Instructions for Use
ORACLE Cage

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
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Instructions for Use

ORACLE Cage
The ORACLE Cage implants are intervertebral body fusion devices designed for use in the lumbar region of the spine. The cages are inserted within the intervertebral disc space to provide stability. The cages are made from PEEK and include four radiopaque markers, and a central canal that can accept bone graft material.

The cages are offered in multiple footprints and sagittal profiles to accommodate ranges in patient anatomy.

These instructions for use contain information about the following products:

08.809.209S	08.809.257S	08.809.635S
08.809.211S	08.809.269S	08.809.637S
08.809.213S	08.809.271S	08.809.649S
08.809.215S	08.809.273S	08.809.651S
08.809.217S	08.809.275S	08.809.653S
08.809.229S	08.809.277S	08.809.655S
08.809.231S	08.809.609S	08.809.657S
08.809.233S	08.809.611S	08.809.669S
08.809.235S	08.809.613S	08.809.671S
08.809.237S	08.809.615S	08.809.673S
08.809.249S	08.809.617S	08.809.675S
08.809.251S	08.809.629S	08.809.677S
08.809.253S	08.809.631S	
08.809.255S	08.809.633S	

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

Intended Use
The ORACLE implants are intended for use as intervertebral body fusion devices in skeletally mature patients with degenerative disease of the lumbar spine (L1-L5). The ORACLE implants are designed for a lateral approach.

Indications
The ORACLE implants are indicated for degenerative spine disease.

Important: ORACLE implants must be applied in combination with supplemental fixation.

Contraindications
– Vertebral body fractures
– Spinal tumours
– Major spinal instabilities
– Primary spinal deformities
– Osteoporosis

Patient Target Group
The ORACLE 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 ORACLE implants are used as intended and according to the instructions for use and labeling, these devices provide stabilization of the motion segment(s) after intervertebral disc removal as an adjunct to fusion, which is expected to provide relief of back and/or leg pain caused by degenerative conditions of the spine.

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 ORACLE implants are intervertebral body fusion devices, designed to provide stability at the motion segment(s) prior 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; death; swelling, abnormal wound healing or scar formation; heterotopic ossification; functional impairment of the musculoskeletal system; paralysis (temporary or permanent); 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, discs, organs, 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 ORACLE Cage 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.
- Preoperative planning (MRI, CT, X-ray, etc) to determine patient specific and pathological factors relevant to the success of the surgery (including location and orientation of the vascular structures in the vicinity of the operating site) is highly recommended.
- Neuromonitoring may be optionally used throughout the surgery.
- Confirm that the cage construct is in an appropriate position (in anteroposterior [AP] and Lateral fluoroscopy) prior to and during cage placement so that cage insertion does not cause posterior or anterior structure damage.
- Do not use the ORACLE Cage in cases where the anterior blood vessels or their branches (bifurcation) are in the vicinity of the lateral access to the operation site.

Patient positioning
Place the patient in a lateral decubitus position and secure the patient to the table.
- Prevent undue pressure points when positioning and securing the patient.
- If neuromonitoring is planned, the neurophysiologist or neuromonitoring technician should make sure all appropriate electrodes have been applied to the patient prior to patient positioning.

Access and exposure
Approach spine with tissue dissector
- Map out a safe corridor through the psoas muscle to the lumbar spine. Fluoroscopy is recommended to target the anterior two-thirds of the disc space of concern. The anterior third of the psoas muscle is the most likely safe zone for avoiding the neural elements of the lumbar plexus.
- Consider using a blunt tipped probe, like a Penfield 4, to confirm disc and bone beneath the psoas with adequate distance from the aorta.
- Ensure the Kirschner wire remains securely in position during these steps.
- Monitor the tip of the Kirschner wire under fluoroscopy to ensure it does not penetrate the contralateral wall of the vertebral body.

Approach spine with dilators
- Ensure the Kirschner wire remains securely in position during these steps.
- Monitor the tip of the Kirschner wire under fluoroscopy to ensure it does not penetrate the contralateral wall of the vertebral body.

Soft tissue retraction (Retraction with SYNFRAME)
- Careful positioning of the retractors is required to reduce soft tissue damage.

Soft tissue retraction (Retraction with ORACLE access instruments)
- Do not over-tighten the screwdriver. Two finger tightening is sufficient to secure the blades to the retractor handle.
- The third blade should not be placed much beyond the posterior 1/3 margin of the disc space to avoid any neural structures.
- If neuromonitoring is used, stimulate the exposed area to check that the surgical field is free of nerve structures.
- Do not stimulate against the retractor.
- Prior to intradiscal anchor and/or retractor pin placement, both lateral and anterior-posterior fluoroscopy should be performed to confirm that the retractor is safely placed for such instrument insertion.

Discectomy
- Excessive tissue debridement and the removal of dense bone may weaken the endplate and therefore impair the seating of the implant, potentially resulting in subsidence.
- In order to prevent any risk of damaging vital structures, it is recommended to keep intact a few millimeters of the annulus on both anterior and posterior sides.
- In order to prevent weakening of bony structures, any damage to the vertebral endplates caused by curettes, shavers and/or spreaders must be avoided.
- Do not damage major vascular structures, nerve roots, the lumbar plexus and/or the spinal cord.
- The anterior and posterior longitudinal ligaments (ALL and PLL) must stay intact in all cases.
- Avoid over distraction in order to prevent damage to the soft tissue structures.
- Turn the spreader clockwise by a quarter turn to distract the segment. Turn the spreader counterclockwise for removal. Turning the spreader in the wrong direction may cause damage to the bony structures.

Prepare endplates
- Excessive tissue debridement and the removal of dense bone may weaken the endplate and therefore impair the seating of the implant, potentially resulting in subsidence.

Insert implant (Insertion with lateral quick inserter distractor)
- Do not impact on the lateral quick inserter distractor. The instrument is designed to leave the implant 1 mm proud to the proximal aspect of the vertebral bodies. Depending on surgeon preference of final implant position, the surgeon may choose to use the Oracle impactor to seat the implant in its desired position (i.e., flush or recessed).

Implant removal
- The implant may be difficult to remove due to the surface roughness and the position of the cage. If the implant has been inserted past the epiphyseal ring, it may be more difficult to remove, and additional distraction may be required.

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

Combination of Medical Devices
The ORACLE Cage implants are applied using associated ORACLE Cage 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 ORACLE Cage 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 4 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the ORACLE Cage implant with standard screws will produce a temperature rise not greater than 4.0°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 3.0 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 ORACLE Cage 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
The ORACLE Cage 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 an ORACLE cage implant must be removed, the following technique is recommended:
- Attach the ORACLE implant remover to the implant
- Remove the implant

Optional:
Controlled and light hammering on the ORACLE implant remover may be required to remove the implant out of the intervertebral disc space with the ORACLE slide hammer:
- Slide the ORACLE slide hammer onto the end of the ORACLE implant remover with quick coupling.
- While holding the ORACLE implant remover with one hand, apply an upward force to the ORACLE slide hammer with the other hand.
- Repeat this process until the implant is removed.

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.

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

Instructions for Use:
www.e-ifu.com