



Anterior Cervical Plate System

*Surgical
Technique*
Guide
and Ordering
Information



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INTRODUCTION

The UNIPLATE® 2 Anterior Cervical Plate System is designed to simplify anterior cervical fusions through the use of a narrow midline plate and streamlined surgical technique. This unique system features one point of midline fixation per level for improved screw visualization, easier screw placement, and minimized lateral retraction, compared to conventional anterior cervical plate construct.



The UNIPLATE 2 Anterior Cervical Plate System provides upgrades from the original UNIPLATE in that it offers bend-zones and has less material at the inferior and superior ends of the plate to reduce the risk of adjacent level impingement.

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 UNIPLATE 2 Anterior Cervical Plate System with those techniques most familiar to them.



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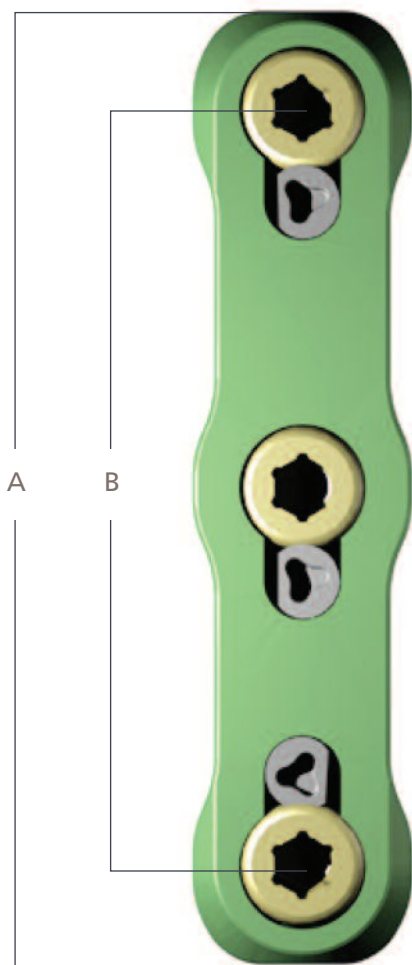
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SYSTEM DESCRIPTION

Key features of the UNIPLATE 2 Anterior Cervical Plate System include:

FIGURE 1



STREAMLINED SURGICAL TECHNIQUE

- Universal Guide/Plate Holder allows the awl, drill, tap and screw to pass through
- Midline screw minimizes lateral retraction
- Self-drilling, self-tapping and large diameter screws
- Pre-lordosed plate

OPTIMIZED PLATE DESIGN

	UNIPLATE 2	UNIPLATE
Width (at screw hole)	10.5mm	10.5mm
Width (at waist)	8.4mm	7.5mm
Max Thickness	2.3mm	2.3mm
Min Thickness (at bend zone)	1.75mm	2.3mm (no bend zone)
Cleats to limit slippage	0.46mm	0.46mm
Plate length differential <i>(Please refer to Figure 1: end-to-end [A] minus hole-to-hole [B])</i>	9.5mm	11.5mm

TECHNOLOGY

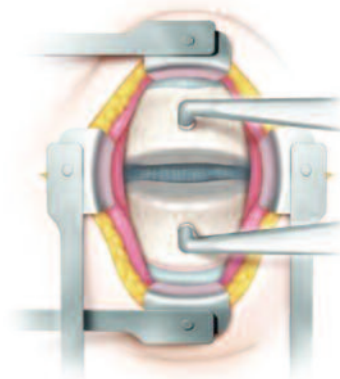
- Equivalent bending strength to traditional cervical plates
- 3rd Generation Tri-lobe CAM-LOC™ Mechanism
- 30° cone of angulation for optimal screw placement

OPERATIVE TECHNIQUE

STEP 1: SITE PREPARATION

Perform disc excision and spinal decompression using standard surgical techniques (Figure 2). Insert appropriate interbody spacer such as VG2® Cervical Allograft or BENGAL® Cage. Care should be taken to perform appropriate soft-tissue dissection and to remove anterior osteophytes to provide an optimal bone-plate interface. When satisfied with the graft position, remove all bone distraction instruments.

