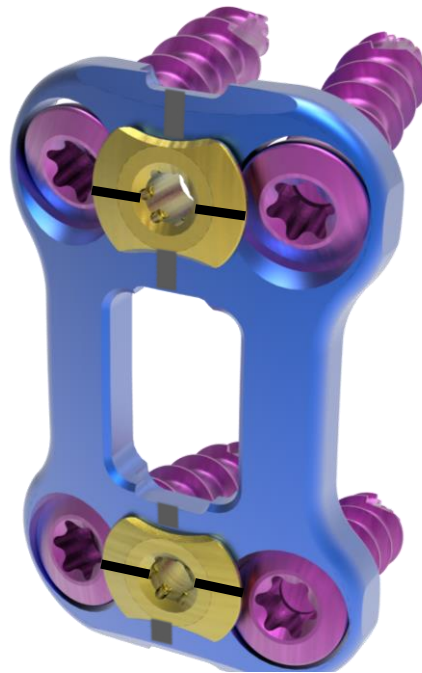


SURGICAL TECHNIQUE

PRECISION SPINE

SLIMPLICITY[®] HP

ANTERIOR CERVICAL PLATING SYSTEM



PRECISION SPINE[®]

Discover the Difference



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SYSTEM OVERVIEW

The Simplicity® HP ACP System offers simplified versatility to accommodate diverse patient anatomies and pathologies. Low profile constrained, semi-constrained, or hybrid constructs are achieved via fixed and variable angle screws.

- **Dual thread screws** maximize cortical and cancellous bone interface
- **One-step locking mechanism** provides tactile and visual confirmation
- **Alignment Markings** and **Large Graft Windows** for increased intra-operative visualization and positioning



INDICATIONS

The **Simplicity HP** 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; deformity (defined as kyphosis, lordosis, or scoliosis); pseudoarthrosis; and failed previous fusions.

SYSTEM FEATURES

PLATES

- **Low Profile** designed to minimize tissue disruption and potential post-op discomfort
- **Visual and Tactile One-Step Locking Mechanism** for increased confidence
- **Alignment Markings** and **Large Graft Windows** for increased intra-operative visualization and positioning

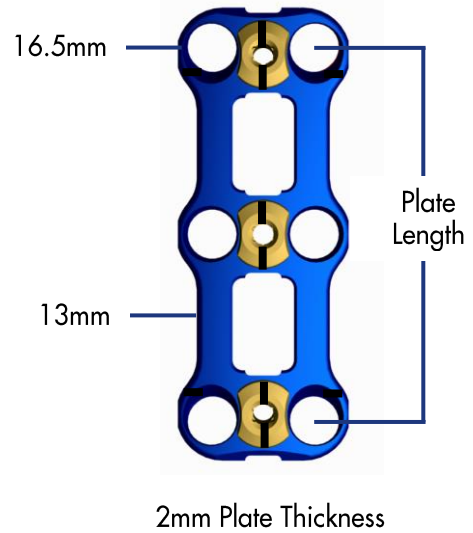


Plate Sizes* (measured center hole to center hole)

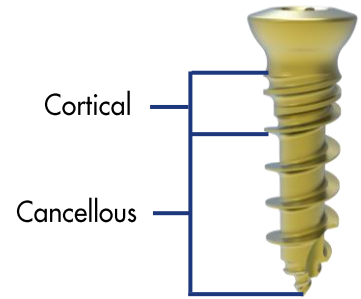
1 Level	2 Level	3 Level	4 Level
10mm	24mm	43mm	60mm
12mm	26mm	46mm	64mm
14mm	28mm	49mm	68mm
16mm	30mm	52mm	72mm
18mm	32mm	55mm	76mm
20mm	34mm	58mm	80mm
22mm	36mm	61mm	
24mm	38mm		
	40mm		
	42mm		
	44mm		

*Add 8mm to plate length for end to end plate length

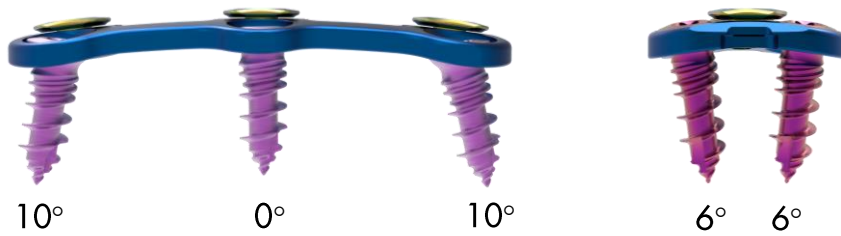
SYSTEM FEATURES

SCREWS

- **Fixed and Variable Screws** to accommodate diverse patient anatomies and pathologies
- **Cortical Cancellous Threads** to maximize bone-screw interface
- **T10 Interface**

