CARBOCLEAR® POSTERIOR CERVICAL SCREW SYSTEM

A COMPOSITE MATERIAL SPINAL SYSTEM

SURGICAL TECHNIQUE FOR ONCOLOGICAL PATIENTS

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OVERVIEW

The CarboClear Posterior Cervical Screw System ("CarboClear System") consists of implants made mostly of carbon fiber-reinforced PEEK (CFR-PEEK), used to build a spinal construct for segmental spinal immobilization and stabilization.
Additionally, the CarboClear Posterior Cervical Screw System includes a set of instruments.

INDICATIONS FOR USE

The CarboClear Posterior Cervical Screw System is intended to restore the integrity of the spinal column even in the absence of fusion for limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is insufficient duration to permit achievement of fusion.

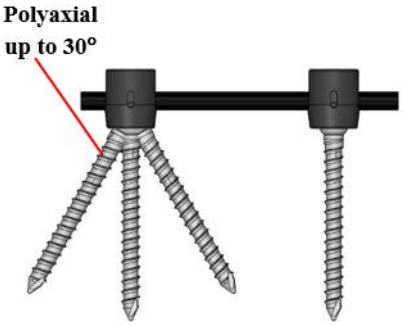
SYSTEM BENEFITS

CarboClear Posterior Cervical Screw System provides for the following benefits in oncological patients:

- Reduced CT artifacts
- Improved pre-radiotherapy planning
- Reduced interference with radiotherapy protocols
- Allows for proton therapy
- Visualization of the construct using the screw titanium shell, evident on x-ray imaging or fluoroscopy

IMPLANTS

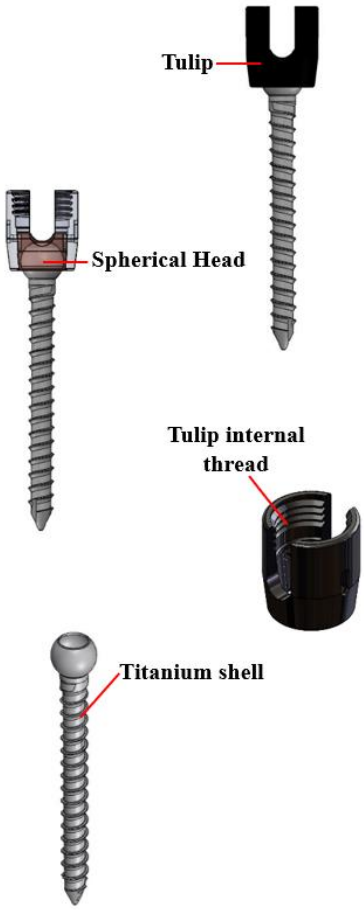
The implants include polyaxial posterior screws, longitudinal rods and locking elements.
The implants are made of CFR-PEEK. The screw shank and head are encased within a titanium shell.



Implants are supplied sterile and are intended for single use.

Posterior Cervical Screws

Polyaxial posterior screws, comprising a spherical head enclosed within a housing (tulip), allowing tulip positioning in a variety of angles (up to 30°).
The tulip has a "U" shape to accommodate the rod. It includes an internal thread, compatible with a locking element that locks the implant construct components.



The screws are made of CFR-PEEK and may incorporate a small tantalum marker close to their distal tip. Their threaded portion and the spherical head are encased within a 3D printed thin shell, made of pure titanium. The thin titanium shell allows the posterior screw to be visualized under X-ray, and it enhances bone integration.

The Posterior Cervical Screws are available in 4.0 mm, and 4.5 mm diameter, and length ranging from 14 mm to 40 mm (with 2 mm increments).

Rods

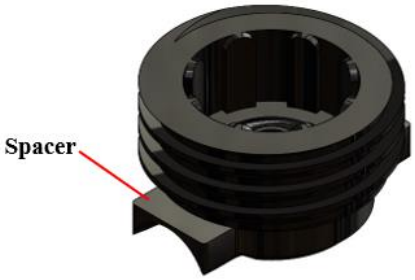
Longitudinal rods made of CFR-PEEK or Ti-Alloy, measuring 4.0 mm in diameter are available in straight or curved options. They can be intraoperatively cut if needed, using the Cutting Set.

The following Rods are available:

- Straight CFR-PEEK rods, lengths 30 - 100 mm (with 10 mm increments), 200 mm.
- Curved CFR-PEEK rods, lengths 30 - 100 mm (with 10 mm increments), 200 mm.
- Titanium alloy rods (Ti-6Al-4V), length 200 mm (for varying rod contouring, if required).

Locking Element

The Locking Element is made of CFR-PEEK, intended to lock the rod to the screw.



The Locking Element incorporates a spacer component at its bottom with a curved inferior surface, configured to match the shape of the rod.

The Locking Element is used with two dedicated screwdrivers (a Starter and a Locker), each comprising an integral torque limiter.

INSTRUMENTS

The surgical instruments are provided non-sterile, in an ***Instrumentation Set***.
Single use, sterile provided, **Cutting Set**, and screw **Extractors** are also provided (described below)

INSTRUMENTATION SET

Cervical Awl

Used to gain access through the bone cortex into the vertebral body.

Cervical Bone Probe

The straight bone probe is intended to tunnel through the cancellous bone into the vertebral body. The probe includes depth markings.

Adjustable Drill Guide

Serves as a guide during the drilling and tapping procedure. Having a length limiter to the drill guide, it assures predetermined depth entrance into the bone. Additionally, the Drill/Tap Guide protects soft tissues surrounding the surgical site.
The Adjustable Drill/Tap Guide provides drilling/tapping depths ranging from 10mm to 40mm.

Feeler

The Feeler is used to verify the integrity of the bone prior to tapping. Its length is marked to assist in the assessment of Screw length.

Bone Taps

The bone Taps are used to prepare the posterior screw canal and are available in 4.0 mm and 4.5 mm diameter. The recommended Tap is of the same diameter as that of the Screw, and tapping shall be carried to the entire length of the selected Screw (slightly deeper than the actual length of the screw to be placed).

The Taps are marked to assist in Screw length selection.

The Bone Taps are used with the AO Connection Straight Handle (Torque Limiter Handle).

Tap Sleeve

Used in order to protect the patient's soft tissue during the tapping prosses.

Depth Gauge

Used to measure depth of the prepared hole and determine the appropriate screw length for accurate placement.

Torque Limiter Straight Handle

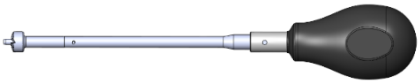
Dedicated handles containing an internal torque limiter and a ratchet mechanism that allows for changing the direction of rotation by moving it forward (clockwise) or backward (counterclockwise).

Two handles are available:

- A handle that features a Square connection and a torque limiter of 0.8Nm. It is specifically designed for use with the Cervical Screwdriver and Starter.
- A handle that features an AO connection and has a torque limiter of 2.5Nm. It is designed to be used with the Drill Bit, Bone Tap and Locker.

