

CARBOCLEAR® X PEDICLE SCREW SYSTEM

A COMPOSITE MATERIAL SPINAL SYSTEM

SURGICAL TECHNIQUE



TABLE OF CONTENTS

OVERVIEW	3
INDICATIONS FOR USE.....	3
SYSTEM BENEFITS.....	4
IMPLANTS	5
INSTRUMENTS	9
SURGICAL TECHNIQUE	17
IMPLANT REMOVAL PROCEDURE	34
ORDERING INFORMATION	36
FURTHER INFORMATION	42

OVERVIEW

The CarboClear X Pedicle Screw System consists of implants made of carbon fiber-reinforced PEEK (CFR-PEEK), used to build a spinal construct for segmental spinal immobilization and stabilization.

Additionally, the CarboClear X Pedicle Screw System includes a set of instruments.

Note:

The system is indicated for the treatment of several conditions, including oncological patients, as detailed in the “Indications for Use” Section. Although the implantation procedure is similar for the different indications, there is a separate set of implants for oncological patients’ use, as detailed in the “Implants” Section and in the “Ordering Information” Section of this document, eliminating the use of tantalum wire marking where applicable.

INDICATIONS FOR USE

The CarboClear X Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities and DDD of the thoracolumbar and sacral spine.

The system is intended for posterior, thoracolumbar and sacral pedicle fixation for the following indications: degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudoarthrosis, and failed previous fusion.

The CarboClear X Pedicle Screw System is also indicated for non-cervical, posterior pedicle screw fixation for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, who are receiving fusions using autogenous bone graft, with the device attached to the lumbar and sacral spine (L3 to S1), and for whom the device is intended to be removed after the attainment of a solid fusion.

SYSTEM BENEFITS

CarboClear X Pedicle Screw System provides for the following benefit:

- Good visualization of the peri-implant area when using fluoroscopy or x-ray imaging, allowing effective follow-up.
- Negligible CT / MRI artifacts, allowing effective imaging follow-up and diagnosis.
- Excellent Fatigue Strength.
- Enhanced Modulus of Elasticity.
- Low-profile implant construct

Furthermore, when referring to the treatment of oncological patients, CarboClear X Pedicle Screw System provides for the following additional benefits:

- Improved pre-radiotherapy planning.
- Reduced interference with radiotherapy protocols: no backscattering or attenuation, and no overdose and under-dose seen with metal instrumentation.
- Allows for particle therapy (proton, carbon-ion).

IMPLANTS

The implants include polyaxial pedicle screws, longitudinal rods, locking elements, and transverse connectors.

The implants are made of CFR-PEEK, and may be marked with radiopaque markers. The screw shank is encased within a thin titanium shell.

Implants are supplied sterile and are intended for single use.

Pedicle Screws

Polyaxial pedicle screws, comprising a spherical head enclosed within a housing (tulip), allowing tulip positioning in a variety of angles (up to 34°).

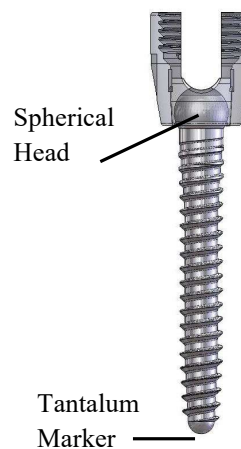
The tulip has a "U" shape to accommodate the rod. It includes an internal thread, compatible with a locking element that locks the implants construct components.

Both cannulated and non-cannulated Pedicle Screws are available.

The screws are made of CFR-PEEK, and their threaded portion is encased within a thin titanium shell, to provide for their visualization under X-ray and enhance bone integration. A small tantalum marker is located at the Screw distal end.

The Pedicle Screws are available in 5.0mm, 5.5mm, 6.5mm, 7.5mm and 8.5mm diameter and in lengths ranging 25mm - 95mm (diameter-dependent).

Rods

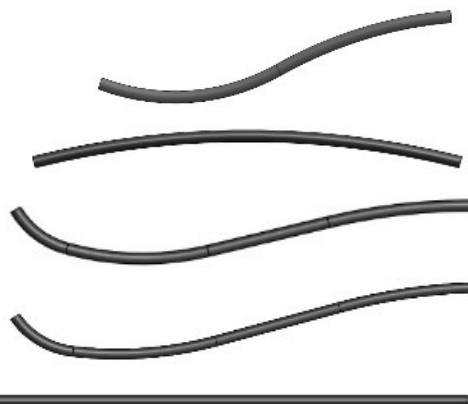


CFR-PEEK rods of 6.0 mm diameter, available in short and long versions.

The short rods include lengths ranging from 35mm to 80mm (in 5mm increments). They are provided pre-cut, either straight or curved.



The long rods are available in five types, including straight and pre-contoured rods (curved or shaped rods with different radii), available in lengths of up to 285 mm.



The rods can be cut intraoperatively to the desired length using the single use Cutting Set.

A tantalum wire may be incorporated along the long axis of the “short” rods (not provided in the oncological patients’ implants).

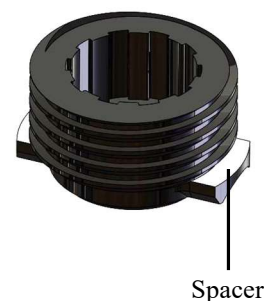
Titanium alloy rods of 300 mm are also available, in case different rod contouring is required.

Locking Element

Used to lock the Rod and the Pedicle Screw.

It comprises an external thread, compatible with the internal thread of the Pedicle Screw tulip.

At its lower portion, the Locking Element incorporates a "spacer", located over the Rod.



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

Transverse Connector (Trans-Connector) Unit

The Trans-Connector Unit is used for transverse connection of the Rods. The Trans-Connector Unit includes rods, locking elements and locking rings.

Trans-Connector Rod

The Trans-Connector Rod is made of CFR-PEEK and is similar to the pedicle screw rod (longitudinal Rod), with the exception that its ends are spherical. It is secured to the longitudinal Rod using the Trans-Connector Locking Element and the Trans-Connector Locking Ring (described below).

The Trans-Connector Rod is available in 6.0mm diameter and in lengths ranging from 30mm to 70mm (in 2mm increments).



Iliac Crest Rod

The Iliac Crest Rod is made of CFR-PEEK. It has one spherical end at which it is connected and locked to the longitudinal Rod (using the Trans-Connector Locking Element and Locking Ring). At its other end, the Iliac Crest Rod is connected and locked to the Screw (implanted in the iliac bone), using the Locking Element.



The Iliac Crest Rod is available in 6.0 mm diameter and in length of 100 mm. It may be cut intraoperatively to the desired length, using the single use Cutting Set.

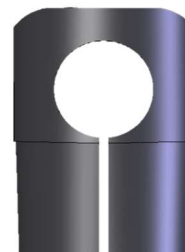
Trans-Connector Locking Element & Locking Ring

The Trans-Connector Locking Element and Locking Ring are made of CFR-PEEK and are used to lock the Trans-Connector Rod to the longitudinal Rod.

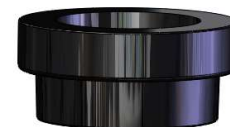
The Trans-Connector Locking Element has a lumen to accommodate the longitudinal Rod, and should be placed over the longitudinal Rod prior to its implantation.

The Trans-Connector Locking Ring is designed to be placed over the Trans-Connector Locking Element.

Trans-Connector
Locking Element



Trans-Connector
Locking Ring



Rod Connectors

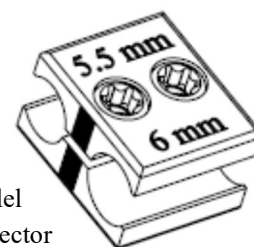
The Rod Connectors are used for connection of longitudinal rods, where needed, *e.g.*, for extension of a construct to additional levels.

The Rod Connectors are made of Ti-alloy.

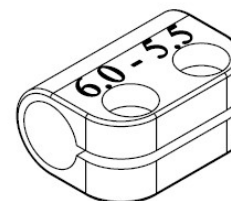
Two types of Rod Connectors are available – allowing connection of rods in parallel or in line.

The Rod Connectors allow connection of 2 CarboClear Rods (6mm diameter rods) or of one CarboClear Rod and one other 5.5mm diameter rod.

Parallel
Connector



Linear
Connector



INSTRUMENTS

Note:

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

Single use, sterile provided, ***Guide Wires***, ***Cutting Set***, and ***Extractors*** are also provided (as described below).

