Instructions for Use
SYNFIX™ Evolution Implants

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

Not all products are currently available in all markets.

EC REP

Authorised Representative

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork Ireland

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Instructions for Use

SYNFIX™ Evolution Implants
SYNFIX Evolution is a stand-alone anterior lumbar interbody fusion (ALIF) device designed for use in the lumbar region of the spine. The device incorporates an anterior fixation titanium plate with titanium locking screws and a radiolucent PEEK interbody cage with tantalum marker pins. The cage consists of a central lumen that can accept bone graft material.

These implants are available in differing height and footprint options with 4 lordotic angulation options to choose from.

These instructions for use contain information about the following products:

04.835.120.02S	08.815.145S	08.815.232S	08.815.314S
04.835.125.02S	08.815.146S	08.815.233S	08.815.315S
04.835.130.02S	08.815.152S	08.815.234S	08.815.316S
04.835.220.02S	08.815.153S	08.815.235S	08.815.322S
04.835.225.02S	08.815.154S	08.815.236S	08.815.323S
04.835.230.02S	08.815.155S	08.815.241S	08.815.324S
08.815.101S	08.815.156S	08.815.242S	08.815.325S
08.815.102S	08.815.163S	08.815.243S	08.815.326S
08.815.103S	08.815.164S	08.815.244S	08.815.331S
08.815.104S	08.815.165S	08.815.245S	08.815.332S
08.815.105S	08.815.166S	08.815.246S	08.815.333S
08.815.106S	08.815.173S	08.815.252S	08.815.334S
08.815.111S	08.815.174S	08.815.253S	08.815.335S
08.815.112S	08.815.175S	08.815.254S	08.815.336S
08.815.113S	08.815.176S	08.815.255S	08.815.341S
08.815.114S	08.815.201S	08.815.256S	08.815.342S
08.815.115S	08.815.202S	08.815.263S	08.815.343S
08.815.116S	08.815.203S	08.815.264S	08.815.344S
08.815.122S	08.815.204S	08.815.265S	08.815.345S
08.815.123S	08.815.205S	08.815.266S	08.815.346S
08.815.124S	08.815.206S	08.815.273S	08.815.352S
08.815.125S	08.815.211S	08.815.274S	08.815.353S
08.815.126S	08.815.212S	08.815.275S	08.815.354S
08.815.131S	08.815.213S	08.815.276S	08.815.355S
08.815.132S	08.815.214S	08.815.301S	08.815.356S
08.815.133S	08.815.215S	08.815.302S	08.815.363S
08.815.134S	08.815.216S	08.815.303S	08.815.364S
08.815.135S	08.815.222S	08.815.304S	08.815.365S
08.815.136S	08.815.223S	08.815.305S	08.815.366S
08.815.141S	08.815.224S	08.815.306S	08.815.373S
08.815.142S	08.815.225S	08.815.311S	08.815.374S
08.815.143S	08.815.226S	08.815.312S	08.815.375S
08.815.144S	08.815.231S	08.815.313S	08.815.376S

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

For accompanying information, such as Surgical Techniques, please visit www.jnjmedtech.com/en-EMEA/product/accompanying-information or contact local customer support.

Materials
PEEK: Polyetheretherketone according to ASTM F 2026
Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium) according to ISO 5832-11
Tantalum according to ISO 13782

Intended Use
The SYNFIX Evolution implants are intended for use as stand-alone anterior lumbar interbody fusion (ALIF) devices in skeletally mature patients in lumbar spine (L1-S1). The SYNFIX Evolution implants are designed for an anterior approach.

Note: Supplemental fixation may be required in cases of segmental instability.

Indications
The SYNFIX Evolution implants are indicated for degenerative spine disease of the lumbar spine.

Contraindications
– Severe Osteoporosis

Patient Target Group
The SYNFIX Evolution implants are intended for use in skeletally mature patients. These products are to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Expected Clinical Benefits
When the SYNFIX Evolution implants are used as intended and according to the instructions for use and labeling, these devices provide stabilization of the motion segment(s) after intervertebral disc removal as an adjunct to fusion, which is expected to provide relief of back and/or leg pain caused by degenerative conditions of the spine.

