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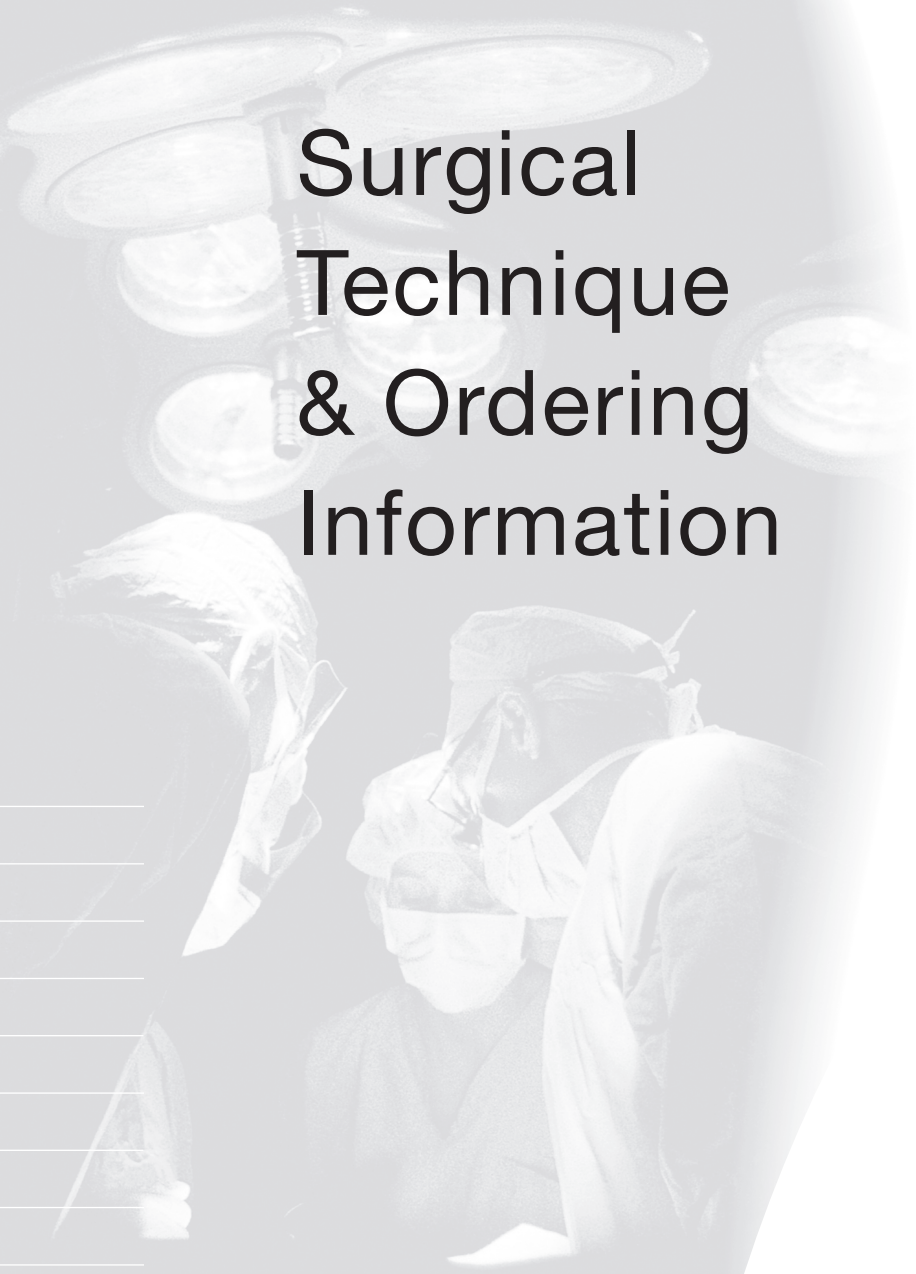

Surgical Technique & Ordering Information

Skyline®

Anterior Cervical Plate System

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Skyline®

Anterior Cervical Plate System

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.

CONTENTS

The SKYLINE ACP
SYSTEM DESCRIPTION

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

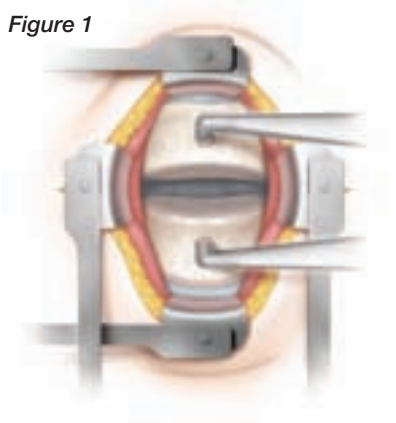
- Thickness = 2.5 mm
- Width = 16 mm
- Waist = 14 mm
- Plates are pre-lordosed, reducing the need for contouring.
- Unique window design allows for optimal visualization of the graft, vertebral bodies, and endplates.

