Instructions for Use
ORACLE™ Cage

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

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: Nov 09, 2016

DePuy Synthes
COMPANIES OF Johnson&Johnson

CE
0123

 SE_528809 AC 03/2016

Instructions for Use

ORACLE™ Cage
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material

Material:	Standard:
PEEK	ASTM F 2026
TAN	ISO 5832-11

Intended use
The ORACLE Cage is intended to replace lumbar intervertebral discs and to fuse the adjacent vertebral bodies together at vertebral levels L1 to L5. Additionally, the use of autogenous bone or bone graft substitute as well as supplemental fixation is always recommended. ORACLE implants are inserted via the lateral approach.

Indications
Lumbar pathologies with indicated segmental spondylodesis,
e.g.:
– Degenerative disc diseases and spinal instabilities
– Revision procedures for post-discectomy syndrome
– Pseudoarthrosis or failed spondylodesis
– Degenerative spondylolisthesis
– Isthmic spondylolisthesis

ORACLE Cage is intended to be used in combination with supplemental fixation.

Contraindications
– Vertebral body fractures
– Spinal tumors
– Major spinal instabilities
– Primary spinal deformities

Side effects
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common may include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/hypersensitivity reactions, side effects associated with implant or hardware prominence, malunion, non-union, ongoing pain; damage to adjacent bones, discs, or soft tissue, dural tear or spinal fluid leak; spinal cord compression and/or contusion, partial displacement of the graft, vertebral angulation.

Sterile device

STERILE R Sterilized using irradiation

Store implants 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.

Do not resterilize

Single-use device

Do not re-use

Products intended for single-use must not be re-used.
Re-use or 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, reuse 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.

Precautions
The general risks associated with surgery are not described in these instructions for use. For more information, please refer to the Synthes brochure "Important Information".
Confirm that the cage construct is in an appropriate position (in 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 System in cases where the anterior blood vessels or their branches (bifurcation) are in the vicinity of the lateral access to the operation site.

Warnings
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.
All required instruments (see associated surgical technique) should be available for the surgery and a vascular surgeon should be available for potential vascular related issues.
Neuromonitoring may be optionally used throughout the surgery.

It is strongly advised that ORACLE Cage is implanted only by operating surgeons who are familiar with the general problems of spinal surgery and who are able to master the product-specific surgical techniques. 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.

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 the implants of the ORACLE Cage 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 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.

CE
0123

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
Fax: +41 61 965 66 00
www.depuysynthes.com