INSTRUMENTATION SET

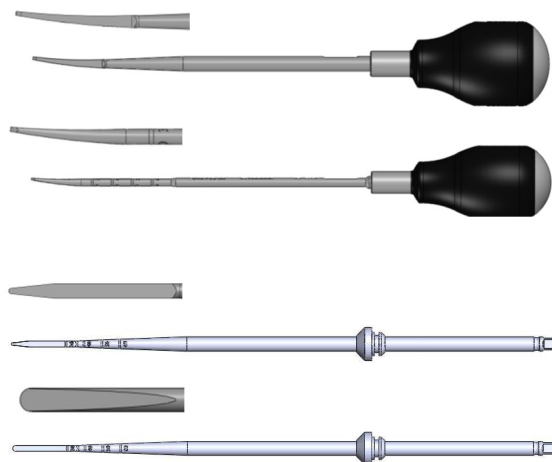
Pedicle Awl

Used to gain access through the bone cortex into the pedicle.



Pedicle Probes

Straight or curved, blunt/pointed, pedicle probes, intended to tunnel through the pedicle cancellous bone into the vertebral body. The probes include depth markings. The straight probes may be provided without integrated handles, and shall be connected to one of the CarboClear Handles.



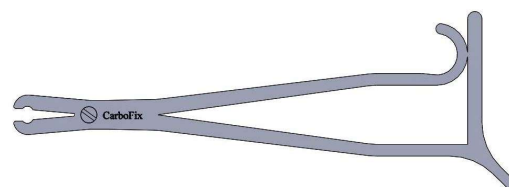
Pedicle Feeler

A ball-tipped device, used to check pedicle wall integrity prior to tapping. Its length is marked to assist in the assessment of Screw length.



Rod Holding Forceps

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



Bone Taps

Cannulated taps, used to prepare the pedicle screw canal; may be used over the Guide Wire.

The taps are available in 5.0mm, 5.5mm, 6.5mm, 7.5mm and 8.5mm diameter, corresponding to the Pedicle Screws' diameters.



Tap diameter of the used Tap shall be the same diameter as that of the Screw (*e.g.*, a 7.5mm diameter Tap for a 7.5mm diameter Screw), and tapping shall be carried out 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 one of the provided Handles.

Additional Bone Taps in the range of 4.5mm – 8.5mm in 0.5mm steps may be provided upon request.

Pedicle Surface Reamer

May be used, if required, to ream the pedicle surface to allow accommodation of the Pedicle Screw head and tulip. The Reamer is cannulated, to enable reaming over the Guide Wire.



Pedicle Screw Screwdriver

A dedicated screwdriver, for the insertion of the Pedicle Screws into the vertebra pedicles. It is cannulated, to allow use over the 1.2 mm Guide Wire.



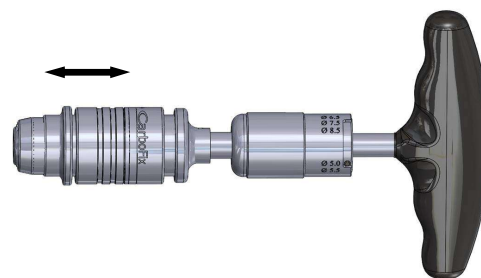
The Screwdriver is used with a Handle Torque Limiter.

Handle-Torque Limiter (to be used with all screws)

Two dedicated handles (T-Handle and Straight Handle) containing an integral Torque Limiter, compatible with the used Screw diameter. Prior to use, the Torque Limiter is adjusted according to the selected Screw diameter.

The handles with torque limiter are to be used with the Screwdrivers and may be used with other instruments as applicable.

Those handles include a ratchet mechanism. Movement direction of the ratchet mechanism can be changed (right or left) by moving the mechanism forward (for clockwise rotation – "R") or backward (for counterclockwise rotation – "L"). Alternatively, Handles may be provided where the ratchet mechanism movement direction is changed by rotating a dial clockwise or counterclockwise.



Pear Handle

A dedicated pear-shaped handle, for use with the different instruments, as required, according to surgeon preference.



Tulip Adjuster

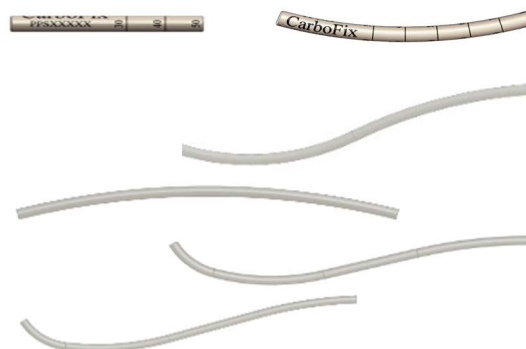
Used to adjust Screws' tulip orientation following their introduction into the bone.



Rod Measuring Templates

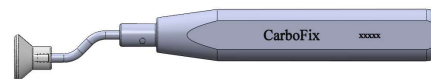
Polymeric straight and curved rods in several lengths, as well as metallic rods shaped like Rod Types 1 – 4; used to aid in selecting the proper Rod length and curvature.

May be used with the Rod Holding Forceps.



Rod End Shaper

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



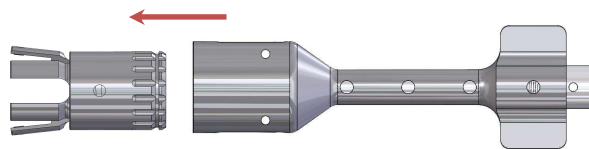
Rod Pusher

Used to push the Rod, for its location within the Screw' saddle, if required.



Rod Reducer and Handle

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



Locking Element Starter

A dedicated, self-retaining driver for the insertion and initial tightening of the Locking Element within the Screw tulip.

The Starter includes an integral Torque Limiter, and shall be used with one of the provided Handles.



Locker

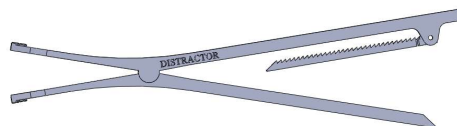
The Locker is used for final locking of the locking element within the screw tulip.

The Locker includes an integral Torque Limiter, and shall be used with one of the provided Handles.



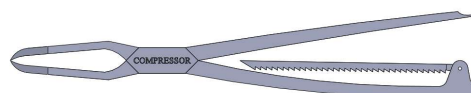
Distractor

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



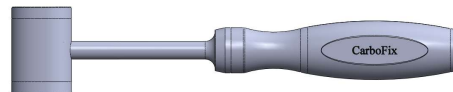
Compressor

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



Mallet

Provided as part of the set, in case required.



Spreader

May be used to assist in Trans-Connector Locking Element placement and movement over the Rod.



Trans-Connector Locker

The Trans-Connector Locker is used to firmly lock the trans-connector components.



Trans-Connector Unlocker and Wrench

The Unlocker is used to disconnect the locked Trans-Connector components, in case re-positioning or removal of the unit is required. It is used in combination with a Wrench.



T15 Torx Screwdriver Bit (Optional)

A T15 Torx Screwdriver Bit, used to tighten the screws of the Rod Connector. Shall be used with a Handle-Torque Limiter.



GUIDE WIRES [SINGLE USE; PROVIDED STERILE]***1.2 mm Guide Wire***

May be used to maintain trajectory during the insertion of the cannulated pedicle screw.

**PEDICLE SCREW EXTRACTOR [SINGLE USE; PROVIDED STERILE]**

The Screw Extractor, assembled to a Handle, may be used in case removal of a damaged (*e.g.*, broken) Pedicle Screw is required, when positioned under the bone surface.

The Extractor is available in five dimensions (5.0mm, 5.5mm, 6.5mm, 7.5mm, 8.5mm diameter), to comply with the different diameters of the Pedicle Screw.



The Extractor shall be inserted into the pedicle in counterclockwise rotation until the broken Screw is engaged within the Extractor tube. It shall then be removed by pulling backwards.

CUTTING SET [SINGLE USE; PROVIDED STERILE]

The single use, sterile provided Cutting Set, includes the following components:

Flexible Ruler

Used for assistance in selecting the proper rod length and curvature.



Saw

Used for shortening the CFR-PEEK rods.



Optionally, the Flexible Ruler may be provided separately (for single use) while cutting and shaping are accomplished using a Burr (standard burr as available in the operating room).

