CARBOCLEAR® CERVICAL CAGE SYSTEM

SURGICAL TECHNIQUE

TABLE OF CONTENTS

OVERVIEW

The CarboClear® Cervical Cage System consists of implants made of carbon fiber-reinforced PEEK (CFR-PEEK), with a thin, porous, titanium alloy layers at the superior and inferior surfaces.

Additionally, the CarboClear Cervical Cage System includes a set of instruments.

Special Features of the CarboClear Cervical Cage include:

- CFR-PEEK core, allowing effective post-operation imaging.
- Large cavity for bone graft packing.
- Porous titanium endplates intended to allow patient's bone to grow into the porous plates.
- Serrated top and bottom surfaces to resist implant migration.
- Visualization of the implant using x-ray or fluoroscopy, due to titanium endplates located at the implant top and bottom surfaces.

INDICATIONS FOR USE

The CarboClear Cervical Cage System is indicated for intervertebral body fusion procedures of the cervical spine in skeletally mature patients with degenerative disc disease (DDD) at levels C2 – T1. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The implants are to be implanted via an open, anterior approach and packed with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine.

Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with the CarboClear Cervical Cage System.

IMPLANT

The **CarboClear® Cervical Cage** is inserted between two cervical vertebral bodies to stabilize the spine and maintain disc height during cervical interbody fusion surgeries.

Parallel (Up) and Lordotic Cages

The device is made of CFR-PEEK, with thin titanium-alloy, integrated porous layers at its top and bottom surfaces.

CarboClear Cervical Cage has a trapezoid ("D-Shaped") footprint. The hollow geometry of the implant allows it to be packed with bone graft. It has serrated top and bottom surfaces to resist implant migration. The device includes a threaded port and side grooves at its anterior side, for connection to the insertion tool.

CarboClear Cervical Cages are available in parallel and lordotic profiles, in several dimensions, as listed in the following table:

Width (Anterior) [mm]	Depth [mm]	Height (anterior) [mm]	Lordosis [Degrees]
14	12	4 – 8 (at 1 mm increments)	0, 8
16	14		

CarboClear Cervical Cage is implanted via anterior cervical interbody fusion approach.

The implants are intended for single use and are provided sterile.

INSTRUMENTS

The surgical instruments are provided non-sterile, in an ***Instrumentation Set*** combining the instruments used with the different CarboClear cervical implant systems.

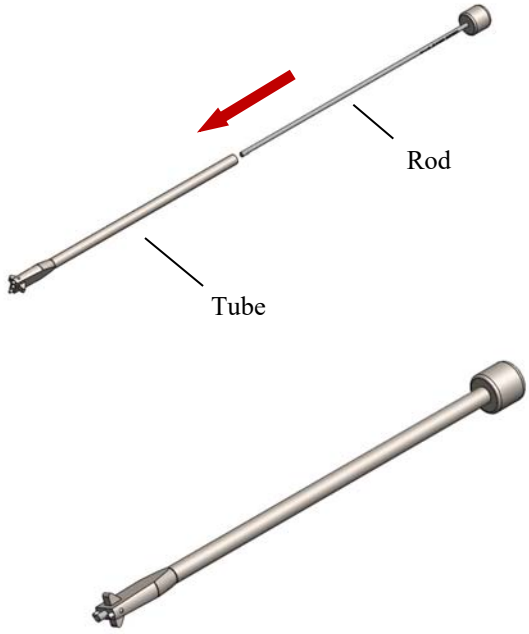
Note: General instruments needed for exposure of the spine and preparation of the implantation site (*e.g.*, curettes) are not provided with the CarboClear Cervical Cage System; conventional instruments, available in the hospital, should be used for those steps.

INSTRUMENTATION SET

Insertion Handle (Inserter)

The CarboClear cervical cage insertion handle is connected anteriorly to the implant via a dedicated connection port in the implant (which includes a threaded hole and 2 small notches on its sides). It is composed of a tube and an inner rod. The tube distal tip incorporates 2 protrusions which are situated within the notches. The rod is inserted via the tube and threaded to the hole.

Two (2) handles are provided: one for the 2 smaller cages (4mm- and 5mm-high ones), and the other for the higher cages (6mm-, 7mm- and 8mm-high ones).

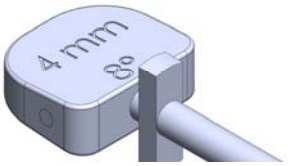


The Inner Rods can be used in case Cage removal is required (optionally, with the help of the Slap Hammer (see below)).

Trial Implants

The trial implants, having the general geometry and dimensions of CarboClear cervical cage, are intended for use before insertion of the implant into the intervertebral space, to assist in selection of correct implant dimensions and to verify implant position within the disc space.

