Instructions for Use
ZERO-P VA™ 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.

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Instructions for Use

ZERO-P VA™ Stand-Alone Implant
ZERO-P VA is a variable angle anterior cervical interbody fusion (ACIF) device. ZERO-P VA cage is supplied with preassembled interbody plate (with integrated one step blocking mechanism).
ZERO-P VA 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
Titanium Alloy: TAV (Titanium - 6% Aluminium – 4% Vanadium) according to ISO 5832-3
PEEK: Polyetheretherketone according to ASTM F 2026
Elgiloy® (40% Cobalt – 20% Chromium – 16% Iron – 15% Nickel – 7% Molybdenum) according to ASTM F 1058
Elgiloy® is a registered trademark of Elgiloy Specialty Metals.

Intended Use
The ZERO-P VA 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 VA 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 VA 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 VA 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 two 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 VA 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 VA 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 lordotic or convex trial spacer of the appropriate height and depth. Anterior osteophytes in the surgical site that prevent desired positioning of a trial spacer will likely prevent desired positioning of the ZERO-P VA implant. It is recommended to remove interfering anterior osteophytes before implant insertion.

– 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 footprint size trial spacers before using large footprint size trial spacers.
– Although the trial spacers have depth stops, use of an image intensifier is recommended to check the position during insertion.
– With the segment fully distracted, the trial spacer must fit tightly between the end plates.

Implant insertion
– Confirm that the ZERO-P VA implant is not placed in direct contact with implanted hardware associated with the previously fused level.
– If the ZERO-P VA implant remains in direct contact with hardware associated with the previously fused level, excessive loading may be placed on the ZERO-P VA implant leading to potential post-op device failure or migration, leading to patient harm.
– Placement of ZERO-P VA adjacent to a previous, multi-level fusion can result in excessive loading.
– Additional posterior supplemental fixation should be considered in cases where ZERO-P VA is placed adjacent to a previous, multi-level fusion.
– 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.

Screw fixation
– Depending on the selected combination of implant, screw length, and trajectory used, the screws may extend beyond the posterior edge of the implant.
– If adjacent hardware prevents both ZERO-P VA screws from being implanted, a different device should be used, as excessive loading may be placed on the implant leading to potential post-op device failure or migration, leading to patient harm.
– If any screw cannot be inserted at the correct trajectory or blocked by the interbody plate, a different device should be used to avoid the risk of screw backout.
– Intraoperative imaging should be used to verify drill bit position.
– When drilling, make sure to drill on-axis, in the same trajectory as the drill guide.
– Applying side loads and/or levering off-axis during drilling may result in broken or damaged instruments which may potentially cause harm to the patient.
– When awl is used instead of drill, intraoperative imaging should be used to verify awl position.
– Do not use the awl without the sleeve; it may cause injury to the patient.
– During screw insertion, intraoperative imaging should be used to verify screw position and to verify the screw follows the trajectory of the pilot hole created by the awl or drill.
– Do not continue advancing any screw after the stops of the interbody plate are lagged to the anterior surface of the vertebral bodies and do not advance any screw more than ½ turn during tightening.
– Over-tightening may strip bone and compromise fixation of the implant in vertebral bodies.

Implant removal
– During screw removal, if the inner shaft is not fully engaged or the outer sleeve not fully seated prior to attempting subsequent screw removal technique steps, breakage of the driver may occur and could potentially harm the patient.
– The removal screwdriver should only be used for screw removal; use of the removal screwdriver for screw insertion may lead to driver and/or implant breakage.

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

Combination of Medical Devices
The ZERO-P VA 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 screw (∅ 3.7 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 VA 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 VA 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 1.5 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 VA 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 VA implant must be removed, the following technique is recommended.

Screw removal
– Engage the tip of the screw removal blade with the blocking mechanism of the plate corresponding to the screw to be removed.
– Attach the handle to the screwdriver shaft, then engage the assembled driver into the first screw to be removed.
– While pressing the blocking mechanism toward the midline with the removal blade, turn the assembled driver counterclockwise to remove the screw.
– Repeat this step with the other screw.

Alternative technique: Screw removal
– Engage the tip of the removal screwdriver in the drive recess of the first screw to be removed.
– Turn the top knob of the removal driver counterclockwise to fully engage the inner shaft into the screw.
– Lower the outer sleeve of the removal driver by turning clockwise until the sleeve retracts the blocking mechanism in the interbody plate.
– Finally, turn the middle section counterclockwise to remove the screw. Repeat this step with the second screw.

Extract implant
– Once the screws are removed, remove the ZERO-P VA implant using the insertion device.
– Engage the insertion device to the implant by first aligning the recessed grooves located midline on the anterior face of the implant with the pronged tabs of the device tip.

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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