CARBOCLEAR® HYBRID PEDICLE SCREW SYSTEM

A COMPOSITE MATERIAL SPINAL SYSTEM

SURGICAL TECHNIQUE – OPEN APPROACH FOR ONCOLOGICAL PATIENTS

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OVERVIEW

The CarboClear® Hybrid Pedicle Screw System consists of implants made of carbon fiber-reinforced PEEK (CFR-PEEK), with titanium alloy screw tulip and set screw. The system is used to build a spinal construct for segmental spinal immobilization and stabilization.
Additionally, the CarboClear® Hybrid Pedicle Screw System includes a set of instruments.

The CarboClear® Hybrid Pedicle Screw System can be used in open or minimally invasive posterior spinal surgeries.
This document describes the system surgical technique for open surgeries.

INDICATIONS FOR USE

The CarboClear® Hybrid Pedicle Screw System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

SYSTEM BENEFITS

CarboClear® Hybrid Pedicle Screw System provides for the following benefits in oncological patients:

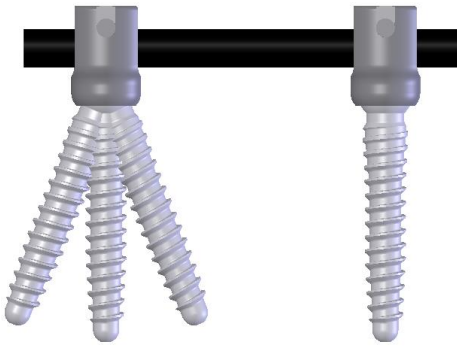
- Reduced CT artifacts
- Improved pre-radiotherapy planning
- Reduced interference with radiotherapy protocols
- Allows for proton therapy
- Visualization of the construct using tantalum marker and screw titanium shell, evident on x-ray imaging or fluoroscopy
- Low-profile implant construct
- Can be implanted in both open and minimally invasive approaches.

IMPLANTS

The implants include polyaxial pedicle screws, longitudinal rods, set screw (locking element), and transverse connectors.

The implants are made of CFR-PEEK, with titanium alloy screw tulip and set screw. The screw shank is encased within a thin titanium shell.

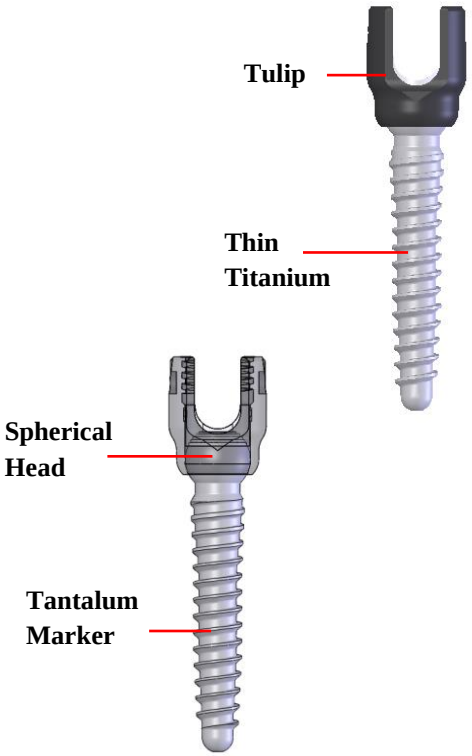
The implants are supplied sterile, and are intended for single use.



Pedicle Screws

Polyaxial CFR-PEEK Pedicle Screws, comprising a spherical head enclosed within a titanium alloy housing (tulip), allowing tulip positioning in a variety of angles (50° - 60°, depending on Screw' diameter).

The tulip has a "U" shape to accommodate the Rod. It includes an internal thread, compatible with a titanium alloy Set Screw that locks the implant construct components.



The Screws 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.

Both non-cannulated (solid) and cannulated-fenestrated Pedicle Screws are available. Fenestrated Screws may also be used (as cannulated Screws) without bone cement.

The Pedicle Screws are offered in 5.0 mm, 5.5 mm, 6.5 mm, and 7.5 mm diameter, and in lengths ranging from 20 mm to 55 mm (diameter-dependent).

Rods

The CarboClear Hybrid Pedicle Screw System uses CarboClear CFR-PEEK Rods of 6.0 mm diameter, available in short and long versions.

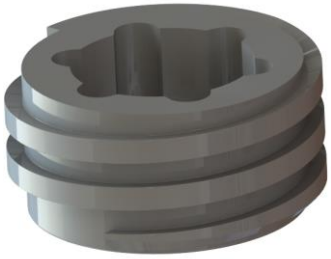
The short Rods include lengths ranging from 35 mm to 80 mm (in 5 mm increments). They are provided pre-cut, either straight or curved.
MIS Rods, with a bullet-tip shaped end, may also be used in open approach surgeries. A tantalum wire is incorporated along their long axis, thus enabling their visualization under X-ray.

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.

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

Set Screw (Locking Element)

Used to lock the Rod and the Pedicle Screws.
It is made of titanium alloy and comprises an external thread, compatible with the internal thread of the Screw tulip.



The Set Screw is used with two dedicated screwdrivers (a Starter and a Locker).

Transverse Connector (Trans-Connector) Unit

CarboClear Hybrid System uses CarboClear Trans-Connector Unit and Iliac Crest Rods.

The Trans-Connector Unit is used for transverse connection of the Rods. The Trans-Connector Unit includes Rods, Locking Element and Locking Ring.

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 Locking Ring (described below).

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

Iliac Crest Rod

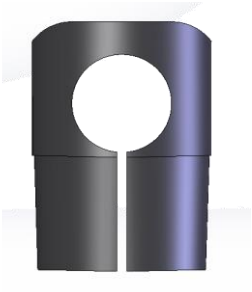
The Iliac Crest Rod is made of CFR-PEEK. It has one spherical end, at which it is connected and locked to the longitudinal Rod (using the Trans-Connector Locking Element and Locking Ring). At its other end, the Iliac Crest Rod is connected and locked to the Screw (implanted in the iliac bone), using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

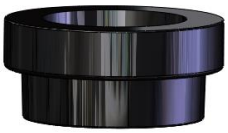
Trans-Connector Locking Element



The Trans-Connector Locking Element has a lumen to accommodate the longitudinal Rod, and it 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 Ring



INSTRUMENTS

The reusable surgical instruments are provided non-sterile, in an ***Instrumentation Set*** (CarboClear Hybrid Instrumentation Set).

The Instrumentation Set includes Navigated Instruments, including ***Navigated Straight Probes***, ***Navigated Bone Taps*** and ***Navigated Screwdriver***, which are intended to be used with Medtronic StealthStation® Navigation platform, to assist surgeons in precisely locating anatomical structures during operation, for preparation and placement of CarboClear Hybrid Pedicle Screws. Refer to CarboClear Hybrid Navigated Instruments Surgical Technique manual (TEC 3174).

