

*Surgical  
Technique*  
and Ordering  
Information

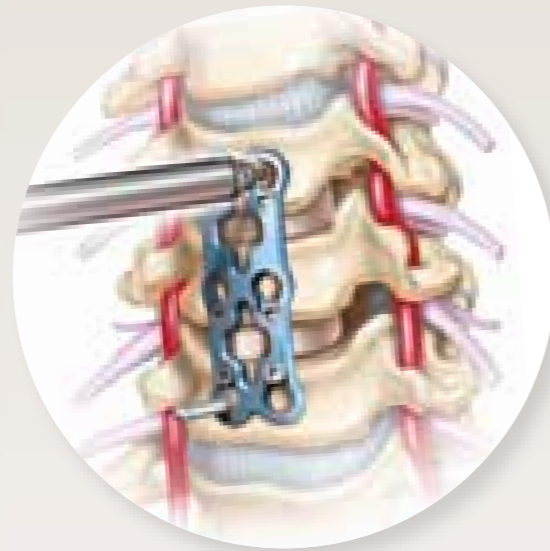


## INTRODUCTION

The SKYLINE® Anterior Cervical Plate provides a versatile system of implants and instruments to accommodate the needs and individual preferences of surgeons. The system offers optimal visualization, adapts to the anatomy of the patient, and instills the confidence afforded through proven technology.

### NOTE:

*The described technique presents only a few of the many approaches to stabilization of the anterior cervical spine. The surgeon is encouraged to utilize the SKYLINE Anterior Cervical Plating System with those techniques that most favor the desired surgical result.*



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**THE SKYLINE ANTERIOR CERVICAL PLATE SYSTEM IS DESIGNED FOR USE IN A VARIABLE, CONSTRAINED, OR HYBRID SCREW CONFIGURATION.**

**IMPLANT & INSTRUMENT VERSATILITY**

- Constrained screws provide up to 5° of angulation in the coronal plane while maintaining sagittal alignment of the screw. This flexibility allows for easier placement of the screw without affecting the stability of the construct.
- Variable screws provide up to 20° of angulation.
- Self-drilling, self-tapping and oversized screws.
- Multiple drill guide and hole preparation options.

**OPTIMIZED PLATE DESIGN**

- Thickness = 2.5 mm
- Width = 16 mm
- Waist = 14 mm
- Plates are pre-lordosed, reducing the need for contouring.
- Unique window design allows for optimal visualization of the graft, vertebral bodies, and endplates.

**CLINICALLY PROVEN TECHNOLOGY**

- Tri-Lobe CAM LOC™ mechanism provides audible, palpable, and visual confirmation of screw lock.

FIGURE 1



**STEP 1: SITE PREPARATION**

- Perform disc excision and spinal decompression using standard surgical technique (Figure 1). Insert appropriate graft such as VG2® Cervical Allograft and HEALOS® Bone Graft Replacement. Care should be taken to perform appropriate soft tissue dissection and to remove anterior osteophytes to provide optimal bone-plate interface. When satisfied with the graft position, remove all bone distraction instruments.

FIGURE 2



**STEP 2: PLATE SIZE SELECTION**

The SKYLINE Anterior Cervical Plates are available in lengths from 1 to 5 levels ranging from 12 to 105 mm. Measurements are taken from the center hole of the cephalad level to the center hole of the caudad level.

- Using the plate holder, position the appropriate plate on the vertebral column to confirm its suitability (Figure 2). When the plate is properly sized and positioned.
- The superior screw holes should align with the inferior 1/3 of the superior vertebral body.
- The inferior screw holes should align with the superior 1/3 of the inferior vertebral body.

FIGURE 3A



**STEP 3: PLATE CONTOURING**

The SKYLINE Anterior Cervical Plates are pre-lordosed. Additional contouring may be accomplished by inserting the plate into the plate bender (Figure 3A) and squeezing the handles.

- The SKYLINE Anterior Cervical Plate is provided with bend zones and may not be bent across the CAM LOC mechanism (Figure 3B). Use only the SKYLINE Plate Bender to bend the plate.
- Plates should be bent in one direction, kyphosis or lordosis only. Never reverse the bend as this may create micro fractures that will weaken the plate.
- Short plates of each level do not have bend zones and therefore cannot be bent.