A summary of safety and clinical performance can be found at the following link (upon activation): https://ec.europa.eu/tools/eudamed

Performance Characteristics of the Device
The SYNFIX Evolution implants are anterior lumbar interbody fusion (ALIF) devices, designed to provide stability at the motion segment(s) prior to fusion.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, there is a risk of adverse events. Possible adverse events may include: problems resulting from anesthesia and patient positioning; thrombosis; embolism; infection; excessive bleeding; neural and vascular injury; death; swelling, abnormal wound healing or scar formation; heterotopic ossification; functional impairment of the musculoskeletal system; paralysis (temporary or permanent); complex regional pain syndrome (CRPS); allergy/hypersensitivity reactions; symptoms associated with implant or hardware prominence, implant breakage, loosening or migration; malunion, non-union or delayed union; decrease in bone density due to stress shielding; adjacent segment degeneration; ongoing pain or neurological symptoms; damage to adjacent bones, discs, organs, or other soft tissues; dural tear or spinal fluid leak; spinal cord compression and/or contusion; device or graft material displacement; vertebral angulation.

Sterile Device

STERILE R Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.

 Do not use when packaging is damaged.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.

 Do not resterilize

Resterilization of the device can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single Use Device

 Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, re-use or reprocessing of single use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings and Precautions
- It is strongly advised that the SYNFIX Evolution 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.

Discectomy
Prepare disc space
- It is essential that the nucleus and the inner annulus are removed to prevent displacement of disc material into the spinal canal during implant insertion and interference with bone ingrowth.
- Overly aggressive preparation can weaken the endplates by removing bone under the cartilaginous layers. Removal of the entire endplate can cause subsidence and lead to loss of segmental stability.

Distraction and Segment mobilization
- In order to minimize the risk of endplate fracture, it is essential that the tips of the spreader are placed to the posterior margin of the vertebral body. In order to ensure this, image intensifier control is advised during insertion of the spreader.
- It is important not to over distract the segment to prevent injury of ligamentous and neural structures.

Trialing
Optional: Trial for footprint size
- Carefully assess the position of the anterolateral edges of the footprint trial to ensure they reside within the periphery of the vertebral body.

Connect trial implant to trial implant holder
- The diamond shaped interface on the Evolution trial spacer and implant holder must reside within the trial spacer interface.

Insert trial implant
- Do not leave the trial implant in the disc space.
- Insufficient disc space preparation may compromise vascular supply to the bone graft.
- Be aware of soft tissue or blood vessels that may be in the pathway of the trial spacer or cause possible interference with retractor blades.
- Ensure the arrow on the trial implant is pointing cranially before insertion, as the SYNFIX Evolution trial implants and implants are asymmetrical.

Assess anterior-posterior depth
- Carefully assess the position of the anterolateral edges of the trial implant to ensure they reside within the periphery of the vertebral body.
- If a deep implant spacer is needed, ensure the trial spacer holder flange is sufficiently recessed to make sure the deep implant will sit completely in the disc space when inserted.

Implant preparation
Pack SYNFIX Evolution implant
- Do not use excessive force to compress or impact the graft into the implant as this may interfere with vascular integration and bone healing.
- The packing station combines the corresponding standard and deep footprints in one mold.
- Avoid damage to the SYNFIX Evolution implant during graft material packing.

Implant insertion
Assemble aiming device
- Do not use awl or screwdriver without appropriate aiming device.

Implant insertion:
Option A: Using aiming device
Attach implant to aiming device
- Ensure the aiming device matches the implant size.
- The aiming device should fit tight against the plate.
- Ensure the aiming device/implant connection is secure.

Insert implant
- Ensure that the SYNFIX Evolution implant is inserted with the arrow pointing cranially as the implant is asymmetrical.
- Remove the coupling prior to hammering to avoid damaging the coupling screw.
- To avoid bone damage to the anterior rim caused by the aiming device, do not insert the implant too deep. Excessive impaction can cause damage to the anterior aspect of the vertebrae.

Optional: Final positioning
- Remove the coupling prior to hammering to avoid damaging the coupling screw.

Implant insertion:
Option B: Using SQUID™ Inserter/Distractor
Assemble Evolution SQUID inserter/distractor and select push block.
- Ensure the SYNFIX Evolution push blocks are used. Do not use the black engraved SYNCAGE Evolution push blocks.