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

SURGICAL TECHNIQUE

1. *Surgical Approach*

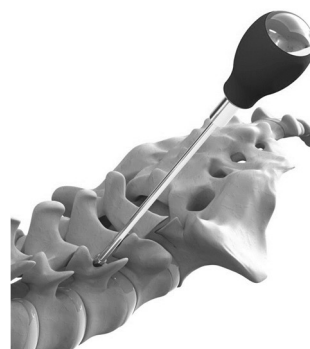
Patient positioning, surgical approach and exposure of the spine shall be performed according to standard procedures.

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

2. *Pedicle Preparation*

- a. After adequate exposure, select the appropriate pedicle entry point.

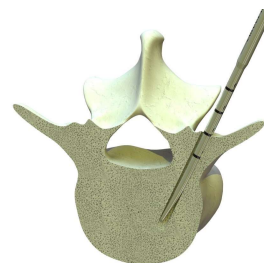
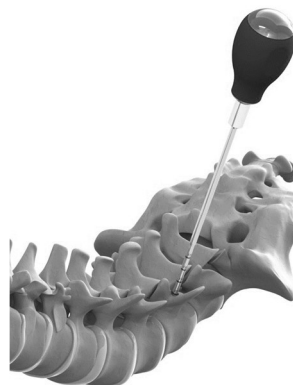
At each entry point, use the supplied **Pedicle Awl** to breach the cortical exterior of the pedicle.



- b. Use the **Pedicle Probe** to create a path through the intrapedicular cancellous bone into the vertebral body. Straight or curved, pointed/blunt Probes are available. If required connect the Probe to a Handle.

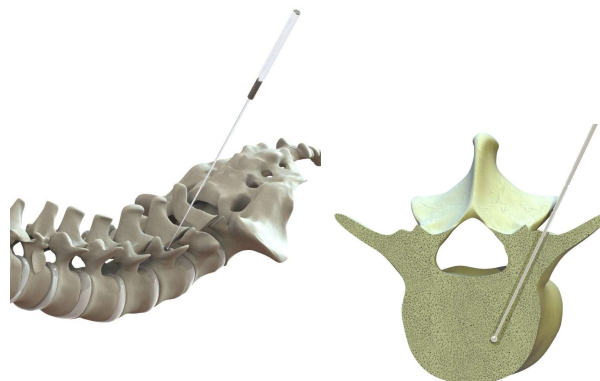
Advance the Probe through the pedicle and into the vertebral body following standard technique.

Probe markings also assist in selecting the appropriate Pedicle Screw length.



- c. Carefully insert the **Pedicle Feeler** to determine the integrity of the pedicle canal walls, as well as the base of the hole created by the Probe.

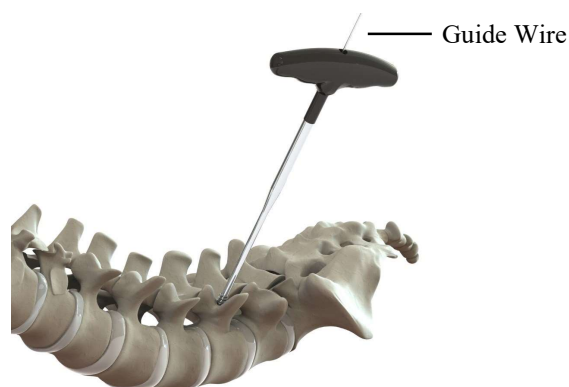
The Feeler markings also assist in selecting the appropriate Pedicle Screw length.



- d. Tapping must be performed, by using the provided **Bone Taps**.

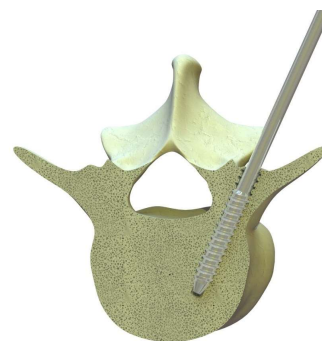
Use a Tap of the same diameter as that of the Screw, and tap the entire length of the selected Screw. Tapping depth shall be slightly deeper than the actual length of the screw to be placed.

In case of low-quality bone, the physician may decide to use a smaller diameter Tap.



Connect a **Handle** to the used Bone Tap.

Note: The **Handles-Torque Limiter** are compatible with the Bone Taps. If used with a Bone Tap, position the Torque Limiter to the Ø6.5/7.5/8.5 marking.

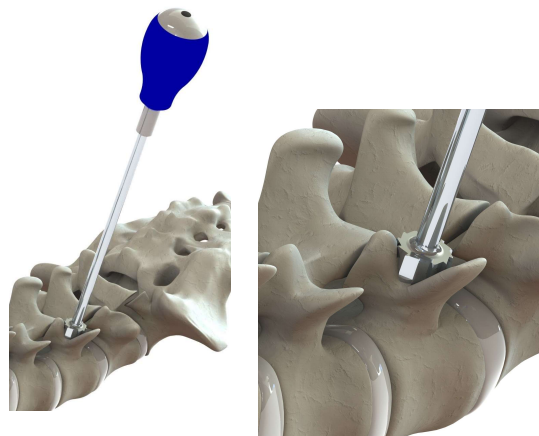


Tap the pedicle by introducing the **Bone Tap** into the previously created tunnel. If the **Guide Wire** is used, make sure it does not advance during tapping.

When reaching the desired depth, remove the Tap by counterclockwise rotation.

- e. If required, use the **Pedicle Surface Reamer** to ream the pedicle, for Pedicle Screw head and tulip accommodation. The Reamer is cannulated, thus may be used over the **Guide Wire**, if desired.

Remove the Guide Wire.

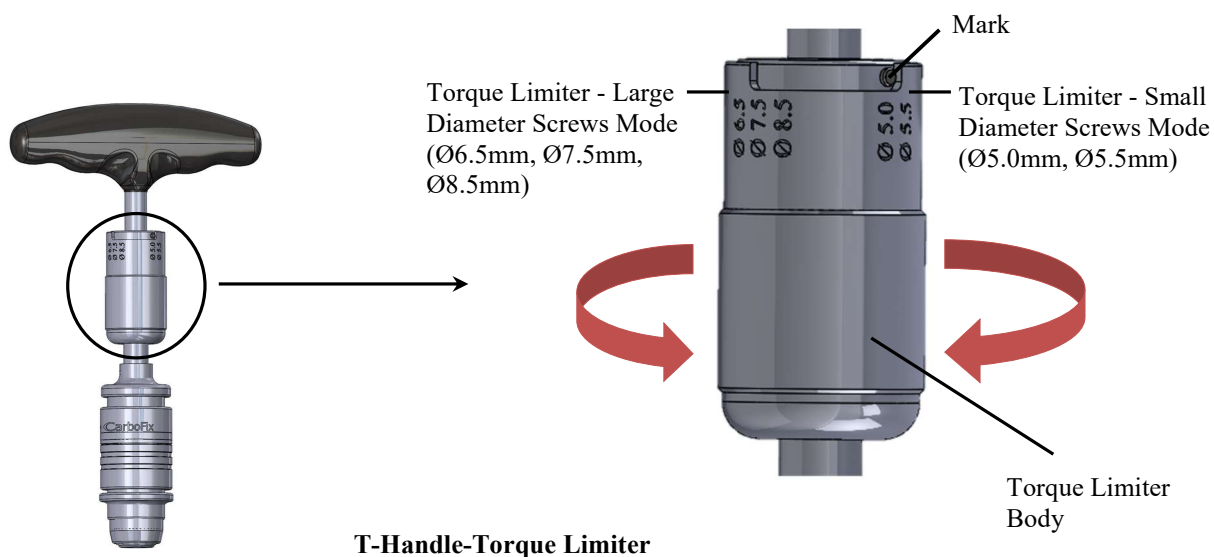


3. *Pedicle Screws Insertion*

- a. Choose the required **Pedicle Screw**.
- b. Connect the **Pedicle Screw Screwdriver** to the dedicated **Handle-Torque Limiter**.

The Torque Limiter has two operation modes:

- For insertion of 5.0 and 5.5 mm diameter Screws - rotate the Torque Limiter body to the Ø5.0/5.5 mark.
- For insertion of larger screws - 6.5, 7.5 and 8.5 mm diameter Screws - rotate the Torque Limiter body to the Ø 6.5/7.5/8.5 mark.