FIGURE 3B

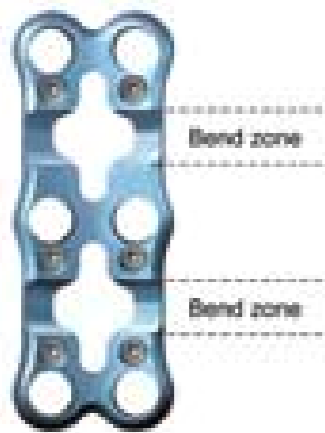
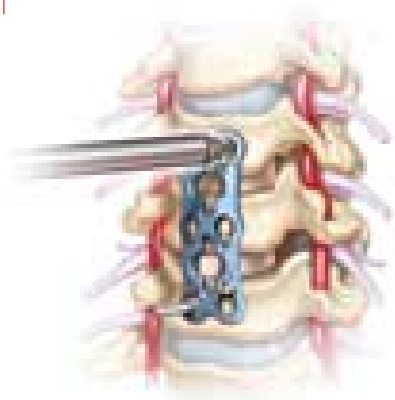


FIGURE 4



**STEP 4: POSITION PLATE AND INSERT TEMPORARY FIXATION PINS**

- Using the plate holder, reposition the plate on the vertebral bodies. Insert a temporary fixation pin, available in both straight and threaded shaft options, into one of the cephalad and one of the caudad screw bores of the plate (Figure 4). Fluoroscopy may be used to confirm alignment of the plate in both planes.

FIGURE 5



**STEP 5: SCREW SELECTION**

The SKYLINE Anterior Cervical Plate System offers two options for screw kinematics, variable or constrained. The variable screw offers a 20° cone of angulation. The constrained screw maintains its sagittal trajectory while allowing up to 5° of angulation in the coronal plane.

Screws are available in self-drilling, self-tapping, and oversized configurations. The screws are color-coded to denote screw kinematics, length, and diameter as illustrated in Figure 5 and the following chart. The screw length corresponds to screw engagement within bone.

	Color Code		4.0mm Self Drilling	4.0mm Self Tapping	4.5mm Oversized
10mm	Green	•		•	
12mm	Blue	•	•	•	•
13mm	Violet	•	•	•	
14mm	Gold	•	•	•	•
15mm	Light Blue	•	•	•	
16mm	Magenta	•	•	•	•
17mm	Light Green	•	•	•	
18mm	Titanium	•	•	•	•
20mm	Titanium	•		•	
22mm	Titanium	•		•	
24mm	Titanium	•		•	
26mm	Titanium	•		•	

FIGURE 6A



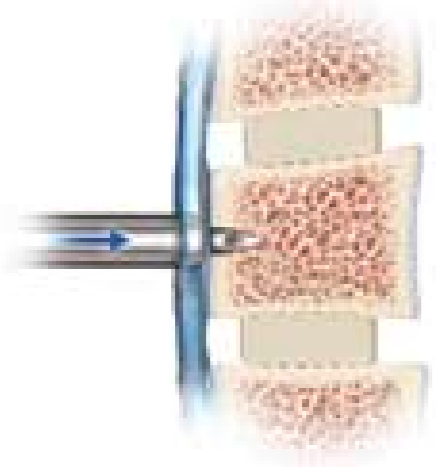
**STEP 6: PREPARE SCREW HOLE**

The SKYLINE System offers multiple drill guide options. Use of the single barrel drill guide is detailed below. The insertion technique for the universal and pistol grip drill guides are detailed in the “Other Instruments” section.

**NOTE:**

Self-drilling screws do not normally require predrilling, however, an awl should be used to perforate the cortex to provide a starting point for screw insertion.

FIGURE 6B



**USING THE SELF-CENTERING AWL**

- The self-centering awl is provided as a two-piece assembly for ease in cleaning and sterilization. Assemble the outer sheath over the handle assembly until the top of the outer sheath bottoms out on the base of the handle (Figure 6A). A tactile and audible click will signify that the outer sheath is properly retained on the handle assembly.
- Once the plate is positioned and temporarily fixed to the vertebral bodies, place the ball tip of the self-centering awl in the screw bore and press it in the direction of the desired screw angle. The self-centering awl can protrude into the bone up to a depth of 7mm (Figure 6B). To penetrate dense cortical bone, strike the handle of the self-centering awl with a mallet.

