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
manual is always available online.
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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. The cages are made from PEEK and include three radiopaque markers, and a central lumen that can accept bone graft material.

The ACIS implants are available in multiple heights, footprints and sagittal profiles.

These instructions for use contain information about the following products:

08.843.005S	08.843.305S	08.843.605S
08.843.006S	08.843.306S	08.843.606S
08.843.007S	08.843.307S	08.843.607S
08.843.008S	08.843.308S	08.843.608S
08.843.009S	08.843.309S	08.843.609S
08.843.010S	08.843.310S	08.843.610S
08.843.011S	08.843.311S	08.843.611S
08.843.012S	08.843.312S	08.843.612S
08.843.105S	08.843.405S	08.843.705S
08.843.106S	08.843.406S	08.843.706S
08.843.107S	08.843.407S	08.843.707S
08.843.108S	08.843.408S	08.843.708S
08.843.109S	08.843.409S	08.843.709S
08.843.110S	08.843.410S	08.843.710S
08.843.111S	08.843.411S	08.843.711S
08.843.112S	08.843.412S	08.843.712S
08.843.205S	08.843.505S	08.843.805S
08.843.206S	08.843.506S	08.843.806S
08.843.207S	08.843.507S	08.843.807S
08.843.208S	08.843.508S	08.843.808S
08.843.209S	08.843.509S	08.843.809S
08.843.210S	08.843.510S	08.843.810S
08.843.211S	08.843.511S	08.843.811S
08.843.212S	08.843.512S	08.843.812S

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: TAV (Titanium – 6% Aluminum – 4% Vanadium) ELI (Extra Low Interstitial) according to 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 ACIS 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 ACIS 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 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 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; 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; 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; 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 ACIS 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, 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 material.
- 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 material
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 applied using associated ACIS Instruments.

03.617.981	Impactor, flat
03.820.113	Mallet
03.841.005	ACIS Trial Implant, standard, lordotic, height 5/6 mm
03.841.007	ACIS Trial Implant, standard, lordotic, height 7/8 mm
03.841.009	ACIS Trial Implant, standard, lordotic, height 9/10 mm
03.841.011	ACIS Trial Implant, standard, lordotic, height 11/12 mm
03.841.050	ACIS Insertion Device
03.841.051	Turning Knob f/ACIS Insertion Device
03.841.053	ACIS Implant Holder
03.841.054	Cancellous Bone Impactor
03.841.055	Packing Block
03.841.057	Inner Shaft, small, w/Stop
03.841.059	Inner Shaft, standard/large, w/o Stop
03.841.060	Inner Shaft, standard/large, w/Stop
03.841.061	Inner Shaft, small, w/o Stop
03.841.105	ACIS Trial Implant, standard, parallel, height 5/6 mm
03.841.107	ACIS Trial Implant, standard, parallel, height 7/8 mm
03.841.109	ACIS Trial Implant, standard, parallel, height 9/10 mm
03.841.111	ACIS Trial Implant, standard, parallel, height 11/12 mm
03.841.150	Endplate Rasp
03.841.205	ACIS Trial Implant, standard, convex, height 5/6 mm
03.841.207	ACIS Trial Implant, standard, convex, height 7/8 mm
03.841.209	ACIS Trial Implant, standard, convex, height 9/10 mm
03.841.211	ACIS Trial Implant, standard, convex, height 11/12 mm
03.841.305	ACIS Trial Implant, large, lordotic, height 5/6 mm
03.841.307	ACIS Trial Implant, large, lordotic, height 7/8 mm
03.841.309	ACIS Trial Implant, large, lordotic, height 9/10 mm
03.841.311	ACIS Trial Implant, large, lordotic, height 11/12 mm
03.841.405	ACIS Trial Implant, large, parallel, height 5/6 mm
03.841.407	ACIS Trial Implant, large, parallel, height 7/8 mm
03.841.409	ACIS Trial Implant, large, parallel, height 9/10 mm
03.841.411	ACIS Trial Implant, large, parallel, height 11/12 mm
03.841.505	ACIS Trial Implant, large, convex, height 5/6 mm
03.841.507	ACIS Trial Implant, large, convex, height 7/8 mm
03.841.509	ACIS Trial Implant, large, convex, height 9/10 mm
03.841.511	ACIS Trial Implant, large, convex, height 11/12 mm
03.841.605	ACIS Trial Implant, small, lordotic, height 5/6 mm
03.841.607	ACIS Trial Implant, small, lordotic, height 7/8 mm
03.841.609	ACIS Trial Implant, small, lordotic, height 9/10 mm
03.841.611	ACIS Trial Implant, small, lordotic, height 11/12 mm
03.841.705	ACIS Trial Implant, small, parallel, height 5/6 mm
03.841.707	ACIS Trial Implant, small, parallel, height 7/8 mm
03.841.709	ACIS Trial Implant, small, parallel, height 9/10 mm
03.841.711	ACIS Trial Implant, small, parallel, height 11/12 mm
03.841.805	ACIS Trial Implant, small, convex, height 5/6 mm
03.841.807	ACIS Trial Implant, small, convex, height 7/8 mm
03.841.809	ACIS Trial Implant, small, convex, height 9/10 mm
03.841.811	ACIS Trial Implant, small, convex, height 11/12 mm

