
Instructions for Use

SYNAPSE™ System and OC FUSION System

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

Products available non-sterile and sterile can be differentiated with the suffix "S" added to the article number for sterile products.

Instructions for Use

SYNAPSE™ System and OC FUSION System

The SYNAPSE System is a posterior cervical fixation system. The SYNAPSE System consists of a set of implants including rods, screws, hooks, transverse connectors, nuts, parallel connectors and transverse bars.

SYNAPSE System is compatible with the OC FUSION System for posterior occipito-cervical fixations.

The OC FUSION System includes a set of implants including occipital plates, occipital screws, occipital clamps, occiput rods and OC-connectors. The OC FUSION System can be used with posterior screw-rod systems.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

For accompanying information, such as Surgical Techniques, please visit www.jnjmedtech.com/en-EMEA/product/accompanying-information or contact local customer support.

Materials

Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium) according to ISO 5832-11

Titanium: TiCP (Commercially pure Titanium) according to ISO 5832-2

Intended Use

The SYNAPSE System is intended for posterior stabilization of the cervical spine and upper thoracic spine as an adjunct to fusion in skeletally mature patients.

The OC FUSION System in combination with a posterior screw-rod system is intended to provide stabilization of the occipito-cervical junction and cervical/upper thoracic spine (Occiput-T3).

Indications

- Traumatic spinal fractures and/or traumatic dislocations
- Instability or deformity
- Tumors involving the cervical/upper thoracic spine
- Degenerative spine disease

Contraindications

- Spinal destruction accompanied by a loss of ventral support (caused by tumors, fractures and infections) results in major instability of the cervical spine and upper thoracic spine. In this situation, stabilization with SYNAPSE/OC FUSION System is not sufficient. Additional anterior stabilization is crucial.
- Severe osteoporosis

Patient Target Group

The SYNAPSE and OC FUSION Systems are intended for use in skeletally mature patients. These products are to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User

These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Expected Clinical Benefits

When the SYNAPSE System is used as intended and according to the instructions for use and labeling, the device provides posterior stabilization of the cervical spine and upper thoracic spine as an adjunct to fusion, which is expected to provide relief of neck and/or arm pain and to prevent further deterioration of neurologic function.

When the OC FUSION System is used as intended and according to the instructions for use and labeling, the device is expected to provide stabilization of the occipito-cervical junction and cervical/ upper thoracic spine as an adjunct to fusion, which is expected to provide relief of neck and/or arm pain and to prevent further deterioration of neurologic function.

A summary of safety and clinical performance can be found at the following link (upon activation): <https://ec.europa.eu/tools/eudamed>

Performance Characteristics of the Device

The SYNAPSE System is a posterior cervical fixation system, designed to provide stability as an adjunct to fusion.

The OC FUSION System is a posterior cervical fixation system, designed to provide stability as an adjunct to fusion.

Potential Adverse Events, Undesirable Side Effects and Residual Risks

As with all major surgical procedures, there is a risk of adverse events. Possible adverse events may include: problems resulting from anesthesia and patient positioning; thrombosis; embolism; infection; excessive bleeding; neural and vascular injury; partial or complete paralysis; death; swelling, abnormal wound healing or scar formation; functional impairment of the musculoskeletal system; complex regional pain syndrome (CRPS); allergy/hypersensitivity reactions; symptoms associated with implant or hardware prominence; malunion; non-union; ongoing pain; damage to adjacent bones, discs, organs or other soft tissues; dural tear or spinal fluid leak; spinal cord compression and/or contusion; device loosening, breakage or other malfunctions; vertebral angulation.

Sterile Device

STERILE R Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.



Do not use when packaging is damaged.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.

Single Use Device



Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.

Furthermore, re-use or reprocessing of single use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings and Precautions

- It is strongly advised that the SYNAPSE System and OC FUSION System are implanted only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures. The operating surgeon must have knowledge of the device limitations, which are detailed in the contraindications as well as warnings and precautions listed below.
- Implantation is to take place as per the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- Be aware of vulnerable patient populations (such as pregnant patients, patients who are not medically optimized, or patients who may be at increased risk of complications from prone positioning) and carefully consider the potential risks associated with using this medical device in such groups.
- Warning: Special considerations should be taken with patients with known allergies or hypersensitivities to implant materials.

SYNAPSE System

The patient should be placed on the operating table in the prone position with the patient's head securely immobilized.

- Always use caution when positioning the patient, as forcing physiological alignment may cause further neurological injury.
- Confirm screw entry point, orientation and depth.
- Ensure that the drill and tap sleeve has been set to the desired depth and the latch has engaged, preventing the sleeve from moving.
- Perform drilling in steps until the desired depth is reached. Confirm screw entry point, orientation and depth.
- Repeated or reverse bending may weaken the rod.
- If intending on inserting a transverse connector for head-to-head connection, the locking screw for transverse connectors and cap nut 7.5 mm must be used.
- Ensure the etched band on the transverse connector shaft is not visible when implanting. If this band is visible, the connector is over-extended. Use the next size up.
- Do not bend the transverse connector.
- Locking more than once may weaken the transverse connector.

OC FUSION System

The patient should be placed on the operating table in the prone position with the patient's head securely immobilized.