FIGURE 7A



**SINGLE BARREL DRILL GUIDE**

**NOTE:**

When using a constrained screw, the constrained single barrel drill guide must be used. The tip of the constrained drill guide mimics the head of the constrained screw (Figure 7A) in order to ensure the drilled hole is within the functional range of the constrained screw as illustrated (Figure 7B).

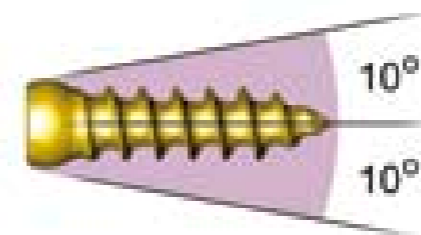
FIGURE 7B



Insert the tip of the single barrel drill guide into the bore of the screw and orient as desired. Exercise caution as certain angles may direct the screws toward vulnerable vascular and neural structures or allow screw tips to intersect one another inhibiting proper screw insertion.

- The neutral angle of a SKYLINE Screw is 10° rostral/caudal and 5° medial.
- The constrained screw can pivot 2.5° medial/lateral from the neutral angle (Figure 7B). The constrained single barrel drill guide will limit drilling trajectory to within the range of the constrained screw.
- The variable screw can pivot 10° in all directions from the neutral angle (20° cone of angulation, Figure 7C).

FIGURE 7C



**DRILL BIT SELECTION AND USE**

The SKYLINE System provides 12mm (blue), 14mm (gold), and 16mm (magenta) fixed depth drill bits. The colors of the collars correspond to their respective screw length colors (Figure 8).

FIGURE 8

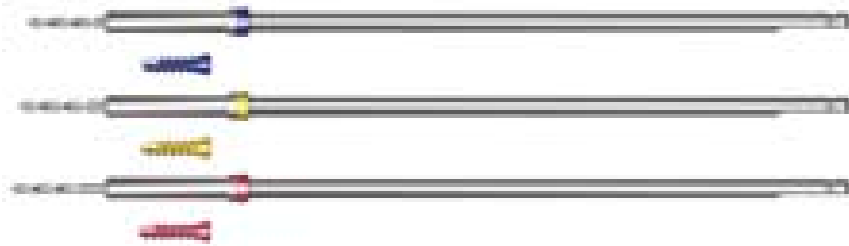


FIGURE 9



- Attach the desired drill bit onto the quick couple handle or power drill. Advance the drill bit through the single barrel drill guide until the shelf of the drill contacts the guide (Figure 9).

The SKYLINE System provides both self-drilling and self-tapping screws. Therefore, a separate tapping operation may not be necessary. A 10 mm tap is provided should tapping be required.

FIGURE 10



**STEP 7: SCREW INSERTION**

- The self retaining screw-driver may be used to remove the desired screw from the screw caddy.
- Insert the screw into the screw bore and advance it into the vertebral body (Figure 10). Use fluoroscopic imaging to confirm the final trajectory of the screw and plate position before screws are fully tightened and secured with the CAM LOC.

FIGURE 11



**STEP 8: LOCKING THE CAMS**

All screws should be secured to the vertebral bodies before beginning the CAM locking procedure.

- Assemble the CAM tightener shaft to the torque handle. Note that the shaft is double-ended to provide an additional tip should a tip become worn. Insert the tip of the CAM tightener shaft into the CAM ensuring that the driver is fully seated within the CAM (Figure 11).
- Rotate the CAM tightener clockwise. Resistance will be felt as the CAM contacts the head of the screw. The CAM tightener incorporates a torque-limiting feature (0.78 Nm) that will release when the appropriate torque level is achieved. When this occurs, an audible click will be heard. A lock is obtained when the CAM tightener torque limit releases or when the CAM is positioned within the typical locking zone shown (Figure 12). **Do not rotate the CAM past 270°.**

**Turn CAM clockwise until you hear an audible click from the CAM torque handle**

**NOTE:**

*Exact position of a locked CAM may vary within the typical locking zone depending on screw angulations.*

FIGURE 12



**STEP 9: FINAL SUPPORT**

For patients with three or four-level constructs, compromised bone quality, or other complications, additional support such as the Songer Cable Systems or the Bremer™ Halo System by DePuy Spine may increase post operative fusion success. The MOUNTAINEER® OCT System may be of value for reinforcement of long anterior constructs.

