INTRUCTIONS FOR USE

Synthetic Injectable Bone Augmentation Material "Synjectos®"

INDICATIONS

Synjectos, synthetic injectable bone augmentation material, is a bone augmentation material which is intended to be used for filling or reconstruction of bony defects, which are stabilized by traditional methods of bone stabilization, for example external fixators, Kirshner wires, screws etcetera. Such defects can origin during surgical interventions, congenital, caused by benign tumor or be originated by traumata.

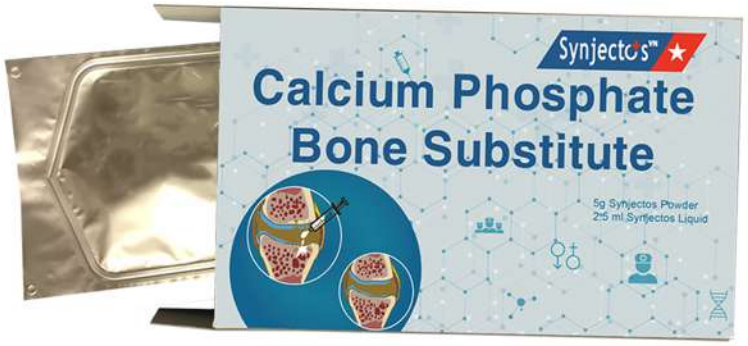
Synjectos must be placed in defects of the skeleton only in non-infected areas, after correct reposition and, if needed, stabilized by corresponding mechanical stabilization.

Typical defects are: proximal humerus fractures, bony defects of the acetabulum, fractures of the tibia head, idiopathic bone cysts, calcaneus fractures and vertebral body fractures after reposition by Kyphoplastic procedures.

PRODUCT DESCRIPTION

Synjectos is a synthetic, sterile osteoconductive material for filling of bone defects. The material consists of a powder source consisting of calcium and phosphate salts and a liquid component, consisting of an aqueous phosphate solution. After combining the powder and the liquid by thorough mixing a paste is formed which is hardening into an apatitic structure resembling the inorganic structure of natural bone.

No materials of biological origin are use during the manufacturing of Synjectos.



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CONTRA-INDICATIONS

Synjectos must not be implanted in following circumstances:

- Acute or chronic infections on the implantation site
- Presence of malign tumors
- Presence of osseous infections and inflammations like osteomyelitis
- Defects in direct apposition of open epiphyseal areas
- Renal or severe hepatic dysfunction
- Treatment with immunosupressive drugs

ADVERSE REACTIONS

- Extravasation of the material in adjacent areas like soft tissue, joint areas or intramedular canal.
- Heterotopic ossification.
- Extravasation of the material in heterotopic sites may cause inflammation of nerves, tendons or articular pain.

WARNINGS

- Synjectos is intended **for single use only. DO NOT RE-STERILIZE or RE-USE.**
- Recondition, refurbish or any modification is prohibited.

ATTENSION

- This product **should be used exclusively by surgeons who are familiar with the handling of calcium phosphates cements** and the corresponding surgical techniques like treatment of osseous defects.
- Osseous defects to be filled by the bone substitute material must be filled completely. The usage of fluoroscopy will help to ensure the complete filling of the defect in cases of minimal invasive procedures.

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PRECAUTIONS

- Read instructions for use intensively before usage of the material.
- Never use the product if the packaging is opened or defective.
- This may affect the functionality and especially the sterility of the material.
- It is important that the user of the product is familiar with the physiopathology of the anatomical region of the implantation site.
- The product **was not evaluated in children or during pregnancy.**
- The use of Synjectos is considered for filling of bony defects which are stabilized by standard orthopedic techniques of fracture reduction and stabilization.
- Before application of Synjectos excessive bleeding on the implantation site must be controlled.
- The material is not allowed to be implanted in soft tissue, avascular bone, sites with predisposition for infections, like open fractures without soft tissue coverage.
- Do not implant Synjectos with pressure in locations with the risk fat embolization or risk of embolization of Synjectos into blood stream.
- Synjectos may not be applied into open epiphyseal aéreas.
- The hardened material will reach its ultimate mechanical strength 24 hours' after implantation; therefore, the patient should avoid active weight bearing movements for the first 24 hours after surgery.

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SECONDARY EFFECTS AND INTERACCIONS

Risk in relation with the material

The formation of renal stones after implantation of Synjectos is very unlikely due to the very slow resorption and the poor solubility in combination with the low amount of implanted material.

PRESENTATION

Synjectos is delivered sterile, within locked syringes and packed in a polyethylene coated aluminum foil. In case of damage to the sterile package do not use and inform the manufacturer.

STORAGE

The material must be stored between 15°C and 25°C.

PACKAGE SIZE AND DELIVERY

Synjectos are packages in several sizes. Each package contains of a certain amount gram of powder and ml of liquid syringe.
Content: 1 powder syringe, 1 liquid syringe, transparent connector, instruction manual.

STERILIZATION

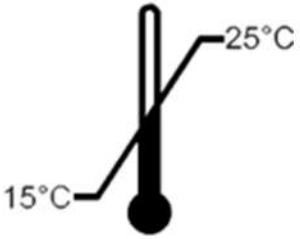
Sterilized by gamma irradiation

LIMITATIONS OF LIABILITY

No responsibility by misuse, reuse, outside indication….

REQUESTS FOR INFORMATION

SYNJECTOS VN
Email: info@synjectos.com
Website: www.synjectos.com
Hotline: 02383.218.886



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Synthetic Injectable Bone Augmentation Material "Synjectos®"

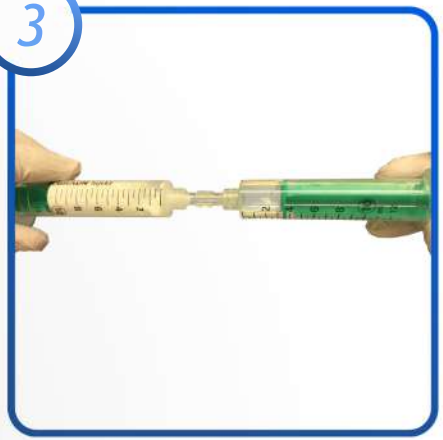
1

Hold the syringes in a vertical position and open the red obturator cap on both syringes.

2

Fix the transparent connector onto the small syringe with a firm rotation to the right and connect the screw tip of the bigger syringe with the connector until both syringes are firmly connected.

3



Slowly inject the liquid of the small syringe into the powder containing syringe by concurrently pulling back the plunger in order to avoid overpressure in the syringe.

4

Disassemble the connector plus the small syringe from the bigger syringe and obturate the tip of the bigger syringe with the red obturator.

5

Shake the syringe vigorously for 5 seconds until a homogenous paste has been formed.

6

The paste is now ready to be injected into the defect site.

Website: www.synjectos.com

Email: info@synjectos.com