Instructions for Use
XRL® Vertebral Body Replacement Device

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

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each manual is always available online.
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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

XRL® Vertebral Body Replacement Device
The XRL implants are expandable vertebral body replacement devices designed for use in the thoracic and lumbar region of the spine. The XRL implant can be packed with bone graft material.

The XRL modular implant is assembled before implantation and consists of five components; one central body (spacer), two endplates and two endplate screws. The central body is available in modular and integrated options. A cranial and caudal endplate are attached with endplate screws onto the XRL modular central body. The integrated XRL implants require no assembly.

The XRL implants are available in different footprints and angles, allowing the implant to be assembled as a spinal construct.

These instructions for use contain information about the following products:

08.807.200.02S	08.807.211S	08.807.233S
08.807.201S	08.807.212S	08.807.234S
08.807.202S	08.807.213S	08.807.235S
08.807.203S	08.807.214S	08.807.236S
08.807.204S	08.807.215S	08.807.241S
08.807.205S	08.807.221S	08.807.242S
08.807.206S	08.807.222S	08.807.243S
08.807.207S	08.807.223S	08.807.244S
08.807.208S	08.807.224S	08.807.245S
08.807.209S	08.807.231S	08.807.246S
08.807.210S	08.807.232S	

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
PEEK: Polyetheretherketone according to ASTM F 2026
Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium) according to ISO 5832-11
Tantalum according to ISO 13782, ASTM F 560

Intended Use
The XRL implants are intended for use as vertebral body replacement devices in the thoracic and lumbar spine (T3-L5) in skeletally mature patients.
Depending on the patient's pathology, XRL implants can be used for one and two vertebral level fusions.
XRL implants must be used with supplemental internal fixation.

Indications
– Traumatic fractures with destruction of the vertebral body
– Replacement of vertebral bodies due to tumor resection

Contraindications
– Poor bone quality in which adequate anterior support cannot be established
– Multilevel metastatic destruction of the spine
– Absence of intact neighboring segments
– Active systemic infection

Patient Target Group
The XRL implants 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 XRL implants are used as intended and according to the instructions for use and labeling, they are expected to provide maintenance or improvement of patient function and/or relief of pain.

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 XRL implants are vertebral body replacement devices, designed to provide anterior and middle spinal column support when used with supplemental fixation.

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; device or graft material displacement; 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.

Do not resterilize

Resterilization of the device can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

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 XRL implant 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 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.
- The components of this device are manufactured from PEEK, titanium alloy and tantalum. For metallurgical, mechanical, and functional reasons, devices other than the provided components (e.g., supplemental fixation) should not contact the XRL construct if made from materials not listed here. Also, mixing titanium or titanium alloy with stainless steel implant components is not recommended for metallurgical, mechanical and functional reasons.
- Excessive strain by patient prior to sufficient bone bridge formation can lead to implant failure.

Perform corpectomy
Perform a partial or complete corpectomy as required.
- Excessive tissue debridement and the removal of dense bone may weaken the endplate and therefore impair the seating of the XRL implant, potentially resulting in subsidence.

Insert trial implant
Select endplate footprint size and angle.
- Make sure that the endplate trial contacts the maximum area of the neighboring vertebral bodies but do not project over the edge.

Determine central body size
The central body height is calculated using endplate trial.
- The trials are not for implantation and must be removed before insertion of the XRL implant. Total construct angle must not exceed 30° lordosis/kyphosis.

Insert trial
Using the implant holder, insert the trial into the corpectomy site.
- Do not excessively impact on trial implants and or implant holder. Use light impaction only.

Implantation
Assemble implant
Select implant based on corresponding trial.
- When pressing on the endplates, ensure the endplate properly seats on the central body. This can be checked visually. If the endplate is not properly seated, there is a risk that it could detach from the central body (see Fig. 1).
- The XRL central body must never be implanted without cranial and caudal endplates properly secured with endplate screws.

Reposition endplates
- Endplates release from central body abruptly. Make sure to have a firm grip on both the central body and the endplate during removal.

Prepare implant
Prior to implanting, use the graft packing preparation tamp to facilitate packing of bone graft material into the XRL implant.
- DO NOT pack graft into the locking ring. DO NOT use excessive force while packing graft. DO NOT pack graft while implant is loaded onto the spreader.

Insert implant
- Do not adjust spreader handle when ratchet lever is set to "ON". This will result in premature distraction of the implant. Do not insert the implant into corpectomy until spreader handle is locked into desired position.
- Do not impact on spreader or implant. Do not manipulate implant unless both the slot and notch are engaged.

Distract and check position
- Do not reposition spreader handle during or after distraction. Do not impact on the XRL spreader or implant when repositioning the implant. Be sure to apply constant clockwise torque when switching the ratchet lever to "OFF". Else, the T-driver may release abruptly.
- Distraction of the implant is only permitted with the XRL instrument set.