Clinically Proven Technology

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

The SKYLINE ACP
OPERATIVE TECHNIQUE

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

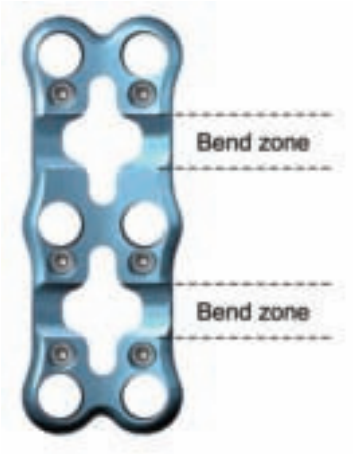
STEP 2: PLATE SIZE SELECTION

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 ⅓ of the superior vertebral body.
- The inferior screw holes should align with the superior ⅓ of the inferior vertebral body.

Figure 3A

Figure 3B

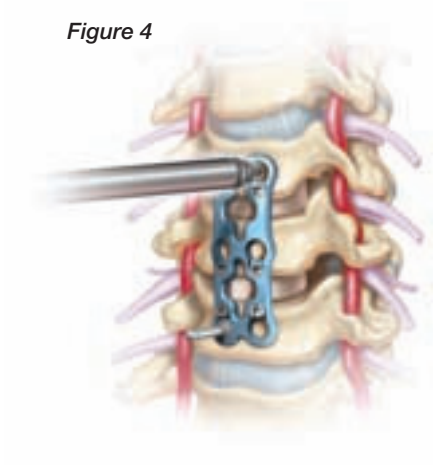


STEP 3: PLATE CONTOURING

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 4



STEP 4: POSITION PLATE AND INSERT TEMPORARY FIXATION PINS

- Using the plate holder, re-position 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	4.5 mm 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		•	

The SKYLINE ACP
OPERATIVE TECHNIQUE

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.

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 6B

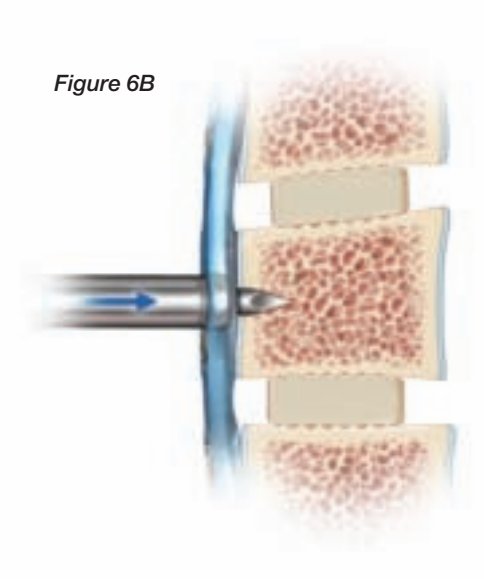


Figure 7A

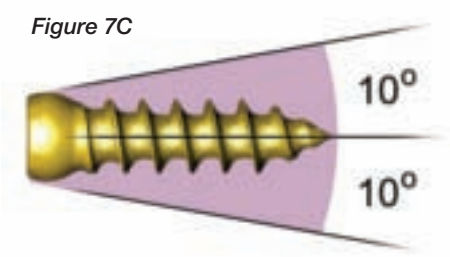
Single Barrel Drill Guide

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.

Figure 7C



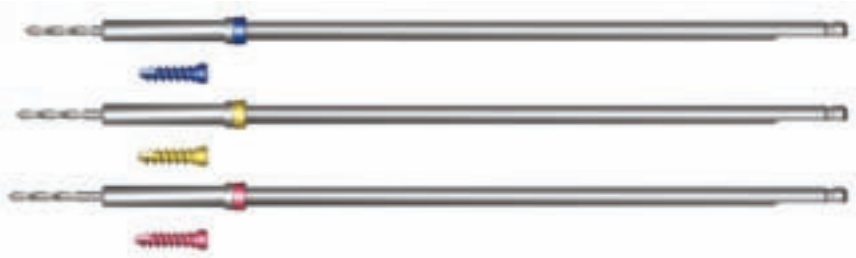
- The neutral angle of a SKYLINE Screw is 10° rostral /caudal and 5° medial.
- The constrained screw can pivot 2.5° medial/lateral from the neutral angle (Figure 7B). The constrained single barrel drill guide will limit drilling trajectory to within the range of the constrained screw.
- The variable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

