Osteosynt

CMO

CE 1023

CMO HA/TCP PHOSPHOCALCIUM MATRIX Micro-, meso- and macroporous biphasic calcium phosphate Bioceramic

DESCRIPTION

Bone graft and associated devices, characterized by being a material implanted to provide osteogenesis and/or for structural bone replacement during plastic surgery (reconstructive or aesthetic); it is also a filling and bone regeneration material, and other associated devices.

OSTEOSYNT® CMO is a state-of-the-art bioactive and biomimetic phosphocalcium matrix of biphasic calcium phosphate bioceramics, composed mainly of an intimate mixture of hydroxyapatite (HA) and tricalcium phosphate (ß-TCP) with interconnected micro, meso and macropores and nanostructured surface topography. It presents two phases: an amorphous one (i.e. more soluble, corresponding to β-TCP) and a crystalline phase (i.e. more stable, corresponding to HA), usually in the range of 60% HA / 40% β-TCP, with possible variations). These components and characteristics (chemical composition and physical structure) mimic the bone mineral matrix and dental enamel and ensure the intrinsic properties of osteoinduction (chemotaxis) and osteoconduction (haptotaxis) to this bioceramic matrix, which are crucial steps for bone regeneration process.

OSTEOSYNT® CMO is characterized by forming a Bone Morphogenetic Complex - CMO (Patent Letter No. PI9104220-8).

OSTEOSYNT® CMO is biocompatible and presents the necessary mechanical strength, which is clearly perceived under normal compression during application to the surgical bed. It is gradually resorbed, providing the requiered support for the formation of new bone, without leading to secondary defects, while it is replaced by the natural bone remodeling process.

Scientific research and clinical observations demonstrate the absence of undesirable inflammatory reactions, rejection, cytotoxic reactions, immunoallergic reactions, systemic reactions and other biological risks. Radiologically, it is radiopaque, due to its calcium (Ca) content, which facilitates its identification.

OSTEOSYNT® CMO has micropores with diameters ranging from 1 to 10 µm. Consequently, this bioceramic has significant capillarity and surface tension, which favors the storage, transport and release of the patient's own proteins - such as individual signaling morphogenetic factors - or extrinsic substances, such as growth factors, antibiotics and chemotherapy drugs. These characteristics favor the intrinsic osteoinduction property of this material. The physical geometry of the pores represents an additional advantage of this bioceramic over others that do not have these characteristics, since osteogenesis (bone neoformation) is geometrically dependent.

Furthermore, the meso and macropores of up to 500 µm in diameter, which depend on the dimensions of the biomaterial presentation form, particularly the granules, allow cell adhesion and migration, angiogenesis and the development of the haptotaxis process (directed movement of cells on the surface of the material). This favors bone formation, both inside the pores and on the surface of the material, as well as neovascularization. The result is an excellent integration of the biomaterial with the host tissue, which is also enhanced by the formation of an amorphous cementing substance, which is dependent on the controlled release of calcium and phosphate ions into the microenvironment.

PRODUCT FORMS

OSTEOSYNT® CMO is available in different forms:

- **Granules:**
  - Granules in applicator
  - General purpose granules
  - Granules for use in dentistry
- **Blocks:**
  - Spheres
  - Blocks – general
  - Wedges
  - Cervical
  - Buttons
  - Mass-produced devices that need to be adapted to meet the specific requirements of any professional user
  - Devices that are mass-produced through industrial manufacturing processes in accordance with the written prescription of any authorized person.

All presentation forms feature interconnected micro, meso and macropores and nanostructured surface topography.

The granules are also available in applicator (syringes), containing 0.5 g to 10.0 g (0.4 cm^3 to 8.0 cm^3). The product is indicated for cavitary or segmental bone defects, such as inlay (inside) or onlay (outside) grafts, and must be in contact with remaining viable bone tissue.