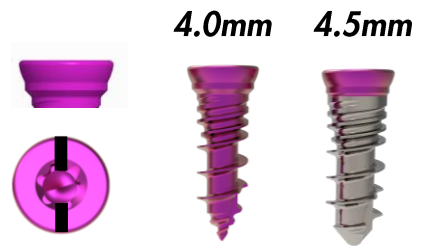


Fixed Angulation

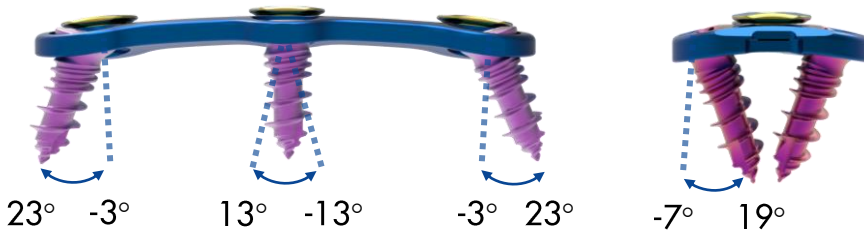


Fixed Screw

Black Line on Screw Head



Variable Angulation



Variable Screw



Screw Lengths

12mm
Magenta

14mm
Gold

16mm
Green

18mm
Dark Blue









SET CONFIGURATION 65-BK-0101

CERVICAL PLATES*

Item No.	Description	Qty/Set
1 LEVEL		
65-CA-1010	1 Level - 10mm	2
65-CA-1012	1 Level - 12mm	2
65-CA-1014	1 Level - 14mm	2
65-CA-1016	1 Level - 16mm	2
65-CA-1018	1 Level - 18mm	2
65-CA-1020	1 Level - 20mm	2
65-CA-1022	1 Level - 22mm	2
65-CA-1024	1 Level - 24mm	2
2 LEVEL		
65-CA-2024	2 Level - 24mm	2
65-CA-2026	2 Level - 26mm	2
65-CA-2028	2 Level - 28mm	2
65-CA-2030	2 Level - 30mm	2
65-CA-2032	2 Level - 32mm	2
65-CA-2034	2 Level - 34mm	2
65-CA-2036	2 Level - 36mm	2
65-CA-2038	2 Level - 38mm	2
65-CA-2040	2 Level - 40mm	2
65-CA-2042	2 Level - 42mm	2
65-CA-2044	2 Level - 44mm	2

*Plate Sizes measured center hole to center hole
Add 8mm to plate length for end to end plate length

BONES SCREWS

Item No.	Description	Qty/Set
4.0mm Self-Drilling FIXED SCREWS		
65-DF-4012	4.0mm x 12mm SD Fix Screw	12 
65-DF-4014	4.0mm x 14mm SD Fix Screw	12 
65-DF-4016	4.0mm x 16mm SD Fix Screw	12 
65-DF-4018	4.0mm x 18mm SD Fix Screw	12 
4.5mm Self-Tapping FIXED SCREWS		
65-TF-4512	4.5mm x 12mm ST Fix Screw	12 
65-TF-4514	4.5mm x 14mm ST Fix Screw	12 
65-TF-4516	4.5mm x 16mm ST Fix Screw	12 
65-TF-4518	4.5mm x 18mm ST Fix Screw	12 

Item No.	Description	Qty/Set
3 LEVEL		
65-CA-3043	3 Level - 43mm	2
65-CA-3046	3 Level - 46mm	2
65-CA-3049	3 Level - 49mm	2
65-CA-3052	3 Level - 52mm	2
65-CA-3055	3 Level - 55mm	2
65-CA-3058	3 Level - 58mm	2
65-CA-3061	3 Level - 61mm	2
4 LEVEL		
65-CA-4060	4 Level - 60mm	2
65-CA-4064	4 Level - 64mm	2
65-CA-4068	4 Level - 68mm	2
65-CA-4072	4 Level - 72mm	2
65-CA-4076	4 Level - 76mm	2
65-CA-4080	4 Level - 80mm	2

DISPOSABLES

Item No.	Description	Qty/Set
FIXATION PINS		
65-FS-2010	Fixation Pin, Locking Mechanism	4
65-FS-2510	Fixation Pin, Screw Hole	4

SET CONFIGURATION 65-BK-0101

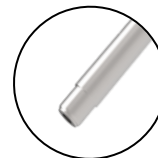
INSTRUMENTS

Item No.	Description	Qty/Set
55-CH-0001	AO Modular Handles	2
65-IN-0010	10° Fixed Angle Awl (2.3mm x 9mm)	1
65-IN-0020	Variable Angle Awl (2.3mm x 9mm)	1
65-IN-0030	10° Fixed Angle Drill Guide	1
65-IN-0033	Variable Angle Drill Guide	1
65-IN-0750	Locking Driver (GOLD)	2
65-IN-0600	Plate Bender	1
65-IN-0620	Plate Holder	1
65-IN-0730	Bone Screwdriver, T10 (SILVER)	2
65-SP-0512	AO Drill - 12mm x 2.3mm	1
65-SP-0514	AO Drill - 14mm x 2.3mm	1
65-SP-0516	AO Drill - 16mm x 2.3mm	1
65-SC-0100	Sterilization Tray	1