Single use, sterile provided, ***Guide Wires***, ***Cutting Set***, and ***Extractors*** are also provided (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 (blunt and pointed) are *Navigated Instruments*, designed for use with Medtronic StealthStation® Navigation System and include a connector to Medtronic NavLock Tracker. They are used with the provided Handles.

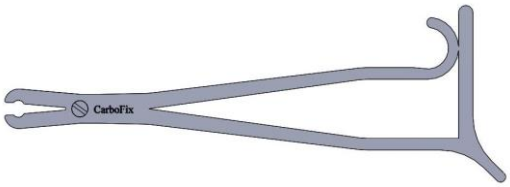
The Navigated Straight Probes may also be used as non-navigated probes.

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) the Rods.



Navigated Bone Taps

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

The taps are available in 5.0 mm, 5.5 mm, 6.5 mm and 7.5 mm 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 7.5 mm diameter Tap for a 7.5 mm 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).

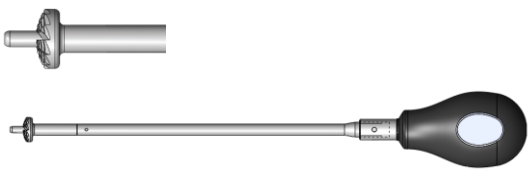
The Taps are marked to assist in Screw length selection.

The Bone Taps may be used as *Navigated Taps* with Medtronic StealthStation® Navigation System, and include a connector to Medtronic NavLock Tracker. They may also be used as non-navigated instruments.

The Bone Taps are used with one the provided Handles. Additional Bone Taps in the range of 4.5 mm – 7.0 mm in 0.5mm steps may be provided upon request.

CarboClear Hybrid 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.



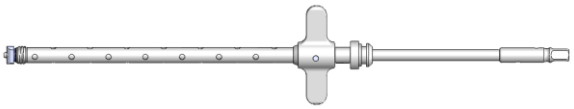
CarboClear Hybrid Pedicle Screw Screwdriver

Navigated and non-navigated Screwdrivers are offered, for insertion of the Pedicle Screws into the vertebra pedicles. The Screwdrivers are cannulated, to allow their usage over the 1.2 mm Guide Wire.

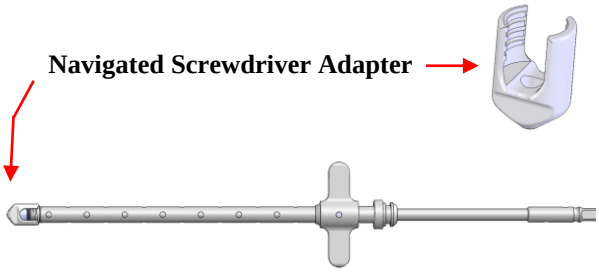
The Screwdrivers are used with a Handle-Torque Limiter.

The Navigated Screwdriver may be used with Medtronic's StealthStation® Navigation System and includes a connector to Medtronic NavLock Tracker. Registration to the StealthStaion® is performed with a dedicated adapter assembled to the Driver' distal end.

Pedicle Screw Screwdriver



Navigated Screwdriver



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 Screwdriver and may be used with the 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 rachet mechanism movement direction is changed by rotating a dial clockwise or counterclockwise.

Pear Handle

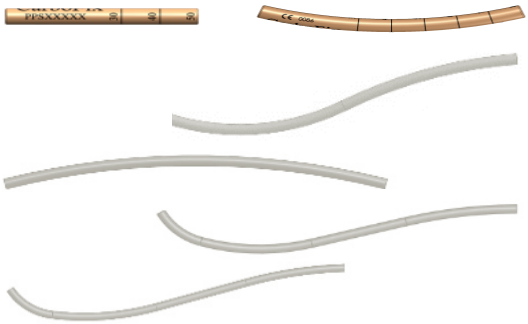
A dedicated pear-shaped Handle, for use with the different instruments, as required, according to surgeon preference.

CarboClear Hybrid Tulip Adjuster

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

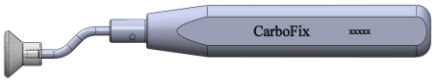
Rod Measuring Templates

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.

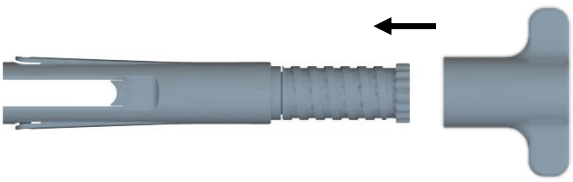


Rod Pusher

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

CarboClear Hybrid Rod Reducer and Handle

Used for Rod reduction within the Screw' saddle, if required.



CarboClear Hybrid Set Screw Starter

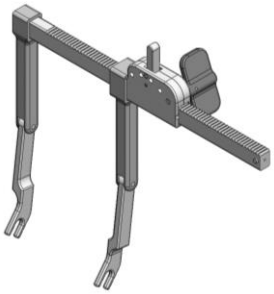
A dedicated, self-retaining driver for the insertion and initial tightening of the Set Screw, within the Screw tulip. The Starter is used with one of the provided Handles.

CarboClear Hybrid Locker

The Locker is used for final locking of the Set Screw within the Screw tulip.
The Locker includes an integral Torque Limiter, and shall be used with one of the provided Handles.

Distractor/Compressor

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



Mallet

Provided as part of the set, in case required.

Spreader

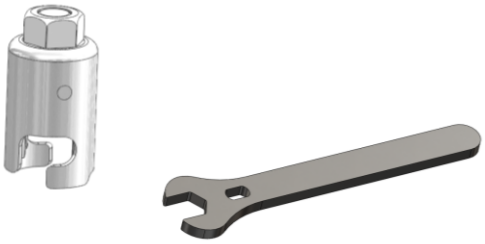
May be used to assist in Trans-Connector Locking Element placement and movement over the Rod.

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.



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

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.

CUTTING SET [SINGLE USE; PROVIDED STERILE]

A 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.

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 four dimensions (5.0 mm, 5.5 mm, 6.5 mm, 7.5 mm 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.

SURGICAL TECHNIQUE

1. *Surgical Approach*

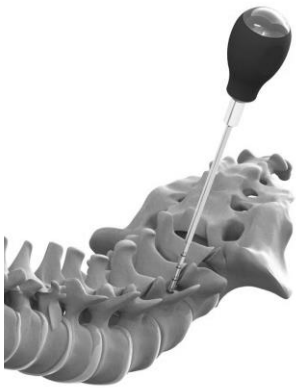
Patient positioning, surgical approach and exposure of the spine shall be performed according to standard procedures.