Insert implant
- Ensure that the Evolution SQUID inserter/distractor is inserted with the arrow on the SYNFIX Evolution implant pointing cranially, as the implant is asymmetrical.
- The implant, as well as the SQUID inserter/ distractor stop, are moving towards the vertebral body. Be aware of soft tissue and blood vessels that may be in the pathway of the implant and the SQUID inserter/distractor stop, as they may be pushed against the vertebral bodies or interfere with retractor blades. Non-observance can lead to injuries of adjacent structures.
- It is important to refrain from using an implant that is too tall for the disc space to prevent over distraction of the segment and prevent injury of the ligamentous, neural structures and/or vertebral endplates.
- Use fluoroscopy to confirm the position of Evolution SQUID inserter/distractor and the SYNFIX Evolution implant, restoration of disc and foraminal height, and overall alignment.

Remove SQUID inserter/distractor
- Be aware of soft tissue or blood vessels that may be in the pathway of the Evolution SQUID inserter/ distractor or cause possible interference with retractor blades.

Attach aiming device
- The aiming device should fit tight against the plate.
- Ensure the aiming device/implant connection is secure.
- Ensure the aiming device matches the implant size.

Optional: Final positioning
- Remove the coupling before hammering to avoid damage of the coupling screw.

Mini-open aiming devices
- The 25 mm screws are the longest that can be used with the mini-open aiming devices as there is insufficient guidance for the 30 mm screws. The standard aiming devices (03.835.001, 03.835.002, 03.835.003) must be used for the 30 mm screws.

Screw insertion: Mini-open drivers with mini-open aiming devices
– The mini-open screwdrivers (03.835.410 and 03.835.413) cannot be used with the standard aiming devices (03.835.001, 03.835.002, 03.835.003) as they are not long enough to fully tighten and lock the screws in the implant plates. Screw will continue to spin freely inside aiming device as screw will not engage into SYNFIX Evolution implant plate; required final torquing will not be possible.
– A second mini-open screwdriver (03.835.410 and/ or 03.835.413) should be available as a backup.

Short mini-open screwdriver
– The short screwdriver can only be used for initial screw insertion and requires using the standard (03.835.013) or mini-open screwdriver (03.835.413) for final tightening. Each screw should be fully inserted before proceeding to insertion of the next screw to avoid jamming two intersecting screws in the aiming device.

Screw insertion
Optional: Assemble protection sleeve
– Carefully slide the protection sleeve in a straight manner over the awl tip to avoid damage to the protection sleeve. Take care to avoid injury from the sharp point of the awl.

Create pilot hole
– Before using the soft tissue retractor, it is recommended to insert one screw to prevent implant migration.
– Do not impact on awl during pilot hole creation to avoid damaging the awl joint or handle connection.
– Always use an aiming device to guide the awl during pilot hole creation.

Select screw
– For a two-level procedure, proper consideration should be given to the screw length on the common vertebral body to prevent screw interference.
– Do not use SYNFIX-LR screws in combination with SYNFIX Evolution or SYNFIX Evolution screws in combination with SYNFIX-LR. These devices are distinct and not backwards compatible.

Load screw to screwdriver
– Do not over tighten the screw in the thread lock sleeve to avoid damage to the thread lock sleeve.
– Do not load the screw without the screw loading station as this might cause damage and inhibit proper function of the thread lock sleeve.

Insert and tighten screws
– Before using the soft tissue retractor, it is recommended to insert one screw to prevent implant migration.
– Use only the handles provided with this set.
– Screw insertion must be done through a SYNFIX Evolution aiming device to ensure proper locking of the screw to the plate.
– Four screws should always be used for every SYNFIX Evolution implant construct.
– The four locking screws should be inserted sequentially.
– Avoid excessive tightening of the screws to prevent damage to screwdriver tip and joint.
– When dealing with sclerotic bone, ensure the screws are fully locked to the locking plate.

Screw removal
Assemble aiming device
– Do not use the screwdriver without appropriate aiming device.

Implant removal
Assemble screwdriver and removal tool
– The diamond-shape surface of the trial implant holder interface should reside inside of the removal tool interface.

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

Combination of Medical Devices
The SYNFIX Evolution implants are applied using associated SYNFIX Evolution instruments.

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 articles of the SYNFIX Evolution 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 2 W/kg for 15 minutes of scanning

Based on non-clinical testing, the SYNFIX Evolution implant will produce a temperature rise not greater than 5.2 °C at a maximum whole body averaged specific absorption rate (SAR) of 2 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 SYNFIX Evolution 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.