Occipito-cervical fixation with occipital plate

- Extreme bending over the rod attachment body travel slot will limit the amount of medial/lateral adjustment in the rod attachment body.
- Extreme bending over the screw holes will limit the ability to insert the screw properly.
- Reverse bending of the plates should not be attempted.
- Ensure that the drill and tap sleeve has been set to the desired depth and the latch has engaged, preventing the sleeve from moving.
- Drilling must occur through the occipital plate to ensure proper drilling depth.
- Use caution when determining the screw length to not insert depth gauge beyond the bone edge.
- Tapping must be conducted through the occipital plate to ensure correct tapping depth is achieved.
- Tapping for the screws should be conducted for all occipital screws.
- Repeated or reverse bending may weaken the rod.

Occipito-cervical fixation with occipital clamps

- Repeated or reverse bending may weaken the rod.
- Ensure that the drill and tap sleeve has been set to the desired depth and the latch has engaged, preventing the sleeve from moving.
- Drilling must be conducted through the occipital clamp to ensure correct drilling depth is achieved.
- Use caution when measuring to not insert depth gauge beyond the bone edge.
- Tapping must be conducted through the occipital clamp to ensure correct tapping depth is achieved.
- Tapping for the screws should be conducted for all occipital screws.

Occipito-cervical fixation with occiput rods

- Repeated or reverse bending may weaken the rod.
- Drilling must be conducted through the occiput rod to ensure correct drilling depth is achieved.
- Use caution when measuring to not insert depth gauge beyond the bone edge.
- Tapping must be conducted through the occiput rod to ensure correct tapping depth is achieved.
- Tapping for the screws should be conducted for all screws.

Using OC-connector top loading with occipital plate

- The most cranial locking screw must be replaced with a locking screw for transverse connectors.
- Repeated or reverse bending may weaken the OC-connector.
- Bending the rod portion too close to the loop portion can result in bushing/loop damage.
- Ensure that the rod extends slightly past the end of the plate.

Using OC-connector top loading with occipital clamps

- The most cranial locking screw must be replaced with a locking screw for transverse connectors.
- Repeated or reverse bending may weaken the OC-connector.
- Bending the rod portion too close to the loop portion can result in bushing/loop damage.
- Ensure that the locking screw for transverse connector is fully locked by using the screwdriver shaft Stardrive and handle with torque limiter, 2.0 Nm.

Combination of Medical Devices

SYNAPSE System is compatible with the OC FUSION System for posterior occipito-cervical fixations. The SYNAPSE System uses 3.5 mm and 4.0 mm rods, designed to allow components from OC FUSION System to be used interchangeably. This allows the construct to extend from the occiput to the lower spine using the OC FUSION System.

The SYNAPSE System consists of a set of implants including rods, screws, hooks, transverse connectors, nuts, parallel connectors and transverse bars.

When using the transverse bars, parallel connectors ensure that the matching diameter is used with the corresponding implants.

The table below provides compatibility information for SYNAPSE and OC FUSION System.

SYNAPSE System		3.5 Rod System	4.0 Rod System
Connecting Rods	∅ 3.5 mm/∅ 4.0 mm	X	X
	∅ 3.5 mm/∅ 5.0 mm	X	
	∅ 3.5 mm/∅ 5.5 mm	X	
	∅ 3.5 mm/∅ 6.0 mm	X	
	∅ 4.0 mm/∅ 5.0 mm		X
	∅ 4.0 mm/∅ 5.5 mm		X
Polyaxial Screws	∅ 4.0 mm/∅ 6.0 mm		X
	∅ 3.5 mm Cancellous Screws	X	X
	∅ 4.0 mm Cancellous Screws	X	X
	∅ 4.5 mm Cancellous Screws	X	X
Hooks	∅ 3.5 mm Cortex Shaft Screws	X	X
	Top loading Lamina hooks	X	X
Transverse connectors	Head to head loading	X	X
	Rod to rod	X	X

The OC FUSION System includes a set of implants including occipital plates, occipital screws, occipital clamps, occiput rods and OC-connectors. The OC FUSION System can be used with posterior screw-rod systems. Ensure these devices are used with the appropriate rod diameter.

SYNAPSE System and OC FUSION System are intended to be used with associated Instruments.

SYNAPSE System

292.745	Kirschner Wire ∅ 2.4 mm w/Stop
388.397	Awl ∅ 3.5 mm, L 179.5 mm
311.349	Tap f/Cancellous Bone Screws ∅ 3.5 mm
324.107	Handle w/Quick Coupling
388.038	Crimper f/Transverse Connectors
388.393	Drill Sleeve w/Scale, f/No. 388.394
388.394	Drill Bit ∅ 2.4 mm w/Stop, 2-flute
388.407	Holding Forceps f/Rods ∅ 3.5 mm, L 181 mm
388.549	Feeler, straight, w/rounded tip
388.868	Trial Rod ∅ 3.5 mm
389.473	Pedicle Marker, small, w/short markings
389.474	Pedicle Marker, small, w/long markings

