

CARBOCLEAR® LUMBAR CAGE SYSTEM

SURGICAL TECHNIQUE

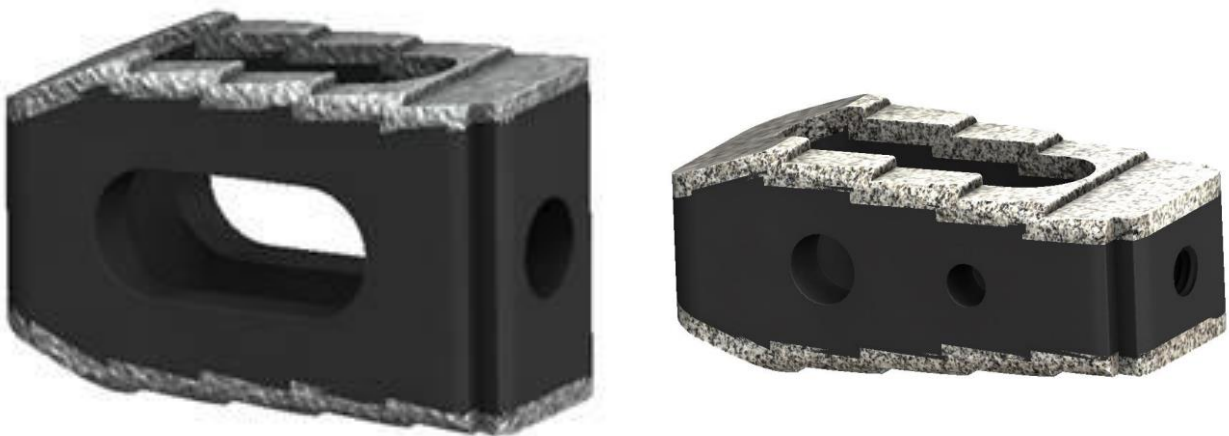


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OVERVIEW

The CarboClear® Lumbar Cage System consists of implants made of carbon fiber-reinforced PEEK (CFR-PEEK), with a thin, porous, titanium alloy layer at the superior and inferior surfaces. Additionally, the CarboClear Lumbar Cage System includes a set of instruments.

Special Features of the CarboClear Lumbar Cage include:

- Porous titanium endplates intended to allow the patient bone to grow into the porous plates
- CFR-PEEK core, allowing effective post-operation imaging for fusion assessment
- Large opening for bone graft packing
- Bulleted nose to ease implant insertion into the disc space
- Serrated top and bottom surfaces to resist implant migration
- Visualization of the implant using x-ray or fluoroscopy, due to titanium endplates located along the entire implant top and bottom surfaces

CarboClear Lumbar Cage is intended to be used with supplementary instrumentation.

INDICATIONS FOR USE

The CarboClear® Lumbar Cage System is indicated for intervertebral body fusion of the lumbar spine in skeletally mature patients with degenerative disc disease (DDD), at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The patients may also have up to Grade I spondylolisthesis at the involved levels.

CarboClear® Lumbar Cage System is intended for use with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and with supplemental fixation cleared for use in the lumbosacral spine.

Patients should have at least six months of non-operative treatment prior to surgery.

IMPLANT

The **CarboClear® Lumbar Cage** is inserted between two lumbar or lumbosacral vertebral bodies to stabilize the anterior column and maintain disc height during lumbar interbody fusion surgeries.

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

CarboClear Lumbar Cage has a cubic shape with a bulletted nose for ease of insertion. 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 posterior end, for connection to the inserter tool.



Parallel (Left) and Lordotic Cages –
Height: 12 mm and 14 mm



Parallel (Left) and Lordotic Cages –
Height: 8 mm and 10 mm

CarboClear Lumbar Cages are available in parallel and lordotic profiles, with a width of 10 mm; lengths of 23 mm or 27 mm; and several heights, as presented in the following table:

	WIDTH [MM]	LENGTH [MM]	HEIGHT [MM]	LORDOSIS [°]
PARALLEL CAGES	10	23 (Small)	8, 10, 12, 14	0
		27 (Large)	8, 10, 12, 14	0
LORDOTIC CAGES	10	23 (Small)	8	5
			10, 12, 14	5, 10
		27 (Large)	8	5
			10, 12, 14	5, 10

CarboClear Lumbar Cage is implanted via posterior lumbar interbody fusion (PLIF) approach or via transverse lumbar interbody fusion (TLIF) approach.