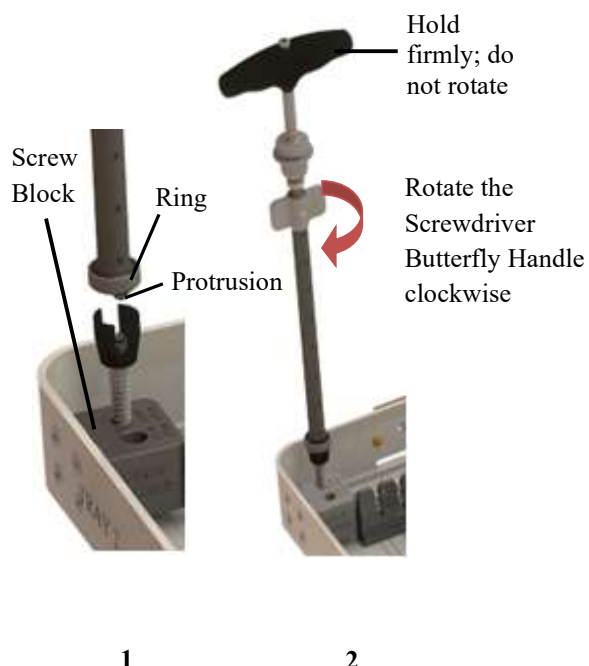


- c. The **Screw Block** located within the Instrumentation Set may be used to facilitate connection of the Screw and **Screwdriver**.

The Pedicle Screw is to be located within the corresponding hole of the block and the Screwdriver can be easily connected to the Pedicle Screw as further described below.

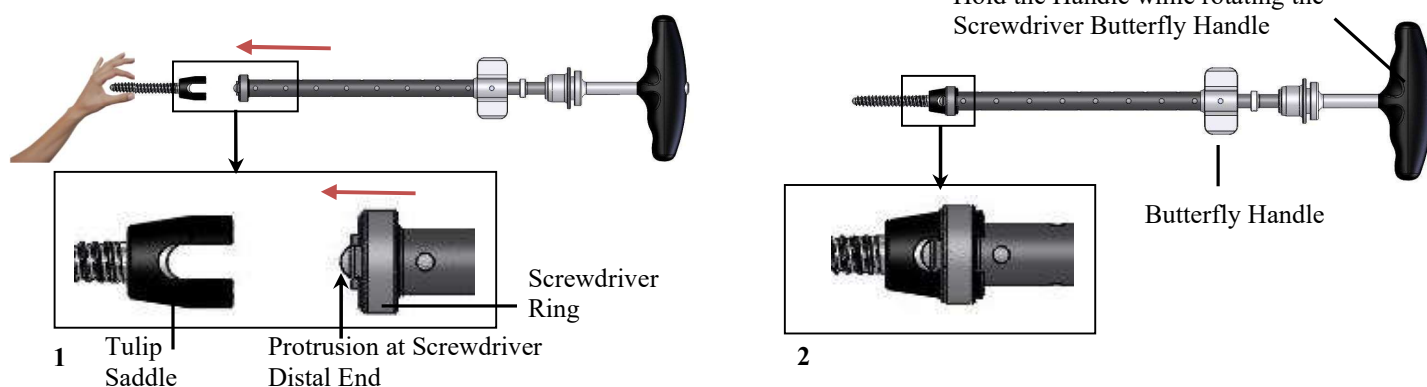
There are two holes in the Screw Block for the different diameter Screws:

- 5.0, 5.5 and 6.5 mm diameter Screws
- 7.5 and 8.5 mm diameter Screws



- d. Connect the Pedicle Screw to its 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 Screwdriver Butterfly Handle all the way, to secure the Screw. Do not over-tighten, as it may be difficult to regain Screw polyaxiality following disconnection from the Screwdriver.

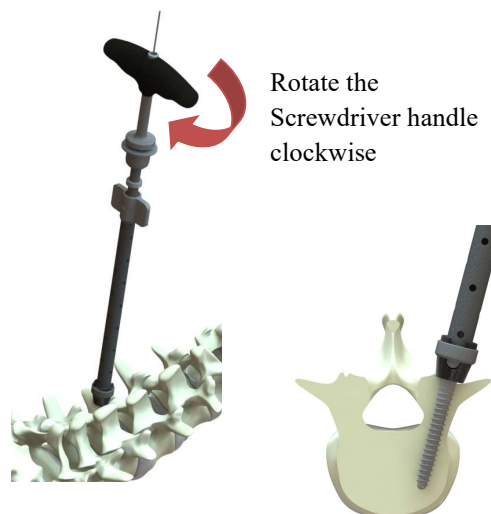


In case a cannulated Pedicle Screw is used, insert first the **1.2mm Guide Wire** to the pedicle.

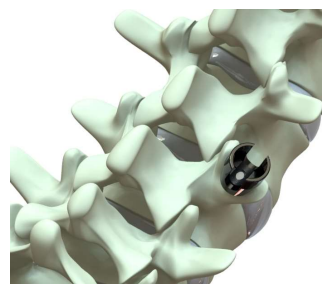
- e. Advance the Pedicle Screw down the prepared pedicle canal, by rotating the Screwdriver Handle clockwise, until the Screw is seated in the bone with the correct dorsal height. The Screw shall protrude 1–2 mm above the bone in order to maintain its polyaxial properties.

If performed over the **1.2mm Guide Wire**, make sure the Guide Wire does not advance upon Screw insertion.

In case the Torque Limiter is activated (click sound) remove the screw and re-tap (to the entire length of the selected Screw).



- f. Disconnect the Screwdriver from the Pedicle Screw: Counter-clockwise rotate the Screwdriver Butterfly Handle (while holding the Screwdriver Handle with the other hand) until the Screwdriver Sleeve disengages from the Tulip thread.



- g. Insert the other Screws in the same manner.

- h. Check Screws positioning radiographically, to ensure their proper placement



- i. Use the **Tulip Adjuster** to regain the Screw polyaxiality, by gentle maneuvering of the tool right and left.

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

Note:

If any of the Screws is protruding too much, or is located too deep, the Screwdriver may be re-connected to the Screw to adjust the Screw depth within the pedicle.

Note that if the Pedicle Screw is inserted too deep and its tulip is touching the bone, the polyaxial properties will be diminished.



4. *Rods Selection*

Once all Pedicle Screws have been placed, use the different **Rod Measuring Templates** configurations to determine the appropriate Rod length and shape required. The Rod Template may be held using the **Rod Holding Forceps**.

When selecting Rod length, consider whether distraction or compression will be required. Also, consider whether it may be desired to connect the rods to those of an additional pedicle screw construct using Rod Connectors.



Notes:

1. Rod selection shall be made carefully in order to provide for best compliance with the Pedicle Screws placement and orientation.
2. When evaluating the required Rod length, make sure that the distance between the end of the Rod and the closest Tulip shall be at least 3mm. This is true also when

using a Parallel Rod Connector (make sure that the distance between the end of the Rod and the Rod Connector end shall be at least 3mm).

If long Rods (longer than 80mm) are required – the length/type of the Rod may be assessed using the **Flexible Ruler** and with the help of the **Rod Measuring Templates**. According to this measurement the requested Rod can be selected (Type 1 – Type 5 CFR-PEEK Rods). If required, the long Rods may be shortened during the procedure, using the provided instrumentation.

