Instructions for Use
ACIS®– Anterior Cervical Interbody Spacer

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
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Printed on: Feb 04, 2021

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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SE_528349 AE 12/2020

Instructions for Use

ACIS® – Anterior Cervical Interbody Spacer
The ACIS implants are anterior cervical interbody fusion devices designed to be inserted within the intervertebral disc space to provide stability in skeletally mature individuals. These devices are radiolucent with radiopaque markers and a central lumen that can accept bone graft or bone graft substitute.
The ACIS implants are available in multiple heights, footprints and sagittal profiles.

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:
PEEK	ASTM F 2026
TAV ELI	ASTM F 136

Intended Use
The ACIS implants are intended for use as an intervertebral body fusion device in skeletally mature patients with degenerative disease of the cervical spine (C2-C7). The ACIS implants are designed for an anterior approach.

Indications
The ACIS implants are indicated for degenerative spine disease.

For multisegmental fusions with the ACIS system supplemental fixation is recommended.

Contraindications
- Osteoporosis
- Major spinal instabilities without supplemental fixation
- Vertebral body fractures
- Spinal tumors
- 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.

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.

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
When the ACIS implants are used as intended and according to the instructions for use and labeling the device is expected to provide stabilization of the motion segment(s) after intervertebral disc removal as an adjunct to fusion.

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 ACIS implants are cervical intervertebral body fusion 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, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, complex regional pain syndrome (CRPS), allergy/hypersensitivity reactions, symptoms associated with implant or hardware loosening, malunion, non-union, ongoing pain; damage to adjacent bones (e.g. subsidence), disc (e.g. adjacent level degeneration), or soft tissue, dural tear or spinal fluid leak; spinal cord compression and/or contusion, esophageal perforation, erosion or irritation, cage displacement, vertebral angulation.

Sterile Device

Sterilized using irradiation

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


Do not use when packaging is damaged.

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


Do not resterilize

Resterilization of ACIS 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 ACIS 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, exposure and discectomy
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.

Endplate preparation
When the discectomy is complete, remove the superficial cartilaginous layers of the endplates.
- Adequate cleaning of the endplates is important for vascular supply of the bone graft or bone graft substitute.
- Excessive cleaning, however, may result in removal of bone underlying the cartilaginous layers and weaken the endplates.
- The removal of any osteophytes is crucial for achieving complete decompression of the neural structures and for reducing the risk of partial compression after implant insertion.

Insert trial implant into the intervertebral disc space
– Ensure that all disc material has been removed from the insertion path to avoid displacing it into the spinal canal.
– Excessive impaction force during trial implant insertion must be avoided.
– The trial implants do not have a depth limiter; an image intensifier should be used to check the position during insertion.
– The height of the trial implants is undersized by 0.5 mm compared to the implant, to help ensure a tight fit of the ACIS implant upon insertion.
– With the segment fully distracted, the trial implant must fit tightly between the endplates. To reduce potential increased risk to the patient, it is recommended to first trial with smaller height trial implants before trialing with taller trial implants.
– Trial implants are not for implantation and must be removed before insertion of the ACIS implant.

Pack implant with bone graft or bone graft substitute
Place the ACIS implant (PEEK) into the packing block.
– Excessive impaction of the implant with the cancellous bone impactor should be avoided to prevent possible implant damage.

Insert implant into the intervertebral disc space
Option A: Attach implant to insertion device
– If an inner shaft without stop is used, then an image intensifier should be used to check the position during insertion.
– Excessive impaction must be avoided to prevent implant damage or too deep insertion.
– Excessive tilting of the insertion device must be avoided to prevent implant separation or damage.
– Verify final implant position relative to the vertebral bodies in the anteroposterior (AP) and lateral views using intraoperative imaging. The ACIS implant has three x-ray markers incorporated in the implant to enable intraoperative radiographic assessment of the implant position.

Option B: Attach implant to implant holder
– The implant holder does not feature a depth stop. Image intensifier control should be used to check the position during insertion.
– Excessive tilting of the implant holder must be avoided to prevent implant separation or damage.
– Excessive impaction must be avoided to prevent implant damage or too deep insertion.
– Verify final implant position relative to the vertebral bodies in the anteroposterior (AP) and lateral views using intraoperative imaging. The ACIS implant has three x-ray markers incorporated in the implant to enable intraoperative radiographic assessment of the implant position.

Implant removal with the insertion device
– Take care not to push the implant towards the posterior elements.
– Excessive tilting of the insertion device must be avoided to prevent implant separation or damage.

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

Combination of Medical Devices
ACIS implants are intended to be used with associated ACIS 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 ACIS 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 ACIS implant will produce a temperature rise not greater than 2.6 °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 ACIS 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 an ACIS implant must be removed, the following technique is recommended.

Implant removal with the insertion device
– Attach the ACIS insertion device to the implant in the disc space by aligning the pronged tabs of the instrument tip to the recessed grooves located on the side walls of the implant.
– Tighten the knob clockwise until the implant has a rigid connection.
– Ensure that the implant is held flush against the insertion device and securely in the tabs.
– Remove the implant from the disc space.
– The mallet can be used for implant removal.
– While holding the insertion device, slide the mallet over the shaft of the insertion device and apply an upward force.
– Repeat this process until the implant has been removed.

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.

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