The chemical safety of OSTEOSYNT® CMO is based on the recognized consensus standard specification, ASTM F 1185-88 (reapproved 1993, superseded by ASTM F 1185-23) Ceramic Hydroxyapatite Composition for Surgical Implants. OSTEOSYNT® CMO complies with

the required specifications for the level of trace elements and heavy metals. The biocompatibility of HA, β-TCP, a mixture of both, and OSTEOSYNT® CMO is well documented. All of these biomaterials have consistently proven to be nontoxic, nonallergenic, biocompatible, and noninflammatory. No adverse effects or foreign body reactions have been reported.

MEDICAL DEVICE CLAIMS

OSTEOSYNT® CMO is a synthetic bioceramic matrix for bone reconstruction/regeneration that presents several advantages and benefits when compared to autologous bone grafts, biologically derived biomaterials and other classes of synthetic biomaterials, such as polymers. Therefore:

OSTEOSYNT® CMO does not require another surgical procedure to be harvested, as is the case with autologous bone grafts. Consequently, the use of OSTEOSYNT® CMO reduces the time and costs of surgeries, as well as pain, blood loss and patient discomfort in the postoperative period.

OSTEOSYNT® CMO does not present any risk of transmitting diseases and various other pathogens, as is known with grafts of animal (biological) origin.

OSTEOSYNT® CMO mimics the composition of bone tissue and does not cause foreign body reaction or exacerbated inflammation.

OSTEOSYNT® CMO is biocompatible, inducing the formation of new bone directly in contact with its surface (bone/biomaterial interface), without the formation of fibrous tissues, as observed with inert materials such as polymers (e.g. PMMA).

OSTEOSYNT® CMO presents controlled degradation and resorption, which occur simultaneously with the formation of new bone. Therefore, it will not be degraded/resorbed before the new bone is formed. Consequently, it will not lead to a secondary defect, will not lose volume before bone formation occurs and will not require a second grafting procedure, as can be observed with rapidly degrading biomaterials (such as those composed only of tricalcium phosphates, calcium sulfate, among others).

OSTEOSYNT® CMO is stable over time and will not distort or cause aesthetic or functional deficiencies.

OSTEOSYNT® CMO is easily handled and applied.

OSTEOSYNT® CMO is available in different presentations, giving the surgeon more options for surgical planning.

OSTEOSYNT® CMO is manufactured using a well-controlled process, which allows obtaining a biomaterial with fully reproducible chemical composition and physical characteristics.

Other claims: OSTEOSYNT® CMO can be mixed with the patient's own blood and/or other types of cells before application, as well as other molecules such as drugs, fibrin and L-PRF, without losing its chemical and physical characteristics and properties.

PRINCIPLE OF OPERATION

OSTEOSYNT® CMO is a bioactive and biomimetic biphasic calcium phosphate bioceramic matrix, which presents interconnected pores of different sizes, a nanostructured surface (surface topography) and is available in several presentation forms. It comprises a desirable scaffold, which will remain stable and active for the time necessary for the deposition and maintenance of the newly formed bone tissue, which adheres to its surface through a chemical process (mineralization of amorphous cementing substance) and due the physical characteristics of its surface (nanostructured surface). The newly formed bone and blood vessels penetrate the pores of the bioceramics, fully incorporating it into the new tissue and making it an integral part of the bone. The bioceramic matrix also provides support for the deposition and accumulation of the patient's own substances and proteins, which will favor new tissue formation. It also induces osteoblastic differentiation of cells, a process that is related to the controlled release of calcium and phosphate ions at the surgical site, which occurs naturally during the dissolution and/or reabsorption process of the bioceramic. These ions, however, do not induce abnormal levels of calcium or phosphate in the urine, serum or organs such as the liver, skin, heart, kidney, lung and intestine. Therefore, the bioceramic acts as an intrinsic conductor and inducer of the process, without losing its mechanical resistance.

Its replacement occurs gradually through the bone remodeling process, which depends particularly on osteoclastic activity, that is observed in the microenvironment after the maturation of the newly formed bone. The time that OSTEOSYNT® CMO remains in the body varies according to the patient’s organic capacity for bone formation and remodeling, as well as to the bioceramics presentation form that is used.

NOTICE

OSTEOSYNT® CMO should be applied after complete cleaning of the surgical site, i.e. after removal of fibrosis, debris and dead or infected tissue.