Implant Removal
The SYNFIX Evolution 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 SYNFIX Evolution implant has to be removed, the following technique is recommended.
– Assemble the aiming device and attach it to the implant.
– Remove all screws with the screwdriver. In case the access does not allow usage of the straight screwdriver, use the angled screwdriver.
– Remove the implant with the aiming device or with the optional removal tool in case reattaching of the aiming device holder to the cage is not possible.
– Completely separate the endplate fusion areas prior to implant removal. An osteotome may be required to mobilize the implant if bone healing and integration has commenced.
– Remove the SYNFIX Evolution implant from disc space by pulling on the attached holder. Controlled, light hammering with a slotted mallet may be required to remove the implant from the disc space.

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

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.

Special Operating Instructions

Access and Exposure

Position the patient
– For an anterior approach to the lower lumbar levels, position the patient in a slight Trendelenburg position.

Anterior access and approach
– The surgical approach depends on the level to be treated.
– Locate the correct operative level and incision site by taking a lateral fluoroscopic view while holding a straight metal instrument on the side of the patient. This helps ensure that the incision and exposure will allow direct access to the operative level and enable screw insertion.
– It is recommended to expose the operative level through a standard retroperitoneal approach. However, other approaches may be indicated based on the patient’s anatomy and pathology.

Exposure
– Expose the operative level such that there is sufficient space on either side of the vertebral midline equal to half the width of the SYNFIX Evolution implant.
– The locking screws of the SYNFIX Evolution implant must be inserted from a direct anterior direction.

Discectomy

Cut anterior window
– Create an annulotomy centered on the midline and wide enough to accommodate the SYNFIX Evolution implant. Optionally, a footprint trial or trial implant may be used as a template to indicate the width of the annular window.
– Retain as much of the anterolateral, lateral and posterior annulus as possible in order to provide stability of the instrumented segment.

Prepare disc space
– Remove disc material through an incision in the annulus fibrosus. Excise the disc material and remove the cartilaginous endplates to expose the underlying bony vertebral endplates.
– Adequate cleaning of the endplates is important to enable the provision of a vascular supply to the bone graft.
– Once the endplates have been prepared, complete additional surgical procedures.

Distraction and Segment Mobilization

Mobilize segment
– Under fluoroscopic control, insert the vertebral body spreader to the posterior margin of the vertebral bodies to gradually remobilize the motion segment.
– Placement of the tips to the posterior margin will help minimize the risk of endplate fracture. Place the spreader on one side to facilitate the discectomy on the contralateral side, and then repeat for the other side.
– Distract the intervertebral space with the vertebral body spreader in such a way to restore the height of the disc and to enable access to the posterior aspect of the disc space.
– Distraction of the segment is essential for restoration of disc height, opening of the neural foramina and indirect decompression of the canal. Achieving appropriate fit, fill and distraction of the disc space is also important for the initial stability of the SYNFIX Evolution implant.
– The height of the spreader is 6 mm (3 mm per side) when collapsed.

Trialing

Optional: Trial for footprint size
– Choose an appropriately sized footprint trial and slide the footprint trial into the disc space.
– Anterior-posterior (AP) and lateral fluoroscopy can be used to confirm correct footprint choice.
– The footprint trial can be rotated slightly in the disc space to make the anterior margin more visible on fluoroscopy.

Assemble trial implant holder
– Thread the spindle into the cannulated shaft of the trial implant holder.

Connect trial implant to trial implant holder
– Select the trial implant corresponding to the footprint size determined by the footprint trialing. Select the height and angle corresponding to that considered appropriate based on preoperative planning, the anatomical features evident after disc clearance and endplate preparation, and the requirements in order to restore normal spinal alignment and disc height.
– Mount the chosen SYNFIX Evolution trial implant on the trial implant holder. Secure it by fully tightening the knurled knob on the back of the trial implant holder.
– The trial implant height is 0.8 mm undersized in comparison to the implant. This corresponds to half the implant teeth height on each side.

Insert trial implant
– Insert the trial implant into the disc space.
– The anterior slots on the trial implant indicate the entry points of the locking screws in the anterior aspect of the adjacent vertebrae.
– Controlled light hammering on the trial implant holder may be required to position the trial implant between the vertebral bodies to the desired depth.
– If a tight fit is not achieved, repeat the process using incrementally larger trial implants or one with a different angle to best fit the anatomical features of the disc space.
– If the trial spacer is too large, preventing insertion with an appropriate amount of force, repeat using an incrementally smaller trial spacer or different angle.
– Use fluoroscopy during trial insertion and to confirm final position and fit of the trial implant.