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*

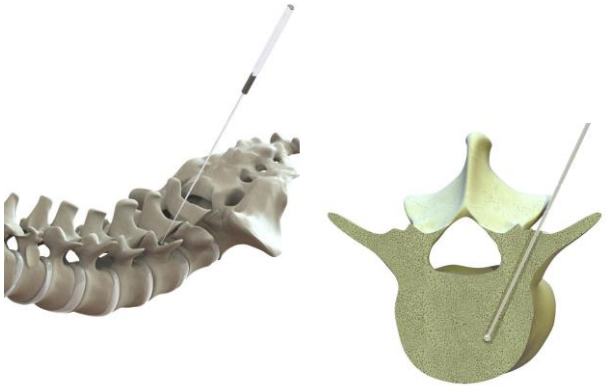
a. After adequate exposure, select the appropriate pedicle entry point.
At each entry point, use the supplied **Pedicle Awl** to breach the cortical exterior of the pedicle.

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.

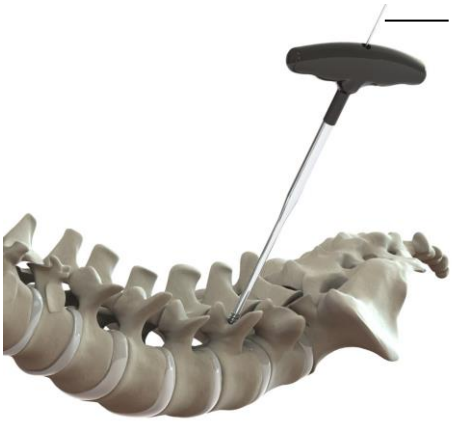


If the Straight Probes are used as a *Navigated Probes*, refer to CarboClear X Navigated Instruments Surgical Technique manual (TEC 3174) for detailed instructions.

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.

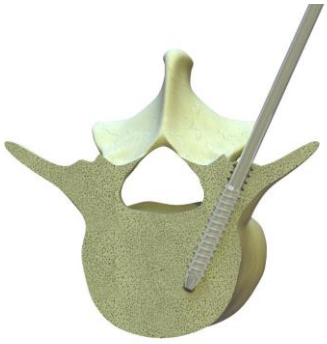


d. Tapping must be performed, by using the provided **Bone Taps**.
Use a Tap of the same diameter as that of the Screw, and tap to the entire length of the selected Screw. Tapping depth shall be slightly deeper than the actual length of the Screw to be placed.
In case of low-quality bone, the physician may decide to use a smaller diameter Tap.



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

<u>*Note*</u>: 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.

If the instrument is used as a *Navigated Bone Tap*, refer to CarboClear Hybrid Navigated Instruments Surgical Technique manual (TEC 3174) for detailed instructions.

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. *Assembly of Pedicle Screw and Screwdriver*

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

The Torque Limiter has two operation modes:

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

T-Handle-Torque Limiter

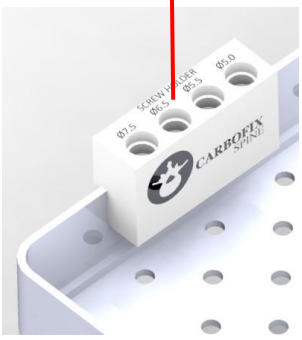
If the instrument is used as a *Navigated Screwdriver*, refer to CarboClear Hybrid Navigated Instruments Surgical Technique manual (TEC 3174) for detailed instructions.

b. Choose the **Pedicle Screw** of the required size.

c. Connect the Pedicle Screw to its Driver (using the Screw Block, or manually; see figures below):

Use the **Screw Block** located within the Instrumentation Set to facilitate connection of the Screw and Screwdriver, as detailed hereinafter.

Place the Screw Block on the railling of the **Instrumentation Set tray**. The Pedicle Screw is to be located within the corresponding hole diameter of the block, and the Screwdriver is connected to the Pedicle Screw:



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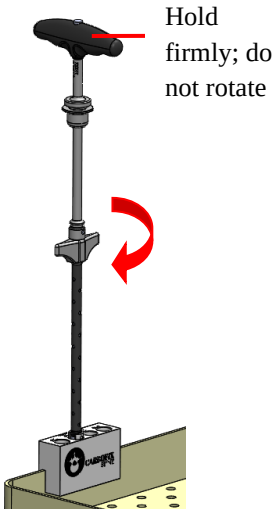
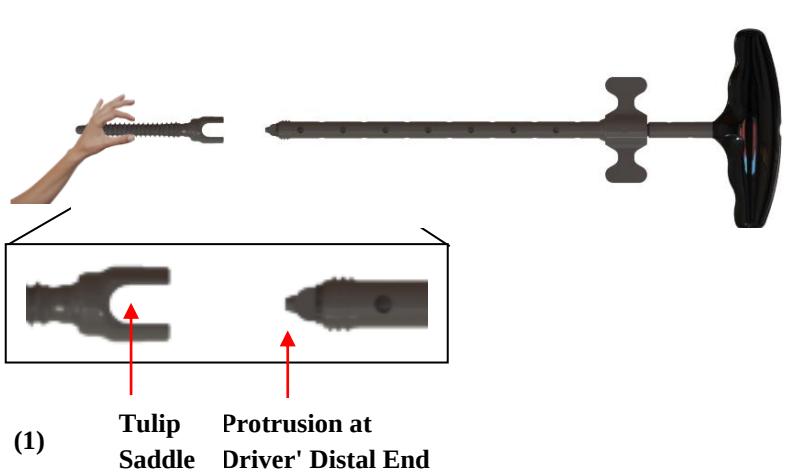


2

(1) Locate the Screwdriver distal end within the Screw tulip, so that the protrusion at the center of the Screwdriver distal end is seated within the base of tulip saddle. Make sure that the tulip and Screwdriver are aligned, to allow proper connection.

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



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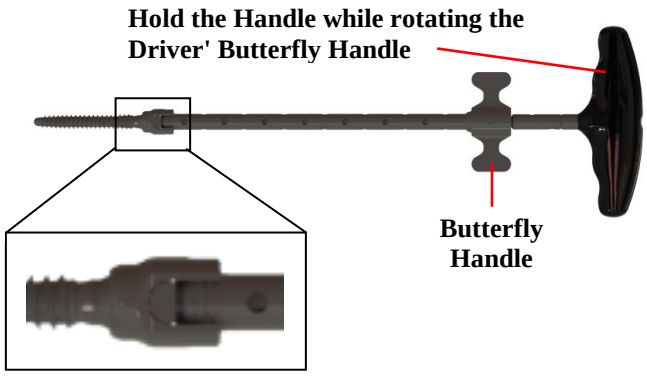


(2)

4. *Pedicle Screws Insertion*

a. In case a cannulated Pedicle Screw is used, insert first the **1. 2 mm Guide Wire**.