OSTEOSYNT® CMO must be applied and accommodated in the surgical site, as is usually done with autografts, and be in contact with viable and bleeding bone tissue (even if only one bony wall is present).

Ensure adequate coverage of OSTEOSYNT® CMO, regardless of its presentation, with healthy soft tissue, which must be sutured without tension.

NOTICE: OSTEOSYNT® CMO can be mixed with the patient's own blood before application - although it is not mandatory - as well as with other bioactive molecules such as antibiotics, fibrin and L-PRF. It will not lose its chemical and physical characteristics and properties.

INTENDED USE

OSTEOSYNT® CMO is an elective bioceramic indicated for osteogenesis, bone filling, reconstruction of bone defects and restoration and maintenance of anatomical structures, in the following areas:

- Orthopedics and Traumatology

- Neurosurgery
- Oral and Maxillofacial Surgery
- Dentistry
- Reconstructive Plastic Surgery
- Craniomaxillofacial Surgery
- Ophthalmology
- Otorhinolaryngology
- Spinal Surgeries

INDICATIONS

OSTEOSYNT® CMO is indicated for the treatment of segmental and cavitary bone loss and spaces, subsidence; dehiscence; pseudoarthrosis; bone infectious processes that have been treated (correctly cleaned), sequelae of osteomyelitis; osteolysis; treatment of cysts and tumors; placement and revision of hip and knee prostheses; arthroplasties; laminectomies; arthrodesis including in spinal fusions; osteotomies; aesthetic repairs and bone augmentations (such as inlay grafts - inside or onlay - outside); reconstruction of long, short and flat bones of the locomotor system and skull, face and jaw, including septorhinoplasties (replacement of the septal skeleton, in cases where it is absent or unusable, in Otorhinolaryngology); to maintain the volume of the structures as necessary in cases of removal of the eyeball or its contents (application in Ophthalmology); flap reconstructions; to fill dental alveoli; alveolar ridge reconstruction; implantology and cosmetic reconstruction; sinus lift; craniotomies; craniectomies; correction of congenital deformities; ostectomies; for placement of dental implants; for the stabilization of osteotomies and prostheses in general, both in medicine and dentistry, for facial and bone reconstructions in general and fractures.

OSTEOSYNT® CMO is available in different forms (Table 1):

GRANULES: General purpose granules, like the others, including for use in Dentistry, are indicated in the treatment of fractures, segmental and cavitary bone loss, in the treatment of pseudoarthrosis, in treated infectious processes, sequelae of osteomyelitis, osteolysis, revision of hip and knee prostheses, arthroplasties, in the treatment of subsidence, dehiscence, in the treatment of cysts and tumors, in laminectomies, spinal fusions (spine), osteotomies, bone augmentation (such as inlay or onlay grafts), in Orthopedics and Traumatology, Spinal Surgeries, Neurosurgery, Oral and Maxillofacial Surgery, Dentistry, Reconstructive Plastic Surgery and Craniofacial Surgery.

- **Granules in applicator:** The granule in applicator is indicated for filling bone cavities and as onlay grafts (outside) in Orthopedics and Traumatology, Oral and Maxillofacial Surgery, Dentistry, Reconstructive Plastic Surgery and Craniofacial Surgery.

BLOCKS: All blocks, including those for general use, are indicated for stabilizing osteotomies and maintaining and filling spaces, including in high-load bearing areas, in Orthopedics and Traumatology, Oral and Maxillofacial Surgery, Dentistry, Reconstructive Plastic Surgery and Craniomaxillofacial Surgery.

- **Buttons:** Buttons are indicated in cranioplasties, after ostectomies or osteotomies, in Neurosurgery and Craniomaxillofacial Surgery.
- **Cervical:** Stand-alone osseointegrated cervical blocks are indicated for use without rigid fixation in the spine. However, if indicated by the professional, intervertebral fixation materials may be used.
- The surgeon is responsible for indicating the size of the block that best suits the patient, preferably based on imaging tests or another method, such as the use of templates. Its handling does not require specific instruments.
- **Wedges:** Wedges are indicated to stabilize osteotomies in Orthopedics and Traumatology, Reconstructive Plastic Surgery, Craniofacial Reconstructions and Oral and Maxillofacial Surgeries.
- **Spheres:** Spheres are indicated to replace the eyeball or its contents, in Ophthalmology.
- **Mass produced devices:** Mass produced devices that need to be adapted to meet the specific requirements of any professional use and devices that are mass-produced through industrial manufacturing processes in accordance with the written prescription of any authorized person.

