SYMPHONY™

OCT System

Surgical Technique

DePuy Synthes

COMPANIES OF Johnson & Johnson

Contents

For MR information, please see Symphony IFU 0902-90-161.

Product Description

Introduction

The DePuy Synthes Spine SYMPHONY™ Occipito-Cervico-Thoracic (OCT) System is an enhanced set of instruments and implants, including polyaxial screws, 3.5 mm and 4.0 mm rods, compatible hooks, cross connectors, lateral offset connectors, and rod connectors designed for posterior stabilization of the upper spine. The implants provide the flexibility required to accommodate variations in patient anatomy.

The DePuy Synthes Spine SYMPHONY OCT System is compatible with occipital fusion components (plates, rods and clamps) from the SYNAPSE™ OCT System and the MOUNTAINEER® OCT Spinal System. Additionally, tapered rods and connectors are available to extend constructs to utilize both the DePuy Synthes Spine EXPEDIUM® and VIPER® Spine Systems.


SYMPHONY™

Preoperative Planning

1

Imaging

It is a prerequisite that, due to the anatomic variability of each patient, the surgeon has available the range of necessary images in order to plan the operation appropriately.

Use of cross sectional imaging (i.e., CT and/or MRI) for posterior cervical screw placement is recommended. The use of planar radiographs (or fluoroscopy) alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

2

Assemble Instruments

The following instruments must be assembled prior to use:

- Drill Guide, page 50
- Polyaxial Screwdriver, page 54
- AO Handles, page 56
- Reducer Kerrison, page 58

3

Patient Positioning

Patient positioning is critical for cervical posterior fusion procedures. Place the patient on the operating table in the prone position with the patient's head securely immobilized. Proper patient position should be confirmed via direct visualization and by radiographs prior to draping.

4

Approach

Expose the posterior bony elements sufficiently to allow placement of instrumentation as well as preferred graft material in and around the decorticated posterior elements.

Step 1

Start Screw Hole

Awl 2.0 mm	2020-00-101

Determine the entry point per screw and pierce the cortex using the Awl 2.0 mm (Fig. 1) or a 2.0 mm high speed burr.

Fig. 1

Drill Guide-Drill Bit Table

Screw Size	Drill Bit	Code	Drill Guide	Code
3.0 mm	Long 2.2 mm Drill for 3.0 mm Screw	2020-00-222	Long Drill Guide Body 2.2-2.4 mm	2020-00-120
3.5 mm	Long 2.4 mm Drill for 3.5 mm Screw	2020-00-224		
4.0 mm	Long 2.8 mm Drill for 4.0 mm Screw	2020-00-228	Long Drill Guide Body 2.8-3.2 mm	2020-00-123
4.5 mm	Long 3.2 mm Drill for 4.5 mm Screw	2020-00-232		

Step 2

Prepare Screw Pathway

Drill

Drill Guide Modular Handle	2020-00-119
Long Drill Guide Body 2.2-2.4 mm	2020-00-120
Long 2.4 mm Drill for 3.5 mm Screws	2020-00-224

a. Select appropriate drill bit corresponding to the screw diameter being used (see above Drill Guide-Drill Bit Table) Each drill bit has a color band corresponding to the shank of the screw.
b. Set the depth of the Drill Guide Assembly by pushing the knob of the Drill Guide Body down and turn clockwise to increase the depth (Fig. 2), each activation represents a 2 mm adjustment. The depth will appear in the window. (Fig. 3) Always confirm depth before drilling.
c. Dock the drill tip in the prepared entry point then lower Drill Guide onto bone for stability. (Fig. 4)
d. Drill hole to desired trajectory and depth, power may be used if desired.

Fig. 2

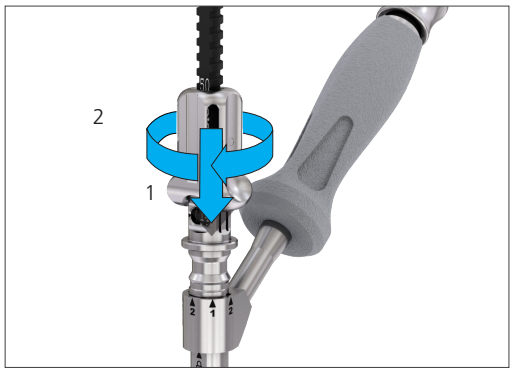
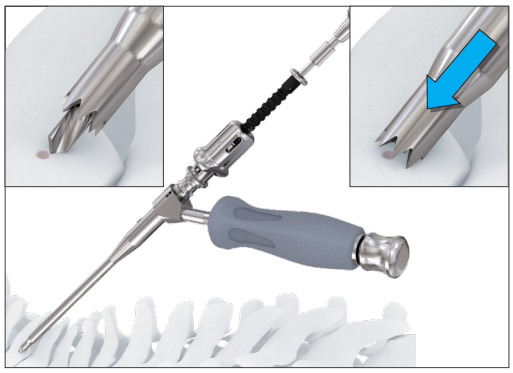


Fig. 3

Fig. 4



Optional Instrument

Trocar 2.4mm with Stop	2020-00-107

Can also be used to create screw pathway

Alternative Technique

Probe

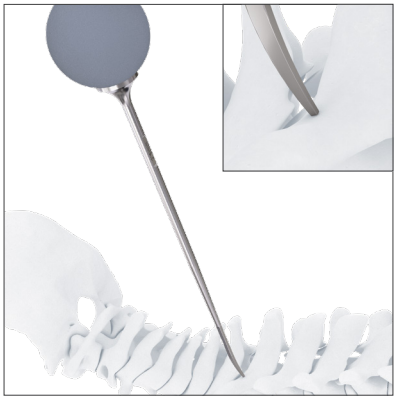
Pedicle Probe 3.2 mm, Straight	2020-00-158
Pedicle Probe 3.2 mm, Curved	2020-00-159
Pedicle Probe 2.2 mm, Straight*	2020-00-102
Pedicle Probe 2.2 mm, Curved*	2020-00-103

Pedicle preparation may be done using either the straight or curved probe. (Fig. 5)

2.2 mm Probes are designed for 3.0 mm, 3.5 mm and 4.0 mm screws

3.2 mm Probes are designed for 4.5 mm screws and above

Fig. 5



Step 3

Confirm Depth and Pathway

Sounding Probe	2025-49
Depth Gauge Sleeve with Ball Tip Probe	2883-03-000
Small Pedicle Marker-Beaded*	389.473
Small Pedicle Marker-Long Beaded*	389.474

Use the Sounding Probe to confirm, by palpation, placement within the bony anatomy.

The Small Pedicle Markers may be used to radiographically confirm position and orientation of screw sites.

Use the Depth Gauge Sleeve with Ball Tip Probe to confirm hole depth and select the corresponding screw length. The depth gauge must sit directly on the bone. (Fig. 6)

Fig. 6

* Instrument does not come standard in Core Instrument Set

Step 4

Tap

All SYMPHONY OCT System Screws have a fully threaded, tapered tip. Taps are provided with an intended interference (see Table 1). The SYMPHONY OCT System Screws have 2 different, anatomically designed thread forms. Each of these thread forms requires a different tap. Cortical Fix thread screws utilize gold colored taps, while standard dual-lead thread screws utilize steel colored taps, as shown in the picture below. Select the correct tap to correspond with the chosen screw as shown below in Table 1.

In cases of hard bone, sequential tapping may be utilized by tapping progressively larger sizes until desired screw size is reached. Care should be taken not to mix differing thread forms, (see Table 1).

Note: **Tapping is required on all screws.**

Fig. 7

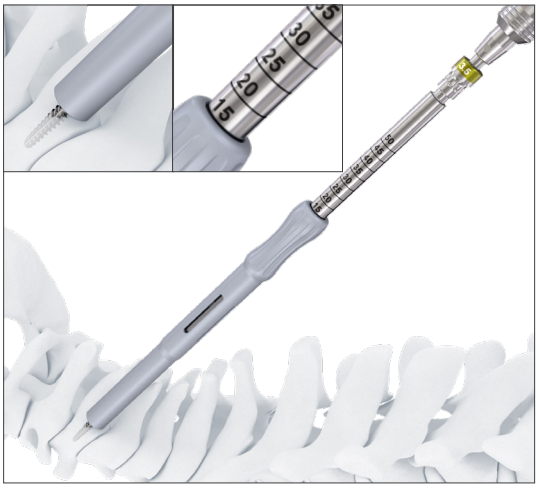


Table 1

Screw /Tap Sizing					Tap Size Interference	
ST Screw Size	Standard Thread	Cortical Fix Thread Taps and Standard Thread Taps are not interchangeable	CFX Screw Size	CFX Thread	Minor Thread Diameter	Major Thread Diameter
3.0 mm	2020-33-330		N/A	N/A	-0.15 mm	-0.13 mm
3.5 mm	2020-33-335		N/A	N/A	-0.15 mm	-0.2 mm
4.0 mm	2020-33-340		N/A	2020-33-540	-0.15 mm	-0.2 mm
4.5 mm	2020-33-345		4.5 mm	2020-33-545	-0.15 mm	-0.2 mm
N/A	N/A		5.0 mm	2020-33-550	-0.15 mm	-0.2 mm
N/A	N/A		5.5 mm	2020-33-555	-0.15 mm	-0.2 mm

The Tap Sleeve may be used as a tissue protector and to indicate tap depth. (Fig. 7)

Precautions:

- **The reported depth of the Tap Sleeve may be more shallow than actual due to interference on bony anatomy and soft tissue. Verfication of actual depth using depth gauge is recommended.**
- **Taps for Standard and CFX threadforms are not interchangeable. Taps are designed to undertap by default (see Table 1).**

Step 5

Insert Screws

Polyaxial Screw Driver Shaft X20	2020-33-400
Polyaxial Screw Driver Retention Sleeve	2020-00-401
Polyaxial Screw Driver Tissue Sleeve	2020-00-410

Always confirm screw length before insertion. (Fig. 8)

Attach screwdriver to polyaxial screw. (Fig. 9)

(1). Ensure that the Retention Sleeve is retracted by pushing down the release mechanism and sliding back.

(2). Insert the tip of the Polyaxial Screw Driver Shaft X20 into the drive feature of the polyaxial screw.

(3). Slide the Polyaxial Screw Driver Retention Sleeve until it comes in contact with the body of the polyaxial screw. Rotate the sleeve clockwise until it bottoms out on the cross pin of the screwdriver shaft.

The polyaxial screw is ready for bone insertion.

Screw can also be loaded from directly inside the caddy.

Remove screwdriver from the polyaxial screw by turning the knob counterclockwise. (Fig. 10, 11)

Precaution: **Polyaxial Screw Driver Tissue Sleeve is optional. If not using, be mindful that not allowing rotation of the retention sleeve during insertion can lead to screw disengagement.**

Fig. 8

Fig. 9

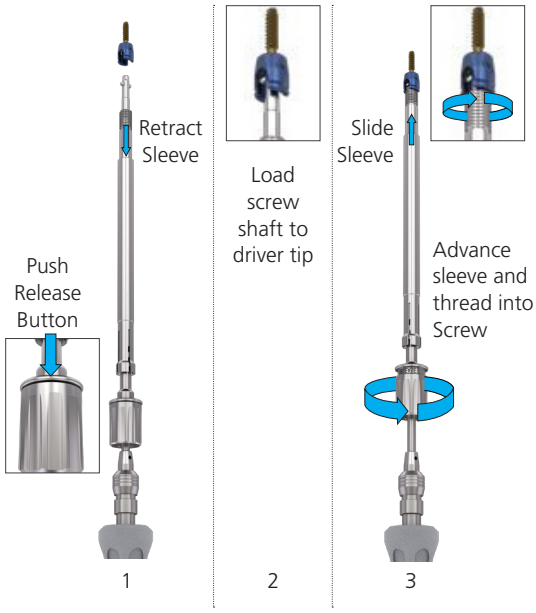
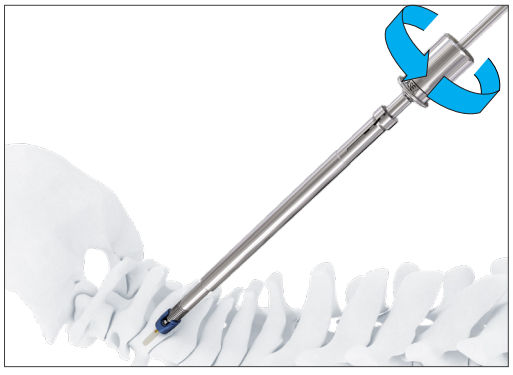


Fig. 10

Fig. 11



Step 6

Align Screw Heads and Perform Adjustments

Screw, Head and Rod Adjuster	2020-00-134

Utilize the Screw, Head and Rod Adjuster to align the screw heads. If the screw is over tightened the head will not rotate. In this situation, utilize the X20 end of the Screw, Head and Rod Adjuster, to back the bone screw out until polyaxial motion is achieved. (Fig. 12)

Fig. 12

Step 7

Template the Rod

Rod Template 240 mm	388.868

If desired, contour the Rod Template 240 mm to fit the anatomy. (Fig. 13)

Fig. 13

Step 8

Contour and Cut the Rod

Rod Cutter for 3.5 and 4.0 mm Rods	2020-00-135
Bending Iron Right	2020-00-146
Bending Iron Left	2020-00-147
French Rod Bender for 3.5 and 4.0 mm Rods	2020-00-145
Rod Introducer	2883-05-007

If necessary, cut and bend the rod to match the template. Pre-cut, Pre-Lordosed rods are also available.

