Syntricer• Instruction for Use

Description, Composition and Structure

Syntricer• is a ceramic bone void filler which comprises ≥ 95% of a ß-TCP (tricalciumphosphate) $Ca_3(PO_4)_2$. The composition of Syntricer® is in accordance with the ASTM F 1088 standard. Syntricer® exists as a 3-D shell scaffold that is fully interconnected.

Syntricer® is available in geometric shapes such as cylinders, blocks, wedges, spheres (Syntricer®*Ceraball®),* granules and rounded granules (Syntricer®*Ceround®)*. Syntricer®*Ceraball®* represent micro-chambered shell-like structured beads with a fully interconnected system of marrow spaces to form an entire implant, thus creating an osteoconductive structure for yielding a primary formation of a cancellous bone scaffold.

All geometric shapes of Syntricer® are offered with standardized micro- and macroporosities.

Syntricer® having a trabecular structure is offered with macro-pores of 300, 600 und 1000 µm. Overall, fully interconnected porosity reaches 80 – 88%.

Clinical evidence proves the following properties of Syntricer® products:

- Defect filling / Bone void filling
- Osteoconductivity
- Radiopaque material
- Biocompatibility
- Purity of the Material
- Nearly complete biodegradation within 3 – 4 months

No interactions between Syntricer• products and pharmaceuticals or other medical devices have been reported to date except the direct in-contact combination with stiff implants.

Intended use

Syntricer® Calcium Salt Bone Void Filler is intended for use as a bone void filler for voids or gaps in bone that are not intrinsic to the stability of the bony structure.

Medical indication

Syntricer® is indicated for use in the treatment of surgically created osseous defects or osseous defects of other origin:

- Trauma-related bone voids
- Donor-site defects (i.e. defect filling at the harvest site of autologous cancellous bone, preferably in the iliac crest, gathering of osteocartilage grafts from the patellar groove, and other harvest sites)
- Bone augmentation in oral and maxillary surgery

Fields of application include trauma surgery, orthopedics, restorative plastic surgery, oral and maxillary surgery, as well as E.N.T (Ear, Nose, Throat) surgery.

Syntricer® (β-TCP ceramic) and Synthacer® (hydroxyapatite ceramic) generally share the same indications, but on the basis of their respective physical and biological properties, they each have preferred applications, and they also can be combined. Biodegradation of the hydroxyapatite ceramic Synthacer® is a much slower process compared to β-TCP Syntricer®, and resorption of HA is limited. Therefore, the surgeon is advised to choose HA implants (Synthacer®) in case of pronounced osteoporosis and for defect filling in the iliac crest, i.e. in cases where maintenance of physical strength and stability of the implant over a long time period is required. Moreover, in defects, where the deformation is more pronounced, i.e. in the iliac crest, HA implants (Synthacer®) are requested, whereas in the patellar donor bed ß-TCP implants (Syntricer®) are preferred.

Bone defects or bone cavities in which the Syntricer® implants are primarily ex-posed to lower pressure rather than bending or shearing forces includes applications in all cancellous bone defects in the epiphysis and metaphysis, where the flow of force through the given structures must be supported, and damping is ensured by remaining cancellous bone in the bone bed or implanted cancellous grafts (Sandwich ceramic = layering of damping cancellous bone - ceramic - damping cancellous bone).

It is the responsibility of the (trained) surgeon to evaluate the present defect condition and location, and patient's status and preferences, in order to decide which ceramic product to use.