Table 1: Presentation forms indicated for each area of specialty.

Areas of Expertise	Presentation Form
Orthopedics and Traumatology	Granules – general purpose; granules in applicator; wedges; blocks – general; mass produced devices, including the ones produced through industrial manufacturing processes.
Spine Surgery	Granules – general purpose; granules in applicator; cervical blocks; mass produced devices, including the ones produced through industrial manufacturing processes.
Neurosurgery	Granulesm- general purpose; granules in applicator; bottons; mass produced devices, including the ones produced through industrial manufacturing processes.
Reconstructive Plastic Surgery	Granules – general purpose; granules in applicator; wedges; blocks – general; buttons; mass produced devices, including the ones produced through industrial manufacturing processes.
Craniomaxillofacial Surgery	Granules – general purpose; granules in applicator; wedges; blocks – general; buttons; mass produced devices, including the ones produced through industrial manufacturing processes.
Oral and Maxillofacial Surgery	Granules (all of them); wedges; blocks – general; mass produced devices, including the ones produced through industrial manufacturing processes.
Dentistry	Granules (all of them); blocks – general.
Otorhinolaryngology	Mass produced devices, including the ones produced through industrial manufacturing processes.
Ophthalmology	Spheres.

NOTICE

OSTEOSYNT® CMO, in all its forms of presentation, is indicated for osteogenesis, reconstruction and bone repair, with osseointegration, in spaces and defects.

OSTEOSYNT® CMO is indicated for pediatric and adult patients (1.5 to 90 years).

OSTEOSYNT® CMO does not induce immunological or cytotoxic reactions.

WARNING OF CONTRAINDICATIONS

The use of OSTEOSYNT® CMO is not indicated in the presence of infection and/or necrotic and/or compromised tissues, without treatment.

Its use in patients with systemic diseases, such as diabetes mellitus, AIDS, osteoporosis, diseases or situations that lead to bone demineralization, or who are using corticosteroid therapy or radiotherapy, does not imply undesirable reactions. In these situations, however, due to the patient's own systemic impairments, the results presented may not be as expected.

Contraindication also includes implantation in acute osteomyelitis without cleaning, debridement and/or ostectomy.

There are no data on the effects of implanting this biomaterial in the growth zone (or articular cartilage) and epiphysis in children. Therefore, these applications should be avoided.

ADVERSE EFFECTS WARNING

Possible adverse effects include, but are not limited to:

- Wound complications, including hematoma, infection, and other complications that are possible with any surgery.
- Incomplete or lack of bone growth into the bone void, as is possible with any bone void filler.

It may result from the use of the bioceramic matrix in patients prone to allergic reactions to products derived from calcium salts.

Complications related to wound healing, such as bruising, swelling, and infection can occur, as with any surgical procedure.

TARGET POPULATION

OSTEOSYNT® CMO is indicated for pediatric and adult patients (1.5 to 90 years) who present acquired and congenital bone defects and/or deformities, including those caused by trauma, tumors, cysts, aging, sequelae of bone infections, pseudoarthrosis, bone reconstruction for revision of hip and knee arthroplasties, spinal fusions, cranial reconstructions, facial bone augmentation and reconstruction, mandibular and maxillary reconstructions, sinus lift and alveolar bone reconstruction and/or augmentation.

PREGNANCY / BREASTFEEDING

There are no data available for the use of the product during pregnancy or lactation.

NOTICE: For safety reasons, pregnant or lactating women should not be treated with the OSTEOSYNT® CMO product.

WARNINGS AND PRECAUTIONS

Rigid fixation techniques may be necessary to ensure rigid stabilization of the defect in all planes.