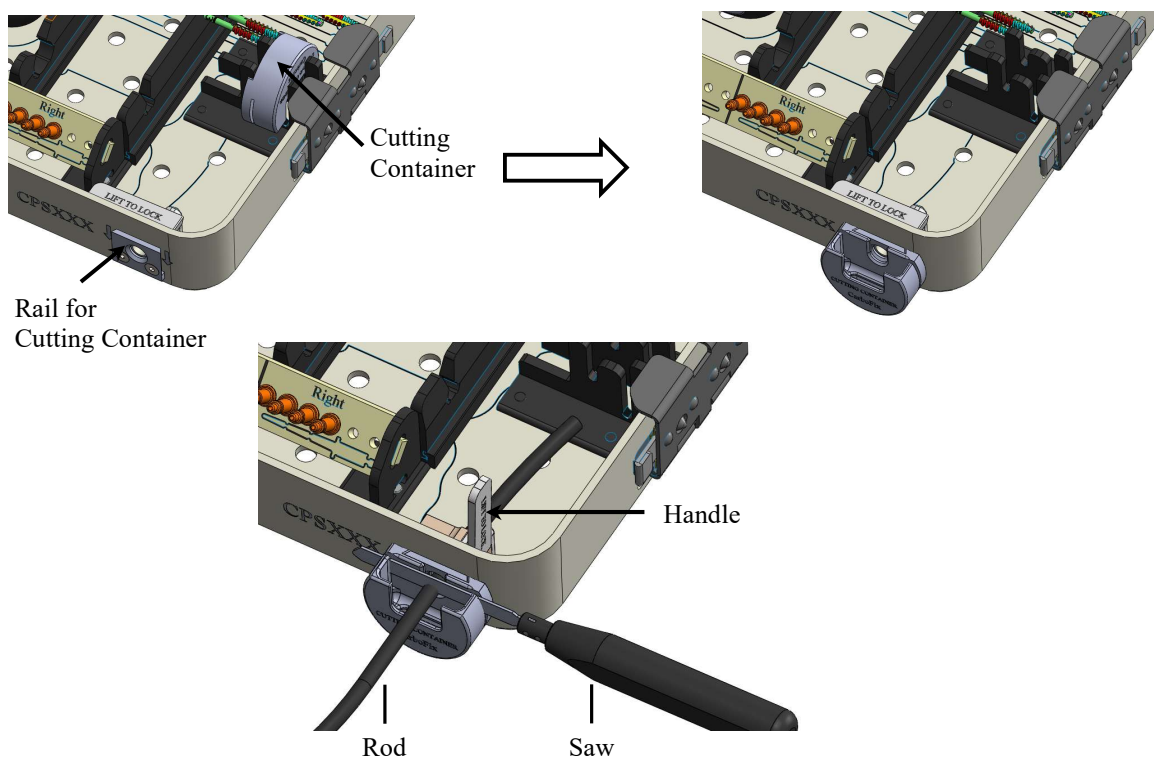
As a rule, the CFR-PEEK Rods shall be used. In case the desired Rod length and curvature is not available in CFR-PEEK, use the CarboClear Ti-alloy Rod, which complies with the CFR-PEEK Screws and Locking Elements.

For CFR-PEEK rods:

The CFR-PEEK Rod shall be cut using the **Saw** (provided in the Cutting Set).

Connect the Cutting Container to the rail provided on the upper instrumentation tray.

Place the Rod in the dedicated jig provided within the tray, lift the jig handle to the “lock” position, and use the single use Saw to cut the Rod to the desired length.



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

Wash the cut Rod with sterile saline/water.

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.

For Ti-Alloy rods (if intraoperative rod contouring is desired use the Ti-Alloy rods):

The Rod may be cut and bent using conventional rod cutter and rod bender available in the hospital.

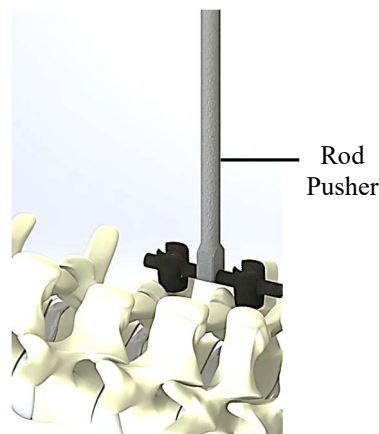
5. *Rod Application*

- a. In case Trans-Connectors are to be used – place the **Trans-Connector Locking Elements** over the selected Rod; make sure to place the Trans-Connector Locking Elements according to the desired Trans-Connector Unit location.

If the **Spreader** is used - insert its tip into the Trans-Connector Locking Element slot, from one of the slot's sides. Place the Trans-Connector Locking Element over the Rod and position it at the desired position. Remove the Spreader.

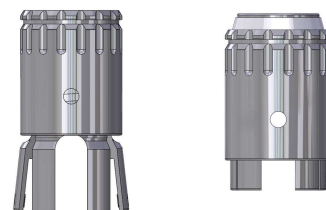
If additional repositioning of the Trans-Connector Locking Element is required – reinsert the Spreader into the Trans-Connector Locking Element slot.

- b. Place the selected Rod within the Screws' tulip, so that it is fully seated in the saddle of the Screws. Use the **Rod Holding Forceps** and **Rod Pusher** to assist in Rod placement or manipulation.

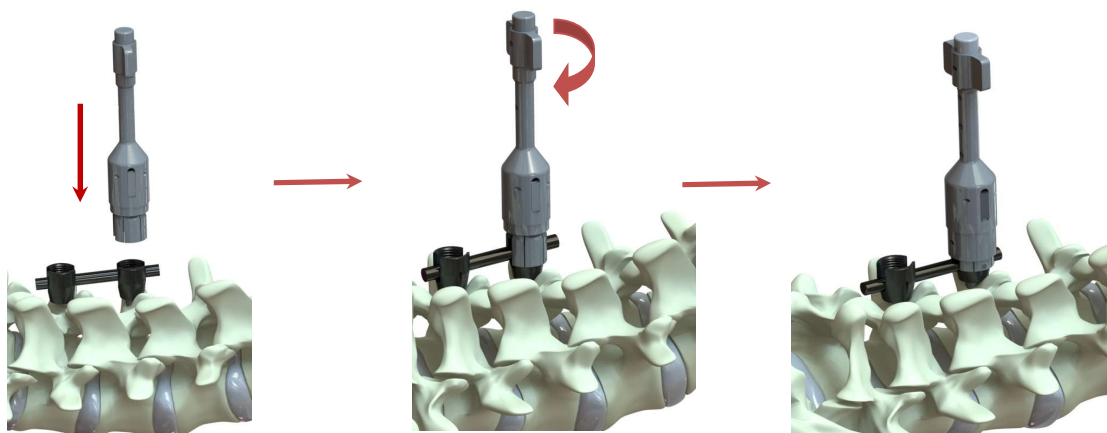


If needed, use the **Rod Reducer** to force the Rod into the Screw saddle:

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



Open Position Close Position
 Rod Reducer



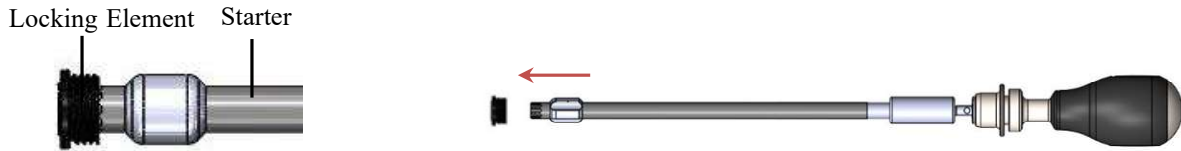
Disconnect the Handle by pressing the bottom at the Handle proximal end.

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 counter-clockwise all the way. Gently pull the Rod Reducer from the implant construct.

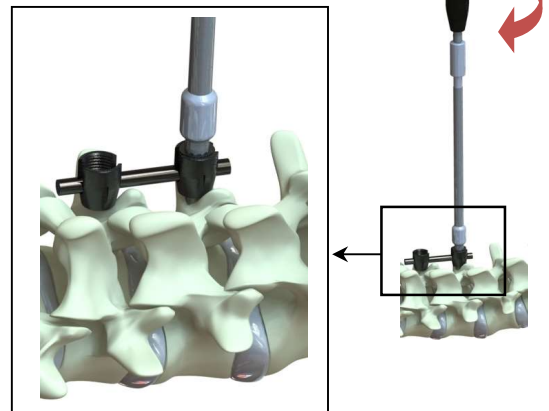
6. *Locking Element Positioning and Initial Locking*

- a. Engage the self-retaining **Locking Element 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 Handle clockwise until an audible "click" is heard.

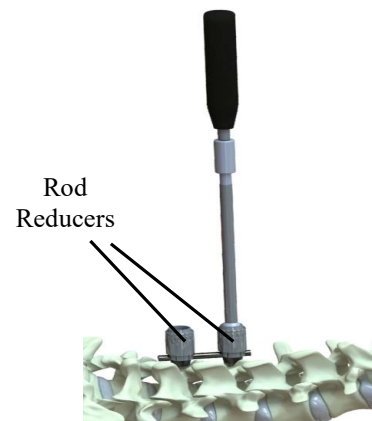
In case the Rod Reducer is used, insert the Locking Element Starter through the Rod Reducer and continue as described above.



Remove the Locking Element Starter.

Important Note:

The Locking Element Starter is not designed for final tightening of the component.