The SKYLINE ACP
OPERATIVE TECHNIQUE

Drill Bit Selection and Use

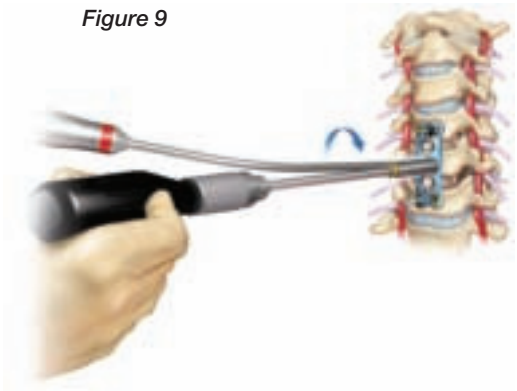
The SKYLINE System provides 12mm (blue), 14mm (gold), and 16mm (magenta) fixed depth drill bits. The colors of the collars correspond to their respective screw length colors (Figure 8).

Figure 8



- 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).

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.

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 10

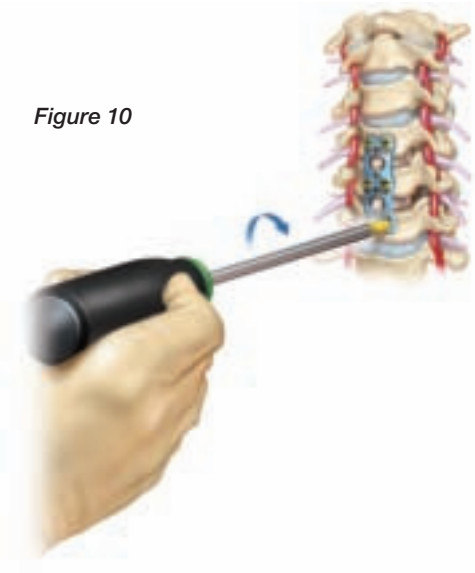
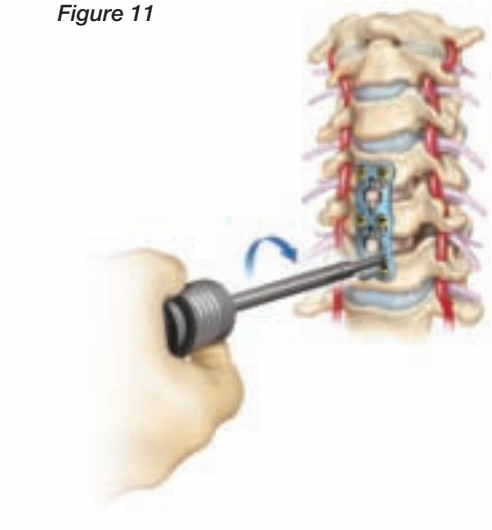


Figure 11



STEP 8: LOCKING THE CAMS

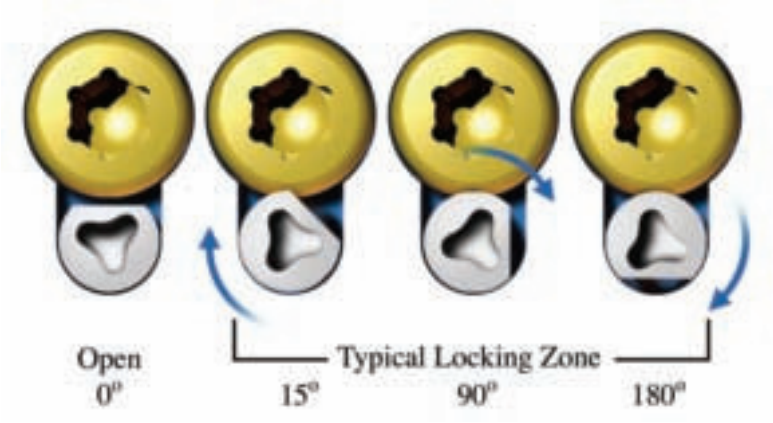
All screws should be secured to the vertebral bodies before beginning the CAM locking procedure.

- 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

Figure 12



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

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.