Assess anterior-posterior depth
– The trial spacer holder has a flange adjacent to its connection with the trial. When attached to the standard trial spacers, the flange represents the anterior aspect of a deep implant. The additional 3.0 mm depth enables assessment of the appropriate implant to be used, standard or deep, based on the fluoroscopic evaluation and direct visualization of the trial in the disc space.
– The deep implants and trial implants of a corresponding footprint (S/SD, M/MD, L/LD) are 3.0 mm deeper in anterior-posterior direction but have the same width, anterior and posterior height.

Implant Preparation

Select implant
– Select the SYNFIX Evolution implant that corresponds to the footprint, height and angle chosen using the trial implant in the previous surgical steps.
– To facilitate selection of the implant, the trial implants are labelled with the height, lordotic angle and footprint of the implant. In addition, the trial implants and integrated locking plates are color-coded to match height.

Pack SYNFIX Evolution implant
– Insert the SYNFIX Evolution implant into the appropriate mold in the packing station.
– Fill the SYNFIX Evolution implant in the packing station with the graft material until it protrudes from its cavities in order to ensure contact with the vertebral endplates.
– Use a graft packing tamp to firmly pack the graft material into the implant cavities.

Implant Insertion

Assemble aiming device
– Choose the aiming device corresponding to the implant height. The heights 10.5/12 mm, 13.5/15 mm and 17/19 mm are combined in one aiming device each.
– Fully engage the coupling screw in the aiming device with the coupling.
– Assemble the aiming device holder.
– The 17/19 mm aiming device is a 2 hole aiming device and needs to be rotated during screw insertion (see surgical step “Screw insertion”).
– Attach the aiming device holder to the aiming device by pulling the outer shaft on the aiming device holder towards the handle and engage the aiming device. Align the vertical black lines on the aiming device holder and the aiming device. Release the outer shaft to lock the assembly.
– Insert the coupling into the aiming device holder.
– Ensure the aiming device holder is fully seated on the aiming device.

Option A: Using aiming device
Attach implant to aiming device
– Dock the keyed connection interface of the assembled aiming device into the corresponding docking feature on the implant. After the aiming device has been positioned, secure it by turning the coupling clockwise to tighten the coupling screw.
– Remove the coupling from aiming device before impacting the implant into the disc space.

Insert implant
– Confirm the aiming device/implant connection is locked into position.
– The arrow on the SYNFIX Evolution implant has to point cranially to ensure appropriate fit within the disc space. Insert the SYNFIX Evolution implant into the disc space.
– Controlled and light hammering on the aiming device holder may be required to advance the SYNFIX Evolution implant into the intervertebral disc space.
– Use fluoroscopic imaging during implant insertion to assess implant positioning.
– The SYNFIX Evolution implant should fit firmly with a tight press-fit between the endplates.

Verify placement
– The optimal position for the SYNFIX Evolution implant is centered within the periphery of the vertebral body and having achieved appropriate fit and fill of the disc space.
– Verify the location of the SYNFIX Evolution implant relative to the vertebral bodies in the AP and lateral directions under fluoroscopy.
– Optionally the aiming device can be removed during fluoroscopy to improve the visualization of the anterior aspect of the implant.
– The titanium plate and single posterior tantalum X-ray marker incorporated into the implant are designed to allow intraoperative radiographic assessment of the position of the implant.
– The X-ray marker is parallel to endplates and flush with the posterior wall of the SYNFIX Evolution implant.

Optional: Final positioning
– In case the SYNFIX Evolution implant needs to be repositioned use the attached aiming device to manually manipulate the implant position.
– Controlled and light hammering on the aiming device holder may be required to reposition the implant.
– Use fluoroscopic control during the repositioning of the implant.

Option B: Using Squid inserter/distractor
Assemble Evolution SQUID inserter/distractor and select push block
– Assemble the Evolution SQUID inserter/distractor. Release the spindle of the Evolution SQUID inserter/ distractor by pushing the “release” button on the grip and slide the pusher block fully back. Lock the spindle by pushing the “engage” button and slide a push block into the pusher block coupling until it is fully seated.

– For the 19 mm SYNFIX Evolution implant, first perform "mount SYNFIX Evolution implant" surgical step then slide the push block into the pusher block.
– With the proud push blocks the implant is anteriorly protruding from the anterior rim of the vertebral body and can be fully seated using the aiming device.