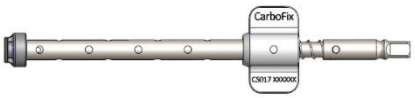
Bone Surface Reamer

May be used, if required, to ream the bone surface to allow accommodation of the Posterior Screw head and tulip.



Cervical Screwdriver

The Screwdriver is used for screw insertion into the bone and is used with the Square connection Straight Handle.

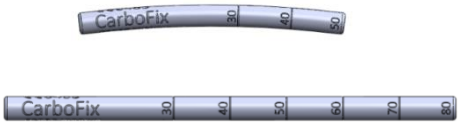


Tulip Adjuster

Used to adjust the orientation of the Screw Tulip.

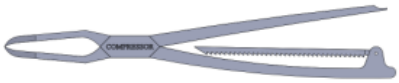
Rod Measuring Templates

Polymeric rods, both straight and curved, come in lengths of 50mm and 80mm. They are designed for selecting the appropriate rod length and curvature. May be used with the Rod Holding Forceps.



Compressor

Used to perform compression between opposing vertebrae, in case required.

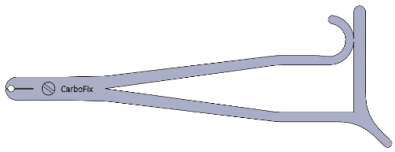


Distractor

Used to perform distraction between opposing vertebrae, in case required.

Rod Holding Forceps

Used to hold the (a) Rod Measuring Template and (b) the Rods.

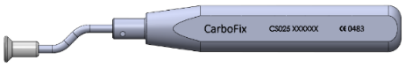


Cutting Container

The container is designed to hold the rod while it is being cut.

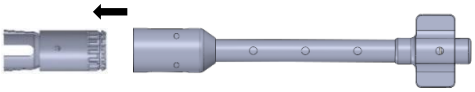
Rod End Shaper

Used in case CFR-PEEK Rods are cut (after CFR-PEEK Rods shortening), to refine the cut surface.



Rod Reducer and Handle

Used to assist in location of the Rod within the Screw Tulip, if required.



Starter

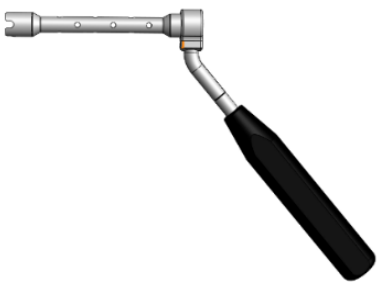
A self-retaining driver for the insertion and initial tightening of the Locking Element, within the Screw Tulip. The Starter is used with the Square connection Straight Handle.

Locker

The Locker is used for final locking of the Locking Element within the Screw Tulip. The Locker is used with the 2.5 Nm torque limiter AO connection Straight Handle.

Counter Torque

Used during locking of the Locking Element to the implant construct. The Counter Torque incorporates a sleeve, into which the Locker is inserted.



DRILL BITS [SINGLE USE; PROVIDED STERILE]

The drill bits are used to create the posterior screw canal and are available in 3.2 mm and 3.6 mm diameter.

- 3.2 mm is used for the 4.0 mm Posterior Screw
- 3.5 mm is used for the 4.5 mm Posterior Screw

The Drill Bits are used with the AO connection Straight Handle (Torque Limiter Handle).

CUTTING SET [SINGLE USE; PROVIDED STERILE]

Saw

Used for shortening the CFR-PEEK Rods.

SCREW EXTRACTOR [SINGLE USE; PROVIDED STERILE]

The Screw Extractors may be used in case removal of a damaged (e.g., broken) Screw is required, when positioned under the bone surface. The Extractor is available in two dimensions (4.0 mm and 4.5 mm diameter), to comply with the different diameters of the Posterior Screw. The Extractors are used with the Square connection Straight Handle (Torque Limiter Handle).

SURGICAL TECHNIQUE

1. *Surgical Approach*

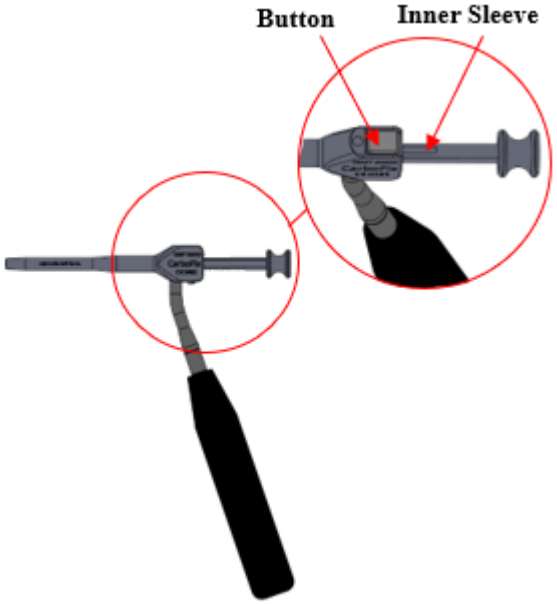
Patient positioning, surgical approach and exposure of the spine shall be performed according to standard procedures.

Note: Pre-surgical planning defines the most appropriate implants, as well as the optimal location of the implants. Appropriate Posterior Screw ("Screw") dimensions are determined by a combination of preoperative planning/measurement and intraoperative observation.

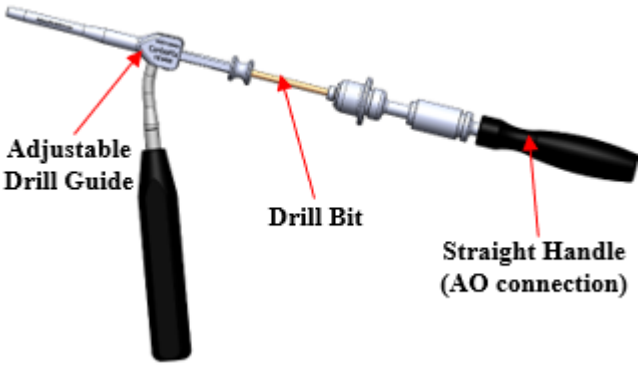
2. *Bone Preparation*

a. After adequate exposure, select the appropriate posterior entry point. At each entry point, use the supplied **Cervical Awl** to breach the cortical surface.