Maximum contact between the product and the recipient bone must be established.

As with any surgical procedure, caution should be exercised in treating individuals with pre-existing conditions that may affect the success of the surgical procedure. This includes (but is not limited to) individuals on long-term steroid therapy or treatment that affects calcium or phosphorus metabolism.

OSTEOSYNT® CMO is radiopaque until resorbed. Radiopacity may mask underlying pathological conditions. Radiopacity may also make radiographic assessment of new bone growth difficult.

OSTEOSYNT® CMO operates safely and effectively without the need for specific precautions regarding exposure, under reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharges, pressure or pressure variations and acceleration. Do not expose the product to thermal sources of ignition.

OSTEOSYNT® CMO is intended for use by surgeons familiar with bone grafting and rigid fixation techniques.

ATTENTION

Successful bone formation requires the existence of at least four basic factors:

1. Existence of a framework or scaffold that allows vascular neoformation, cell migration, adhesion and proliferation and deposition of bioactive molecules.
2. Existence of the patient's own bioactive molecules, such as BMPs (bone morphogenetic proteins), which occur naturally in the body.
3. Existence of specific cells (such as stem cells and osteoprogenitor cells), naturally existing in the body.
4. Vascularization, adequate blood supply.

The absence of any of these factors may compromise the results.

Complications associated with the use of OSTEOSYNT® CMO reported to date are mainly related to surgical techniques and procedures, and include particle extrusion, granule migration, soft tissue dehiscence and delayed healing. However, these complications may not necessarily compromise the final clinical results; therefore, adequate preparation of the surgical site and the use of an appropriate surgical technique are mandatory to allow for the above-mentioned conditions.

NOTICE

If the compromised tissues are not removed, the product may not lead to and/or induce new bone formation and will only function as a gap filler. Therefore, precautions for use include:

- Removal of fibrosis and devitalized tissue from the surgical site, prior to implantation of bioceramics;
- Proper cleaning of the surgical site;
- Use sterile surgical instruments;
- The use of aseptic technique for preparing and applying the product;
- Ensure direct contact of the product with clean, healthy and bleeding remaining bone tissue, even when using bioceramics presented as granules in applicator.

NOTICE

Surgical use of OSTEOSYNT® CMO should be restricted to qualified and trained professionals, as improper application may result in relative failure and/or migration of the product.

Adequate preoperative evaluation, correct indication of the presentation form and use of appropriate surgical techniques, adequate handling of the bioceramics as indicated, as well as postoperative monitoring and control are necessary for desirable results to be achieved.

Patients must be properly instructed regarding postoperative care.

Practitioners and patients should be informed that this material is radiopaque, visible under X-ray and other imaging techniques.

ATTENTION

There are no data on the effects of implanting this biomaterial in the growth zone (or cartilage) and epiphysis. Therefore, these applications should be avoided.

Inform patients: Physical activities may be restricted during the recovery period and should be assessed according to the type of surgery, extent of the injury and site of application. The time limits for walking and/or movement may vary, always following the recommendations of professionals.

The desired time for tissue neoformation is usually similar to that for the use of autograft, according to data from technical and scientific studies.

CARE IN STORAGE AND TRANSPORTATION

Store in a clean, dry place, not exposed to sunlight.

Store at room temperature (between 15ºC and 30ºC).

Transport must be carried out as described for storage.

USE OF LABELS

Labels stating the name and type of product, batch and serial numbers, date of manufacture and expiration date of the product are provided and must be attached to medical records, health plan documents, hospital files, tax documents and patient documents, as determined by current national and international standards and rules.

Additionally, labels are provided to be filled out with data related to the patient who received the bioceramic implant, the surgical procedures and the presentation form of the biomaterial that was used and must be filled out by the professional/team who opens and applies the biomaterial. This ensures the traceability of the bioceramic.

Traceability

Traceability is a mandatory requirement, in accordance with the legal standards and regulations of National and International Health Surveillance Agencies (such as ANVISA, in Brazil) and the Federal Council of Medicine and the European Community.

