Instructions for Use
ZERO-P™ VA Spacer

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™ VA Spacer
The ZERO-P VA cages are stand-alone anterior cervical interbody fusion (ACIF) devices designed to be inserted within the intervertebral disc space. The cage is supplied as a preassembled device with an anterior cervical plate.

The ZERO-P VA cages are available in different shapes, sizes and heights. Screws are offered in different lengths.

These instructions for use contain information about the following products:

04.647.120S	04.647.137S	04.647.232S
04.647.121S	04.647.138S	04.647.235S
04.647.122S	04.647.139S	04.647.236S
04.647.125S	04.647.220S	04.647.237S
04.647.126S	04.647.221S	04.647.238S
04.647.127S	04.647.222S	04.647.239S
04.647.128S	04.647.225S	04.647.834
04.647.129S	04.647.226S	04.647.834S
04.647.130S	04.647.227S	04.647.836
04.647.131S	04.647.228S	04.647.836S
04.647.132S	04.647.229S	04.647.878
04.647.135S	04.647.230S	04.647.878S
04.647.136S	04.647.231S	

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
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
Titanium Alloy: TAV (Titanium – 6% Aluminum – 4% Vanadium) ELI (Extra Low Interstitial) according to ASTM F 136
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; death, stroke; 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; retraction injury; laryngeal swelling; dural tear or spinal fluid leak; spinal cord compression and/or contusion; hoarseness; dysphagia; esophageal perforation, erosion or irritation; device or graft material displacement; dislocation of graft material; 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 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 as per 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.
- Warning: Special considerations should be taken with patients with known allergies or hypersensitivities to implant materials.

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 following screw option is available for use with the ZERO-P VA cage.
- Cervical spine screw (∅ 3.7 mm)

The ZERO-P VA cage and screws are applied using the associated ZERO-P VA instruments.

03.617.900	Screwdriver Stardrive, T8, self-holding
03.617.902	Screwdriver Shaft Stardrive, T8, self-holding
03.617.905	Shaft f/angled Screwdriver, w/Quick Coupling
03.617.912	Drill Bit ∅ 2.0 mm, drilling depth 12 mm
03.617.914	Drill Bit ∅ 2.0 mm, drilling depth 14 mm
03.617.916	Drill Bit ∅ 2.0 mm, drilling depth 16 mm
03.617.940	Handle w/Large Quick Coupling
03.617.981	Impactor, flat
03.647.750	Zero-P VA Trial Spacer, lordotic, height 10 mm
03.647.751	Zero-P VA Trial Spacer, lordotic, height 11 mm
03.647.752	Zero-P VA Trial Spacer, lordotic, height 12 mm
03.647.755	Zero-P VA Trial Spacer, lordotic, height 5 mm
03.647.756	Zero-P VA Trial Spacer, lordotic, height 6 mm
03.647.757	Zero-P VA Trial Spacer, lordotic, height 7 mm
03.647.758	Zero-P VA Trial Spacer, lordotic, height 8 mm
03.647.759	Zero-P VA Trial Spacer, lordotic, height 9 mm
03.647.760	Zero-P VA Trial Spacer, large, lordotic, height 10 mm
03.647.761	Zero-P VA Trial Spacer, large, lordotic, height 11 mm
03.647.762	Zero-P VA Trial Spacer, large, lordotic, height 12 mm
03.647.765	Zero-P VA Trial Spacer, large, lordotic, height 5 mm
03.647.766	Zero-P VA Trial Spacer, large, lordotic, height 6 mm
03.647.767	Zero-P VA Trial Spacer, large, lordotic, height 7 mm
03.647.768	Zero-P VA Trial Spacer, large, lordotic, height 8 mm
03.647.769	Zero-P VA Trial Spacer, large, lordotic, height 9 mm
03.647.780	Zero-P VA Trial Spacer, convex, height 10 mm
03.647.781	Zero-P VA Trial Spacer, convex, height 11 mm
03.647.782	Zero-P VA Trial Spacer, convex, height 12 mm
03.647.785	Zero-P VA Trial Spacer, convex, height 5 mm
03.647.786	Zero-P VA Trial Spacer, convex, height 6 mm
03.647.787	Zero-P VA Trial Spacer, convex, height 7 mm
03.647.788	Zero-P VA Trial Spacer, convex, height 8 mm
03.647.789	Zero-P VA Trial Spacer, convex, height 9 mm
03.647.790	Zero-P VA Trial Spacer, large, convex, height 10 mm
03.647.791	Zero-P VA Trial Spacer, large, convex, height 11 mm
03.647.792	Zero-P VA Trial Spacer, large, convex, height 12 mm
03.647.795	Zero-P VA Trial Spacer, large, convex, height 5 mm
03.647.796	Zero-P VA Trial Spacer, large, convex, height 6 mm
03.647.797	Zero-P VA Trial Spacer, large, convex, height 7 mm
03.647.798	Zero-P VA Trial Spacer, large, convex, height 8 mm
03.647.799	Zero-P VA Trial Spacer, large, convex, height 9 mm
03.647.901	Holding Sleeve f/Screws f/No. 03.617.902
03.647.903	Handle, small, w/Quick Coupling
03.647.962	Drill Guide w/Handle
03.647.963	Insertion Device f/Zero-P VA
03.647.970	Cancellous Bone Impactor
03.647.971	Screw Removal Screwdriver
03.647.980	Implant Holder f/Zero-P VA
03.647.982	Impactor w/ball tip f/Zero-P VA
03.647.984	Packing Block f/Zero-P VA
03.647.985	Screw Removal Blade
03.647.990	Awl ∅ 2.5 mm, w/Sleeve
03.647.993	Awl ∅ 2.5 mm, angled
03.820.113	Mallet

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.

