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.

Manuals are subject to change;
the most current version of each manual is always available online.
Printed on: Sep 21, 2021

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE
0123

 SE_528362 AE 07/2021

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.

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

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.
- Implantation is to take place with 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.

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
	∅ 4.0 mm/∅ 6.0 mm		X
Polyaxial Screws	∅ 3.5 mm Cancellous Screws	X	X
	∅ 4.0 mm Cancellous Screws	X	X
	∅ 4.5 mm Cancellous Screws	X	X
	∅ 3.5 mm Cortex Shaft Screws	X	X
Hooks	Side loading Lamina hooks	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.

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, and 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. Do not use if the package is damaged.

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
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 ∅ 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 countertorque.

– 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.

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.

CE
0123

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

Instructions for Use:
www.e-ifu.com