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

INSTRUMENTS

The surgical instruments are provided non-sterile, in an **Instrumentation Set**.

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

INSTRUMENTATION SET

Shavers

A set of eight Shavers, intended for discectomy and eroding the endplate. The Shavers have blunt tip and cutting sides for safety.

The width of the Shavers' distal section ranges between 7 mm to 14 mm, in one mm steps (thus covering the available implant heights).

Once rotated, the Shaver width also enables estimation of the intervertebral space height.

The Shaver width, and distances of 23 mm and 27 mm from the distal end, are marked on the Shavers. The Shavers are used with CarboClear Handle (described below).



Implant Trials

The Trials, having the general geometry and dimensions of CarboClear Cages, 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 Trials are visible when using radiographic means such as X-ray or fluoroscopy.



There are four small Trials (length: 23 mm), each with a different height matching the heights of the CarboClear Cages (8 mm, 10 mm, 12 mm, and 14 mm); and one large Trial (length: 27 mm; height: 8 mm). The small trials include a slot at a distance of 27 mm from trial distal end, indicating the length of the large implants.

The Trials are used with CarboClear Handle. They may be used with the Slap Hammer.

Handle

A T-Handle, to be used with the Shavers and the Trials.



Implant Inserter

The Inserter is used for introduction of the CarboClear Lumbar Cage into the disc space.

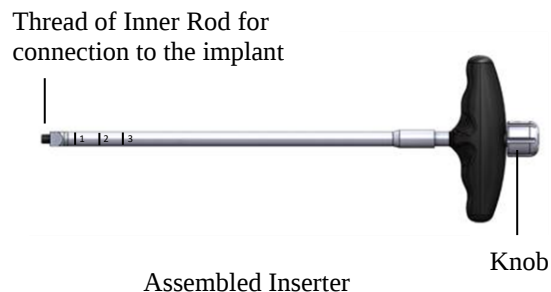
It is composed of an outer sleeve component with an integral T-handle, and an inner rod.

The **inner rod** has a thread at its distal tip, protruding from the outer sleeve, that is connected to the Cage's threaded port; and a knob at its proximal end. Two inner rods are available:

- Inner Rod with smaller thread matching the port of lordotic cages of 8 mm and 10 mm high;
- Inner Rod for the rest of the cages.

At its distal end, the **outer sleeve** grips the implant from both sides. The outer sleeve's distal end also contains markings (centimeters), to assist in cage depth positioning.

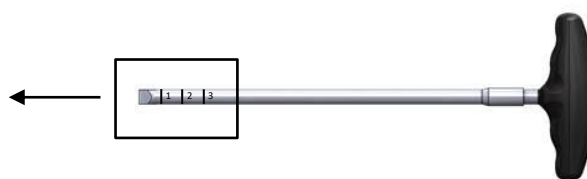
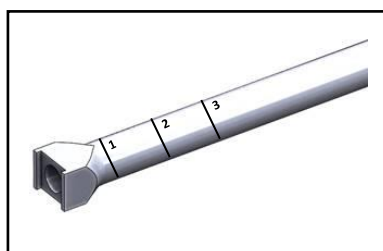
The Inserter may be used with the Slap Hammer.



Assembled Inserter



Inserter – Inner Rod



Inserter – Outer Sleeve

Bone Funnel and Bone Tamp

Used for introducing bone graft into the intervertebral space. The Funnel is a tube with a cone shaped cup at its proximal end. The bone graft/chips are inserted into the cup and then “pushed” forward through the tube into the disc space using the Tamp (an impact pool).



Slap Hammer

May be used with the Implant Trials, if required, to assist in Trial removal from the disc space.

May also be used for implant extraction.

It is placed over the shaft of the Implant Trial / Implant Inserter and tapped to extract the device.



Mallet

May be used to gently hammer on the Cage Inserter during implant insertion, if required.



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

SURGICAL TECHNIQUE

1. *Surgical Approach*

CarboClear Lumbar Cage may be implanted via a PLIF or TLIF approach.