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 including the sealing for completeness and uniformity.
– Inspect the integrity of the sterile packaging to ensure there are no holes, channels or voids.

Do not use if the package is damaged or expired.

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

The ZERO-P VA implant is intended for permanent implantation and is not intended for 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 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.

Special Operating Instructions

Patient positioning, exposure and discectomy

– Using the standard surgical approach, expose the vertebral bodies to be fused. Prepare the fusion site following appropriate technique for the given indication.

Patient positioning

– Position the patient in a supine position on a radiolucent operating table. Ensure that the neck of the patient is in a sagittally neutral position and supported by a cushion. When treating C6–C7 make sure that the shoulders do not limit the x-ray monitoring. For all cases, both vertebrae should be completely visible on radiographic imaging.

Access

– Locate the correct operative level using radiographic imaging.
– Expose the intervertebral disc and the adjacent vertebral bodies through a standard anterior approach to the cervical spine.

Discectomy

– Prepare the fusion site following the appropriate technique for the given indication.
– Perform segmental distraction.
– Distraction of the segment is essential for restoring disc height and for providing access to the intervertebral space.

Implant insertion

Determine appropriate implant

– Selection of the trial spacer depends on the height and depth of the intervertebral space, the preparation technique, and patient anatomy. Choose a lordotic or convex trial spacer of the appropriate height and depth.
– Position the trial spacer in the correct cranial/caudal alignment and carefully insert it into the disc space.
– The mallet can be used to help insert and/or remove the trial spacer.
– Trial spacers have depth stops corresponding to the depth stops of the ZERO-P VA implant.
– Trial spacers are color-coded by shape. The height of the trial spacer is 0.8 mm less than that of the corresponding implant to account for penetration of the teeth into the vertebral end plate.
– Trial spacers are not for implantation and must be removed before insertion of the ZERO-P VA implant.

Pack implant with bone graft material

– It is recommended to pack the ZERO-P VA implant with bone graft material.
– Place the ZERO-P VA implant into the packing block.
– Use the cancellous bone impactor to firmly pack the bone graft material into the implant cavity.
– To ensure contact with the vertebral endplates, it is important to fill the implant until the bone graft material protrudes from the lumen in the cage.
– The bone impactor and the packing block can only be used with the standard size footprints of ZERO-P VA.

Implant insertion

– Use the insertion device or implant holder to introduce the implant into the disc space.

Implant insertion using the insertion device

– Attach the insertion device to the implant by aligning the recessed grooves located midline on the anterior face of the implant with the pronged tabs of the device tip. Squeeze the insertion device handles to secure the implant; the thumb nut on the insertion device may then be advanced clockwise to affix the implant to the insertion device.
– Carefully insert the implant into the distracted segment. Advance the implant until the implant stops rest on the anterior surface of the vertebral body. The implant should fit tightly between the endplates.
– If necessary, the top of the insertion device can be tapped with a mallet to advance the implant into the disc space. If distraction has been applied, release the distraction, leaving the insertion device attached to the implant.

Implant insertions using the implant holder

– Alternatively, the implant can be carefully inserted into the disc space with the forceps-style implant holder. Attach the implant holder to the implant by aligning the recessed grooves located midline on the anterior face of the implant with the ends of the implant holder. Once the implant is partially introduced into the disc space, the implant can be advanced using the flat impactor and/or ball tip impactors.
– The ZERO-P VA interbody plate is marked with an arrow to indicate implant orientation. When inserting the ZERO-P VA implant, the arrow should point to the cranial vertebral body upon insertion.

Screw fixation

– The ZERO-P VA implant is only intended to be implanted with two ZERO-P VA screws, forming a stand-alone interbody fusion construct. By design, the ZERO-P VA implant enables insertion of ZERO-P VA screws within a range of acceptable trajectories.

– Using an awl or drill to prepare screw holes is recommended; these instruments are designed to facilitate subsequent placement of screws at the desired trajectory.
– The screw trajectory achieved during screw insertion will result in varied screw penetration into the vertebral bodies.

Screw fixation – Option A: Awl and self-drilling screws
– A recommended screw fixation technique is to create pilot holes and then insert self-drilling screws.

