

Combat Anterior Cervical Plate System

iSpine

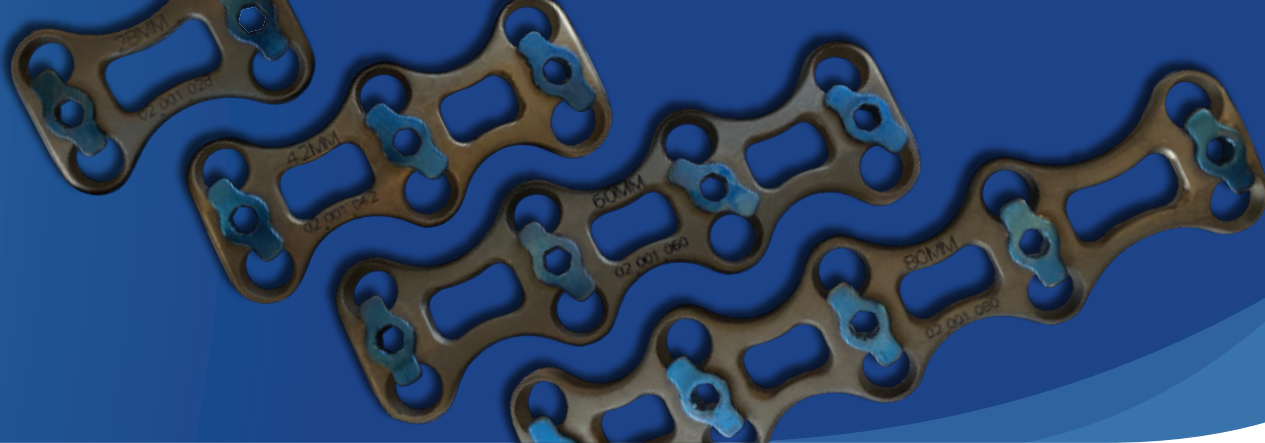
The Combat Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine at levels C2-T1.



The system is indicated for use in the anterior spine in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions.

The Combat Anterior Cervical Plate System consists of cervical plates, locking caps, bone screws, and the instruments necessary to implant this specific system. All implant components are made from a titanium alloy (Ti-6Al-4V).

The Combat Anterior Cervical Plate System is intended to provide stabilization of the cervical vertebra. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping and self-drilling bone screws using an anterior approach. Bone screws are available for fixed angle or variable angle implantation.



Surgical Technique

Exposure and discectomy:

The patient is placed in the supine position.

An anterior approach to the cervical spine is used through a right or left cervicotomy.

The anterior aspect of the vertebral bodies cephalad and caudal to the segment involved are exposed. The longus colli muscles are bluntly dissected from deep adherence and then retracted laterally. The surgeon incises the annulus with a scalpel and completely excises the disc by means of a pituitary rongeur until the posterior longitudinal ligament is reached.

End plate preparation:

After decompressing the spinal cord and nerve roots, the surgeon prepares the endplates using a curette without damaging the underlying cortical bone.

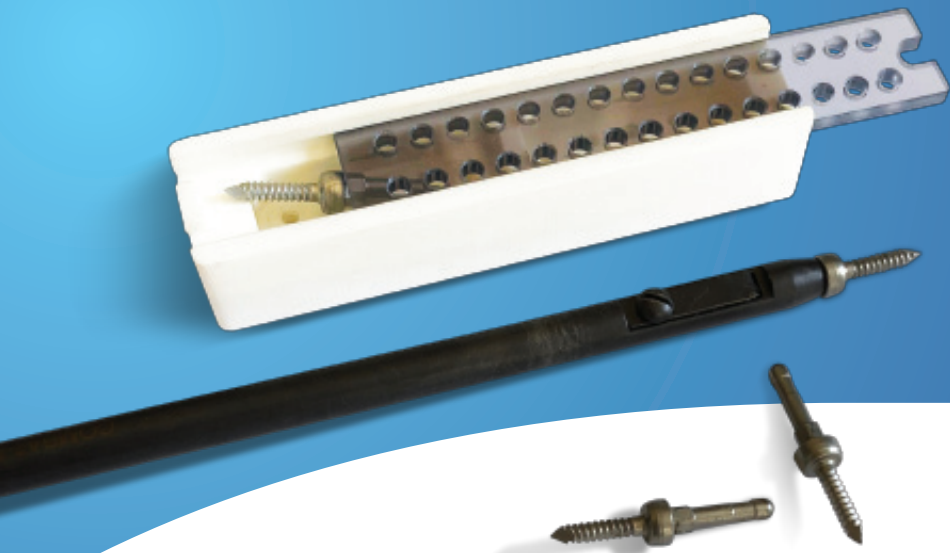
A bone graft or cage is inserted into the disk space.