The trial implants are visible when using radiographic means.

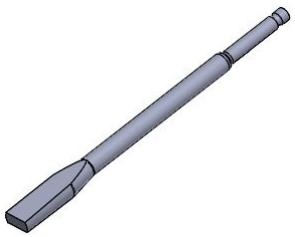


The trial implants are double sided – one end provides for 0 degrees lordosis trial implant and the other for 8 degrees lordosis trial implant. The trial implants are provided in heights matching those of the cage implant, with footprint of 12mm x 14mm.

Rasp

The Rasp is intended to prepare the endplates of the adjacent vertebrae prior to implant insertion. It is to be connected to the provided Handle (see below).

Impactor

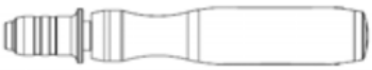


The impactor is used to assist in cage positioning within the disc space when required (after disconnecting the cage from the insertion handle).

It is to be connected to the provided Handle (see below). Gentle hammering may be applied to the impactor (connected to the handle) if required.

Handle

A dedicated handle, intended for use with the Impactor.



Slap Hammer

May be used for implant extraction. It is placed over the shaft of the Implant Inserter Rod and tapped to extract the device.
It may also be used with the Trial Implants, if required, to assist in their removal from the disc space.

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

SURGICAL TECHNIQUE

1. *Surgical Approach*

CarboClear Cervical Cage shall be implanted via an anterior approach.

Patient positioning and exposure of the spine shall be performed according to standard procedures.

Notes: a. Implant dimensions are calculated prior to surgery, using lateral and A-P x-rays and CT or MRI, and are then verified during surgery.

b. CarboClear Cervical Cage is implanted in conjunction with supplemental fixation (*e.g.*, cervical plate).

c. Initial procedure steps are performed following the standard practice for anterior cervical interbody fusion procedures.

2. *Discectomy, and Disc Space / Endplate Preparation*

Perform discectomy using standard practice.

Distract the disc space using a distractor. If necessary, repeat sequentially with additional distractor sizes, until adequate disc space height is obtained.

Use the **Rasp** to separate and remove any remaining disc and cartilage from the bony endplates, until endplate bleeding is stimulated. Make sure the endplates remain intact.

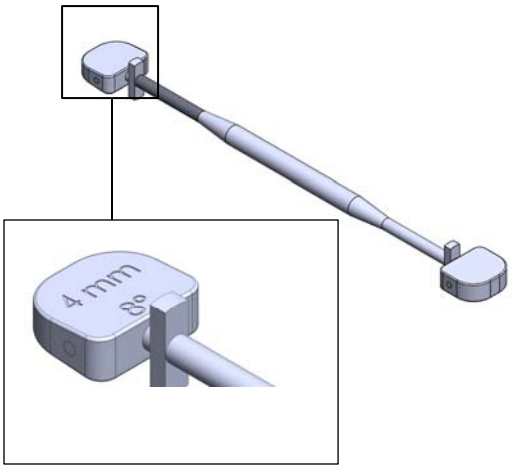
Curettes can also be used according to physician preference.

3. *Determining Cage Size (Trialing)*

Using the **Trial Implants** to facilitate correct selection of the implant and evaluate cage placement is extremely important.

The Trials are provided with both 0 degrees and 8 degrees lordosis and match the general configuration and dimensions of the corresponding implants.

There are several Trials, each with a different height matching the heights of the CarboClear Cervical Cages; they are “double-sided” – one end provides for the 0 degrees trial implant and the other end provides for 8 degrees trial implant. The depth and width of the trial implants are 12mm x 14mm.



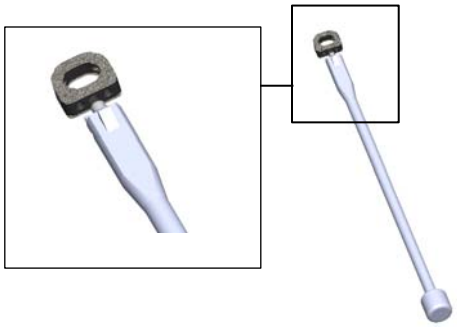
Insert the trials sequentially, starting with a small trial. Use A-P and lateral fluoroscopy to confirm proper placement and trajectory.

4. *Implant Insertion*

a. The appropriately sized CarboClear Cervical Cage is chosen during the trialing step.

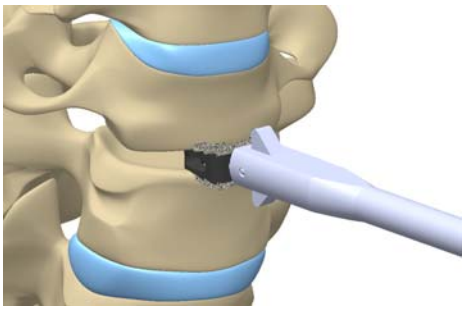
b. Pack bone graft into the cage cavity.

c. Choose the **Insertion Handle** compatible with the selected cage size.



