

CARBOCLEAR[®] CERVICAL PLATE SYSTEM

A COMPOSITE MATERIAL SPINAL SYSTEM

SURGICAL TECHNIQUE

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OVERVIEW

The CarboClear Cervical Plate System consists of plates made of carbon fiber-reinforced PEEK, in various dimensions, and of Ti-alloy screws, used to build a spinal construct for segmental spinal immobilization and stabilization.

Additionally, the CarboClear Cervical Plate System includes a set of instruments to assist in the introduction of the system implants.

INTENDED USE & INDICATIONS FOR USE

CarboClear Cervical Plate System is intended for anterior fixation of the cervical spine.

The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spine fusion in patients with the following:

Degenerative disc disease (DDD) (as identified by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (*i.e.*, fractures or dislocations), spinal stenosis and tumors, deformity (*e.g.*, scoliosis, kyphosis, lordosis), pseudoarthrosis, failed previous fusions.

IMPLANTS

The implants include plates and screws allowing polyaxial locking.

The plates are supplied sterile and the screws may be supplied either sterile or not. The implants are intended for single use.

Plates

A set of plates, in various lengths, allowing the treatment of 1 – 4 spinal levels. Plate holes and screws design allow for introduction of the screws into the plate screw holes at an angle (up to $\pm 6^\circ$).

The plates are made of CFR-PEEK and may incorporate tantalum as marker.

The plates are provided with an axial bend radius of 25mm and with a lordotic radius of 330mm. Plate thickness is 2.5mm and plate width is 18mm.



Screws

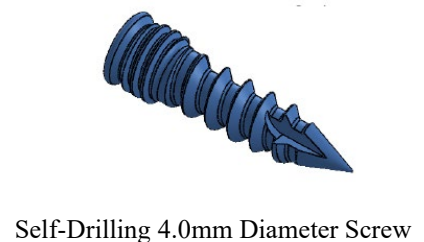
The screws provided with the CarboClear Cervical Plate System are made of Ti-alloy.

The screw head incorporates a Torx recess, allowing its connection to a screwdriver, for screw insertion, and removal (if desired).

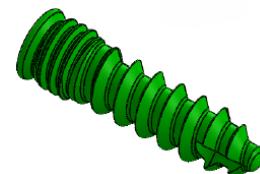
The screws are available with the following dimensions:

Diameter: 4.0mm (self-drilling) / 4.5mm (self-tapping)

Lengths: 10 - 20mm (in 2mm increments)



Self-Drilling 4.0mm Diameter Screw

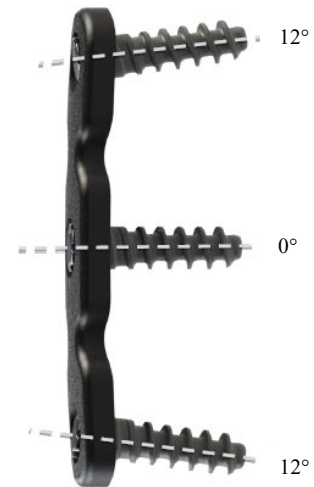


Self-Tapping 4.5mm Diameter Screw

Implants Assembly

Once locked as a construct, the cephalad/caudal screw orientation is 12° (relative to the line perpendicular to the plate at the screw hole), while the intermediate screws are oriented at 0° . The medial/lateral screws orientation is 6.5° .

As indicated above, the screws may be introduced at an angle of $\pm 6^\circ$ relative to the above indicated screws initial orientation.



Cephalad/Caudal Screw Orientation



Medial/Lateral Screw Orientation

INSTRUMENTS

Plate Holder (multiuse)

Used to securely hold the plate for proper placement and positioning.



Pre-Fixation Pins (multiuse)

Used to hold the plate during screw hole preparation. The pins are inserted using a dedicated screwdriver.



Screwdriver Handle (multiuse)

A dedicated handle for use with the screwdriver bits provided with the system.



