Instructions for Use
ZERO-P® Stand-Alone Implant

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

Not all products are currently available in all markets.

Products available non-sterile and sterile can be differentiated with the suffix "S" added to the article number for sterile products.

Manuals are subject to change;
the most current version of each manual is always available online.
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Instructions for Use

ZERO-P® Stand-Alone Implant
ZERO-P is an anterior cervical interbody fusion (ACIF) device. ZERO-P cages are available in different sizes, heights and angulations. Screws are offered in different lengths.

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
Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium) according to ISO 5832-11
PEEK: Polyetheretherketone according to ASTM F 2026
Titanium Alloy: TAV ELI (Titanium - 6% Aluminum – 4% Vanadium (Extra Low Interstitial) according to ASTM F 136

Intended Use
The ZERO-P system is intended for use in skeletally mature patients following anterior cervical discectomy for reduction and stabilization of the cervical spine (C2–C7).

Indications
– Degenerative disc disease (DDD)
– Spinal stenosis

Contraindications
– Spinal fracture
– Spinal tumor
– Severe osteoporosis
– Spinal infection

Patient Target Group
The ZERO-P system is 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 ZERO-P system is used as intended and according to the instructions for use and labeling, the device provides stabilization of the motion segment(s) after intervertebral disc removal as an adjunct to fusion, which is expected to provide relief of neck and/or arm 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 ZERO-P system is a stand-alone device for use in cervical interbody fusion, designed to combine the functionality of a cervical interbody cage with an anterior cervical plate with four cervical locking screws.

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; 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; dysphagia; 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; esophageal perforation; erosion or irritation; device or graft 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 ZERO-P 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 ZERO-P 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.

Patient positioning and exposure
– Position the patient in a supine position on a radiolucent operating table. Careful positioning of the retractor is required to protect against soft tissue damage.

Trial insertion
- After the discectomy is complete, choose a parallel, lordotic or convex trial spacer of the appropriate height and depth. The trial spacers do not have a depth limiter; an image intensifier should be used to check the position during insertion. With the segment fully distracted, the trial spacer should fit tightly between the end plates. Choose the appropriate implant footprint and size to accommodate variations in patient anatomy; failure to do so may injure the patient.
- To minimize potential risk to the patient, it is recommended to use shorter height trial spacers before using taller height trial spacers, and to use standard size footprint trial spacers before using large size footprint trial spacers.

Implant insertion
- Placement of ZERO-P adjacent to a previous, multi-level fusion could result in increased loading on the screws.
- Additional posterior supplemental fixation should be considered in cases where ZERO-P is placed adjacent to a previous, multi-level fusion.
- Do not orient ZERO-P implants having convex sagittal profiles with medial screws facing cranial.
- Orienting convex sagittal profile implants with medial screws facing cranial may prevent proper seating of the implant between vertebral bodies.
- Use the aiming device or implant holder to introduce the implant into the disc space. The aiming device and the implant holder do not have a depth limiter; therefore, an image intensifier should be used to check the position while inserting.
- Once the implant is inserted, verify final implant position relative to the vertebral bodies in the anteroposterior (AP) and lateral views and remaining implanted hardware associated with the previously fused level with the help of an intraoperative imaging. The PEEK cage has a single posterior radiopaque marker incorporated into the implant to enable intraoperative radiographic assessment of the implant position.
- Confirm that the ZERO-P implant is not placed in direct contact with implanted hardware associated with the previously fused level.
- If the ZERO-P implant remains in direct contact with hardware associated with the previously fused level, increased loading may be placed on the ZERO-P implant leading to potential post-operative device failure and potential harm to the patient.

Screw fixation
- Before drilling a hole, intraoperative imaging should be used to verify drill position.
- If adjacent hardware prevents all four screws from being implanted, a different device should be used, as increased loading may be placed on the screws leading to potential post-operative device failure and potentially increased harm to the patient.
- If any screw cannot be inserted at the correct trajectory or locked to the plate, a different device should be used to avoid the potential risk of screw back-out or screw failure.
- When awl is used instead of drill, intraoperative imaging should be used to verify awl position.
- Take care that the awl does not move the implant relative to the vertebral body. For particularly hard bone, drilling is recommended to minimize implant movement.
- When using the drill bit in combination with the aiming device, take care to apply only axial forces to the drill bit. Bending forces applied when the tip of the drill bit is engaged in the aiming device can lead to the drill bit breaking.
- While using the screwdriver, if the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.
- During screw insertion, intraoperative imaging should be used to verify screw position.
- The screws should be tightened only after all screws have been inserted.

Implant removal
- Screw loosening with the torque limiting handle may damage the torque limiting handle. Therefore, always use the standard handle for screw loosening.
- While removing screw using conical extraction screw, drilling into the screw recess with the 2.0 mm drill bit will cause metal debris. Use of suction and irrigation is recommended to remove the debris from the wound.
- Do not use the conical extraction screw with power tools.
- Use of power tools with the conical extraction screw may potentially damage the screw recess and/or extraction screw, preventing subsequent removal.
- Do not use the conical extraction screw with torque-limiting attachment, as this prohibits removal of the screws and may cause additional damage to the instrumentation.

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

Combination of Medical Devices

The ZERO-P cage (with preassembled plate) and screws are applied using the associated ZERO-P instrumentation. The following screw option is available for use with the cage.
- Cervical spine locking screw (∅ 3.0 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 ZERO-P 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 ZERO-P 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 3.0 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 ZERO-P 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.

Non-Sterile Device:
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Implant Removal

If a ZERO-P implant must be removed, the following technique is recommended.

Remove screw with screwdriver
- Attach the handle to the screwdriver shaft, then engage the assembled driver into the drive recess of the screw to be removed.
- Rotate the driver counterclockwise to first loosen the screw from the ZERO-P implant. Continue to rotate the driver counterclockwise to remove the loosened screw from the implant.

Note: If multiple screws need to be removed, it is recommended to first loosen all screws before removing any of the screws from the implant. Loosening all screws before removal of any screw helps to ensure that the implant will be properly secured during removal.

Remove screw with conical extraction screw
- In the event the screwdriver cannot properly engage the drive recess of the screw to loosen the screw, or if the screw recess is damaged, the conical extraction screw may be used to remove the screw.
- First, use the 2.0 mm drill bit to prepare the screw recess. Under full power and on axis with the screw, insert the drill bit into the screw head to lightly pre-drill the screw recess.
- Advance the drill bit until the stop of the drill bit contacts the top of the screw. This facilitates deeper anchoring of the conical extraction screw into the screw recess.
- Connect the conical extraction screw to the handle with quick coupling.
- Insert the tip of the conical extraction screw into the screw recess on axis with the screw.
- Turn counterclockwise until the extraction screw grasps into the screw recess. Continue to turn counterclockwise to remove the screw.

Note: The conical extraction screw is single use only.

Extract implant
- Once all screws are removed, the ZERO-P implant may be removed using the aiming device.
- Attach the aiming device to the implant by aligning the screw holes of the implant with the retention features on the aiming device and then expanding the aiming device.
- After the implant is securely attached, carefully remove the implant.

Note: Use of distraction at the disc space is recommended to facilitate removal.

Please note that precautions/warnings related to implant removal are listed in section "Warnings and Precautions".

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

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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