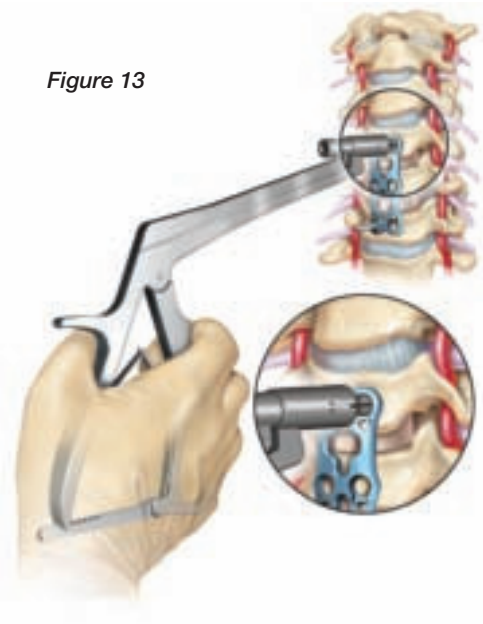
In order to provide versatility and options, the SKYLINE System was designed with multiple instruments to facilitate a variety of surgical preferences and situations.

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.

The SKYLINE ACP
OTHER INSTRUMENTS

Figure 13

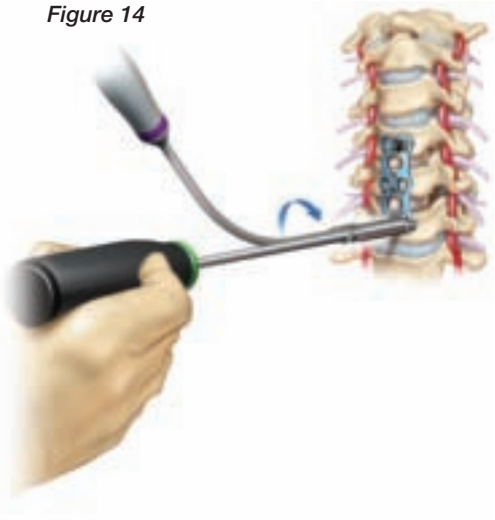


PISTOL GRIP DRILL GUIDE (OPTIONAL)

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



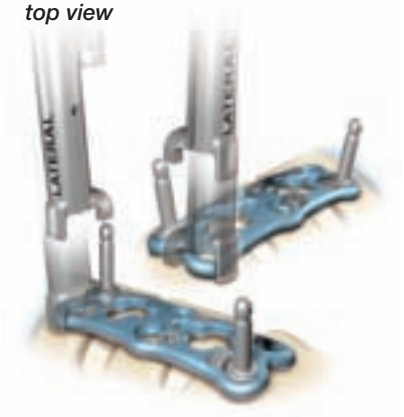
UNIVERSAL DRILL GUIDES

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).

The SKYLINE ACP
OTHER INSTRUMENTS

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

- 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 16A
Universal Double Barrel
top view

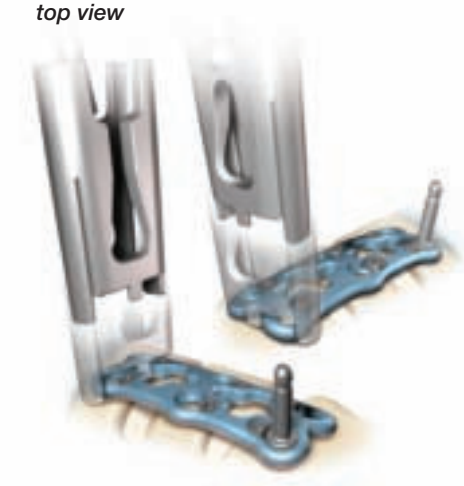


Figure 16B
Universal Double Barrel
bottom view

FREEHAND AWL

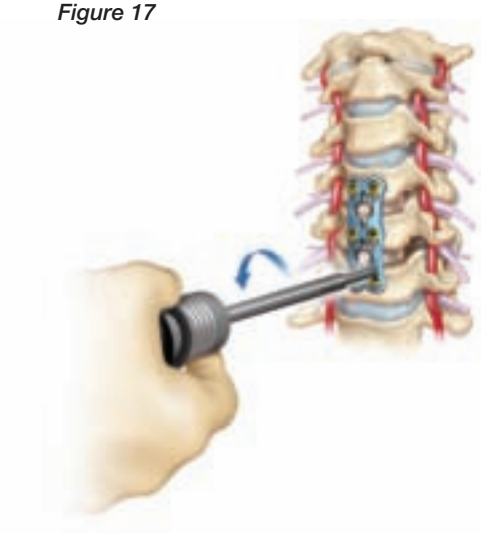
The freehand awl may be used to begin a hole in place of the self-centering awl. As with the self-centering awl it may be used with or without a drill guide. To use, place the trocar tip of the awl in the center of the screw bore and press it in the direction of the screw angle desired. The awl can protrude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

The SKYLINE ACP
PLATE REMOVAL

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.

Figure 17



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.