Use the French Rod Bender for 3.5 and 4.0 mm Rods to contour the rod to match the curve of the template. (Fig. 14)

The Bending Irons can also be used as pipe rod benders. Insert the rod into the rear of each bending iron and lock in place by turning the thumbwheels clockwise if desired. (Fig. 15) As the rod is fed into the pipe, it will pass through on the other side. (Fig. 15)

As the bent portion of the rod is fed through into the frame of the benders, it can pass through the clearance cut to allow further bending. (Fig. 16)

Precaution: **Repeated bending of rods may lead to rod fracture.**

Fig. 14

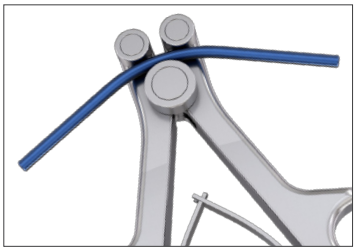


Fig. 15

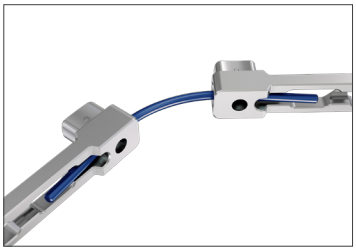


Fig. 16

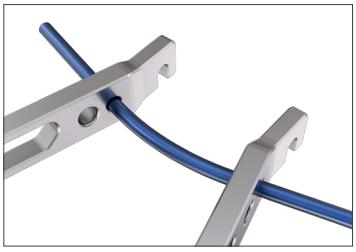
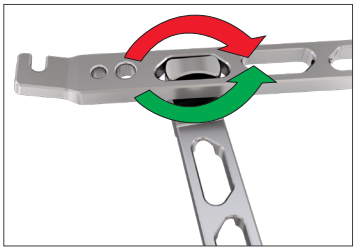


Fig. 17



Utilize open architecture to loosen clamps if stuck. It is not intended for tightening

Straight rods can be bent via the through holes marked for either 3.5 or 4.0 mm rods. (Fig. 18, 20) Bent rods needing adjustment can be cut using the open saw. (Fig. 19)

Precautions:

- **Care should be taken to secure the retained and cut ends during cutting to prevent injury.**
- **Keep fingers away from within the open span of the Rod Cutters during use to avoid injury.**
- **Ensure rod is fully seated in cutting slot with each use to avoid potential user harm.**

Warning: Rod cutters are not intended to be used *in situ* due to the risk of patient injury.

Fig. 18

Fig. 19

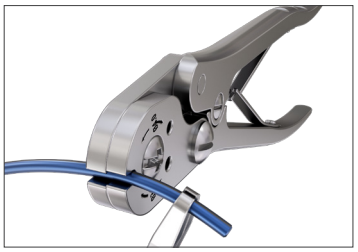
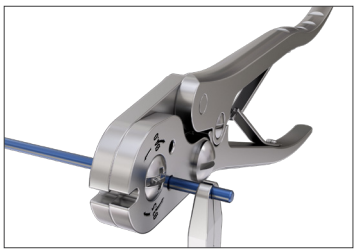


Fig. 20



Step 9

Place the Rod

Rod Introducer	2883-05-700

Insert the rod into the heads of the polyaxial screws using the Rod Introducer. (Fig. 21)

Fig. 21

Step 10

Reduce the Rod

Reducer Kerrison	2020-00-140
Reducer Rocker Fork*	2020-00-139

Use the Reducer Kerrison to reduce the rod into the polyaxial head of the screw. Place the reducer over the rod and onto the polyaxial head until seated. (Fig. 22) Squeeze the handle to engage and reduce the rod into the head of the screw. Set screws can be inserted through the cannula with the X15 Self Retaining Set Screw Inserter which is identifiable via three alignment bosses, two of which are toward the distal tip. (Fig. 23)

Use the Reducer Rocker Fork by placing it onto the top of the rod, with the legs below the screw side notches. Lever the fork in a slow and controlled way until the rod is seated into the polyaxial head. Proceed with set screw insertion. (Fig. 24)

Note: **The Reducer Kerrison helps ensure the rod is fully seated in the saddle before final tightening.**

Precaution: **Care should be taken to avoid using excessive force during rod reduction steps that may undermine bony purchase and result in screw pullout.**

Fig. 22

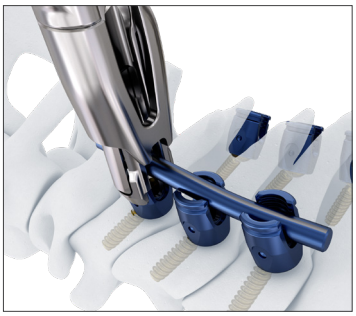
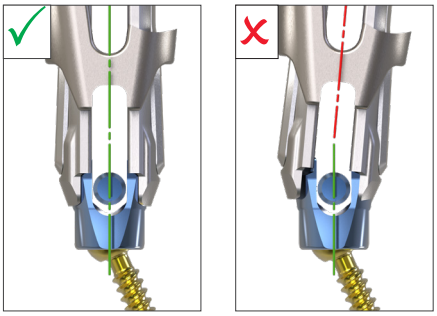


Fig. 22a,b



Aligned Misaligned

Fig. 23

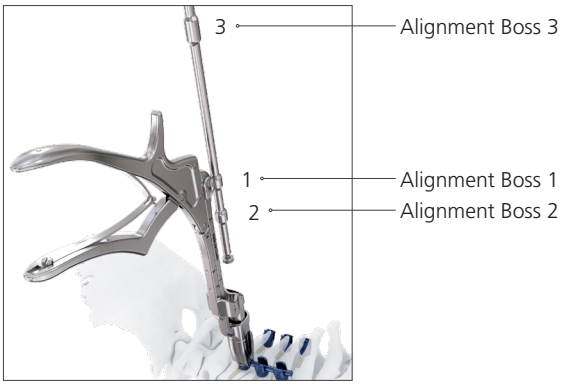
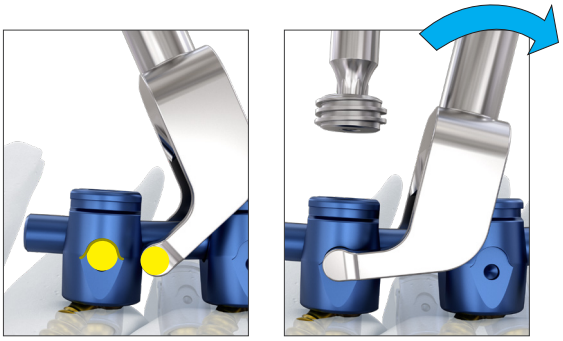


Fig. 24



* Instrument does not come standard in Core Instrument Set

Step 11

Insert Set Screws

X15 Self Retaining Set Screw Inserter	2020-00-407
Dual Sided Set Screw Inserter*	2020-00-402

Insert the set screws using the X15 Self Retaining Set Screw Inserter or the Dual Sided Set Screw Inserter. Set screws can be inserted through either the Counter Torque or the Reducer Kerrison using the X15 Self Retaining Set Screw inserter. (Fig. 25)

Fig. 25

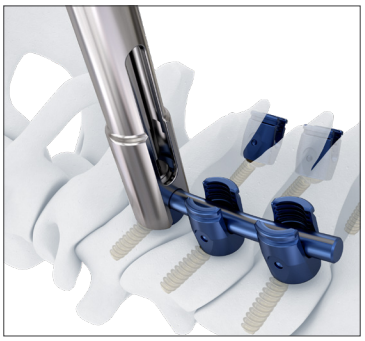
Step 12

Lock the Construct

X15 Driver Final Tightener	2020-00-403
AO Handle, Torque Limiting 3.0 Nm	2020-00-504
Counter Torque	2020-00-138

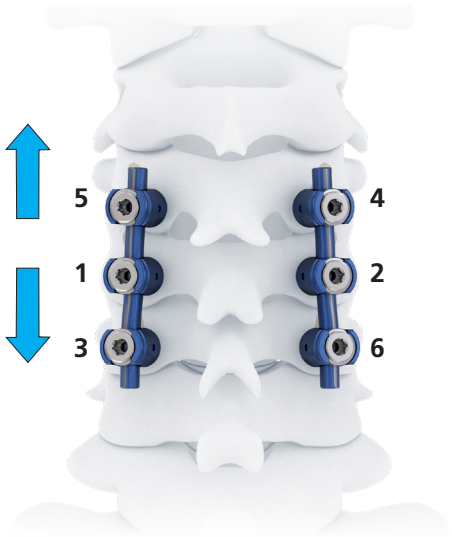
Fully tighten all set screws with the X15 Driver Final Tightener, the Counter Torque, and the AO Handle, Torque Limiting 3.0 Nm. (Fig. 26)

Fig. 26



The construct is now rigidly locked. Final tightening should be attempted only after all locking screws have been placed. Tightening should be revisited to ensure all levels are seated using a middle out tightening pattern, alternating levels & rod locations. Ensure each screw is final tightened. Now the construct is locked.

Recommended Tightening Order



Precautions:

- **The Screw Inserters are not intended for use in final tightening. Damage to Set Screw Driver feature may occur.**
- **Always fully reduce rod in all bone anchors prior to final tightening.**
- **Failure to use provided 3.0Nm torque limiting handle when final tightening may lead to set screw back out.**

* Instrument does not come standard in Core Instrument Set

Place Laminar Hooks

Implant Holding Forceps*	03.614.030

The SYMPHONY OCT System is reverse compatible with the existing SYNAPSE OCT System Hooks.

Attach Implant Holding Forceps to the appropriate hook. Place the hook in the desired location using the X15 Self Retaining Inserter as an aid. (Fig. 27, 28)

Fig. 27

Fig. 28

* Instrument does not come in standard instrument set

Apply Compression or Distraction

Distraction Forceps	03.614.028
Compression Forceps	03.614.029

Compression and distraction can only be achieved if one of the screws receiving the force is unlocked. Use the Compression Forceps to achieve compression (Fig. 29), or the Distraction Forceps to achieve distraction. (Fig. 30)

Fig. 29

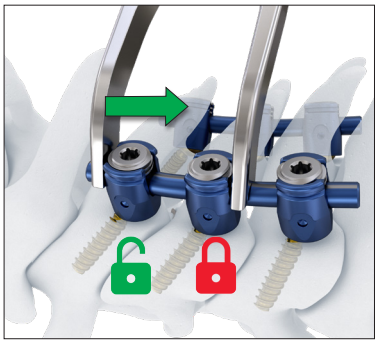
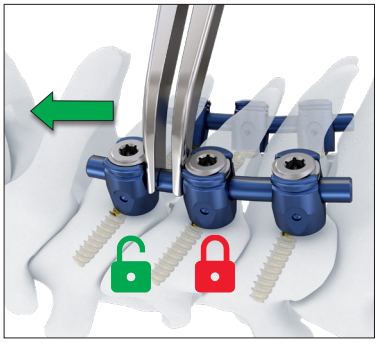


Fig. 30

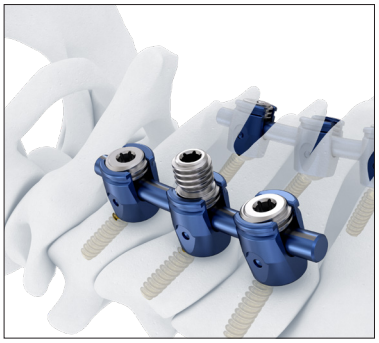


Head to Head Cross Connector

X15 Self Retaining Set Screw Inserter	2020-00-407
X15 Driver Final Tightener	2020-00-403
Rod Template 240 mm	388.868
Cross Connector Bender	2883-07-100
Nut Driver Self Retaining	2020-00-405
AO Handle, Torque Limiting 3.0 Nm	2020-00-504
Counter Torque	2020-00-138

Insert tall set screw through Counter Torque tube using X15 Self Retaining Set Screw Inserter. Final tighten when ready before implanting the H2H Cross Connector using the AO Handle, Torque Limiting 3.0 Nm and Counter Torque. (Fig. 31)