Select the appropriately-sized plate for fixation to the vertebral bodies. A properly-sized plate will bridge the affected segment(s) without overhanging into the adjacent disc space. A Plate Holder is included in the Combat instrument set to facilitate plate selection and initial placement. It may be used to stabilize the plate during the insertion of the Temporary Fixation Pins or initial Bone Screws.

All plates in the Combat Anterior Cervical Plate System are prelordosed to match the curvature of the cervical spine.

A Plate Bender is also provided in the Combat instrument set if additional plate contouring is desired.

Increase Lordosis: To increase the bend of the plate, insert the plate in the Plate Bender such that the concave surface of the plate is resting against the anvil and the hammer is positioned such that the convex portion is facing the plate. Once positioned, squeeze the pliers-style handle to obtain the desired plate curvature.



Decrease Lordosis: To decrease the bend of the plate, insert the plate in the Plate Bender such that the convex bottom surface of the plate is resting against the anvil and the hammer is positioned such that the concave portion is facing the plate. Once positioned, squeeze the pliers-style handle to obtain the desired plate curvature.

Note: Plate Bending can significantly weaken the plate. Avoid plate bending when possible.

The Combat Anterior Cervical Plate System is equipped with Temporary Fixation Pins to provide short-term stability during plate placement and initial fixation. The Temporary Fixation Pins may be placed through the bone screw holes or the center of the locking cap on the Combat plate.

Screw Selection

The Combat self-drilling screws seek to provide the surgeon the option to reduce the amount of instruments used in a Combat Anterior Cervical Plate surgery. Reducing the amount of instruments has the potential to reduce the amount of retraction and time to implant a cervical plate.

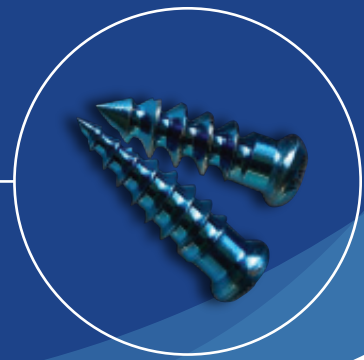
The difference between self-drilling and self-tapping screws is in the tip of the screw. The cutting flute design on the self-drilling screws eliminates the need for a drill or awl to penetrate the cortex of the vertebral body.

Note: The trajectory of the screws must be considered when using the free hand approach to placing self-drilling screws. It is recommended that the appropriate All-Through-One Guide Tube (variable or fixed angle) be used when placing self-drilling screws. If the angle of the screw trajectory is too great, it may not be possible to fully seat the screw within the plate and will cause difficulty when closing the Combat locking mechanism.

A 4.6mm Variable Bone Screw is available for situations where bony purchase has been lost with a 4.2mm Variable Bone Screw. Use the screw in a manner similar to the 4.2mm Variable Bone Screw, but without using a tap.

Screws available:

12mm	14mm	16mm	Variable angle screws
12mm	14mm	16mm	Conical variable angle screws
12mm	14mm	16mm	Variable angle rescue screws
12mm	14mm	16mm	Fixed angle screws



A Variable Angle Guide is included in the Combat instrument set. The Variable Angle Guide is designed to allow varied placement of the bone screws. This guide allows for screw placement at a conical angle of +/- 12° (superior/ inferior) from the fixed reference point.