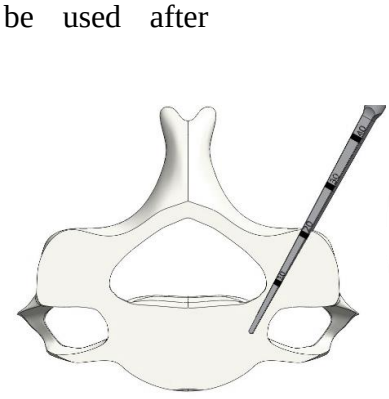
b. **Drill Bit** or **Cervical Bone Probe** can be used to reach desired depth and trajectory in bone for screw placement. Follow one of the following methods, as described in Sections b.1 and b.2:



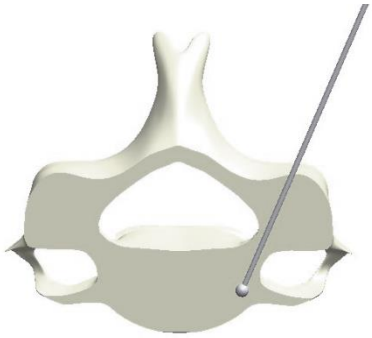
b.1 The **Drill Bit** can be used after perforating the outer cortex. The drill must always be used with the **Adjustable Drill Guide** ("**Guide**")**,** and the Drill Bit shall correspond to the screw diameter being used. At the top of the Guide, there is a button that enables extension or retraction of the inner sleeve. This serves as the scale for setting the desired drilling depth, corresponding with the screw length being used. After setting the desired drilling depth, attach the appropriate diameter Drill Bit to a **Straight Handle** (AO connection), insert the Drill Bit into the Guide (as it is hollow). The Guide will prevent further drilling at the correct depth based on your prior setting.

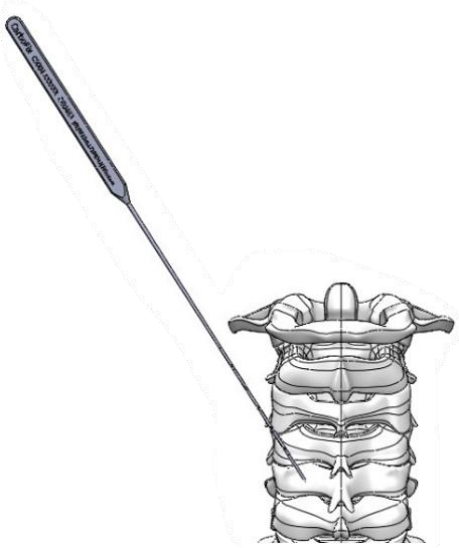


b.2 The **Bone Probe** can be used after perforating the outer cortex. It is marked to indicate length. Slowly twist and drive the Bone Probe to the desired depth.

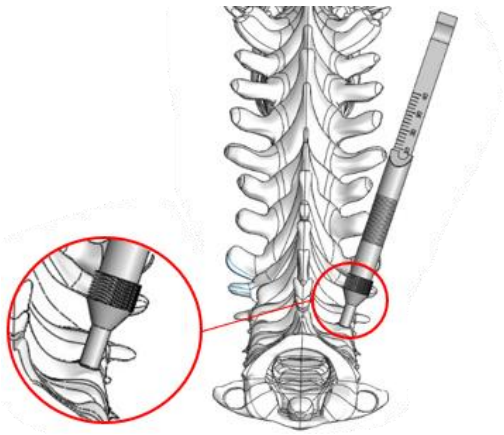


c. Inspect the integrity of the bone by placing the **Feeler** into the pilot hole and palpating the hole wall on all sides.

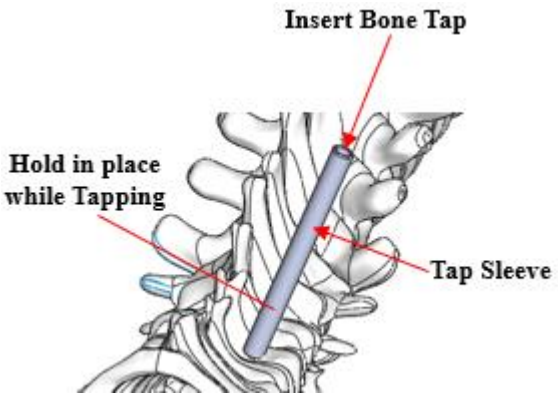




d. The **Depth Gauge** can be used to verify the depth of the prepared hole and to determine the required Screw length. The nose of the Depth Gauge shall sit on the bone (see figure).



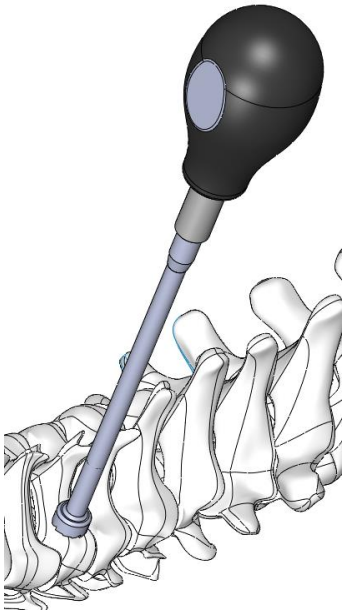
e. Tapping must be performed, by using the provided **Bone Taps**. Bone Taps are available to prepare the threads for the different diameter screws. Attach the appropriate diameter Bone Tap (corresponding with the screw diameter being used) to a **Straight Handle** (AO connection).



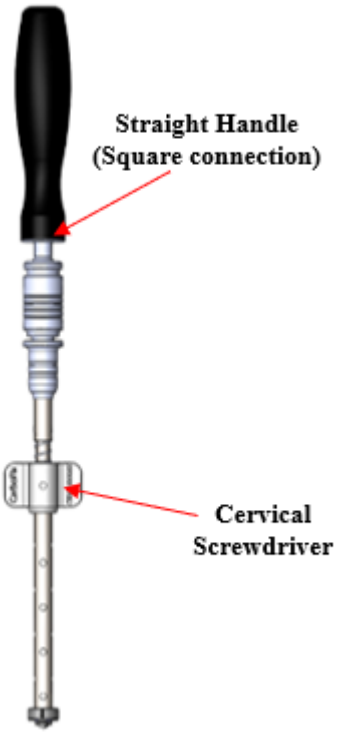
For tapping use the **Tap Sleeve**, in order to protect the patient's soft tissue during the insertion of the Bone Tap. When using the Tap Sleeve, position it on the bone surface aligned with the pilot hole, and hold it in place. Insert the Bone Tap into the Tap Sleeve, as it is hollow. Initiate tapping.

Note: Tapping should be performed to the entire length of the selected Screw. Tapping depth shall be slightly deeper than the actual length of the screw to be placed.

f. If required, use the **Bone Surface Reamer** to ream the bone surface, for Screw head and tulip accommodation.