NOTICE: We recommend that the surgeon responsible for implanting the biomaterial inform the distributor and/or other network agent about the implanted product, patient and type of surgery. The labels for collecting this information, i.e. patient name, implantation date, customer CNPJ or patient CPF (identification numbers), are provided inside the OSTEOSYNT® CMO packaging.

STERILIZATION

Products are sterilized in moist steam and ethylene oxide (ETO).

The sterilization process guarantees a Sterility Assurance Level (SAL) of 10-6.

NOTICE: The product is sterilized in ethylene oxide (ETO), for single use only. Do not reuse. Do not resterilize the product.

Do not use if packaging is open or damaged.

Do not use if the product is out of date. Check the expiration date described on the product label.

PROCEDURES

After receiving the Product:

- Check the description, according to the purchase order (type of material, part shape, etc.).
- Check the manufacturing batch and expiration date on the labels and/or packaging box (cartridge).
- Remove the product from the surgical grade envelope only inside the surgical center, using aseptic technique, and when performing the surgical procedure.

ATTENTION: For products available in glass bottles, carefully remove the seal.

PREPARATION AND USE OF THE PRODUCT IN GRANULATES

Prepare the product: Prepare the product on site, using aseptic techniques. The product can be used pure, that is, applied to the surgical site as it comes, without being previously mixed with blood or any bioactive molecule. When implanted, the product immediately absorbs the patient's local blood, including fibrin and factors for angiogenesis and osteogenesis, derived from platelet degradation.

It can also be combined with autogenous blood and/or bone marrow, blood products, fibrin, platelet concentrate and/or cell concentrates obtained from the patient, always observing their capacity to produce desirable results, regardless of the association with any exogenous substances or molecules, such as bone morphogenetic proteins (BMPs) and/or concentrates of specific cells, including platelets. This is due to the bioceramic's capacity to absorb and adsorb fluids and molecules and favor cell deposition. The product can be mixed with perforated medullary blood carrying stem cells. Each gram of OSTEOSYNT® CMO in granule form has the capacity to absorb approximately 0.7 cm^3 to 0.8 cm^3 of medullary blood.

NOTICE: Each gram of OSTEOSYNT® CMO in granule form has the potential to absorb approximately 0.7 cm^3 to 0.8 cm^3 of substances such as medullary blood and its components (including cells), antibiotics and other bioactive molecules.

Depending on the indication, it can also be associated with binders, such as organic or synthetic polymeric materials that allow it to be modeled for the desired function and results, depending on the situation and indication for use.

Product Application: Apply the product after cleaning and removing all compromised tissue, ensuring that it is in direct contact with the healthy, bleeding bone, for faster regeneration and better results.

The physical-chemical characteristics and properties indicate the use of OSTEOSYNT® CMO as a vehicle for the release of protein drugs, chemotherapeutics, antibiotics, including as a preventive measure and others.

It is essential to completely fill the surgical space corresponding to the bone loss with adequate compaction of the bioceramic matrix. This gives the reconstructed area adequate resistance to compression, containment of the biomaterial to the surgical site and stabilization of the area.

OSTEOSYNT® CMO in applicator should be applied directly to the surgical site, without the need to be mixed with the patient's blood before use and it easily adapts to the antomy of the space.

FASTER EVOLUTION/REGENERATION AND BETTER RESULTS

Clean the surgical site efficiently so that the product has direct contact with the bleeding bone, allowing immediate absorption of the blood.

The product can be mixed with the patient's own venous or medullary blood. Each gram of OSTEOSYNT® CMO granules has the capacity to absorb approximately 0.7 to 0.8 cm^3 of blood.

Mixing the product with other morphogenetic substances, drugs, cells and/or tissues may influence the process of tissue neoformation.

USING BLOCKS AND MASS-PRODUCED DEVICES

OSTEOSYNT® CMO in the form of blocks and/or mass-produced devices, including those that are produced through industrial manufacturing processes are made available according to the base design and may, in specific and required situations, have small adjustments (small adjustments within the tolerance of the parts cannot alter the dimensional structure, as they cannot be resized), with the use of a drill for better and also adequate osseointegration, using the lateral surface of the same in rotation, gently manipulated over the biomaterial.