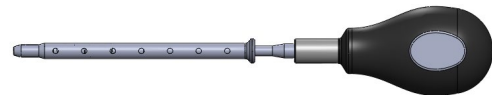
Screwdriver Bits (multiuse)

T 15 Bit - intended for inserting the Pre-Fixation Pins and the Screws.



Cervical Bone Awl (multiuse)

Used to gain access through the bone cortex.



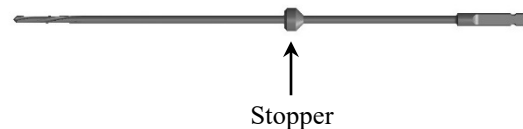
Cervical Drill Guide (multiuse)

Used to direct the drill bit to prepare the screw pathway.



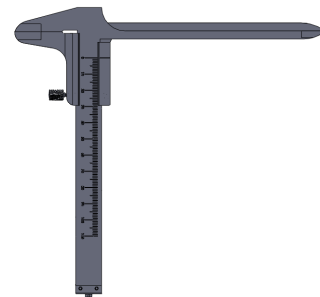
Drill Bits (single use)

Used to prepare the screw canal in combination with the Cervical Drill Guide. Available in 2.5mm diameter. For accurate drilling depth, a **Stopper** is provided. Five (5) different Drill Bits are provided with the Stopper located at 12, 14, 16, 18 or 20mm from the Drill Bit tip.



Caliper (multiuse)

Intended to assist in determining the required plate length during operation.



Additional surgical instruments may also be provided, to assist in the procedure, when required.

SURGICAL TECHNIQUE

1. *Preparation*

Patient positioning, and exposure of the anterior cervical spine, shall be performed according to standard surgical approach. Make sure to remove any osteophytes from the ventral cortical surface.

Interbody bone grafting shall be performed at the required levels.

2. *Plate Selection*

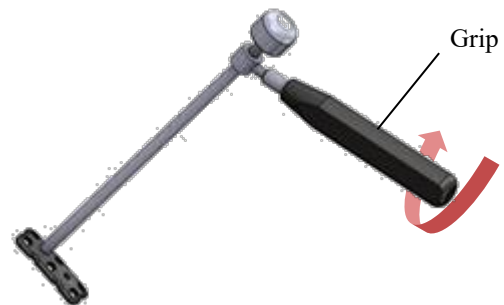
Note: Pre-surgical planning defines the most appropriate implants, as well as the optimal location of the implants. Appropriate implants dimensions are determined by a combination of preoperative planning/measurement and intra-operative observation.

- a. In general, plate length shall be determined by the number of levels to be fused.
- b. Use the **Caliper** to assess the required Plate length.
Plate length as indicated corresponds to the overall plate length (and not the distance between screw holes).
- c. select a plate such that the screw holes are located in the middle portion of the vertebra.

The **Plate Holding Device** may be used to assist in plate placement. It shall be placed in one of the plate holes not intended for screw insertion.

The grip orientation of the Plate Holding Device can be adjusted by rotating the handle grip counterclockwise, this enables to change orientation of the grip.

In order to lock the grip orientation in place rotate clockwise.



3. Plate Placement and Temporary Fixation

Place the plate over the bone. The **Pre Fixation Pins** may be placed through the screw holes (with the help of the T15 Screwdriver Bit connected to the supplied Handle) as needed, to temporarily affix the plate to the vertebral bodies.

4. Bone Penetration

Use the **Cervical Bone Awl** to penetrate the cortical bone of the vertebra through each of the plate screw holes.



5. Screw Hole Drilling

The CarboClear Cervical Plate System Screws are available in the following diameters:

4.0mm self-drilling screws.

4.5mm self-tapping screws.

In general, the CarboClear Cervical Plate is intended to be initially used with the 4.0mm self-drilling screws. Nevertheless, if desired, screw hole drilling may be performed for the 4.0mm screws, using the 2.5mm Drill Bit (with its dedicated Stopper, as detailed hereinafter).