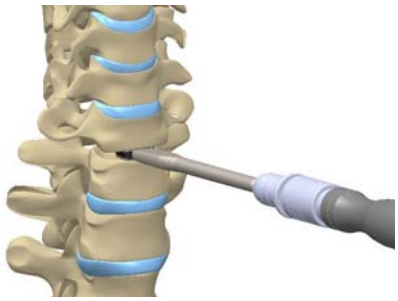
Insert the **Inner Rod** into the **Outer Sleeve**. Locate the protruding pins provided at the Insertion Handle outer sleeve distal end within the matching holes provided on the Cage and screw the Inserter inner rod tip into the threaded port of the Cage. Secure the Inserter and implant by turning clockwise the knob at the proximal end of the Inserter rod. Do not overtighten the Inserter.

d. Carefully insert and position the CarboClear Cervical Cage within the intervertebral body space, using the Inserter, assuring correct orientation of the Cage.
If required, gently impact the Inserter for implant pushing/pulling, respectively.



Precaution: Avoid excessive torque or impact force to long-handle insertion tools, as it may result in damage to the implant.

e. If the implant needs to be further pushed into the intervertebral space, after removal of the Inserter, the Impactor may be used. Place the impactor against the Cage and gently hammer (by tapping on the Handle).



f. The correct position of the implant should be confirmed by direct visualization of implant location and/or with lateral and A-P fluoroscopic images. The Ti-alloy superior and inferior surfaces of the CarboClear Cervical Cage are visualized under fluoroscopy, thus enabling the verification of implant positioning.

g. Additional bone graft may be placed in the disc space.

h. For ***intraoperative removal*** of the CarboClear Cervical Cage, use the Inserter Rod (re-connect it to the implant). If needed, the Slap Hammer can be used, placed over the Inserter Rod.

5. *Supplemental Fixation*

The CarboClear Cervical Cage is to be used with supplemental fixation (*i.e.*, posterior cervical screw and rod systems or anterior cervical plate systems) that is cleared for use in the cervical spine.

Intraoperative coronal and sagittal radiographic views should be used to confirm satisfactory position of the CarboClear Cervical Cage, supplemental fixation and bone graft.

6. *Closure*

Close the operation site using common surgical practice.

IMPLANT REMOVAL PROCEDURE

Removal of the CarboClear Cervical Cage is performed in the following manner:

1. Use imaging to determine exact implant location.

2. Expose the implantation site using conventional procedures.

3. Remove the additional internal fixation as required.

4. Connect the **Inserter Rod** of the appropriate size to the implant (by clockwise rotation); remove the Cage from the disc space. If greater force is needed, use the **Slap Hammer** placed over the Inserter Rod, and gently impact the Slap Hammer to remove the implant.

   Note: distraction, bone removal, and removal of fibrous tissue surrounding the Cage may also be required before the Inserter can be connected to the implant.

5. Alternatively, extraction can be performed utilizing a forceps or other manual surgical instruments that grasp and extract the implant.

6. Close the operation site according to common surgical practice.

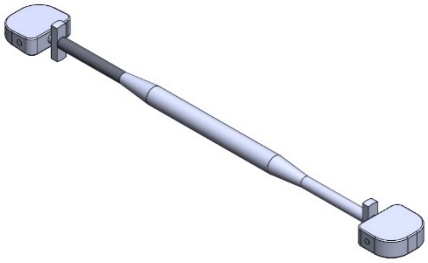
ORDERING INFORMATION

Implants

Width (Anterior) [mm]	Depth [mm]	Lordosis [Degrees]	Height (anterior) [mm]	Catalogue No.
14	12	0	4	CC121440
			5	CC121450
			6	CC121460
			7	CC121470
			8	CC121480
		8	4	CC121448
			5	CC121458
			6	CC121468
			7	CC121478
			8	CC121488
16	14	0	4	CC141640
			5	CC141650
			6	CC141660
			7	CC141670
			8	CC141680
		8	4	CC141648
			5	CC141658
			6	CC141668
			7	CC141678
			8	CC141688

Instrumentation

(the instruments may be provided as part of a CarboClear Cervical Systems Instrumentation Set – Catalogue No. PL940100)