FIGURE 2



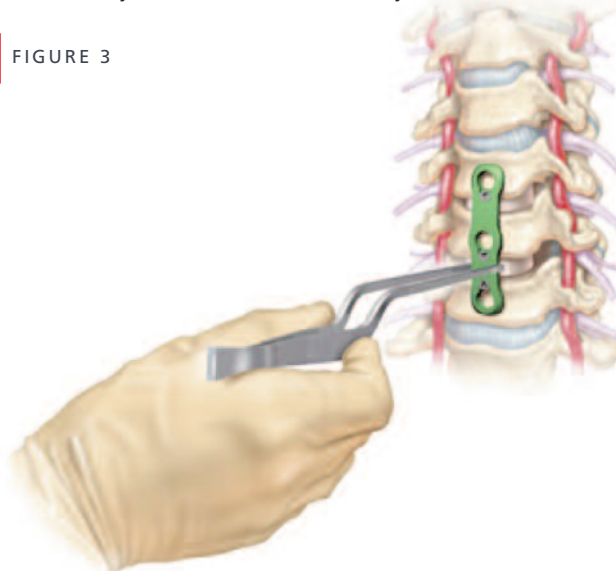
STEP 2: PLATE SIZE SELECTION

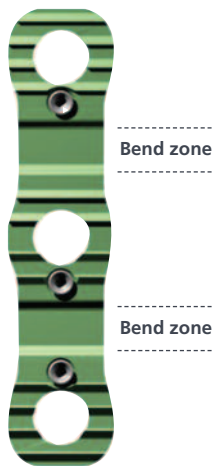
UNIPLATE 2 Anterior Cervical Plates are available in configurations with two or three holes, in lengths ranging from 13 to 24mm for one level procedures and 26 to 40mm for two level procedures.

Use forceps to select the appropriate plate size and place it on the vertebral column (Figure 3). The plate should span the entire fusion segment.

Alternatively, the Universal Guide may be used to insert the plate.

FIGURE 3





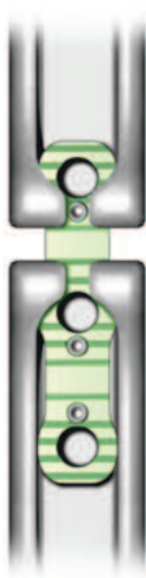
STEP 3: PLATE CONTOURING

UNIPLATE 2 Anterior Cervical Plates are pre-lordosed. Additional contouring may be accomplished by inserting the plate into the Plate Bender as shown in Figure 5A and applying force to the bender.

NOTE:

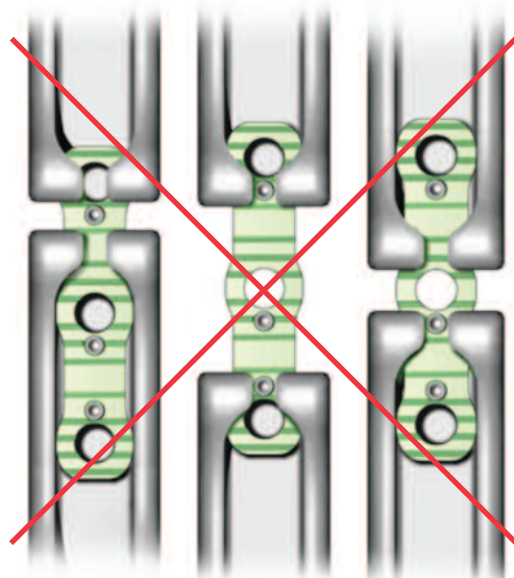
- The UNIPLATE does not have a bend-zone and cannot be bent.
- The UNIPLATE 2 system is equipped with bend zones on 16mm and larger one-level plates and 30mm and larger two-level plates. Do not bend across the CAM-LOC mechanism (Figure 5B) as it will compromise the cams ability to lock the screw. Use only the UNIPLATE 2 Plate Bender to bend the plate.
- Plates should be bent in one direction – kyphosis or lordosis only. Never reverse the bend as this will weaken the plate.