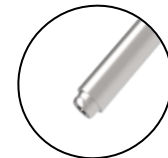


55-CH-0001
Modular Handle

AWLS 9mm depth

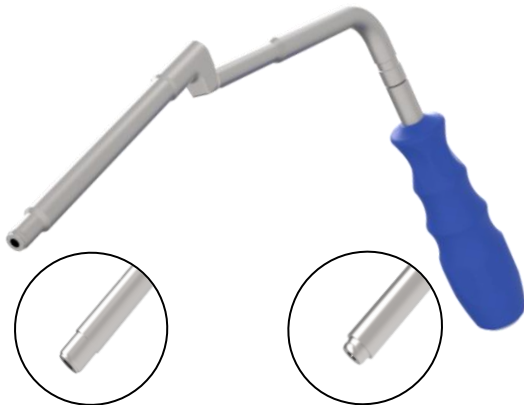


65-IN-0010
Fixed Angle Awl



65-IN-0020
Variable Angle Awl

DRILL GUIDES



65-IN-0030
Fixed Angle Drill Guide

65-IN-0033
Variable Angle Drill Guide



65-SP-0512
AO Drill - 12mm



65-SP-0514
AO Drill - 14mm



65-SP-0516
AO Drill - 16mm



65-IN-0730
Bone Screwdriver, T10



65-IN-0750
Locking Driver



65-IN-0600
Plate Bender



65-IN-0620
Plate Holder

IMPLANTS

PLATES

Part No.	Description
65-CA-4056	4 Level - 56mm

BONE SCREWS

Part No.	Description	
65-DF-4010	4.0mm x 10mm Self-Drilling Fixed Screw	
65-TF-4510	4.5mm x 10mm Self-Tapping Fixed Screw	
65-DV-4010	4.0mm x 10mm Self-Drilling Variable Screw	
65-TV-4510	4.5mm x 10mm Self-Tapping Variable Screw	



INSTRUMENTS

HANDLES

Part No.	Description
65-CH-0038	AO Modular Large Handle, 5 1/4"



65-CH-0038

DRILLS

Part No.	Description
65-SP-0510	AO Drill - 10mm x 2.3mm



65-SP-0510

DRILL, TAP, SCREW (DTS) GUIDES

Part No.	Description
65-IN-0035	Double Barrel DTS Guide - 10°, Small Handle, 3 1/2"
65-IN-0090	Double Barrel DTS Guide - 0°, Small Handle, 3 1/2"



65-IN-0035
10° DTS Guide

65-IN-0090
0° DTS Guide

DRIVERS

Part No.	Description
65-IN-0060	Locking Driver, T8 (GOLD)