Description		Catalogue No.
Trial Implant – 12 mm x 14 mm x 4 mm		CVBR001
Trial Implant – 12 mm x 14 mm x 5 mm		CVBR002
Trial Implant – 12 mm x 14 mm x 6 mm		CVBR003
Trial Implant – 12 mm x 14 mm x 7 mm		CVBR004
Trial Implant – 12 mm x 14 mm x 8 mm		CVBR005
Rasp		CVBR010
Implant Inserter – Outer Tube (Large)		CVBR006
Implant Inserter – Outer Tube (Small; for H4, H5)		CVBR007
Implant Inserter – Inner Rod (Large)		CVBR008
Implant Inserter – Inner Rod (Small; for H4, H5)		CVBR009
Impactor		CVBR011
Handle		PL921870
Sterilization Box		PL940105

CONTRAINDICATIONS

1. Any medical or surgical condition precluding the potential benefit of spinal surgery
2. Acute or chronic systemic, spinal or localized infections
3. Marked local inflammation
4. Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopedic implant.
5. Severe instabilities
6. Vertebral body fractures
7. Spinal tumors [in the region of the implant anchoring]
8. Systemic and metabolic diseases
9. Conditions that may place excessive stress on bone and implants, such as severe obesity.
10. Pregnancy
11. Prior fusion at the level(s) to be treated
12. Demonstrated allergy or foreign body sensitivity to the implant materials.
13. Generally poor condition of the patient
14. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, lifestyle, or neuromuscular deficit may interfere with their ability to follow postoperative restrictions and/or who may place undue stresses on the implant during healing and may be at a higher risk of implant failure.
15. Anytime implant utilization would interfere with anatomical structures or physiological performance.

WARNINGS AND PRECAUTIONS

1. Do not use this system without fully reading these instructions for use.
2. The implantation of intervertebral body fusion devices should be performed only by experienced spinal surgeons with specific training in the use of this cervical cage system, as well as in the use of the supplemental internal fixation to be used with this system, as these are technically demanding procedures presenting a risk of serious injury to the patient.
3. Correct selection of the implant is extremely important. The potential for satisfactory anterior column support is increased by selection of proper size device. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
4. Proper handling and storage of the system components is mandatory. Implants should not be bent, notched or scratched. Damage or alterations to the system components may produce stresses and cause defects, which could become the focal point for failure.
5. The sterile packaging of the relevant system components shall be inspected for visible damage prior to use. Do not use if damage is suspected.
6. Do not use sterile supplied items if the expiration date is overdue.
7. The sterile supplied components should be handled with appropriate precautions to maintain sterility. Do not re-sterilize the sterile-supplied, single use items!
8. Do not re-use the components which are intended for single use. Re-use of items indicated for single use may result in mechanical failure. Re-use may also result in biological implications (*e.g.*, contamination).
9. All parts that are provided non-sterile and/or are intended for multiple uses shall be handled per Packaging and Sterilization Section of this document.
10. Verify the integrity of all multi-use instruments (including functionality, where applicable). Do not use an instrument that is severely marred and/or worn, or a cutting instrument with dull edges. Note that at some point in time, instruments may wear out and should be replaced.
11. CFR-PEEK implants are designed to support physiologic loads. Excessive torque, when applied to long-handle insertion tools, can cause splitting or fracture of the CFR-PEEK implants. Damaged implants should be removed and replaced.

12. This device is not intended to be the sole means of spinal support. A supplemental fixation system should be used.
13. Bone graft should be packed inside the device and around it. The graft must extend from the upper to the lower vertebrae to be fused.
14. Extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
15. Implants can break when subjected to the increased loading associated with delayed union or nonunion. The implants are load sharing devices which are used until fusion occurs. If union is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of success of fusion, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant.
16. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be cautioned regarding weight bearing and body stress on the implant prior to secure bone healing. The patient should understand that implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of fusion. Implants displaced or damaged by improper activities may experience migration and damage to nerves or blood vessels.
17. The patients should be advised about the limitations of the implants and be taught to govern their activities.
18. Patients who smoke have been shown to have increased rates of non-unions. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Therefore, these patients should be advised of this fact and warned of the potential consequences. Obese, malnourished and/or alcohol abuse patients are also poor candidates for spine fusion.
19. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
20. As with all orthopedic implants, the CarboClear implants should never be reused under any circumstance. Any retrieved devices should be treated in a manner that reuse in another surgical procedure is not possible.
21. The system implants have not been evaluated for safety and compatibility in the MR environment; they have not been tested for heating, migration, or image artifacts in the MR environment. The safety of the implants in the MR environment is unknown. Scanning a patient who has such implants may result in patient injury. Please note that in such case there are potential hazards which include, but are not limited to:
    - Heating or migration of the device
    - Artifacts on MR images.
22. Disposal of implants and single use instruments shall be performed following the common facility procedures for such waste

FURTHER INFORMATION

Important Note:

Refer to the system Instructions for Use (TEC 3036) for additional information regarding the CarboClear Cervical Cage System, including 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

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Patents are pending