Sintered bioceramic cervical blocks are used to provide fusion of intervertebral spaces, provide osteogenesis and/or for structural bone replacement with osseointegration. The surgeon is responsible for choosing the block size that best suits the patient.

For mass-produced devices, including those that are produced through industrial manufacturing processes, when fixation is required, holes for the placement of screws with a diameter of 1.5 to 2 mm may preferably be made at a minimum distance of 7 mm from the edge of the device, including for the use of rigid fixation plates or using special fasteners, as long as they comply with current health legislation. We recommend, when indicated, using universal fasteners in the joints between two pieces and/or natural bone to facilitate and force their alignment, until the sutures are consolidated.

Apply the product, ensuring that it is in direct contact with the healthy and bleeding bone, after cleaning and removing all compromised tissue.

DISPOSITION/DISPOILAGE

Implantable devices of any nature, classified as single-use, are prohibited from being reprocessed.

Any damaged, expired or remaining product that is not used in surgery must be de-identified, rendered useless and discarded after being removed from the primary packaging in cases where it was not implanted in the patient. It must also be disposed of in an environmentally correct manner, in accordance with current legislation.

Explanted devices are considered hospital waste and must be treated as such, in accordance with the regulations of the local health authority.

PACKAGING

The product is individually packaged in a glass bottle, applicator and surgical grade envelope, which in turn is sterilized and placed in a cardboard cartridge.

Instructions for use and traceability labels are sent with the product and placed inside the surgical grade envelope.

The product's validity (expiration date) is indicated on the outer packaging (cardboard cartridge).

COMMENTS

The dimensions of OSTEOSYNT® CMO products, as well as the granulometries presented in the table below, are illustrative (Table 2).

ADVERSE REACTION NOTIFICATION

In case of suspicion of any unreported event or even product change, EINCO Biomaterial Ltda. must be notified immediately, by telephone +55 (31) 3335-2905, through the website (www.eincobio.com.br) or email (eincobio@eincobio.com.br).

INSTRUCTIONS FOR USE

The version of this instruction for use can be found in the footer using an alphanumeric code, where EB167 is the instruction for use code, and the last two digits after the period correspond to the current version of the document.

User alert: always observe the correlation of the version of the instructions for use with the product purchased.

If you would like to obtain these instructions for use in printed format, at no additional cost (including shipping), please request them by phone at +55 (31) 3335-2905, via the website (www.eincobio.com.br) or by email (eincobio@eincobio.com.br).