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.
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
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 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".

Special Operating Instructions
Preparation

Preparation
– Have all necessary imaging studies readily available to plan implant placement and visualize individual patient anatomy. Have all necessary sets readily available prior to surgery.

Assemble insertion device
– Assemble the insertion device prior to use.

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

Exposure and discectomy

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.

Segment distraction
– Perform segmental distraction.
– Distraction of the segment is essential for restoring disc height and for providing access to the intervertebral space.

Endplate preparation
– When the discectomy is complete, remove the superficial cartilaginous layers of the endplates to expose bleeding bone.
– The endplate rasp is double sided with a standard depth on one side and a large depth on the other side. These are indicated by one (standard) and two (large) white bands on the shaft as well as etchings on the rear side of the rasp. The depth is limited by a stop. Depths are 14 mm for the standard and 16 mm for the large. The width is 8 mm and the height is 4 mm.

Implant size and shape determination
– The selection of the trial implant depends on the height, width and depth of the intervertebral space, the preparation technique and the patient's anatomy. Choose a standard, large or small footprint trial implant with convex, lordotic or parallel sagittal shape of the appropriate height.
– The trial implants are double sided with different heights on either side. Colored bands on the shaft indicate which side is of lesser (one band) or greater (two bands) height. In addition, heights are etched on the cranial and caudal surfaces of the trial implants.
– Trial implants are color coded by sagittal shape: yellow, blue and purple bands on the shaft indicate that a trial implant is convex, lordotic or parallel. Furthermore, the following etchings on the cranial and caudal surfaces indicate the sagittal shape: "C" for convex, "L" for lordotic, and "P" for parallel.
– The footprint is indicated by the etchings "Small", "Standard" and "Large" on the cranial and caudal surfaces of the trial implants.
– Before carefully inserting the trial implant, ensure that the orientation of the trial implant is correct. Each convex trial implant is etched with an arrow pointing cranially on the lateral walls to indicate the correct cranial/caudal alignment.
– The lordotic and parallel trial implants do not have a dedicated cranial or caudal surface. They can be inserted into the intervertebral disc space with either surface pointing cranially.
– If necessary, controlled and light hammering with the mallet can be used to help advance the trial implant into the intervertebral disc space.
– Use image intensifier to confirm the fit of the trial implant. If the trial implant appears too loose or too tight, try the next larger or smaller size height until the most secure fit is achieved.
– The mallet can be used for trial implant removal. While holding the trial implant slide the mallet over the upper part of the trial implant's shaft and apply an upward force. Repeat this process until the trial implant has been removed.