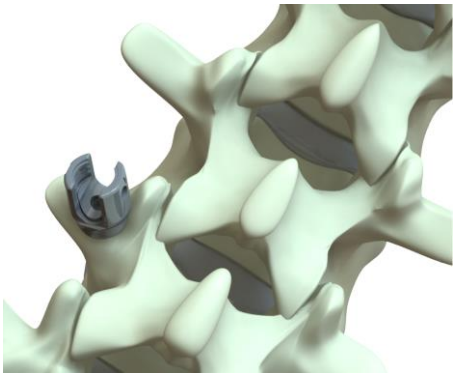
a. Advance the Pedicle Screw down the prepared pedicle canal, by rotating the Screwdriver Handle clockwise, until the Screw is seated in the bone with the correct dorsal height. The Screw shall protrude 1– 2 mm above the bone in order to maintain its polyaxial properties.

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

Rotate the Screwdriver handle clockwise

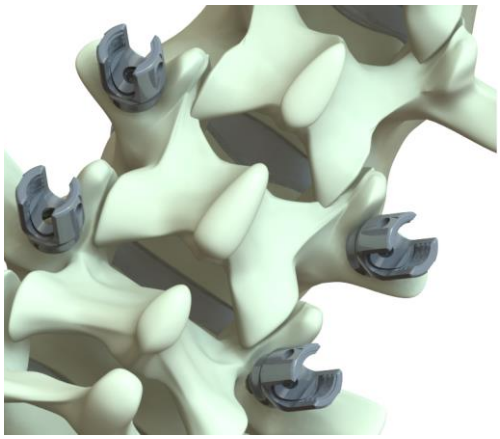
In case the Torque Limiter is activated (click sound) remove the screw and re-tap (to the entire length of the selected Screw).

b. 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 disengages from the Tulip thread.

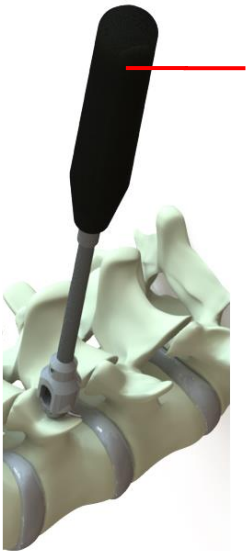


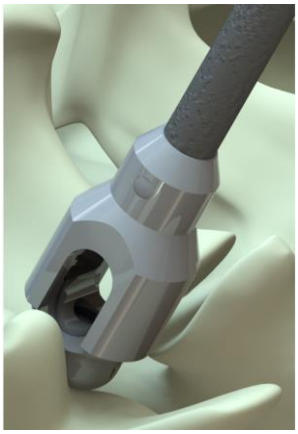
c. Insert the other Screws in the same manner.

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



e. If required, adjust tulip orientation using the **Tulip Adjuster**, by gentle maneuvering of the tool.





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.

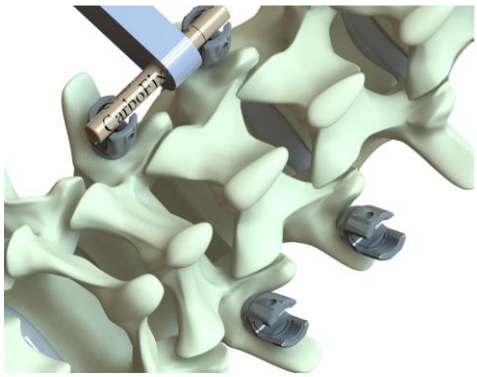
Note that if the Screw is inserted too deep and its tulip is touching the bone, the polyaxial properties will be diminished.

5. *Rods Selection*

The CarboClear Hybrid Screws and Set Screw are used with **CarboClear Rods**.

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

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



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 3 mm.

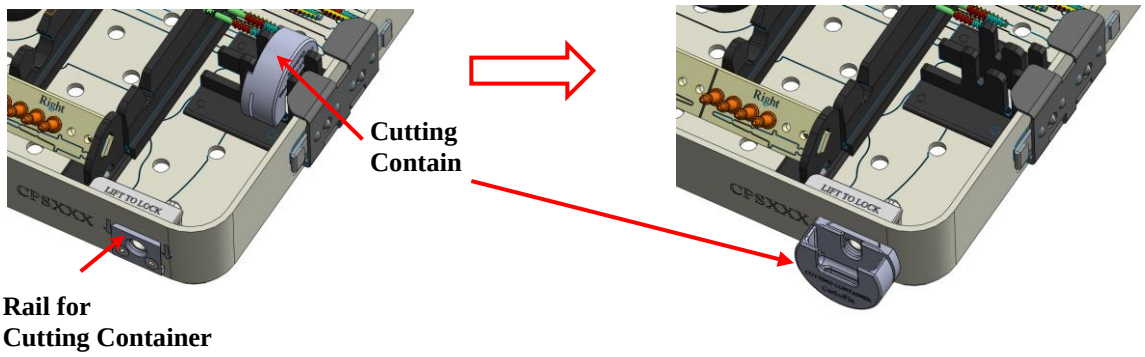
If long Rods (longer than 80 mm) are required – the length/type of the Rod may be assessed using the **Flexible Ruler** and with the help of the **Rod Measuring Templates**. According to this measurement, the required Rod can be selected (Type 1 – Type 5 CFR-PEEK Rods).

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 CarboClear Hybrid Screws and Set Screw.

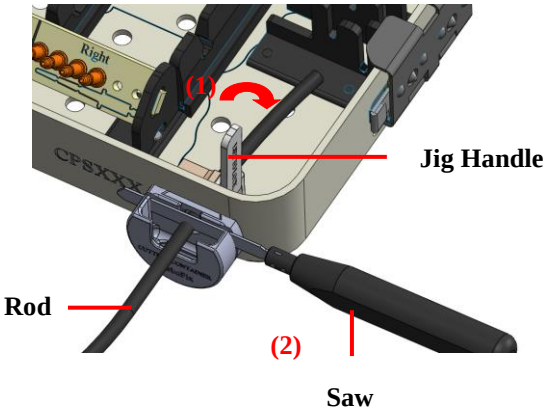
For CFR-PEEK Rods:

The CFR-PEEK 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 Rod to the desired length (indicated as step (2) in the figure).



If needed, refine the cut edge 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 CFR-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.

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.