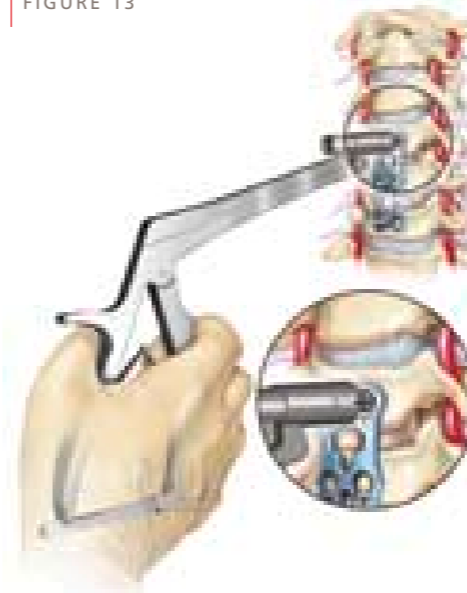
In order to provide versatility and options, the SKYLINE System was designed with multiple instruments to facilitate a variety of surgical preferences and situations.

**NOTE:**

*Only the constrained single barrel drill guide should be used with constrained screws.*

**For closure of surgical incisions, you can use DERMABOND® Topical Skin Adhesive.**

FIGURE 13



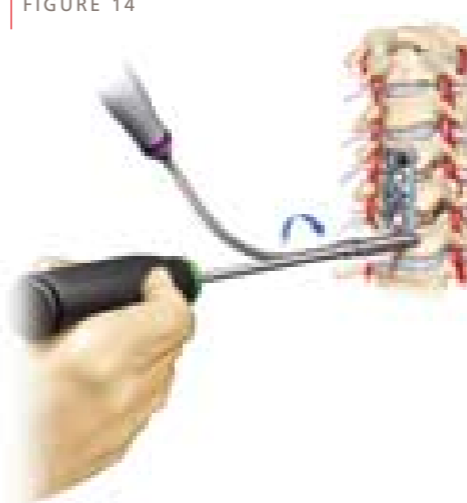
**PISTOL GRIP DRILL GUIDE (OPTIONAL)**

The pistol grip drill guide, similar in function to the variable single barrel drill guide, is additionally able to lock the guide to the plate; thereby, allowing it to be used as a plate holder. To attach, ensure that the ratchet mechanism on the handle is in place. Then place the tip of the pistol grip drill guide within the screw bore and orient as desired. Squeeze the trigger to engage the ratchet mechanism and lock the drill guide to the plate at the angle chosen (Figure 13).

**NOTE:**

*The pistol grip drill guide can only be used with the variable screws.*

FIGURE 14



**UNIVERSAL DRILL GUIDES**

The universal drill guides, available in single and double barrel configurations, facilitate the use of awls, drills, taps, and screw insertion without the need to remove the guide from the plate.

Both the single barrel and double barrel drill guides utilize the outer and window profiles of the plate to index the drill tubes with the screw bores. The guides are self retaining, allowing them to be used as plate holders. The universal single barrel drill guide also features a 180° rotating handle allowing it to be placed out of the way of anatomical obstructions (Figure 14).

FIGURE 15A  
UNIVERSAL SINGLE BARREL  
TOP VIEW



**Instructions for using the universal drill guides:**

- Place the selected drill guide over the selected screw holes such that the lateral tabs hug the outer profile of the plate and the medial tabs engage the window of the plate as illustrated (Figures 15 & 16).