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

7. *Distraction and Compression*

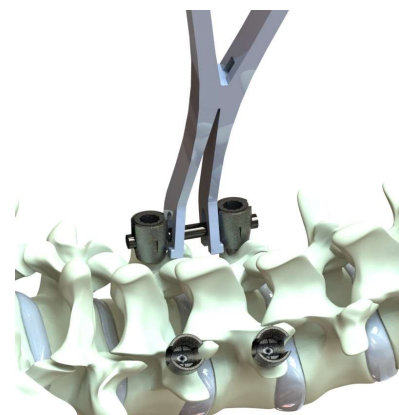
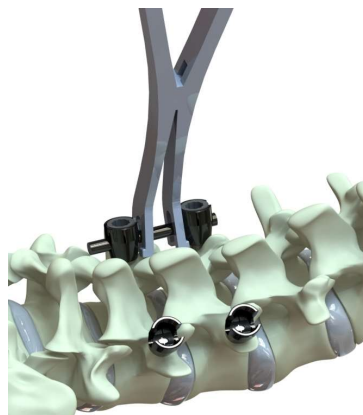
If required, distraction or compression may be performed at this stage, using the provided **Distractor** and **Compressor**.

If **distraction** is required:

- a. Connect a Handle to the Starter.
- b. Lock the Locking Element of both Pedicle Screws (using the Locking Element Starter, as described above in *Section 6*); in case distraction is performed at the end of the Rod, leave long enough portion protruding from the Pedicle Screw on the other side.
- c. Connect a Handle to the Locker.
- d. Perform final locking of the Locking Element of one of the Pedicle Screws as described below in *Section 8*.
- e. Position the Locker on the other Pedicle Screw.
- f. Place the Distractor in-between the Pedicle Screws, all the way over the Rod, and perform distraction.
- g. Once the desired distraction is achieved, perform final locking of the Locking Element of the other Pedicle Screw as described below in *Section 8* (if needed, with the Distractor still in place).



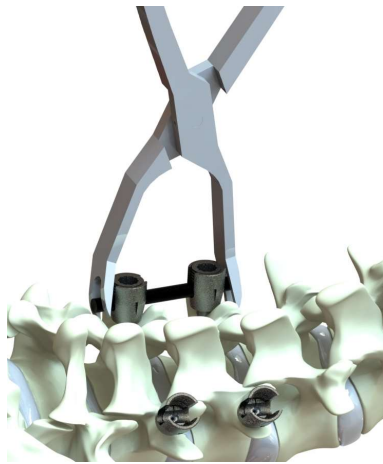
Before Distraction



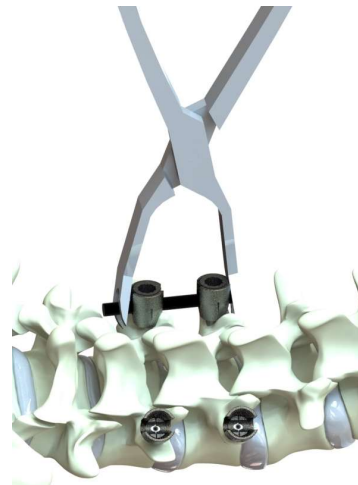
After Distraction

If *compression* is required:

- a. Connect a Handle to the Starter.
- b. Lock the Locking Elements of both the Pedicle Screws (using the Locking Element Starter, as described above in Section 6).
- c. Connect a Handle to the Locker.
- d. Perform final locking of the Locking Element of one of the Pedicle Screws (as described below in Section 8).
- e. Position the Locker on the other Pedicle Screw.
- f. Place the Compressor at the outer side of the Screws' tulips.
- g. Compress using the Compressor.
- h. Once the desired compression is achieved, perform final locking of the Locking Element of the other Pedicle Screw (as described below in *Section 8*).



Before Compression

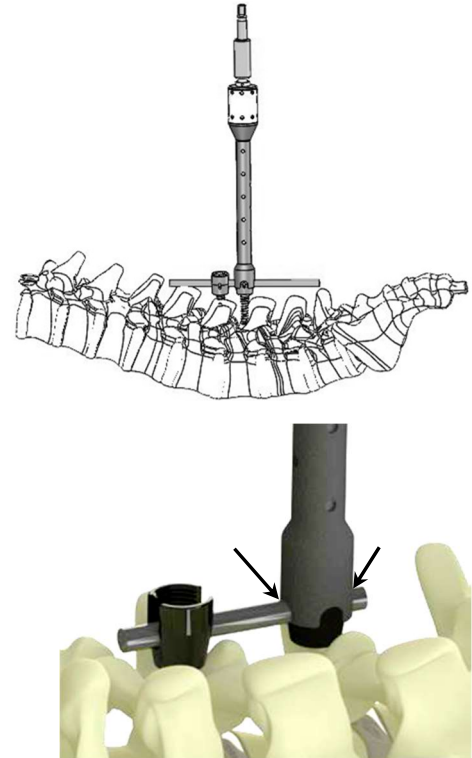


After Compression

8. Locking Element Final Locking

- a. Connect the **Handle** to the **Locker**.
- b. Position the **Locker** over the Tulip and the Rod. Verify that the Locker is fully seated on both sides of the Rod (as shown in the figure). If needed, slightly rotate the Locker handle for full engagement.
- c. Rotate the Locker Handle clockwise until an audible "click" is heard.

Repeat the steps above for all Screws.

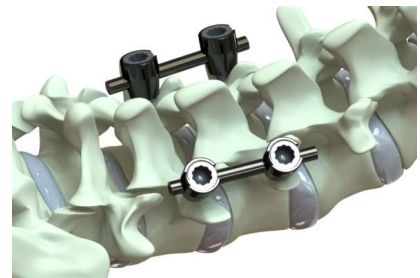


9. Unlocking (if required)

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

10. Second Rod Placement and Locking

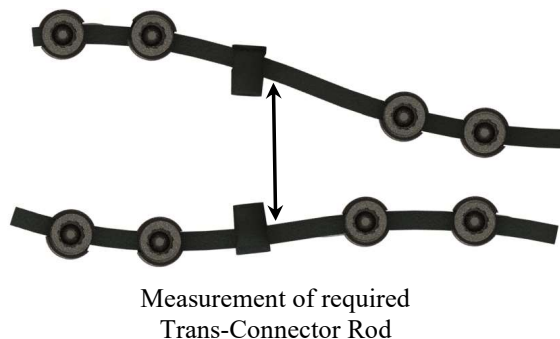
Place additional Rod in the same manner, on the contralateral side, and lock the components using the Locking Element, as described above.



11. Addition of Trans-Connectors and Rod Connectors

a. In case Trans-Connectors are to be placed as well, act according to the following steps:

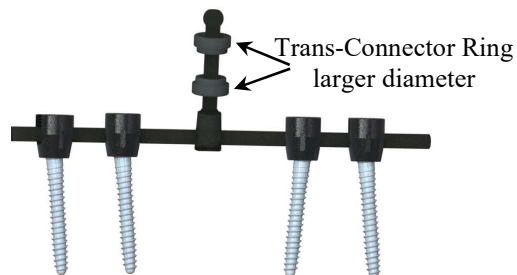
- i. Use the **Flexible Ruler** to measure the inner distance between the two parallel locked Rods. Choose the **Trans-Connector Rod** with the same length as measured (if, for example, the measurement was 40mm, use a 40mm Trans-Connector Rod).



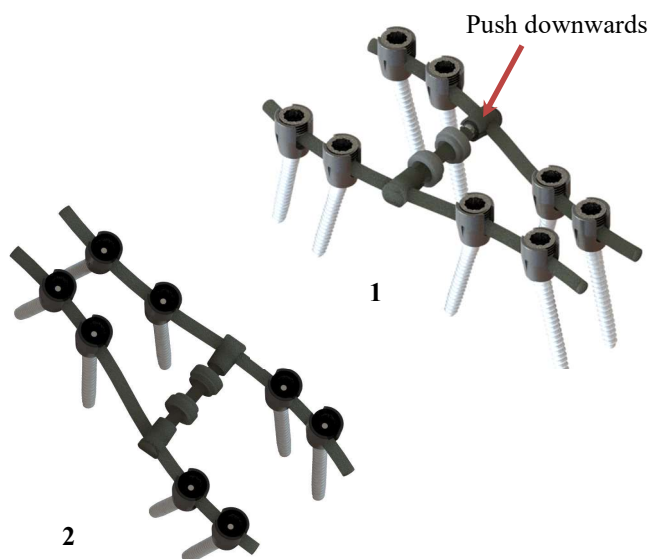
- ii. Snap (“click”) the spherical end of the Trans-Connector Rod into the **Trans-Connector Locking Element** on one side (if needed, tilt upwards the Trans-Connector Locking Element for easier approach).



- iii. Place two **Trans-Connector Rings** over the Trans-Connector Rod. Make sure the Trans-Connector Rings’ larger diameters are facing laterally.