FIGURE 5A



Proper Bending technique

FIGURE 5B

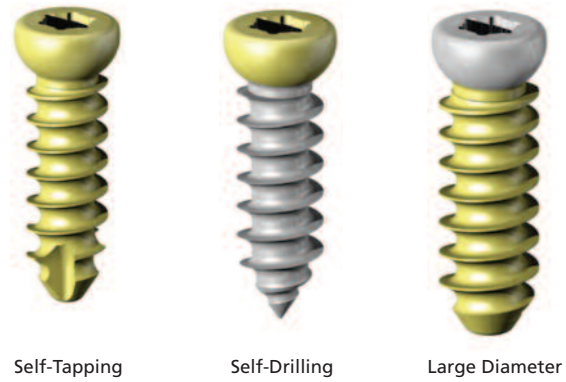


Improper Bending technique

STEP 4: SCREW SELECTION

Screws are available in Self-Drilling, Self-Tapping, and Large Diameter configurations. The screws are color-coded to denote length and diameter as illustrated in Figure 6 and the following chart.

FIGURE 6



		4.6mm Self Tapping	4.6mm Self Drilling	5.2mm Large Diameter
12mm	Blue	X	X	X
13mm	Violet	X	X	
14mm	Gold	X	X	X
15mm	Light Blue	X	X	
16mm	Magenta	X	X	X
18mm	Titanium	X	X	X
26mm	Titanium	X		X

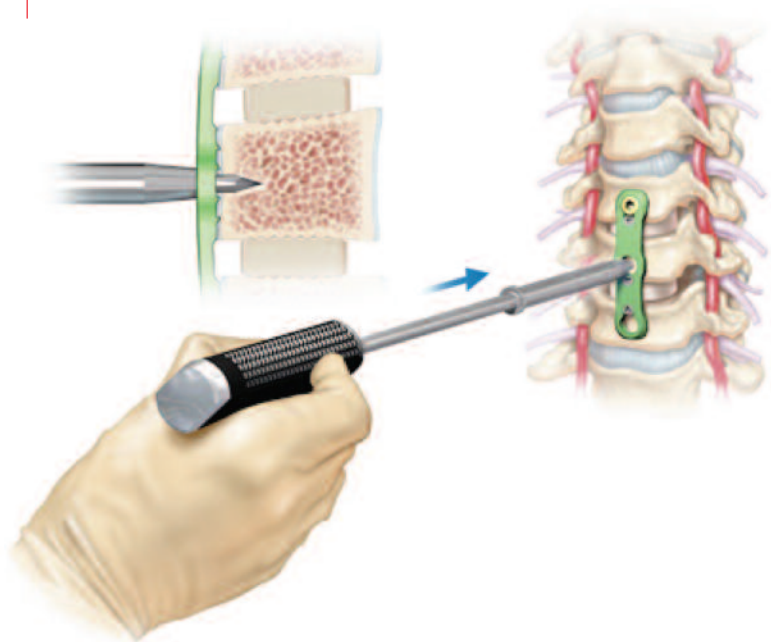
STEP 5: SCREW HOLE PREPARATION

Using the UNIPLATE 2 Awl

Two options are available to hold the plate in position – temporary fixation pins and the universal drill guide. After the plate is positioned and aligned with the midline of the anterior cervical spine, the awl may be used to mark the entry points for the screws.

Place the tip of the awl in the center of the screw hole and press it in the direction of the screw angle desired (Figure 7). The awl will protrude into the bone a maximum of 7mm. To penetrate dense cortical bone, gently strike the handle of the awl with a mallet.

FIGURE 7



Using the Universal Guide

The UNIPLATE 2 System provides a Universal Guide that allows the awl, drill bits, tap and screws to pass through. The handle of the guide is oriented laterally to avoid interference with the patient's chin or chest. The Universal Guide has a forked distal tip that grasps the plate at the perimeter of the screw holes.

NOTE:

The forked distal tip features cleats to minimize slip on the vertebral body.