Syntricer®Cylinder

- Bone Void Filler
- for replacing damaged, lost or removed cancellous bone in all parts of the skeleton, preferably in the metaphyseal or epiphyseal segments, maxilla and mandible, Processus mastoideus and other sections with bone defects
- Filling of bone cysts

Syntricer®Ceraball®

- Bone Void Filler
- for replacing damaged, lost or removed cancellous bone in all parts of the skeleton, preferably in the metaphyseal or epiphyseal segments, maxilla and mandible, Processus mastoideus and other sections with bone defects
- Filling of bone cysts

Syntricer®Granules

- Bone Void Filler
- of bone defects, preferably in combination with cancellous bone chips, e.g. with a 50:50% mixture with autologous bone graft or bank bones or a mixture of 50:50 Synthacer®/Syntricer®

Syntricer®Ceround®

- Bone Void Filler

Contraindications

Syntricer® should not be applied in the case of:

- osteomyelitis, non-vascularized bone defects or atrophic non-unions even when combined with an osteosynthesis.
- suspected focal infections because Syntricer® products, as non-vascularized implants, are not protected against bacterial colonization.
- defects open to the articular joint space or in the active growth plate
- non-stabilized non-unions and amphiarthroses
- pre-existing calcium metabolism disorder, unless specifically intended

Moreover, use is restricted in case of severe metabolic diseases, uncontrollable diabetes mellitus, treatment with steroids, immunosuppressive treatment, endocrinological bone diseases, and treatment with drugs that interfere with calcium metabolism.

Furthermore, the material properties of a ceramic material such as Syntricer®, especially its brittleness, should be taken into consideration. Consequently, the bone graft substitute should never be exposed to shear, bending and tension forces or even high compressive forces or to relative motion. Micro-motion or relative movements of parts of the implants against each other or against stiff implants like screws or against a metal stem, plate or nail cause degradation of the ceramic material. This can be avoided by combining with damping materials according to the "sandwich-principle". The combination of ceramic implants with cancellous bone chips or morsellized bone, preferably of the same size, offers advantages for healing. Ceramic implants behave in the same way in a healthy well-vascularized cancellous bone environment with damping properties. Both procedures help avoid micro and relative motion.

Precautions and Warnings

Syntricer® cannot assume any load-bearing functions. Additional stabilization using osteosynthetic measures may be needed depending on the type and location of the defect to be treated.

When filling the defect with rods or blocks, attention should be paid to the damping properties of the recipient bed or a combination with cancellous chips in order to avoid relative motion and resulting degradation of the material.

Side Effects / General risks for use

Syntricer® may only be inserted by trained surgeons. Since Syntricer® products are implants without an own defense mechanism, there is an imminent danger of contamination by hematogenous or intraoperative infection. As in all operations of the lower extremities, thromboembolism may be another common complication. In both, these circumstances, an antibiotic prophylaxis and a thromboembolic prophylaxis, preferably using heparin-based pharmaceuticals, is strongly recommended – at least during the non-weight bearing period after the operation.

Syntricer® are implanted devices that are not accessible to the body`s immune system; therefore, there is a general hematogenic and intraoperative risk of contamination.

All procedures at the lower extremities also involve a risk of thrombosis; this risk is equal to that of other orthopedic procedures.

Therefore, they require the general precautions of antibiotic administration as well as general thrombosis prevention with heparin administration for non-weight-bearing patients.

Operating Instructions

Syntricer® may only be employed by, or under the supervision of, surgeons or medical doctors, or under supervision of medical professionals with experience in the required surgical techniques and the use of biomaterials. The selection of the form of application and the surgical procedure depend on the location, type and size of the defect. In general, the medical doctor should pay attention to a well-vascularized recipient bed freed from necrotic tissue and a complete filling of the bony defect avoiding mechanical compaction of the implant.

When filling the defect with rods, blocks or wedges, attention should be paid to the damping properties of the recipient bed or a combination with cancellous chips in order to avoid relative motion and resulting degradation of the material.

Product and geometric shapes

Syntricer® is available in a variety of geometric shapes such as cylinders, blocks, wedges, balls or beads Syntricer® *(Ceraball®)* in different sizes. The surfaces can show open pores; or one or more surfaces may be "closed" or even covered by a dense compact ceramic structure. Syntricer® products are available as a conglomerate of shells or a conglomerate of ceramic beads with different diameters and in form of cylinders and blocks with different lengths. The macro-pores of the structured material show an average size of 300, 600 or 1000 µm or a mixture thereof.