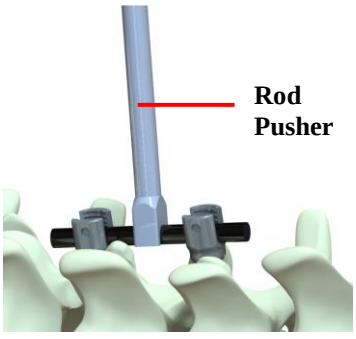
6. *Rod Application*

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' sides. Place the Trans-Connector Locking Element over the Rod and position it at the desired position. Remove the spreader.

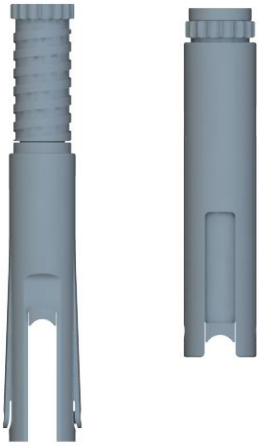
If additional repositioning of the Trans-Connector Locking Element is required – reinsert the Spreader into the Trans-Connector Locking Element slot.

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

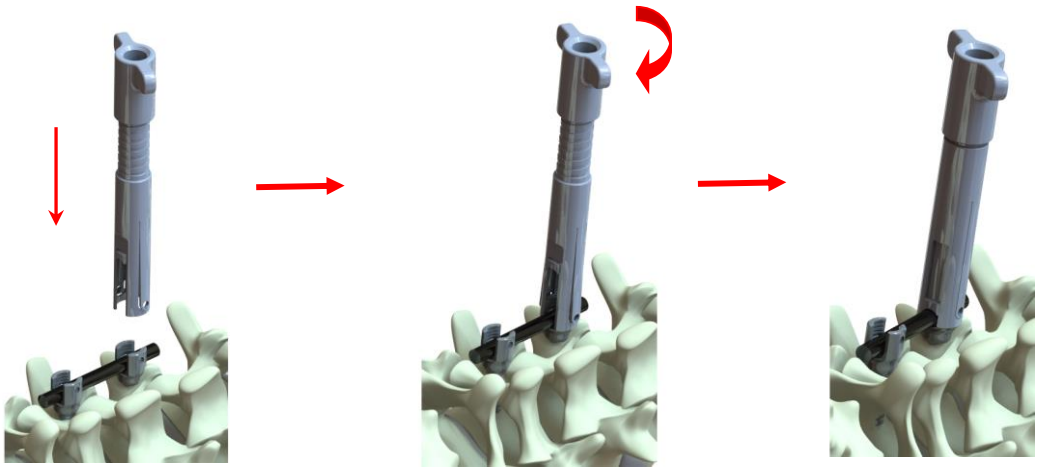


If needed, use the **Rod Reducer** to force the Rod into the Screw saddle:

- 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 <u>all the way</u> until the Rod is fully seated within the Tulip saddle.



Rod Reducer
Open Position Close Position



c. Remove the Handle.

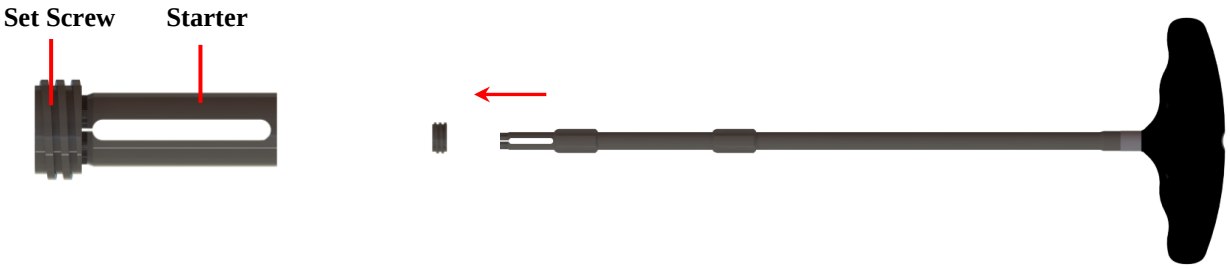
d. Repeat the above steps for the other Screws, if required (the Instrumentation Set includes a few Rod Reducers). It is recommended to apply at least 2 Rod Reducers at the extremities of the Rod. If Rod Reducers are used, placement of the Set Screw as detailed in Section 7 below should only be conducted after the 2 Rod Reducers are fully engaged at both sides.

To remove the Rod Reducer, reconnect the Handle and rotate counter-clockwise <u>all the way</u>. Gently pull the Rod Reducer form the implant construct.

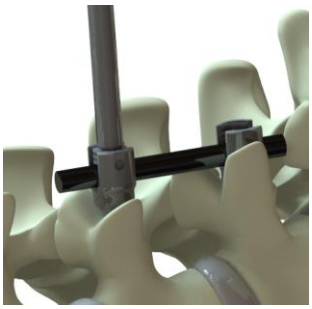
7. *Set Screw Positioning and Initial Locking*

a. Connect the **Handle** to the **Set Screw Starter**.

b. Engage the self-retaining Set Screw Starter to the **Set Screw** (the Set Screw must be fully engaged to the Starter).



c. Locate the Set Screw within the Screw' Tulip, and tighten it by rotating the Handle clockwise.



In case the Rod Reducer is used, insert the Set Screw Starter through the Rod Reducer and continue as described above.
Remove the Set Screw Starter.

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

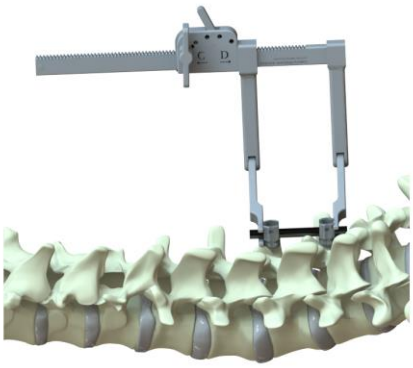
d. Repeat the above steps for all remaining Screws in the construct.