Fig. 31



Warning: **Failure to final tighten before implanting Cross Connector may result in postoperative loosening.**

After final tightening of all screws:

a. Utilize the Rod Template 240 mm to measure the space between the screws and choose an appropriate sized Cross Connector. (Fig. 32)

Fig. 32

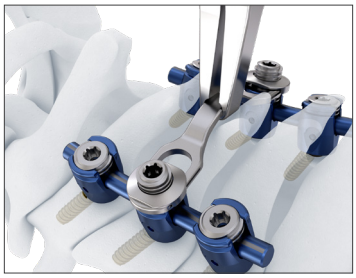
b. Contour as needed, using the Cross Connector Benders provided, ensuring eyelets are able to fully seat on Tall Set Screw. (Fig. 33)

Precaution: **Reverse bending of the plates should not be attempted. Extreme bending over the rod attachment body travel slot will limit the amount of medial/lateral adjustment in the rod attachment body.**

Fig. 33

c. Place Cross Connector onto screw heads so the Tall Set Screw extends through the Cross Connector. (Fig. 34)

Fig. 34



d. Select and load the Locking Nut to the Nut Driver Self Retaining by aligning the driver with the flats of the nut. (Fig. 35)

Fig. 35

e. After all locking nuts have been placed, firmly tighten them with the Nut Driver Self Retaining connected to the AO Handle, Torque Limiting 3.0 Nm. (Fig. 36) Counter torquing is achieved by placing the Counter Torque on the adjacent screw head on the same side of the construct. (Fig. 37)

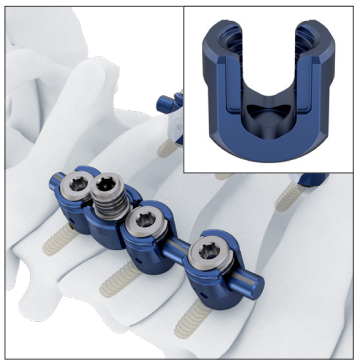
Precaution: **Failure to use provided 3.0 Nm torque limiting handle when final tightening may lead to set screw back out.**

Fig. 36, 37

Head to Head Cross Connectors may also be used where a screw is not present by using the Cross Connector Head Adapter. The set screw must be fully tightened using an adjacent level Counter Torque as shown in Figure 37 prior to implanting any connectors. (Fig. 38)

Warning: **Failure to final tighten before implanting Cross Connector may result in postoperative loosening.**

Fig. 38

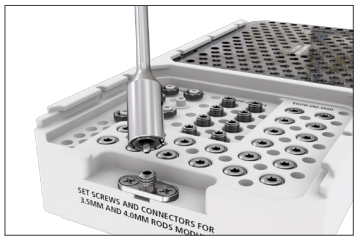


Removal of nut from driver

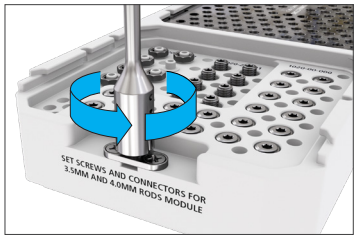
If at any time unloading of the Nut from the Nut Driver Self Retaining is required, utilize the threaded post on Caddy. Engage one or more threads and gently pull. Nut is then removed from post by unthreading in a counterclockwise direction. (Fig. 39a-c)

Fig. 39

a



b



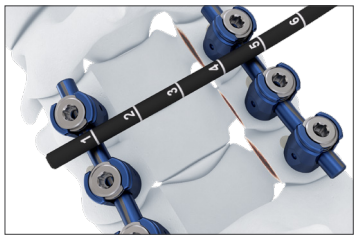
c

Rod to Rod Cross Connector

X15 Self Retaining Set Screw Inserter	2020-00-407
X15 Driver Final Tightener	2020-00-403
Rod Template 240 mm	388.868
AO Handle, Torque Limiting 3.0 Nm	2020-00-504
Rod to Rod Cross Connector Counter Torque	2020-00-163

a. Place the Rod Template between the Screw Heads and measure. Then choose the appropriate size Rod to Rod Cross Connector. (Fig. 40)

Fig. 40



b. The open jaws of the Rod to Rod Cross Connector have a retaining feature and can be placed onto the rod, it may require a gentle push to snap on. (Fig. 41, 42)

Fig. 41

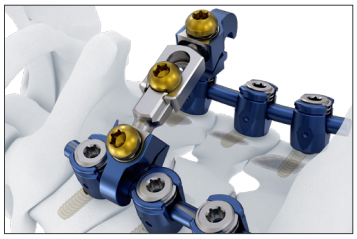
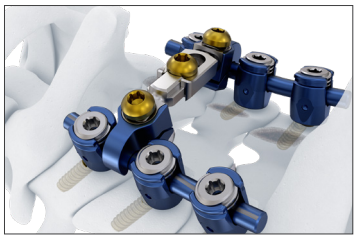


Fig. 42

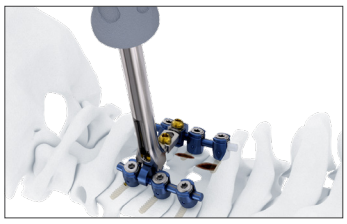


c. Assemble X15 Final Tightener, AO Handle Torque Limiting 3.0 Nm, and Cross Connector Counter Torque. Insert Driver tip into set screw then lower Counter Torque body over Cross Connector. Then, slide the Counter Torque over the head of the set screw. Tighten each end first and then the center using the AO Handle, Torque Limiting 3.0 Nm. (Fig. 43a-c)

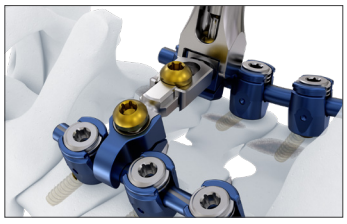
The two smallest sizes of Rod to Rod Cross Connector only have two set screws.

Fig. 43

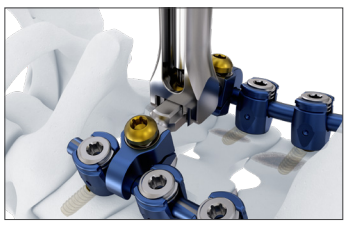
a



b



c



Precautions:

- **Always use Rod to Rod Counter Torque when tightening set screws as it facilitates alignment of the set screw and reduces risk of disengagement.**
- **Failure to use provided 3.0 Nm torque limiting handle when final tightening may lead to set screw back out.**

Lateral Offset Connectors

X15 Self Retaining Set Screw Inserter	2020-00-407
X15 Driver Final Tightener	2020-00-403
AO Handle, Torque Limiting 3.0 Nm	2020-00-504
Counter Torque	2020-00-138

Place the opening of the chosen Lateral Offset Connector on the rod. (Fig. 44) Loosely tighten the connector to the rod. Introduce the bar of the Lateral Offset Connector into the polyaxial head of the screw. Insert the set screw using X15 Inserter into the polyaxial head and lock into place.

Counter torquing is achieved by placing the Counter Torque on the adjacent screw head on the same side of the construct. (Fig. 45)

Tighten the set screw of the polyscrew using the X15 Final Tightener Set Screw Inserter and AO Handle, Torque Limiting 3.0 Nm.

Precaution: **Failure to use provided 3.0 Nm torque limiting handle when final tightening may lead to set screw back out.**

Fig. 44

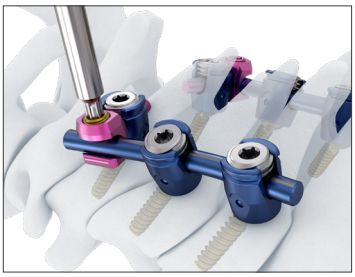


Fig. 45

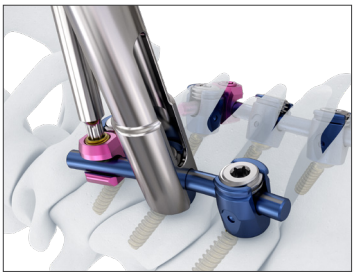


Fig. 46

Parallel Connectors

X15 Self Retaining Set Screw Inserter	2020-00-407
X15 Driver Final Tightener	2020-00-403
AO Handle, Torque Limiting 3.0 Nm	2020-00-504

Parallel connectors allow adjacent coupling of two rods of the same or differing diameters. The self-retaining feature of the X15 Self Retaining Set Screw Inserter can aid with insertion. Either side of the connector may be connected first. Tighten the set screw on one side, then connect the remaining rod and tighten the set screws using the X15 Driver, Final Tightener and the AO Handle, Torque Limiting 3.0 Nm. All set screws are designed to be flush or recessed from the top of the implant when locked. (Fig. 46)

Precaution: **Failure to use provided 3.0 Nm torque limiting handle when final tightening may lead to set screw back out.**

Axial Connectors

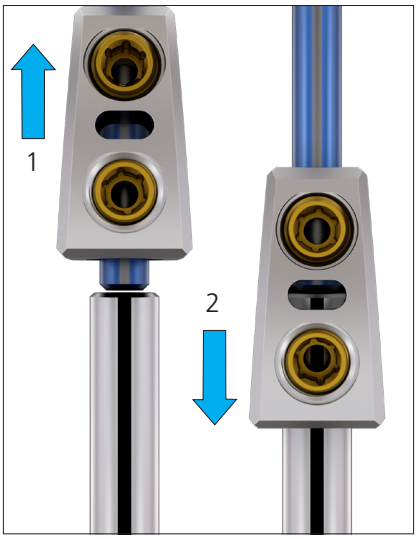
X15 Self Retaining Set Screw Inserter	2020-00-407
X15 Driver Final Tightener	2020-00-403
AO Handle, Torque Limiting 3.0 Nm	2020-00-504
Counter Torque	2020-00-138

Insert contoured rods into axial connector and final tighten using the AO Handle, Torque Limiting 3.0 Nm. This can be done prior to rod insertion in connectors or in vivo using the following technique:

1. Insert Axial Connector onto smaller rod first.
2. Slide Axial Connector onto second rod until both rod ends are visible in window. (per Fig. 47)
3. Tighten Axial Connector using the AO Handle, Torque Limiting 3.0 Nm and apply Counter Torque by placing the Counter Torque over the rod closest to each set screw during final tightening.

Precaution: **Failure to use provided 3.0 Nm torque limiting handle when final tightening may lead to set screw back out.**

Fig. 47



Cable Connector

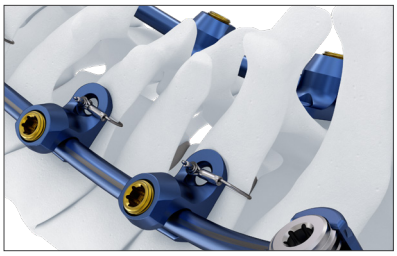
X15 Self Retaining Set Screw Inserter	2020-00-407
X15 Driver Final Tightener	2020-00-403
AO Handle, Torque Limiting 3.0 Nm	2020-00-504

Cable Connector can be added to rod using X15 Self Retaining Set Screw Inserter.

Cabling technique is detailed in the DePuy Synthes Spine Songer Cable Technique Guide. (Fig. 48)

Precaution: Failure to use provided 3.0 Nm torque limiting handle when final tightening may lead to set screw back out.

Fig. 48



Implant Removal Instructions:

If the decision is made to remove implants the following steps should be taken after the implant is exposed.

For set screw and rod, clean debris from set screw and lower the Counter Torque over the screw head. Insert the X15 into the Counter Torque and engage the set screw. Turn handle counterclockwise to loosen the set screws. Once the set screws are removed the rods can then be removed.

All SYMPHONY OCT System Bone Screws can be removed with an X20 screwdriver. Once the rods are removed, align the polyaxial head to allow access to drive feature and engage the X20. Turn counterclockwise to remove the screw.

All other implants are removed using an X15 screwdriver.

Certain connectors require the use of the Nut Driver for removal.

Compatibility

The SYMPHONY OCT System has been designed to be compatible with specific DePuy Synthes Spine Occipital Cervical Fusion Systems as well as specific Thoracolumbar Systems.

