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.
Printed on: Nov 03, 2023

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE
0123

SE_479332 AF 08/2023

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.

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

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 and/or handled by qualified health care professionals who are experienced in spinal surgery, 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 as per 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 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 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.
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.

Implant Removal
The XRL 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.
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.

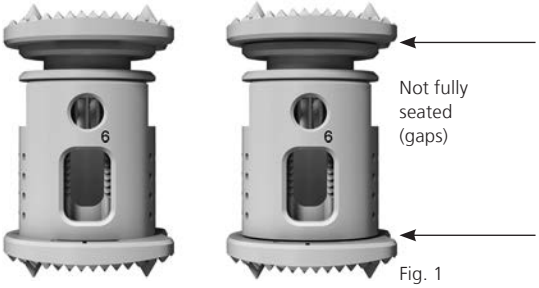

Fig. 1

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

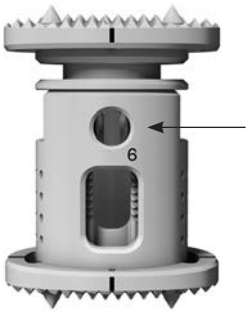

Fig. 3

Surgical Procedural steps:

Preparation
Access
– Various approaches are suitable depending on the affected spinal level involved.
– The following technique is described using a lateral approach from the left at L1. As with all vertebral body replacement systems, preoperative planning is always required to ascertain that the implant matches the patient specific anatomy.
– The desired approach respecting the patient specific situation has to be established by the surgeon.

Perform corpectomy
– Perform a partial or complete corpectomy as required. Remove the superficial layers of the entire cartilaginous endplates and expose bleeding bone.

Trial implant selection and insertion
– The XRL vertebral body replacement contains a complete line of central body and endplate trials that correspond to each central body and endplate implant. Trials are placed into the corpectomy site intraoperatively to determine the appropriate implant footprint, lordotic/kyphotic angle and central body height.
– Use the central body and endplate trials to determine the largest implant size (integrated or modular) that will fit the corpectomy site. Trials may be secured and lowered into corpectomy defect using the implant holder. Allow 1 mm clearance on each end for the tall spikes on the endplates (modular only).

Determine defect size
– The metal tape gauge can be used to determine the overall defect size.
– If the corpectomy height is less than 34 mm, then proceed to step "Insert trial" step and use the integrated trials.

Select endplate footprint size and angle
– The endplate footprint trial can be adjusted to represent the desired approach. Pull the sleeve and turn the endplate trial to the desired position. Release the sleeve to lock the position of the trial.
– Determine the footprint using the endplate footprint trial. Determine the angle using lateral x-ray imaging.

Determine central body size
– The central body height is calculated using endplate trial height which is found on the back of the module lid for reference. The trials do not account for the implant spikes; therefore, 1 mm clearance on each end of the trial is required.
– Central Body Height (CBH) = Overall defect – Cranial trial endplate height – Caudal trial endplate height – Clearance for spikes
– Example for 46 mm defect with a 5° cranial endplate and 10° caudal endplate: CBH = 46 mm–6.5 mm–8.5 mm–2 mm = 29 mm
– Insert the selected trial endplates onto the trial central body. Align the etch lines before pressing the components together. Ensure there is no gap between the endplate and central body trial.
– The endplate height is independent of the footprint and of the endplate (cranial/caudal).
– See section "Cross Reference List" for endplate and central body cross reference list.

Insert trial
- Using the implant holder, insert the trial into the corpectomy site. Be sure the appropriate endplate is oriented in the cranial/caudal position and the etch lines on the trial are facing anterior. Position the trial centered on the vertebral bodies with clearance to account for the implant spikes. Trials must always be securely held while in the wound.
- Integrated implants do not have tall spikes and therefore the integrated trials are the same height as the corresponding collapsed implant.
- Change trial central body and endplates as necessary to achieve the desired height, angle, and footprint.