8. *Distraction and Compression*

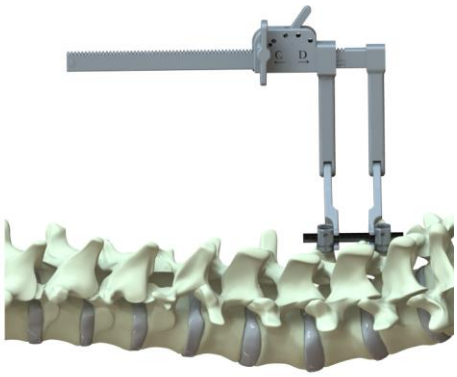
If required, distraction or compression may be performed at this stage, using the provided **Distractor/Compressor**.

a. In case distraction is performed at the end of the Rod, leave long enough portion protruding from the Pedicle Screw on the other side.
b. Connect a Handle to the Locker.
c. After both Pedicle Screws are partially locked using the Set Screw Starter, perform final locking of the Set Screw of one of the Pedicle Screws as described below in *Section 10.*
d. For distraction - place the Distractor/Compressor in-between the Pedicle Screws, all the way over the Rod.
   For compression - place the Distractor/Compressor at the outer side of the Screws' tulips.
e. To set the distance between the Distractor/Compressor "arms" move the mode selection handle to F (Free).
f. Position the Locker on the other Pedicle Screw (where the Set Screw was locked only with the Starter Driver.
g. Perform distraction / compression – move the Distractor/Compressor mode selection handle to D (Distraction) or C (Compression), and rotate the handle to achieve the required movement.

Compression



Distraction



h. Once the desired distraction / compression is achieved, perform final locking of the Set Screw of the other Pedicle Screw as described below in *Section 10* (if needed, with the Distractor/Compressor still in place).

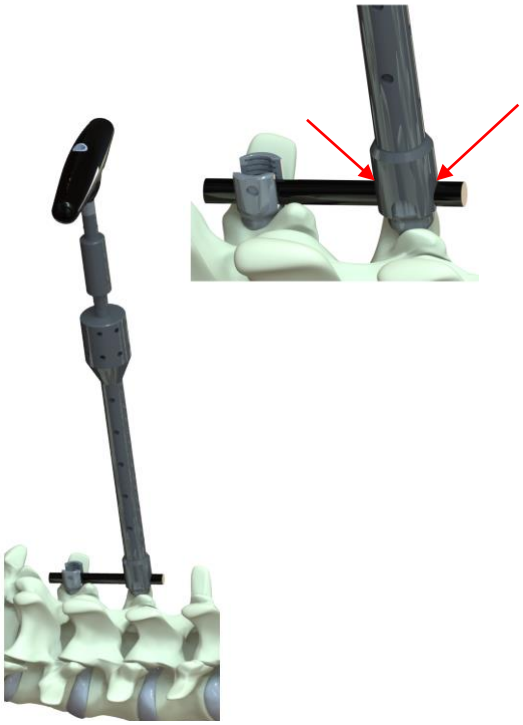
9. *Set Screw Final Locking*

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.

d. Repeat the steps above for all Screws.

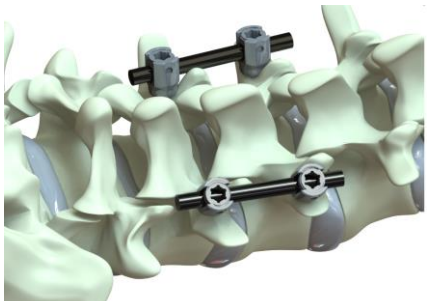


10. *Unlocking (if required)*

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

11. *Second Rod Placement and Locking*

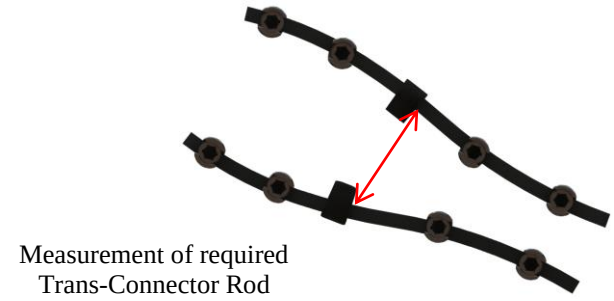
Place additional **Rod** in the same manner, on the contralateral side, and lock the components using the Set Screw, as described above.



12. *Addition of Trans-Connectors (Use CarboClear Trans-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 locked Rods. Choose the **Trans-Connector Rod** with the same length as measured (if, for example, the measurement was 40 mm, use a 40 mm Trans-Connector Rod).

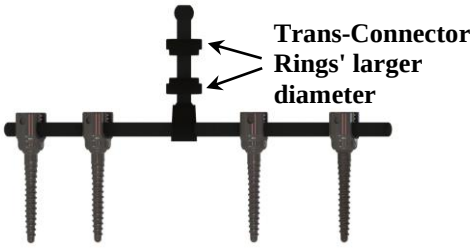


Measurement of required Trans-Connector Rod

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).

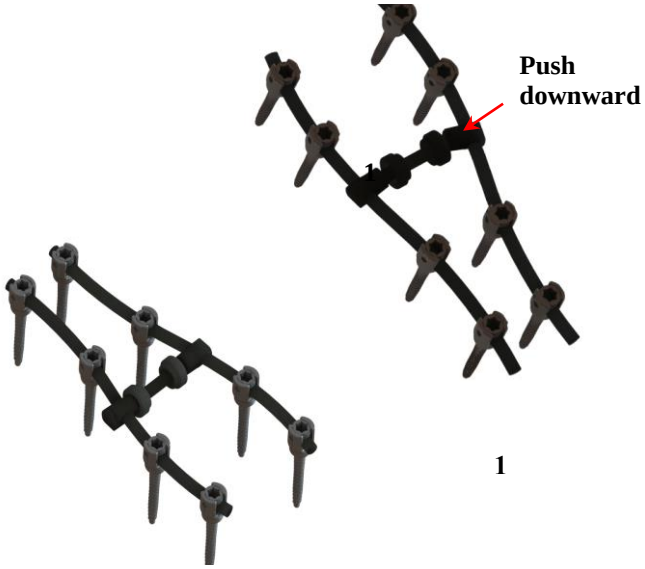
1 **2**

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, and 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.



1

2

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

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

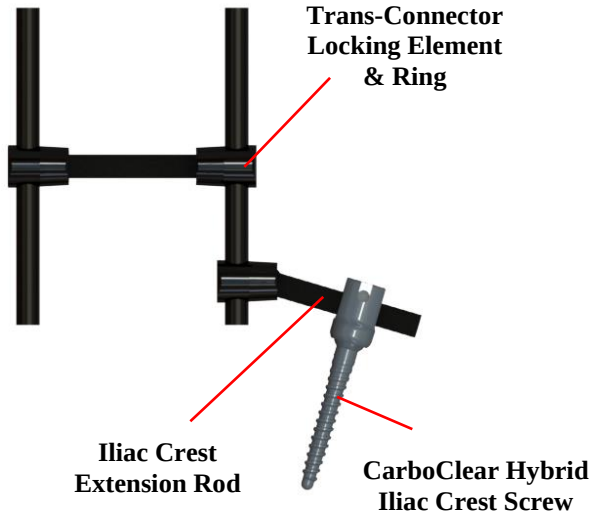
Make sure the Locker flat surface is positioned over the Trans-Connector Locking Element. Lock using the Locker; gradually increase the locking force – press the Locker handle and then rotate the Locker screw and re-press the Locker handle, until the marking on the Locker' shaft is aligned with marking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

b. <u>In case there is a need to connect the construct to a Screw located at the iliac crest</u>, use an **Iliac Crest Rod** (use CarboClear 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 5*).