FIGURE 15B  
UNIVERSAL SINGLE BARREL  
BOTTOM VIEW

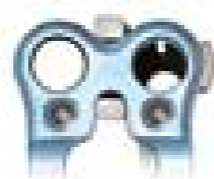
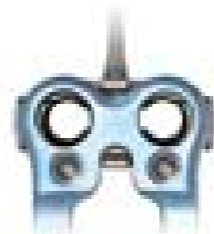


FIGURE 16A  
UNIVERSAL DOUBLE BARREL  
TOP VIEW



- The drill guide will place the screws with a 5° medial trajectory. Rocking the guide to the desired angle will change the sagittal trajectory of the screw.
- Awl, drill, and/or tap the screw holes, as desired. Attach the screws to the self retaining screwdriver and insert them through the drill guide barrels. Screw progress will be visible through the windows in the guide.
- Remove the drill guide and finish tightening.

FIGURE 16B  
UNIVERSAL DOUBLE BARREL  
BOTTOM VIEW



**FREEHAND AWL**

The freehand awl may be used to begin a hole in place of the self-centering awl. As with the self-centering awl it may be used with or without a drill guide. To use, place the trocar tip of the awl in the center of the screw bore and press it in the direction of the screw angle desired. The awl can protrude into the bone a depth of 7mm. To penetrate dense cortical bone, strike the handle of the awl with a mallet.

FIGURE 17



**ITEMS NEEDED:**

- Standard screwdriver. Note: The self retaining screwdriver should not be used to remove the screws. The screwdriver tip should be in good condition.
- CAM tightener shaft and torque handle.

**REMOVAL TECHNIQUE:**

- Thoroughly clean out the inside of the screw head and CAM driver pocket.
- Assemble the CAM tightener shaft to the torque handle.
- Insert the tip of the CAM tightener shaft into the CAM ensuring that the driver is fully seated within the CAM.
- Rotate the CAM counter-clockwise until the flat of the CAM is parallel with the vertebral body (Figure 17). Be careful to ensure that the CAM is not over turned, as damage to the driver and CAM can occur if turned past parallel. Any increase in resistance is an indication that the CAM has been turned too far.
- Insert the standard screwdriver ensuring the tip of the screwdriver is fully seated within the head of the screw. The shaft of the screwdriver should be aligned with the screw shank.
- Disengage the screws from the plate.
- Repeat for all screws.





**ONE LEVEL PLATES**

Part Number	Level	Size
1868-01-012*	One level plate	12mm
1868-01-014*	One level plate	14mm
1868-01-016	One level plate	16mm
1868-01-018	One level plate	18mm
1868-01-020	One level plate	20mm
1868-01-022	One level plate	22mm
1868-01-024	One level plate	24mm
1868-01-026	One level plate	26mm
1868-01-028	One level plate	28mm
1868-01-030	One level plate	30mm



**TWO LEVEL PLATES**

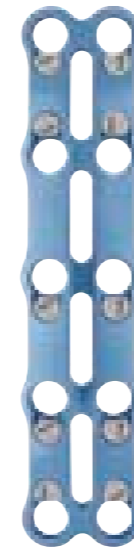
Part Number	Level	Size
1868-02-030*	Two level plate	30mm
1868-02-032	Two level plate	32mm
1868-02-034	Two level plate	34mm
1868-02-036	Two level plate	36mm
1868-02-038	Two level plate	38mm
1868-02-040	Two level plate	40mm
1868-02-042	Two level plate	42mm
1868-02-044	Two level plate	44mm



**THREE LEVEL PLATES**

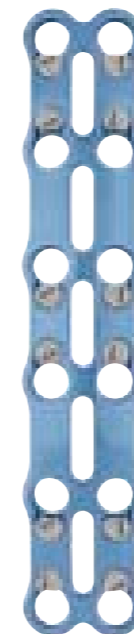
Part Number	Level	Size
1868-03-042*	Three level plate	42mm
1868-03-045*	Three level plate	45mm
1868-03-048	Three level plate	48mm
1868-03-051	Three level plate	51mm
1868-03-054	Three level plate	54mm
1868-03-057	Three level plate	57mm
1868-03-060	Three level plate	60mm
1868-03-063	Three level plate	63mm
1868-03-066	Three level plate	66mm

\*Shorter level plates have medial slot only.