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

- Notes:**
- a. Implant dimensions are decided prior to surgery, using lateral and A-P x-rays and CT or MRI, and are then verified during preparation of the implantation site.
 - b. CarboClear Lumbar Cage is implanted in conjunction with supplemental fixation (*e.g.*, pedicle screws). Follow the instructions and procedure defined by the manufacturer of the said system for its implantation.
 - c. Initial procedure steps are performed with conventional instruments available in the hospital for PLIF/TLIF procedures.

2. *Discectomy*

Meticulously remove the disc using Pituitary Rongeurs, Curettes and Shavers. Shavers are provided as part of CarboClear Instrumentation Set.

CarboClear Shavers are used with CarboClear Handle.

If there is significant disc collapse, completion of the discectomy may require distraction of the disc space.

3. *Disc Space Preparation*

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

A Curette or a Rasp can be used in a scraping fashion to separate and remove any remaining disc and cartilage from the bony endplates.

4. *Endplate Preparation*

Decortication is done meticulously with the provided Shavers to stimulate endplate bleeding, which facilitates bone fusion.

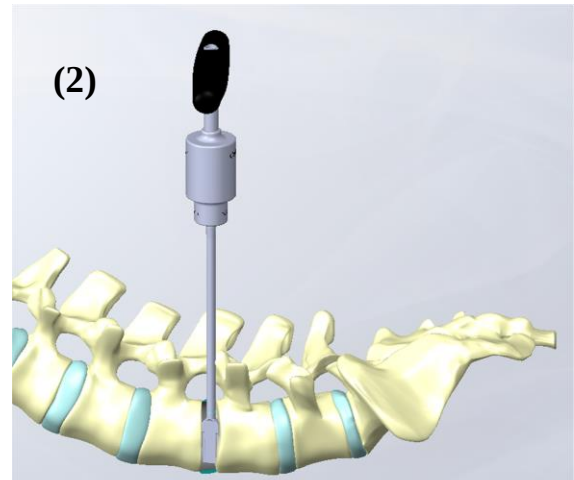
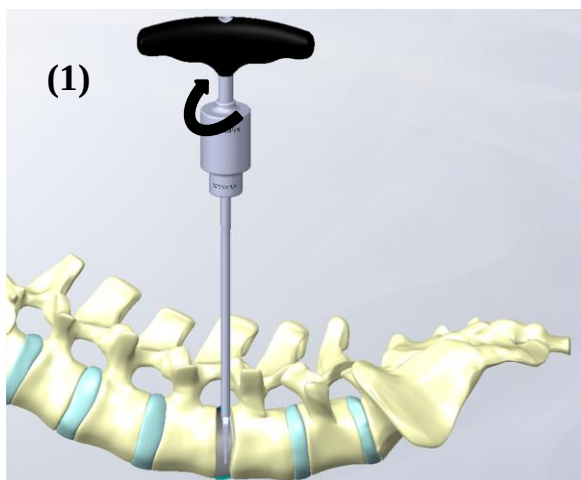
Connect the Shaver to CarboClear Handle.

Insert the Shaver into the intervertebral space (1) and rotate it (2). Start with a small Shaver and increase the Shaver size. Be careful not to exert excessive force.

Once rotated, the width of the Shaver distal section (7 mm – 14 mm, in 1 mm increments) enables estimation of the intervertebral space height and the required implant height.

Curettes can also be used according to physician preference.

The quality of disc space and endplate preparation is an important factor for subsequent fusion.



5. *Trial Sizing*

Trialing to facilitate correct selection of the implant is extremely important.

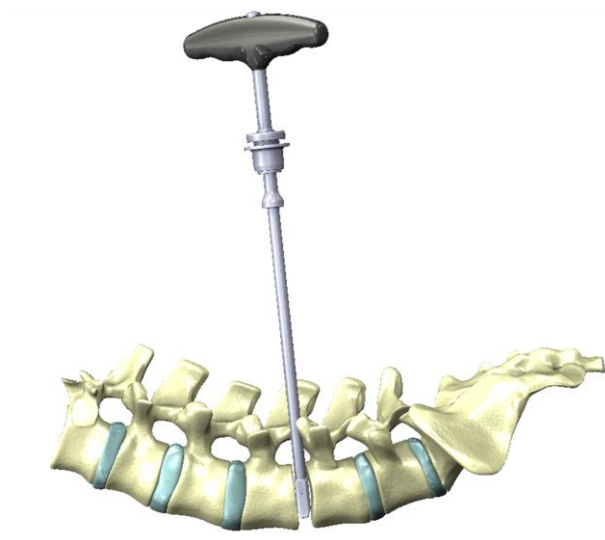
The Trials have parallel profile and match the general configuration and dimensions of the corresponding implants. The Trials are used with CarboClear Handle.