Attach the Universal Guide to the plate by slipping the forked distal ends over the lateral edges of the plate at the perimeter of a screw hole. The guide may be used to position the plate onto the vertebral body. The angle of the guide may be adjusted as desired for the screw trajectory. Either the drill or awl may be used to start the screw hole (Figure 8).

FIGURE 8

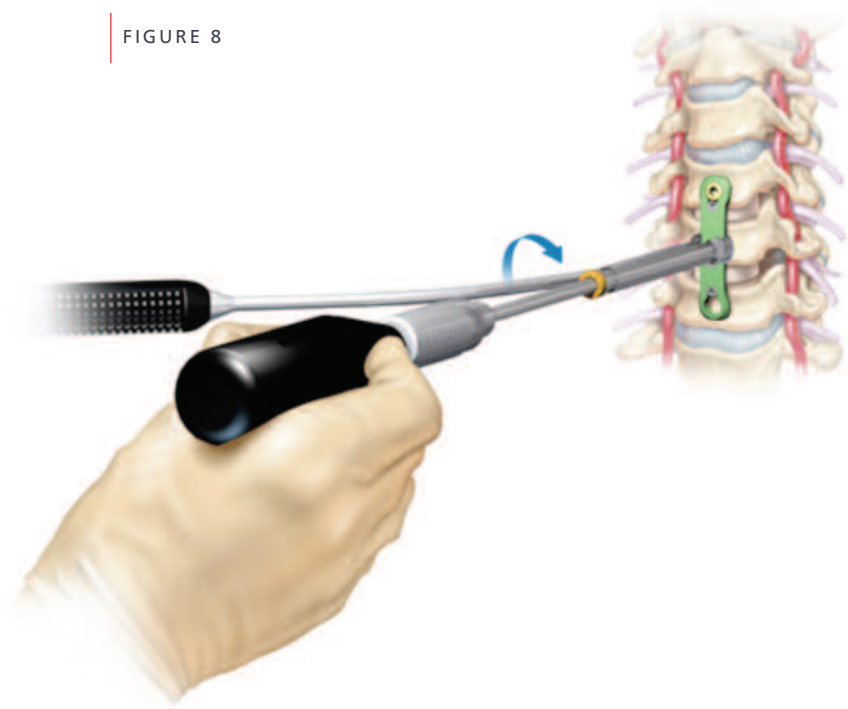
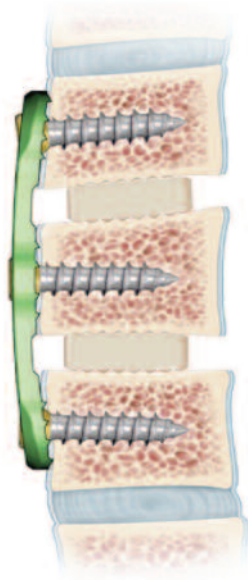


FIGURE 9



STEP 6: DRILL BIT SELECTION AND USE

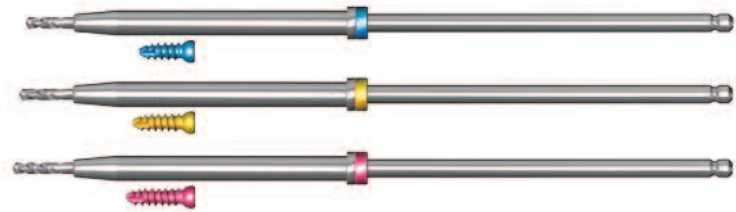
The UNIPLATE 2 Anterior Cervical Plate System allows screws to be directed at angles needed to conform to individual patient anatomy. This may be necessary to avoid vulnerable vascular and neural tissues. Use fluoroscopy to confirm drill bit penetration depth and angular orientation to assure that those structures are not at risk.

Typical screw placement is 5-10° rostral and caudal to the disc space (Figure 9).

Avoid angulation of the screws greater than 15° to ensure optimal locking of the screw to the plate.

The UNIPLATE 2 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 10).