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 CarboClear Hybrid Screw located at the iliac crest, using the Locking Element (as described in the *Sections, 7 and 9*).



c. Verify radiographically the entire construct placement. In case it is desired to unlock any of the components, refer to the "Implant Removal Procedure" Section.

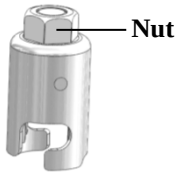
d. Close the operation site according to common surgical practice.

IMPLANT REMOVAL PROCEDURE

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

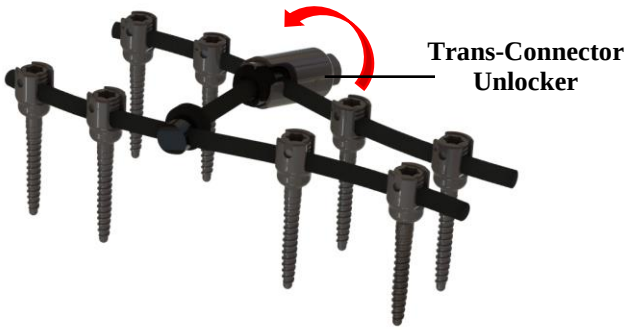
1. *Trans Connectors Removal*

In case **Trans-Connectors** were used –
Use the **Trans-Connector Unlocker**. Verify its Nut is rotated all the way counterclockwise.



Trans-Connector Unlocker

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



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*.

2. *Set Screw Removal*

Connect the **Starter** to a **Handle**. Engage the Starter with the **Set Screw**. Unthread the Set Screw by counterclockwise rotation of the Starter Driver.

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

3. *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 3c. Remove the Screw by counterclockwise rotation of the Screwdriver Handle.

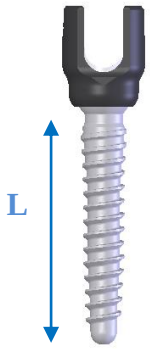
   Note: The **Handles-Torque Limiter** are compatible with the Pedicle Screw removal procedure.

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.

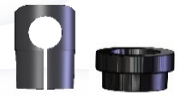
ORDERING INFORMATION

Implants

COMPONENT	SIZE (MM)	CATALOGUE NO. *	
CarboClear Hybrid Pedicle Screw - Non-Cannulated (Solid)	Diameter: 5.0 Length (L): 20, 25, 30, 35, 40, 45	HYB50XX	
	Diameter: 5.5 Length (L): 30, 35, 40, 45	HYB55XX	
	Diameter: 6.5 Length (L): 35, 40, 45, 50, 55	HYB65XX	
	Diameter: 7.5 Length (L): 35, 40, 45, 50, 55	HYB75XX	
CarboClear Hybrid Pedicle Screw - Cannulated-Fenestrated	Diameter: 5.0 Length (L): 35, 40, 45	HYBF50XX	
	Diameter: 5.5 Length (L): 35, 40, 45	HYBF55XX	
	Diameter: 6.5 Length (L): 35, 40, 45, 50, 55	HYBF65XX	
	Diameter: 7.5 Length (L): 35, 40, 45, 50, 55	HYBF75XX	
CarboClear Hybrid Set Screw	-	HYB4000	
Straight Rods	Diameter: 6.0 Length (in 5 mm steps): 35-80	PPLOSR60XX	
Curved Rods	Diameter: 6.0 Length (in 5 mm steps): 35-80	PPLOCR60XX	
Straight Rod (Ball Tip, with Tantalum Wire Marker)	Diameter: 6.0 Length: 35-80 (in 5 mm steps)	MRS6XX	
Curved Rod (Ball Tip, with Tantalum Wire Marker)	Diameter: 6.0 Length: 35-80 (in 5 mm steps)	MRC6XX	

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

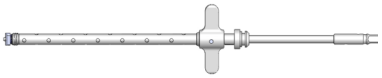
CARBOCLEAR LONG RODS (6.0 MM DIAMETER)	TYPE	LENGTH	CATALOGUE NO.	
"S"-Shaped Rod, R=240/120 mm	Type 1	190 mm	PPLCR6190S	
Curved Rod, R=440 mm	Type 2	280 mm	PLMCR6200 / LMRC6200	
Shaped Rod, R=45/145/310 mm	Type 3	270 mm	PNNSR4270	
Shaped Rod, R=45/200/310 mm	Type 4	285 mm	PNNSR6270	
Straight Rod	Type 5	270 mm	PPLSR6270 / LMRS6270	
Straight Rod (Ti-6Al-4V)		300 mm	PNNER6300	

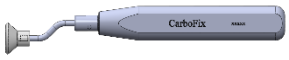
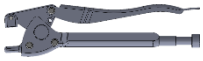
COMPONENT	SIZE (MM)	CATALOGUE NO.*	
CarboClear Trans-Connector Rod	Diameter: 6.0 Length (in 2mm steps): 30 - 70	PPTCR60XX	
CarboClear Iliac Crest Rod	Diameter: 6.0 Length: 100	PPILR6100	
CarboClear Trans-Connector Locking Element & Ring	—	PPTCC4000	

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

CARBOCLEAR HYBRID INSTRUMENTATION SET - CATALOGUE NO. HYB101

DESCRIPTION	CATALOGUE NO.	
Pedicle Awl	PPS922110	
Pedicle Probe - Blunt, Curved	PPS922240	
Pedicle Probe - Pointed, Curved	PPS922390	
Navigated Pedicle Probe – Blunt, Straight	PPS922390N	
Navigated Pedicle Probe - Pointed, Straight	PPS922650N	
Pedicle Feeler	PPS922130	
T-Handle-Torque Limiter	PPS922700	
Straight Handle-Torque Limiter	PPS922702	
Pear Handle	PPS922701	
Navigated Bone Tap - Ø 7.5 mm	PPS922710N	
Navigated Bone Tap - Ø 7.0 mm (Optional)	PPS922720N	
Navigated Bone Tap - Ø 6.5 mm	PPS922730N	
Navigated Bone Tap - Ø 6.0 mm (Optional)	PPS922740N	
Navigated Bone Tap - Ø 5.5 mm	PPS922750N	
Navigated Bone Tap - Ø 5.0 mm	PPS922760N	
Navigated Bone Tap - Ø 4.5 mm (Optional)	PPS922770N	
Rod Holding Forceps	PPS922230	
Pedicle Surface Reamer	HYB019	