389.477	Tap f/Cortex Screw Ø 3.5 mm, L 185 mm
03.161.028	Depth Gauge f/Screws Ø 3.5 to 5.0 mm
03.614.010	Drill Bit Ø 3.2 mm w/Stop, 2-flute
03.614.011	Drill Sleeve w/Scale, f/Drill Bits Ø 3.2 mm
03.614.012	Pedicle Probe Ø 2.4 mm, straight
03.614.013	Pedicle Probe Ø 2.4 mm, curved
03.614.015	Tap f/Cancellous Bone Screws Ø 4.5 mm
03.614.016	Guide Sleeve f/Tap Ø 3.5 mm and Ø 4.5 mm
03.614.017	Holding Sleeve w/thread
03.614.019	Screwdriver Shaft Stardrive f/Locking Screw
03.614.021	Cutting Pliers f/Rods
03.614.022	Bending Pliers f/Rods Ø 3.5 mm and Plates 3.5
03.614.023	Holding Forceps f/Rods Ø 3.5 mm
03.614.024	Bending Iron f/Rods Ø 3.5 mm, left
03.614.025	Bending Iron f/Rods Ø 3.5 mm, right
03.614.026	Rod Pusher
03.614.027	Rod Introduction Instrument
03.614.028	Distraction Forceps
03.614.029	Compression Forceps
03.614.030	Holding Forceps f/Implants
03.614.034	Alignment Tool
03.614.035	Handle w/Torque Limiter, 2.0 Nm
03.614.036	Outer Sleeve f/Holding Sleeve No. 03.614.017
03.614.037	Pedicle Probe Ø 3.2 mm, L 220 mm
03.614.038	Pedicle Probe Ø 3.2 mm, curved
03.614.039	Hexagonal Screwdriver Shaft, cross pinned
03.614.040	Screwdriver, hexagonal Ø 7.5 mm
03.614.041	T-Handle w/Ratchet Wrench, f/Quick Coupling
03.614.048	Screwdriver Shaft Stardrive f/Torque Limiter 2.5 Nm
03.615.009	Rod Introduction Instrument Ø 4.0 mm
03.615.010	Rod Pusher f/Rods Ø 4.0 mm
03.615.011	Rod Shearer f/Rods Ø 4.0 mm
03.615.040	Torque Limiter 2.5 Nm, f/Locking Nut Ø 7.5 mm
03.615.041	Top-Loading Implant Remover
03.615.042	Handle f/Rod Introduction Instrument w/Speed Nut
03.688.505	Handle w/Ratchet Wrench f/Quick Coupling, small

OC FUSION System

03.161.001	Bending Template f/Occipital Plate, medial, small
03.161.002	Bending Template f/Occipital Plate, medial, large
03.161.003	Occiput Trial Rod Ø 3.5 mm
03.161.011	Bending Template f/Occipital Plate, lateral, small
03.161.012	Bending Template f/Occipital Plate, lateral, large
03.161.023	Drill and Tap Sleeve w/Scale
03.161.024	Drill Bit Ø 3.2 mm w/Stop, L 245/69 mm
03.161.026	Tap f/Cortex Screw Ø 4.5 mm, L 245 mm
03.161.027	Tap Ø 4.5 mm, w/Cardan Joint
03.161.028	Depth Gauge f/Screws Ø 3.5 to 5.0 mm
03.161.031	Screwdriver Shaft Stardrive T15, self-holding
03.161.041	Positioning Instrument f/Occipital Plate
03.161.042	Bending Pliers f/Occipital Plate
03.161.105	Drill Bit Ø 3.2 mm, w/Flexible Shaft, f/Quick Coupling
03.614.019	Screwdriver Shaft Stardrive f/Locking Screw
03.614.026	Rod Pusher
03.614.027	Rod Introduction Instrument
03.614.035	Handle w/Torque Limiter, 2.0 Nm
03.614.048	Screwdriver Shaft Stardrive f/Torque Limiter 2.5 Nm
03.614.055	Template f/Occipital Angles
03.615.007	Positioning Instrument f/Occipital Pl. Ø 4.0 mm
03.615.009	Rod Introduction Instrument Ø 4.0 mm
03.615.010	Rod Pusher f/Rods Ø 4.0 mm
03.615.011	Rod Shearer f/Rods Ø 4.0 mm
03.615.040	Torque Limiter 2.5 Nm, f/Locking Nut Ø 7.5 mm

03.615.042	Handle f/Rod Introduction Instrument w/Speed Nut
324.107	Handle w/Quick Coupling
387.689	Plate Holder
388.392	Screwdriver Shaft Stardrive 3.5, T15
388.407	Holding Forceps f/Rods Ø 3.5 mm, L 181 mm
388.868	Trial Rod Ø 3.5 mm
389.478	Bending Pliers f/Rods Ø 3.5 mm
391.880	Vice Grip, L 180 mm
391.990	Cutting Pliers f/Plates and Rods

Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance Environment

MR Conditional:

Non-clinical testing of the worst-case scenario has demonstrated that the implants of the SYNAPSE and OC FUSION System are MR conditional. These articles can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla.
- Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
- Maximum whole body averaged specific absorption rate (SAR) of 1.8 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the SYNAPSE and OC FUSION implant will produce a temperature rise not greater than 5.7 °C at a maximum whole body averaged specific absorption rate (SAR) of 1.8 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.

MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the SYNAPSE and OC FUSION device.

Treatment before Device is Used

Sterile Device:

The devices are provided sterile. Remove products from the package in an aseptic manner.

Store sterile devices in their original protective packaging.

Do not remove them from the packaging until immediately before use.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging by visual inspection:

- Inspect the entire area of sterile barrier package including the sealing for completeness and uniformity.
- Inspect the integrity of the sterile packaging to ensure there are no holes, channels or voids.

Do not use if the package is damaged or expired.

Non-Sterile Device:

Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Implant Removal

The SYNAPSE System and OC FUSION System is intended for permanent implantation and is not intended for removal.

Any decision to remove the device must be made by the surgeon and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

OC FUSION System

- All OC FUSION implants can be removed with a T15 Stardrive screwdriver. For removal of the SYNAPSE implants, please see below.

SYNAPSE System

If a SYNAPSE implant must be removed, the following technique is recommended.

