Instructions for Use
FACET WEDGE

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

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each manual is always available online.
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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

FACET WEDGE
FACET WEDGE includes a spacer and a FACET WEDGE specific screw.
The FACET WEDGE system is comprised of implants offered in small, medium and large sizes. Each construct is fixed in place with two screws.

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

Materials

Material:	Standard:
TAN (Ti-6Al-7Nb)	ISO 5832-11

Intended Use
FACET WEDGE is intended for the fixation of the spine as an aid to fusion through immobilization of the facet joints, with or without bone graft, at one or two levels, from L1 to S1 in skeletally mature patients. FACET WEDGE can be inserted minimal invasively and should only be used to augment other fusion and stabilization techniques.

Indications
- Degenerative disc disease
- Degenerative facet joint disease (isolated facet based symptomatic back pain)
- Pseudarthrosis post anterior fusion with intact instrumentation

Contraindications
- Unilateral application, except in combination with pedicle screw fixation on the contralateral side
- Compromised facets due to decompression techniques
- Spondylolisthesis
- Fracture or other instabilities of the posterior elements
- Tumor
- Acute or chronic systemic or localized spinal infections

Patient Target Group
The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Please note that not all patients can be treated with FACET WEDGE. Patient specific anatomy needs to be considered e.g. if the facet joint orientation is in conflict with the iliac crest.

Intended User
This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the Instructions for use and, the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure as appropriate.
Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits
Expected clinical benefits of supplemental fixation devices such as FACET WEDGE when used to augment other fusion and stabilization techniques include the symptomatic improvement obtained from spinal fusion surgery.

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

Performance Characteristics of the Device
The FACET WEDGE system is designed to stop the translational motion in the facet joints, which is achieved through insertion of a press fit block (implant) between the articulating surfaces.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, there are risks of side effects and adverse events. Possible side effects may include: problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments); thrombosis, embolism, infection, hemorrhage, neural or vascular injury; damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, complex regional pain syndrome, allergy/hypersensitivity reactions, symptoms associated with implant or hardware prominence; ongoing pain, damage to adjacent bones or discs; dural tear or spinal fluid leak; nerve root or spinal cord compression and/or contusion; nonunion (pseudarthrosis), malunion or delayed union; bending, breakage, loosening or migration of the implant; decrease in bone density due to stress shielding; sensitivity or foreign body reaction; postoperative pain or discomfort; fracture of bony structures, necrosis of bone.

Sterile Device

Sterilized using irradiation

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


Do not use when packaging is damaged.

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


Do not resterilize

Re-sterilization of FACET WEDGE 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, reuse 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 FACET WEDGE is implanted only by operating surgeons who are experienced in spinal surgery and who are aware of general risks of spinal surgery and the product-specific surgical procedures. Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

Patient positioning
- Position the patient on a radiolucent operating room (OR) table in prone and natural alignment of the spine. The FACET WEDGE offers no reduction possibilities.

Incision
- Separate the soft tissue and localize the facet joint. Dilate soft tissue by inserting the dilator. Open capsula, then visualize and prepare the facet joints including the removal of osteophytes to ensure the correct placement of the FACET WEDGE implant.
- For better visualization the facet joint capsula is removed, care must be taken to avoid articular process weakening during osteophytes removal.

Wire insertion
- Before inserting the Kirschner Wire use the facet opener to ensure proper insertion location.
- Do not use the facet opener to distract the joint and/or to rasp the joint.
- Do not insert the facet opener beyond the stop.
- Only use the Kirschner Wire from the FACET WEDGE system.

Facet joint preparation and trial insertion
- Consider following points during insertion of trial/rasp, do not use the trial/rasp if the tip is bent.
- Check if the trial/rasp tip is bent by inserting the Kirschner Wire into the cannula of the trial/rasp and control axial alignment of the tip to the Kirschner Wire axis.
- Excessive hammering may lead to facet joint fracture.
- Make sure the Kirschner Wire is not pushed forward during trial/rasp insertion.
- Selecting appropriate trial/rasp size is important, selection of a too large implant might lead to closing of the facet joint on the contralateral side.
- The trial/rasp shall not be inserted beyond the stop.
- Excessive removal of the subchondral bone may weaken the articular process and may result in pseudarthrosis, segmental instability or facet joint fracture.

Implant insertion
- During implant insertion make sure the Kirschner Wire is not pushed forward during the implant insertion.
- Hammer on the top cap of the implant holder only.
- When the implant has reached final depth excessive hammering may lead to facet joint fracture.
- After removing Kirschner Wire, connect the handle to the awl. Care must be taken, always use the awl in combination with the implant holder.
- Always use the awl prior to screw insertion.
- Once awling is complete, insert the screws in loading station. Assemble the torque limiter to the screwdriver shaft and handle. If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.
- Always use the screwdriver in combination with the implant holder.
- Screw loosening with the torque limiting handle may damage the torque limiting handle. Therefore, always use the standard handle for screw loosening.
- The FACET WEDGE must be secured with two screws.

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

Combination of Medical Devices
FACET WEDGE implants are intended to be used with associated FACET WEDGE 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 implants of the FACET WEDGE 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 FACET WEDGE implant will produce a temperature rise not greater than 3.5 °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 FACET WEDGE device.

Treatment before Device is used

Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged.

Implant Removal

If a FACET WEDGE implant must be removed, the following technique is recommended.
Please note that precautions/warnings related to implant removal are listed in section "Warnings and Precautions".

Remove screws:
- Connect the handle to the screwdriver shaft.
- Connect implant holder to the implant.
- Loosen both screws a maximum of two turns with the screwdriver inserted in the screw guide. After loosening the first screw the screwdriver must be removed and the screw guide must be flipped.
- Remove the implant holder.
- Remove both screws with the screwdriver. Tweezers may be necessary to remove the screws.

Note: The screwdriver shaft must be in line with the screw axis when torque is applied.

Remove implant:
- Connect implant holder to the implant
  Note: Make sure the arrows are pointing to each other to control that the screw guide is locked into position.
- Controlled and light hammering on the implant holder cap may be required to retract the implant.

Disposal
Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

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