SYMPHONY OCT System Compatibility Chart	Compatible		Not Compatible
DePuy Synthes Spine Cervico-Thoracic Screw-Rod Systems			
SYNAPSE OCT System Instruments	Compatible with specific instruments. See p. 25		
SYNAPSE OCT System Rod and Hook Implants	X		
SYNAPSE OCT System Screw Implants			X
MOUNTAINEER OCT System Instruments			X
MOUNTAINEER OCT System Screw and Rod Implants			X
AXON™ Pedicle Screw System Instruments and Implants			X
SUMMIT® SI OCT Spinal Fixation System Instruments and Implants			X
DePuy Synthes Spine OC Fusion Systems			
SYNAPSE OCT System - OC Fusion Instruments and Implants	Except for Top Loading Occipital Fusion Connectors		
MOUNTAINEER OCT System - OC Fusion Instruments and Implants	X		
DePuy Synthes Spine Posterior Thoracolumbar Screw and Rod Systems			
EXPEDIUM® 5.5 Spine System	X	Via the use of Transition Rods and Connectors	
EXPEDIUM 6.35 Spine System	X		
EXPEDIUM 4.5 Spine System	X		
EXPEDIUM VERSE® System	X		
VIPER® 2 System	X		
VIPER® Cortical Fix Fenestrated Screw System	X		
VIPER PRIME™ System	X		
MATRIX Spine System	X		
USS™ Spinal System	X		

SYNAPSE OCT System Compatibility

The SYMPHONY OCT System has been designed to be compatible with specific SYNAPSE OCT System Instruments.

The following instruments are compatible to be used with SYMPHONY OCT System Implants. These instruments are provided as part of the SYNAPSE OCT System and are designed for storage within the SYNAPSE-to-SYMPHONY Upgrade Set. For usage instructions please refer to the SYNAPSE OCT System Surgical Technique.

SYNAPSE OCT System Code	Description	Step	Notes
388.397	Awl	Start screw hole	
388.394	2.4 mm Drill Bit/QC with 65 mm Stop	Prepare screw pathway	
2020-00-155	2.8 mm Drill for Synapse Upgrade	Prepare screw pathway	
03.614.010	3.2 mm Drill Bit with 65 mm Stop QC	Prepare screw pathway	
388.393	Drill Guide with Graduation for 2.4 mm Drill Bit	Prepare screw pathway	
03.614.011	Drill Guide with Graduation for 3.2 mm Drill Bit	Prepare screw pathway	
03.614.012	Pedicle Probe 2.4 mm	Prepare screw pathway	For inserting screws 4.5, 5.0, 5.5, 3.2 mm probes should be used
03.614.013	Curved Pedicle Probe 2.4 mm	Prepare screw pathway	For inserting screws 4.5, 5.0, 5.5, 3.2 mm probes should be used
03.161.028	Depth Gauge	Confirm depth and pathway	
388.549	Straight Ball Tip Probe-Small	Confirm depth and pathway	
03.614.036	Slip Sleeve for Threaded Holding Sleeve	Insert screws	
03.614.017	Threaded Holding Sleeve for Polyaxial Screws	Insert screws	
03.614.034	Alignment Tool	Align screw heads and perform adjustments	
03.614.022	Rod/Plate Bender	Contour and cut the rod	
03.614.024	Bending Iron-Left	Contour and cut the rod	
03.614.025	Bending Iron-Right	Contour and cut the rod	
03.614.021	Rod Cutter	Contour and cut the rod	SYNAPSE Rod Cutter not designed to cut Cobalt Chrome Rod
03.615.011*	Table Top Rod Cutter	Contour and cut the rod	
388.407	Holding Forceps	Place the rod	
03.614.027	Persuader	Reduce the rod	
324.107	Quick Coupling Handle with Swivel Cap	Various	
03.688.505*	Ratchet Handle with Sports Grip	Various	
03.614.041*	Ratchet Handle with T-Handle	Various	

* Not housed in the Synapse-to-Symphony Upgrade Set

Not Compatible

The following instruments from the SYNAPSE OCT System are NOT COMPATIBLE with the SYMPHONY OCT System:

SYNAPSE OCT System Code	Description	Product Type
03.614.026	Counter Torque for 3.5 mm Rods	Counter Torque
03.615.010	Counter Torque for 4.0 mm Rods	Counter Torque
03.615.016	Rocker Fork for 4.0 mm Rods	Reducer
03.615.009	Persuader for 4.0 mm Rods	Reducer
03.614.052	Undersized tap for 3.5 mm Cancellous Screws	Tap
03.614.053	Undersized tap for 4.5 mm Cancellous Screws	Tap
03.614.045	Short tap for 3.5 mm Cancellous Bone Screws with Sharp Tip	Tap
03.614.046	Short Tap for 4.5 mm Cancellous Bone Screws with Sharp Tip	Tap
311.349	Tap for 3.5 mm Cancellous Bone Screws	Tap
389.477	Tap for 3.5 mm Cortex Screws	Tap
03.614.035	2 Nm Torque Limiting Handle, with Quick Coupling	Torque Limiting Handle
03.614.018	Cross Pinned Star Drive Screw Driver Shaft, T15, Self-retaining, Quick Coupling	Bone Screw Driver
03.614.039	Cross Pinned Hexagonal Screw Driver Shaft, Quick Coupling	Bone Screw Driver
03.614.019	Star Drive Screw Driver Shaft, T15, Self-Retaining, Quick Coupling	Set Screw Driver
03.614.050	Dual Sided Locking Cap Inserter	Set Screw Driver
03.614.048	T15 Shaft for Torque Limiting Nut Driver	Set Screw Driver

Occipital Cervical Fusion

SYNAPSE OCT System

The DePuy Synthes Spine SYMPHONY OCT System is compatible with additionally available implants and instruments that are intended to provide immobilization and stabilization as an adjunct to fusion of the occipitocervical junction. The OC Fusion System includes a complete set of implants and instruments designed to optimize fixation to the occiput and connect with DePuy Synthes Spine Cervical and Thoracic Systems.

Features

The OC Fusion System offers the surgeon several implant options for the occiput. The instrumentation is designed to accommodate mid-line exposures and varying patient anatomy.

Preoperative Planning

1

Imaging

All necessary imaging studies should be available to plan occipital screw placement and accommodate anatomic variations in individual patient anatomy.

2

Position Patient

Patient positioning is critical for occipitocervical fusion procedures. The patient should be placed on the operating table in the prone position with the patient's head securely immobilized. Confirm proper patient position by direct visualization and reconciliation with radiographs before draping.

3

Approach

Make a standard midline incision from the external occipital protuberance and continue caudally, and then expose the posterior bony elements sufficiently to allow placement of instrumentation as well as preferred graft material in and around the decorticated posterior elements.

Step 1

Attach Bone Anchors

Attach bone anchors to the cervical and/or thoracic spine as described in the DePuy Synthes Spine SYMPHONY OCT System as needed.

Step 2

Select Occipital Plate

03.161.0xx	Template, for Occipital Plate
387.689	Plate Holder

Select a template of the plate style and size estimated to best fit the occiput. Contour the template to fit the anatomy. (Fig. 49)

Fig. 49

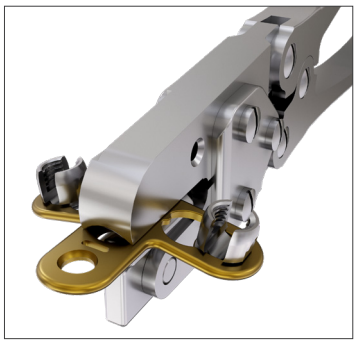
Step 3

Contour Plate

03.161.042	Plate Bender

Use the Plate Bender to contour the plate to fit the anatomy. Use the template as a guide. The Plate Bender can be used across any section of the plate, including the area lateral to the rod attachment bodies. (Fig. 50)

Fig. 50



Precaution: **Reverse bending of the plates should not be attempted. Bending over the rod attachment body travel slot may limit the amount of medial/lateral adjustment in the rod attachment body.**

Alternative Instrument

391.88	Locking Pliers

Locking Pliers can be also used to create bends. (Fig. 51)

Fig. 51

Precaution: **Reverse bending of the plates should not be attempted. Extreme bending over the rod attachment body travel slot will limit the amount of medial/lateral adjustment in the rod attachment body.**

Step 4

Set Drill Guide Depth

03.161.023	Adjustable Drill Guide

Set the Adjustable Drill Guide to the desired depth. Slide back the latch to release the inner tube. Align the indicator of the inner tube with the appropriate depth calibration on the outer tube. Release the latch to lock the Adjustable Drill Guide at the desired depth. (Fig. 52)

Fig. 52

Step 5

Drill

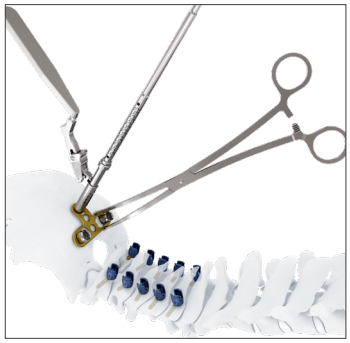
03.161.023	Adjustable Drill Guide
03.161.024	3.2 mm Drill Bit
387.689	Plate Holder

Drill hole along the desired trajectory to the required depth, using the 3.2 mm Drill Bit through the Adjustable Drill Guide. Drilling must occur through the occipital plate to ensure proper drilling depth. (Fig. 53, 54)

Warning: Do not actuate latch when drilling. This could disengage the lock and result in uncontrolled depth and resulting in patient harm.

Fig. 53

Fig. 54



Alternative Instrument

03.161.105*	3.2 mm Drill Bit with Flexible Shaft

Step 6

Measure

03.161.028	Depth Gauge

Use the Depth Gauge to confirm hole depth and select the corresponding screw length. The Depth Gauge reading and the screw length indicate actual bone purchase. The Depth Gauge must sit directly on the bone. (Fig. 55)

Fig. 55

* Instrument does not come standard in OC Fusion Set

Step 7

Tap

03.161.023	Adjustable Drill Guide
03.161.026	Tap for 4.5 mm Occipital Screws

Tap through the Adjustable Drill Guide and occipital plate, to ensure proper tapping depth. (Fig. 56)

Note: **Tapping is required for all screws.**

Warning: **Do not actuate latch when tapping. This could disengage the lock, and result in uncontrolled depth and resulting in patient harm.**

Fig. 56

Alternative Technique

03.161.023	Adjustable Drill Guide
03.161.027	Universal Joint Tap for 4.5 mm Occipital Screws

Set the tap depth by turning the tap sleeve to the desired depth. Lock the tap sleeve by turning down the locking nut to contact the tap sleeve. Finger tighten the locking nut. Use the Holding Forceps to provide axial force and stability. Tapping must occur through the occipital plate to ensure proper tapping depth. (Fig. 57)

Warning: **Do not touch the latch when tapping. Touching the latch could disengage the lock resulting in uncontrolled depth and potential harm to the patient.**

Fig. 57

Step 8

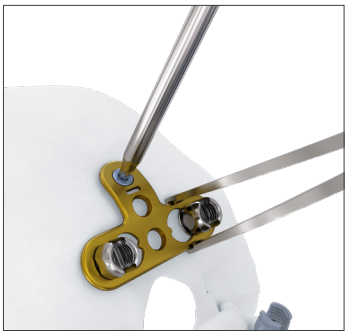
Insert Screw

388.392	Stardrive, Locking Screwdriver Shaft, T15

Insert the selected 4.5 mm occipital screw and tighten using the Stardrive, Locking Screwdriver Shaft, T15. (Fig. 58)

Precaution: **A 5.0 mm screw is available if the primary screw has unsatisfactory fixation.**

Fig. 58

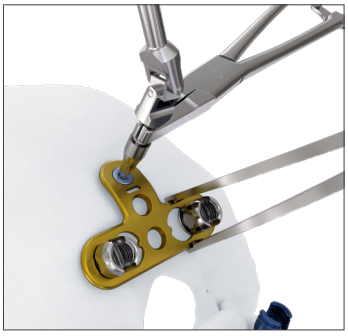


Alternative Technique

03.161.031	Universal Joint Screwdriver, T15
388.407	Holding Forceps

Use the universal joint screwdriver to insert the selected screw. Use the Holding Forceps to provide axial force and stability. (Fig. 59)

Fig. 59

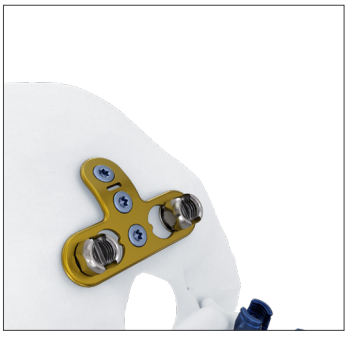


Step 9

Insert Additional Screws

Insert remaining screws, per steps 4–8. (Fig. 60)

Fig. 60



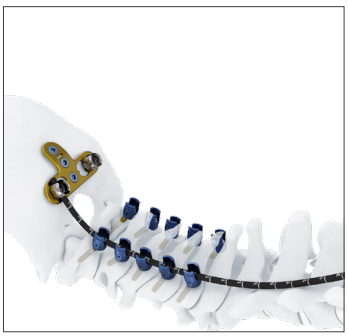
Step 10

Contour Rod Template

388.868	Rod Template, 240 mm

Contour the Rod Template, 240 mm to fit the anatomy and to seat fully in the cervical and upper thoracic bone anchors. Create the occipitocervical bend and ensure sufficient rod length to connect with the occipital plate. (Fig. 61)

Fig. 61



Step 11

Bend and Cut Rod

French Rod Bender for 3.5 and 4.0 mm Rods	2020-00-145
Rod Cutter for 3.5 and 4.0 mm Rods	2020-00-135

Use the Rod Cutter to cut the rod to the appropriate length. Contour the 3.5 mm or 4.0 mm rod to match the template. (Fig. 62)

Fig. 62

Precautions:

- **Care should be taken to secure the retained and cut ends during cutting to prevent injury.**
- **Repeated bending may weaken the rod and lead to rod fracture.**
- **Keep fingers away from within the open span of the Rod Cutters during use to avoid injury.**
- **Ensure rod is fully seated in cutting slot with each use to avoid potential user harm.**

Warning: Rod cutters are not intended to be used *in situ* due to the risk of patient injury.