- All SYNAPSE implants can be removed with a T15 Stardrive screwdriver.
- The transverse connectors also require that the crimper be used for removal.
- Additionally, removal of head to head transverse connectors requires that the screwdriver, hexagonal Ø 7.5 mm be used.

Note: SYNAPSE polyaxial screws may also be removed with the cross pinned hexagonal screwdriver shaft.

Removing transverse connectors for head to head connection

- If required, secure the transverse connector using the holding forceps.
- Unlock the transverse connector using the crimper.
- Ensure that the gold tip of the instrument is touching the blue portion of the transverse connector.
- Remove all cap nuts using the hexagonal screwdriver.

Note: If required, the screwdriver shaft Stardrive can be used as counter torque.

- Using the top loading implant remover, approach the transverse connector from the lateral side until the forked opening sits just underneath the loop of the transverse connector.
- The inner shaft portion should contact the upper surface of the locking screw.
- Slowly turn the top handle to thread the shaft down onto the locking screw.
- Continue turning slowly until the implant is removed.
- Repeat on the other side.

Removing transverse connector for rod to rod connection

- Unlock both bushing connections with the crimper.
- Ensure that the gold tip of the instrument is facing laterally.
- Using the holding forceps to hold the transverse connector, use the Stardrive screwdriver and the handle to unscrew the set screw.
- Slide the rod within the hook if necessary to access the second set screw.

Clinical Processing of the Device

Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Special Operating Instructions

SYNAPSE System

Preparation

Position patient

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

Approach

- Use the standard surgical approach to expose the spinous processes and laminae of the vertebrae to be fused.

Assemble instruments

- The following instruments have to be assembled prior to use:
 - Screwdriver
 - Rod introduction instrument
 - Drill sleeve
 - Depth gauge
 - Top loading implant remover
- Assemble instruments according to the assembling instructions.

Surgical technique

Start screw hole

- Determine the entry point and trajectory for the screw and use the awl to create a pilot hole. This helps to prevent displacement of the drill bit during initial insertion.

Select screw and drill sleeve

- Select the drill bit and drill sleeve that correspond to the screw diameter to be used. \varnothing 3.5 mm and \varnothing 4.0 mm screws have the same core diameter (2.4 mm) and are to be used with the same drill bit and drill sleeve, identified by a yellow band. \varnothing 4.5 mm screws have a larger core diameter (3.2 mm) and are to be used with the drill bit and drill sleeve identified by a light blue color band. See table below.

Screw diameter	3.5 mm	4.0 mm	4.5 mm
Drill bit	388.394	388.394	03.614.010
Drill sleeve	388.393	388.393	03.614.011

Set drill sleeve depth

- To set the drill sleeve to the desired depth, slide back the latch to release the inner tube; align the distal end of the internal drill sleeve tube with the appropriate depth calibration on the window. Release the latch to lock the drill sleeve at the desired depth.

Drill hole

- Drill to the desired trajectory and depth, using the \varnothing 2.4 mm drill bit and drill sleeve. Use the feeler to confirm, by palpation, accurate placement within the pedicle or lateral mass.
- Alternative technique: Pedicle preparation may also be performed using either the straight or curved pedicle probe.
- Optional technique: The small pedicle markers may be used to radiographically confirm position and orientation of screw sites.

Screw length determination

- 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.

Tapping (optional)

- Dense bone may be tapped using the appropriate tap, depending on the chosen screw.
- The guide sleeve may be used as a tissue protector, and to indicate tap depth.

Insert screw

- Insert the selected \varnothing 3.5 mm or \varnothing 4.5 mm self-tapping SYNAPSE screw. A \varnothing 4.0 mm emergency screw may be used if the primary \varnothing 3.5 mm screw has less than the desired fixation.
- The outer sleeve should be used to grip the holding sleeve during screw insertion.

Place additional screws

- Use the same technique to insert the remaining screws.

Contour template

- Contour the trial rod to fit the anatomy.

Bend and cut rod

- Use the bending pliers to contour the rod to match the curve of the template. The bend line arrow indicates where the rod will be bent.
- Use the cutting pliers to cut the rod to the appropriate length.
- Alternative technique: Shorter rod sections may be bent by placing one end of the rod on the internal ledge of the bending feature.
- Alternative bending technique: The bending irons can be used for both \varnothing 3.5 mm and \varnothing 4.0 mm rods. 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. With both ends locked inside the irons, the rod may be contoured.

Insert rod

- Insert the rod into the variable axis heads of the screws using the holding forceps. The holding forceps can be used for both \varnothing 3.5 mm and \varnothing 4.0 mm rods. The alignment tool may be used to help orient the heads to the correct position. The bending irons may be used to adjust the curve of the rod.

Insert locking screw

- Loosely fasten the locking screws using the screwdriver shaft with the 2 Nm torque limiting handle. When inserting the locking screws, they may be turned one-quarter to one-half turn counterclockwise to seat the thread before tightening.
- Alternative technique: Use the rod introduction instrument or rod pusher to introduce the rod into the variable axis head of the screws. Place the instrument over the rod and onto the variable axis head until the tip of the instrument sits below the screw head reduction feature. Squeeze the handle to engage the instrument and introduce the rod into the head of the screw. Loosely fasten the locking screws using the screwdriver shaft with the 2 Nm torque limiting handle through the cannulation of the rod introduction instrument. When inserting the locking screws, they may be turned one-quarter to one-half turn counterclockwise to seat the thread before tightening. Alternatively, when using the handle for rod introduction instrument with speed nut, squeeze the handle to engage the instrument and introduce the rod into the head of the screw. Thread the speed nut down to lock the instrument into the reduced position.