Create first pilot hole
– It is recommended to create the first hole for the caudally aimed screw.
– Determine the entry point and trajectory for the first screw. The correct angulations for the screws range between 27°–44° cranial/caudal and 15°–29° medial/lateral.
– Insert the awl into the first screw hole of the interbody plate. To ensure proper angle of the pilot hole, fully seat the outer sleeve tip of the awl into the interbody plate. To fully seat the outer sleeve of the awl it is required to push and hold the sleeve at the same time.
– Once the sleeve is fully seated and the correct trajectory is confirmed, push down on the ball handle of the awl while simultaneously twisting the handle to advance the awl. Remove the awl while maintaining alignment of the hole and implant.
– When using the awl, the insertion device or implant holder should be used to minimize implant movement.
– The tip of the awl fits into the screw hole of the interbody plate to produce the correct angle.
– The upper shaft of the awl, near the awl handle, is marked with two black rings. When advancing the awl, the appropriate depth has been reached when the end of the outer sleeve falls between the two black rings.

Insert first screw
– Select the appropriate screw length according to the preoperative plan and intraoperative findings.
– Attach the screwdriver shaft to the handle then load the selected screw to the assembled driver. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.
– Advance the screw until the screw head passes beyond the blocking feature of the interbody plate. Confirm visually that the blocking feature covers the screw head.
– When inserting screws, the insertion device or implant holder should be used to minimize implant movement.

Insert second screw
– Repeat the previous steps for the second screw.

Tighten screws and lag plate (optional)
– If necessary, use the screwdriver to advance each screw another ¼–½ turn. This tightening step lags the stops of the interbody plate to the anterior surface of the vertebral bodies and increases the apposition of the implant to the vertebral body endplates.
– When tightening screws, the insertion device or implant holder should be used to minimize implant movement.

Screw fixation – Option B: Drill guide
– Alternatively, use a drill guide and drill to create a pilot hole. Then insert the screws.

Drill first pilot hole
– It is recommended to create the first hole for the caudally aimed screw.
– Determine the entry point and trajectory for the first screw. The correct angulations for the screws range between 27°–44° cranial /caudal and 15°–29° medial/lateral.
– Select a drill bit of appropriate length and assemble the drill bit to the handle.
– Insert the drill guide into the screw hole of the interbody plate. To ensure proper angle of the pilot hole, fully seat the tip of the drill guide into the interbody plate and confirm correct trajectory. Insert the drill bit into the guide and drill until the stop of the drill contacts the guide.
– Remove the drill bit and drill guide.
– The drill bits are marked with a colored ring corresponding to the color-coded screw lengths. When the ring is flush with the top of the drill guide, the appropriate depth has been reached.
– When drilling, the insertion device or implant holder should be used to minimize implant movement.

Insert first screw
– Select the appropriate screw length according to the preoperative plan and intraoperative findings.
– Attach the screwdriver shaft to the handle, then load the selected screw to the assembled driver. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.
– Advance the screw until the screw head passes beyond the blocking feature of the interbody plate. Confirm visually that the blocking feature covers the screw head.
– When inserting screws, the insertion device or implant holder should be used to minimize implant movement.

Insert second screw
– Repeat the previous steps for the second screw.

Tighten screws and lag plate (optional)
– If necessary, use the screwdriver to advance each screw another ¼ – ½ turn. This tightening step lags the stops of the interbody plate to the anterior surface of the vertebral bodies and increases the apposition of the implant to the vertebral body endplates.
– When tightening screws, the insertion device or implant holder should be used to minimize implant movement.

Screw fixation – Option C: Angled instruments
– When screws holes are difficult to prepare or screws difficult to insert due to interfering anatomy, the angled awl and angled screwdriver may be used.

Create first pilot hole
– It is recommended to create the first hole for the caudally aimed screw.
– Determine the entry point and trajectory for the screw. The correct angulations for the screws range between 27°–44° cranial/caudal and 15°–29° medial/lateral.
– Insert the awl at the appropriate angle into the first screw hole of the plate and tap with the mallet until the awl is seated. Remove the awl while maintaining alignment of the hole and implant.
– When using the angled awl, the insertion device or implant holder should be used to minimize implant movement.

Insert first screw
– Select the appropriate screw length according to the preoperative plan and intraoperative findings.
– Load the selected screw onto the angled screwdriver. Advance the screw until the screw head passes beyond the blocking feature of the interbody plate. Confirm visually that the blocking feature covers the screw head.
– When inserting screws, the insertion device or implant holder should be used to minimize implant movement.

Insert second screw
– Repeat the previous steps for the second screw.

Tighten screws and lag plate (optional)
– If necessary, use the angled screwdriver to advance each screw another ¼–½ turn. This tightening step lags the stops of the interbody plate to the anterior surface of the vertebral bodies and increases the apposition of the implant to the vertebral body endplates.
– When tightening screws, the insertion device or implant holder should be used to minimize implant movement.

Considerations for use adjacent to prior fusion
– If a ZERO-P VA implant is intended to be placed adjacent to a prior fusion, care must be taken to avoid placement of ZERO-P VA implant and screws in direct contact of previously placed hardware.
– As necessary, remove components of the implanted hardware associated with the previously fused level that may prevent ZERO-P VA from being properly implanted per recommended techniques.

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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Instructions for Use:
www.e-ifu.com