There are four small Trials (length: 23 mm), each with a different height matching the heights of the CarboClear Cages (8 mm, 10 mm, 12 mm, and 14 mm); and one large Trial (length: 27 mm; height: 8 mm). The small trials include a slot at a distance of 27 mm from their distal end, indicating the length of the large implants.

CarboClear Implant Trial should be used prior to insertion of the implant to evaluate cage placement and determine the optimal implant fit.

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

If required, CarboClear Slap Hammer may be placed over the Trial shaft, to assist in pulling the Trials from of the disc space.



6. *Bone Graft Placement*

In order to achieve a solid interbody fusion, the disc space should be filled with as much bone graft as possible.

Bone graft may be placed anteriorly in the interbody space prior to insertion of the implant. Use autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

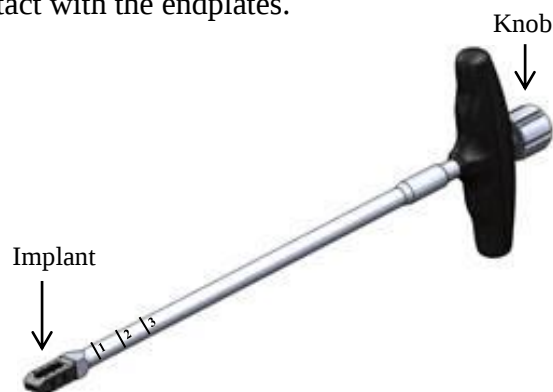
Introduce the bone graft into the disc space using the provided Bone Funnel and Tamp or by manually inserting bone chips within the intervertebral space with the help of a pinch.

7. Implant Insertion

- a. The appropriately sized CarboClear Cage is chosen during the trialing step.
- b. Pack bone graft into the device. The compacted graft should be flush with the upper and lower surfaces of the implant, to later be in contact with the endplates.

- c. Choose an Inserter inner rod compatible with the selected Cage, and assemble the Inserter components.

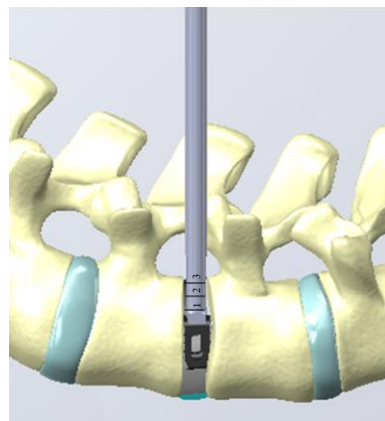
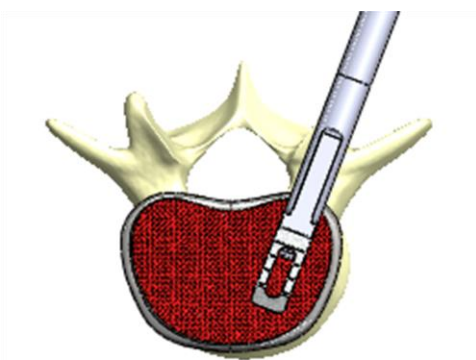
The inner rod with the smaller thread is used with lordotic cages of 8 mm and 10 mm high.



