Instructions for Use
ZERO-P™ 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™ Implant
The ZERO-P 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 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:

04.617.110S	04.617.132S	04.617.226S
04.617.111S	04.617.135S	04.617.227S
04.617.112S	04.617.136S	04.617.228S
04.617.115S	04.617.137S	04.617.229S
04.617.116S	04.617.138S	04.617.230S
04.617.117S	04.617.139S	04.617.231S
04.617.118S	04.617.210S	04.617.232S
04.617.119S	04.617.211S	04.617.235S
04.617.120S	04.617.212S	04.617.236S
04.617.121S	04.617.215S	04.617.237S
04.617.122S	04.617.216S	04.617.238S
04.617.125S	04.617.217S	04.617.239S
04.617.126S	04.617.218S	04.617.812
04.617.127S	04.617.219S	04.617.812.02S
04.617.128S	04.617.220S	04.617.814
04.617.129S	04.617.221S	04.617.814.02S
04.617.130S	04.617.222S	04.617.816
04.617.131S	04.617.225S	04.617.816.02S

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
PEEK: Polyetheretherketone according to ASTM F 2026
Titanium Alloy: TAV (Titanium – 6% Aluminum – 4% Vanadium) ELI (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; 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 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 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 following screw option is available for use with the ZERO-P cage.
- Cervical spine locking screw (∅ 3.0 mm)

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

03.110.002	Torque Limiter, 1.2 N m
03.110.005	Handle f/Torque Limiters 0.4/0.8/1.2 Nm
03.617.720	Zero-P Trial Spacer, parallel, height 10 mm
03.617.721	Zero-P Trial Spacer, parallel, height 11 mm
03.617.722	Zero-P Trial Spacer, parallel, height 12 mm
03.617.725	Zero-P Trial Spacer, parallel, height 5 mm
03.617.726	Zero-P Trial Spacer, parallel, height 6 mm
03.617.727	Zero-P Trial Spacer, parallel, height 7 mm
03.617.728	Zero-P Trial Spacer, parallel, height 8 mm
03.617.729	Zero-P Trial Spacer, parallel, height 9 mm
03.617.730	Zero-P Trial Spacer, large, parallel, height 10 mm
03.617.731	Zero-P Trial Spacer, large, parallel, height 11 mm
03.617.732	Zero-P Trial Spacer, large, parallel, height 12 mm
03.617.735	Zero-P Trial Spacer, large, parallel, height 5 mm
03.617.736	Zero-P Trial Spacer, large, parallel, height 6 mm
03.617.737	Zero-P Trial Spacer, large, parallel, height 7 mm
03.617.738	Zero-P Trial Spacer, large, parallel, height 8 mm
03.617.739	Zero-P Trial Spacer, large, parallel, height 9 mm
03.617.750	Zero-P Trial Spacer, lordotic, height 10 mm
03.617.751	Zero-P Trial Spacer, lordotic, height 11 mm
03.617.752	Zero-P Trial Spacer, lordotic, height 12 mm
03.617.755	Zero-P Trial Spacer, lordotic, height 5 mm
03.617.756	Zero-P Trial Spacer, lordotic, height 6 mm
03.617.757	Zero-P Trial Spacer, lordotic, height 7 mm
03.617.758	Zero-P Trial Spacer, lordotic, height 8 mm
03.617.759	Zero-P Trial Spacer, lordotic, height 9 mm
03.617.760	Zero-P Trial Spacer, large, lordotic, height 10 mm
03.617.761	Zero-P Trial Spacer, large, lordotic, height 11 mm
03.617.762	Zero-P Trial Spacer, large, lordotic, height 12 mm
03.617.765	Zero-P Trial Spacer, large, lordotic, height 5 mm
03.617.766	Zero-P Trial Spacer, large, lordotic, height 6 mm
03.617.767	Zero-P Trial Spacer, large, lordotic, height 7 mm
03.617.768	Zero-P Trial Spacer, large, lordotic, height 8 mm
03.617.769	Zero-P Trial Spacer, large, lordotic, height 9 mm
03.617.780	Zero-P Trial Spacer, convex, height 10 mm