65-IN-0060

LARGE HANDLE INSTRUMENT SET

Set No.	Description
65-BK-0102	5 1/4" Large Handle Implant and Instrument Set

TRAY LAYOUT 65-BK-0101

IMPLANTS

4.5mm Screw Caddy

4.5mm Variable Screws
4.5mm Fixed Screws

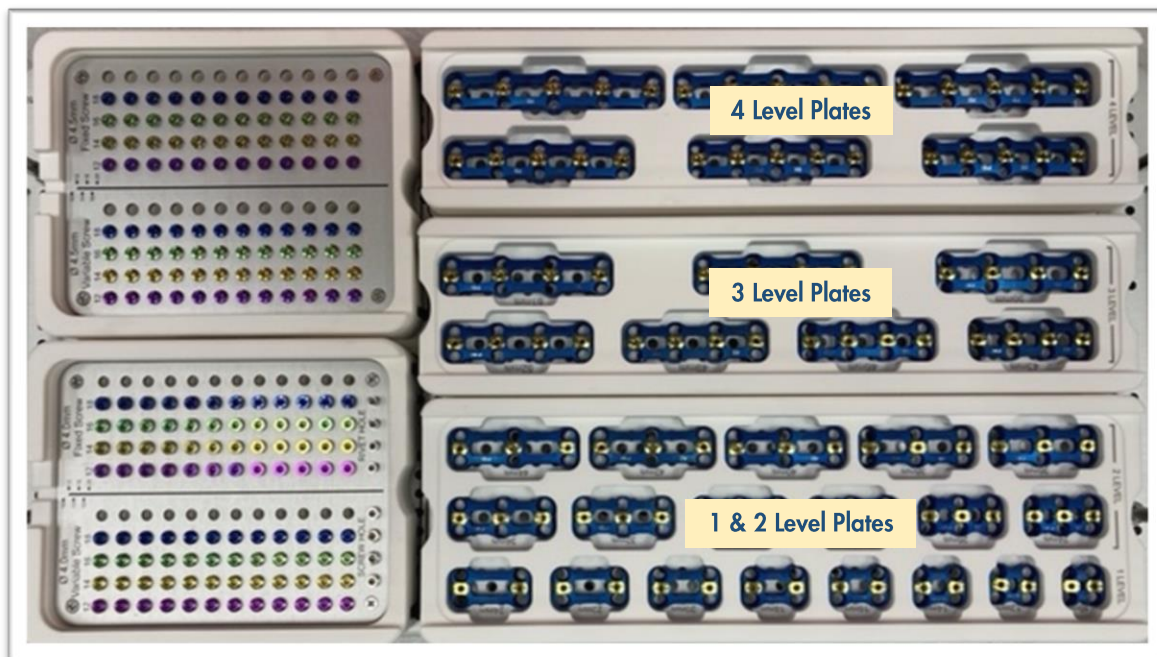
Extra Screw Hole Slots

4.0mm Screw Caddy

4.0mm Variable Screws
4.0mm Fixed Screws

Fixation Pins, Screw Hole
Fixation Pins, Locking Mech

Extra Screw Hole Slots

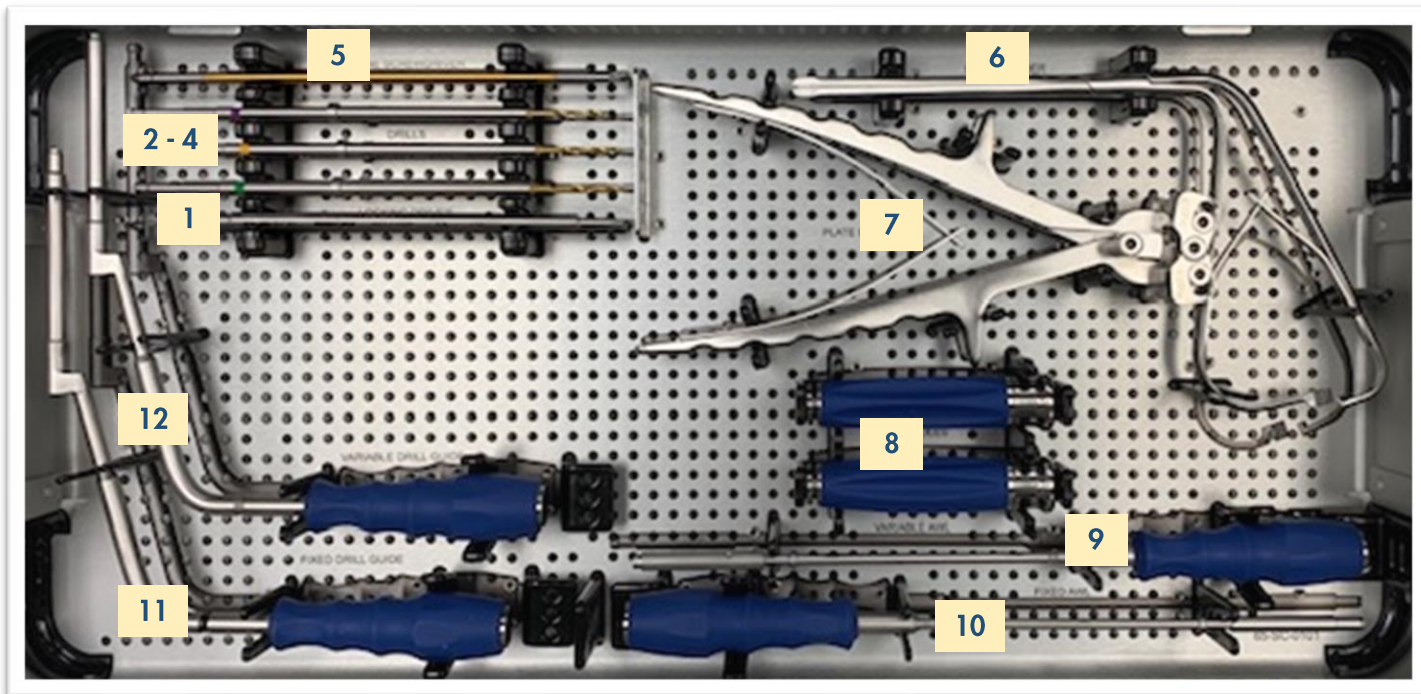


Item No.	Description	Qty/Set
1 LEVEL PLATES		
65-CA-1010	1 Level - 10mm	2
65-CA-1012	1 Level - 12mm	2
65-CA-1014	1 Level - 14mm	2
65-CA-1016	1 Level - 16mm	2
65-CA-1018	1 Level - 18mm	2
65-CA-1020	1 Level - 20mm	2
65-CA-1022	1 Level - 22mm	2
65-CA-1024	1 Level - 24mm	2
2 LEVEL PLATES		
65-CA-2024	2 Level - 24mm	2
65-CA-2026	2 Level - 26mm	2
65-CA-2028	2 Level - 28mm	2
65-CA-2030	2 Level - 30mm	2
65-CA-2032	2 Level - 32mm	2
65-CA-2034	2 Level - 34mm	2
65-CA-2036	2 Level - 36mm	2
65-CA-2038	2 Level - 38mm	2
65-CA-2040	2 Level - 40mm	2
65-CA-2042	2 Level - 42mm	2
65-CA-2044	2 Level - 44mm	2
4.0mm Self-Drilling FIXED SCREWS		
65-DF-4012	4.0mm x 12mm SD Fix Screw	12
65-DF-4014	4.0mm x 14mm SD Fix Screw	12
65-DF-4016	4.0mm x 16mm SD Fix Screw	12
65-DF-4018	4.0mm x 18mm SD Fix Screw	12
4.5mm Self-Tapping FIXED SCREWS		
65-TF-4512	4.5mm x 12mm ST Fix Screw	12
65-TF-4514	4.5mm x 14mm ST Fix Screw	12
65-TF-4516	4.5mm x 16mm ST Fix Screw	12
65-TF-4518	4.5mm x 18mm ST Fix Screw	12