The blocks measure 5 x 5, 10 x 10, 15 x 15 and 20 x 20 mm with a height of 15 mm.

The wedges have a height of 9, 11 and 13 mm.

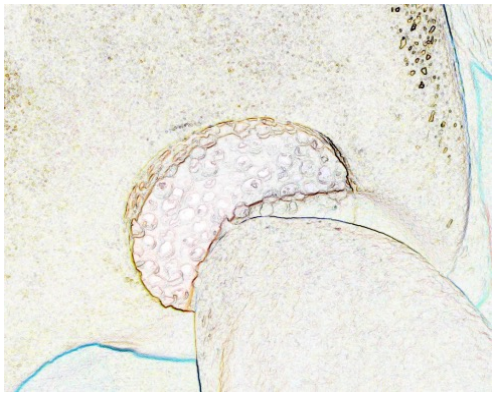
Syntricer®*Ceraball*® is available with different diameters. The macro-pores of the structured material show an average of 300, 600 or 1000 µm or a mixture thereof.

Syntricer® is also offered as a granulated material in natural form or rounded (Syntricer® *Ceround*®) providing graduated particle sizes ranging from 0,1 - 0,9 mm (powder); 1,0 - 2,5 mm (medium coarse) up to 2,6 - 4,8 mm (coarse).

Syntricer®*Cylinders*

For joint reconstruction the SDI®/Diamond TwInS™ procedure comprises a grafting technique where load-bearing surfaces are reconstructed with autologous cartilage-bone cylinder grafts. These are harvested using an atraumatic wet grinding technique using diamond instruments (SDI®/Diamond TwInS™) with an internal rinsing system and where the donor bed is filled by a press-fit inserted Syntricer® ceramic implant as a non-load bearing bone void filler. A corresponding Syntricer®*Cylinder* is offered for each diamond tool in order to ensure a precise press-fit for filling the void.

Syntricer®*Cylinder* implants must not be hammered; they are inserted by finger only. Any mechanical compaction has to be avoided (Fig.1).



Interactions

No interactions between Syntricer® products and pharmaceuticals or other medical devices have been reported to date, except the direct in-contact combination with stiff implants.

Single Use, Sterilization, Shelf life and Storage

Syntricer®*Cylinders*, Syntricer®*Blocks and* Syntricer®*Wedges* are packaged double sterile (Gamma irradiation). Implants are delivered in shockproof membrane-boxes.

Syntricer®*Ceraball*® and Syntricer®*Granules*, as well as Syntricer®*Ceround*® are packaged double sterile in small ampoules ready for application.

Syntricer® products are intended for single use only; re-sterilization is not allowed.

Syntricer® products are packaged shockproof and should only be removed from the box immediately before use; the package provides damping properties and protects the implant.

Mechanical damage can infringe the strength of the material; therefore attention has to be paid to open the membrane-box or the ampoule only shortly before use.

The product must not be used if the sterile packaging shows visible signs of damage. Before use, the intactness of the packaging has to be checked.

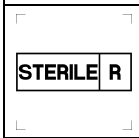
The medical device must be stored dry in its transport box.

Syntricer® products must not be used after the expiration date.

Unused and unopened expired products can be disposed as household waste. Discarded (used and unused) devices are classified as healthcare (clinical) waste and have to be disposed

It is recommended to order a new unit of 5 items, when there are only two items of the same size at hand.

EN 980 / EN 15223-1 Symbols and description

	CONSULT INSTRUCTIONS FOR USE
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	DO NOT REUSE
	USE BY
	BATCH CODE
	CATALOGE NUMBER
	METHOD OF STERILIZATION USING RADIATION
	MANUFACTURER
	DO NOT USE IF PACKAGE IS DAMAGED
	STORE DRY
Rx ONLY	CAUTION:FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
	Store in a dry place with 30-65 % r.F.
	Store in a dry place and at room temperature (10-30 °C)
	Keep away from sunlight

medArtis
Medizinprodukte und Forschung AG
Gabriel-Max-Straße 3
D - 81545 München/Germany