
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.

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 material.

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

These instructions for use contain information about the following products:

08.803.050S
08.803.051S
08.803.052S
08.803.053S
08.803.055S
08.803.107S
08.803.108S
08.803.109S
08.803.110S
08.803.111S
08.803.112S
08.803.113S
08.803.115S
08.803.117S
08.803.131S
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08.803.213S
08.803.215S
08.803.217S
08.803.230S
08.803.231S
08.803.232S
08.803.233S
08.803.235S

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

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
- 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; 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.

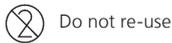
 Do not use when packaging is damaged.

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 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 disectomy

- Appropriate cleaning of the endplates is important for the vascularization 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 material

- 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.
- Excessive impaction on the implant holder must be avoided to prevent implant damage or too deep insertion.

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

Combination of Medical Devices

The OPAL cages are applied using associated OPAL Instruments.

389.767	Shaver f/Intervertebral Discs, size 7 mm
389.777	Shaver f/Intervertebral Discs, size 17 mm
394.951	T-Handle w/Quick Coupling
03.605.504	Bone Curette, 5.5 mm, bayoneted, black
03.605.505	Bone Curette, 45° angled, 5.5 mm, bayoneted
03.605.507	Rasp, dual-sided, bayoneted, black
03.605.508	Osteotome, straight, black
03.803.001	Opal Implant Holder
03.803.002	Opal Implant Holder, w/Pistol Grip
03.803.007	Trial Implant Opal, size 7 mm
03.803.008	Trial Implant Opal, size 8 mm

03.803.009	Trial Implant Opal, size 9 mm
03.803.010	Trial Implant Opal, size 10 mm
03.803.011	Trial Implant Opal, size 11 mm
03.803.012	Trial Implant Opal, size 12 mm
03.803.013	Trial Implant Opal, size 13 mm
03.803.015	Trial Implant Opal, size 15 mm
03.803.017	Trial Implant Opal, size 17 mm
03.803.054	Curette, rectangular, bayoneted, black
03.803.055	Slide Hammer w/Connector
03.803.057	Cancellous Bone Impactor OPAL
03.803.058	Packing Block OPAL, size 28 × 10 mm
03.803.059	Packing Block OPAL, size 32 × 10 mm

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 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 1.5Tesla 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 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 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.

Special Operating Instructions

Access and Exposure

Position the patient

- Position the patient in a restored physiological lordosis, avoiding abdominal restriction to reduce venous stasis.

Preparation and discectomy

- Resect the posterior anatomy and perform the discectomy. Use a transforaminal approach for insertion of 28 mm and 32 mm spacers. Use a bilateral posterior approach for insertion of 24 mm spacers.
- Use the curette to remove the disc through the incision window.
- Shavers and excision instruments for intervertebral discs can facilitate removal of the nucleus pulposus and the surface layers of the cartilaginous endplates.

Trial for Implant Size

Determine implant size: Option A (Insert and rotate technique)

- In order to rotate the trial implant in situ, extend the T-handle.
- Push the green T-handle out of handle body.
- Press and hold the button while sliding the T-handle to the end of the instrument.
- Release the button, allowing the T-handle to lock into position.
- Insert the trial implant with the etch representing the height of the trial facing the vertebral endplate.
- Gently impact on the end of the trial implant until the implant is positioned across the midline and 3 mm–4 mm from the anterior longitudinal ligament.
- The trial implant shaft should be oriented 30–45° from mid-line. When the trial implant reaches the desired depth, rotate 90° clockwise to distract and assess height adequacy.
- Repeat using the next larger size trial implant, sequentially distracting until adequate anterior height is obtained.
- With the segment fully distracted, the trial implant must fit tightly inside the disc space.
- The trial implants represent implants with a 28 mm length.
- Use fluoroscopy during the insertion to confirm positioning of the trial implant.

Determine implant size: Option B (Impact technique):

- Impact an appropriately sized trial implant with the etch representing the axial canal positioned cranial/caudal.
- Continue to impact on the end of the trial implant until the cage is positioned across the midline and 3 mm–4 mm from the anterior longitudinal ligament. The trial implant shaft should be oriented 30–45° from midline.
- Repeat using the next larger size trial implant, sequentially distracting until adequate anterior height is obtained. With the segment fully distracted, the trial implant must fit tightly inside the disc space.
- The trial implants represent implants with a 28 mm length.

Screw/rod fixation (optional)

- For the unilateral oblique posterior approach, a screw/rod construct can be placed on the contralateral side while the trial implant is still in position. Provisionally tighten the construct on the contralateral side to maintain the height in the anterior column.

Remove trial implant

- When using the insert and revolve technique, it is recommended that the trial implant be rotated 90° counterclockwise before removal.
- If removal of the trial implant requires too much force, the slide hammer can be used.
- Slide the slide hammer onto the end of the trial implant. While holding the handle of the trial implant with one hand, apply an upward force to the slide hammer with the other hand.
- Repeat this process until the trial implant is removed from the disc space.
- The slide hammer can be removed by pushing on the end of shaft.

Implantation

Prepare the implant holder

- The implant holder must be assembled before insertion of the cage.
- Attach the knob to the distal end of the implant holder sleeve by turning the knob counterclockwise.
- Insert the shaft into the sleeve making sure to align the arrows on the end of the shaft with those on the sleeve.
- Press the button on the distal end of the implant holder and push the shaft into the holder. The shaft should now be held inside the sleeve.

Select the OPAL cage

- Select a cage that corresponds to the size measured using the trial implant in the

previous steps.

- 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.

Pack implant with bone graft material

- After the cage is fixed to the implant holder, insert it into the appropriate packing block.
- It is important to fill the implant until the filling material protrudes from its perforations in order to provide contact with the vertebral endplates
- Use the cancellous bone impactor to pack the filling material into the implant cavities.

Insert OPAL cage: Option A (Insert and rotate technique)

- Use the pistol grip implant holder and the revolvable cage for this technique. Orient the cage so that the lateral graft window is facing the vertebral endplate.
- Gently impact on the end of the implant holder, until the cage is positioned across the midline and 3 mm–4 mm from the anterior longitudinal ligament. The implant holder shaft should be oriented 30–45° from midline.
- Once the cage is in position, rotate the implant holder 90° clockwise so that the main graft window of the cage is oriented in the cranial/caudal direction.
- The implant must fit tightly in order to preserve the segmental height.
- Use fluoroscopy to confirm position and fit of the implant.
- When the cage is in the desired location, hold the handle firmly and turn the knob counterclockwise on the end of the implant holder to release it.

Insert OPAL cage: Option B (Impact technique)

- Using the implant holder, orient the cage with the main graft window in the cranial/caudal direction.
- Gently impact on the distal end of the implant holder, until the cage is positioned across the midline and 3 mm–4 mm from the anterior longitudinal ligament. The implant holder shaft should be oriented 30–45° from midline.
- With the segment fully distracted, the implant must fit tightly in order to preserve the segmental height.
- Use fluoroscopy to confirm position and fit of the implant.
- When the cage is in the desired location, hold the handle firmly and turn the knob on the end of the implant holder counterclockwise to release it.

Supplemental posterior fixation

- The OPAL implants must be applied in combination with posterior fixation.

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 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

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