Implant insertion

Option A: Insertion device
Attach implant to insertion device
– Select the ACIS implant that corresponds to the footprint, shape and height determined using the trial implant.
– If desired, the insertion device can be combined with an inner shaft with stop. It has a depth limiter that will contact the anterior edge of the vertebral body when the ACIS implant is inserted approximately 1 mm beyond the anterior edge of the vertebral body.
– Attach the implant to the ACIS insertion device by aligning the recessed grooves located on the side walls of the implant with the prolonged tabs of the instrument tip and engaging those. Turn the knob clockwise to secure the implant. Ensure that the implant is held flush against the insertion device and securely in the tabs.

Pack implant with bone graft material
– It is recommended to pack the ACIS implant with bone graft material.
– Place the ACIS implant into the packing block (PEEK only). Small and standard footprint implants fit into the cavity marked "Standard" while large footprint implants fit into the cavity marked "Large".
– The cancellous bone impactor can be used to firmly pack the bone graft material into the implant cavity.
– To ensure contact with the vertebral endplates, it is important to fill the implant until the bone graft material protrudes from the openings of the implant.

Insert implant
– Confirm the implant is securely attached. Carefully insert the implant into the distracted segment, ensuring that the orientation of the implant is correct. Each convex implant is etched with an arrow pointing cranially on the left lateral wall to indicate the correct cranial/caudal alignment. The lordotic and parallel implants have a symmetrical sagittal profile and therefore do not require specific orientation.
– If necessary, controlled and light hammering with the mallet can be used to help advance the implant into the intervertebral disc space.
– Turn the knob in a counterclockwise direction to release the implant from the insertion device.
– Remove the insertion device and if required use the flat impactor to seat the implant into its final position.
– Use image intensifier to confirm the position of the implant.
– The distance between pins and the anterior and posterior walls of the implant is approx. 1.0 mm.
– The posterior pin is centered.

Option B: Implant holder
Attach implant to implant holder
– Select the ACIS implant that corresponds to the footprint, shape and height determined using the trial implant.
– Attach the implant to the ACIS implant holder by aligning the recessed grooves located on the side walls of the implant with the prolonged tabs of the instrument tip. Engage the squeeze-lock by applying slight pressure on the arms of the implant holder.

Pack implant with bone graft material
– It is recommended to pack the ACIS implant with bone graft material.
– Place the ACIS implant into the packing block (PEEK only). Small and standard footprint implants fit into the cavity marked "Standard" while large footprint implants fit into the cavity marked "Large".
– The cancellous bone impactor can be used to firmly pack the bone graft material into the implant cavity.
– To ensure contact with the vertebral endplates, it is important to fill the implant until the bone graft material protrudes from the openings of the implant.

Insert implant
– Confirm the implant is securely attached, carefully insert the implant into the distracted segment, ensuring that the orientation of the implant is correct. Each convex implant is etched with an arrow pointing cranially on the left lateral wall to indicate the correct cranial/caudal alignment. The lordotic and parallel implants have a symmetrical sagittal profile and therefore do not require specific orientation.
– Release the implant holder by applying slight pressure on the arms of the implant holder and disengaging the squeeze-lock. Remove the holder and if required use the flat impactor to seat the implant into its final position.
– Use image intensifier to confirm the position of the implant.
– The distance between pins and the anterior and posterior walls of the implant is approx. 1.0 mm.
– The posterior pin is centered.

Supplemental fixation
– For multisegmental fusions with the ACIS system, supplemental fixation is recommended. Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effects and Residual Risks.

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

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

Implant Card & Patient Information Leaflet
If supplied with the original packaging, provide the implant card as well as the relevant information according to the patient information leaflet to the patient. The electronic file containing the patient information can be found at the following link: ic.jnjmedicaldevices.com

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Instructions for Use:
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