Item No.	Description	Qty/Set
3 LEVEL PLATES		
65-CA-3043	3 Level - 43mm	2
65-CA-3046	3 Level - 46mm	2
65-CA-3049	3 Level - 49mm	2
65-CA-3052	3 Level - 52mm	2
65-CA-3055	3 Level - 55mm	2
65-CA-3058	3 Level - 58mm	2
65-CA-3061	3 Level - 61mm	2
4 LEVEL PLATES		
65-CA-4060	4 Level - 60mm	1
65-CA-4064	4 Level - 64mm	1
65-CA-4068	4 Level - 68mm	1
65-CA-4072	4 Level - 72mm	1
65-CA-4076	4 Level - 76mm	1
65-CA-4080	4 Level - 80mm	1
FIXATION PINS		
65-FS-2010	Fixation Pin, Locking Mechanism	4
65-FS-2510	Fixation Pin, Screw Hole	4
4.0mm Self-Drilling VARIABLE SCREWS		
65-DV-4012	4.0mm x 12mm SD Var Screw	12
65-DV-4014	4.0mm x 14mm SD Var Screw	12
65-DV-4016	4.0mm x 16mm SD Var Screw	12
65-DV-4018	4.0mm x 18mm SD Var Screw	12
4.5mm Self-Tapping VARIABLE SCREWS		
65-TV-4512	4.5mm x 12mm ST Var Screw	12
65-TV-4514	4.5mm x 14mm ST Var Screw	12
65-TV-4516	4.5mm x 16mm ST Var Screw	12
65-TV-4518	4.5mm x 18mm ST Var Screw	12

TRAY LAYOUT 65-BK-0101

INSTRUMENTS



Item No.	Description	Qty/Set	Item No.	Description	Qty/Set
1.	65-IN-0730 Bone Screwdriver, T10 (SILVER)	2	7.	65-IN-0600 Plate Bender	1
2.	65-SP-0512 AO Drill - 12mm x 2.3mm	1	8.	55-CH-0001 AO Modular Handles	2
3.	65-SP-0514 AO Drill - 14mm x 2.3mm	1	9.	65-IN-0020 Variable Angle Awl (2.3mm x 9mm)	1
4.	65-SP-0516 AO Drill - 16mm x 2.3mm	1	10.	65-IN-0010 10° Fixed Angle Awl (2.3mm x 9mm)	1
5.	65-IN-0750 Locking Driver (GOLD)	2	11.	65-IN-0030 10° Fixed Angle Drill Guide	1
6.	65-IN-0620 Plate Holder	1	12.	65-IN-0033 Variable Angle Drill Guide	1

SURGICAL TECHNIQUE

1

PATIENT POSITIONING

Place the patient in the supine position with the head in slight extension and slight rotation opposite the side of incision.

Confirm surgical level via fluoroscopy.

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 POSITIONING & SELECTION

All plates are measured by the center screw hole to center screw hole distance (Figure 1).

Utilizing the alignment markings on the plate, position the plate on the surgical level with the Plate Holder (65-IN-0620) and confirm proper mediolateral and caudocranial alignment (Figure 2) visually and via fluoroscopy.

Select the length of the plate so that the bone screws enter the superior and inferior vertebral bodies as close to the edge of the disc space as possible.

Do not extend the plate over the adjacent disc spaces.

Note: Alignment markings should be in-line with the superior endplate

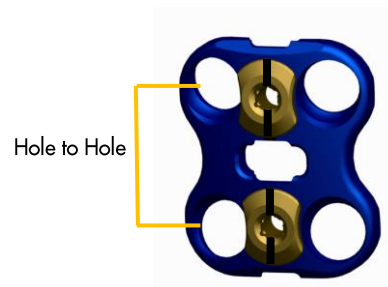


Figure 1

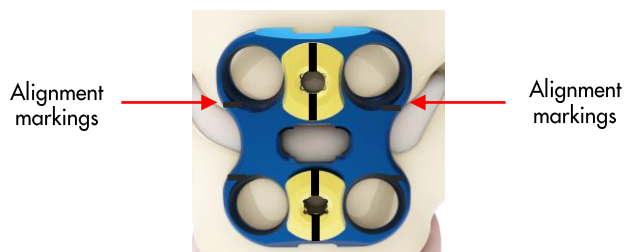


Figure 2

SURGICAL TECHNIQUE

3

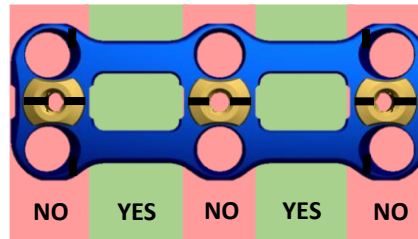
PLATE CONTOURING

The Simplicity® HP Plate is pre-contoured with lordotic curvature to minimize intraoperative contouring (Figure 3). If the curvature of the plate needs to be modified, the Plate Bender (65-IN-0600) may be used for contouring.

