Indications:

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

Indications include symptomatic cervical spondylosis, trauma, fracture, post traumatic kyphosis or lordosis, tumour, 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.

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FUSION

MOTION

TISSUE MANAGEMENT

Surgical Technique

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Contents

Note: *The described technique presents only a few of the many approaches to stabilisation of the anterior cervical spine. The surgeon is encouraged to utilise the Uniplate™ Anterior Cervical Plate System with those techniques most familiar to the operating surgeon.*

uniPlate™

The Uniplate™ Anterior Cervical Plate is a unique single or two level system designed to be used in conjunction with suitable anterior column support whether this be by means of cervical cage or other structural bone graft material and provides the simplicity of single screw fixation at each vertebral body level for secure fixation.

System Description

Key features and advantages of the Uniplate™ System:

Streamlined Surgical Technique

- A single Universal Guide/Plate Holder allows the awl, drill, tap and screw to each to be inserted through this single instrument
- Midline screw minimizes lateral tissue retraction
- Self-Drilling and Self-Tapping Screws
- Pre-lordosed plate*

Plate Design

- Single midline screw
- Thickness = 2.3mm
- Width = 10.5mm
- Waist = 7.5mm

Other Features

- Equivalent bending strength to traditional cervical plates
- Tri-lobe CAM-LOC™ Mechanism
- Cleats to limit plate slippage
- 30° cone of angulation for optimal screw placement

** The Uniplate™ System has a pre-contoured lordotic curvature manufactured to replicate the normal anatomic cervical spine. The plate does not have a bend zone and therefore it should not be bent. Attempting to bend the plates in the region of the Cam Loc can significantly weaken the plate and compromise the Cam's ability to lock the screw and prevent screw backout.*

Operative Technique

Step 1: Site Preparation

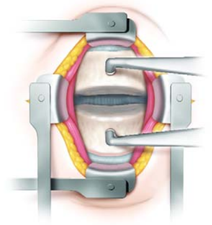

Figure 1

Perform the disc excision and spinal decompression using your standard surgical techniques (Figure 1). Insert the appropriate interbody graft material i.e. structural autograft or other structural graft material. 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.

Step 2: Plate Size Selection

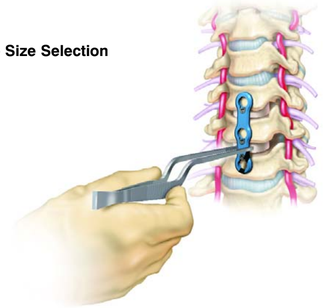

Figure 2

Uniplate™ Anterior Cervical Plates are available in configurations with 2 or 3 screw holes, in lengths ranging from 13-22mm (2 holes) or 28-40mm (3 holes).

Use the forceps to select the appropriate plate size and place it onto the vertebral column (Figure 2).

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

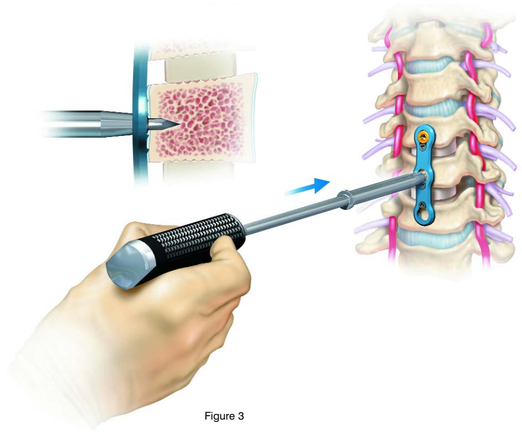

Figure 3

Step 3: Screw Hole Preparation

Using the Uniplate™ Awl

After the plate is positioned and aligned to the midline of the exposed anterior cervical spine, the awl may be used to mark the entry points for the screws.

Place the tip of the awl in the centre of the screw hole and press it in the direction of the screw angle desired (Figure 3). The awl can protrude into the bone to a depth of 7mm. To penetrate dense cortical bone, strike the handle of the awl with a mallet.

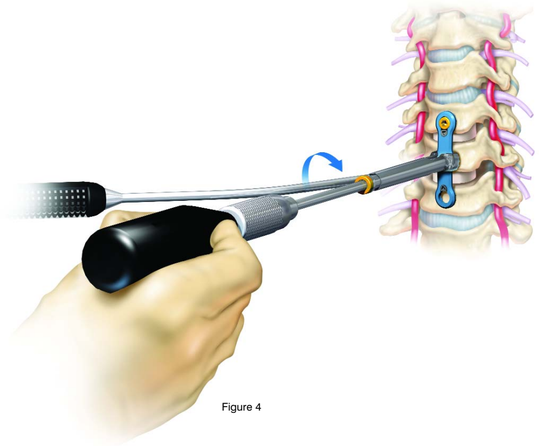

Figure 4

Step 3: Screw Hole Preparation (cont.)

Using the Universal Guide

The Uniplate™ System provides a Universal Guide that allows the awl, drill bits, tap, and screws to pass through the guide. 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 4).