**FOUR LEVEL PLATES**

Part Number	Level	Size
1868-04-064*	Four level plate	64mm
1868-04-068	Four level plate	68mm
1868-04-072	Four level plate	72mm
1868-04-076	Four level plate	76mm
1868-04-080	Four level plate	80mm
1868-04-084	Four level plate	84mm
1868-04-088	Four level plate	88mm



**FIVE LEVEL PLATES**

Part Number	Level	Size
1868-05-075*	Five level plate	75mm
1868-05-080*	Five level plate	80mm
1868-05-085	Five level plate	85mm
1868-05-090	Five level plate	90mm
1868-05-095	Five level plate	95mm
1868-05-100	Five level plate	100mm
1868-05-105	Five level plate	105mm

\*Shorter level plates have medial slot only.



**VARIABLE SELF DRILLING SCREWS (4.0MM)**

Part Number	Description	Size
1868-50-012	Self-Drilling Screw	12mm
1868-50-013	Self-Drilling Screw	13mm
1868-50-014	Self-Drilling Screw	14mm
1868-50-015	Self-Drilling Screw	15mm
1868-50-016	Self-Drilling Screw	16mm
1868-50-017	Self-Drilling Screw	17mm
1868-50-018	Self-Drilling Screw	18mm



**CONSTRAINED SELF DRILLING SCREWS (4.0MM)**

Part Number	Description	Size
1868-60-012	Self-Drilling Screw	12mm
1868-60-013	Self-Drilling Screw	13mm
1868-60-014	Self-Drilling Screw	14mm
1868-60-015	Self-Drilling Screw	15mm
1868-60-016	Self-Drilling Screw	16mm
1868-60-017	Self-Drilling Screw	17mm
1868-60-018	Self-Drilling Screw	18mm



**VARIABLE SELF TAPPING SCREWS (4.0MM)**

Part Number	Description	Size
1868-52-010	Self-Tapping Screw	10mm
1868-52-012	Self-Tapping Screw	12mm
1868-52-013	Self-Tapping Screw	13mm
1868-52-014	Self-Tapping Screw	14mm
1868-52-015	Self-Tapping Screw	15mm
1868-52-016	Self-Tapping Screw	16mm
1868-52-017	Self-Tapping Screw	17mm
1868-52-018	Self-Tapping Screw	18mm
1868-52-020	Self-Tapping Screw	20mm
1868-52-022	Self-Tapping Screw	22mm
1868-52-024	Self-Tapping Screw	24mm
1868-52-026	Self-Tapping Screw	26mm



**CONSTRAINED SELF TAPPING SCREWS (4.0MM)**

Part Number	Description	Size
1868-62-010	Self-Tapping Screw	10mm
1868-62-012	Self-Tapping Screw	12mm
1868-62-013	Self-Tapping Screw	13mm
1868-62-014	Self-Tapping Screw	14mm
1868-62-015	Self-Tapping Screw	15mm
1868-62-016	Self-Tapping Screw	16mm
1868-62-017	Self-Tapping Screw	17mm
1868-62-018	Self-Tapping Screw	18mm
1868-62-020	Self-Tapping Screw	20mm
1868-62-022	Self-Tapping Screw	22mm
1868-62-024	Self-Tapping Screw	24mm
1868-62-026	Self-Tapping Screw	26mm



**VARIABLE OVERSIZED SCREWS (4.5MM)**

Part Number	Description	Size
1868-54-012	Large Diameter	12mm
1868-54-014	Large Diameter	14mm
1868-54-016	Large Diameter	16mm
1868-54-018	Large Diameter	18mm



**CONSTRAINED OVERSIZED SCREWS (4.5MM)**

Part Number	Description	Size
1868-64-012	Large Diameter	12mm
1868-64-014	Large Diameter	14mm
1868-64-016	Large Diameter	16mm
1868-64-018	Large Diameter	18mm

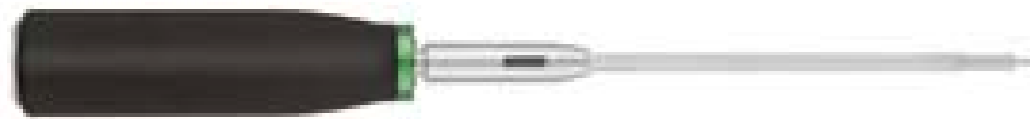
**DRILL GUIDES**

Part Number	Description
2868-00-000	Constrained Single Barrel Guide
2868-10-000*	Variable Single Barrel Guide
2868-10-100	Variable Pistol Grip Guide
2868-10-200	Single Barrel Universal Guide
2868-10-300	Double Barrel Universal Guide



