Instructions for Use
chronOS Prefilled Cages

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

chronOS Prefilled Cages
Please read this instruction for use and the Synthes brochure "Important Information".

Compositions
chronOS prefilled cages are radiolucent PEEK-Cages filled with chronOS. chronOS is a synthetic, porous, resorbable and biocompatible ceramic made of β-tri-calcium phosphate [$Ca_3(PO_4)_2$] with a defined, uniform pore structure. chronOS is replaced by autologous bone.

Intended Use
chronOS Prefilled Cages are designed for Posterior Lumbar Interbody Fusion (PLIF) and Anterior Cervical Interbody Fusion (ACIF).

Application Fields/Indications
The porous structure of chronOS implants acts as a matrix for the ingrowth of bone. chronOS implants must always be applied by enosseal or subperiosteal implantation, i.e. by direct contact with the vital bone.

Anterior Cervical Interbody Fusion:
Cervical pathologies where segmental spondylodesis is indicated:
– Ruptured and herniated discs
– Degenerative disc disease and instabilities
– Pseudoarthrosis or failed spondylodesis

For multisegmental arthodesis additional fixation with a plate is recommended.

Posterior Lumbar Interbody Fusion:
Lumbar and lumbosacral pathologies for which segmental spondylodesis is indicated, especially:
– Degenerative disc disease and instability
– Degenerative spondylolisthesis, grade I or II
– Spondylolisthesis with stenosis, grade I or II
– Pseudarthrosis or failed spondylodesis

As a rule, chronOS is resorbed within 6 to 18 months and converted into autologous bone; depending on patient conditions.

Note: Since Synthes Lumbar Interbody Fusion implants were not developed as "stand-alone" implants, the use of additional anterior or posterior instrumentation (for example with pedicle screws) is required.

Contraindications
chronOS prefilled cages should not be used in the following circumstances:

Anterior Cervical Interbody Fusion:
– Osteoporosis
– Severe instabilities
– Spinal fractures
– Spinal tumors
– Spinal infections

Posterior Lumbar Interbody Fusion:
– Osteoporosis
– Burst and compression fractures
– Destructive tumors
– Spondylolisthesis, grade lll and lV
– Infections
– Extensive peridural scar formations

Precautions
When using chronOS prefilled cages, patient clinical outcome can be influenced by the following:
– Severe, endocrine-induced bone diseases (e.g. hyperparathyroidism)
– 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

Warning Notices
– Do not attempt to re-sterilize the unused contents of an opened pack, but dispose of such remnants: this applies to both the inner primary and the outer secondary packaging.
– Do not use chronOS prefilled cages after the expiry date printed on the packaging.

Surgical Harms / Side Effects
As with all major surgical procedures, risks, side effects and adverse events can occur. Known side effects are:
Infection, problems with anesthesia, ongoing pain, dural tear or spinal fluid leak, neurological injury, injury to blood vessels, or bleeding.

Device Related Harms / Side Effects
Adverse response to foreign material, effects of abnormal biomechanics, change in implant position or implant breakage, abnormal bone formation, malunion or non-union, injury to adjacent organs, or injury to adjacent bones, disks or soft tissue.

Interactions
No negative interactions with autologous blood and bone marrow have been reported as yet.

Handling
Keep the sterile chronOS prefilled cages in its protective packaging until ready to use. Check that the packaging has not been damaged before opening as this might impair sterility. In removing the implant from its packaging, strictly observe the instructions concerning asepsis.

chronOS prefilled cages must always be applied by enosseal or subperiosteal implantation, i.e. by direct contact with the vital bone. The surgical procedure depends on the localization, nature and extent of the bone defect and is described in the surgical technique of the different cages. To prepare the implant site, remove all inflamed necrotic tissue and bone particles.

The appropriate implant size is determined by the size of the bone defect, the vascularity and the size of the cancellous bone chips, if used. Keep the regions of enosseal vessel and nerve cords clear to avoid pressure sores. Optionally, the chronOS portion can be enriched by soaking or perfusing the implant with the patient's own bone marrow or blood.

Storage
Store implant in its original protective packaging. Only remove implant from the packaging immediately before use.

MRI safety
Non-clinical testing of the worst-case scenario has demonstrated the articles of the chronOS Prefilled Cages (Cervios chronOS and Plivios chronOS) are MR conditional. These products can be scanned safely under the following conditions:
– Static magnetic field of 1.5 Tesla and 3 Tesla
– Spatial gradient magnetic field of 300 mT/cm (3000 G/cm) or less
– Maximum whole body averaged specific absorption rate (SAR) of 4 W/kg for the First Level Control Mode for 15 minutes of scanning

In non-clinical testing, the chronOS Prefilled Cages (Cervios chronOS and Plivios chronOS) produced a temperature rise of equal to or less than 3 °C at a maximum whole body average 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 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 chronOS Prefilled Cage (Cervios chronOS and Plivios chronOS).

Caution
Sufficient experience in the field of spinal surgery and biomaterials is recommended for using chronOS prefilled cages.

Additional Instructions for Use
For additional information, please contact your local Synthes representative.

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