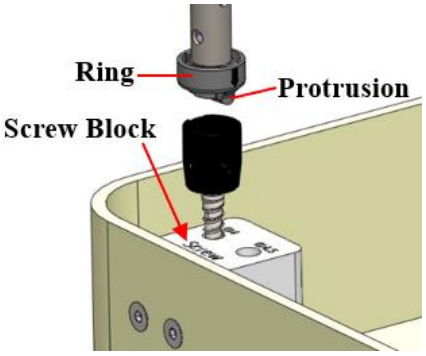
3. *Screw Insertion*



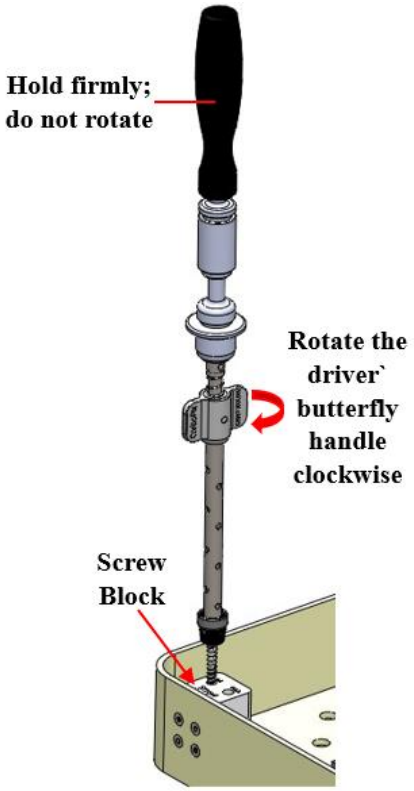
a. Connect the **Cervical Screwdriver** ("**Screwdriver**") to the **Straight Handel** with the Square connection. The Torque Limiter complies with the torque required for insertion of the 4.0 and 4.5 mm diameter Screws.

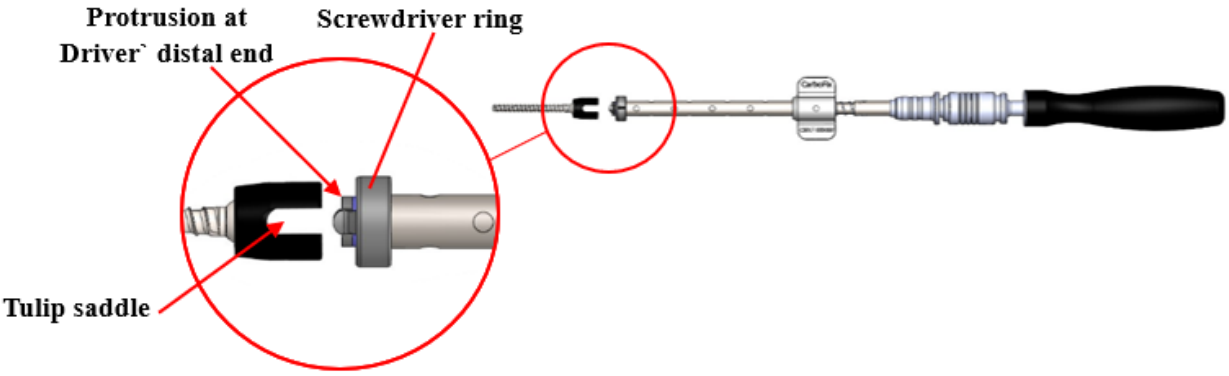
b. The **Screw Block** located within the Instrumentation Set may be used to facilitate connection of the **Screw** to the **Screwdriver**.
The Screw is to be located within the corresponding hole of the block and the Screwdriver can be easily connected to the Screw as further described below. The two holes in the Screw Block compile with the 4.0 and 4.5 mm diameter Screws.

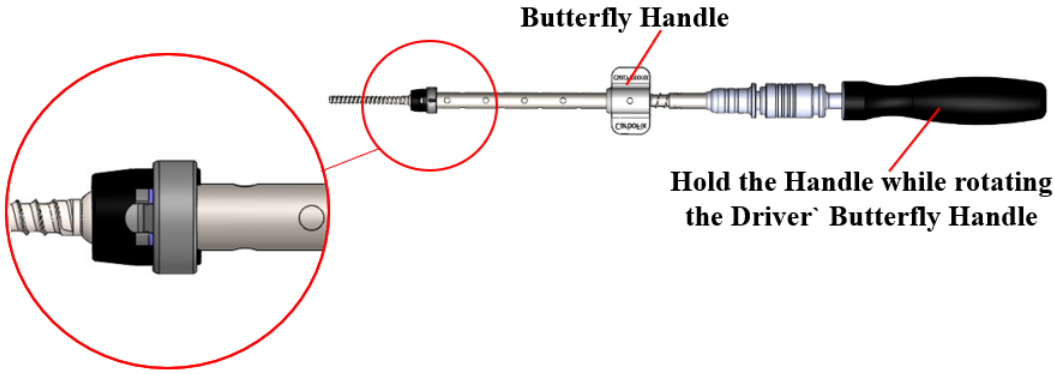
c. Connect the **Screw** to the **Screwdriver** (using the Screw Block, or manually):
   1) Locate the Screwdriver distal end within the Tulip, so that the protrusion at the center of the Screwdriver distal end is seated within the base of Tulip saddle, and the ring surrounds the Tulip proximal end. Make sure that the Tulip and Screwdriver are aligned, to allow proper connection.



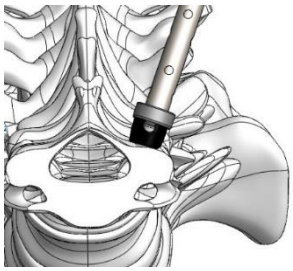
2) While pushing down the Screwdriver Handle, clockwise rotate (hand tighten) the Butterfly Handle all the way, to secure the Screw.



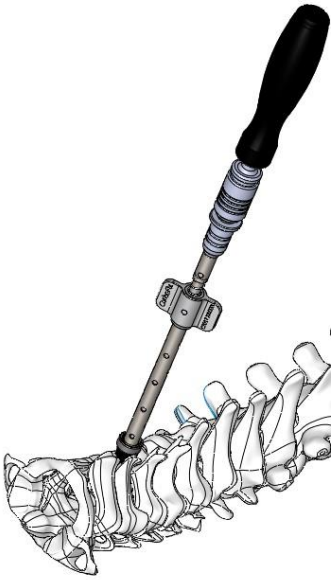




d. Rotate the **Screwdriver** Handle clockwise to insert the **Screw**. The Screw shall protrude 1– 2 mm above the bone in order to maintain its polyaxial properties.



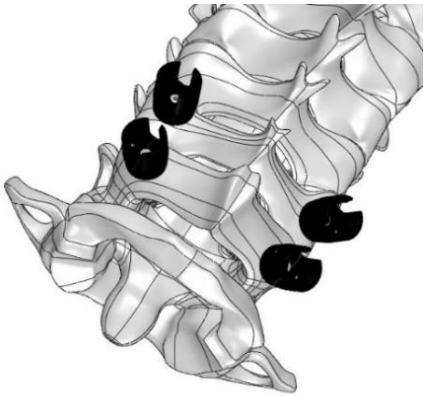
In case the Torque Limiter is activated (click sound) and the Screw is not fully inserted, remove the screw and re-tap, (to the entire length of the selected Screw and slightly longer).



e. Disconnect the Screwdriver from the Screw: Counter-clockwise rotate the Screwdriver Butterfly Handle (while holding the Driver Handle with the other hand) until disconnected.