**HOLE PREPARATION**

Part Number	Description
2868-20-400*	Self Centering Awl
2868-20-500	Freehand Awl
2868-20-012	12mm Drill (AO)
2868-20-014	14mm Drill (AO)
2868-20-016	16mm Drill (AO)
2868-20-112	12mm Drill (Jacobs)
2868-20-114	14mm Drill (Jacobs)
2868-20-116	16mm Drill (Jacobs)
2868-20-300	Tap Shaft
2865-22-000	Quick Couple Handle



**DRIVERS**

Part Number	Description
2868-30-000*	Spring Clip Driver
2868-30-100	Standard Driver
2868-30-200	Expansion tip screw driver



\*Picture illustrated.

**CAM LOCKING**

Part Number	Description
2868-40-000*	Cam Tightener Shaft
2897-07-000	Cam Tightener Torque Handle



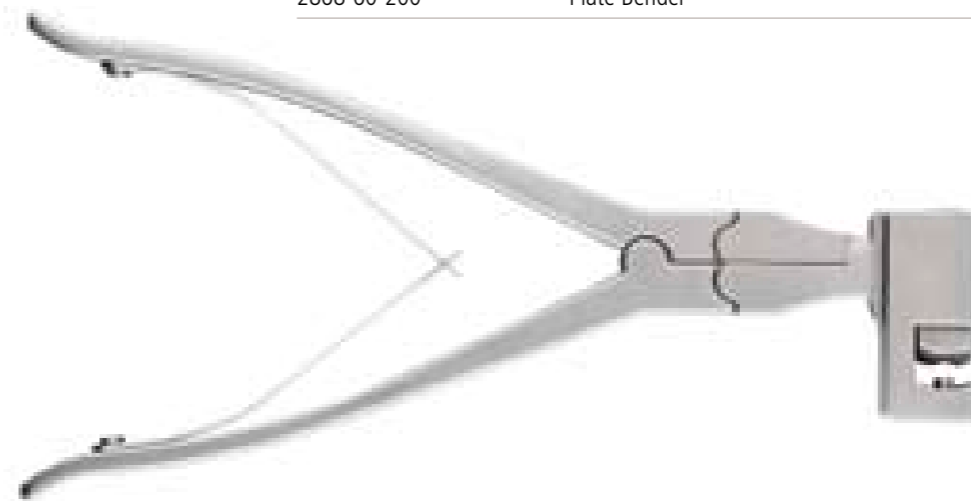
**TEMPORARY FIXATION PINS**

Part Number	Description
2868-50-000	TFP Inserter
2868-50-100	Straight TFP
2868-50-200*	Threaded TFP



**OTHER**

Part Number	Description
2865-06-000	Plate Holder
2868-60-200*	Plate Bender



\*Picture illustrated.

**CASES & TRAYS**

Part Number	Description
2868-80-001	Plate Caddy
2868-80-002	Variable Screw Caddy
2868-80-003	Constrained Screw Caddy
2868-80-004	4&5 Level plates Caddy
2868-80-006	Implants Tray (part of case & tray)
2868-80-007	Implants Tray (part of case & tray)
2868-80-005*	Case & Trays



\*Picture illustrated.

## INDICATIONS

The SKYLINE Anterior Cervical Plate System is indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy. These devices are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.



Anterior Cervical Plate System

## CONTRAINDICATIONS (IFU):

- Active systemic infection or an infection localized to the site of the proposed implantation.
- Severe osteoporosis may prevent adequate fixation of screws and thus preclude the use of this or any other spinal instrumentation system.
- Patients who have been shown to be safely and predictably treated without internal fixation.
- Open wounds.
- Relative contraindications include any entity or condition that totally precludes the possibility of fusion (e.g., cancer, kidney dialysis or osteopenia), obesity, certain degenerative diseases, and foreign body sensitivity.

DePuy Spine EMEA is a trading division of DePuy International Limited.  
Registered Office: St. Anthony's Road, Leeds LS11 8DT, England  
Registered in England No. 3319712

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