Optional techniques:

- Rod rotation: If rotation of the rod is desired, it is recommended that the holding forceps be used.
- Compression or distraction: Compression or distraction with variable axis heads is only possible with the locking screws not tightened. Use compression forceps to achieve compression, or the distraction forceps to achieve distraction, and then fully tighten the locking screws as described in step "Lock construct".

Lock construct

- After final adjustment of the construct, fully tighten all locking screws with the screwdriver shaft and the 2 Nm torque limiting handle by turning the torque limiting handle until it clicks once on all sections. The construct is now rigidly locked. Final tightening should be accomplished after all locking screws have been placed and should be aided by a rod pusher.
- The rod introduction instrument may be used in place of the rod pusher to lock the construct.

Additional technique – Top loading hooks

Place top loading hooks

- Position hook: Attach the holding forceps to the appropriate hook. Place the hook in the desired location using the screwdriver as an aid.
- Insert rod.
- Insert locking screw: Tighten the locking screw using the screwdriver shaft for locking screw. Turn the screwdriver one-quarter to one-half turn counterclockwise to seat the thread before tightening.

Additional technique – Transverse connector (head to head)

Tighten locking screw for transverse connectors

- Insert a locking screw for transverse connectors into the required screw head. Fully tighten all locking screws for transverse connectors with the screwdriver shaft and the 2.0 Nm torque limiting handle before seating the transverse connectors by turning the torque limiter handle until it clicks once.
- The rod introduction instrument may be used in place of rod pusher.

Insert transverse connector for head to head connection

- Select a straight or angled transverse connector of appropriate length. Place the transverse connector on the SYNAPSE screw construct to assess fit. Hold the transverse connector with the holding forceps. Adjust as necessary. Both sides of the transverse connector should be placed over the locking screws for transverse connectors before proceeding.

Insert and tighten cap nut 7.5 mm for transverse connectors

- Select and place the cap nut 7.5 mm onto the locking screw for transverse connector using the torque limiter, 2.5 Nm, for cap nut 7.5 mm. To provide alignment, insert the screwdriver shaft Stardrive into the cannula of the torque limiter and engage the T15 recess.
- After all cap nuts have been placed, firmly tighten them with the 2.5 Nm torque limiter by turning the handle until it clicks, using the Stardrive screwdriver shaft and the handle as counter torque.
- Use the torque limiter for locking nut to help seat the transverse connector onto the transverse connector locking screw.
- When inserting the cap nuts, they may be turned one-quarter to one-half turn counterclockwise to seat the thread before tightening.

Lock connection

- Secure the locking sleeve with the crimper. When locking the connection, ensure that the gold tip of the instrument is touching the gold portion of the transverse connector shaft. The transverse connector is now rigidly locked.
- If necessary, the connection can be unlocked using the same instrument with the gold tip touching the blue portion of the transverse connector.

Additional Technique – Transverse connector (rod to rod)

Position the transverse connectors

- Place the transverse connectors on the SYNAPSE rod construct. The transverse connectors may be held with the holding forceps.

Tighten clamp

- Tighten the setscrew of the transverse connector hook on the rod with the screwdriver shaft. Slide the rod within the hook if necessary. Hold the second hook in the appropriate position and tighten the setscrew.
- The rod may be bent to accommodate the anatomy.
- Locking one end of the transverse connector with the crimper may facilitate placement.

Lock connections

- Lock both bushing connections with the crimper. Ensure that the golden tip of the instrument is facing medially when locking the connection. The transverse connector is now rigidly locked.
- If necessary, the connection can be unlocked using the same instrument with the golden tip facing laterally.
- The rod may be shortened with the cutting pliers.

Additional techniques

Adding transverse bars

- Place the opening of the transverse bar over the rod. Loosely attach the transverse bar to the rod. Introduce the transverse bar into the variable axis head of the screw. Insert the locking screw in the variable axis head as described in steps “Insert rod” and “Insert locking screw”. Tighten the setscrew of the transverse bar using the screwdriver shaft.

Occipital fusion technique

- Occipital plates or occipital clamps may be attached to the occiput as described in the section “Special Operating Instructions” of OC FUSION. These plates or clamps can then be connected to the SYNAPSE system via \varnothing 3.5 mm or \varnothing 4.0 mm rods or pre-bent rods.

Parallel connectors

- All parallel connectors are open and allow side-loading of the rods. They link \varnothing 3.5 mm to \varnothing 3.5 mm, \varnothing 4.0 mm, \varnothing 5.0 mm and \varnothing 6.0 mm rods. Either side of the connector may be connected first. Tighten the setscrew on one side, then connect the remaining rod and tighten the setscrews. Parallel connectors are also available to link \varnothing 4.0 mm to \varnothing 4.0 mm, \varnothing 5.0 mm and \varnothing 6.0 mm rods.

Connecting rods

- Connecting rods may be used to extend a SYNAPSE construct. Connect the \varnothing 3.5 mm or \varnothing 4.0 mm rod section to the SYNAPSE polyaxial screws as instructed in steps “Contour template”, “Bend and cut rod” and “Insert rod”. Connect the \varnothing 5.0 mm/5.5 mm/6.0 mm end of the rod to the appropriate qualified posterior spinal stabilization system. For a listing of qualified posterior spinal stabilization systems please refer to the respective Instructions for Use.

OC FUSION System

Preparation

Position the patient

- Patient positioning is critical for occipito-cervical fusion procedures. The patient should be placed on the operating table in the prone position with the head securely immobilized. Proper patient position should be confirmed via direct visualization and by radiograph prior to draping.