- iv. Tilt upwards the Trans-Connector Locking Element of the contralateral side. Place the spherical end of the Trans-Connector Rod into the Trans-Connector Locking Element. Push downwards with your fingers the Trans-Connector Rod and Locking Element until a “click” is heard, and the spherical end of the Trans-Connector

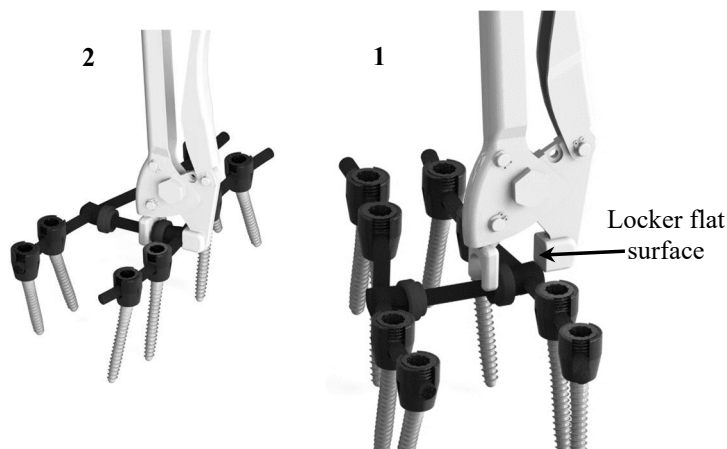


Rod is snapped into the Locking Element.

- v. Move the Trans-Connector Locking Rings and position them over the Trans-Connector Locking Elements.

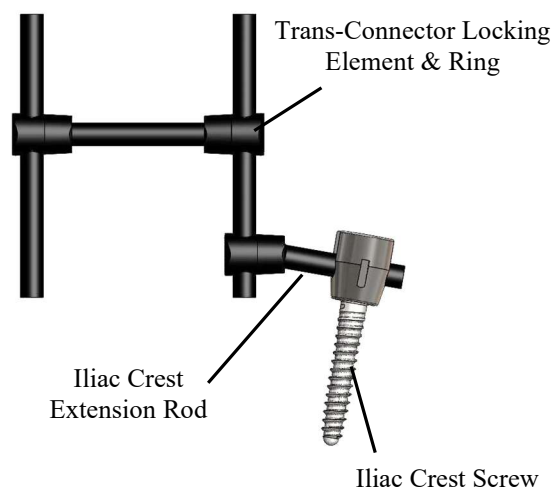
Lock the construct using the **Trans-Connector Locker**.

Make sure the Locker flat surface is positioned over the Trans-Connector Locking Element. Lock using the Locker; gradually increase the locking force – press the locker handle and then rotate the Locker screw and re-press the Locker handle, until the marking on the Locker shaft is aligned with the marking on the Locker screw.



- b. In case there is a need to connect the construct to a Screw located at the iliac crest, use an Iliac Crest Rod:
 - i. If required, cut the Iliac Crest Rod to the desired length using the instrumentation provided in the **Cutting Set** (as described for the longitudinal Rods in *Section 4*).

- ii. Use a Trans-Connector Locking Element and Ring to connect the spherical end of the Iliac Crest Rod to the main construct. Lock it using a Trans-Connector Locker according to the procedure steps detailed above for the trans-connectors.



- iii. Lock the other Iliac Crest Rod end to the Screw located at the iliac crest, using the Locking Element (as described in the *Sections 5, 6 and 8*).

- c. In case there is a need to connect the pedicle screw construct to an additional pedicle screw construct, use the **Rod Connectors**:

The rod connectors enable the connection of 6.0mm rods to 5.5mm rods or to 6.0mm rods.

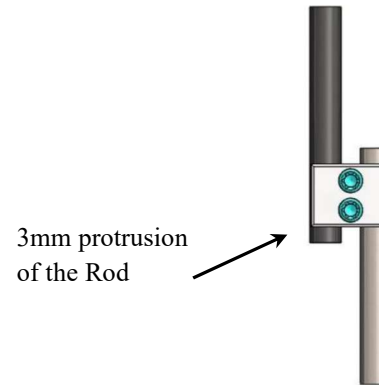
- i. Choose the desired Rod Connector type – parallel or linear, and the desired dimensions, depending on the dimensions of the rods to be connected.

- ii. **Linear Rod Connector:** Place the rods in the rod connector so that they meet in the middle of the connector and tighten the screws. Tightening shall be performed with the T15 Torx Screwdriver Bit connected to a Handle-Torque Limiter; position the Torque Limiter to the Ø5.0/5.5 marking. Tightening shall be performed alternately (*i.e.*, turn each screw a little



and then turn the other screw a little, and so on), about $\frac{1}{4}$ round each time.

- iii. **Parallel Rod Connector:** Place the rods in the rod connector so that they protrude at least 3mm from the ends of the rod connector and tighten the screws. Tightening shall be performed with the T15 Torx Screwdriver Bit connected to a Handle-Torque Limiter; position the Torque Limiter to the Ø5.0/5.5 marking. Tightening shall be performed alternately (*i.e.*, turn each screw a little and then turn the other screw a little, and so on), about $\frac{1}{4}$ round each time.



- d. Verify radiographically the entire construct placement. In case it is desired to unlock any of the components, refer to the "Implant Removal Procedure" Section.
- e. Close the operation site according to common surgical practice.

IMPLANT REMOVAL PROCEDURE

Removal of the implants of CarboClear X Pedicle Screw System is performed in the following manner:

1. Rod Connectors Removal

In case Rod Connectors were used -

Use the **Rod Connector Screwdriver** to unlock the screws of the Rod Connector and remove it.

2. Trans Connectors Removal

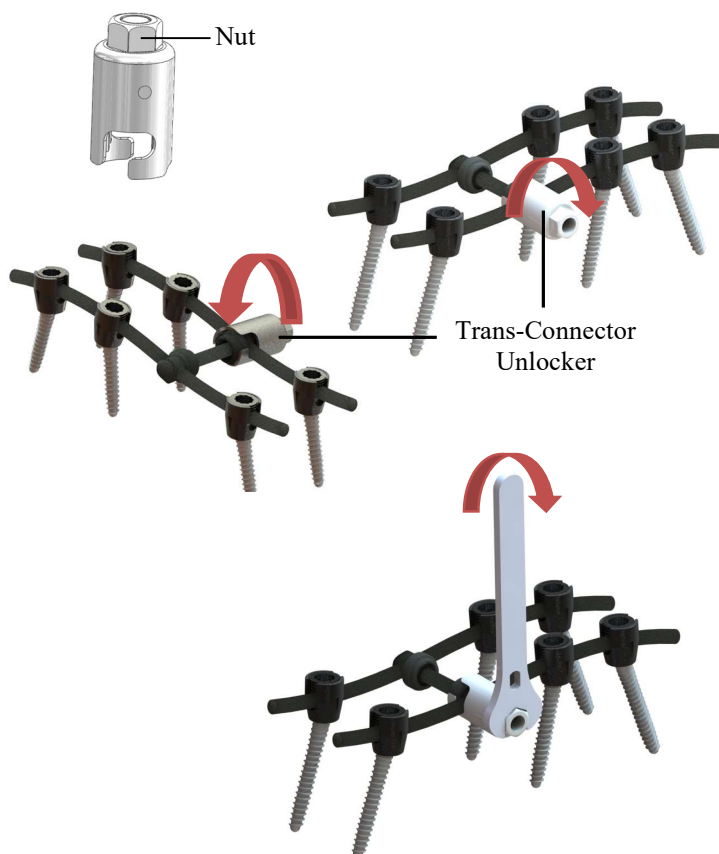
In case **Trans-Connectors** were used –

Use the **Trans-Connector Unlocker**.
Verify its Nut is rotated all the way counterclockwise.

Mount the distal tip of the **Trans-Connector Unlocker** over the Trans-Connector Locking Element, and secure it in place by fully rotating it.

Use the **Wrench** to rotate the Trans-Connector Unlocker Nut clockwise, to unlock the Trans-Connector Ring.

Repeat the same procedure on the contralateral side.



Pull out the Trans-Connector Rod from the Trans-Connector Locking Elements.

Note:

In case the entire construct is removed, including the longitudinal Rods, unlock the long construct Rods from the Pedicle Screws. There is no need to unlock the Trans-Connector construct first.

3. Locking Element Removal

Connect the **Starter** to a **Handle**. Engage the **Starter** with the Locking Element. Unthread the **Locking Element** by counterclockwise rotation of the Starter.

Note: Optionally, the Locker can be used for unlocking.