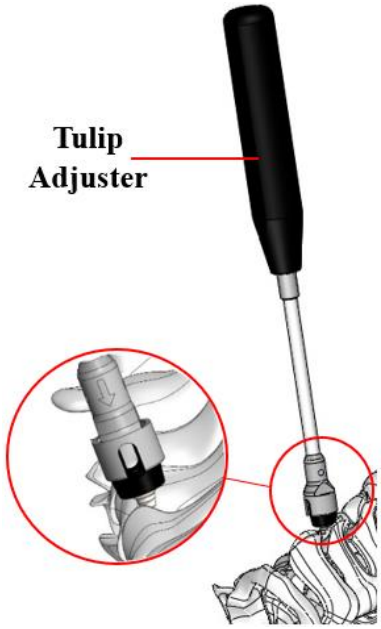
f. Insert the other Screws in the same manner.

g. Check Screws' positioning radiographically, to ensure their proper placement.



h. Use the **Tulip Adjuster** to regain the Screw polyaxiality, by gentle maneuvering of the tool up and down and then right and left.

i. Adjust **Tulip** orientation using the Tulip Adjuster. The arrows on the Tulip Adjuster indicate Rod positioning.

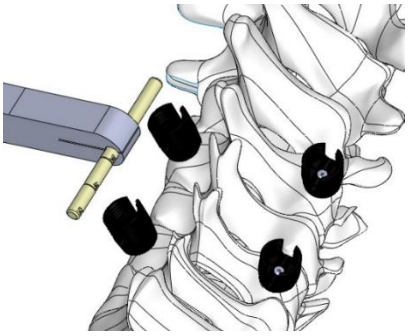


Note: If any of the Screws is protruding too much, or is located too deep (relative to the Rod), the Screwdriver may be re-connected to the Screw to adjust the Screw depth within the bone.

Note: If the Screw is inserted too deep and its tulip is touching the bone, the polyaxial properties will be diminished.

4. Rod Selection

Once all Screws have been placed, use the different **Rod Measuring Templates** to determine the appropriate **Rod** length and shape required. The Rod Template is positioned using the **Rod Holding Forceps**.



When selecting Rod length, consider whether distraction or compression will be required.

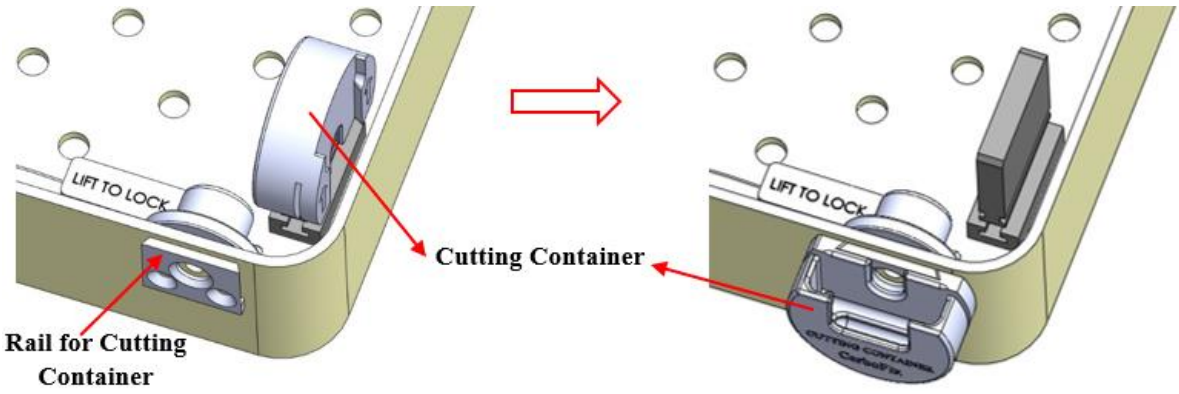
Note: Rod selection shall be made carefully in order to provide for best compliance with the Posterior Screws placement and orientation.

Note: When evaluating, the required rod length shall protrude 3 mm out of the tulip on each end of the rod.

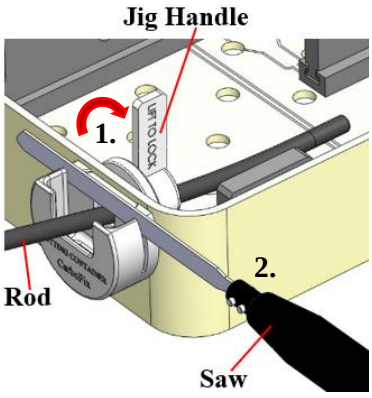
As a rule, the CFR-PEEK **Rods** shall be used. In case the desired Rod curvature is not available in CFR-PEEK, use the CarboClear bendable Ti-alloy Rod.

CFR-PEEK rods:

The **Rod** shall be cut using the **Saw** (provided in **the Cutting Set**): Attach the **Cutting Container** to the outer side of the sterile Instrumentation Set tray, by its connection to a dedicated Jig via a rail, as seen in the figure below.



Place the Rod within the dedicated Jig through the Cutting Container. The Rod is locked in place by lifting the Jig Handle to lock position (as marked on the handle) (indicated as step (1) in the figure).



Following locking of the Rod in place, the sterile Saw is used to cut the Rd to the desired length (indicated as step (2) in the figure).

Ather shortening, the cut end shall be refined using the Rod End Shaper.

Wash the cut Rod with sterile saline/water.

Note: Be aware of debris.

The cutting container enables the collection of particles generated when cutting Carbon/PEEK rods.

Alternatively – use a surgical burr (not provided) to trim the Rod to the desired length:

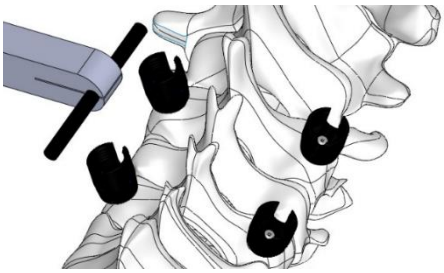
a. Immerse the Rod in a container filled with sterile saline/water;
b. Cut the Rod;
c. If needed, refine the cut edge using the burr or the Rod End Shaper.

Ti-Alloy rods:

The Rod may be cut and bent using conventional rod cutter and rod bender.