Implantation
Assemble implant
- Select implant based on corresponding trial.
- If an integrated assembly is selected, skip to step "Prepare implant".
- The endplate assembly fixture is found in the trial end-plate module. When assembling the implant, orient the caudal endplate into the endplate assembly fixture spike side down, aligning the "A" (Anterior) on the endplate with the "A" on the endplate assembly fixture. Position the central body with the locking ring facing the direction of the desired approach. Attach the caudal endplate first by pressing the endplate onto the octagon until fully seated. Repeat with the cranial endplate.
- The etch lines on the ends of the central body, the graft window, and the locking ring may all be used to indicate the direction of approach.
- The etch line on the anterior aspect of the endplate ensures that both endplates are in the same direction.

Reposition endplates (optional) instrument
- If necessary, the endplates can be repositioned by manually removing them from the central body, except for the round endplates which are removed using the XRL endplate removal tool. Be sure to perform endplate removal over a sterile table.
- To remove round endplates, align the tip of the XRL endplate removal tool with the slot in the endplate. Apply a slight, constant pressure and rotate the tool to release the endplate.

Attach endplate screws
- Align the endplate screwdriver tip into the open end of the torque limiting handle.
- Press until an audible "click" is heard.
- Align the tri-lobal feature of the tip and the etchings on the endplate screw. Lightly press the screw onto the screwdriver tip. The screwdriver tip will retain the screw.
- Align the torque limiting handle with the central body to prevent cross threading. While gripping the large end of the torque limiting handle, rotate the torque limiting handle clockwise to advance the screw through the caudal endplate and into the central body. Tighten until an audible "click" in the torque limiting handle is heard. Repeat this step to fixate the cranial endplate.
- Follow torque limiting handle calibration instructions to ensure proper functionality.

Prepare implant
- Prior to implanting, use the graft packing preparation tamp to facilitate packing of bone graft into the XRL implant. Graft can be packed through the cannulation in the endplate and graft windows.

Assemble spreader instrument
- Assemble the appropriate size spreader top to the XRL spreader according to the implant central body size selected (see section "Determine central body size" for trial/implant list for cross reference list). The spreader tops are designed to prevent over-distracting the implant.
- While holding the spreader with the shaft in the horizontal position, set ratchet lever to the "OFF" position.
- Press T-driver release button and pull back on the T-driver. Release the button to set T-driver in the open position. T-driver should not be fully removed during this operation.
- Insert the selected spreader top into the spreader shaft and insert the T-driver by gently pushing and turning the T-driver into the spreader assembly.
- Check functionality of the spreader top by rotating the T-driver. If properly assembled, the spreader top should translate during T-driver rotation, and the T-driver will remain retained by the spreader assembly.

Secure implant to spreader
- To load the implant, fully collapse the spreader top and set the ratchet lever to the "OFF" position.
- With the opening of the locking ring facing the instrument, slide the spreader top into the slots below the cranial endplate. Do not force the spreader top onto the implant. Set the ratchet lever "ON" and slightly turn the T-driver clockwise until the spreader shaft engages the notch on the implant for a secure hold. Verify the implant is secured over the sterile field.
- Set the scale to zero.
- Completely insert the release tool through the XRL spreader and into the locking ring.

Insert implant
- Prior to inserting the implant the spreader handle can be rotated at 90° increments to aid in visualization. Set ratchet lever to "OFF" position. With one hand gripping the spreader shaft, pull back on retaining collar and rotate the spreader handle to the desired position. Release retaining collar. Verify that the spreader handle is locked into position. Reset scale to zero.
- Guide and position the implant with the spreader. Slight distraction of the vertebral bodies may be necessary to ease insertion.
- Position the implant in the center of the vertebral body endplate. Maintain space around the endplate of the implant to allow peripheral bony fusion.
- Verify the position of the implant using the image intensifier.
  - Tantalum markers and a titanium locking ring is used to determine orientation of the implant.
  - The 1 mm diameter tantalum markers are embedded into the PEEK endplates to provide radiographic markers for intraoperative or postoperative imaging.
  - The anterior and medial/lateral markers are located approximately 1 mm from the edges of the implant. The posterior marker is located 1 mm from the edge of the round implant, and 2 mm from the edge of the anatomically shaped endplates. The cranial/caudal locations of the markers are 2 mm from the end of the pyramidal teeth.