DESCRIPTION	CATALOGUE NO.	
CarboClear Hybrid Pedicle Screw Screwdriver	HYB008	
CarboClear Hybrid Pedicle Screw Navigated Screwdriver	HYB001	
CarboClear Hybrid Navigated Screwdriv Adapter	HYB002	
CarboClear Hybrid Tulip Adjuster	HYB003	
CarboClear Hybrid Set Screw Starter Driver	HYB004	
CarboClear Hybrid Locker	HYB005	
CarboClear Hybrid Rod Reducer	HYB006	
CarboClear Hybrid Rod Reducer Handle	HYB007	
Rod Pusher	PPS922440	
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	

DESCRIPTION	CATALOGUE NO.	
Mallet	Q9105110	
Rod End Shaper	PPS922920US	
Distractor/Compressor	PPS922450	
Spreader	PPS922990	
Trans Connector Locker	PPSLTC100	
Trans Connector Unlocker	PPSLTC101	
Trans Connector Wrench	PPSLTC102	

Cutting Container	PPS180218	
Sterilization Box	HYB103	

Guide Wires [Single Use, Provided Sterile]

Description	Catalogue No.	
Guide Wire Ø 1.2 mm	PPS922501	

Cutting Set [Single Use, Provided Sterile] - Catalogue No. PPS925100US

Description	Catalogue No.	
Flexible Ruler	PPS925110	
Saw	PPS925120US	

Extractors [Single Use, Provided Sterile]

Description	Catalogue No.	
Screw Removal (Extractor) - Ø 7.5 mm	PPS922930	
Screw Removal (Extractor) - Ø 6.5 mm	PPS922940	
Screw Removal (Extractor) - Ø 5.5 mm	PPS922950	
Screw Removal (Extractor) - Ø 5.0 mm	PPS922670	

CONTRAINDICATIONS

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.
4. Although not absolutely contraindicated, conditions at the vertebrae intended to be fixated that should 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 life style 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)).
10. Contraindications under Medtronic StealthStation® Navigation System are all applicable to the use of CarboClear Hybrid Navigated Instruments.

WARNINGS AND PRECAUTIONS

GENERAL

1. **Warning**: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
2. **Precaution**: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

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 pedicle screw systems, and should be familiar with the CarboClear Hybrid Pedicle 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 Hybrid Pedicle 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 Hybrid Pedicle Screws should be used exclusively with CarboClear Hybrid Set Screw and with CarboClear Rods and Transverse Connectors, using the CarboClear Hybrid instruments.
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 his/her 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. For insertion of cannulated screw, a guide wire may first be used, followed by a tap. Be careful that the guide wire is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide wire does not advance during tapping or screw insertion. Remove the guide wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.
5. Do not overtap or use a screw that is too long. Overtapping, using an incorrectly sized screw, or accidentally advancing the guide wire during tap or screw insertion, may cause nerve damage, hemorrhage, 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.
8. Do not bend the CFR-PEEK rods. These rods are not suitable for manual contouring due to their inherent material properties. Incorrect manipulation may compromise their integrity and performance intraoperatively and postoperatively.
9. Use the CarboClear Ti-alloy rod when the ideal rod curvature is not available in the CarboClear CFR-PEEK rods. The Ti-alloy rods are compatible with CarboClear hybrid screws and set screw. If intraoperative rod contouring is necessary, use standard rod-cutting and rod-bending surgical tools available in the hospital for Ti-alloy rods.

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. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility.
4. The patient should be advised of its inability to bend at the point of spinal surgery and taught to compensate for this permanent physical restriction in body motion.
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.

6. 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.
7. 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. Implant removal should be followed by adequate postoperative management to avoid fracture.
8. As with all orthopedic implants, none of the CarboClear Hybrid Pedicle 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.
9. **MRI Safety Information** - The CarboClear Hybrid device has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the CarboClear Hybrid device in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

WARNINGS & PRECAUTIONS RELATED TO THE NAVIGATED INSTRUMENTS:

1. The surgeon should be familiar and experienced in preforming spinal surgeries with Medtronic StealthStation® Navigation System.
2. CarboClear Hybrid Navigated Instruments are designed for use only with Medtronic StealthStation® S7 Navigation System hardware and software (v2.1.0).
3. CarboFix is not a navigation provider. The Navigated Instruments have been validated for use with Medtronic StealthStation® Navigation System. Instructions for use and handling of third-party navigation systems are the responsibility of the hospital and navigation company. Refer to the navigation software and user guides for calibration and navigation guidance.
4. The navigation system should be set up per its manufacturer's instructions.
5. Plan the setup of the OR and instrument array orientation prior to surgery. The navigation camera must have an unobstructed and simultaneous view of the instrument and navigation array.
6. Users must complete verification steps as required per the Medtronic Navigation Operative Technique.
7. Registration of CarboClear Hybrid Navigated Screwdriver to Medtronic StealthStaion® System is performed with a dedicated adapter assembled to the driver' distal end, as detailed in the Surgical Technique manual for CarboClear Hybrid Navigated Instruments.
8. The CarboClear Hybrid Navigated Instruments should only be used with the CarboClear Hybrid Pedicle Screw System.
9. The navigated instrument is a highly accurate and sensitive medical device. Handle it with extreme care. If you drop or otherwise damage it, verify its calibration accuracy. Failure to do so may lead to serious injury to the patient.
10. Care should be taken to limit bending forces on calibrated Navigated Instruments as deflection can influence navigation accuracy.
11. Users must ensure that surgical accuracy be assessed before the procedure and repeatedly throughout the procedure, by positioning the tip of each Navigated Instrument on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system. When verifying the accuracy of the Navigated Screwdriver, the accuracy test must include the Screw (of which diameter and length are selected/entered in the software) assembled securely onto the screwdriver. The screw tip will be placed on an identifiable anatomical landmark and compared to the tip location as displayed on the screen.
12. In the event of a registration failure or suspected inaccuracy of the stereotaxic navigation system, the CarboClear Hybrid Navigated Instruments should not be used with the navigation system and the instruments should be inspected for damage before continuing with the traditional, non-navigated procedure.

FURTHER INFORMATION

Important Notes:

- Refer to the system Instructions for Use (TEC 3163) for additional information regarding the CarboClear Hybrid Pedicle Screw System including Possible Adverse Events and Packaging and Sterilization information.
- Refer to CarboClear Hybrid Navigated Instruments Surgical Technique manual (TEC 3174) if CarboClear Hybrid Navigated Instruments are used.
- 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 a physician

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Patents are pending.