Placement/Hole Preparation:

To use the Variable Angle Drill Guide, insert the tip of the Drill Guide into the screw pocket and position the guide at the desired angle. Once positioned, insert the standard Drill into the Drill Guide. Advance the Drill using a clockwise rotational motion until the positive stop on the Drill comes into contact with the Variable Angle Drill Guide. When complete, remove the Drill from the Drill Guide.

A Tap is provided in the Combat instrument set to create threads in the bone. To use the Tap, position the Drill Guide over the previously drilled hole. Insert the Tap into the Drill Guide and advance using a clockwise rotational motion until the positive stop comes into contact with the Variable Angle Drill Guide. Once contact is obtained, rotate the Tap counterclockwise until it is free of the bone and remove from the Drill Guide.

After the bone screw hole has been prepared, remove the Variable Angle Drill Guide and place the bone screw. Repeat the bone screw preparation and placement procedure for all remaining bone screw preparation sites.

Select the desired screw type and length. Insert the tip of the Hex Driver into the socket of the bone screw using downward pressure on the driver to secure the screw to the driver tip. Insert the screw in the desired bone site and rotate the Hex Driver clockwise to advance the screw until it is firmly seated.

Caution: *Do not continue to advance the bone screw once the screw is firmly seated in the plate. Continued screw tightening may strip the bone threads.*

For placement of fixed angle screws make use of the fixed angle drill guide following the steps listed above. The single barrel drill guide may be used in instances where space is limited.

The Single-Twist anti-migration caps are pre-installed and positioned on the plate to allow insertion of the bone screws.

Each cap will retain the bone screws within the plate when the cap is rotated to a secure position.

Placement/Positioning:

Once all bone screws have been placed, use the Hex Driver to rotate the Single-Twist cap clockwise approximately 45° to secure it properly. The cap will tighten and you will be able to confirm visually the cap covering the screws.

Optional:

The Ball-End Hex Driver may be used in situations where the Standard Hex Driver cannot be inserted directly into the locking cap. This situation may exist at the plate extremes due to interference with anatomical structures or retraction limitations. The Ball-End Driver allows the tip to be inserted into the locking cap at angles up to 25° off the central axis.

Once the plate is in the correct position and the screws are locked, the wound is closed in the normal fashion.

Instrument Log

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1. Combat Plate Bender



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2. Combat Plate Holder





3. Combat Straight Awl



4. Combat Ball-end Hex Driver



5. Combat Tap



6. Combat Rasp (5mm, 6mm, 7mm, 8mm)



7. Combat Hex Driver



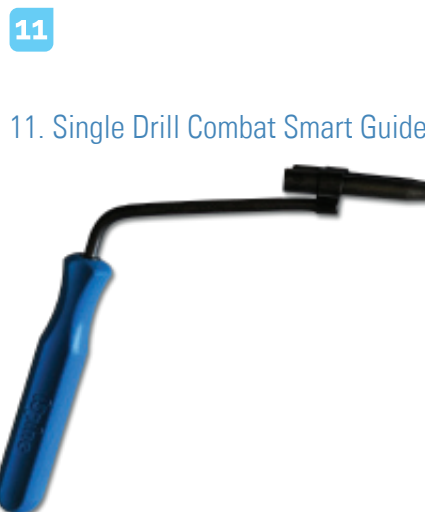
8. Combat Pin Inserter



9. Combat Quick Coupling Drill



10. Double Drill Combat Smart Guide



11. Single Drill Combat Smart Guide



12. Combat Screws



13. Combat Plates

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www.ispine.co.za • admin@ispine.co.za • Mulberry Hill Office Park, Unit 10, Broadacres Drive, Dainfern, Midrand
+27 11 469 0060

24 Hour Emergency Number: +27 82 881 8929