Instructions for Use
Connecting Rods

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.

EC REP

Authorised Representative

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork Ireland

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

Connecting Rods
Connecting Rods are solid rods made of Titanium, Titanium alloy or Cobalt-Chromium-Molybdenum Alloy. Each end of the rod has a fixed diameter to connect one posterior stabilization system with another. These devices have a soft taper in the middle of the rod to form diameter transition.

Connecting Rods are used as part of a qualified posterior spinal stabilization construct. Posterior spinal stabilization systems are pedicle screw, hook and rod systems that form constructs which attach to either the thoracolumbar or cervical spine.
Connecting Rods are offered in two lengths (300 mm and 500 mm) and in different diameters.

These instructions for use contain information about the following products:

04.614.509	04.633.188S
04.614.509S	04.633.190
04.614.510	04.633.190S
04.614.510S	04.633.191
04.614.511	04.633.191S
04.614.511S	09.633.187
04.614.512	09.633.187S
04.614.512S	498.936
04.615.510S	498.936S
04.615.511S	498.937
04.615.512S	498.937S
04.615.515S	498.938
04.615.516S	498.938S
04.633.187	498.939
04.633.187S	498.939S
04.633.188	498.944

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
Cobalt-Chromium-Molybdenum Alloy: CoCrMo (Cobalt – 28% Chromium – 6% Molybdenum) according to ISO 5832-12

Intended Use
Connecting Rods are intended to facilitate the connection of qualified posterior spinal stabilization systems together.

Note: For use of the Connecting Rods in conjunction with the qualified posterior spinal stabilization systems; please refer to the corresponding instructions for use for specific information on its intended use, indications, contraindications, patient target group, warnings, and precautions, potential adverse events, undesirable side effects and residual risks.

Indications/Contraindications
Connecting Rods are used in conjunction with qualified posterior spinal stabilization systems; please refer to the corresponding instructions for use for specific information on its indications and contraindications.

Patient Target Group/Performance Characteristics of the Device
Connecting Rods are used in conjunction with qualified posterior spinal stabilization systems; please refer to the corresponding instructions for use for specific information on its patient target group and Performance Characteristics.

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
Connecting Rods are used in conjunction with qualified posterior spinal stabilization systems; please refer to the corresponding instructions for use for specific information on its Expected Clinical Benefits.

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

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; 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, implant breakage, loosening or migration; malunion, non-union or delayed union; decrease in bone density due to stress shielding; adjacent segment degeneration; ongoing pain or neurological symptoms; damage to adjacent bones, organs, discs, or other soft tissues; dural tear or spinal fluid leak; spinal cord compression and/or contusion; displacement of the graft material; 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 Connecting Rods (as part of the posterior spinal stabilization construct) is 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 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.
- The Connecting Rods are an addition to the qualified posterior spinal stabilization systems below in section "Combination of Medical Devices". Be aware that you need both, the implants and instruments of all qualified posterior spinal stabilization systems that will be used to perform the procedure.
- Ensure the matching Connecting Rod diameters are used with the corresponding implants of posterior spinal stabilization system.
- Connecting Rods with Cobalt-Chromium-Molybdenum Alloy (Co-Cr-Mo) material are not intended to connect to the EXPEDIUM™ Spine System.
- Warning. Allergic reactions to implant materials (e.g. Titanium Alloy, Titanium, Cobalt-Chromium-Molybdenum Alloy).
- For use of the Connecting Rods in conjunction with the qualified posterior spinal stabilization systems; please refer to the corresponding instructions for use for specific information on its warnings and precautions.

For more information, please refer to the Synthes brochure "Important Information".

Combination of Medical Devices
The Connecting Rods are an addition to the qualified posterior spinal stabilization systems below. Be aware that you need both, the implants and instruments of all qualified posterior spinal stabilization systems that will be used to perform the procedure.

Ensure the matching Connecting Rod diameters are used with the corresponding implants of posterior spinal stabilization system.

Overview of posterior qualified spinal stabilization systems:

Posterior Spinal Stabilization System	Rod Diameter (mm)
SYNAPSE™ System and OC FUSION System	3.5/4.0
MATRIX Spine System	5.5
USS™	5.0/6.0
EXPEDIUM Spine System	5.5

Only the specific use of the Connecting Rods with the EXPEDIUM Spine System in conjunction with the SYNAPSE System is has been assessed. Connecting Rods with Cobalt-Chromium-Molybdenum Alloy (Co-Cr-Mo) material are not intended to connect to the EXPEDIUM Spine System.

For use of the Connecting Rods in conjunction with the qualified posterior spinal stabilization systems; please refer to the corresponding instructions for use for specific information on Combination of Medical Devices.

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 a Connecting Rod construct with Synthes Posterior Spinal Stabilization Systems is 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 1.5 W/kg for 15 minutes of scanning.

Based on non-clinical testing, a Connecting Rod construct with Synthes Posterior Spinal Stabilization Systems will produce a temperature rise not greater than 5.7 °C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 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 implant.

For information on the use of a Connecting Rod construct with EXPEDIUM Spine System in a MR environment, please refer to the EXPEDIUM Spine System instructions for use for specific information.

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 Connecting Rod (as part of the posterior spinal stabilization construct) implant 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.

For use of the Connecting Rods in conjunction with the qualified posterior spinal stabilization systems; please refer to the corresponding instructions for use for specific information on Implant Removal.

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.

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

Instructions for Use:
www.e-ifu.com