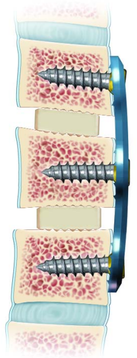

Figure 5

Step 4: Drill Bit Selection and Use

The Uniplate™ 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 x-rays to confirm drill bit penetration depth and orientation to ensure that these structures are not at risk.

Typical screw placement is 5-10° rostal & caudal to the disc space (Figure 5). Avoid angulation of the screws greater than 15° to ensure optimal locking of the screw to the plate. (See Step 5).

The Uniplate™ System provides 12mm (blue), 14mm (gold) and 16mm (magenta) fixed-depth drill bits. The colours of the collars correspond to their respective screw length colours (Figure 6).

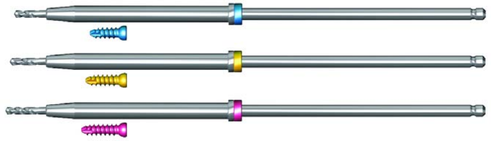

Figure 6

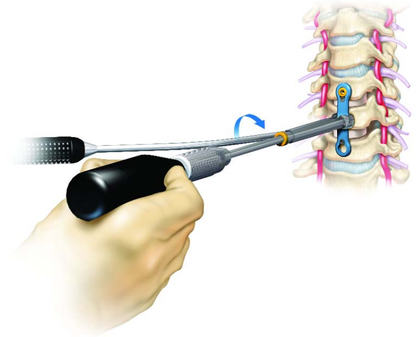

Figure 7

Insert the desired drill bit into the Quick Couple Handle or power drill. Advance the drill bit through the Universal Guide until the coloured collar contacts the guide (Figure 7).

The Uniplate™ 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 8

Step 5: Screw Placement

The Uniplate™ System offers self-drilling, self-tapping, and oversized screws. The screws are colour-coded to denote screw tip geometry, screw diameter, and screw length, as illustrated in the following chart and Figure 8. Please note that the Uniplate™ Screw length corresponds to the screw engagement length within the bone.

			4.6mm Self-Drilling	4.6mm Self-Tapping	5.2mm Oversized
12mm	Blue	●	•	•	•
13mm	Violet	●	•	•	
14mm	Gold	●	•	•	•
15mm	Light Blue	●	•	•	
16mm	Magenta	●	•	•	•
18mm	Titanium			•	•

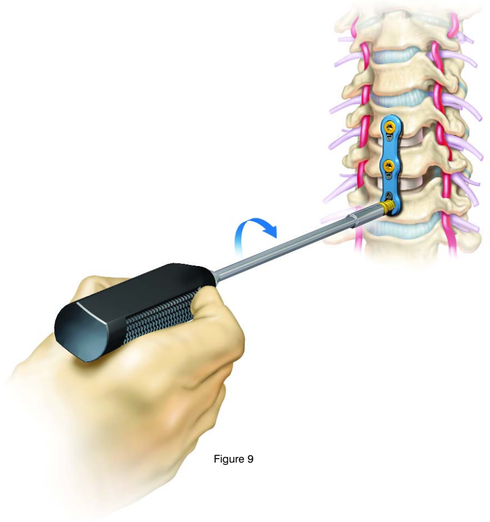

Figure 9

The Self-Retaining Screwdriver may be used to remove the desired screw from the screw caddy.

Insert the screw into the plate and advance it into the vertebral body (Figure 9). Use x-rays to confirm the final screw and plate position before the screws are fully tightened and secured by means of the CAM-LOC locking mechanism.

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.*

Step 6: Locking the CAMs

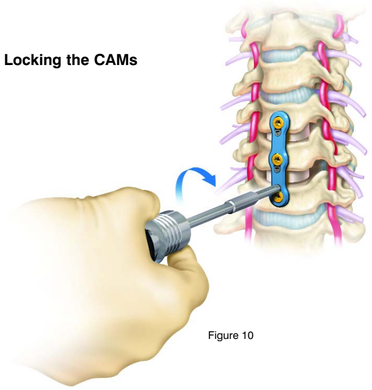

Figure 10

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 a Cam ensuring that the driver is fully seated within the Cam (Figure 10).

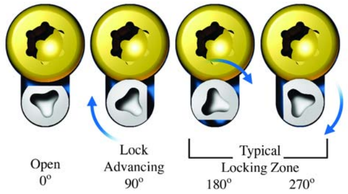

Figure 11

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 recommended locking zone as shown in Figure 11. Do not rotate the Cam beyond 270.°

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

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2761-01-015	Conduit™ TCP Granules	15 ml
2761-01-030	Conduit™ TCP Granules	30 ml

2761-60-002	Healos® Bone Graft Replacement	2.5 ml Strip
2761-60-005	Healos® Bone Graft Replacement	5 ml Strip
2761-60-010	Healos® Bone Graft Replacement	2 x 10 ml Strips

Notes