Instructions for Use
PLIVIOS™ REVOLUTION

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

EC REP

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DePuy Synthes
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Instructions for Use

PLIVIOS™ REVOLUTION
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
TAV (Ti-6Al-4V)	ISO 5832-3

Intended use
PLIVIOS is the Synthes Cage System for Posterior Lumbar Interbody Fusion (PLIF). It consists of radiolucent PEEK implants and the corresponding instruments.
The PLIVIOS REVOLUTION implants represent a further development of the PLIVIOS System. The cages are aligned in situ by rotation and allow an atraumatic restoration of the body's natural lordosis.

Indications
Degenerative lumbar and lumbosacral conditions requiring segmental fusion:
– Degenerative disc disease and instability
– Degenerative spondylolisthesis, grade I or II
– Spondylolisthesis with stenosis, grade I or II
– Pseudarthrosis or failed arthrodesis

Notes:
Since the PLIVIOS REVOLUTION Cages were not developed as "stand-alone" implants, the use of additional posterior instrumentation (for example with pedicle screws) is strongly advised.
The management of spondylolisthesis in grades III and IV, or higher levels of scarring deserves special attention. The same applies to destructive tumours. (Note that the PLIVIOS REVOLUTION System was not primarily developed for the restoration of the natural anatomy if three or more motion segments are involved.)

Contraindications
– Severe osteoporosis
– Unstable burst and compression fractures
– Acute infections

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), disc (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
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
It is strongly advised that PLIVIOS REVOLUTION is 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:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the PLIVIOS REVOLUTION 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 PLIVIOS REVOLUTION 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 PLIVIOS REVOLUTION device.

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