Distract and check position
- Ensure the release tool is engaged and the ratchet lever is set to the "ON" position, then turn the spreader T-driver clockwise and expand the implant until the desired amount of distraction is achieved.
- Once the implant has been distracted, fully remove the release tool, and with constant clockwise torque on the T-driver, place the ratchet lever in the "OFF" position.
- The release tool may also be set in the resting position instead of being fully removed from the spreader. Pull up on the release tool until it travels ~15 mm and it will be retained by the spreader in the resting position.
- Before removing the spreader, verify the locking ring is properly closed by collapsing the spreader top and visually inspecting the slot through the spreader top. When the slot is approximately 1 mm, the implant is locked and secured. If the slot is larger, re-expand the spreader top and distract the implant slightly to close the locking ring. If implant remains unlocked, follow step "Reposition implant (optional)". If the locking ring is not visible, inspect lock after spreader is removed (see step "Verify lock"). Remove the spreader from the implant by setting the ratchet lever to "OFF" and turning the T-driver counterclockwise. When spreader top is fully collapsed, the spreader can be removed.
- Visually inspect implant/vertebral body interface for gaps to prevent point loading. If a gap is found, repositioning (see step "Reposition implant (optional)") is necessary to ensure full endplate surface contact.
- Verify the position of the implant using the image intensifier. The stop pin can be used to approximate the amount of distraction available. When stop pin is within 1 mm of the locking ring, the implant is fully expanded.

Reposition implant (optional)
- To reposition 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. Reposition the implant to the desired location and follow step "Distract and check position" to re-distract implant.

Verify lock
- 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, the implant is locked and secured. If the slot is larger, re-engage the implant with the spreader, with the ratchet lever in the "OFF" position, and with the release tool fully removed, distract the implant slightly to close the locking ring. If implant remains unlocked, repeat step "Reposition implant (optional)" and verify locking ring is closed.

Supplemental Fixation
Apply bone graft material
- In situ graft packing must not occur until final implant position is achieved, as additional bone graft may obstruct repositioning of the implant.
- Before packing additional bone graft in or around the cage, use anteroposterior (AP) and lateral radiographs to verify the position of the implant in relation to the vertebral bodies using the tantalum markers and locking ring for references.
- The graft packing tamp has two different ends to fit the corresponding window of the expanded central body. The preparation tamp has an angled end that can be used to gain compression on graft that is not accessible with the graft packing tamp.
- Graft packing tamp will not fit inside the window of integrated implant, however, can still be used to tamp graft material.

Apply internal fixation system
- For spinal stability and to maintain adequate compression on the construct, XRL must be used with an internal fixation system.

Cross Reference List

Endplate angle (°)	–10	–5	0	5	10	15
Endplate height (mm)	8.5	6.5	5	6.5	8.5	10.5

Central Body Number	Central Body Height (mm)	Distraction Range (mm)	Spreader Top
1*	22*	3	1
2*	24	5	2
3*	28	8	3
4	22	5	6
5	25	8	3
6	29	10	4
7	33	10	4
8	37	15	5
9	44	15	5
10	51	15	5
11	62	15	5
12	73	15	5
13	84	15	5
14	95	15	5
15	106	15	5

*Integrated assembly, no endplates needed

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

Additional Device-Specific Information
XRL is intended to restore the integrity of the spinal column in the absence of fusion in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to achieve fusion. Bone graft material may be used at the surgeon's discretion, understanding that no spinal implant can withstand physiologic loads indefinitely in the absence of bony fusion. An assessment of the benefits of such a palliative surgery versus the surgical risks, including those of implant failure, must be undertaken as a part of preoperative informed consent and planning between the surgeon and patient.

CE
0123

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

Instructions for Use:
www.e-ifu.com