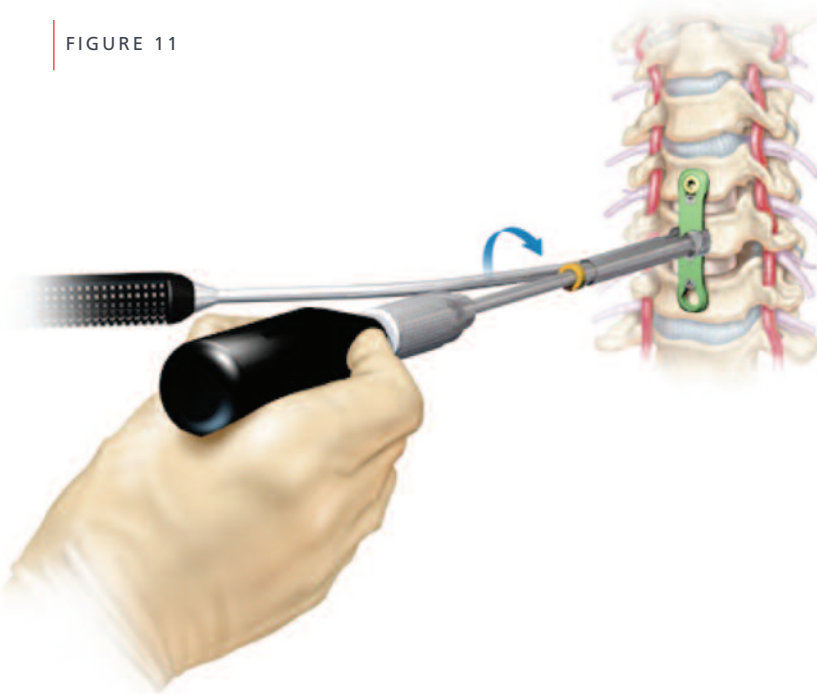
FIGURE 10



Insert the desired drill bit into the Quick Couple Handle or power drill. Advance the drill bit through the Universal Guide until the colored collar contacts the guide (Figure 11).

The UNIPLATE 2 System provides both self-drilling and self-tapping screws therefore, a separate tapping operation may not be necessary. A 12mm tap is provided, should tapping be required.

FIGURE 11

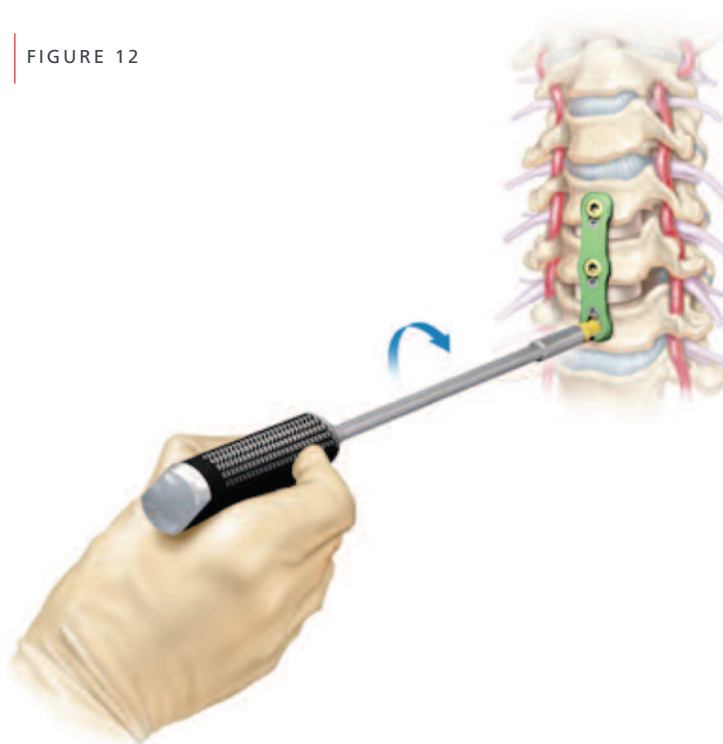


STEP 7: SCREW PLACEMENT

Use the Self Retaining Screw-Driver to remove the desired screw from the screw caddy.