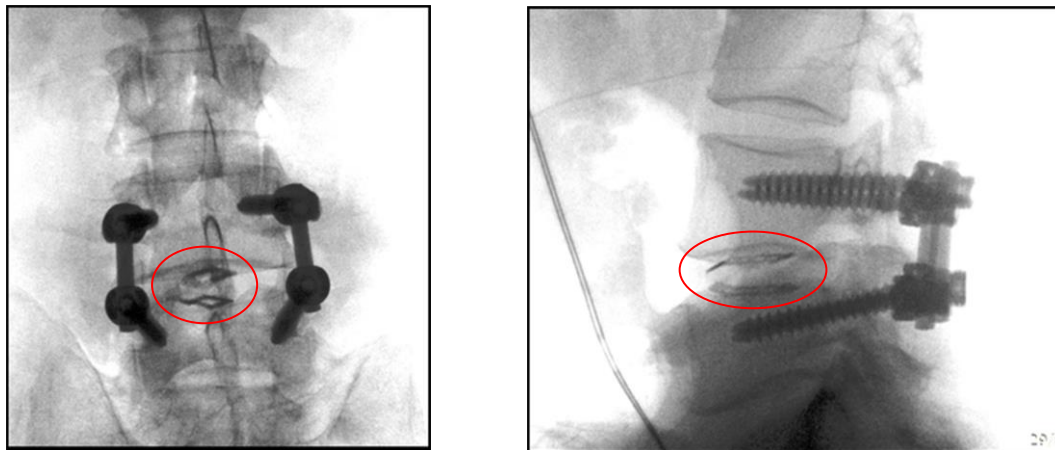
Insert the inner rod into the outer sleeve, and firmly attach the Inserter to the Cage: Align the distal end of the Inserter outer sleeve with the Cage side grooves, and the threaded tip of the Inserter inner rod with the Cage' threaded port. Secure the Inserter and implant by turning clockwise the Inserter knob. Do not overtighten the Inserter.

- d. Carefully insert and position the CarboClear Cage into the intervertebral space, using the Inserter, in the orientation that the Cage is intended to sit. The outer sleeve' distal end contains markings (centimeters from distal end), to assist in cage depth positioning. If required, use the Mallet/Slap Hammer provided in the CarboClear Instrumentation Set to gently impact the Inserter for implant pushing/pulling, respectively.

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



- e. Verify implant position with fluoroscopy. The Ti-alloy superior and inferior surfaces of the CarboClear Cage (including over implant "nose") are visualized in fluoroscopy, thus enabling the verification of implant positioning.



A-P (left) and lateral X-rays of CarboClear Lumbar Cage and metal pedicle screw construct

- f. With the desired position achieved, detach the Inserter from the implant by turning the knob on the Inserter inner rod in the counterclockwise direction. Additional bone graft may be placed in the disc space.
- g. The correct position of the implant should be confirmed by a direct visualization of implant location and/or with lateral and A-P fluoroscopic images.
- h. For ***intraoperative removal*** of the CarboClear Cage, when deemed medically necessary, perform distraction. Use the Inserter still attached to the implant to remove the cage from the disc space. If needed, CarboClear Slap Hammer can be used.
- In case the Inserter was disconnected from the Cage and it is desired to remove the implant intraoperatively, use imaging to determine its exact location. Thread the Implant Inserter inner rod to the implant (by rotating the Inserter knob), and remove the Cage. If needed, CarboClear Slap Hammer can be used. If possible, removal should be performed in-line and in the same trajectory that the implant was inserted.

8. Supplemental Fixation

The CarboClear Cage is to be used with supplemental fixation (*e.g.*, pedicle screws) that is cleared for use in the lumbosacral spine. Pedicle screws can be implanted either before or after cage implantation. If pedicle screws were not inserted earlier in the procedure, insert pedicle screws (or other appropriate supplemental fixation) at this point.

The remaining bone graft may be placed in the decorticated facets to promote fusion.

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

9. Closure

Close the operation site using common surgical practice.

IMPLANT REMOVAL PROCEDURE

Removal of the CarboClear Lumbar cage is performed in the following manner:

1. Use imaging to determine exact implant location.
2. Expose the implantation site using conventional procedures (and complying with the surgical approach used during the implantation (PLIF/TLIF)).
3. Thread the Implant Inserter inner rod to the implant (by rotating the Inserter knob), and remove the Cage from the disc space.
If greater force is needed, attach the Slap Hammer to the Inserter, 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.

4. Alternatively, extraction can be performed utilizing a forceps or other manual surgical instruments that grasp and extract the implant.
5. Close the operation site according to common surgical practice.