Step 12

Attach Rods

03.161.041	Positioning Tool
03.615.007	Positioning Tool, for 4.0mm Rods
388.392	Stardrive, Locking Screwdriver Shaft, T15

Insert rods into the rod attachment body. Ensure that the rods extend slightly past the end of the plate. Use the locking screwdriver shaft to insert the titanium locking screw. Use the Positioning Tool to facilitate rod placement and locking screw insertion. (Fig. 63)

Alternatively, the Universal Joint Screwdriver and Holding Forceps may also be used to insert the titanium locking screw. (Fig. 64)

Fig. 63

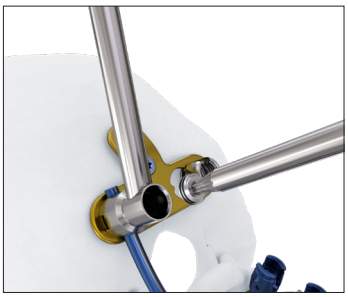
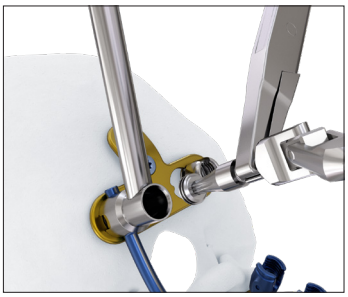


Fig. 64

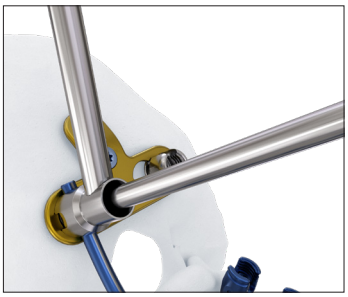


Final Tightening

388.392	Stardrive, Locking Screwdriver Shaft, T15

Use the Stardrive, Locking Screwdriver Shaft, T15 for final tightening of all occipital screws and locking screws. (Fig. 65)

Fig. 65



Note:

Ensure the correct set screw is used to match the correct Occipital Plate.

- **OC Fusion Plate (Gold) for 4.0 mm Rod takes: 04.614.508**

04.614.508

- **OC Fusion Plate (Green) for 3.5 mm Rod takes: 406.104**

406.104

Occipital Clamps

Step 1

Attach Bone Anchors

Attach bone anchors to the cervical and thoracic spine as described in the DePuy Synthes Spine SYMPHONY OCT System.

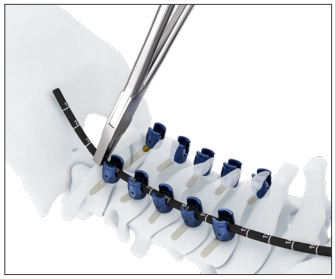
Step 2

Contour Rod Template

388.868	Rod Template, 240 mm

Contour the Rod Template to fit the anatomy and to seat fully in the cervical and upper thoracic bone anchors. Create the occipitocervical bend and ensure sufficient rod length to connect with the occipital clamp. (Fig. 66)

Fig. 66



Step 3

Cut and Bend Rod

Rod Cutter for 3.5 and 4.0 mm Rods	2020-00-135
French Rod Bender for 3.5 and 4.0 mm Rods	2020-00-145

Use the Rod Cutter to cut the rod to the appropriate length. Contour the 3.5 mm or 4.0 mm rod to match the template. (Fig. 67)

Fig. 67

Precautions:

- **Care should be taken to secure the retained and cut ends during cutting to prevent injury.**
- **Repeated bending may weaken the rod and lead to rod fracture.**
- **Keep fingers away from within the open span of the Rod Cutters during use to avoid injury.**
- **Ensure rod is fully seated in cutting slot with each use to avoid potential user harm.**

Warning: Rod cutters are not intended to be used *in situ* due to the risk of patient injury.

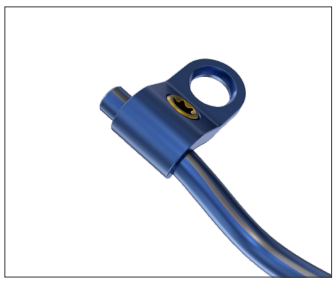
Step 4

Place First Clamp on Rod

388.392	Stardrive, Locking Screwdriver Shaft, T15

Place the occipital clamp on the titanium rod and tighten the set screw in the clamp to engage the rod, thus facilitating placement. Do not firmly tighten as it must be able to be positioned on bone. (Fig. 68)

Fig. 68



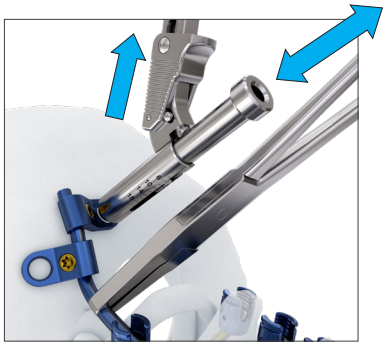
Step 5

Set Drill Guide Depth

03.161.023	Adjustable Drill Guide

Set the Adjustable Drill Guide to the desired depth. Slide the latch to release the inner tube. Align the indicator of the inner tube to the desired depth on the outer tube. Release the latch to lock. (Fig. 69)

Fig. 69



Adjustment Image

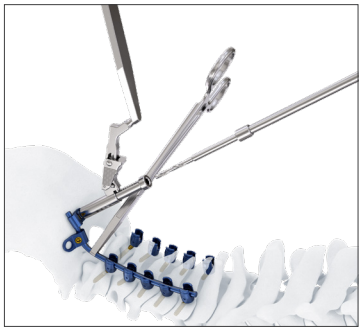
Step 6

Drill

03.161.023	Adjustable Drill Guide
03.161.024	3.2 mm Drill Bit
388.407	Holding Forceps
03.161.105	3.2 mm Drill Bit with Flexible Shaft

To hold the rod in position use the Holding Forceps. Drill to the desired trajectory and depth using the 3.2 mm Drill Bit through the Adjustable Drill Guide. Drill to the stop. Drilling must occur through the occipital plate to ensure proper drilling depth. (Fig. 70)

Fig. 70



Drilling Image

Warning: Do not touch the latch when drilling. Touching the latch could disengage the lock, resulting in uncontrolled depth and potential harm to the patient.

Alternatively, the 3.2 mm Drill Bit with Flexible Shaft may be used for drilling.

Step 7

Measure

3.161.028	Depth Gauge

Use the depth gauge to confirm hole depth and screw selection. The Depth Gauge must sit directly on the bone. (Fig. 71)

Fig. 71

Step 8

Tap

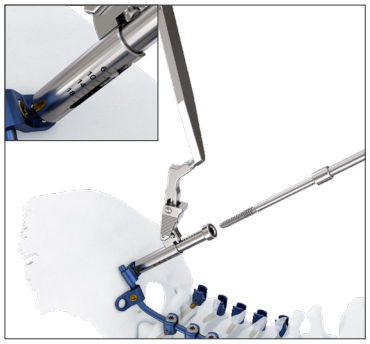
03.161.023	Adjustable Drill Guide
03.161.026	Tap for 4.5 mm Occipital Screws

To ensure proper tapping depth, tap through the Adjustable Drill Guide and occipital plate. (Fig. 72)

Note: **Tapping is required for all screws.**

Warning: **Do not actuate latch when tapping or drilling. This could disengage the lock, and result in uncontrolled depth and resulting in patient harm.**

Fig. 72



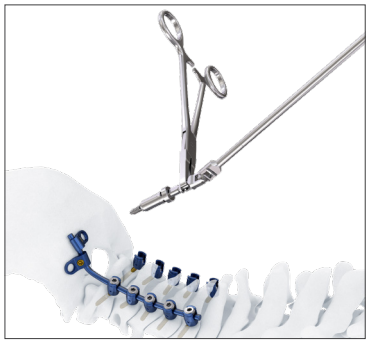
Alternative Technique

03.161.027	Universal Joint Tap for 4.5 mm Occipital Screws
388.407	Holding Forceps

Tapping must occur through the occipital plate to ensure proper tapping depth. Set the desired tap depth by turning the tap sleeve. Lock the tap sleeve by turning the locking nut until finger tight. Use the Holding Forceps to provide stability. (Fig. 73)

Warning: **Do not actuate latch when tapping. This could disengage the lock, and result in uncontrolled depth and resulting in patient harm.**

Fig. 73



Step 9

Insert Screw

388.392	Stardrive, Locking Screwdriver Shaft, T15

Insert the selected 4.5 mm occipital screw and tighten. (Fig. 74)

Note: **A 5.0 mm screw is available if the primary screw has unsatisfactory fixation.**

Alternative Technique

03.161.031	Universal Joint Screwdriver, T15
388.407	Holding Forceps

Use the Universal Joint Screwdriver, T15 to insert the selected screw. Use the Holding Forceps to provide axial force and stability. (Fig. 75)

Step 10

Insert Additional Screws and Clamps

Insert remaining screws and clamps as in steps 4-9. A minimum of 2 clamps per rod is required. (Fig. 76)

Precaution: **A minimum of 2 clamps per rod is required.**

Step 11

Final Tightening

388.392	Stardrive, Locking Screwdriver Shaft, T15

Use the locking screwdriver shaft for final tightening of all occipital screws and clamp set screws. (Fig. 77)

The Universal Joint Screwdriver, T15 and Holding Forceps may also be used for final tightening.

Precaution: **Always use Counter Torque using adjacent level method to avoid transmission of tightening forces to patient. Failure to do so could result in loss of correction.**

Fig. 74

Fig. 75

Fig. 76

Fig. 77

Occipital Plate Rod

Step 1

Attach Bone Anchors

Attach bone anchors to the cervical and thoracic spine as described in the DePuy Synthes Spine SYMPHONY OCT System.

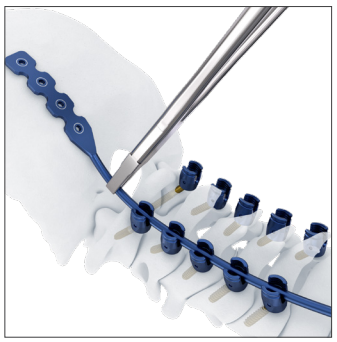
Step 2

Contour Rod Template

03.161.003	Template for Occipital Plate/Rod

Contour the Template for Occipital Plate/Rod to fit the anatomy and to seat fully in the cervical and upper thoracic bone anchors. (Fig. 78)

Fig. 78



Step 3

Cut and Bend Rod

2020-00-135	Rod Cutter for 3.5 and 4.0 mm Rods
2020-00-145	French Rod Bender for 3.5 and 4.0 mm Rods

Contour the 3.5 mm or 4.0 mm rod to match the template. Use the Rod Cutter to cut the rod to the appropriate length.

Precautions:

- **Care should be taken to secure the retained and cut ends during cutting to prevent injury.**
- **Keep fingers away from within the open span of the Rod Cutters during use to avoid injury**
- **Ensure rod is fully seated in cutting slot with each use to avoid potential user harm**
- **Repeated bending may weaken the rod and lead to rod fracture.**

Warning: Rod cutters are not intended to be used in situ due to the risk of patient injury.

Step 4

Set Drill Guide Depth

03.161.023	Adjustable Drill Guide

Set the Adjustable Drill Guide to the desired depth by sliding back the latch to release the inner tube. Align the indicator of the inner tube with the appropriate depth marking on the outer tube. Release the latch to lock the drill guide.

Step 5

Drill

03.161.023	Adjustable Drill Guide
03.161.024	3.2 mm Drill Bit
388.407	Holding Forceps
03.161.105	3.2 mm Drill Bit with Flexible Shaft

Drill hole along the desired trajectory to the required depth, using the 3.2 mm Drill Bit through the Adjustable Drill Guide. Drilling must occur through the occipital plate to ensure proper drilling depth. (Fig. 79)

Warning: Do not actuate latch when drilling. This could disengage the lock, and result in uncontrolled depth and resulting in patient harm.

