Self-Drilling Variable Screw
08-4514v	4.5mm x 14mm Self-Drilling Variable Screw
08-4516v	4.5mm x 16mm Self-Drilling Variable Screw
08-4518v	4.5mm x 18mm Self-Drilling Variable Screw
08-5012f	5.0mm x 12mm Self-Drilling Fixed Screws
08-5014f	5.0mm x 14mm Self-Drilling Fixed Screws
08-5016f	5.0mm x 16mm Self-Drilling Fixed Screws
08-5018f	5.0mm x 18mm Self-Drilling Fixed Screws
08-5012v	5.0mm x 12mm Self-Drilling Variable Screw
08-5014v	5.0mm x 14mm Self-Drilling Variable Screw
08-5016v	5.0mm x 16mm Self-Drilling Variable Screw
08-5018v	5.0mm x 18mm Self-Drilling Variable Screw

Instruments

Part No.	Description
08-9001	Lock/Unlock Tool
08-9002	Plate Bender
08-9003	4.0mm Bone Tap
08-9004	Bone Awl (2.7mm x 10mm)
08-9012	2.7mm x 12mm Drill
08-9014	2.7mm x 14mm Drill
08-9016	2.7mm x 16mm Drill
08-9018	2.7mm x 18mm Drill
08-9020	All-in-One Plate Holder
08-9021	Depth Gauge
08-9024	2.5mm Hex Screw Driver
08-9025	Fixed Drill Guide
08-9026	Variable Drill Guide
ACP-009	Fixation Pin, 2.5mm Hex, 2mm x 10mm

* Special Order

Indications, Contraindications, Warnings, and Precautions

INDICATIONS:

The **Simplicity Solo Anterior Cervical Plate System** is intended for anterior cervical fixation to the cervical spine C2-C7 for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

PRECAUTIONS:

Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fixation device. The implantation of the intervertebral body fixation device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

CONTRAINDICATIONS:

The **Simplicity Solo 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.

Potential adverse effects include, but are not limited to, the following:

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. 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 for 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 rivets 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.



Precision Spine, Inc.

2050 Executive Drive, Pearl, MS 39208

Customer Service: 1.888.241.4773

Phone: 601.420.4244

Toll Free: 877.780.4370

Fax: 601.420.5501

www.precisionspineinc.com

Caution: Federal (USA) law restricts these devices to sale by, or on the order of, a physician.
Simplicity® and Precision Spine® are trademarks of Precision Spine, Inc.
Copyright 2020 Precision Spine, Inc. All rights reserved. P/N LBL-STG-015 Rev. E 06/2020

CE 2797