Approach

- Use the standard midline posterior surgical approach to expose the spinous processes and laminae of the vertebrae to be fused, and the external occipital protuberance.

Assemble instruments

- The following instruments have to be assembled prior to use:
 - Depth Gauge
 - Tap for cortex screw
 - Drill and tap sleeve with scale
- Assemble instruments according to the assembling instructions.

Occipito-cervical fixation with occipital plate

Fixation to the cervical and upper thoracic spine

- Insert bone screws and/or hooks into the cervical and upper thoracic spine as required by the patient’s pathology. The technique is described in the section “Special Operating Instructions” of SYNAPSE.

Determine shape and size of occipital plate

- Select a bending template of the plate style estimated to best fit the occiput. Estimate the medial/lateral distance of the rods to determine the appropriate plate size. Contour the plate template to fit the anatomy.

Contour occipital plate

- Use the bending pliers for contouring the plate to fit the anatomy. They can be used across any section of the plate including the area lateral of the rod attachment bodies.
- To create more acute bends vice grips can be used.

Drill pilot hole

- Set the drill and tap sleeve to the desired depth. Slide back the latch of the drill and tap sleeve to release its inner tube. Adjust position of inner tube in window so that the mark on the inner tube indicates the required depth. Release the latch to lock the drill and tap sleeve at the desired depth.
- Ensure that the plate is correctly positioned according to the patients anatomy before drilling. Drill to desired trajectory and depth using the drill bit and the drill and tap sleeve.

Determine screw size

- Use the depth gauge to confirm hole depth and select the corresponding screw length. The depth gauge must sit directly on the bone.
- The depth gauge indicates the working length. For example, if 10 mm is indicated on the gauge, select a 10 mm screw. The length indicated on the gauge accounts for the depth of the bone and the thickness of the plate.

Tap

- Tap to desired depth using the tap and the drill and tap sleeve.
- Set the tap depth by turning the tap sleeve to the desired depth. Lock the tap sleeve by turning down the locking nut until it contacts the tap sleeve. Finger tighten the locking nut. Use the holding forceps to provide axial force and stability.

Insert screw

- Load the selected \varnothing 4.5 mm occipital screw from the screw rack. Insert screw and tighten it provisionally.
- A \varnothing 5.0 mm occipital screw may be used if the primary screw has less than desired fixation.
- Alternatively the screwdriver shaft with cardan joint may be used to insert the selected screw. Use the holding forceps to provide axial force and stability.

Insert remaining screws

- Repeat steps “Drill pilot hole”, “Determine screw size”, “Tap” and “Insert screw” to insert the remaining screws.

Contour trial rod

- Contour the trial rod to fit the anatomy and to seat fully in the bone screws. Create the occipito-cervical bend and ensure sufficient rod length to connect with the occipital plate.
- When using the template for occipital angles, place the template into the saddle of the occipital plate and pivot the opposite arm until it matches the anatomy as required. Remove the template to read the required angle indicated.

Bend and cut rod

- Contour the rod using the bending pliers to match the curve of the trial rod.
- The bending pliers can be used for both rods \varnothing 3.5 mm and \varnothing 4.0 mm.
- Cut the rod with the cutting pliers to the appropriate length.

Rod attachment

- Use the positioning instrument to facilitate rod placement and locking screw insertion.
- Insert rod into the rod attachment body. Ensure that the rod extends slightly past the end of the plate. Provisionally tighten the locking screw using the screwdriver shaft Stardrive. The holding forceps can be used for both rods \varnothing 3.5 mm and \varnothing 4.0 mm.
- Alternatively the screwdriver shaft with cardan joint may be used for provisional tightening of the locking screw. Use the holding forceps to provide axial force and stability.

Insert rod in contralateral side

- Repeat steps “Contour trial rod”, “Bend and cut rod” and “Rod attachment” of step “Occipito-cervical fixation with occipital plate” in the section “Special Operating Instructions” of OC FUSION to insert rod on the contralateral side.

Final tightening

- Firmly tighten all occipital and locking screws using the screwdriver shaft Stardrive with the handle with quick coupling. To provide counterforce for tightening the locking screws, the positioning instrument may be used.
- Alternatively, the screwdriver shaft with cardan joint may be used for final tightening of the occipital and locking screws. Use the holding forceps to provide axial force and stability.
- To provide counterforce for tightening the locking screws, the positioning instrument may be used.

Occipito-cervical fixation with occipital clamps

Fixation to the cervical and upper thoracic spine

- Insert bone screws and/or hooks into the cervical and upper thoracic spine as required by the patient’s pathology. The technique is described in the section “Special Operating Instructions” of SYNAPSE.

Contour trial rod

- Contour the trial rod to fit the anatomy and to seat fully in the bone screws. Create the occipito-cervical bend and ensure sufficient rod length to connect with the occipital clamp.

Bend and cut rod

- Contour the rod using the bending pliers to match the curve of the trial rod.
- The bending pliers can be used for both rods \varnothing 3.5 mm and \varnothing 4.0 mm.
- Cut the rod with the cutting pliers to the appropriate length.

Attach occipital clamp to rod

- Provisionally attach the occipital clamp to the rod by tightening the set screw in the clamp.
- The holding forceps can be used for both rods \varnothing 3.5 mm and \varnothing 4.0 mm.

Drill pilot hole

- Set the drill and tap sleeve to the desired depth. Slide back the latch of the drill and tap sleeve to release its inner tube. Adjust position of inner tube in window so that the mark on the inner tube indicates the required depth. Release the latch to lock the drill and tap sleeve at the desired depth.
- Drill to desired trajectory and depth using the drill bit and drill and tap sleeve.

