Instructions for Use
CERVIOS™ Cage System

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
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Instructions for Use

CERVIOS™ Cage System
The CERVIOS implants are anterior cervical interbody fusion (ACIF) devices designed to be inserted within the intervertebral disc space to provide stability. The cages are made from PEEK and include three titanium radiopaque markers and a central lumen that can accept bone graft material.

The CERVIOS implants are available in two shapes (wedge and curved) and different heights.

These instructions for use contain information about the following products:
889.921S
889.922S
889.923S
889.924S
889.925S
889.926S
889.931S
889.932S
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889.936S

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
PEEK: Polyetheretherketone according to ASTM F 2026
Titanium: TiCP (Commercially pure Titanium) according to ISO 5832-2

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

Indications
The CERVIOS implants are indicated for degenerative spine disease.

For multisegmental fusions, additional stabilization with a plate is recommended.

Contraindications
– Osteoporosis
– Major spinal instabilities without supplemental fixation
– Spinal fractures
– Spinal tumors
– Spinal infections

Patient Target Group
The CERVIOS 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 CERVIOS 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 CERVIOS 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 CERVIOS 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 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 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
– Before inserting the trial 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.
– An image intensifier should be used to check the position during 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 implant.

Pack implant with bone graft material
Place the CERVIOS implant 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
Connect the selected implant to the holder.
– An image intensifier control should be used to check the position during implant insertion.
– Excessive impaction must be avoided to prevent implant damage or inserting the cage too deep.
– Verify final implant position relative to the vertebral bodies in the anteroposterior (AP) and lateral views using intraoperative imaging.
– The CERVIOS implant has three x-ray markers incorporated in the implant to enable intraoperative radiographic assessment of the implant position.

Implant removal with the implant holder
– 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
The CERVIOS cages are applied using associated Cervical Cage Instrumentation.

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 CERVIOS 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 CERVIOS implant will produce a temperature rise not greater than 3 °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 CERVIOS 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 by visual inspection:
– Inspect the entire area of sterile barrier package, and the sealing, for completeness and uniformity.
– Inspect for the absence of holes, channels or voids of the sterile barrier package and the sealing.
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 a CERVIOS implant must be removed, the following technique is recommended.

– Attach implant to implant holder in the correct cranial/caudal alignment.
– Carefully remove the implant from the disc space.

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

Special Operating Instructions
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 and endplate preparation
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.

Implant size and shape determination
Determine implant size and shape with trial implant
– Choose the trial implant based on the height of the disc space and the patient's anatomy. Select the shape of trial implant (curved or wedge-shaped) that best matches the prepared end plates.
– To distinguish the curved and wedge-shaped design the trial implants are colour-coded. Curved trial implants are golden, wedge-shaped trial implants are dark blue.

Connect trial implant holder
– Holders are etched "CRANIAL" and "CAUDAL" to properly engage the trial implants with the holders.
– Connecting curved trial implant:
The curved surface of the trial implants and implants must always face cranially. They are marked with 2 arrows pointing cranially. Connect the trial implant to the holder so that the cranial implant surface matches with the side etched "CRANIAL" of the holder.

– Connecting wedge-shaped trial implant:
  The wedge-shaped trial implants and implants do not have a dedicated cranial or caudal side. They can be attached to the holder with any surface pointing cranially.

Option: Attach depth limitator to holder
– The depth limitator can be attached to the side of the holder. It has a stop that will contact the anterior edge of the vertebral body when the CERVIOS implant is inserted 2 mm beyond the anterior edge of the vertebral body.

Insert trial implant and check size
– Orient the holder in the correct cranial/caudal alignment and carefully insert the trial implant into the disc space.
– If necessary, controlled and light hammering with the mallet can be used to help advance the trial implant into the intervertebral disc space.
– 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 height of the trial implants is the same as the height of the implants

Determine size
– Select the curved or wedge-shaped cage corresponding to the trial implant.

Prepare the implant
– Remove the depth limitator from the holder. Connect the selected implant to the holder.
– Connecting curved implant:
  The curved surface of implants must always face cranially. They are marked with 2 arrows pointing cranially. Connect the implant to the holder so that the cranial implant surface matches with the side etched "CRANIAL" of the holder.
– Connecting wedge-shaped implant:
  The wedge-shaped trial implants and implants do not have a specified cranial or caudal side. They can be attached to the holder with either surface pointing cranially.
– Place CERVIOS implant with the cranial side facing upwards into the open packing block.
– Close the lid of the packing block.
– Fill the packing block through the lid opening with bone graft material using the cancellous bone impactor. The implant must be completely filled.

Implant insertion
Implant cage
– If desired, attach the depth limitator to the side of the holder.
– Orient implant and holder in the correct cranial/caudal alignment and carefully insert the implant into the distracted segment. Positioning may be accomplished by gentle impaction with a hammer on the holder.
– Release the distractor and remove all instruments.

Verify cage position
– The optimal position of the cage is centred within the periphery of the vertebral end plates.
– The x-ray markers are 2 mm from the anterior edge of the implant and 1 mm from the posterior edge.

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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