4. Pedicle Screw Removal

- a. Connect the **Pedicle Screw Screwdriver** to a **Handle**. Connect the Screwdriver to the **Pedicle Screw** by rotating the Screwdriver' Butterfly Handle clockwise – see Section 3d. Remove the Screw by counterclockwise rotation of the Screwdriver Handle.

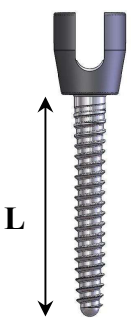
Note: The **Handles-Torque Limiter** is compatible with the Pedicle Screw removal procedure.

- b. In case of damage to a Pedicle Screw already located within the pedicle, 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 **Pedicle Screw Extractor**. Choose the Extractor complying with the Pedicle Screw diameter, connect it to a Handle and insert it into the pedicle (over the Pedicle Screw), in counterclockwise rotation. Once the Pedicle Screw is located within the Extractor, pull the Extractor backwards.
- c. Close the operation site according to common surgical practice.

ORDERING INFORMATION

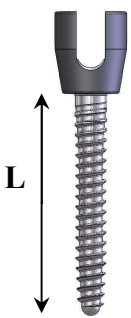
Implants

Screws for Oncology

Component	Size (mm)	Catalogue No. *	
Polyaxial Pedicle Screw; Non-Cannulated	Diameter: 5.0 Length (L): 25, 30, 35, 40, 45	PNNS50XXN	
	Diameter: 5.5 Length (L): 30, 35, 40, 45	PNNS55XXN	
	Diameter: 6.5 Length (L): 35, 40, 45, 50, 55	PNNS65XXN	
	Diameter: 7.5 Length (L): 35, 40, 45, 50, 55	PNNS75XXN	
Polyaxial Pedicle Screw; Cannulated	Diameter: 6.5 Length (L): 35, 40, 45, 50, 55	PNNSC65XXN	
	Diameter: 7.5 Length (L): 35, 40, 45, 50, 55	PNNSC75XXN	
	Diameter: 8.5 Length (L): 40, 45, 50, 55, 65, 75, 85, 95	PNNSC85XXN	

* XX – represent the length of the component, in mm.

Screws for DDD

Component	Size (mm)	Catalogue No. *	
Polyaxial Pedicle Screw; Non-Cannulated	Diameter: 5.0 Length (L): 30, 35, 40, 45	PPLS50XX	
	Diameter: 5.5 Length (L): 30, 35, 40, 45	PPLS55XX	
Polyaxial Pedicle Screw; Cannulated	Diameter: 6.5 Length (L): 35, 40, 45, 50, 55	PPLS65XX	
	Diameter: 7.5 Length (L): 35, 40, 45, 50, 55	PPLS75XX	
	Diameter: 8.5 Length (L): 40, 45, 50, 55, 65, 75, 85, 95	PPLS85XX	

* XX – represent the length of the component, in mm.

Component	Catalogue No.	
Locking Element (Set Screw)	PPLCUR4000N	

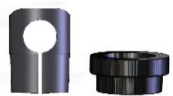
Component	Size (mm)	Catalogue No. *	
Short Straight Rod	Diameter: 6.0 Length (in 5 mm steps): 35-80	PPLOSR60XX § PPLSR60XX	
Short Curved Rod	Diameter: 6.0 Length (in 5 mm steps): 35-80	PPLOCR60XX § PPLCR60XX	

* XX – represent the length of the component, in mm.

§ Implants provided without tantalum markers; for oncological patients

Component – Long Rods	Type	Length (mm)	Catalogue No.	
"S"-Shaped Rod, R=240/120 mm	Type 1	190	PPLCR6190S §	
Curved Rod, R=440 mm	Type 2	280	PLMCR6200 §	
Shaped Rod, R=45/145/310 mm	Type 3	270	PNNSR4270 §	
Shaped Rod, R=45/200/310 mm	Type 4	285	PNNSR6270 §	
Straight Rod	Type 5	270	PPLSR6270 §	
Straight Rod (Ti-6Al-4V) + Spreader		300	PNNER6300	

§ Implants provided without tantalum markers; for oncological patients

Component	Size (mm)	Catalogue No. *	
Trans-Connector Rod	Diameter: 6.0 Length (in 2mm steps): 30 – 70	PPTCR60XX	
Iliac Crest Rod	Diameter: 6.0 Length: 100	PPILR6100	
Trans-Connector Locking Element + Ring	—	PPTCC4000	

* XX – represent the length of the component, in mm.

Component – Rod Connector	Size (Compatible Rod Size)	Catalogue No.	
Parallel Connector	6mm – 6mm 6mm – 5.5mm	PPPRC6060 PPPRC6055	
Linear Connector	6mm – 6mm 6mm - 5.5mm	PPLRC6060 PPLRC6055	

Instrumentation Set – Catalogue No. PPS922100G2

Description	Catalogue No.	
Pedicle Awl	PPS922110	
Pedicle Probe - Blunt, Straight	PPS922390N	
Pedicle Probe - Blunt, Curved	PPS922240	
Pedicle Probe - Pointed, Straight	PPS922650N	
Pedicle Probe - Pointed, Curved	PPS922390	
Pedicle Feeler	PPS922130	
Straight Handle-Torque Limiter	PPS922702	
Pear Handle	PPS922701	
Bone Tap - Ø 8.5mm	PPS922630N	
Bone Tap - Ø 8.0mm (Optional)	PPS922640N	
Bone Tap - Ø 7.5mm	PPS922710N	
Bone Tap - Ø 7.0mm (Optional)	PPS922720N	
Bone Tap - Ø 6.5mm	PPS922730N	
Bone Tap - Ø 6.0 mm (Optional)	PPS922740N	
Bone Tap - Ø 5.5 mm	PPS922750N	
Bone Tap - Ø 5.0 mm	PPS922760N	
Bone Tap - Ø 4.5 mm (Optional)	PPS922770N	
Rod Holding Forceps	PPS922230	
Pedicle Surface Reamer	PPS922150	
Pedicle Screw Screwdriver	PPS922160G2	
Pedicle Screw Screwdriver	PPS922162N	
T-Handle-Torque Limiter	PPS922700	

Description	Catalogue No.	
Tulip Adjuster	PPS922420G2	
Locking Element Starter	PPS922790G2	
Locker	PPS922460G2	
Rod Pusher	PPS922440	
Rod Reducer	PPS922440G2	
Rod Reducer Handle	PPS922781G2	
Rod Measuring Template – 50 mm	PPS922170	
Rod Measuring Template – 80 mm	PPS922430	
Rod Arc Measuring Template – 50 mm	PPS922960	
Rod Arc Measuring Template – 80 mm	PPS922970	
Type 1 Rod Template	PPS018278	
Type 2 Rod Template	PPS018279	
Type 3 Rod Template	PPS018269	
Type 4 Rod Template	PPS018277	
Distractor	PPS922450	
Compressor	PPS922980	
Spreader	PPS922990	
Trans Connector Locker	PPSLTC100	
Trans Connector Unlocker	PPSLTC101	
Trans Connector Wrench	PPSLTC102	
Mallet	Q9105110	
Rod End Shaper	PPS922920US	

Description	Catalogue No.	
T15 Torx Screwdriver Rod (Optional)	PPS933180	

Sterilization Box	PPS922105G2	Includes 3 trays and a lid
Cutting Container	PPS180218	

Guide Wires [single use, provided Sterile]

Description	Catalogue No.	
Guide Wire Ø 1.2 mm	PPS922501	

Cutting Set - Catalogue No. PPS925100US [single use, provided Sterile]

Description	Catalogue No.	
Flexible Ruler	PPS925110	
Saw	PPS925120US	

Extractors [single use, provided Sterile]

Description	Catalogue No.	
Screw Removal (Extractor) - Ø8.5 mm	PPS922660	
Screw Removal (Extractor) - Ø7.5 mm	PPS922930	
Screw Removal (Extractor) - Ø6.5 mm	PPS922940	
Screw Removal (Extractor) - Ø5.5 mm	PPS922950	
Screw Removal (Extractor) - Ø5.0 mm	PPS922670	

FURTHER INFORMATION

Important Note:

- Refer to the system Instructions for Use (TEC 2847) for additional information regarding the CarboClear X Pedicle Screw System, including Contraindications, Warnings and Precautions, Possible Adverse Events and Packaging and Sterilization information.
- For reprocessing of the reusable instruments, refer to CarboFix' Spine Instrumentation Handling Instructions (Ref. 4698).

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