Alternatively, the 3.2 mm Drill Bit with Flexible Shaft may be used for drilling.

Fig. 79

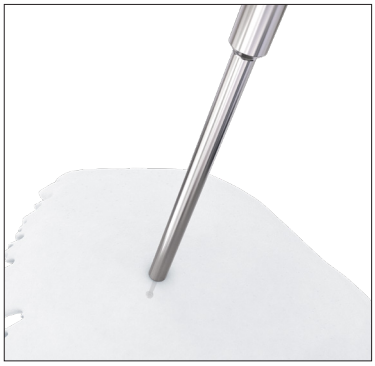
Step 6

Measure

03.161.028	Depth Gauge

Use the Depth Gauge to confirm hole depth and screw selection. The Depth Gauge must sit directly on the bone. (Fig. 80)

Fig. 80



Step 7

Tap

03.161.023	Adjustable Drill Guide
03.161.026	Tap for 4.5 mm Occipital Screws

To ensure proper tapping depth, tap through the Adjustable Drill Guide and occipital plate. (Fig. 81)

Precaution: **Tapping is required for all screws.**

Warning: **Do not actuate latch when tapping. This could disengage the lock, and result in uncontrolled depth and resulting in patient harm.**

Fig. 81

Alternative Technique

03.161.027	Universal Joint Tap for 4.5 mm Occipital Screws
388.407	Holding Forceps

Tapping must occur through the occipital plate to ensure proper tapping depth. Set the desired tap depth by turning the tap sleeve. Lock the tap sleeve by turning the locking nut until finger tight. Use the Holding Forceps to provide stability. (Fig. 82)

Warning: **Do not actuate latch when tapping. This could disengage the lock, and result in uncontrolled depth and resulting in patient harm.**

Fig. 82

Step 8

Insert Screw

388.392	Stardrive, Locking Screwdriver Shaft, T15

Insert the selected 4.5 mm occipital screw and tighten. (Fig. 83)

Note: **A 5.0 mm screw is available if the primary screw has unsatisfactory fixation.**

Fig. 83

Alternative Technique

03.161.031	Universal Joint Screwdriver, T15
388.407	Holding Forceps

Use the Universal Joint Screwdriver, T15 to insert the selected screw. Use the Holding Forceps to provide axial force and stability. (Fig. 84)

Fig. 84

Step 9

Insert Additional Screws

Insert remaining screws as previously described in steps 4–8. A minimum of 3 screws per Plate/Rod is required. (Fig. 85, 86)

Fig. 85

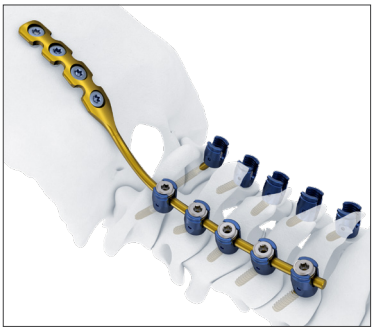
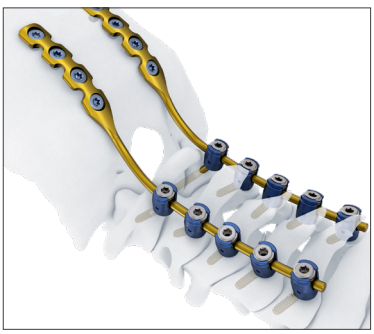


Fig. 86



MOUNTAINEER OCT Spinal System
Fusion Technique

The MOUNTAINEER OC Fusion Set is offered as a stand alone add-on to the SYMPHONY OCT System.

The MOUNTAINEER OCT Spinal System offers an OC Plate for occipital fixation. The OC Plate is available in three sizes (Small – 31 mm, Medium – 37 mm, and Large – 45 mm) maximizing versatility in the medial-lateral position of the rods. Each OC Plate size has three midline holes for occipital fixation and two lateral arms with sliding and rotating connection points for the rods.

The Large OC Plate (45 mm) offers two lateral holes for additional fixation. (Fig. 87)

Fig. 87

Step 1

Attach Bone Anchors

Attach bone anchors to the cervical and thoracic spine as described in the DePuy Synthes Spine SYMPHONY OCT System and SYNAPSE OCT System Technique Guides.

Step 2

Select Occipital Plate

Optimal OC Plate size is determined by measuring the distance between the two longitudinal rods at the occiput.

Distance Between Rods (mm)

	Small	Medium	Large
OC Plate	31 mm	37 mm	45 mm
	(+/- 4 mm)	(+/- 4 mm)	(+/- 4 mm)

Step 3

Plate Placement

2865-06-000	OC Plate Holder

Identify the external occipital protuberance (EOP) and the posterior border of the foramen magnum. Utilizing the OC Plate Holder, grasp the OC Plate and position it in the midline between the EOP and the foramen magnum. (Fig. 88)

The OC Plate can be oriented with the single limb of the implant cephalad in the midline and below the EOP or with the V portion of the implant cephalad in the midline and below the EOP (Fig. 89, 90). The two limbs of the OC Plate can be placed above the foramen magnum allowing for a generous bone graft caudal to the implant.

Note: **The OC Plate can be fixed to the occiput first or to the rods then fixed to the occiput.**

Step 4

Contour OC Plate

2883-13-000	OC Plate Bender

The OC Plate should lay smoothly against the occiput. It may be necessary to smooth irregular bony protuberances slightly to optimize the bone to OC Plate interface, but avoid removing significant portions of cortical bone especially in the vicinity of planned screw holes.

To contour the OC Plate, place it securely in the bender and gently bend to desired radius. The contouring should be performed only in the bend zones to avoid damage to the sliding connectors. The OC Plate can be bent to a maximum of 15° in either direction. (Fig. 91, 92, 93)

The top tab of the OC plate may also be contoured as shown.

Precaution: **Reverse bending of the plates should not be attempted. Extreme bending over the rod attachment body travel slot will limit the amount of medial/lateral adjustment in the rod attachment body. To maintain the integrity of the occipital implant, the OC Plate must be bent in one direction only.**

Fig. 88

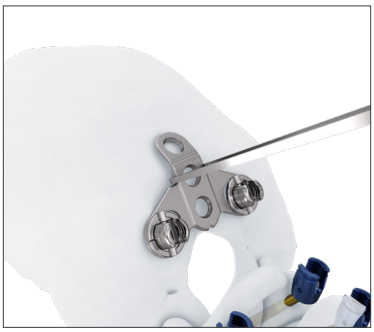


Fig. 89, Fig. 90

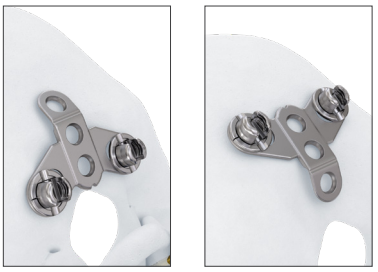


Fig. 91

Fig. 92

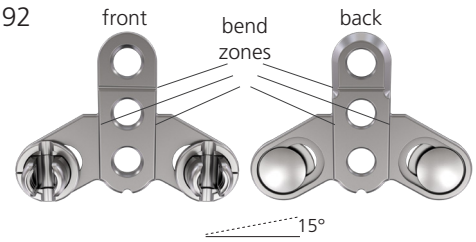


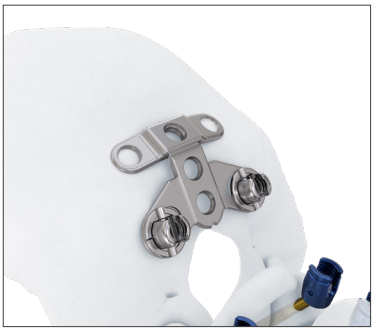
Fig. 93

Optional Technique

Add Lateral Fixation Washer

The Lateral Fixation Washer with the OC Plate: The Lateral Fixation Washer provides two additional lateral fixation points. The Lateral Fixation Washer connects to the OC Plate with a sliding dovetail connection. When using the Lateral Fixation Washer assemble the washer to the OC Plate first, then select the appropriate Occipital Fixed Depth Drill Guide. (Fig. 94)

Fig. 94



Step 5

Drill

2883-10-306	OC Drill Guide 6/8 mm
2883-10-310	OC Drill Guide 10/12 mm
2883-10-314	OC Drill Guide 14/16 mm
2883-10-035	OC 3.5 mm Drill

Select the appropriate Occipital Fixed Depth Drill Guide. With the OC Plate in position, insert the Fixed Depth Drill Guide into the superior midline hole of the OC Plate. Utilizing the 3.5 mm Drill Bit, drill the initial occipital hole through the plate (and OC Washer, if used). For more challenging anatomy a Flexible Shaft Drill is alternatively available. (Fig. 95)

Fig. 95

If drilling the initial occipital pilot hole directly to bone instead of through the OC Plate, increase the screw length by 2 mm to allow for the OC Plate and washer width (example: when drilling 10 mm deep, select a 12 mm screw).

Note: **5.25 mm bone screws, with a self-tapping feature, are also available. Use 4.5 mm bone screws first and reserve the 5.25 mm bone screws for revision purposes.**

Warning: **The midline ridge of bone is shaped like a keel, and it is possible to penetrate the inner cortex on one side of the ridge and still be unicortical in the midline. The occipital sinus is located in the midline and drains into the transverse sinus. The consequences of penetrating this small sinus potentially include thrombosis and hemorrhage.**

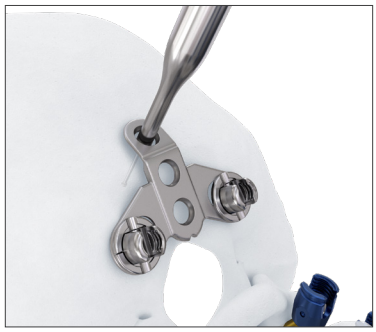
Step 6

Confirm Depth

2883-03-000	Depth Gauge with Ball Tip

Always confirm drilling depth with the Depth Gauge. (Fig. 96)

Fig. 96



Step 7

Tap

2883-10-3XX	OC Drill Guide XX/XXmm
2883-10-045	OC 4.5 mm Tap

The pilot hole is then tapped with a 4.5 mm Tap.

Optional Instrument

2883-11-045	OC 4.5 mm Universal Joint Tap

For difficult anatomy, a Minimal Access Tap with a universal joint is available. (Fig. 97)

Fig. 97

Precaution: **Use the same fixed depth drill guide as used to drill the pilot hole. Stop tapping the hole before the tap "bottoms out" on the drill guide to avoid stripping the bone threads.**

Step 8

Insert Screw

2883-12-300*	OC Straight Driver
2883-12-000	OC Universal Joint Screwdriver
2883-14-200*	Minimal Access OC Driver

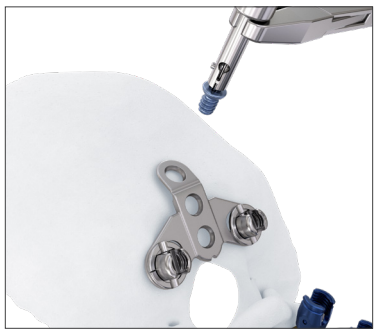
Utilizing the 2.5 mm Self Retaining Screwdriver, insert the selected 4.5 mm Outer Diameter Occipital Bone Screw and tighten.

For difficult anatomy, a Minimal Access Self Retaining Screwdriver is available.

Do not fully tighten the bone screws until the construct has been fully assembled. A small gap ventral to the OC Plate is helpful to allow the rod connectors to slide within the OC Plate, which facilitates placement of the rods.

Insert the remaining Occipital Bone Screws in the same manner. Final tightening is performed once the construct is fully assembled. (Fig. 98)

Fig. 98



Occipital Bone Screws are removed with the 2.5 mm Self Retaining Screwdriver.

Note: **5.25 mm bone screws, with self-tapping feature are also available. Use 4.5 mm bone screws first and reserve the 5.25 mm bone screws for revision purposes.**

*Instrument does not come in standard Mountaineer OC kit

Step 9

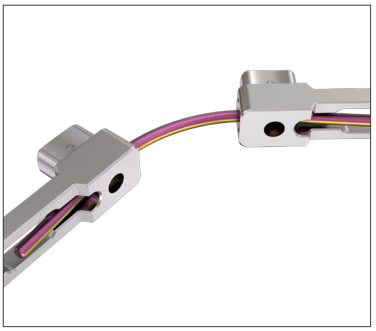
Bend, Cut, and Place Rod

French Rod Bender for 3.5 and 4.0 mm Rods	2020-00-145
Rod Cutter for 3.5 and 4.0 mm Rods	2020-00-135
OC Tube Benders	2746-50-300
Rod Introducer	2883-05-700
Bending Iron Left	2020-00-147
Bending Iron Right	2020-00-146
AO Handle, Torque Limiting 3.0 Nm	2020-00-504
Polyaxial Screw Driver Shaft X20	2020-33-400
X15 Self Retaining Set Screw Inserter	2020-00-407

Cut and contour the rods so that they lay against the posterior surface of the occipital plate and the proposed final location of all polyaxial screw heads. The final length of the rod should extend from the occipital fixation points (approximately 10 mm caudal to the EOP) and 1-2 mm distal to the first caudal fixation point. Care should be taken to protect adjacent non instrumented levels.