Reposition implant
- Do not impact on the XRL spreader or implant when repositioning the implant. Be sure to apply constant clockwise torque when switching the ratchet lever to "OFF". Else, the T-driver may release abruptly.
- Repositioning of the implant is only permitted with the XRL Instrument set.

Verify lock
- Locking ring must be properly closed to ensure final implant height is maintained.

Supplemental fixation
Apply bone graft material
- Do not use excessive force while packing graft.

Apply internal fixation system
- Take care when applying supplemental fixation that the superior and inferior vertebral body endplates remain fixed. Manipulation of vertebral bodies may cause the XRL implant to shift in the wound possibly resulting in a need to reposition the implant.

Implant removal
- Do not impact on the XRL spreader or implant when removing the implant. Be sure to apply constant clockwise torque when switching the ratchet lever to "OFF". Else, the T-driver may release abruptly.
- Removing of the implant is only permitted with the XRL Instrument set.

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

Combination of Medical Devices
The XRL implants are applied using associated XRL Instrumentation.

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 XRL are MR conditional. These articles can be scanned safely under the following conditions:
- Static magnetic field of 1.5 Tesla and 3 Tesla.
- Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
- Maximum whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the XRL implant will produce a temperature rise not greater than 4.1 °C at a maximum whole body averaged specific absorption rate (SAR) of 4 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3 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 XRL 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 by visual inspection:
- Inspect the entire area of sterile barrier package, and the sealing, for completeness and uniformity.
- Inspect for the absence of holes, channels or voids of the sterile barrier package and the sealing.

Do not use if the package is damaged or expired.

Implant 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.
If a XRL implant has to be removed, the following technique is recommended:
– Assemble spreader instrument
– To remove the implant, fully collapse the spreader top and set the ratchet lever to the "OFF" position.
– Be sure the release tool is removed or disengaged and set to the resting position.
– Slide the spreader top into the slots below the cranial endplate. Set ratchet lever to "ON" and turn the T-driver clockwise until spreader engages the notch on the implant for a secure hold. Fully insert the release tool.
– With constant clockwise torque on the T-driver, set the ratchet lever to "OFF" position and compress the implant by turning the T-driver counterclockwise.
– Remove the implant.

Please note that precautions/warnings related to implant removal are listed in section "Warnings and Precautions".

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.

Special Operating Instructions
Selection
The selected endplate size should provide the widest support of the neighboring vertebral bodies. Make sure that the endplates of the implant do not project in any direction beyond the endplates of the neighboring vertebral bodies. This could cause serious vascular or neurological damage.

The angle of the endplate should correspond to the anatomy and pathology of the respective patient. A wrong angle or size could cause the implant to subside into the bone, or prevent a successful correction.

Make sure that the central body is expanded with the corresponding spreader top.

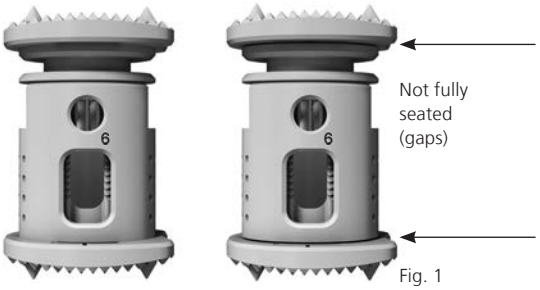

Fig. 1

Mounting
When mounting the endplates, observe the following:
– The access to release the locking ring in the central body has to face the direction of the desired approach.
– Ensure that both endplates are in the same direction.

Implantation
Observe the following points when using the XRL implant:
– With the locking ring facing the instrument, slide the spreader top into the slots below the cranial endplate. Do not force spreader top onto implant. Slightly turn the T-driver clockwise until the detent on the fork of the spreader shaft engages the implant for a secure hold. Set the scale to zero.
– Completely insert the release tool through the XRL spreader and into the locking ring.
– The central body must not be excessively expanded. Otherwise the danger exists that the implant may be pressed into the neighboring vertebral body.
– When the implant is in its final position, verify the locking ring on the central body is closed. When the slot is approximately 1 mm (Fig. 2), the implant is locked and secured. If the slot is larger (Fig. 3), re-engage the implant with the spreader, and with the release tool disengaged, distract the implant slightly to close the locking ring.
– Check the implant for proper alignment after implantation.

Fig. 2

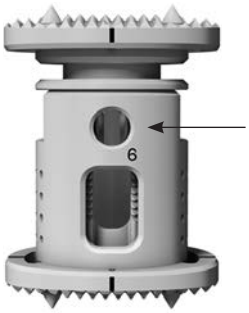

Fig. 3

Implant Card & Patient Information Leaflet
If available, 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

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