Insert the screw into the screw bore and advance it into the vertebral body (Figure 12). 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 12



NOTE:

If screws are inserted through the Universal Guide, remove the guide prior to performing final tightening. The Universal Guide may be damaged if final tightening is performed with the guide in place.

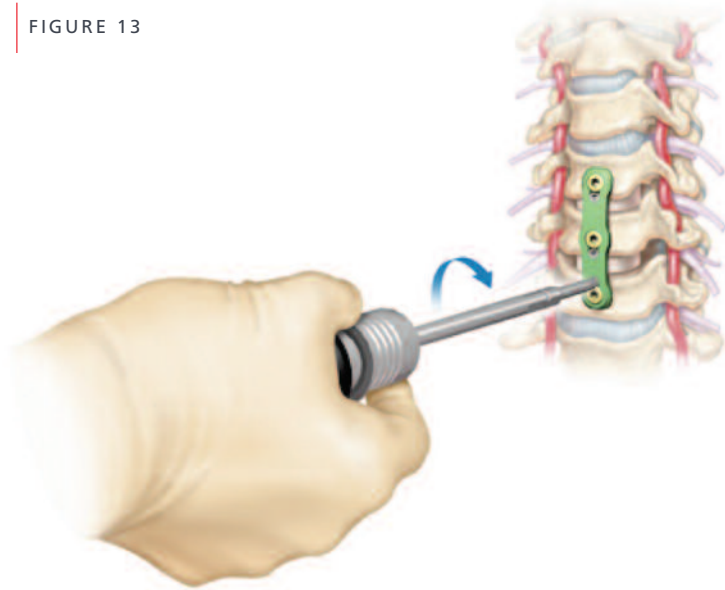
		4.6mm Self Tapping	4.6mm Self Drilling	5.2mm Large Diameter
12mm	Blue	X	X	X
13mm	Violet	X	X	
14mm	Gold	X	X	X
15mm	Light Blue	X	X	
16mm	Magenta	X	X	X
18mm	Titanium	X	X	X
26mm	Titanium	X		X

STEP 8: LOCKING THE CAMS

All screws should be secured to the vertebral bodies before beginning the CAM-LOC 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 13).

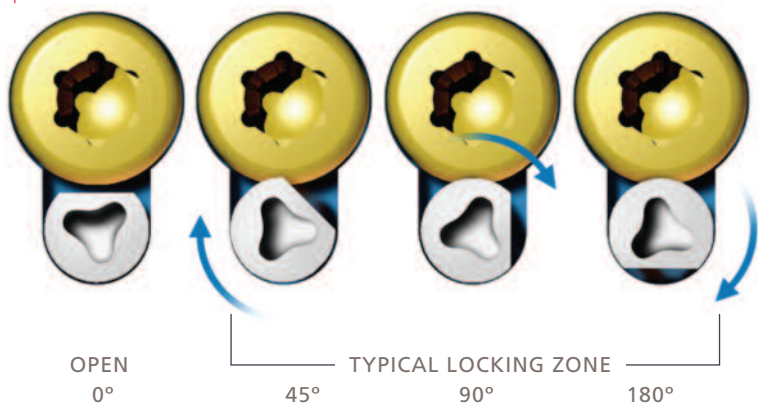
FIGURE 13



STEP 8: LOCKING THE CAMS (CONT.)

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 N.m.) 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 in Figure 14.

FIGURE 14



NOTE:

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

Turn CAM clockwise until you hear an audible click from the CAM Handle Torque.