Measure hole depth

- Use the depth gauge to confirm hole depth and select the corresponding screw length. The depth gauge must sit directly on the bone.
- The depth gauge indicates the working length. For example, if 10 mm is indicated on the gauge, select a 10 mm screw. The length indicated on the gauge accounts for the depth of the bone and the thickness of the plate.

Tap

- Tap to desired depth using the tap and the drill and tap sleeve.
- Set the tap depth by turning the tap sleeve to the desired depth. Lock tap sleeve by turning down the locking nut until it contacts the tap sleeve. Finger tighten the locking nut. Use the holding forceps to provide axial force and stability.

Insert screw

- Load the selected \varnothing 4.5 mm occipital screw from the screw rack. Insert screw and tighten it provisionally.
- A \varnothing 5.0 mm occipital screw may be used if the primary screw has less than desired fixation.
- Alternatively, the screwdriver shaft with cardan joint may be used to insert the selected screw. Use the holding forceps to provide axial force and stability.

Insert remaining screws and clamps

- Repeat steps “Attach occipital clamp to rod”, “Drill pilot hole”, “Measure hole depth”, “Tap” and “Insert screw” of step “Occipito-cervical fixation with occipital clamps” in the section “Special Operating Instructions” of OC FUSION to insert the remaining screws and clamps. A minimum of two clamps shall be used.

Insert second rod and remaining clamps and screws

- Repeat steps “Contour trial rod”, “Bend and cut rod”, “Attach occipital clamp to rod”, “Drill pilot hole”, “Measure hole depth”, “Tap”, “Insert screw” and “Insert remaining screws and clamps” of step “Occipito-cervical fixation with occipital clamps” in the section “Special Operating Instructions” of OC FUSION to insert implants on the contralateral side.

Final tightening

- Firmly tighten all occipital screws and occipital clamp set screws using the screwdriver shaft with the handle with quick coupling.
- Alternatively, the screwdriver shaft with cardan joint may be used for final tightening all occipital screws and occipital clamp set screws. Use the holding forceps to provide axial force and stability.

Occipito-cervical fixation with occiput rods

Fixation to the cervical and upper thoracic spine

- Insert bone screws and/or hooks into the cervical and upper thoracic spine as required by the patient’s pathology. The technique is described in the section “Special Operating Instructions” of SYNAPSE.

Contour trial rod

- Contour the occiput trial rod to fit the anatomy and to seat fully in the bone screws.

Bend and cut occiput rod

- Contour the occiput rod using the bending pliers to match the curve of the occiput trial rod. The bending pliers can be used for both \varnothing 3.5 and \varnothing 4.0 rods.
- Cut the rod with the cutting pliers to the appropriate length.

Drill pilot hole

- Set the drill and tap sleeve to the desired depth. Slide back the latch of the drill and tap sleeve to release its inner tube. Adjust position of inner tube in window so that the mark on the inner tube indicates the required depth. Release the latch to lock the drill and tap sleeve at the desired depth.
- Drill to desired trajectory and depth using the drill bit and the drill and tap sleeve.
- The holding forceps can be used for both rods \varnothing 3.5 mm and \varnothing 4.0 mm.

Measure hole depth

- Use the depth gauge to confirm hole depth and select the corresponding screw length. The depth gauge must sit directly on the bone.
- The depth gauge indicates the working length. For example, if 10 mm is indicated on the gauge, select a 10 mm screw. The length indicated on the gauge accounts for the depth of the bone and the thickness of the plate.

Tap

- Tap to desired depth using the tap and the drill and tap sleeve.
- Set the tap depth by turning the tap sleeve to the desired depth. Lock the tap sleeve by turning down the locking nut until it contacts the tap sleeve. Finger tighten the locking nut. Use the holding forceps to provide axial force and stability.

Insert screw

- Load the selected \varnothing 4.5 mm occipital screw from the screw rack. Insert screw and tighten it provisionally.
- An \varnothing 5.0 mm occipital screw may be used if the primary screw has less than desired fixation.
- Alternatively use the screwdriver shaft with cardan joint to insert the selected screw. Use the holding forceps to provide axial force and stability.

Insert remaining screws

- Repeat steps “Drill pilot hole”, “Measure hole depth”, “Tap” and “Insert screw” of step “Occipito-cervical fixation with occiput rods” in the section “Special Operating Instructions” of OC FUSION to insert the remaining screws.

Insert second occiput rod and corresponding screws

- Repeat steps “Contour trial rod”, “Bend and cut occiput rod”, “Drill pilot hole”, “Measure hole depth”, “Tap”, “Insert screw” and “Insert remaining screws and clamps” of step “Occipito-cervical fixation with occiput rods” in the section “Special Operating Instructions” of OC FUSION to insert the second occiput rod and corresponding screws.

Final tightening

- Firmly tighten all occipital screws using the screwdriver shaft with the handle with quick coupling.
- Alternatively, the screwdriver shaft with cardan joint may be used for final tightening the occipital screws. Use the holding forceps to provide axial force and stability.

Optional technique: Using OC-connector top loading with occipital plate

Fixation to the cervical and upper thoracic spine

- Insert bone screws and/or hooks into the cervical and upper thoracic spine as required by the patient’s pathology.
- The technique is described in the section “Special Operating Instructions” of SYNAPSE.