Do NOT contour the plate on the locking mechanism as it could become damaged.

Insert the plate into the bender and ensure that the locking mechanism is seated within the groove of the bender (Figure 4).

Once securely positioned, apply moderate pressure to the handle to obtain the desired curvature.



DO NOT BEND PLATE ON OR NEAR THE LOCKING MECHANISMS AND SCREW HOLES.

Bending in these regions may weaken the plate and/or prevent proper functionality of the locking mechanism.

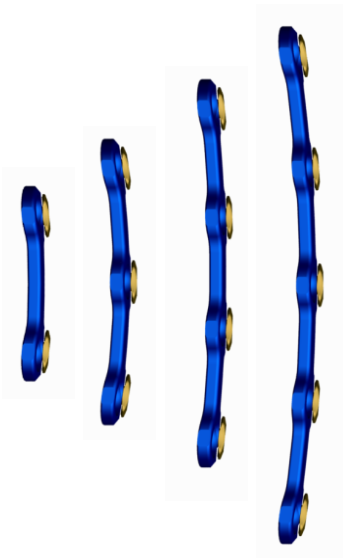


Figure 3

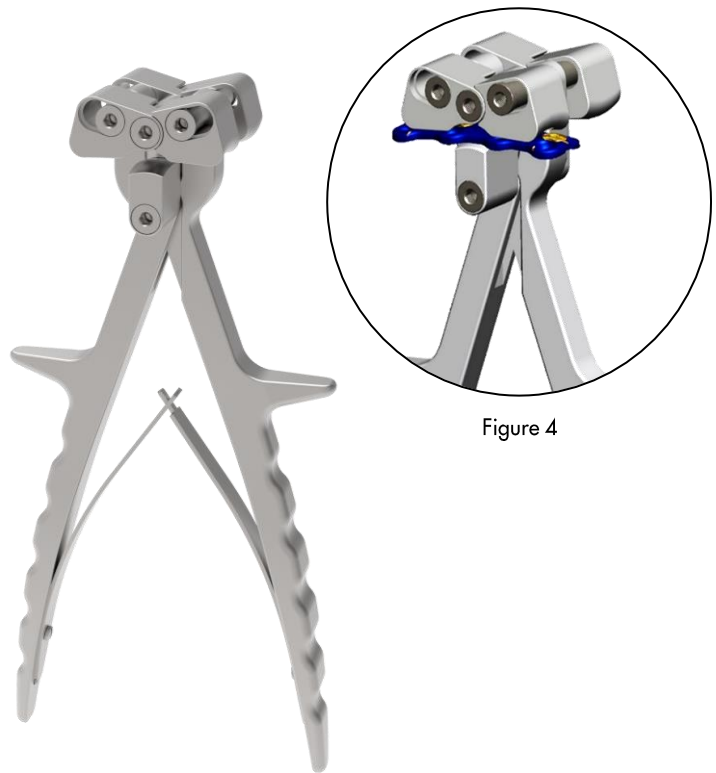


Figure 4

SURGICAL TECHNIQUE

4 TEMPORARY PIN PLACEMENT

Temporarily fix the plate using the temporary Fixation Pins (65-FS-2010 or 65-FS-2510) and the Bone Screwdriver (65-IN-0730).

Attach the Bone Screwdriver (65-IN-0730) securely into the Modular Handle (55-CH-0001).

Insert the tip of the bone screwdriver firmly into the desired fixation pin.

Insert the Fixation Pin through any of the bone screw holes in the plate or the hole within the locking mechanism hole to provide stability during screw placement (Figures 5 and 6).