Mount SYNFIX Evolution implant
– Insert the SYNFIX Evolution implant in between the paddles of the Evolution SQUID inserter/distractor so that the grooves of the SYNFIX Evolution implant connect to the rails of the blades. Turn the T-handle of the Evolution SQUID inserter/distractor clockwise to advance the pushing block until it contacts the SYNFIX Evolution implant. The SYNFIX Evolution implant is now held securely in place and is ready for insertion.
– Mounting of the 19 mm SYNFIX Evolution implant can only be performed prior to installing the push block (see previous surgical step).
– The tip of the paddles will be inserted into the disc space up to the depth-stops on the paddles. To allow full insertion, the tip must be fully closed.
– The image on the push block depicts the protrusion of the SYNFIX Evolution implant from the disc space.

Insert implant
– Insert the tip of the Evolution SQUID inserter/distractor into the disc space until the depth-stops on the paddles touch the anterior rim of the vertebral body. The tip of the Evolution SQUID inserter/distractor is 25 mm deep and 28 mm wide. To assist with inserting the SYNFIX Evolution implant symmetrically into the disc space, the central opening of the Evolution SQUID inserter/ distractor paddles should be aligned with the anterior midline of the vertebral bodies.
– Actuate SQUID inserter/distractor to distract the disc space as the implant is inserted.
– With the spindle engaged, turn the T-handle on the Evolution SQUID inserter/ distractor to advance the implant down the paddles and into the disc space. The force required to turn the T-handle will increase as the SYNFIX Evolution implant advances down the paddles and the Evolution SQUID inserter/distractor elevates the disc space. Under fluoroscopic control continue turning the T-handle until the SYNFIX Evolution implant is fully ejected and released from the Evolution SQUID inserter/distractor. A click, as the paddles close, confirms that the SYNFIX Evolution implant is seated, and the Evolution SQUID inserter/distractor is fully ejected and released. Depending on the size of the vertebrae, the anterior edge of the SYNFIX Evolution implant will usually be positioned +/–1 mm to the amount listed on the chosen push block.
– The Evolution SQUID inserter/distractor can only be used for an anterior approach.

Remove SQUID inserter/distractor
– When the SYNFIX Evolution implant is correctly positioned carefully remove the Evolution SQUID inserter/ distractor.

Attach aiming device
– Insert the assembled aiming device into the exposure.
– Dock the keyed connection interface of the aiming device into the corresponding docking feature on the implant.
– After the aiming device has been positioned, secure it by turning the coupling clockwise to tighten the coupling screw.
– Remove the coupling from aiming device.

Verify placement
– The optimal position for the SYNFIX Evolution implant is centered within the periphery of the vertebral body and having achieved appropriate fit and fill of the disc space.
– Verify the location of the SYNFIX Evolution implant relative to the vertebral bodies in the AP and lateral directions under fluoroscopy.
– Optionally the aiming device can be removed during fluoroscopy to improve the visualization of the anterior aspect of the implant.
– The titanium plate and single posterior tantalum X-ray marker incorporated into the implant are designed to allow intraoperative radiographic assessment of the position of the implant.
– The X-ray marker is parallel to endplates and flush with the posterior wall of the SYNFIX Evolution implant.

Optional: Final positioning
– In case the SYNFIX Evolution implant needs to be repositioned, use the attached aiming device to manually manipulate the implant position.
– Controlled and light hammering on the aiming device holder may be required to reposition the implant.
– Use fluoroscopic control during the repositioning of the implant.

Mini-Open Technique

Mini-open aiming devices
– The overall profile of the aiming devices has been reduced by including only two side-by-side holes; therefore the aiming device needs to be rotated after the first two screws are inserted (the same as with the 17/19 mm aiming device in the standard SYNFIX Evolution instrument set).
– The aiming devices are coated (black) to differentiate them from the standard aiming devices.

Screw insertion: Standard drivers with mini-open aiming devices
– Note that the etch lines on the screwdriver and awl will be in different locations compared to use with the standard aiming devices. The etch line on the SYNFIX Evolution screwdriver without thread lock sleeve will not line up with the edge of the aiming device when the screw is locked to the plate. For the SYNFIX Evolution screwdriver one green etch line will be visible at the proximal side of the thread lock sleeve when the screw is locked to the plate. The screws are fully inserted when there is a firm end point.
– Loosen the coupling screw that connects the aiming device to the SYNIFX Evolution implant and rotate the aiming device 180° in preparation of the final two screws.