Step 9 continued

Fig. 99



Process Steps

To contour the rods, place the rod within the French Rod Bender secure with forceps and gently contour until desired radius is achieved. OC Tube Benders can be slid over each end of the rod to provide additional contouring for the OC junction. (Fig. 99)

Place contoured rods in the implant heads where possible and secure with set screw.

Additionally, an Adjustable Rod is offered for use with the SYMPHONY OCT System. When using the Adjustable Rod, first adjust the angle of the joint to match the patient anatomy and tighten the screw. For final tightening use the AO Handle, Torque Limiting 3.0 Nm to lock the joint.

Precautions:

- **Care should be taken to secure the retained and cut ends during cutting to prevent injury.**
- **Repeated bending may weaken the rod and lead to rod fracture.**
- **Keep fingers away from within the open span of the Rod Cutters during use to avoid injury.**
- **Ensure rod is fully seated in cutting slot with each use to avoid potential user harm.**
- **Failure to use provided 3.0 Nm torque limiting handle when final tightening may lead to set screw back out.**
- **To avoid potential fatigue of the implant do not make sharp bends or unbend the rod.**

Warning: Rod cutters are not intended to be used *in situ* due to the risk of patient injury.

Step 10

Construct Assembly

French Rod Bender for 3.5 and 4.0 mm Rods	2020-00-145
Rod Cutter for 3.5 and 4.0 mm Rods	2020-00-135
OC Tube Bender	2746-50-300

Confirm height and alignment of Polyaxial Screw Heads, such that the slot within each screw head is directed in line with the intended rod position.

Place the rod in the Polyaxial Screw Heads and then into the slots of the OC Plate. The sliding connectors in the OC Plate should allow nearly parallel alignment of the rods with minimal, if any, additional contouring required in coronal plane. (Fig. 100)

The final length of the rod should extend from just cranial to the OC Plate connection to the lowest level to be instrumented taking care to preserve adjacent anatomy. (Fig. 101)

If additional contouring is required, secure the rod within the French Rod Bender or the OC Tube Benders and gently contour until desired radius is achieved.

Fig. 100

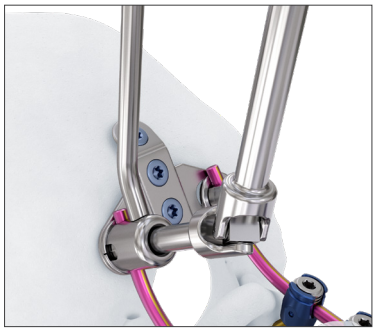


Fig. 101

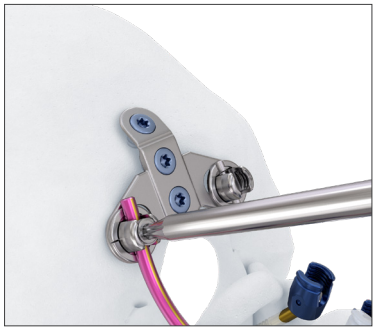


Fig. 102

Step 11

Final Tightening

2883-14-000	OC Universal Joint Torque Driver
2883-14-100	OC Counter Torque Device

Perform final tightening of the Inner Set Screws on the OC Plate by rotating the OC Universal Torque Driver clockwise while providing counter torque on the rod with the Counter Torque Device. The Inner Set Screw is completely tightened when the Torque Driver clicks. OC Plate Inner Set Screws are removed with the OC Universal Torque Driver. (Fig. 102)

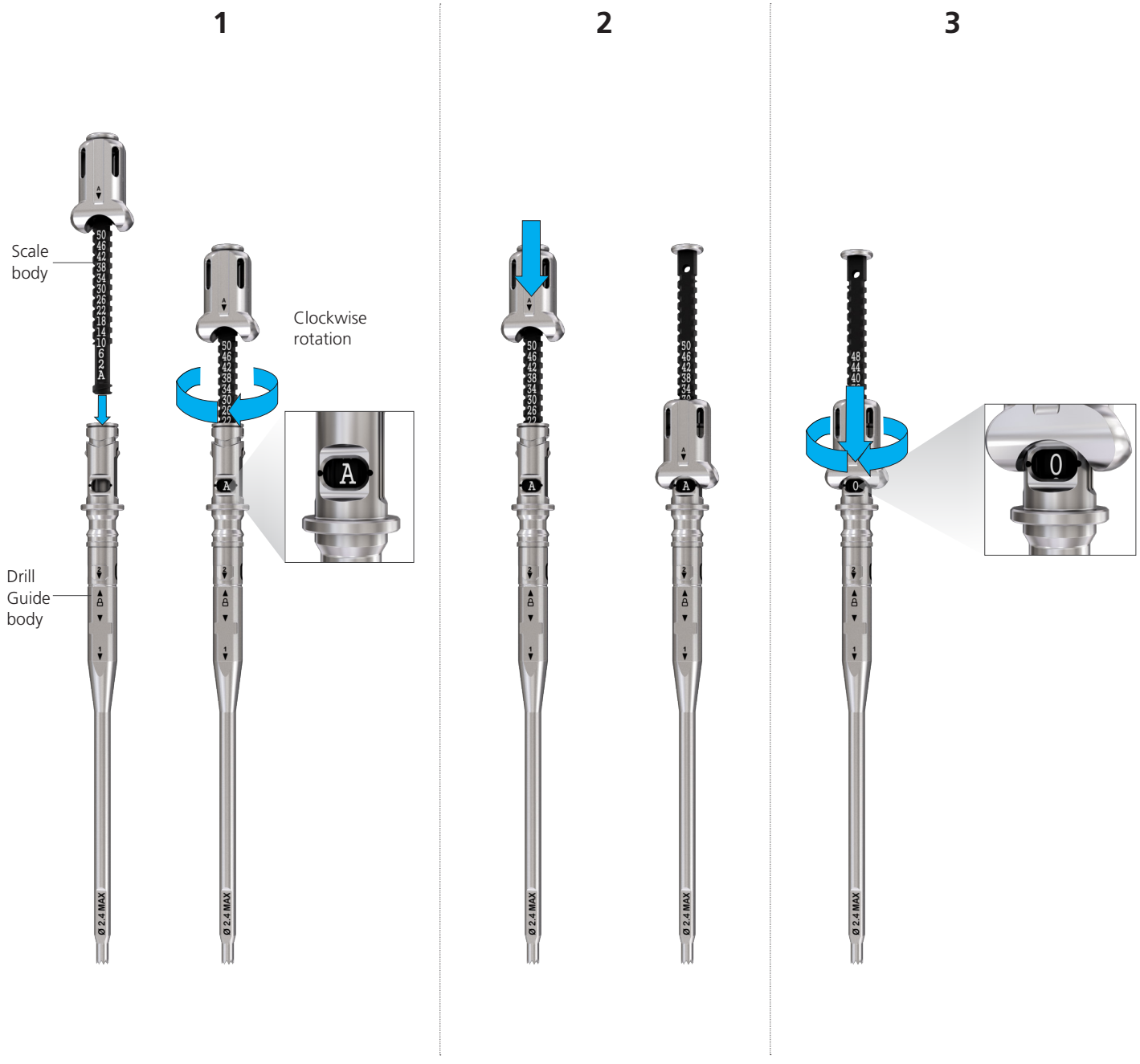
Drill Guide

Assembly

1. Thread scale body into Drill Guide Body until "A" symbol ("A" for Assembly) appears in window.

2. Push knob assembly down until it is just over the window. Ensure the "A" remains in the window as you push it into place. There is an A on the knob that lines up with the A in the window

3. Simultaneously push down and rotate the knob to advance until numbers indicating depth appear in the window.

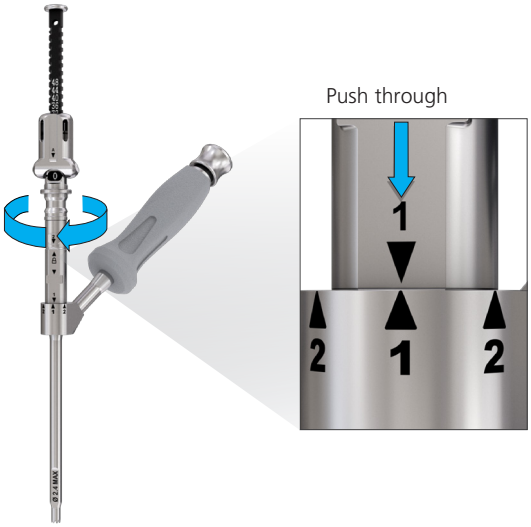


Assembly

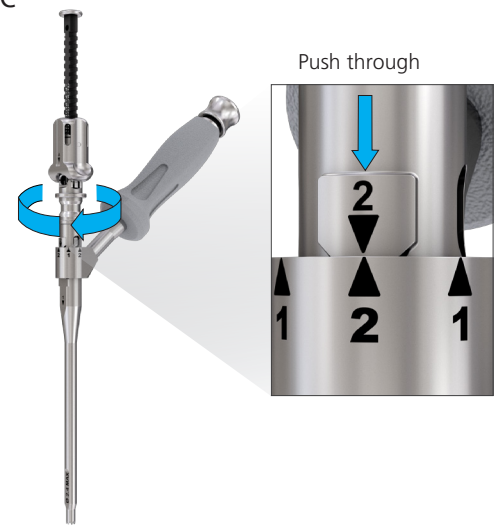
Place Drill Guide into Modular Handle and Line up 1 to 1. With 1 to 1 lined up push the body through until it clicks into place. Then rotate the body to line up 2 to 2 and push through until it clicks a second time into place.

a

b



c

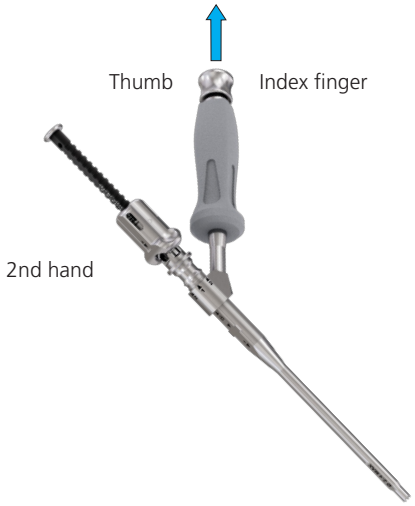


Disassembly

1. Pull the knob at the rear of the modular handle to release the body from the handle. This is best accomplished by putting the handle in the palm of your hand, upside-down, with the knob facing up. Then use your thumb and index finger to push the knob.

2. With the knob pulled up, pull the body from the handle until it hits the stop. Rotate the body to line up 1 to 1 and slide body out from handle.

1



2

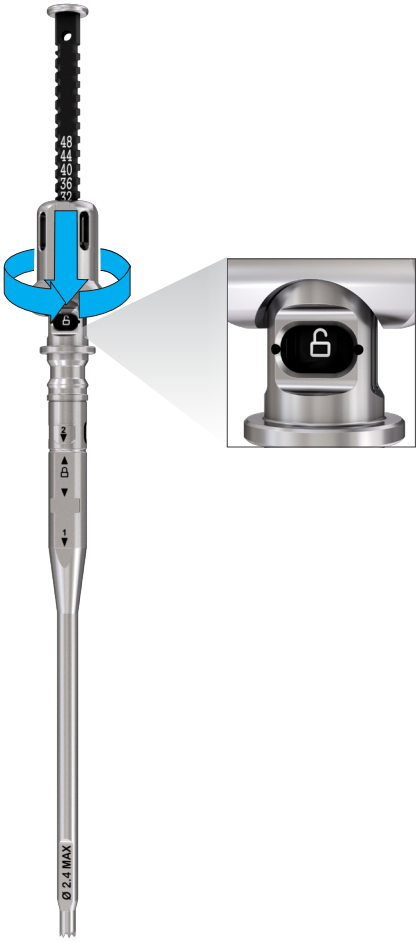
Disassembly

1. Simultaneously push and rotate the knob to advance the scale towards 0 and progress past this point until unlock symbol is shown.