03.617.781	Zero-P Trial Spacer, convex, height 11 mm
03.617.782	Zero-P Trial Spacer, convex, height 12 mm
03.617.785	Zero-P Trial Spacer, convex, height 5 mm
03.617.786	Zero-P Trial Spacer, convex, height 6 mm
03.617.787	Zero-P Trial Spacer, convex, height 7 mm
03.617.788	Zero-P Trial Spacer, convex, height 8 mm
03.617.789	Zero-P Trial Spacer, convex, height 9 mm
03.617.790	Zero-P Trial Spacer, large, convex, height 10 mm
03.617.791	Zero-P Trial Spacer, large, convex, height 11 mm
03.617.792	Zero-P Trial Spacer, large, convex, height 12 mm
03.617.795	Zero-P Trial Spacer, large, convex, height 5 mm
03.617.796	Zero-P Trial Spacer, large, convex, height 6 mm
03.617.797	Zero-P Trial Spacer, large, convex, height 7 mm
03.617.798	Zero-P Trial Spacer, large, convex, height 8 mm
03.617.799	Zero-P Trial Spacer, large, convex, height 9 mm
03.617.900	Screwdriver Stardrive, T8, self-holding
03.617.901	Holding Sleeve f/Screws f/use w/No. 03.617.902
03.617.902	Screwdriver Shaft STARDRIVE, T8, self-holding
03.617.903	Handle w/Quick Coupling
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
03.617.962	Drill Guide w/Handle
03.617.963	Aiming Device f/Zero-P
03.617.968	Drill Guide w/threaded tip
03.617.970	Cancellous Bone Impactor f/Zero-P
03.617.971S	Extraction Screw, conical
03.617.975S	Drill Bit ∅ 2.0 mm
03.617.980	Implant Holder f/Zero-P
03.617.981	Impactor, flat
03.617.982	Impactor w/ball tip
03.617.984	Packing Block f/Zero-P
03.617.990	Awl ∅ 2.0 mm, w/Sleeve
03.617.993	Awl ∅ 2.0 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 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.

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 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 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.

Special Operating Instructions

Patient positioning, exposure and discectomy

Patient positioning

- Using the standard surgical approach, expose the vertebral bodies to be fused. Prepare the fusion site following appropriate technique for the given indication.
- 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.
– If preferred, a larger handle can be attached to the trial spacer.
– The 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 endplates.
– Trial spacers are not for implantation and must be removed before insertion of the ZERO-P implant.

Pack implant with bone graft material
– It is recommended to pack the ZERO-P implant with bone graft material. Place the ZERO-P implant into the packing block.
– Use the cancellous bone impactor to firmly pack the graft material into the implant cavity.
– To ensure contact with the vertebral endplates, it is important to fill the implant until the 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.

Insert implant
– Use the aiming device or implant holder to introduce the implant into the disc space. The recommended orientation is with the medial screws pointing caudally.

Insert implant 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. Once the implant is securely attached, carefully insert the implant into the distracted segment.
– If necessary, the top of the aiming device can be tapped with the mallet to advance the implant into the disc space. If distraction has been applied, release the distraction while leaving the aiming device attached to the implant.

Insert implant using the implant holder
– The implant can be inserted into the disc space with the forceps-type implant holder. Once the implant is partially introduced into the disc space the implant can be advanced to the correct posterior depth using the flat impactor and/or the impactor with ball tip.
– The recommended orientation for the implant is with the medial screws pointing caudally. For convex shaped cages this is the only orientation possible.

Screw fixation
Screw fixation – Option A: Aiming device
– The aiming device allows one screw to be inserted with the instrument attached to the implant. This helps to keep the implant in place while the other screw holes are prepared and screws inserted.

Drill first pilot hole through drill and screw hole of aiming device
– Select a drill bit of appropriate length. Insert the drill bit into the drill and screw hole of the aiming device and drill until the stop on the drill bit contacts the guide.
– Remove drill bit.
– The drill bits are marked with a colored ring corresponding to the color-coded screw lengths.

Insert first screw
– Select the appropriate screw length according to the preoperative planning and intraoperative findings.
– Assemble the torque limiter to the screwdriver shaft and handle.
– Load a screw onto the screwdriver with torque limiter. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.
– Retract the sleeve when inserting the first screw through the aiming device.
– Advance the screw until the head of the screw contacts the plate.

Drill remaining pilot holes
– Select a drill bit of appropriate length. Insert the drill bit into a drill hole of the aiming device and drill until the stop on the drill bit contacts the guide.
– Remove the drill bit.
– Repeat for the remaining screw holes.
– The drill bits are marked with a colored ring corresponding to the color-coded screw lengths.

Insert remaining screws
– Remove the aiming device from the implant.
– Load a screw onto the screwdriver with torque limiter. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.
– Advance the screw until the head of the screw contacts the plate.
– Repeat for the remaining screws.
– If the aiming device is difficult to remove, verify that the screw is advanced far enough so that the aiming device is not contacting the screw during removal.

Tighten screws
– To lock the screwhead in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.
– Screws placed using the surgical procedure may not always be flush with the plate but will be sufficiently locked when 1.2 Nm torque is achieved.

Screw fixation – Option B: Drill guide and freehand screw
– If use of the aiming device is not the preferred surgical procedure, follow these alternative technique steps.

Drill first pilot hole
– It is recommended that the first hole be created for a caudally pointing screw.
– Select a drill bit of appropriate length. Determine the entry point and trajectory for the screw. The correct angulations for the screws are 40° in the caudal or cranial direction. The medial screws point 2.5° laterally and the lateral screws point 2.5° medially.
– Lateral screws should always point medially.
– Insert the drill guide into the screw hole at the appropriate angle. The tip of the drill guide is designed to fit inside the screw hole of the plate and guide the correct angle.
– Insert the drill bit into the guide and drill until the stop on the drill bit contacts the guide.
– Remove the drill bit and 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.