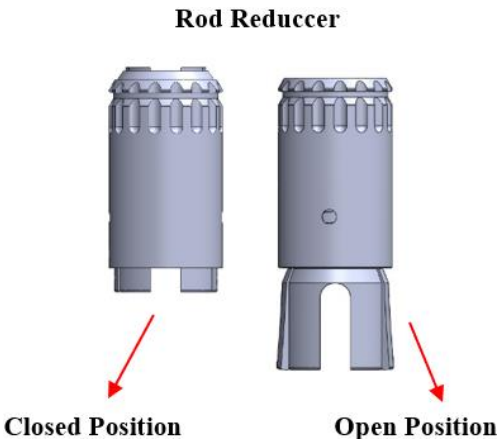
5. *Rod Application*

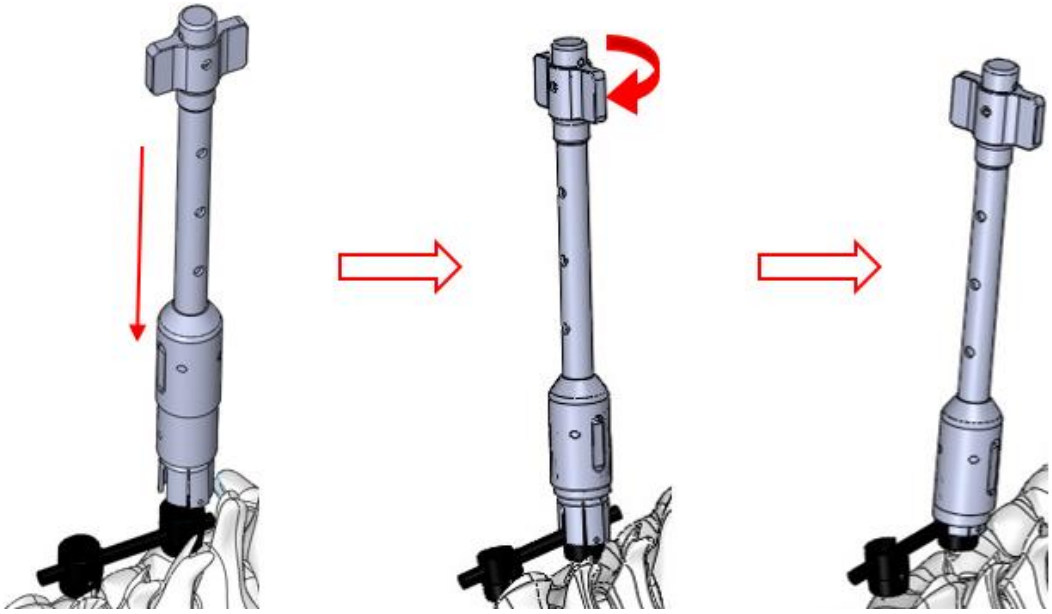
Place the selected Rod in the Screws' tulips, so that it is fully seated in the Screws' saddles. Use the **Rod Holding Forceps** to assist in Rod placement or manipulation.



If needed, use the **Rod Reducer** to force the Rod into the Screw saddle:

- Connect the Rod Reducer to its Handle;
- Verify the Rod Reducer is in an open position (see figure). If not, hold the Reducer distal end and rotate the Handle counterclockwise;
- Place the Rod Reducer over the Rod and Screw tulip.
- Rotate the **Rod Reducer Handle** clockwise all the way until the Rod is fully seated within the Tulip saddle.



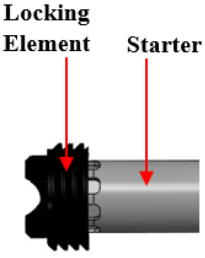


Disconnect the Rod Reducer Handle by pressing the button at the Handle' proximal end.

Repeat the above steps for the other Screws, if required (the Instrumentation Set includes a few Rod Reducers). It is recommended to apply at least 2 Rod Reducers at the extremities of the Rod. If Rod Reducers are used, placement of the Locking Element as detailed in Section 6 below should only be conducted after the 2 Rod Reducers are fully engaged at both sides.

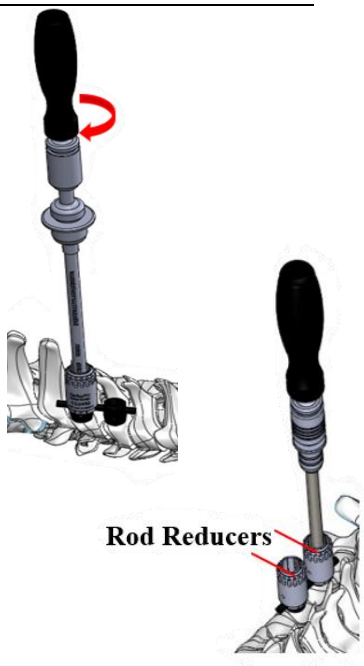
To remove the Rod Reducer, reconnect the Handle and rotate counterclockwise all the way. Gently pull the Rod Reducer from the implant construct.

6. *Locking Element Positioning and Initial Locking*



a. Connect the **Starter** to the **Straight Handel** with the Square connection. Engage the self-retaining Starter to the **Locking Element** (the Locking Element must be fully engaged to the Starter).

b. Locate the Locking Element within the Screw' Tulip, by rotating the Straight Handle clockwise until an audible "click" is heard.
In case the **Rod Reducer** is used, insert the Starter through the Rod Reducer and continue as described above. Remove the Starter.



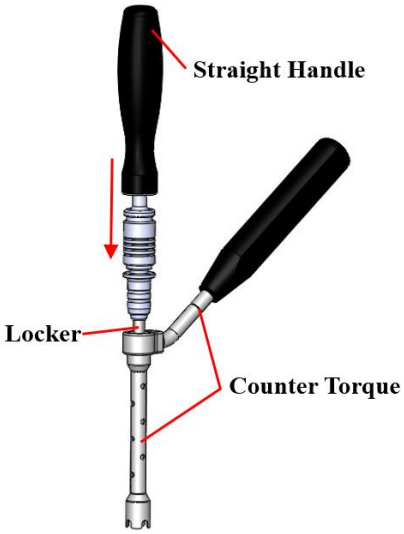
<u>Important Note</u>: The Starter is not designed for final tightening of the component.

Repeat the above steps for all remaining Screws in the construct.

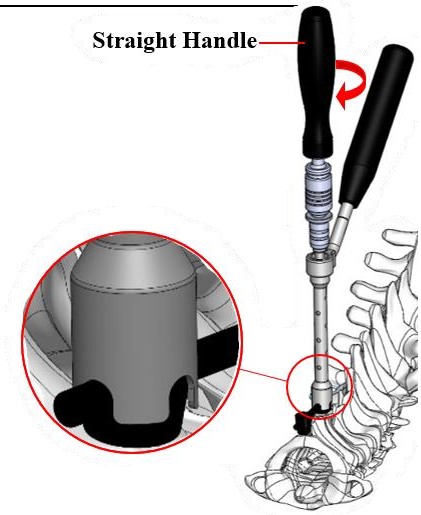
7. *Locking Element Final Locking*

a. Connect the **Locker** to the **Straight Handle** with the AO Connection.

b. Insert the Locker into the **Counter Torque**.



c. Position the **Counter Torque** over the Tulip and the Rod. Verify that the Counter Torque is fully seated on both sides of the Rod (as shown in the figure). If needed, slightly rotate the Handle for full engagement.



d. Rotate the Locker Straight Handle clockwise, while using the Counter Torque handle to counter the final locking of the Locking Element. Stop when you hear a "click."