Insert occipital plate

- Follow steps “Bend and cut rod”, “Attach occipital clamp to rod”, “Drill pilot hole”, “Measure hole depth”, “Tap” and “Insert screw” of step “Occipito-cervical fixation with occipital plate” in the section “Special Operating Instructions” of OC FUSION to insert the occipital plate.

Bend and cut OC-connector

- Contour the rod portion of the OC-connector using the bending pliers to match the curve of the trial rod/or occipital angle template established in step “Contour trial rod” of step “Occipito-cervical fixation with occipital plate” in the section “Special Operating Instructions” of OC FUSION.
- The bending pliers can be used for both rods \varnothing 3.5 mm and \varnothing 4.0 mm.
- Cut the rod with the cutting pliers to the appropriate length.

Insert locking screw for transverse connectors

- Insert a locking screw for transverse connectors into the upper most screw and fully tighten using the screwdriver shaft and the 2.0 Nm torque limiting handle.
- Turn the 2.0 Nm torque limiting handle until it clicks.
- The rod introduction instrument may be used in place of the rod pusher to lock the construct.

Insert the OC-connector

- Ensure that the locking screw for transverse connector is fully locked by using the screwdriver shaft Stardrive and handle with torque limiter, 2.0 Nm. Turn the torque limiter handle until it clicks once.
- Place the loop portion of the OC-connector over the locking screw for transverse connectors using the holding forceps.

Insert the OC-connector into the occipital plate

- Insert to the rod portion of the OC-connector into the rod attachment body of the plate.
- Provisionally tighten the locking screw using the screwdriver shaft Stardrive.
- The holding forceps can be used for both rods 3.5 mm and 4.0 mm.

Insert cap nut for transverse connectors

- Select and place the cap nut onto the locking screw using the torque limiter 2.5 Nm. To provide alignment, insert the Stardrive screwdriver shaft into the cannula of the torque limiter 2.5 Nm and engage the T15 recess.
- Loosely thread the locking nut onto the locking screw.

Final tightening

- Firmly tighten the cap nut using the torque limiter 2.5 Nm for cap nuts. Turn the handle until it clicks once. The screwdriver shaft Stardrive for torque limiter and the handle with quick coupling can be used as counter torque.
- Firmly tighten the occipital screws using the screwdriver shaft Stardrive. To provide counter torque, the positioning instrument can be used. Use only one hand to tighten.

Insert OC-connector on contralateral side

- Repeat all steps in step “Optional technique: Using OC-connector top loading with occipital plate” to insert the OC-connector on the contralateral side.

Optional technique: Using OC-connector top loading with occipital clamps

- Insert bone screws and/or hooks into the cervical and upper thoracic spine as required by the patient’s pathology.
- The technique is described in the section “Special Operating Instructions” of SYNAPSE.

Bend and cut OC-connector

- Contour the rod portion of the OC-connector using the bending pliers to match the curve of the trial rod established in step “Contour trial rod” of step “Occipito-cervical fixation with occipital clamps” in the section “Special Operating Instructions” of OC FUSION.
- The bending pliers can be used for both rods \varnothing 3.5 mm and \varnothing 4.0 mm.
- Cut the rod with the cutting pliers to the appropriate length.

Attach occipital clamp to OC-connector

- Provisionally attach the occipital clamp to the OC-connector by tightening the set screw in the clamp.
- The holding forceps can be used for both rods \varnothing 3.5 mm and \varnothing 4.0 mm.

Insert locking screw for transverse connectors

- Insert a locking screw for transverse connectors into the upper most screw and fully tighten using the screwdriver shaft and the 2.0 Nm torque limiting handle.
- Turn the 2.0 Nm torque limiting handle until it clicks.
- The rod introduction instrument may be used in place of the rod pusher to lock the construct.

Insert the OC-connector onto locking screw for transverse connectors

- Turn the torque limiter handle until it clicks once.
- Place the loop portion of the OC-connector over the locking screw for transverse connectors using the holding forceps.

Insert occipital clamp

- Follow steps “Drill pilot hole”, “Measure hole depth”, “Tap”, “Insert screw”, “Insert remaining screws and clamps”, “Insert second rod and remaining clamps and screws” and “Final tightening” of step “Occipito-cervical fixation with occipital clamps” in the section “Special Operating Instructions” of OC FUSION.

Insert cap nut for transverse connectors and lock construct

- Select and place the cap nut onto the locking screw using the torque limiter 2.5 Nm. To provide alignment, insert the Stardrive screwdriver shaft and the handle with torque limiter into the cannula of the torque limiter 2.5 Nm and engage the T15 recess. Loosely thread the locking nut onto the locking screw.
- Firmly tighten the cap nut using the torque limiter 2.5 Nm for cap nuts. Turn the handle until it clicks once. The screwdriver shaft Stardrive for torque limiter and the handle with quick coupling can be used as counter torque.

Insert OC-connector on contralateral side

- Repeat steps “Bend and cut OC-connector”, “Attach occipital clamp to OC-connector”, “Insert locking screw for transverse connectors”, “Insert the OC-connector onto locking screw for transverse connectors”, “Insert occipital clamp” and “Insert cap nut for transverse connectors and lock construct” of step “Optional technique: Using OC-connector top loading with occipital clamps” in the section “Special Operating Instructions” of OC FUSION.

Disposal

Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Implant Card & Patient Information Leaflet

If supplied with the original packaging, provide the implant card as well as the relevant information according to the patient information leaflet to the patient. The electronic file containing the patient information can be found at the following link: ic.jnjmedicaldevices.com



Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
www.jnjmedtech.com

Instructions for Use:
www.e-ifu.com