*Table 2:*Commercial presentation of OSTEOSYNT® CMO products

Type		Dimension	Amount	Code
Granules	Granules Dentistry	10-20 mesh (200-850) microns	0.5 g 1 g	OSGD 0.5 [10:20] OSGD 1 [10:20]
		20 – 40 mesh (850 – 425) microns	0.5 g 1 g	OSGD 0.5 [20:40] OSGD 1 [20:40]
		40 – 60 mesh (425 – 250) microns	0.5 g 1 g	OSGD 0.5 [40:60] OSGD 1 [40:60]
		60 – 80 mesh (250 – 180) microns	0.5 g 1 g	OSGD 0.5 [60:80] OSGD 1 [60:80]
		80 – 100 mesh (180 – 150) microns	0.5 g 1 g	OSGD 0.5 [80:100] OSGD 1 [80:100]
		100 – 200 mesh (150 – 75) microns	0.5 g 1 g	OSGD 0.5 [100:200] OSGD 1 [100:200]
	Granules General	5-10 mesh (4000-2000) microns	2 g 5 g 10 g	OSGP 2 [5:10] OSGP 5 [5:10] OSGP 10 [5:10]
		10-20 mesh (200-850) microns	2 g 5 g 10 g	OSGP 2 [10:20] OSGP 5 [10:20] OSGP 10 [10:20]
		20 – 40 mesh (850 – 425) microns	2 g 5 g 10 g	OSGP 2 [20:40] OSGP 5 [20:40] OSGP 10 [20:40]
		40 – 60 mesh (425 – 250) microns	2 g 5 g 10 g	OSGP 2 [40:60] OSGP 5 [40:60] OSGP 10 [40:60]
		60 – 80 mesh (250 – 180) microns	2 g 5 g 10 g	OSGP 2 [60:80] OSGP 5 [60:80] OSGP 10 [60:80]
		100 – 200 mesh (150 – 75) microns	2 g 5 g 10 g	OSGP 2 [100:200] OSGP 5 [100:200] OSGP 10 [100:200]
		200 – 400 mesh (74 – 23) microns	2 g 5 g 10 g	OSGP 2 [200:400] OSGP 5 [200:400] OSGP 10 [200:400]
	Granules in Applicator	100 – 200 mesh (150 – 75) microns	0.5 g 1 g	OSGI 0.5 [100:200] OSGI 1 [100:200]
			2 g 5 g 10 g	OSGI 2 [100:200] OSGI 5 [100:200] OSGI 10 [100:200]
Blocks	Spheres	Sphere 14 mm	01 unit	OSEP Ø 14 mm
		Sphere 16 mm		OSEP Ø 16 mm
		Sphere 18 mm		OSEP Ø 18 mm
		20mm sphere		OSEP Ø 20 mm
	Blocks - General	Segment 5x5x5 mm	01 unit	OSBP 5.5.5
		Segment 8x10x12 mm		OSBP 8.10.12
		Segment 5x10x20 mm		OSBP 5.10.20
		Segment 8x12x20 mm		OSBP 8.12.20
		Segment 10x15x25 mm		OSBP 10.15.25
		Segment 8x15x25 mm		OSBM 8.15.25
		Segment 10x10x10 mm		OSBM 10.10.10
		Segment 10x10x40 mm		OSBM 10.10.40
		Segment 6x15x50 mm		OSBM 6.15.50
	Wedges	Segment 6x8x10x12 mm	01 unit	OSBC 6.8.10.12
		Segment 6x8x12x20 mm		OSBC 6.8.12.20
		Segment 8x10x15x25 mm		OSBC 8.10.15.25
		Segment 3x5x15x10 mm		OSBC 3.5.15.10
		Segment 3x7, 5x15x20 mm		OSBC 3.7,5.15.20
		Segment 3x10x15x25 mm		OSBC 3.10.15.25
		Segment 3x12.5x15x35 mm		OSBC 3.12,5.15.35
		Segment 3x15X15X45 mm		OSBC 3.15.15.45
	Cervical	Segment 6x4x10x12 mm	01 unit	OSTC 6.4.10.12
		Segment 6x4x12x12 mm		OSTC 6.4.12.12
		Segment 6x4x14x12 mm		OSTC 6.4.14.12
		Segment 8x6x10x12 mm		OSTC 8.6.10.12
		Segment 8x6x12x12 mm		OSTC 8.6.12.12
		Segment 8x6x14x12 mm		OSTC 8.6.14.12
		Segment 10x8x10x12 mm		OSTC 10.8.10.12
		Segment 10x8x12x12 mm		OSTC 10.8.12.12

		Segment 10x8x14x12 mm		OSTC 10.8.14.12
		Segment 2.5x3.5x10x14 mm		OSDI 2,5.3,5.10.14
		Segment 2.5x4.5x10x14 mm		OSDI 2,5.4,5.10.14
	Buttons	Segment 10 mm	01 unit	OSBT Ø 10 mm
		Segment 12 mm		OSBT Ø 12 mm
		Segment 14 mm		OSBT Ø 14 mm
		Segment 16 mm		OSBT Ø 16 mm
		Mass-produced devices that need to be adapted to meet the specific requirements of any professional user.		OSPP
		Devices that are mass-produced through industrial manufacturing processes in accordance with the written prescriptions of any authorized person.		OSPP

MADE BY

Einco Biomaterial Ltda.

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EC REP

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 Do not reuse	 Do not resterilize	 Temperature limit	 Keep dry
 See instructions of use	 Do not use if packaging is damaged.	 Keep away from sunlight	 For prescription use only
 Sterilized using ethylene oxide	 Sterilized using moist steam		