Insert first screw
– Select the appropriate screw length according to the preoperative planning and intraoperative findings.
– Assemble the torque limiter to the screwdriver shaft and handle.
– Load a screw onto the screwdriver with torque limiter. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.
– Retract the sleeve when inserting the first screw through the aiming device.
– Advance the screw until the head of the screw contacts the plate.

Insert remaining screws
– Repeat previous steps for the remaining screws.

Tighten screws
– To lock the screwhead in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.
– Screws placed using the surgical procedure may not always be flush with the plate but will be sufficiently locked when 1.2 Nm torque is achieved.

Screw fixation – Option C: Threaded drill guide and freehand screw
Drill first pilot hole
– It is recommended that the first hole be created for a caudally pointing screw.
– Determine the trajectory for the threaded drill guide. The correct angulations are 40° in the caudal or cranial direction.
– Screw the threaded drill guide into the thread of the ZERO-P plate at the appropriate angle until 2-finger tight. The thread of the drill guide is designed to fit inside the thread of the ZERO-P plate.
– Determine a drill bit of appropriate length. Insert the drill bit into the guide and drill until the stop on the drill bit contacts the guide.
– Remove the drill bit and the threaded 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.

Insert first screw
– Select the appropriate screw length according to the preoperative planning and intraoperative findings.
– Assemble the torque limiter to the screwdriver shaft and handle.
– Load a screw onto the screwdriver with torque limiter. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.
– Retract the sleeve when inserting the first screw through the aiming device.
– Advance the screw until the head of the screw contacts the plate.

Insert remaining screws
– Repeat the previous steps for the remaining screws.

Tighten screws
– To lock the screwhead in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.
– Screws placed using the surgical procedure may not always be flush with the plate but will be sufficiently locked when 1.2 Nm torque is achieved.

Screw fixation – Option D: Awl and freehand screw
– If surgeon preference is to awl and not to use the drilling technique, this alternative technique may be used.

Awl first pilot hole
– It is recommended that the first hole be created for a caudally pointing screws.
– Determine the entry point and trajectory for the screw. The correct angulations for the screws are 40° in caudal or cranial direction. The medial screws point 2.5° laterally and the lateral screws point 2.5° medially.
– Lateral screws should always point medially.
– Insert the awl at the appropriate angle into a screw hole in the plate and push down, while simultaneously twisting the handle. Remove the awl, maintaining alignment of the hole and plate.
– The tip of the awl is designed to fit inside the screw hole of the plate and guide the correct angle.

Insert first screw
– Select the appropriate screw length according to the preoperative planning and intraoperative findings.
– Assemble the torque limiter to the screwdriver shaft and handle.
– Load a screw onto the screwdriver with torque limiter. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.
– Retract the sleeve when inserting the first screw through the aiming device.
– Advance the screw until the head of the screw contacts the plate.

Insert remaining screws
– Repeat the previous steps for the remaining screws.

Tighten screws
– To lock the screwhead in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.
– Screws placed using the surgical procedure may not always be flush with the plate but will be sufficiently locked when 1.2 Nm torque is achieved.

Screw fixation – Option E: Angled instruments
– For screws that are difficult to drill or insert because of interfering anatomy, the angled awl and angled screwdriver may be used.

Awl first pilot hole
– It is recommended that the first hole be created for a caudally pointing screws.
– Determine the entry point and trajectory for the screw. The correct angulations for the screws are 40° in the caudal or cranial direction. The medial screws point 2.5° laterally and the lateral screws point 2.5° medially.
– Lateral screws should always point medially.
– Insert the awl at the appropriate angle into the screw hole of the plate and tap with the mallet until the awl is seated.
– Remove the awl, maintaining alignment of the hole and plate.

Insert first screw
– Select the appropriate screw length according to the preoperative planning and intraoperative findings.
– Load a screw onto the angled screwdriver. Advance the screw until the head of the screw contacts the plate.

Insert remaining screws
– Repeat the previous steps for the remaining screws.

Tighten screws
– To lock the screwhead in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.
– Screws placed using the surgical procedure may not always be flush with the plate but will be sufficiently locked when 1.2 Nm torque is achieved.

Considerations for use adjacent to a prior fusion
– When implanting ZERO-P adjacent to a prior fusion, take care to avoid placing the ZERO-P cage and screws in direct contact with previously implanted hardware. As necessary, remove adjacent-level hardware that prevents ZERO-P from being implanted using the correct technique.
– Do not place ZERO-P adjacent to previously implanted hardware if the adjacent level cannot be confirmed to be fused or where fusion has not occurred.
– To accommodate previously placed hardware, orient the ZERO-P implants with lordotic and parallel sagittal profiles with either the medial screws facing cranially or caudally. Consider screw dimensions to determine desired orientation.

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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