PLATE REMOVAL

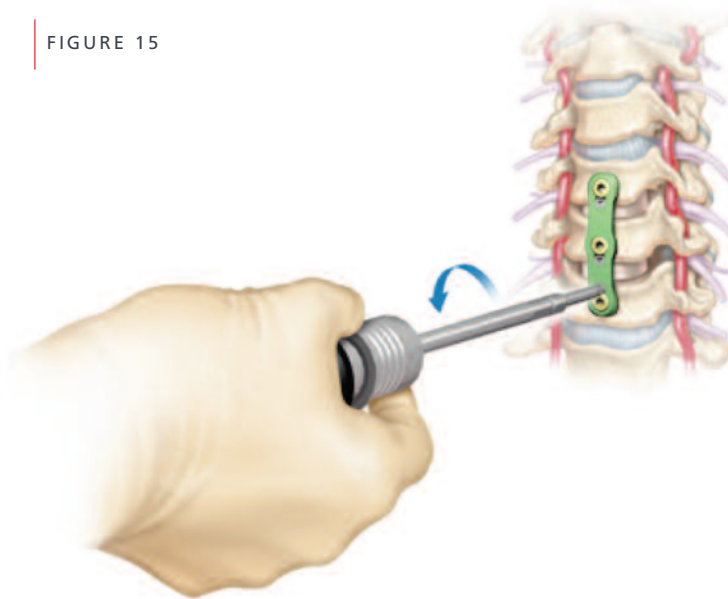
Items Needed:

- Standard Screw-Driver (Note: The Self Retaining Screw-Driver should not be used to remove the screws. The Screw-Driver tip should be in good condition.)
- CAM Tightener Shaft and Torque Handle

Removal Technique:

- Thoroughly clean the inside of the screw head and CAM.
- Assemble the CAM Tightener Shaft into 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 15). 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 Screw-Driver ensuring the tip of the Screw-Driver is as fully seated within the head of the screw as possible. The shaft of the screw should be aligned with the screw shank.
- Disengage the screws from the plate.
- Repeat for all screws.
- For revision cases please keep in mind that UNIPLATE 2 has 4.6mm regular size screws and 5.2mm large diameter screws.

FIGURE 15



ORDERING INFORMATION

ITEM #	DESCRIPTION	
1897-21-013	UNIPLATE 2 - 1 Level Plate	13mm*
1897-21-014	UNIPLATE 2 - 1 Level Plate	14mm*
1897-21-016	UNIPLATE 2 - 1 Level Plate	16mm
1897-21-018	UNIPLATE 2 - 1 Level Plate	18mm
1897-21-020	UNIPLATE 2 - 1 Level Plate	20mm
1897-21-022	UNIPLATE 2 - 1 Level Plate	22mm
1897-21-024	UNIPLATE 2 - 1 Level Plate	24mm
1897-21-026	UNIPLATE 2 - 1 Level Plate	26mm
1897-21-028	UNIPLATE 2 - 1 Level Plate	28mm
1897-22-026	UNIPLATE 2 - 2 Level Plate	26mm
1897-22-028	UNIPLATE 2 - 2 Level Plate	28mm*
1897-22-030	UNIPLATE 2 - 2 Level Plate	30mm**
1897-22-032	UNIPLATE 2 - 2 Level Plate	32mm
1897-22-034	UNIPLATE 2 - 2 Level Plate	34mm
1897-22-036	UNIPLATE 2 - 2 Level Plate	36mm
1897-22-038	UNIPLATE 2 - 2 Level Plate	38mm
1897-22-040	UNIPLATE 2 - 2 Level Plate	40mm
1897-22-042	UNIPLATE 2 - 2 Level Plate	42mm
1897-22-044	UNIPLATE 2 - 2 Level Plate	44mm
1897-06-010	UNIPLATE 2 - Self-Tapping Screw	10mm
1897-06-012	UNIPLATE 2 - Self-Tapping Screw	12mm
1897-06-013	UNIPLATE 2 - Self-Tapping Screw	13mm
1897-06-014	UNIPLATE 2 - Self-Tapping Screw	14mm
1897-06-015	UNIPLATE 2 - Self-Tapping Screw	15mm
1897-06-016	UNIPLATE 2 - Self-Tapping Screw	16mm
1897-06-018	UNIPLATE 2 - Self-Tapping Screw	18mm
1897-06-026	UNIPLATE 2 - Self-Tapping Screw	26mm
1897-07-012	UNIPLATE 2 - Self-Drilling Screw	12mm
1897-07-013	UNIPLATE 2 - Self-Drilling Screw	13mm
1897-07-014	UNIPLATE 2 - Self-Drilling Screw	14mm
1897-07-015	UNIPLATE 2 - Self-Drilling Screw	15mm
1897-07-016	UNIPLATE 2 - Self-Drilling Screw	16mm