ORDERING INFORMATION

Implants

Parallel Devices

Width [mm]	Length [mm]	Height [mm]	Lordosis [Degrees]	Bone Graft Volume [cc]	Catalogue Number
10	23 (Small)	8	0	0.62	CCLC2308
		10		0.76	CCLC2310
		12		0.97	CCLC2312
		14		1.25	CCLC2314
	27 (Large)	8	0	0.62	CCLC2708
		10		0.76	CCLC2710
		12		0.97	CCLC2712
		14		1.25	CCLC2714

Lordotic Devices

Width [mm]	Length [mm]	Height [mm]	Lordosis [Degrees]	Bone Graft Volume [cc]	Catalogue Number
10	23 (Small)	8	5	0.52	CCLC230805
		10	5	0.70	CCLC231005
		10	10	0.65	CCLC231010
		12	5	0.91	CCLC231205
		12	10	0.85	CCLC231210
		14	5	1.13	CCLC231405
		14	10	1.12	CCLC231410
	27 (Large)	8	5	0.50	CCLC270805
		10	5	0.68	CCLC271005
		10	10	0.61	CCLC271010
		12	5	0.88	CCLC271205
		12	10	0.80	CCLC271210
		14	5	1.15	CCLC271405
		14	10	1.05	CCLC271410

Instrumentation Set – Catalogue No. CCLC1000

Description	Catalogue No.	
Shaver – 7 mm	CCLC9007	
Shaver – 8 mm	CCLC9008	
Shaver – 9 mm	CCLC9009	
Shaver – 10 mm	CCLC9010	
Shaver – 11 mm	CCLC9011	
Shaver – 12 mm	CCLC9012	
Shaver – 13 mm	CCLC9013	
Shaver – 14 mm	CCLC9014	
Implant Trial – 10 mm x 23 mm x 8 mm	CCLC02308	
Implant Trial – 10 mm x 23 mm x 10 mm	CCLC02310	
Implant Trial – 10 mm x 23 mm x 12 mm	CCLC02312	
Implant Trial – 10 mm x 23 mm x 14 mm	CCLC02314	
Implant Trial – 10 mm x 27 mm x 8 mm	CCLC02708	
Implant Inserter – Outer Part	CCLC9040A	
Implant Inserter – Inner Rod (Large)	CCLC9040B	
Implant Inserter – Inner Rod (Small), for lordotic cages of 8mm and 10 mm high	CCLC9040C	
T-Handle	CCLC9020	
Bone Funnel	CCLC9050	
Bone Tamp	CCLC9090	
Slap Hammer	CCLC9060	
Mallet	Q9105110	
Sterilization Box	CCLC9070	

CONTRAINDICATIONS

1. Active systemic infections, significant risk of infection (immunocompromise), or infection localized to the site of the proposed implantation.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Although not absolutely contraindicated, conditions to be considered as potential factors for not using this device include: rapidly progressive joint disease, severe bone resorption, osteomalacia, and severe osteoporosis, which may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.
5. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
6. Pregnancy.
7. Suspected or documented allergy or foreign body sensitivity to any of the implant materials.
8. Prior fusion at the level/s to be treated.
9. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
10. Medical conditions that preclude patient operation (*e.g.*, coagulation disorder).
11. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
12. Any case not needing a fusion or not described in the indications.
13. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
14. Spondylolisthesis unable to be reduced to Grade I.
15. Any patient in which implant utilization would interfere with anatomical structures or expected 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 lumbar cage system, as well as in the use of the supplemental internal fixation to be used with this system, as these are a technically demanding procedure 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 nerves or blood vessels.
17. The patient should be advised of its inability to bend at the point of spinal surgery and taught to compensate for this permanent physical restriction in body motion.
18. Patients who smoke have been shown to have an increased level of non-unions. Therefore, these patients should be advised of this fact and warned of the potential consequences.
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 implants of the CarboClear Lumbar Cage System have not been evaluated for safety and compatibility in the MR environment; they have not been tested for heating, migration or image artifact in the MR environment. The safety of the implants in the MR environment is unknown. Scanning a patient who has such implant may result in patient injury.

FURTHER INFORMATION

Important Note:

Refer to the system Instructions for Use (TEC 2734) for additional information regarding the CarboClear Lumbar 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