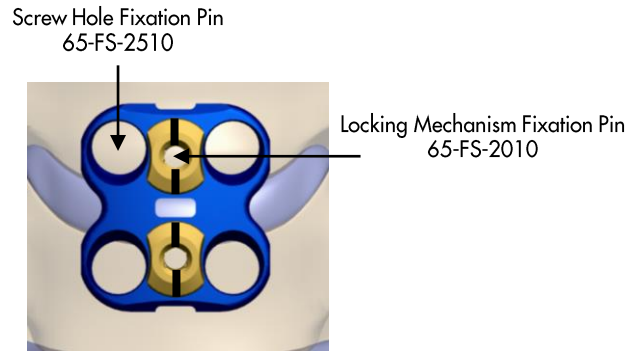


Figure 5

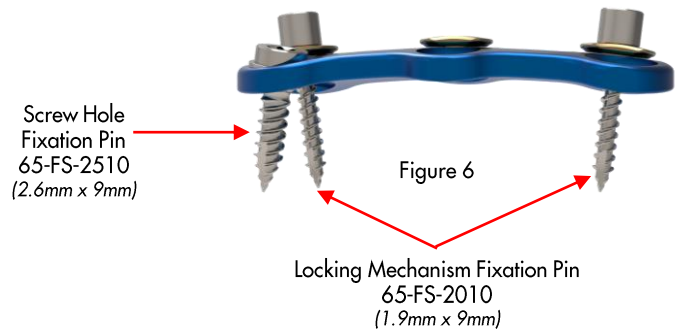


Figure 6

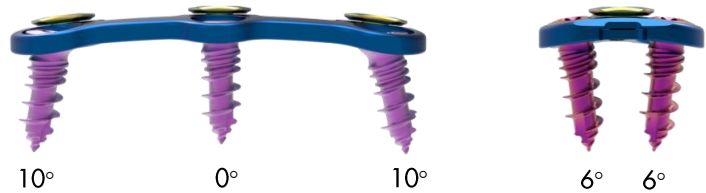
5 PREPARING THE SCREW HOLE

In preparing the screw hole, create a pilot hole using the Fixed (65-IN-0010) or Variable Angle Awl (65-IN-0020).

The Fixed Angle Awl (65-IN-0010) provides 10° of angulation (Figure 7).

The Variable Angle Awl (65-IN-0020) provides a maximum angle of 23° (Figure 7).

Fixed Angulation



Variable Angulation

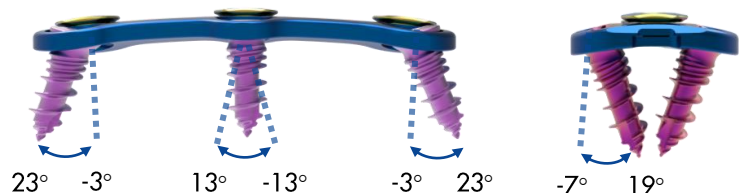


Figure 7

SURGICAL TECHNIQUE

5

PREPARING THE SCREW HOLE

Firmly seat and angle the Fixed (65-IN-0010) or Variable Angle Awl (65-IN-0020) into the desired bone screw hole (Figure 8).

Press the Awl through the plate and into the bone until the depth has bottomed out against the Plate.

Awl depth - 9mm

Securely attach the desired drill (65-SP-05XX) to the Modular Handle (55-CH-0001).

Securely seat the Fixed (65-IN-0030) or Variable Angle Drill Guide (65-IN-0033) within the screw hole prior to drilling.

Position the drill guide to the desired angulation (Figure 9).

The Fixed Drill Guide (65-IN-0030) provides 10° of angulation.

The Variable Drill Guide (65-IN-0033) provides a maximum angle of 23°.

Insert the drill into the drill guide and drill to the appropriate depth. When used in conjunction with the drill guides, there is a positive stop on the drill bits to prevent over-drilling.

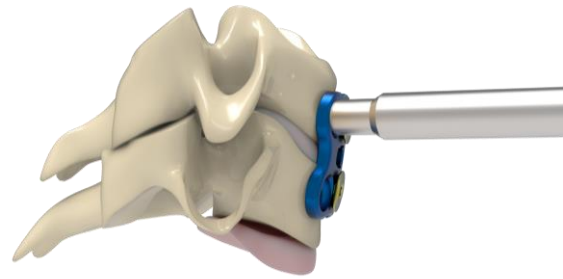


Figure 8

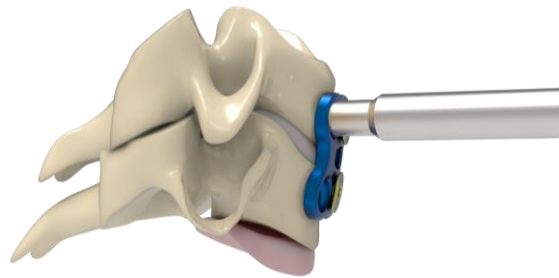
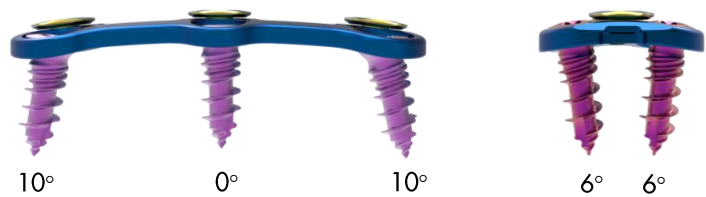
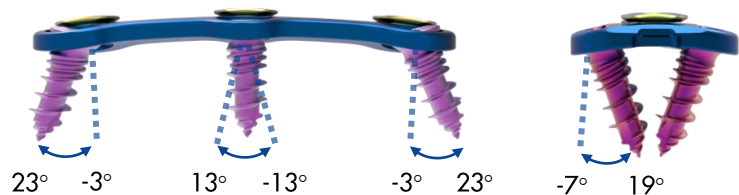


Figure 9

Fixed Angulation



Variable Angulation



SURGICAL TECHNIQUE

6

SCREW INSERTION

Securely attach the Bone Screwdriver (65-IN-0730) to the Modular Handle (55-CH-0001).