Screw insertion: Mini-open drivers with mini-open aiming devices
– The mini-open screwdrivers and awl have a shorter functional end. The mini-open screwdriver is designed to work with the standard thread lock sleeve.
– The proximal end of the shaft on the mini-open screwdrivers and awl is coated (black) to differentiate them from the standard screwdrivers and awl.
– Loosen the coupling screw that connects the aiming device to the SYNFIX Evolution implant and rotate the aiming device 180° in preparation of the final two screws.

Short mini-open screwdriver
– Note that an additional short screwdriver is available as an alternative driver depending on access and patient anatomy. This screwdriver also includes a coated band (black) to differentiate it from the screwdrivers in the standard SYNFIX Evolution set.

Screw Insertion

Assemble awl and screwdrivers
– Attach a handle to the AO coupling of the awl.
– Next, attach a handle to the AO coupling of the SYNFIX Evolution screwdriver. Then thread the thread lock sleeve all the way down on the screwdriver tip.
– Ensure the arrow on the sleeve is pointing towards the screwdriver handle.

Optional:
– Upon surgeon preference, an optional handle with ratchet wrench, a screwdriver without thread lock sleeve or a straight screwdriver can be assembled.
– Upon surgeon preference, the screw insertion and the final tightening can be combined in one step by assembling the torque limiting handle to the SYNFIX Evolution screwdriver.

Optional: Assemble protection sleeve
– The protection sleeve can be assembled to all jointed SYNFIX Evolution instruments.
– Slide the protection sleeve, with the arrow pointing to the handle end of the instrument, over the distal end of the instrument towards the joint. Carefully seat the protection sleeve in the corresponding grooves.
– The protection sleeve has a pre-angulation of 35° to facilitate insertion into the aiming device and provides additional positional memory of the joint.
– Verify the sleeve is correctly oriented and seated on the instrument.

Create pilot hole
– Insert the awl into the aiming device. Create a pilot hole in the vertebral body for screw insertion by applying pressure on the handle of the awl with rotational motions.
– Soft tissue retractor can be used for additional tissue retraction and protection after the first screw has been inserted. Anchor the retractor in the corresponding groove on the selected aiming device.
– If required, the holding instrument may be used to control the tip of the awl and to avoid injury to the surrounding soft tissues or vessels.
– The holding instrument may also be used for removal of the awl, to avoid damaging adjacent structures.
– After the first pilot hole continue with insertion of the first screw to stabilize the implant before preparing any other holes.
– It is recommended to start screw insertion with the easiest screws to insert (e.g., S1 screws for L5/S1).
– It is not necessary to impact or completely rotate the awl to break the cortex. Rotational motions clockwise and counter-clockwise are typically sufficient.
– The purchase length of all screws exceeds the penetration depth of the awl.

Select screw
– Select an appropriate screw type and length based on patient anatomy and clinical requirements.
– Fine tip screws support penetration of sclerotic bone.
– It is recommended to use the longest screw length possible depending on patient anatomy and safe usage.

Load screw to screwdriver
– Securely position the screw loading station on any flat surface or hold it in one hand while loading a screw. Place a screw in the screw loading station with the tip down.
– Engage the screwdriver in the screw recess and ensure the thread lock sleeve is fully seated in the screw loading station. It may be necessary to push the sleeve down so it is in contact with the screw.
– Load the screw two-finger tight by turning the screwdriver counter-clockwise until the screw is loaded and the sleeve is fully seated on the screw head.
– Pull the screwdriver with the loaded screw out of the screw loading station.

Insert and tighten screws
– The soft tissue retractor is designed to provide additional tissue retraction and protection and to provide clearance for screw insertion along the screw trajectory. Anchor the retractor in the corresponding groove on the selected aiming device.
– Insert the loaded screw through the aiming device and into the pilot hole created by the awl. Use fluoroscopic imaging during screw insertion to assess positioning.
– The holding instrument may be used to control the screwdriver while inserting into or removing from the aiming device.
– As soon as both green rings are visible in the windows on the thread lock sleeve and a firm end point is noted, the screw is fully inserted.
– A constant force along the screw axis should be applied during entire screw insertion.
– Attach the torque limiting handle to the screwdriver. Tighten again until there is a tactile release which indicates that the required torque has been applied.
– To ensure appropriate locking it is important that the angle of the U-joint does not cross over the aiming device holder during final tightening. Reduce the angulation of the U-joint by retracting tissue with the soft tissue retractor.
– Verify screw position under fluoroscopy.
– Optionally the aiming device holder can be removed after the first screw is inserted and tightened to facilitate screw insertion.
– Repeat the above listed screw insertion surgical steps for the remaining 3 screws.
– If a 17/19 mm implant is being used, the aiming device must be rotated after the second screw is inserted.
– If screw insertion is blocked or difficult, verify that the previously placed screws are advanced far enough and are not blocking the current screw and that a screw has not been inserted in that hole already.
– For final tightening, it is suggested to use the straight screwdriver if access allows or straighten the angled screwdriver as far as possible.