2. With the Unlock Symbol in the window pull the knob back.

3. Turn counterclockwise to unthread the Scale body from the Drill Guide body.

1



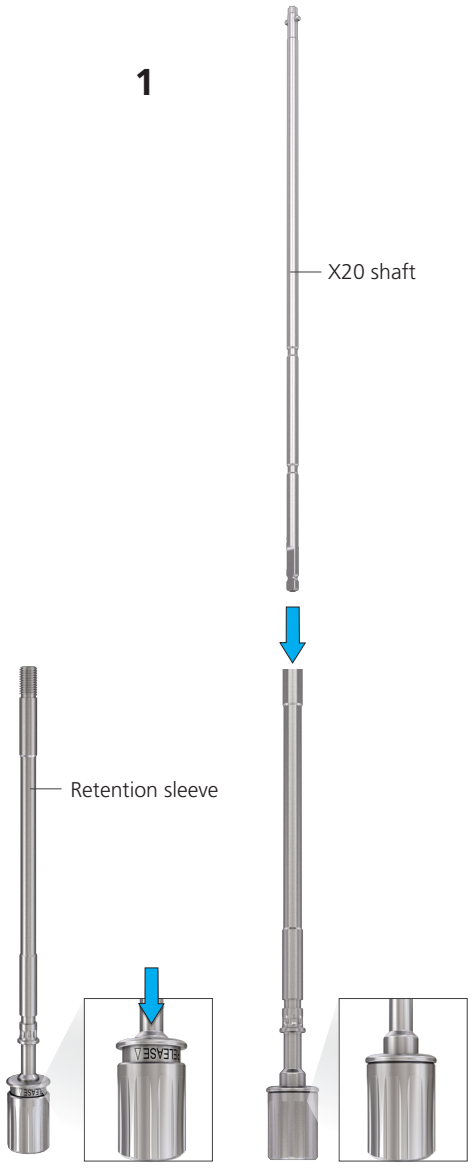
2

3

Polyaxial Driver

Assembly

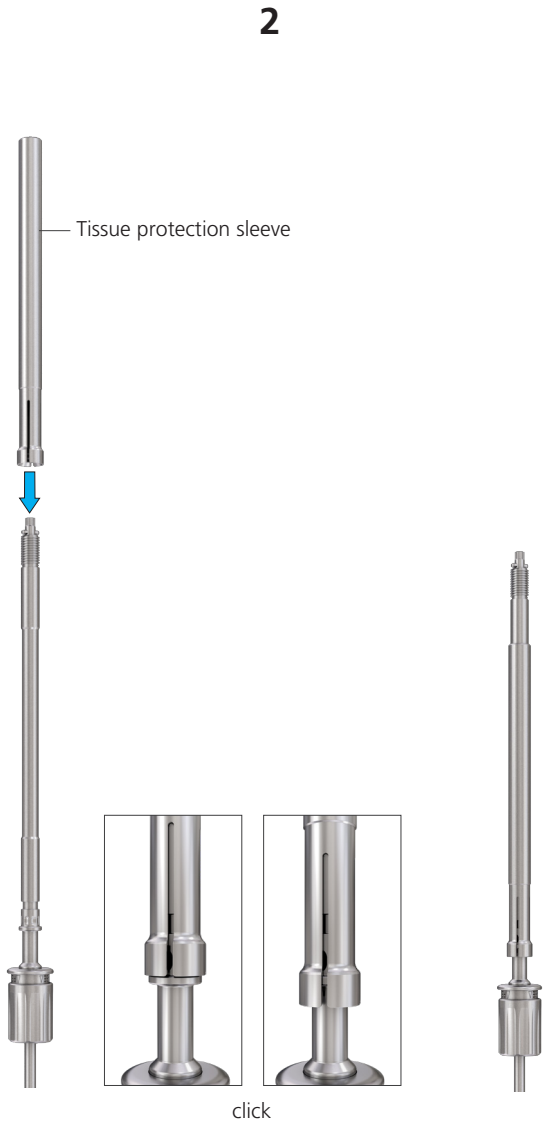
1. Depress the release button on the retention sleeve and feed the X20 shaft through until it clicks into place.



2. Place tissue protection sleeve onto retention sleeve and apply force until it clicks into place

Precautions:

- **Polyaxial Screw Driver Tissue Sleeve is optional. If not using, be mindful that not allowing rotation of the retention sleeve during insertion can lead to screw disengagement.**
- **Ensure tissue sleeve is inserted with the retention feature toward the handle.**



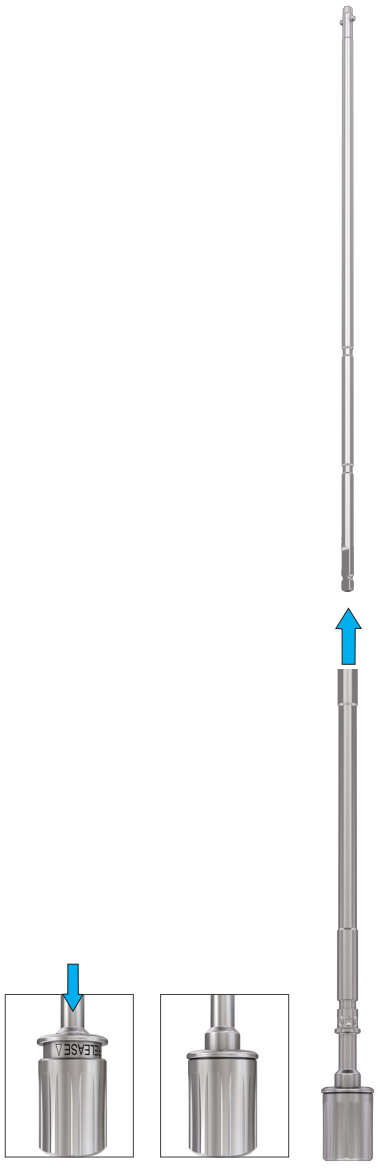
Disassembly

1. Pull tissue protection sleeve off.

2. Depress button on Retention sleeve and slide X20 out.

1

2



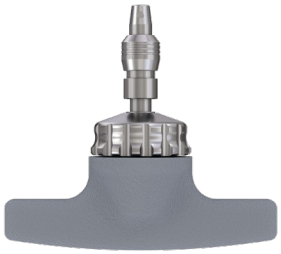
AO Handle Connections

Assembly

SYMPHONY OCT System offers three optional AO Handles. They are utilized to connect to the drills, taps, and screw drivers.

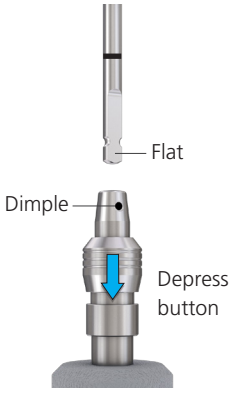
AO Handle Small with Swivel
2020-00-500

AO Handle Medium with Ratchet
2020-00-501



AO Handle T Style with Ratchet
2020-00-503*

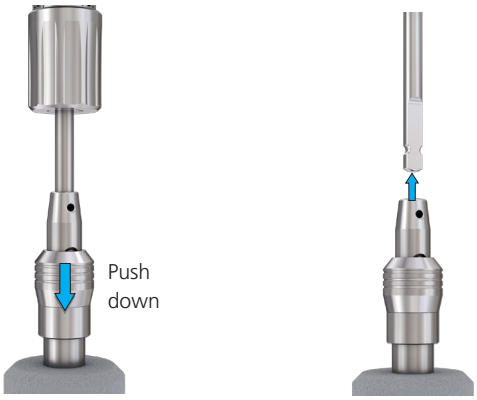
Align the dimple on the handle with the flat on the X20 and depress the button. Feed the shaft into the handle and release the button. The line on the shaft will meet the top of the handle.



* Instrument does not come standard in Core Instrument Set

Disassembly

Remove Handle by depressing button AO Handle.



Reducer Kerrison

Assembly

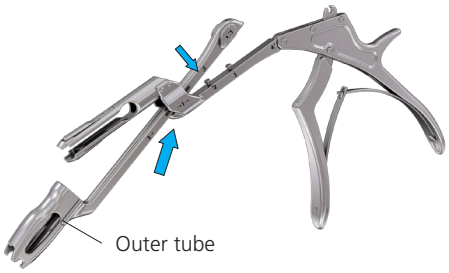
1. Slide the outer tube into inner tube assembly, then align 2 to 2 and lower the outer tube over the posts.

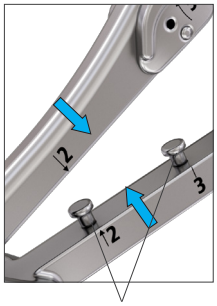
2. Slide the outer tube along the inner shaft until the release lever is over the notch.

While holding the release lever in the up position, lever the distal portion of the outer tube down from the pivot point to align the internal pin into the notch.

3. Release the lever.

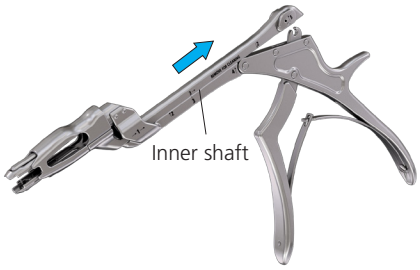
1



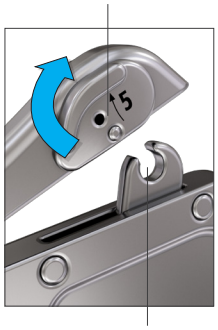


Posts

2

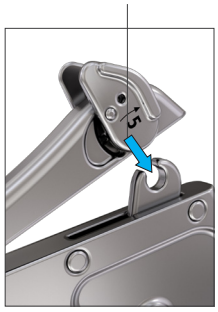


Release lever



Notch

Internal pin



3

Disassembly

1. Rotate the release lever up and lever the outer tube down from the pivot point.

2. Slide the outer tube assembly along the Kerrison shaft until it can go no further. At that point the "2" alignment notches will line up. Lift the outer tube off of the pins and slide the outer tube out of the assembly.

1

2

Indications and Contraindications

Indications

The SYMPHONY OCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the upper thoracic spine (T1-T3):

- Traumatic spinal fractures and/or traumatic dislocations;
- Instability or deformity;
- Failed previous fusions (e.g. pseudarthrosis);
- Tumors involving the cervical/thoracic spine; and
- Degenerative spine disease.

When used in the pediatric population, the SYMPHONY OCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the upper thoracic spine (T1-T3):

- Traumatic spinal fractures and/or traumatic dislocations;
- Instability or deformity; and
- Tumors involving the cervical/thoracic spine.

The SYMPHONY OCT System is also 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 cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The SYMPHONY OCT System is compatible with occipital fusion components (plates, rods and clamps) from the SYNAPSE Occipital-Cervical-Thoracic (OCT) System and the MOUNTAINEER OCT Spinal System. Additionally, the SYMPHONY OCT System is compatible with SYNAPSE OCT System hooks and rods.

The SONGER Wire/Cable System may be used with the SYMPHONY OCT System to allow for wire/cable attachment to the posterior cervical spine.

The SYMPHONY OCT System may be connected to the EXPEDIUM Spine System and VIPER System using connectors and tapered rods. The SYMPHONY OCT System can also be linked to the USS Spinal System and MATRIX Spine System using connectors and tapered rods.

Contraindications

- Active systemic infection or an infection localized to the site of the proposed implantation.
- Severe osteoporosis may prevent adequate fixation of screws and thus preclude the use of this or any other spinal instrumentation system.
- Patients who have been shown to be safely and predictably treated without internal fixation.
- Open wounds.

Relative Contraindications

Relative contraindications include any entity or condition that totally precludes the possibility of fusion (e.g., kidney dialysis or osteopenia), obesity, certain degenerative diseases, and foreign body sensitivity.

Warnings

1. 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. Metallic 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.
2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
3. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as stainless steel and Cobalt-Chromium-Molybdenum or Cobalt-Nickel-Chromium-Molybdenum, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals.
4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be extremely important to the eventual success of the procedure:
   A. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
   B. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
   C. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.

D. Foreign body sensitivity. The surgeon is advised that no pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

E. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

Precautions

1. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.
2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of metal implants should be done only with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage of the implant.
3. BENDING THE CONSTRUCT. Titanium alloy components should never be bent sharply or reverse bent. If a construct is over-contoured it is recommended that a new construct is contoured correctly rather than reverse bending the over-contoured construct.
4. REMOVAL OF THE IMPLANT AFTER HEALING. If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from post-operative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. 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 refracture or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved in a second surgery.
5. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and participating in any type of sports. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

Possible Adverse Effects

1. Nonunion, delayed union.
2. Bending or fracture of implant. Loosening of the implant.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. Infection, early or late.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
8. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late post-operative period.
9. Unintentional dural opening experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
10. Bursitis.
11. Paralysis.
12. Screw back-out, possibly leading to implant loosening, and/or reoperation for device removal.
13. Damage to lymphatic vessels and/or lymphatic fluid exudation.
14. Spinal cord impingement or damage.
15. Fracture of bony structures.
16. Degenerative changes or instability in segments adjacent to fused vertebral levels.
17. Death.

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