Insert the tip of the Bone Screwdriver (65-IN-0730) firmly into the hexalobe of the desired bone screw (Figure 10).

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

Insert and firmly seat bone screws within the plate (Figure 11).

For proper engagement of the locking mechanism, ensure that all bone screws are seated flush and within the bone screw holes.

Confirm plate and bone screw positioning visually and via fluoroscopy.

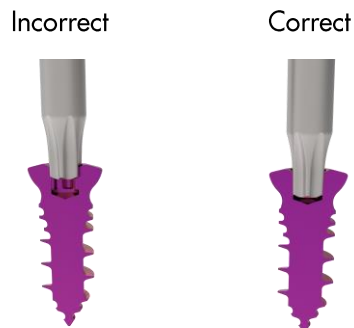


Figure 10

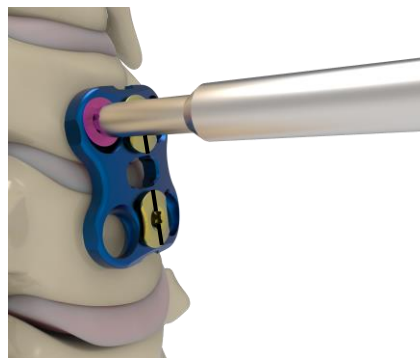


Figure 11

7

LOCKING MECHANISM

Once the bone screws have been properly seated, positioned and tightened, rotate the locking mechanism to secure the seated bone screws within the construct.

Insert the gold Locking Driver (65-IN-0750) securely into the Modular Handle (55-CH-0001).

Seat the Locking Driver securely into and around the locking mechanism and rotate all locking mechanisms clockwise 90° to properly lock the construct (Figure 12).

During rotation, there is an increased tactile resistance to confirm engagement of the locking mechanism.

Alignment markings on the locking mechanism will be in the horizontal position when the properly locked.

Do not rotate locking mechanism more than once as this will weaken it.

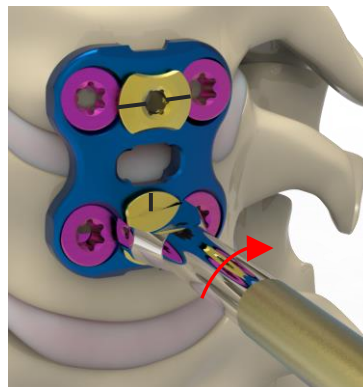


Figure 12

SURGICAL TECHNIQUE

8

CLOSURE

Visually and radiographically confirm construct placement and locking mechanisms (Figure 13), prior to closure.

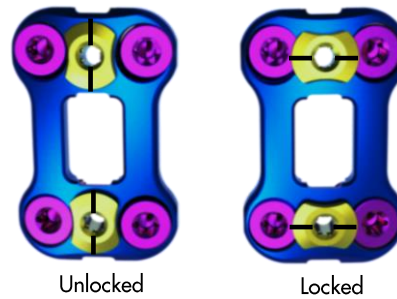


Figure 13

9

SCREW REMOVAL

If required, the construct can be removed utilizing the Locking Driver (65-IN-0060) and Bone Screwdriver (65-IN-0730).

Insert the Locking Driver (65-IN-0750) or T8 Locking Driver (65-IN-0060) securely into the Modular Handle (55-CH-0001).

Seat the Locking Driver securely into and around the locking mechanism and rotate counterclockwise until the bone screws can be removed (Figure 14).

To remove the bone screws, insert the Bone Screwdriver (65-IN-0730) securely into the Modular Handle (55-CH-0001).

Completely seat the tip of the Bone Screwdriver into the hexalobe of the bone screw (Figure 15).

Turn the Bone Screwdriver counterclockwise to remove the bone screws.

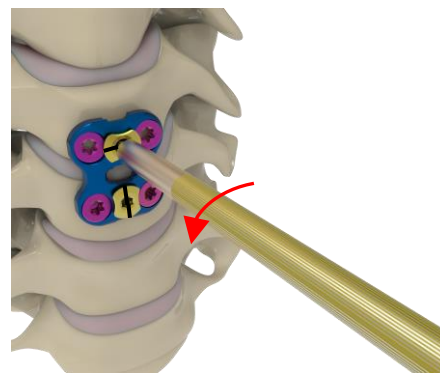


Figure 14

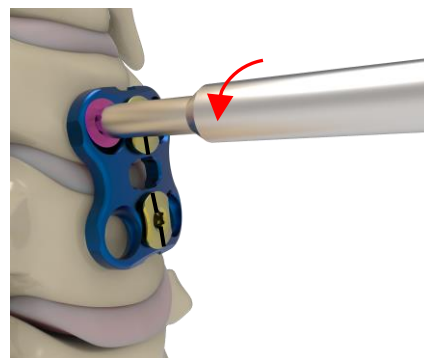


Figure 15

Indications, Contraindications, Warnings, and Precautions

INDICATIONS

The **Simplicity HP** 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; deformity (defined as kyphosis, lordosis, or scoliosis); 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 HP** 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 HP** 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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