Instructions for Use

Anterior Lumbar Interbody Fusion (ALIF) cages:
VISIOS
SYNCAGE™-LR
SYNCAGE™

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

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the most current version of each
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DePuy Synthes
COMPANIES OF Johnson&Johnson

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Instructions for Use

Anterior Lumbar Interbody Fusion (ALIF) cages:
VISIOS, SYNCAGE™-LR, SYNCAGE™

Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material

Material:	Standard:
PEEK (Polyetherether-ketone)	ASTM F 2026
TAN (Ti-6Al-7Nb)	ISO 5832-11
TAV (Ti-6Al-4V)	ISO 5832-3

Intended use

VISIOS:
VISIOS is a system of implants and instruments designed for anterior lumbar interbody fusion (ALIF). The system was developed to achieve the following objectives:
– To distract the disc space and restore normal disc height and physiological lordosis, thereby also widening the foramina
– To preserve the integrity of the vertebral body endplates
– To provide an optimal implant/endplate interface, thus considerably limiting the risk of subsidence into the adjacent vertebrae
– To stabilise the pathologically unstable segment
– To support bone growth through the implant

SYNCAGE-LR:
SYNCAGE-LR is designed for anterior lumbar interbody fusion (ALIF) following the same design principles as SYNCAGE. In order to allow for monitoring of the fusion process, the cages are made of radiolucent PEEK.
Furthermore, two footprints are offered whereof the larger footprint comes in two angles, 10° and in addition 12° – the 12° implants are typically used for the instrumentation of L5/S1 disc levels.

SYNCAGE:
The SYNCAGE system is an implant and instrument system for anterior lumbar interbody fusion (ALIF). It was designed to:
– allow for interbody fusion in an optimum anatomical position
– allow distraction of the disc space and permit restoration of disc height, lordosis, and consequent widening of the neural foramina
– maintain the integrity of the endplates
– provide optimal implant/endplate interface, limiting the risk of sinkage into the adjacent vertebrae
– allow for bone ingrowth though the cage

Indications

VISIOS:
Lumbar and lumbosacral pathologies for which segmental spondylodesis is indicated, for example:
– Degenerative disc diseases and spinal instabilities
– Primary procedures for certain advanced disc diseases
– Revision procedures for post-discectomy syndrome
– Pseudoarthrosis or failed spondylodesis
– Degenerative spondylolisthesis
– Isthmic spondylolisthesis

SYNCAGE-LR:
Lumbar and lumbosacral pathologies which may require anterior segmental arthrodesis, including:
– Degenerative disc disease and instability
– Revision surgery for failed decompression syndrome or pseudoarthrosis
– Reduced spondylolisthesis

SYNCAGE:
Lumbar and lumbosacral pathologies which may require segmental arthrodesis, including:
– degenerative disc disease and instability
– primary surgery for certain advanced disc disease
– revision surgery for post-discectomy syndrome
– pseudarthrosis or failed arthrodesis
– degenerative spondylolisthesis
– isthmic spondylolisthesis

Note:
The ALIF Cages (VISIOS, SYNCAGE-LR, SYNCAGE) are not designed or intended to be used as a stand-alone device; the use of supplementary posterior or anterior instrumentation is therefore strongly recommended.

Contraindications

For VISIOS:
– Vertebral body fractures
– Serious spinal instabilities
– Primary spinal deformities
– Spinal tumours

For SYNCAGE-LR:
– Spinal fractures
– spinal tumour
– osteoporosis
– infection

For SYNCAGE:
– spinal fractures
– spinal tumours
– major spinal instability
– primary spinal deformity

Potential adverse events

As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common may include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic 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, side effects associated with implant or hardware prominence, malunion, non-union, ongoing pain; damage to adjacent bones (e.g.subsidence), discs (e.g. adjacent level degeneration), or soft tissue, dural tear or spinal fluid leak; spinal cord compression and/or contusion, partial displacement of the graft, vertebral angulation.

Sterile device

STERILE R Sterilized using irradiation

Store implants 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.

Do not resterilize

Single-use device

Do not re-use

Products intended for single-use must not be re-used.
Re-use or 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.

Precautions

When using ALIF cages patient clinical outcome can be influenced by the following:
– Severe, endocrine-induced bone diseases (e.g. hyperparathyroidsm)
– Current therapy with steroids and with drugs, which intervene in calcium metabolism (e.g. calcitonin)
– Severe, poorly controlled diabetes (diabetes mellitus) with bad wound healing tendencies
– Immunosuppressive therapy
– Poor bone quality, osteoporotic bone
– excessive patient loading beyond design limits (i.e. trauma, obesity)
– age of the patient
– poor nutritional status

The general risks associated with surgery are not described in these instructions for use. For more information, please refer to the Synthes brochure "Important Information".

Warnings
ALIF approach holds specific risks: excessive blood loss due to damage to large blood vessels (quoted rates in the medical literature put this risk at 1% to 15%); for males, another risk unique to this approach is that approaching the L5-S1 (lumbar segment 5 and sacral segment 1): retrograde ejaculation.

It is strongly advised that ALIF Cages are implanted only by operating surgeons who are familiar with the general problems of spinal surgery and who are able to master the product-specific surgical techniques. 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.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance environment
MR Conditional:

VISIOS:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the VISIOS 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 VISIOS implant will produce a temperature rise not greater than 4.0°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 VISIOS device.

SYNCAGE-LR:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the SYNCAGE-LR 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 SYNCAGE-LR implant will produce a temperature rise not greater than 2.5°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 SYNCAGE-LR device.

SYNCAGE:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the SYNCAGE 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.
In non-clinical testing, the SYNCAGE implant will produce a temperature rise not greater than 4.0°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 SYNCAGE device.

Treatment before device is used
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Processing/reprocessing of the device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling Multipart Instruments" can be downloaded from:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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