Drilling the screw holes may be performed with the help of the **Drill Guide**.

If no bone drilling is desired continue to Step 6.

- a. Use the Drill Bit, complying with the desired drill depth (12-20mm), connected to the provided Handle.

- b. Place the Drill Guide in the desired screw hole of the Plate. Make sure that the Drill Guide is properly seated within the screw hole, at the desired angle (either at no angle to the Screw neutral axis or at an angle of up to $\pm 6^\circ$ to the Screw neutral axis).
- c. To ensure drilling to the required length, drill until the Stopper on the Drill Bit reaches the Drill Guide.



6. *Screw Insertion*

- a. Using the designated T15 Screwdriver Bit (connected to the Handle), insert the Screw.
- b. After placement of all screws verify radiographically the entire construct placement.



7. *Conclusion of Procedure*

Close the operation site according to common surgical practice.

IMPLANT REMOVAL PROCEDURE

Removal of the implants of CarboClear Cervical Plate System is performed in the following manner:

1. Expose the cervical spine along the involved vertebrae.
2. Use the screwdriver to remove the Screws. Rotate the screwdriver in counterclockwise direction.
Repeat the above for all Screws.
3. Remove the Plate.
4. Close the incision according to routine surgical procedure.

ORDERING INFORMATION

Plates

Levels	Thickness [mm]	Width [mm]	Length - Total [mm]	No. of Screw Holes	Catalogue No.
One	2.5	18	22, 24, 26, 28, 30, 32	4	CERVP10XX
Two	2.5	18	31.5, 34, 36.5, 39, 41.5, 44	6	CERVP20XX
Three	2.5	18	44, 47, 50, 53, 59, 62, 65,	8	CERVP30XX
Four	2.5	18	60, 64, 68, 72, 76, 80, 84, 88	10	CERVP40XX

Screws

Diameter [mm]	Length [mm]	Catalogue No.
4.0	12, 14, 16, 18, 20	CERPS40XXX
4.5	10, 12, 14, 16, 18, 20	CERPS45XXX

Instrumentation Set – Catalogue No. PL940100

Description	Catalogue No.
Sterilization Case	PL940105
Plate Holder	PL940220
Pre-Fixation Pin	PL940200
Screwdriver Handle	PL921510S
Screwdriver Bit T15	PL921650

Description		Catalogue No.
Cervical Bone Awl		PL940260
Drill Guide		PL940240
Drill Bit Ø2.5x115 (with stopper for 12mm Drilling)		PL940272
Drill Bit Ø2.5x115 (with stopper for 14mm Drilling)		PL940273
Drill Bit Ø2.5x115 (with stopper for 16mm Drilling)		PL940274
Drill Bit Ø2.5x115 (with stopper for 18mm Drilling)		PL940275
Drill Bit Ø2.5x115 (with stopper for 20mm Drilling)		PL940276
Caliper		PL940230

FURTHER INFORMATION

Important Note:

Refer to the system Package Insert (Instructions for Use; TEC 2531) for additional information regarding the CarboClear Cervical Plate System, including Contraindications, Warnings and Precautions, Possible Adverse Events and Packaging and Sterilization information.

Caution:

In the U.S.A., federal law restricts this device to sale by or on the order of a physician.

MANUFACTURED BY:

CarboFix Orthopedics Ltd.

11 Ha'hoshlim St., Herzeliya 4672411,
Israel

Tel: 972-9-9511511

Fax: 972-9-9548939

E-Mail: info@carbo-fix.com

U.S.A. CONTACT:

CarboFix Spine Inc.

9983 Traders Lane, Ext. 1, Calabash,
NC 28467, USA

Tel: 1-800-408 0120

Fax: 877-754-8652

E-Mail: usa@carbo-fix.com

Web Site: www.carbo-fix.com

Patents are pending