Repeat the steps above for all Screws.

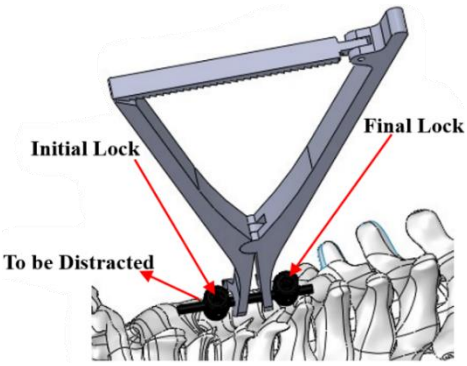
Important Note: If distraction or compression is necessary, the Final Locking should be performed on only one of the screws that require distraction/compression, not both. A detailed explanation of this process is provided in the following Section 8.

8. *Distraction and Compression*

If required, distraction or compression may be performed at this stage, using the provided **Distractor** and **Compressor**.

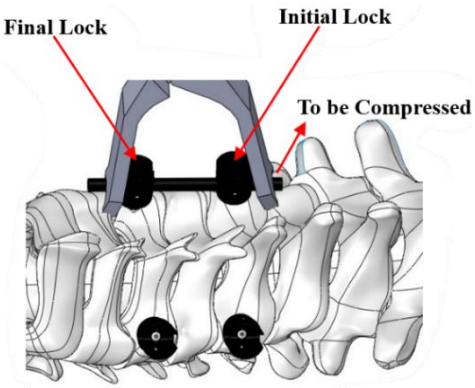
If ***distraction*** is required:

a. Perform final locking of the Locking Element of one of the Screws (per *Section 7*).
b. Leave a long enough portion of Rod protruding from the Screw on the end being distracted.
c. Position the Locker on the other Screw.
d. Place the Distractor in-between the Screws, all the way over the Rod, and perform distraction.
e. Once the desired distraction is achieved, perform final locking of the Locking Element of the other Screw.



If ***compression*** is required:

a. Perform final locking of the Locking Element of one of the Screws (per *Section 7* above).
b. Position the Locker on the other Screw.
c. Place the Compressor at the outer side of the Screws' tulips.
d. Compress using the Compressor.
e. Once the desired compression is achieved, perform final locking of Locking Element of the other Screw.



9. *Unlocking (if required)*

In case it is desired to unlock any of the components, use the **Starter** (refer to *"Implant Removal Procedure" Section* below for description).

10. *Second Rod Placement and Locking*

Place additional **Rod** in the same manner, on the contralateral side, and lock the components using the Locking Element, as described above.

Close the operation site according to common surgical practice.

IMPLANT REMOVAL PROCEDURE

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

1. Locking Element Removal

a. Connect the **Locker** to the **Straight Handle** with the Square connection.

b. Insert the Locker into the **Counter Torque.**

c. Position the **Counter Torque** over the Tulip and the Rod. Verify that the Counter Torque is fully seated on both sides of the Rod. If needed, slightly rotate the Handle for full engagement.

d. Rotate the Locker Straight Handle counterclockwise while using the Counter Torque handle to counter the unthreading of the **Locking Element**.

2. Screw Removal

a. Connect the **Cervical Screwdriver** to the Square connection **Straight Handle**. Connect the Cervical Screwdriver to the **Screw** by rotating the Screwdriver' Butterfly Handle clockwise. Remove the Screw by counterclockwise rotation of the Straight Handle.

b. In case of damage to a Screw already located within the vertebra, where no part of the screw is protruding from the bone (Screw part fully embedded within the bone), and where it is desired to remove the implant from the bone - use the **Extractor**. Choose the Extractor complying with the Screw diameter, connect the Extractor to the **Straight Handle** with the Square connection and insert it into the bone (over the Screw), in counterclockwise rotation. Once the Screw is located within the Extractor, pull the Extractor backwards.

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

ORDERING INFORMATION

Implants

Component	Size (mm)	Catalog No.*	
Polyaxial Posterior Screw	Diameter: 4.0 Length (L): 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40	CS40XX	
	Diameter: 4.5 Length (L): 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40	CS45XX	

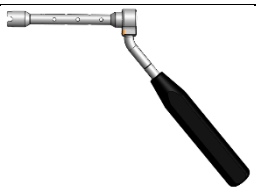
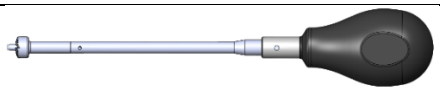
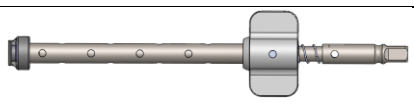
* XX – represents the length of the component, in mm

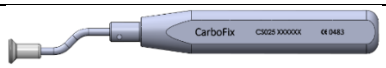
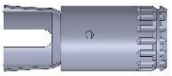
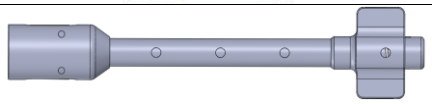
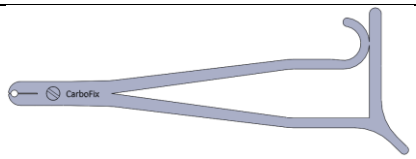
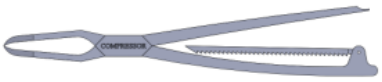
Component	Catalog No.	
Locking Element	CS4000	

Component	Size (mm)	Catalog No.*	
Straight Rods	Diameter: 4.0 Length: 30 – 100 (in 10 mm steps), 200	CRS4XXX	
Curved Rods	Diameter: 4.0 Length: 30 – 100 (in 10 mm steps), 200	CRC4XXX	
Titanium-Alloy Rods	Diameter: 4.0 Length: 200	CRT4200	

* XXX – represents the length of the component, in mm

Instrumentation Set – Catalogue No. CS1000

Description	Catalog No.	
Cervical Awl	CS001	
Cervical Bone Probe	CS002	
Adjustable Drill Guide	CS007	
Bone Tap 4.0 mm	CS010	
Bone Tap 4.5 mm	CS011	
Torque Limiter Straight Handel – Square Connection	CS008	
Torque Limiter Straight Handel – AO Connection	CS009	
Counter Torque	CS021	
Feeler	CS004	
Bone Surface Reamer	CS005	
Depth Gauge	CS006	
Cervical Screwdriver	CS017	
Tulip Adjuster	CS018	

