Instructions for Use
OPAL™ Spacer System

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

Not all products are currently available in all markets.

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Instructions for Use

OPAL™ Spacer System
OPAL is a lumbar interbody cage system designed for a transforaminal approach (28 mm and 32 mm cages) or bilateral posterior approach (24 mm cages). The OPAL cages are made from PEEK and contain two titanium alloy marker pins which allows for visualization of the implant. The axial canal of the implant can be filled with bone graft or bone graft substitute.

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

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 OPAL implants are intended for use as intervertebral body fusion devices in skeletally mature patients with degenerative disease of the lumbar spine (L2-S1). The OPAL implants are designed for a transforaminal or posterior approach.

Indications
The OPAL implants are indicated for degenerative spine disease.

Important: OPAL implants must be applied in combination with posterior fixation.

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

Patient Target Group
The OPAL 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 OPAL 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 OPAL 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; 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; malunion; non-union; ongoing pain; damage to adjacent bones, discs, organs, or other soft tissues; dural tear or spinal fluid leak; spinal cord compression and/or contusion; implant loosening or breakage; device or graft material displacement; dislocation of 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.


Do not resterilize

Resterilization of OPAL 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 OPAL 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.

Preparation and discectomy
- Appropriate cleaning of the endplates is important for the vascularisation of the bone transplant.
- Excessive cleaning however can weaken the endplates by removing bone under the cartilaginous layers.
- Removal of the entire endplate can cause subsidence and lead to loss of segmental stability.

Trial insertion
- The insert and rotate technique can only be used for sizes 10 mm–15 mm. For all other sizes, use the impact technique.

Pack implant with bone graft or bone graft substitute
– The implant holder must be firmly attached to the implant in order to avoid damage to the implant and/or implant holder.
– The 24 mm implant must be packed manually.

Implant insertion
– The insert and rotate technique can only be used for sizes 10 mm–15 mm. For all other sizes, use the impact technique.

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

Combination of Medical Devices
The OPAL cages are applied using associated OPAL 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 OPAL 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 OPAL 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 OPAL 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. Do not use if the package is damaged.

Implant Removal
If an OPAL implant must be removed, the following technique is recommended.

Implant removal with the implant holder
– The implant holder must be assembled before removal of the cage.
– Attach implant to implant holder in the correct cranial/caudal alignment.
– Turn the knob at the distal end of the implant holder counterclockwise to open the jaws.
– Place the jaws over the posterior end of the cage making sure that the jaw's base is firmly seated against the implant.
– Turn the knob on the end of the implant holder clockwise until the jaws of the implant holder have a tight grip on the cage.
– For the Opal Implant Holder, with Pistol Grip: Rotate the implant holder 90° counterclockwise so that the main graft window of the cage is oriented in the cranial/caudal direction.
– Carefully remove the implant from the disc space.

Note: Distraction of the segment may facilitate implant removal. However, if possible, do not distract before ensuring a firm connection between the implant and the applicator.

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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Instructions for Use:
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