Rotate 17 and 19 mm aiming device
– For implant heights 17 and 19 mm, the aiming device needs to be rotated after the first 2 screws are inserted.
– First, re-attach the aiming device holder to the aiming device. Pull the outer shaft of the aiming device holder towards the handle, and then attach to the aiming device. Release the outer shaft of the aiming device holder.
– Insert the coupling in the aiming device holder and disengage the coupling screw from the implant by turning the coupling counter-clockwise.
– Remove the aiming device from the implant, rotate it 180° degrees and re-attach it to the implant.
– Dock the keyed connection interface of the assembled aiming device into the corresponding docking feature on the implant. After the aiming device has been positioned, secure it by turning the coupling clockwise to tighten the coupling screw.
– Remove the coupling from aiming device.
– Repeat the above listed screw insertion surgical steps to insert the remaining 2 screws.

Remove instruments
– First, re-attach the aiming device holder to the aiming device. Pull the outer shaft of the aiming device holder towards the handle and then attach to the aiming device. Release the outer shaft of the aiming device holder.
– Insert the coupling in the aiming device holder and disengage the coupling screw from the implant by turning the coupling counter-clockwise.
– Remove the aiming device from the implant.
– If the aiming device is difficult to remove, verify that all screws are fully seated and not blocking the aiming device during removal.

Verify implant positioning
– The optimal position for the SYNFIX Evolution implant is centered within the periphery of the vertebral body and achieving appropriate fit and fill of the disc space.
– Verify the location of the SYNFIX Evolution implant relative to the vertebral bodies in the AP and lateral directions under fluoroscopy.
– The titanium plate and single posterior tantalum X-ray marker incorporated into the implant are designed to allow intraoperative radiographic assessment of the position of the implant.
– The X-ray marker is parallel to endplates and is flush against the posterior wall of the SYNFIX Evolution implant.

Screw Removal

Assemble aiming device
– Choose the aiming device corresponding to the implant height. Each aiming device combines 2 heights.
– Assemble the aiming device holder.
– Fully engage the coupling screw in the aiming device with the coupling. Attach the aiming device holder to the aiming device by pulling the outer shaft on the aiming device holder towards the handle and then engage the aiming device. Align the vertical black lines on the aiming device holder and the aiming device. Release the outer shaft to lock the assembly.
– Insert the coupling in the aiming device holder.
– Ensure the aiming device holder is fully seated on the aiming device.

Attach aiming device
– Insert the assembled aiming device into the operative site.
– Dock the keyed connection interface of the aiming device into the corresponding docking feature on the implant.
– After the aiming device has been positioned, secure it by turning the coupling clockwise to tighten the coupling screw. Remove the coupling from aiming device.
– The aiming device should fit tight against the plate.
– Ensure the aiming device/implant connection is secure.

Remove screws
– Assemble the screwdriver without thread lock sleeve.
– Depending on the access, the straight screwdriver may be used.
– The soft tissue retractor can be used for additional tissue retraction and protection with the angled screwdriver. Anchor the retractor in the corresponding groove on the selected aiming device.
– Insert the screwdriver in the aiming device and engage it in the screw recess.
– The holding instrument may be used to control the screwdriver while inserting into or removing from the aiming device.
– Turn the screwdriver counter-clockwise to unlock the screw and remove the screw.
– Optionally remove the aiming device holder for better visibility and access. Repeat this step to remove the remaining three screws.
– Verify under fluoroscopy that all screws are removed.
– Do not use the angled screwdriver with thread lock sleeve for screw removal.

Remove aiming device
– If necessary, first re-attach the aiming device holder to the aiming device. Pull the outer shaft of the aiming device holder towards the handle and then attach to the aiming device. Release the outer shaft of the aiming device holder.
– Insert the coupling in the aiming device holder and disengage the coupling screw from the implant by turning the coupling counter-clockwise.
– Remove the aiming device from the implant.
– If the aiming device is difficult to remove, verify that all screws are removed and are not blocking the aiming device during removal.

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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Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
www.jnjmedtech.com

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