* Contain no bend zone

** Can only be bent on one side

ORDERING INFORMATION

ITEM #	DESCRIPTION	
1897-06-112	UNIPLATE 2 - Large Diameter	12mm
1897-06-114	UNIPLATE 2 - Large Diameter	14mm
1897-06-116	UNIPLATE 2 - Large Diameter	16mm
1897-06-118	UNIPLATE 2 - Large Diameter	18mm
1897-06-126	UNIPLATE 2 - Large Diameter	26mm
2897-15-000	UNIPLATE 2 - Drill Guide - L	
2897-12-000	UNIPLATE 2 - Plate Holder	
2897-03-000	UNIPLATE 2 - 7mm Awl	
2897-05-012	UNIPLATE 2 - 12mm Tap Shaft	
2897-06-000	UNIPLATE 2 - CAM Tightener Shaft Tri-lobe	
2897-07-000	UNIPLATE 2 - CAM Tightener Torque Handle	
2897-08-000	UNIPLATE 2 - Self-Retaining Driver	
2897-09-000	UNIPLATE 2 - Standard Driver	
2897-11-000	UNIPLATE 2 - Quick Couple Handle	
2897-01-012	UNIPLATE 2 - Drill	12mm
2897-01-014	UNIPLATE 2 - Drill	14mm
2897-01-016	UNIPLATE 2 - Drill	16mm
2897-50-000	UNIPLATE 2 - Marking Pin	
2897-70-003	UNIPLATE 2 - Bone Screw Caddy	
2897-04-000	UNIPLATE 2 - Plate Bender	



Anterior Cervical Plate System

INDICATIONS:

The UNIPLATE® 2 Anterior Cervical Plate System is intended for anterior cervical intervertebral body fixation. This system is indicated for patients in whom stability is desired following anterior cervical fusion for the indications listed below. The intended levels from treatment range from C2 to T1.

Indications include symptomatic cervical spondylosis, trauma, fracture, post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, re-operation for failed fusion, or instability following surgery for the above indications.

These devices are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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.

WARNINGS:

Correct placement of the device is essential to optimal performance. Use of the UNIPLATE Anterior Cervical Plate System should only be undertaken after the surgeon has become thoroughly knowledgeable about the spinal anatomy and biomechanics, has had experience with anterior approach spinal surgeries, and has had hands-on training in the use of the device.

1. Correct selection of the implant is extremely important.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion.
3. Mixing metals can cause corrosion.
4. In selecting patients for internal fixation devices, the following factors can be extremely important to the eventual success of the procedure, including: the patient's occupation or activity; a condition of senility, mental illness, alcoholism, or drug abuse; certain degenerative diseases; foreign body sensitivity; smoking.
5. If bony fusion does not occur within an expected period of time, the screws may break due to the high and sustained loading of these devices. This has been noted in patients with delayed, pseudoarthrosis or non-union and can result in the need to revise the device.

PRECAUTIONS:

1. Surgical implants must never be reused.
2. Correct handling of the implant is extremely important.
3. Titanium alloy components should never be bent sharply or reverse bent.
4. If the devices are not removed after the completion of its intended use, any of the following complications may occur: corrosion with localized tissue reaction or pain; migration of implant position resulting in injury; risk of additional injury from postoperative trauma; bending, loosening, and/or breakage, which could make removal impractical or difficult; pain, discomfort, or abnormal sensations due to the presence of the device; possible increased risk of infection; and bone loss due to stress shielding. The surgeon should carefully weigh the risks versus the benefits when deciding when to remove the implant.
5. Adequately instruct the patient. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities.

Limited Warranty and Disclaimer: DePuy Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

To order, call DePuy Spine Customer Service (1-800-227-6633).

All products are not currently available in all markets.

CAM-LOC™ is a trademark of Codman & Shurtleff, Inc.

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