Description	Catalog No.	
Tap Sleeve	CS003	
Rod Measuring Template - 50 mm	CS027	
Rod Measuring Template - 80 mm	CS028	
Rod Arc Measuring Template - 50 mm	CS029	
Rod Arc Measuring Template - 80 mm	CS030	
Rod End Shaper	CS025	
Rod Reducer	CS023	
Rod Reducer Handle	CS024	
Rod Holding Forceps	CS014	
Starter	CS019	
Locker	CS020	
Compressor	CS032	
Distractor	CS022	

Cutting Container	PPS180218	

Description	Catalog No.	
Sterilization Box	CS035	

Cutting Instruments [Single Use, Provided Sterile]

Description	Catalog No.	
Saw	CS032	

Drill Bits [Single Use, Provided Sterile]

Description	Catalog No.	
Drill Bit 3.2 mm	CS012	
Drill Bit 3.5 mm	CS013	

Extractors [Single Use, Provided Sterile]

Description	Catalog No.	
Screw Removal (Extractor) – Ø 4.0 mm	CS033	
Screw Removal (Extractor) – Ø 4.5 mm	CS034	

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of this device.
2. Active systemic infections, significant risk of infection (immunocompromise), or infection localized to the site of the proposed implantation.
3. Fever or leukocytosis.
4. Although not absolutely contraindicated, conditions to be considered as potential factors for not using this device include: severe bone resorption, osteopenia, osteomalacia, rapid joint disease, and osteoporosis, which may prevent adequate support and/or fixation of spinal anchor and thus preclude the use of spinal instrumentation system.
5. Conditions that may place excessive stresses on bone and implants, such as severe obesity, are relative contraindications.
6. Pregnancy.
7. Use of the system 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, thereby placing undue stresses on the implant. This could result in a higher risk of implant failure.
8. Suspected or documented allergy or foreign body sensitivity to any of the implant materials.
9. Medical conditions that preclude patient operation (e.g., coagulation disorder).

WARNINGS AND PRECAUTIONS

GENERAL

1. **Precaution**: Preoperative planning prior to implantation of posterior cervical screw systems should include a review of cross-sectional imaging studies (e.g., CT and/or MRI) to evaluate the patient's cervical anatomy including the transverse foramen, neurologic structures, and the course of the vertebral arteries. If any findings would compromise the placement of these screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.
2. **Precaution**: Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.
3. **Precaution**: the implantation of the posterior cervical screw fixation system should be performed only by experienced spinal surgeons with specific training in the use of the posterior cervical screw fixation system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
4. This device is not intended for screw attachment or fixation of the non-cervical spine.

PREOPERATIVE:

1. Do not use this system without fully reading these Instructions for Use.
2. The surgeon should be familiar with the principles and techniques of spinal stabilization and posterior cervical screw systems, including the CarboClear Posterior Cervical Screw System. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and material limitations of the implant. Refer to "Important Information to Physician" Section for additional information.
3. **Patient Selection**: Proper patient selection, and patient compliance to postoperative precautions, is critical to the success of the procedure. Only patients that meet the criteria described in the Indications for Use Section should be selected. Patient conditions and/or predispositions such as those addressed in the aforementioned Contraindications Section should be avoided.
4. **Implant Selection**: Correct selection of the implant is extremely important. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Surgical implants are subject to repeated stresses in use and their strength is limited by the need to adapt the design to the human anatomy. 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.
5. Proper handling and storage of the system components is mandatory. Damage or alterations to the system components may produce stresses and cause defects, which could become the focal point for failure.
6. All the CarboClear Posterior Cervical Screw System components which are supplied sterile should be handled with appropriate precautions to maintain sterility. Do not re-sterilize the sterile-supplied, single use items.
7. The sterile packaging of the relevant system components shall be inspected for visible damage prior to use. Do not use if damage is suspected.
8. Do not use sterile supplied items if the expiration date is overdue.
9. Do not re-use the system 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).
10. 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.
11. 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.
12. The CarboClear Posterior Cervical Screw System should be used exclusively with CarboClear Posterior Cervical Screw System components.
13. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
14. Additional sterile components should be available in case of any unexpected need.
15. Preoperative instructions to the patient are essential. The important medical information given in this document should be conveyed to the patient. The patient should be made aware of the limitations of the implant and potential risks of the surgery, and be warned regarding weight bearing and body stresses on the appliance. The patient should be instructed to limit postoperative activity for the duration of time deemed medically appropriate by their physician.

INTRAOPERATIVE:

1. The instructions of this manual should be carefully followed.
2. Utilize an imaging system to facilitate surgery.
3. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions. Breakage, slippage, misuse, or mishandling of the instruments or implant components, such as on sharp edges, may cause injury to the patient or operative personnel.
4. Taping shall be performed using the provided Bone Taps.
5. Do not overtap or use a screw that is too long or too large. Overtapping, using an incorrectly sized screw, may cause nerve damage, haemorrhage, or other possible adverse events.
6. Excessive loads, such as excessive torque or compression load, applied to long handle tools attached to the implant can damage the implant/instrument interface.
7. Do not use MRI while the system surgical instruments are connected to the implant.

POSTOPERATIVE:

1. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.
2. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. If components loosen, migrate and/or break, the device should be revised and/or removed before serious injury may occur. Failure to immobilize the bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device. It is important that immobilization of the spinal surgical site be confirmed by imaging examination. The patient must be adequately warned of these hazards and closely supervised.
4. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition, the potential risk to the patient of a second surgical procedure, and the difficulty of removal. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implants removal should be followed by adequate postoperative management to avoid fracture.
5. As with all orthopedic implants, none of the CarboClear Posterior Cervical Screw System implants should ever be reused under any circumstance. Any retrieved devices should be treated in a manner that reuse in another surgical procedure is not possible.

MRI SAFETY INFORMATION

The CarboClear device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the CarboClear device in the MR environment is unknown. Scanning a patient who has this medical device may result in injury or device malfunction.

IMPORTANT INFORMATION TO PHYSICIAN

CarboClear CFR-PEEK implants available for implantation, like any other temporary internal fixation devices, have a finite use life. The patient's activity level has a significant impact on this use life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions on their activities during the postoperative period and to examine the patients postoperatively to evaluate the status of the implant components. Implant components may bend, break, or loosen and the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

FURTHER INFORMATION

Important Notes:

- Refer to the system Instructions for Use (TEC 3118) for additional information regarding the CarboClear Posterior Cervical Screw System including Possible Adverse Events and Packaging and Sterilization information.
- For reprocessing of the reusable instruments, refer to CarboFix' Spine Instrumentation Handling Instructions (Ref. 4698).

Caution:

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

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Patents are pending